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National Ambient Air Quality Standards for Particulate Matter; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[OAR–2001–0017; FRL–8015–8]

RIN 2060–AI44

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 national ambient air quality standards (NAAQS) for particulate matter (PM), 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 in monitoring reference methods and data handling conventions for PM.

With regard to primary standards for fine particles (particles generally less than or equal to 2.5 micrometers (μm) in diameter, $PM_{2.5}$), EPA proposes to revise the level of the 24-hour $PM_{2.5}$ standard to 35 micrograms per cubic meter (μg/m^3), providing increased protection against health effects associated with short-term exposure (including premature mortality and increased hospital admissions and emergency room visits) and to retain the level of the annual $PM_{2.5}$ standard at 15 μg/m^3, continuing protection against health effects associated with long-term exposure (including premature mortality and development of chronic respiratory disease). The EPA solicits comment on alternative levels of the 24-hour $PM_{2.5}$ standard (down to 25 μg/m^3 and up to 65 μg/m^3) and the annual $PM_{2.5}$ standard (down to 12 μg/m^3), and on alternative approaches for selecting the standard levels.

With regard to primary standards for particles generally less than or equal to 10 μm in diameter (PM_{10}), EPA proposes to revise the 24-hour PM_{10} standard in part by establishing a new indicator for thoracic coarse particles (particles generally between 2.5 and 10 μm in diameter, $PM_{10-2.5}$), qualified so as to include any ambient mix of $PM_{10-2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and excludes any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. The EPA proposes to set the new $PM_{10-2.5}$ standard at a level of 70 μg/m^3, continuing to provide a generally equivalent level of protection against health effects associated with short-term exposure (including hospital admissions for cardiopulmonary diseases, increased respiratory symptoms and possibly premature mortality). Also, EPA proposes to revoke, upon finalization of a primary 24-hour standard for $PM_{10-2.5}$, the current 24-hour PM_{10} standard in all areas of the country except in areas where there is at least one monitor located in an urbanized area (as defined by the U.S. Bureau of the Census) with a minimum population of 100,000 that violates the current 24-hour PM_{10} standard based on the most recent three years of data. In addition, EPA proposes to revoke the current annual PM_{10} standard upon promulgation of this rule. The EPA solicits comment on alternative approaches for selecting the level of a 24-hour $PM_{10-2.5}$ standard, on alternative approaches based on retaining the current 24-hour PM_{10} standard, and on revoking and not replacing the 24-hour PM_{10} standard.

With regard to secondary PM standards, EPA proposes to revise the current standards by making them identical to the suite of proposed primary standards for fine and coarse particles, providing protection against PM-related public welfare effects including visibility impairment, effects on vegetation and ecosystems, and materials damage and soiling. Also, EPA solicits comment on adding a new sub-daily $PM_{2.5}$ standard to address visibility impairment.

DATES: Written comments on this proposed decision must be received by April 17, 2006.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2001–0017 by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- E-mail: *a-and-r-Docket@epa.gov.*
- Fax: 202–566–1749.
- Mail: Docket ID No. EPA–HQ–OAR–2001–0017, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a total of two copies.
- Hand Delivery: Environmental Protection Agency, EPA West Building, Room B102, 1301 Constitution Avenue, 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–2001–0017. 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 *http://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 *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://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, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room B102, 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.

Public Hearings: The EPA intends to hold public hearings around the end of

February in Philadelphia, Chicago, and San Francisco, and will announce in a separate **Federal Register** notice the date, time, and address of the public hearings on this proposed decision.

FOR FURTHER INFORMATION CONTACT: Dr. Erika Sasser, mail code C539–01, Air Quality Strategies and Standards Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone: (919) 541–3889, e-mail: *sasser.erika@epa.gov.*

SUPPLEMENTARY INFORMATION:

General Information

A. What Should I Consider As I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *http://www.regulations.gov* or e-mail. 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 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.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- 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 documents are available on EPA Web sites. The Air Quality Criteria for Particulate Matter (Criteria Document) (two volumes, EPA/600/P–99/002aF and EPA/600/P–99/002bF, October 2004) is available on EPA's National Center for Environmental Assessment Web site. To obtain this document, go to *http://www.epa.gov/ncea,* and click on ''Particulate Matter''. The Staff Paper, human health risk assessment, and several other related technical documents are available on EPA's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) Web site. The Staff Paper is available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_sp.html,* and the risk assessment and technical documents are available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_td.html.* These and other related documents are also available for inspection and copying in the EPA docket identified above.

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The following topics are discussed in today's preamble:

I. Background

A. Legislative Requirements

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list ''air pollutants'' that ''in his judgment, may reasonably be anticipated to endanger public health and welfare'' and whose ''presence * * * in the ambient air results from numerous or diverse mobile or stationary sources'' and to issue air quality criteria for those that are listed. Air quality criteria are intended to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in ambient air * * *.''

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants listed under section 108. 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]

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 establishing ''requisite'' primary and secondary standards, 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).

The requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association* v. *EPA,* 647 F.2d 1130, 1154 (D.C. Cir 1980), *cert. denied,* 449 U.S. 1042 (1980); *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1186 (D.C. Cir. 1981), *cert. denied,* 455 U.S. 1034 (1982). 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 include 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 Association* v. *EPA, supra,* 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, EPA considers such factors as the nature and severity of the health effects involved, the size of the 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. *Lead Industries Association* v. *EPA, supra,* 647 F.2d at 1161–62.

Section 109(d)(1) of the CAA 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 * * *.'' This independent review function is performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board.

B. Review of Air Quality Criteria and Standards for PM

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. Particles originate from a variety of anthropogenic stationary and mobile sources as well as from natural sources. Particles may be emitted directly or formed in the atmosphere by transformations of gaseous emissions such as sulfur oxides (SO_X), nitrogen oxides (NO_X), and volatile organic compounds (VOC). The chemical and physical properties of PM vary greatly with time, region, meteorology, and source category, thus complicating the assessment of health and welfare effects.

The last review of PM air quality criteria and standards was completed in July 1997 with notice of a final decision to revise the existing standards (62 FR 38652, July 18, 1997). In that decision, EPA revised the PM NAAQS in several respects. While EPA determined that the PM NAAQS should continue to focus on particles less than or equal to 10 μm in

[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.''

diameter (PM_{10}), EPA also determined that the fine and coarse fractions of PM_{10} should be considered separately. The EPA added new standards, using $PM_{2.5}$ as the indicator for fine particles (with $PM_{2.5}$ referring to particles with a nominal mean aerodynamic diameter less than or equal to 2.5 μm), and retained PM_{10} standards for the purpose of regulating the coarse fraction of PM_{10} (referred to as thoracic coarse particles or coarse-fraction particles; generally including particles with a nominal mean aerodynamic diameter greater than 2.5 μm and less than or equal to 10 μm, or $PM_{10-2.5}$). The EPA established two new $PM_{2.5}$ standards: an annual standard of 15 $\mu g/m^3$, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors; and a 24-hour standard of 65 $\mu g/m^3$, 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. Also, EPA established a new reference method for the measurement of $PM_{2.5}$ in the ambient air and adopted rules for determining attainment of the new standards. To continue to address thoracic coarse particles, EPA retained the annual PM_{10} standard, while revising the form, but not the level, of the 24-hour PM_{10} standard 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, petitions for review were filed by a large number of parties, addressing a broad range of issues. In May 1999, 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, EPA removed the vacated 1997 PM_{10} standards from the Code of Federal Regulations (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.

More generally, the three-judge panel held (with one dissenting opinion) that EPA's approach to establishing the level of the standards in 1997, both for PM and for 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 EPA, stating that when 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, the panel also reaffirmed prior rulings holding that in setting NAAQS EPA is ''not permitted to consider the cost of implementing those standards.'' *Id.* at 1040–41.

Both sides filed cross appeals on these issues to the United States Supreme Court, and the Court 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 guided 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 traditional standard of judicial 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, EPA published its plans for the current periodic review of the PM criteria and NAAQS (62 FR 55201, October 23, 1997), including the 1997 $PM_{2.5}$ standards and the 1987 PM_{10} standards. As part of the process of preparing an updated Air Quality Criteria Document for Particulate Matter (henceforth, the ''Criteria Document''), EPA's National Center for Environmental Assessment (NCEA) hosted a peer review workshop in April 1999 on drafts of key Criteria Document chapters. The first external review draft Criteria Document was reviewed by CASAC and the public at a meeting held in December 1999. Based on CASAC and public comment, NCEA revised the draft Criteria Document and released a second draft in March 2001 for review by CASAC and the public at a meeting held in July 2001. A preliminary draft of a staff paper, Review of the National Ambient Air Quality Standards for Particulate Matter: Assessment of Scientific and Technical Information (henceforth, the ''Staff Paper'') prepared by EPA's Office of Air Quality Planning and Standards (OAQPS) was released in June 2001 for public comment and for consultation with CASAC at the same public meeting. Taking into account CASAC and public comments, a third draft Criteria Document was released in May 2002 for review at a meeting held in July 2002.

Shortly after the release of the third draft Criteria Document, the Health Effects Institute (HEI) [3] announced that researchers at Johns Hopkins University had discovered problems with applications of statistical software used in a number of important epidemiological studies that had been discussed in that draft Criteria Document. In response to this significant issue, EPA took steps in consultation with CASAC to encourage researchers to reanalyze affected studies and to submit them expeditiously for peer review by a special expert panel convened at EPA's request by HEI. The results of this reanalysis and peer-review process were subsequently incorporated into a fourth draft Criteria Document, which was released in June 2003 and reviewed by CASAC and the public at a meeting held in August 2003.

The first draft Staff Paper, based on the fourth draft Criteria Document, was released at the end of August 2003, and was reviewed by CASAC and the public at a meeting held in November 2003.

[3] The HEI is an independent research institute, jointly sponsored by EPA and a group of U.S. manufacturers and marketers of motor vehicles and engines, that conducts health effects research on major air pollutants related to motor vehicle emissions.

During that meeting, EPA also consulted with CASAC on a new framework for the final chapter (integrative synthesis) of the Criteria Document and on ongoing revisions to other Criteria Document chapters to address previous CASAC comments. The EPA held additional consultations with CASAC at public meetings held in February, July, and September 2004, leading to publication of the final Criteria Document in October 2004. The second draft Staff Paper, based on the final Criteria Document, was released at the end of January 2005, and was reviewed by CASAC and the public at a meeting held in April 2005. The CASAC's advice and recommendations to the Administrator, based on its review of the second draft Staff Paper, were further discussed during a public teleconference held in May 2005 and are provided in a June 6, 2005 letter to the Administrator (Henderson, 2005a). The final Staff Paper, issued in June, 2005, takes into account the advice and recommendations of CASAC and public comments received on the earlier drafts of this document. The Administrator subsequently received additional advice and recommendations from the CASAC, specifically on potential standards for thoracic coarse particles in a teleconference on August 11, 2005, and in a letter to the Administrator dated September 15, 2005 (Henderson, 2005b).[4]

The schedule for completion of this review is governed by a consent decree resolving a lawsuit filed in March 2003 by a group of plaintiffs representing national environmental organizations. The lawsuit alleged that EPA had failed to perform its mandatory duty, under section 109(d)(1), of completing the current review within the period provided by statute. *American Lung Association* v. *Whitman* (No. 1:03CV00778, D.D.C. 2003). An initial consent decree was entered by the court in July 2003 after an opportunity for public comment. The consent decree, as modified by the court, provides that EPA will sign for publication notices of proposed and final rulemaking concerning its review of the PM NAAQS no later than December 20, 2005 and September 27, 2006, respectively.

C. Related Control Programs to Implement PM Standards

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the CAA (42 U.S.C. 7410) and related provisions, States are to submit, for EPA 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 EPA, also administer the prevention of significant deterioration (PSD) program (42 U.S.C. 7470–7479) for these pollutants. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants through the Federal Mobile Source Control Program under title II of the CAA (42 U.S.C. 7521–7574), which involves controls for automobile, truck, bus, motorcycle, nonroad or off-highway, and aircraft emissions; the new source performance standards under section 111 (42 U.S.C. 7411); and the national emission standards for hazardous air pollutants under section 112 (42 U.S.C. 7412).

As described in a recent EPA report, The Particle Pollution Report: Current Understanding of Air Quality and Emissions through 2003 (EPA, 2004b), State and Federal programs have made substantial progress in reducing ambient concentrations of PM_{10} and $PM_{2.5}$. For example, PM_{10} concentrations have decreased 31 percent nationally since 1988. Regionally, PM_{10} concentrations decreased most in areas with historically higher concentrations—the Northwest (39 percent decline), the Southwest (33 percent decline), and southern California (35 percent decline). Direct emissions of PM_{10} have decreased approximately 25 percent nationally since 1988.

Programs aimed at reducing direct emissions of particles have played an important role in reducing PM_{10} concentrations, particularly in western areas. Some examples of PM_{10} controls include paving unpaved roads and using best management practices for agricultural sources of resuspended soil. Additionally, EPA's Acid Rain Program has substantially reduced sulfur dioxide (SO_2) emissions from power plants since 1995 in the eastern United States, contributing to lower PM concentrations. Of the 87 areas that were designated nonattainment for PM_{10} in the early 1990s, 64 now meet those standards. In cities that have not attained the PM_{10} standards, the number of days above the standards is down significantly.

Nationally, $PM_{2.5}$ concentrations have declined by 10 percent from 1999 to 2003. Generally, $PM_{2.5}$ concentrations have also declined the most in regions with the highest concentrations—the Southeast (20 percent decline), southern California (16 percent decline), and the Industrial Midwest (9 percent decline). With the exception of the Northeast, the remaining regions posted modest declines in $PM_{2.5}$ concentrations from 1999 to 2003. Direct emissions of $PM_{2.5}$ have decreased by 5 percent nationally over the past 5 years.

National programs that affect regional emissions have contributed to lower sulfate concentrations and, consequently, to lower $PM_{2.5}$ concentrations, particularly in the Industrial Midwest and Southeast. National ozone-reduction programs designed to reduce emissions of volatile organic compounds (VOCs) and nitrogen oxides (NO_X) also have helped reduce carbon and nitrates, both of which are components of $PM_{2.5}$. Nationally, SO_2 emissions have declined 9 percent, NO_X emissions have declined 9 percent, and VOC emissions have declined by 12 percent from 1999 to 2003. In eastern States affected by the Acid Rain Program, sulfates decreased 7 percent over the same period.

Over the next 10 to 20 years, national and regional regulations will make major reductions in ambient $PM_{2.5}$ levels. The Clean Air Interstate Rule (CAIR) and the NO_X SIP Call will reduce SO_2 and NO_X emissions from electric generating units and industrial boilers across the eastern half of the U.S., regulations to implement the current ambient air quality standards for $PM_{2.5}$ will require direct $PM_{2.5}$ and $PM_{2.5}$ precursor controls in nonattainment areas, and new national mobile source regulations affecting heavy-duty diesel engines, highway vehicles, and other mobile sources will reduce emissions of NO_X, direct $PM_{2.5}$, SO_2, and VOCs. The EPA estimates that these regulations for stationary and mobile sources will cut SO_2 emissions by 6 million tons annually in 2015 from 2001 levels. Emissions of NO_X will be cut by 9 million tons annually in 2015 from 2001 levels. Emissions of VOCs will drop by 3 million tons, and direct $PM_{2.5}$ emissions will be cut by 200,000 tons in 2015, compared to 2001 levels.

Modeling done by EPA indicates that by 2010, 18 of the 39 areas currently not attaining the $PM_{2.5}$ standards will come into attainment just based on regulatory programs already in place, including CAIR, the Clean Diesel Rules, and other Federal measures. Four more $PM_{2.5}$ areas are projected to attain the standards by 2015 based on the implementation of these programs. All areas in the eastern U.S. will have lower $PM_{2.5}$ concentrations in 2015 relative to present-day conditions. In most cases,

[4] The EPA has posted on its Web site (*http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_index.html*) a second edition of the Staff Paper which was prepared for the purpose of including as an attachment this September 2005 letter from CASAC.

the predicted improvement in $PM_{2.5}$ ranges from 10 percent to 20 percent.

D. Overview of Current PM NAAQS Review

This action presents the Administrator's proposed decisions on the review of the current primary and secondary $PM_{2.5}$ and PM_{10} standards. Primary standards for fine particles and for thoracic coarse particles are addressed separately below in sections II and III, respectively, consistent with the decision made by EPA in the last review and with the conclusions in the Criteria Document and Staff Paper that fine and thoracic coarse particles should continue to be considered as separate subclasses of PM pollution. Thus, the principal focus of this current review of the air quality criteria and primary standards for PM is on evidence of health effects and risks related to exposures to fine particles and to thoracic coarse particles. Secondary standards for fine and coarse-fraction particles are addressed below in section IV.

Past and current decisions to address fine particles and thoracic coarse particles separately are based in part on long-established information on differences in sources, properties, and atmospheric behavior between fine and coarse particles (EPA, 2005a, section 2.2). Fine particles are produced chiefly by combustion processes and by atmospheric reactions of various gaseous pollutants, whereas thoracic coarse particles are generally emitted directly as particles as a result of mechanical processes that crush or grind larger particles or the resuspension of dusts. Sources of fine particles include, for example, motor vehicles, power generation, combustion sources at industrial facilities, and residential fuel burning. Sources of thoracic coarse particles include, for example, resuspension of traffic-related emissions such as tire and brake lining materials, direct emissions from industrial operations, construction and demolition activities, and agricultural and mining operations. Fine particles can remain suspended in the atmosphere for days to weeks and can be transported thousands of kilometers, whereas thoracic coarse particles generally deposit rapidly on the ground or other surfaces and are not readily transported across urban or broader areas. The approach in this review to continue to address fine and thoracic coarse particles separately is reinforced by new information that advances our understanding of differences in human exposure relationships and dosimetric patterns characteristic of these two subclasses of PM pollution, as well as the apparent independence of health effects that have been associated with them in epidemiologic studies (EPA, 2004, section 3.2.3). See also *American Trucking Associations* v. *EPA*, 175 F. 3d at 1053–54, 1055–56 (EPA justified in establishing separate standards for fine and thoracic coarse particles).

Today's proposed decisions separately addressing fine and coarse particles are based on a thorough review in the Criteria Document of the latest scientific information on known and potential human health and welfare effects associated with exposure to these subclasses of PM at levels typically found in the ambient air. These proposed decisions also take into account: (1) Staff assessments in the Staff Paper of the most policy-relevant information in the Criteria Document and as well as a quantitative risk assessment; (2) CASAC advice and recommendations, as reflected in the CASAC's letters to the Administrator, discussions of drafts of the Criteria Document and Staff Paper at public meetings, and separate written comments prepared by individual members of the CASAC PM Review Panel [5] (henceforth, ''CASAC Panel''), and (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately.

The EPA is aware that a number of new scientific studies on the health effects of PM have been published since the 2002 cutoff date for inclusion in the Criteria Document. As in the last PM NAAQS review, EPA intends to conduct a review and assessment of any significant new studies published since the close of the Criteria Document, including studies submitted during the public comment period in order to ensure that, before making a final decision, the Administrator is fully aware of the new science that has developed since 2002. In this assessment, EPA will examine these new studies in light of the literature evaluated in the Criteria Document. This assessment and a summary of the key conclusions will be placed in the rulemaking docket. A preliminary list of potentially significant new studies identified to date has been compiled and placed in the rulemaking docket for this proposal, and EPA solicits comment on other relevant studies that may be added to this list. This list includes a wide array of different types of studies that are potentially relevant to various issues discussed in the following sections, including issues related to the elements of the standards under review.

Throughout this preamble a number of conclusions, findings, and determinations by the Administrator are noted. It should be understood that these are all provisional and proposed in nature. While they identify the reasoning that supports this proposal, they are not intended to be final or conclusive in nature. The EPA invites comments on all issues involved with this proposal, including all such proposed judgments, conclusions, findings, and determinations.

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

As discussed more fully below, the rationale for the proposed revisions of the primary $PM_{2.5}$ NAAQS includes consideration of: (1) Evidence of health effects related to short- and long-term exposures to fine particles; (2) insights gained from a quantitative risk assessment; and (3) specific conclusions regarding the need for revisions to the current standards and the elements of $PM_{2.5}$ standards (i.e., indicator, averaging time, form, and level) that, taken together, would be requisite to protect public health with an adequate margin of safety.

In developing this rationale, EPA has drawn upon an integrative synthesis of the entire body of evidence of associations between exposure to ambient fine particles and a broad range of health endpoints (EPA, 2004, Chapter 9), focusing on those health endpoints for which the Criteria Document concludes that the associations are likely to be causal. This body of evidence includes hundreds of studies conducted in many countries around the world, using various indicators of fine particles. In its assessment of the evidence judged to be most relevant to making decisions on elements of the primary $PM_{2.5}$ standards, 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.

As with virtually any policy-relevant scientific research, there is uncertainty in the characterization of health effects attributable to exposure to ambient fine particles. As discussed below, however, an unprecedented amount of new research has been conducted since the last review, with important new information coming from epidemiologic, toxicologic, controlled human exposure,

[5] The CASAC PM Review Panel is comprised of the seven members of the chartered CASAC, supplemented by fifteen subject-matter experts appointed by the Administrator to provide the types of scientific expertise relevant to this review of the PM NAAQS.

and dosimetric studies. Moreover, the newly available research studies evaluated in the Criteria Document have undergone intensive scrutiny through multiple layers of peer review and extended opportunities for public review and comment. While important uncertainties remain, the review of the health effects information has been extensive and deliberate. In the judgment of the Administrator, this intensive evaluation of the scientific evidence has provided an adequate basis for regulatory decision making at this time. This review also provides important input to EPA's research plan for improving our future understanding of the relationships between exposures to ambient fine particles and health effects.

A. Heath Effects Related to Exposure to Fine Particles

This section outlines key information contained in the Criteria Document (Chapters 6–9 and the Staff Paper (Chapter 3) on known or potential effects associated with exposure to fine particles and their major constituents. The information highlighted here summarizes: (1) New information available on potential mechanisms for health effects associated with exposure to fine particles and constituents; (2) the nature of the effects that have been associated with ambient fine particles or fine particle constituents; (3) an integrative assessment of the evidence on fine particle-related health effects; (4) subpopulations that appear to be sensitive to effects of exposure to fine particles; and (5) the public health impact of exposure to ambient fine particles.

As was true in the last review, evidence from epidemiologic studies plays a key role in the Criteria Document's evaluation of the scientific evidence. Some highlights of the new epidemiologic evidence include:

(1) New multi-city studies that use uniform methodologies to investigate the effects of various indicators of PM on health with data from multiple locations with varying climate and air pollution mixes, contributing to increased understanding of the role of various potential confounders, including gaseous co-pollutants, on observed associations with fine particles. These studies provide more precise estimates of the magnitude of an effect of exposure to PM, including fine particles, than most smaller-scale individual city studies.

(2) More studies of various health endpoints evaluating associations between effects and fine particles and thoracic coarse particles (discussed below in section III), as well as ultrafine particles or specific components (e.g., sulfates, nitrates, metals, organic compounds, and elemental carbon) of fine particles.

(3) Numerous new studies of cardiovascular endpoints, with particular emphasis on assessment of cardiovascular risk factors or physiological changes.

(4) Studies relating population exposure to fine particles and other pollutants measured at centrally located monitors to estimates of exposure to ambient pollutants at the individual level. Such studies have led to a better understanding of the relationship between ambient fine particles levels and personal exposures to fine particles of ambient origin.

(5) New analyses and approaches to addressing issues related to potential confounding by gaseous co-pollutants, possible thresholds for effects, and measurement error and exposure misclassification.[6]

(6) Preliminary attempts to evaluate the effects of fine particles from different sources (e.g., motor vehicles, coal combustion, vegetative burning, crustal[7]), using factor analysis or source apportionment methods with fine particle speciation data.

(7) Several new ''intervention studies'' providing evidence for improvements in respiratory or cardiovascular health with reductions in ambient concentrations of particles and gaseous co-pollutants.

In addition, the body of evidence on PM-related effects has greatly expanded with findings from studies on potential mechanisms or pathways by which particles may result in the effects identified in the epidemiologic studies. These studies include important new dosimetry, toxicologic and controlled human exposure studies, as highlighted below:

(8) Animal and controlled human exposure studies using concentrated ambient particles (CAPs), new indicators of response (e.g., C-reactive protein and cytokine levels, heart rate variability), and animal models simulating sensitive human subpopulations. The results of these studies are relevant to evaluation of plausibility of the epidemiologic evidence and provide insights into potential mechanisms for PM-related effects.

(9) Dosimetry studies using new modeling methods that provide increased understanding of the dosimetry of different particle size classes and in members of potentially sensitive subpopulations, such as people with chronic respiratory disease.

1. Mechanisms

In the last review, EPA considered the lack of demonstrated biologic mechanisms for the varying effects observed in epidemiologic studies to be an important caution in its integrated assessment of the health evidence. Much new evidence is now available on potential mechanisms or pathways for PM-related effects, ranging from effects on the respiratory system to indicators of cardiovascular response; these new findings are discussed in depth in Chapter 7 of the Criteria Document. While questions remain, the new findings have advanced our understanding of the complex and different patterns of particle deposition and clearance in the respiratory tract and provide insights into potential mechanisms for PM-related effects and support the plausibility of the findings of epidemiologic studies.

Although there are differences among the size fractions of particles, fine particles, including accumulation mode and ultrafine particles, and thoracic coarse particles can all penetrate into and be deposited in the tracheobronchial and alveolar regions of the respiratory tract (i.e., the ''thoracic'' regions).[8] Penetration into the tracheobronchial and alveolar regions is greater for accumulation mode particles than for coarse or ultrafine particles, since coarse and ultrafine particles are more efficiently removed from the air in the extrathoracic region than are accumulation-mode fine particles; the evidence from dosimetric studies is

[6] ''Confounding'' occurs when a health effect that is caused by one risk factor is attributed to another variable that is correlated with the causal risk factor; epidemiologic analyses attempt to adjust or control for potential confounders (EPA, 2004, section 8.1.3.2; EPA, 2005a, section 3.6.4). A ''threshold'' is a concentration below which it is expected that effects are not observed (EPA, 2004, section 8.4.7; EPA, 2005a, section 3.6.6). ''Gaseous co-pollutants'' generally refer to other commonly-occuring air pollutants, specifically O_3, CO, SO_2 and NO_2. ''Measurement error'' refers to uncertainty in the air quality measurements, while ''exposure misclassification'' includes uncertainty in the use of ambient pollutant measurements in characterizing population exposures to PM (EPA, 2004, section 8.4.5; EPA, 2005a, section 3.6.2)

[7] ''Crustal'' is used here to describe particles of geologic origin, which can be found in both fine- and coarse-fraction PM.

[8] Particles are often classified in modes based on their distribution by characteristics such as mass, surface area, and particle number. ''Coarse mode'' particles are those with diameters mostly greater than the minimum in the particle mass distribution, which generally occurs between about 1 and 3 μm. ''Accumulation mode'' particles are those with diameters from about 0.1 μm to between about 1 and 3 μm. Ultrafine particles are generally those with diameters below about 0.1 μm (EPA, 2004, pages 2–14).

reviewed in detail in Chapter 6 of the Criteria Document.

Fine particles have varying physical or chemical characteristics that may influence health responses. Physical characteristics that may be of importance are solubility or physical state of the particles (e.g., solid, liquid). Fine particle components include metals, acids, organic compounds, biogenic constituents, sulfate and nitrate salts, elemental carbon, and reactive components such as peroxides; size and surface area of the particles can also influence health responses. By way of illustration, Mauderly et al. (1998) discussed particle components or characteristics hypothesized to contribute to health, producing an illustrative list of 11 components or characteristics of interest for which some evidence existed. The list included: (1) Particle mass concentration, (2) particle size/surface area, (3) ultrafine particles, (4) metals, (5) acids, (6) organic compounds, (7) biogenic particles, (8) sulfate and nitrate salts, (9) peroxides, (10) soot, and (11) co-factors, including effects modification or confounding by co-occurring gases and meteorology. The authors stressed that this list is neither definitive nor exhaustive, and note that ''it is generally accepted as most likely that multiple toxic species act by several mechanistic pathways to cause the range of health effects that have been observed'' (Mauderly et al., 1998). The range of health outcomes linked with fine particle exposures is also broad, including effects on the cardiovascular and respiratory systems, and potential links with developmental effects in children (e.g., low birth weight) and death from lung cancer. It appears unlikely that the complex mixes of particles that are present in ambient air would act alone through any single pathway of response. Accordingly, it is plausible that several physiological responses might occur in concert to produce reported health endpoints.

As discussed in section 7.10 of the Criteria Document, the potential pathways for direct effects on the respiratory system include lung injury and inflammation, increased airway reactivity and asthma exacerbation, and increased susceptibility to respiratory infections. New toxicologic or controlled human exposure studies have reported some evidence of inflammatory responses in animals, as well as increased susceptibility to infections. Toxicologic studies also report evidence of lung injury, inflammation, or altered host defenses with exposure to ambient particles or particle constituents. Some toxicologic evidence, particularly from results of studies using diesel exhaust particle exposures, also indicates that PM can aggravate asthmatic symptoms or increase airway reactivity.

Potential pathways for fine particle-related effects also include systemic effects that are secondary to effects in the respiratory system. These include impairment of lung function leading to cardiac effects, pulmonary inflammation and cytokine production leading to systemic hemodynamic effects, lung inflammation leading to increased blood coagulability, and lung inflammation leading to hematopoiesis effects. While more limited than for direct pulmonary effects, some new toxicologic studies suggest that injury or inflammation in the respiratory system can lead to changes in heart rhythm, reduced oxygenation of the blood, changes in blood cell counts, and changes in the blood that can increase the risk of blood clot formation, a risk factor for heart attacks and strokes. In addition, health studies have suggested potential pathways for effects on the heart that include effects related to uptake of particles or particle constituents in the blood, and effects on the autonomic control of the heart and circulatory system. In the last review, little or no evidence was available from toxicologic studies on potential cardiovascular effects. More recent studies have provided some initial evidence that particles can have direct cardiovascular effects. Particle deposition in the respiratory system also could lead to cardiovascular effects, such as fine particle-induced pulmonary reflexes resulting in changes in the autonomic nervous system that then could affect heart rhythm. Also, inhaled fine particles could affect the heart or other organs if particles or particle constituents are released into the circulatory system from the lungs; some new evidence indicates that the smaller ultrafine particles or their soluble constituents can move directly from the lungs into systemic circulation.

The potential mechanisms and/or general pathways for effects discussed above are primarily effects related to short-term rather than long-term exposure to fine particles; for the most part, air pollution toxicologic studies are not designed to assess long-term exposure effects. While repeated occurrences of some short-term insults, such as inflammation, might contribute to long-term effects, it is likely that wholly different mechanisms are involved in the development of chronic health responses. Some mechanistic evidence is available, however, for potential carcinogenic or genotoxic effects of ambient fine particles and combustion products of coal, wood, diesel, and gasoline (discussed in section 7.8 of the Criteria Document).

Overall, the findings indicate that different health responses are linked with different particle characteristics and that both individual components and complex particle mixtures appear to be responsible for many biologic responses relevant to fine particle exposures. In evaluating the new body of evidence, the Criteria Document states: ''Thus, there appear to be multiple biologic mechanisms that may be responsible for observed morbidity/mortality due to exposure to ambient PM. It also appears that many biologic responses are produced by PM whether it is composed of a single component or a complex mixture'' (EPA, 2004, p. 7–206).

2. Nature of Effects

In the last review, evidence from health studies indicated that exposure to PM (using various indicators) was associated with premature mortality and indices of morbidity including respiratory hospital admissions and emergency room visits, school absences, work loss days, restricted activity days, effects on lung function and symptoms, morphological changes, and altered host defense mechanisms.[9] As reviewed in Chapter 8 of the Criteria Document, recent epidemiologic studies have continued to report associations between short-term exposure to fine particles or fine particle indicators, and effects such as premature mortality, hospital admissions or emergency department visits for respiratory disease, and effects on lung function and symptoms. In addition, recent epidemiologic studies have provided some new evidence linking short-term fine particle exposures to effects on the cardivascular system, including cardiovascular hospital admissions and more subtle indicators of cardiovascular health. Long-term exposure to $PM_{2.5}$ and sulfates has also been associated with mortality from cardiopulmonary diseases and lung cancer, and effects on the respiratory system such as decreased lung function or the development of chronic respiratory disease. The

[9] Historical reports of dramatic pollution episodes, considered in the 1987 review of the PM NAAQS, provided clear evidence of mortality associated with high levels of PM and other pollutants, such as the air pollution episode that occurred in London in 1952 (EPA, 1996a, pp. 12–28 to 12–31).

evidence for such effects is summarized below.

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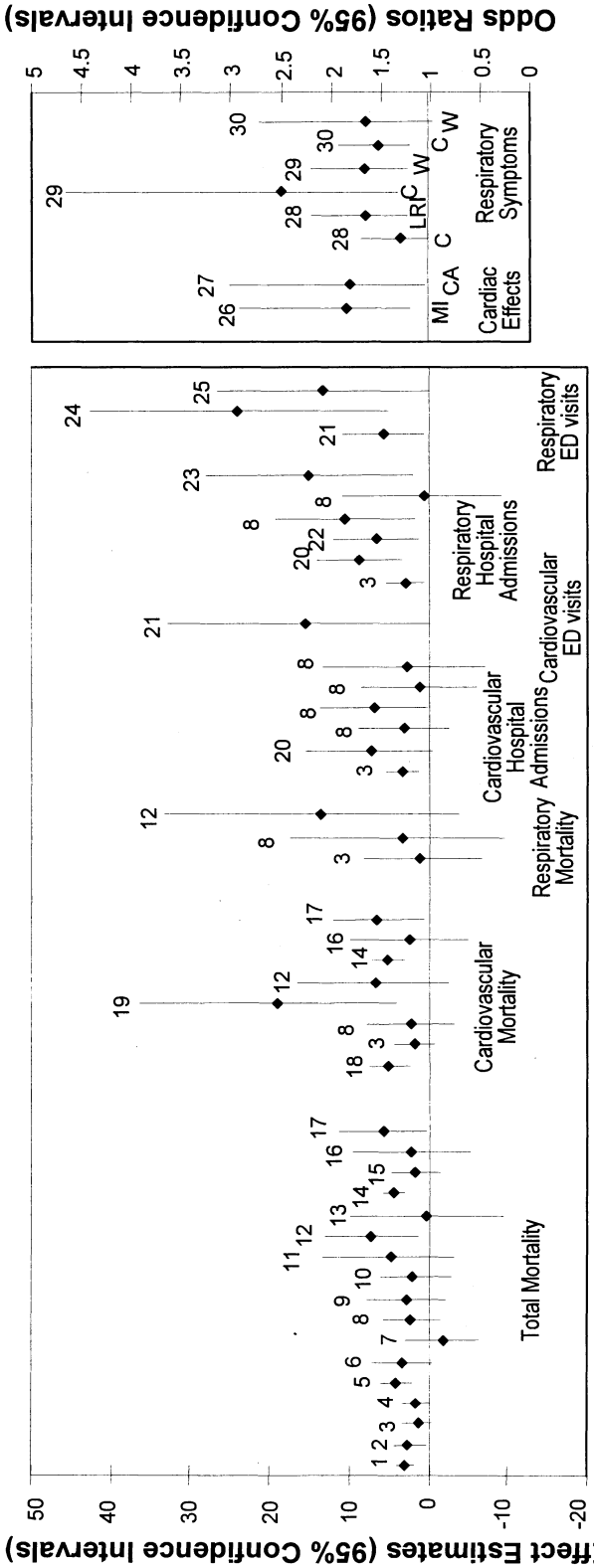

Figure 1. Effect estimates for associations between short-term exposure to $PM_{2.5}$ and mortality or morbidity health outcomes in U.S. and Canadian Studies; multi-city studies noted by bold text below.

(ED=Emergency Department; MI=myocardial infarction; CA=cardiac arrhythmia; C=cough; LRI=lower respiratory infection; W=wheeze)

1. **Klemm and Mason (2003), 6 U.S. cities**
2. **Burnett and Goldberg (2003), 8 Canadian cities**
3. Moolgavkar (2003), Los Angeles
4. Klemm and Mason (2003), St. Louis
5. Klemm and Mason (2003), Boston
6. Klemm and Mason (2003), Kingston-Harriman
7. Klemm and Mason (2003), Portage
8. Ito (2003), Detroit
9. Chock et al. (2000), Pittsburgh (< 75 y.o.)
10. Chock et al. (2000), Pittsburgh (75+ y.o.)
11. Klemm and Mason (2000), Atlanta
12. Fairley (2003), Santa Clara County
13. Klemm and Mason (2003), Topeka
14. Tsai et al. (2000), Newark
15. Klemm and Mason (2003), Steubenville
16. Tsai et al. (2000), Elizabeth
17. Tsai et al (2000), Camden
18. Lipfert et al. (2000), Philadelphia
19. Mar et al. (2003), Phoenix
20. Burnett et al. (1997), Toronto
21. Stieb et al. (2000), St. John
22. Sheppard et al., (2003), Seattle
23. Thurston et al. (1994), Toronto
24. Delfino et al. (1997), Montreal
25. Delfino et al. (1998), Montreal
26. Peters et al. (2001), Boston
27. Peters et al. (2000), Boston
28. **Schwartz and Neas (2000), 6 U.S. cities**
29. Neas et al. (1995), Uniontown
30. Neas et al. (1996), State College

Results presented are from time-series studies that did not use generalized additive models or were reanalyzed using general linear models. For consistency across studies, effect estimates are from single-pollutant, general linear models, based on an increment of 25 μg/m^3 $PM_{2.5}$, and have been plotted in order of decreasing study power, using as an indicator the natural log of the product of the number of study days and number of health events per day. Results for studies of respiratory symptoms are presented as odds ratios; an odds ratio of 1.0 is equivalent to no effect, and thus is presented as equivalent to the zero effect estimate line.

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a. Effects Associated With Short-Term Exposure to Fine Particles

Numerous epidemiologic studies have demonstrated statistical associations between short-term exposure to fine particles and health outcomes ranging from total mortality to respiratory symptoms, as discussed below. Figure 1 summarizes results from both multi-city and single-city epidemiologic studies using short-term exposures to $PM_{2.5}$, including all U.S. and Canadian studies that used direct measurements of $PM_{2.5}$ and for which effect estimates and confidence intervals were reported.[10] The central effect estimate is indicated by a diamond for each study result, with the vertical bar representing the 95 percent confidence interval around the estimate. In the discussions that follow, an individual study result is considered to be statistically significant if the 95 percent confidence interval does not include zero. Positive effect estimates indicate increases in the health outcome with $PM_{2.5}$ exposure. In considering these results as a whole, it is important to consider not only whether statistical significance at the 95 percent confidence level is reported in individual studies, but also the general pattern of results, focusing in particular on studies with greater statistical power that report relatively more precise results.

i. Mortality

Since the last review, a large number of new time-series studies of the relationship between short-term exposure to PM, including $PM_{2.5}$, and mortality have been published, including several multi-city studies that are responsive to the recommendations from the last review. As discussed in section 8.2 of the Criteria Document, these include studies that have been conducted in single cities or locations in the U.S. or Canada, as well as Mexico City and locations in Europe, South America, Asia, and Australia.

Several recent multi-city studies have been published since the last review that are of particular relevance for this review. The results of multi-city studies on associations between PM_{10} and mortality across 90 U.S. cities (Dominici, 2003) and across ten U.S. cities (Schwartz, 2003b), while not specifically on fine particles, have provided important new information to help address uncertainties regarding a number of issues, including model specification, potential confounding by co-pollutants and the form of concentration-response functions (EPA, 2004, section 8.2.2.3). Two multi-city studies have included measurements of $PM_{2.5}$; one was conducted in six U.S. cities (Schwartz et al., 2003a; Klemm and Mason, 2003) and the other in eight Canadian cities (Burnett and Goldberg, 2003). In the last review, results from one multi-city study (the Six Cities study) were available, in which the authors reported significant associations for total mortality with $PM_{2.5}$ and PM_{10}, but not with $PM_{10-2.5}$. Reanalyses of Six Cities data have reported results consistent with the findings of the original study, with statistically significant increases for total mortality with short-term exposure to $PM_{2.5}$ (Schwartz, 2003a; Klemm and Mason, 2003). In a study using data from the eight largest Canadian cities, positive associations were reported for $PM_{2.5}$, PM_{10}, and $PM_{10-2.5}$ with mortality, and the association with $PM_{2.5}$ was statistically significant (Burnett and Goldberg, 2003).

Single-city studies of mortality associations with short-term exposures to fine particles have also been conducted in areas across U.S. and Canada as well as in Europe, Australia and Mexico (some using fine particle indicators such as British Smoke). In general, it can be seen in Figure 1 that the effect estimates for associations between mortality and short-term exposure to $PM_{2.5}$ are positive and a number are statistically significant, particularly when focusing on the results of studies with greater precision. For total nonaccidental mortality, the effect estimates from the multi-city and single-city studies with greater precision generally fall in a range of 2 to 6 percent increases per 25 $\mu g/m^3$ $PM_{2.5}$.[11] Somewhat larger effect estimates have been reported for associations with cardiovascular or respiratory mortality than with total nonaccidental mortality although the confidence intervals may also be larger, especially for respiratory mortality since respiratory deaths comprise only a small proportion of total deaths (EPA, 2005a, p. 3–15). Some studies evaluated seasonal variation in effects, and there is no consistent pattern in results. The Criteria Document concludes that the results of recent epidemiologic studies are generally consistent with findings available in the previous review (EPA, 2004, p. 8–305).

In addition, associations have been reported between mortality and short-term exposure to a number of fine particle components, including sulfates, nitrates, metals, organic compounds and elemental carbon (EPA, 2004, Section 8.2.2.5.2), as well as gaseous precursors such as SO_2 and NO_2 and other gaseous pollutants such as CO. Further, three recent studies have used $PM_{2.5}$ speciation data to evaluate the effects of air pollutant combinations or mixtures using factor analysis or source apportionment methods to evaluate potential associations between mortality and $PM_{2.5}$ from different source categories. These studies reported that short-term exposures to fine particles from combustion sources, including motor vehicle emissions, coal combustion, oil burning and vegetative burning, were associated with increased mortality (EPA, 2004, Section 8.2.2.5.3). However, different patterns of associations between various components or source categories of fine particles and total or cardiovascular mortality are seen in different studies (EPA, 2004, p. 8–70, Tables 8–3, 8–4).

ii. Respiratory Morbidity

As discussed in Section 8.4.6.4 of the Criteria Document, recent epidemiologic studies have provided further evidence for fine particle effects on morbidity, including effects such as hospital admissions or emergency department for respiratory diseases, respiratory symptoms and lung function changes.

(a) Hospital Admissions or Emergency Department Visits for Respiratory Diseases

In the last review, results were available from one study that reported associations between $PM_{2.5}$ and hospitalization for respiratory diseases; these findings were also supported by a number of studies using other fine particle indicators. Numerous studies had also reported statistically significant associations between hospital admissions or emergency department visits for respiratory diseases short-term exposures with various indicators ambient PM, especially PM_{10}, in areas where fine particles are the predominant fraction of PM_{10}, such as locations in the Eastern U.S. and in Ontario, Canada (EPA, 1996a, p. 13–39).

The body of evidence has been expanded with numerous new studies in the U.S. and other countries that have reported associations between $PM_{2.5}$ and hospitalization or emergency department visits (discussed more fully in Section 8.3.2 of the Criteria Document). As shown in Figure 1, all U.S. and Canadian studies report

[10] In the following discussion of specific studies, results from single-pollutant models are referred to, as shown in Figure 1, unless otherwise noted.

[11] In general, the results of studies conducted over shorter time periods and/or smaller areas have a broader range or effect estimates with larger standard errors, as shown in Figure 1.

associations between $PM_{2.5}$ and hospitalization for all respiratory causes that are positive and statistically significant. A number of studies have also reported findings for hospital admissions for individual disease categories (COPD, pneumonia, and asthma) that are positive, but not always statistically significant, perhaps due to smaller sample sizes for the specific respiratory diseases. The effect estimates for respiratory hospital admissions tend to fall in the range of 5 to 15 percent per 25 $\mu g/m^3$ $PM_{2.5}$.[12] In addition, several studies have reported positive, statistically significant associations between exposure to $PM_{2.5}$ and emergency department visits for respiratory diseases. The effect estimates for these associations range up to about 25 percent per 25 $\mu g/m^3$ $PM_{2.5}$ (EPA, 2005a, pp. 3–20, 3–21).

(b) Respiratory Symptoms and Lung Function Changes

Associations between short-term exposure to $PM_{2.5}$ and symptoms in U.S. and Canadian studies are presented in Figure 1. As discussed in Section 8.3.3 of the Criteria Document, a number of new studies have reported significant associations between short-term exposure to PM and increased respiratory symptoms (e.g., cough, wheeze, shortness of breath) and decreased lung function in people with asthma. In studies of nonasthmatic subjects, there were generally positive associations between short-term $PM_{2.5}$ exposures and respiratory symptoms that often were not statistically significant and the results for changes in lung function were somewhat inconsistent. The Criteria Document concludes that the findings of these studies suggest associations with fine PM in reduced lung function and increased respiratory symptoms. For example, significant associations were reported between ambient $PM_{2.5}$ and lower respiratory symptoms in children in a number of U.S. cities (Schwartz and Neas, 2000), and significant associations were found with reduced lung function in Philadelphia (Neas et al., 1999). These findings are supported by results from numerous studies conducted in Europe and Central and South America. The Criteria Document finds that the recent epidemiologic findings are consistent with those of the previous review in showing associations with both respiratory symptom incidence and decreased lung function (EPA, 2004, Section 8.4.6.4).

iii. Cardiovascular Morbidity

In the last review, none of the available studies had evaluated associations between exposure to PM and cardiovascular morbidity, though some studies had reported associations with cardiopulmonary morbidity. In this area, the evidence on PM-related effects has been greatly expanded. Numerous recent studies, including multi-city analyses, have reported significant associations between short-term exposures to PM and health endpoints related to cardiovascular morbidity, including hospitalization or emergency department visits for cardiovascular diseases, incidence of myocardial infarction, cardiac arrhythmia, changes in heart rate or heart rate variability and changes in cardiac health indicators such as fibrinogen or C-reactive protein (EPA, 2004, section 9.2.3.2.1).

(a) Hospital Admissions and Emergency Department Visits for Cardiovascular Diseases

Several recent studies, including multi-city analyses, have reported significant associations between short-term exposures to various PM indicators and hospital admissions or emergency department visits for cardiovascular diseases. Among the studies using $PM_{2.5}$ measurements are a number of single-city analyses of hospitalization or emergency department visits for cardiovascular diseases. As shown in Figure 1, studies conducted in Los Angeles, Toronto and Detroit have reported associations with hospital admissions or emergency department visits for all cardiovascular diseases that are positive and statistically significant or nearly so (Burnett et al., 1997; Ito, 2003; Moolgavkar, 2003). As was true for respiratory diseases, the results for specific diseases (ischemic heart disease, dysrhythmia, congestive heart disease or heart failure, and stroke) are positive but often not statistically significant. The effect estimates reported for associations with hospitalization for cardiovascular diseases range from about 1 to 10 percent per 25 $\mu g/m^3$ $PM_{2.5}$ (EPA, 2004, p. 8–310); effect estimates reported for associations with emergency department visits are generally somewhat larger.

(b) Cardiovascular Health Indicators

In addition to the greatly expanded body of evidence on hospitalization or emergency department visits for cardiovascular diseases, new epidemiologic studies have also reported associations with more subtle physiological changes in the cardiovascular system with short-term exposures to PM, particularly PM_{10} and $PM_{2.5}$ (EPA, 2004, p. 9–67). Associations between short-term exposures to ambient PM (often using PM_{10}) have been reported with measures of changes in cardiac function such as arrhythmia, alterations in electrocardiogram (ECG) patterns, heart rate or heart rate variability changes, although the Criteria Document urges caution in drawing conclusions regarding the effects of PM on heart rhythm, recognizing the need for further research to more firmly establish and understand links between particles and these more subtle endpoints. Recent studies have also reported increases in blood components or biomarkers such as increased levels of C-reactive protein and fibrinogen. Several of these studies report significant associations between various cardiovascular endpoints and short-term $PM_{2.5}$ exposures, including one in which statistically significant associations were reported between onset of myocardial infarction and short-term $PM_{2.5}$ exposures averaged over 2 and 24 hours (EPA, 2004, p. 8–165; Peters et al., 2001). In this study, the effect estimates for the two averaging periods are quite similar in magnitude suggesting that for certain health outcomes very short-term fine particle concentration fluctuations are important (EPA, 2004, p. 9–42; Peters et al., 2001). These new epidemiologic findings provide important insight into potential biologic mechanisms that could underlie associations between short-term PM exposure and cardiovascular mortality and hospitalization that have been reported previously.

b. Effects Associated With Long-Term Exposure to Fine Particles

In the last review, results were available from several cohort studies that suggested associations between long-term exposure to PM (using various indicators) and both mortality and respiratory morbidity. Two studies of adult populations (the Six Cities and ACS studies) reported associations between increases in mortality and long-term exposure to $PM_{2.5}$, and results of a 24-city study indicated that long-term exposure to fine particles was associated with increased respiratory illness in children.

As discussed below, the new evidence available in the current review includes an extensive reanalysis of data from the Six Cities and ACS studies, new analyses using updated data from the ACS and California Seventh Day

[12] Some studies have evaluated seasonal variation in effects, and no consistent pattern is apparent in the results. For example, stronger associations were reported between $PM_{2.5}$ and asthma hospitalization in the warmer season in Seattle (Sheppard et al., 2003) but in the cooler season in Los Angeles (Nauenberg and Basu, 1999).

Adventist (AHSMOG) studies, and a new analysis using data from a cohort of veterans. In addition, new studies have been published on the association between long-term exposure to fine particles and respiratory morbidity using data from a cohort of schoolchildren in Southern California. In general, the newly available evidence has supported earlier findings, and the results of reanalyses have increased confidence in the associations reported in previous prospective cohort studies.

i. Mortality

In the 1996 Criteria Document, statistically significant associations between long-term exposure to both $PM_{2.5}$ and sulfates and mortality were reported in studies from the Six Cities and ACS cohorts (Dockery et al., 1993; Pope et al., 1995). These studies reported effect estimates of 6.6 percent (95 percent CI: 3.5, 9.8) increases in total mortality per 10 $\mu g/m^3$ $PM_{2.5}$ in the ACS study and 13 percent (95 percent CI: 4.2, 23) increases in total mortality per 10 $\mu g/m^3$ $PM_{2.5}$ in the Six Cities study, with somewhat larger effect estimates reported for cardiopulmonary mortality (EPA, 2004, p. 8–117). A number of reviewers raised questions about the adequacy of adjustments for potential confounders and other issues (61 FR 65642, December 13, 1996). Subsequently, as discussed in more detail in Section 8.2.3 of the Criteria Document, the Health Effects Institute conducted a major reanalysis of the data from the Six Cities and ACS studies by a group of independent investigators to address questions and uncertainties raised about these prospective cohort studies. The reanalysis included two major components, a replication and validation study and a sensitivity analysis. In the first part of the reanalysis, the investigators validated the data used by the original investigators in both studies, and they were able to replicate the original results. The results confirmed the original investigators' findings of associations with both total and cardiorespiratory mortality, and the authors reported that the results were not dependent on the computer programs used in the original analyses (EPA, 2004, p. 8–91; Krewski et al., 2000, p. 91).

The second component of the reanalysis project evaluated an array of different models and variables to determine whether the original results would remain robust to different analytic assumptions. This included controlling for other individual level variables, such as cigarette smoking, alcohol consumption, obesity and occupational exposures to dusts or other pollutants, and evaluation of the sensitivity of results to the addition of a range of additional city-level variables such as population change, income, education levels, and access to health care. The sensitivity analysis included assessment of effects in different subgroups of the population. The investigators also evaluated the sensitivity of the results to the inclusion of gaseous co-pollutants, and tested the effects of different statistical modeling approaches, including methods to adjust for spatial patterns, such as the correlation in pollutant levels between cities.

The authors found that adjustment for individual-level variables did not alter the results for the association between long-term $PM_{2.5}$ or sulfate exposure and mortality (Krewski et al., 2000, p. 218). In addition, in most (but not all) cases the associations between mortality and long-term exposure to $PM_{2.5}$ and sulfates were unchanged when additional city-level variables were added to the models (Krewski et al., 2000, p. 233). Analyses to assess the potential modification of effects in different subgroups of the population found, for the most part, little difference in effects for different subgroups. However, education level was found to modify the estimated effect of fine particles, in that associations were statistically significant for those subgroups with lower education levels, whereas the effect estimates from associations for the subgroup with better than high school education were appreciably smaller and were statistically insignificant. The authors suggest that educational attainment may be a marker for lower socioeconomic status and thus greater vulnerability to fine particle-related effects (EPA, 2004, p. 8–94; Krewski et al., 2000, p. 232).[13]

In single-pollutant models, none of the gaseous co-pollutants was significantly associated with mortality except SO_2. Further reanalysis included multi-pollutant models with the gaseous pollutants, and the associations between mortality and both fine particles and sulfates were unchanged in these models, except when SO_2 was included, which decreased the size of the effect estimates for $PM_{2.5}$ to one-sixth of its original value and for sulfates to less than one-third of its original value (EPA, 2004, p. 8–136; Krewski et al., 2000, pp. 183–184).[14] However, the regional association of SO_2 and $PM_{2.5}$ was relatively high, such that the effects of the separate pollutants could not be distinguished. The authors conclude that these findings support the notion that increased mortality may be attributable to more than one component of ambient air pollution, and that throughout the reanalyses, fine particles, sulfates, and SO_2 demonstrated positive associations with mortality (Krewski et al., 2000, p. 233–234). As discussed more generally in the Criteria Document, this result may be reflecting the relatively high correlation between $PM_{2.5}$ levels and SO_2 levels that would be expected in cities across the industrial Midwest and northeastern states, the role that SO_2 has as a precursor to sulfate components in the mix of $PM_{2.5}$, and/or the likelihood that SO_2 is part of the causal pathway linking exposure to $PM_{2.5}$ to adverse health outcomes (EPA, 2004, section 8.1.3.2).

Finally, Krewski and colleagues used several methods to address spatial patterns in the data; for example, concentrations of air pollutants may be correlated between cities within a region. These analyses were primarily based on sulfate concentrations, since more cities had data for sulfates than for fine particles. Addressing spatial patterns in the data generally reduced the size of the association between sulfates and mortality, but the models all continued to show associations between mortality risk and long-term sulfate exposures, although not all were statistically significant (Krewski et al., 2000, p. 228). Overall, considering the results of the extensive set of replication and sensitivity analyses, the authors report that the reanalysis confirmed the association between mortality and fine particle and sulfate exposures (EPA, 2004, p. 8–95; Krewski et al., 2000).

In addition, extended analyses were conducted for the ACS cohort study that included follow-up health data and air quality data from the new fine particle

[13] In multivariate models, the association found between mortality and long-term $PM_{2.5}$ exposure was little changed with addition of education level to the model (Krewski et al., 2000, p. 184). This indicates that education level was not a confounder in the relationship between fine particles and mortality, but the relationship between fine particles and mortality is larger in the population subsets with lower education in this study and not statistically significant in the population subset with the highest education (EPA, 2004, p. 8–100).

[14] For a 24.5 $\mu g/m^3$ change in $PM_{2.5}$, the relative risk for the association between mortality and $PM_{2.5}$ alone was 1.20 (95 percent CI: 1.11–1.29), and after adjustment for SO_2 it was 1.03 (95 percent CI: 0.95–1.13). The relative risk for SO_2 alone was 1.49 (95 percent CI: 1.36–1.64) and after adjustment for $PM_{2.5}$ was 1.46 (95 percent CI: 1.32–1.63) (Krewski et al., 2000, p. 184). The relative risk for sulfates alone was 1.28 (95 percent CI: 1.18–1.40) and after adjustment for SO_2 it was 1.14 (95 percent CI: 1.04–1.25) (Krewski et al., 2000, p. 184). These relative risks for $PM_{2.5}$ are equivalent to effect estimates of 7.5 percent and 1.2 percent increases in mortality per 10 $\mu g/m^3$, in single-pollutant and two-pollutant models, respectively.

monitoring network for 1999–2000. In this study of the expanded ACS cohort, significant associations were reported between long-term exposure to fine particles (using various averaging periods for air quality concentrations) and premature mortality from all causes, cardiopulmonary diseases, and lung cancer (Pope et al., 2002; EPA, 2004, 8–102). This extended analysis included the use of more recent data on fine particle concentrations, as well as data on gaseous co-pollutant concentrations, though no multi-pollutant model results are presented. Further evaluation of the influence of other covariates (e.g., dietary intake data, occupational exposure) used methods similar to those in the reanalysis described above, and new statistical approaches were used for modeling the PM-mortality relationship as well as adjusting for spatial correlation (EPA, 2004, section 8.2.3.2.2). The investigators reported that the associations found with fine particle and sulfate concentrations were not markedly affected by adjustment for numerous socioeconomic variables, demographic factors, environmental variables, indicators of access to health services or personal health variables (e.g., dietary factors, alcohol consumption, body mass index). Similar to the results of Krewski et al. (2000), education level was found to be a modifier in the relationship between fine particles and mortality, in that associations were statistically significant for those subgroups with lower education levels, whereas effect estimates from associations for those with better than a high school education were close to zero and were statistically insignificant.

There are also new analyses using updated data from the AHSMOG cohort. These include estimated $PM_{2.5}$ concentrations from visibility data, along with new health information from continued follow-up of the Seventh Day Adventist cohort. Positive associations were reported for mortality with $PM_{2.5}$ in males, but the estimates were generally not statistically significant (Abbey et al., 1999; McDonnell et al., 2000; EPA, 2004, pp. 8–110 and 8–117). In addition, one new set of analyses was done using subsets of PM exposure and mortality time periods and data from a Veterans Administration (VA) cohort of hypertensive men. The investigators report inconsistent and largely nonsignificant associations between PM exposure (including, depending on availability, TSP, PM_{10}, $PM_{2.5}$, PM_{15} and $PM_{15\text{-}2.5}$) and mortality (EPA, 2004, pp. 8–110 to 8–111; Lipfert et al., 2000b).

The Criteria Document and Staff Paper place greatest weight on the findings of the Six Cities and ACS studies (including reanalyses and extended analyses) that include measured fine particle data (in contrast with AHSMOG effect estimates based on TSP or visibility measurements), have study populations more similar to the general population than the VA study cohort, and have been replicated and examined through exhaustive reanalysis (EPA, 2005a, at 5–22; see also EPA, 2004, at 8.2.3.2.5.). In these studies, effect estimates for deaths from all causes fall in a range of 6 to 13 percent increased risk per 10 $\mu g/m^3$ $PM_{2.5}$, while effect estimates for deaths from cardiopulmonary causes fall in a range of 6 to 19 percent per 10 $\mu g/m^3$ $PM_{2.5}$. For lung cancer mortality, the effect estimate was a 13 percent increase per 10 $\mu g/m^3$ $PM_{2.5}$ in the results of the extended analysis from the ACS cohort (Pope et al., 2002; CD, Table 8–12).

The prospective cohort studies have used air quality measurements averaged over long periods of time, such as several years, to characterize the long-term ambient levels in the community. The exposure comparisons are basically cross-sectional in nature, and do not provide evidence concerning any temporal relationship between exposure and effect (EPA, 2004, p. 9–42). As discussed in the Criteria Document, it is not easy to differentiate the role of historic exposures from more recent exposures, leading to potential exposure measurement error that is increased if average PM concentrations change over time differentially between areas (EPA, 2004, p. 5–118). Several new studies have used different air quality periods for estimating long-term exposure and tested associations with mortality for the different exposure periods. As discussed in section 3.6.5.4 of the Staff Paper, these analyses indicate that averaging PM concentrations over a longer time period results in stronger associations, and that the longer series of data is likely a better indicator of cumulative exposure. Thus, in evaluating these findings, EPA has focused on the results of analyses using fine particle or sulfate measurements for the longer exposure periods in the studies.

ii. Respiratory Morbidity

In the last review, several studies had reported that long-term PM exposure was linked with increased respiratory disease and decreased lung function. One study, using data from 24 U.S. and Canadian cities (''24 Cities'' study), reported associations with these effects and long-term exposure to fine particles or acidic particles, but not with PM_{10} exposure (Dockery et al., 1996; Raizenne et al., 1996). More specifically, statistically significant associations were reported between long-term exposure to fine particles and decreases in several measures of lung function evaluated at a single point in time (Raizenne et al., 1996). In addition, positive but not statistically significant associations were reported between long-term exposure to fine particles and prevalence of a range of respiratory conditions (e.g., asthma, bronchitis, chronic cough) (Dockery et al., 1996).

In the current review, new studies conducted in the U.S. have been based on data from cohorts of schoolchildren in 12 Southern California Communities and an adult cohort of Seventh Day Adventists (AHSMOG) (EPA, 2004, section 8.3.3.2). Information specifically on associations with long-term $PM_{2.5}$ exposures are available from the Southern California children's cohort study. Early findings from cross-sectional analyses done at the beginning of the study suggested associations between long-term $PM_{2.5}$ exposures and respiratory morbidity, but the findings were generally not statistically significant.[15] Later publications from this cohort have reported associations with lung function growth in children over four-year follow-up periods. In a study of a cohort of children followed from 4th to 7th grade, some measures of decreases in lung function growth were statistically significantly associated with increasing exposure to $PM_{2.5}$, whereas in a second cohort of 4th graders, the associations generally did not reach statistical significance (Gauderman et al., 2002). Decreases in measures of lung function growth were also reported for cohorts of older children, but the associations did not reach statistical significance (Gauderman et al., 2000). The Criteria Document finds that these studies ''provide the best evidence'' on effects of long-term fine particle exposure (EPA, 2004, p. 8–314). However, this is the only cohort study to have evaluated associations with decreases in lung function growth in children over time. Considered together, the Criteria Document finds that the evidence from these studies indicates that long-term $PM_{2.5}$ exposures may

[15] In an initial report on the prevalence of respiratory illnesses reported at the beginning of the study, positive associations, though not statistically significant, were reported between long-term $PM_{2.5}$ exposure and risk of bronchitis and cough only in the subset of children with asthma (McConnell et al., 1999), and no significant associations with long-term $PM_{2.5}$ exposure were reported for the full cohort (Peters et al., 1999a). In addition, long-term $PM_{2.5}$ exposure was associated with decreases in some lung function measurements made at that time, but the associations were only statistically significant for females (Peters et al., 1999b).

result in chronic respiratory effects (EPA, 2004, p. 8–314).

3. Integration and Interpretation of the Health Evidence

In evaluating the evidence from epidemiologic studies, the Criteria Document and Staff Paper focused on well-recognized criteria, including the strength of associations; robustness of reported associations to the use of alternative model specifications, potential confounding by co-pollutants, and exposure misclassification related to measurement error; consistency of findings in multiple studies of adequate power, and in different persons, places, circumstances and times; the nature of concentration-response relationships; and information from so-called natural experiments or intervention studies. These evaluations addressed key methodological issues that are relevant to interpretation of evidence from epidemiologic studies. Further, findings from epidemiologic studies were integrated with experimental (e.g., dosimetric and toxicologic) studies, in considering the extent of coherence and biological plausibility of effects observed in epidemiologic studies. This integrative assessment provided the basis for the judgments made in the Criteria Document and Staff Paper about the extent to which causal inferences can be made about observed associations between health endpoints and $PM_{2.5}$ (as well as other indicators or constituents of ambient PM), acting alone and/or in combination with other pollutants. Key elements of these evaluations are briefly summarized below.

(1) For short-term exposures to fine particles, in considering the magnitude and statistical strength of the associations, there is a pattern of positive and often statistically significant associations for cardiovascular and respiratory health outcomes with short-term exposure to PM_{10} and $PM_{2.5}$. Of particular note are several multi-city studies that have yielded relative risk estimates for associations between short-term exposure to various indices of PM and mortality or morbidity. Although small in size, the effect estimates from multi-city studies have great precision due to the statistical power of the studies. New analyses of pre-existing cohorts with studies of long-term exposure to fine particles are available that confirm and strengthen conclusions from the previous review, although the effect estimates are sensitive to education level, co-pollutant effects of SO_2, and spatial correlation, as discussed above.

(2) The Criteria Document and Staff Paper have evaluated the robustness of epidemiologic associations in part by considering the effect of differences in statistical model specification, potential confounding by co-pollutants and exposure error on PM-health associations (EPA, 2004, section 9.2.2.2; EPA, 2005a, sections 3.4.2 and 3.6).

As discussed in section 8.4.2 of the Criteria Document and section 3.6.3 of the Staff Paper, the influence of alternative modeling strategies on epidemiologic study results was assessed, with a particular focus on the recent set of analyses to address statistical modeling questions in epidemiologic studies for short-term PM exposures. Numerous recent studies used a certain type of statistical method (i.e., generalized additive methods (GAM)) in widely used statistical software (Splus), and it was discovered that the default program settings could potentially result in biased effect estimates for associations between pollutants and health outcomes. Results from a number of epidemiologic studies were reanalyzed to address this problem. These reanalyses also more broadly included the use of alternative statistical models and alternative methods of control for time-varying effects, such as weather or season (HEI, 2003). In general, the results of the reanalyses to address the use of default program settings in the Splus software showed little change in effect estimates for some studies; in others the effect estimates were reduced in size, though it was observed that the reductions were often not substantial (EPA, 2004, p. 9–35). For example, in comparing results for numerous studies of mortality associations with PM_{10}, the Criteria Document found that the extent of reduction in effect estimates resulting from reanalysis was smaller than the variation in effect estimate size across studies (EPA, 2004, p. 8–229 and Figure 8–15). A review panel commentary on the set of reanalysis studies (using various PM indicators) notes that most studies were considered to show ''little or no change'' in results with initial reanalyses to address questions about the use of modeling specifications in the statistical software package (HEI, 2003, pp. 258–259).

In addition, the reanalyses also refocused attention in general on the control for relationships between health effects and weather variables in time-series epidemiologic studies; such issues had been also discussed at length in the 1996 Criteria Document (EPA, 2004, section 8.4.3.5). The reanalysis results showed greater sensitivity to the modeling approach used to account for temporal effects and weather variables than to correcting the initial problem with default settings in the use of GAM in Splus software (EPA, 2004, p. 8–236). For example, in the review panel commentary, sixteen of the reanalyzed studies were considered to have ''little or no change'' in results of initial reanalyses, while only two studies showed ''substantial'' changes (Goldberg and Burnett, 2003; some results in Ito, 2003; HEI, 2003, pp. 258–259). In contrast, four of the eight studies that were reanalyzed with additional methods to adjust for time-related variables were considered to show ''substantial'' changes in effect estimate size (HEI, 2003, p. 262).

The recent time-series epidemiologic studies evaluated in the Criteria Document have included some degree of control for variations in weather and seasonal variables. As summarized in the HEI review panel commentary, selecting a level of control to adjust for time-varying factors, such as temperature, in time-series epidemiologic studies involves a trade-off. For example, if the model does not sufficiently adjust for the relationship between the health outcome and temperature, some effects of temperature could be falsely ascribed to the pollution variable. Conversely, if an overly aggressive approach is used to control for temperature, the result would possibly underestimate the pollution-related effect and compromise the ability to detect a small but true pollution effect (EPA, 2004, p. 8–236; HEI, 2003, p. 266). The selection of approaches to address such variables depends in part on prior knowledge and judgments made by the investigators, for example, about weather patterns in the study area and expected relationships between weather and other time-varying factors and health outcomes considered in the study. While recognizing the need for further exploration of alternative modeling approaches for time-series analyses, the Criteria Document found that the studies included in this part of the reanalysis in general continued to demonstrate associations between PM and mortality and morbidity beyond those attributable to weather variables alone (EPA, 2004, pp. 8–340, 8–341). Further, considering the full set of reanalyses, the Criteria Document concludes that associations between short-term exposure to PM and various health outcomes are generally robust to the use of alternative modeling strategies, again recognizing that further evaluation of alternative modeling strategies was warranted (EPA, 2004, p. 9–48).

For long-term exposure to fine particles, the reanalysis and extended analyses of data from prospective cohort studies, discussed above in section II.A.2, have shown that reported associations between mortality and long-term exposure to fine particles are robust to alternative modeling strategies (Krewski et al., 2000). As stated in the reanalysis report, ''The risk estimates reported by the Original Investigators were remarkably robust to alternative specifications of the underlying risk models, thereby strengthening confidence in the original findings'' (Krewski et al., 2000, p. 232). In extended analysis, Krewski et al. (2000) identified model sensitivities related to education level and spatial correlation, as well as to co-pollutant effects of SO_2, as discussed below.

The Criteria Document also included extensive evaluation of the sensitivity of PM-health responses to confounding by gaseous co-pollutants (EPA, 2004, section 8.4.3, Figures 8–16 to 8–19). Results of new multi-city short-term exposure studies, that combine data from locations with different mixes of pollutants, provide important new results. Using PM_{10}, the NMMAPS results indicated that associations with mortality were not confounded by co-pollutant concentrations across 90 U.S. cities (Dominici, 2003),[16] and a similar lack of confounding was observed in a mortality study across 10 U.S. cities (Schwartz, 2003b) (EPA, 2004, Figure 8–16). That is, in these studies, the size of the effect estimates are little changed and the associations remain statistically significant in multi-pollutant models including one or more of the gaseous co-pollutants. Similar results are seen in some single-city studies using $PM_{2.5}$ for some health outcomes in which the single-pollutant model association was statistically significant (EPA, 2004, Figures 8–16 to 8–18), including the association with mortality in Santa Clara County, CA (Fairley, 2003); associations with hospital admissions in Detroit (for heart failure and pneumonia in Ito, 2003) and Seattle (for asthma in Sheppard et al., 2003); and associations with cardiovascular-related biomarkers in Boston (Gold et al., 2000). The size of the effect estimates were little changed in other studies as well in which the single-pollutant model associations were not statistically significant (e.g., for some health outcomes in Ito, 2003; for mortality in Chock et al., 2000). In yet other studies, however, for some combinations of pollutants in some areas, substantial reductions in the size of the effect estimates for $PM_{2.5}$ were observed; notably, Moolgavkar (2003) reports substantial reductions in effect estimates when CO is included in models for mortality and hospitalization in Los Angeles, and Thurston et al. (1994) and Delfino et al. (1998) report substantial reductions when O_3 is included in models for hospital admissions in Toronto and emergency department visits in Montreal, respectively.[17] It is recognized that collinearity between co-pollutants can make interpretation of such multi-pollutant model results difficult (EPA, 2004, p. 8–253). Further, associations between long-term exposure to $PM_{2.5}$ and mortality were not generally sensitive to inclusion of co-pollutants, with the notable exception of the inclusion of SO_2 in multipollutant models used in the reanalysis of the ACS study, as discussed above in section II.A.2 (EPA, 2004, p. 8–136). Overall, the Criteria Document concluded that these studies indicate that effect estimates for associations between mortality and morbidity and various PM indices are generally robust to confounding by co-pollutants, while recognizing that disentangling the effects attributable to various pollutants within an air pollution mixture is challenging (EPA, 2004, p. 9–37).

Finally, as discussed in section 3.6.2, a number of recent studies have evaluated the influence of exposure error on PM-health associations. This includes both consideration of error in measurements of PM and other co-pollutants, and the degree to which measurements from an individual monitor reflect exposures to the surrounding community. As further discussed in section 3.6.2, several studies have shown that fairly extreme conditions (e.g., very high correlation between pollutants and no measurement error in the ''false'' pollutant) are needed for complete ''transfer of causality'' of effects from one pollutant to another (EPA, 2004, p. 9–38). In comparing fine and thoracic coarse particles, the Criteria Document observes that exposure error is likely to be more important for associations with $PM_{10-2.5}$ than with $PM_{2.5}$, since there is generally greater error in $PM_{10-2.5}$ measurements, $PM_{10-2.5}$ concentrations are less evenly distributed across a community, and less likely to penetrate into buildings (EPA, 2004, p. 9–38). Therefore, while the Criteria Document concludes that associations reported with PM_{10}, $PM_{2.5}$ and $PM_{10-2.5}$ are generally robust, it recognizes that factors related to exposure error may result in reduced precision for epidemiologic associations with $PM_{10-2.5}$ (EPA, 2004, p. 9–46).

(3) Consistency refers to the persistent finding of an association between exposure and outcome in multiple studies of adequate power in different persons, places, circumstances and times (CDC, 2004). The 1996 Criteria Document reported associations between short-term PM exposure and mortality or morbidity from studies conducted in locations across the U.S. as well as in other countries, and concluded that the epidemiologic data base had ''general internal consistency'' (EPA, 1996a, p. 13–30). New multi-city studies have allowed evaluation of consistency in effect estimates across geographic locations, using uniform statistical modeling approaches; the results suggest that effect estimates differ from one location to another, but the extent of variation is not clear. For example, the Canadian 8-city study reported no evidence of heterogeneity in city-specific results in the initial study findings; however, in the reanalysis to address model specification issues, the findings suggested more evidence of heterogeneity in associations between mortality and short-term $PM_{2.5}$ exposure (Burnett and Goldberg, 2003; EPA, 2004, p. 9–39). The Criteria Document discussed a number of factors that would be likely to cause variation in PM-health outcomes in different populations and geographic areas in section 9.2.2.3, including indicators of exposure to traffic-related pollution, population characteristics that affect susceptibility or exposure differences, distribution of PM sources, or geographic features that would affect the spatial distribution of PM (EPA, 2004, p. 9–41). In addition, the use of data collected on a 1-in-6 or 1-in-3 day schedule results in reduced statistical power, resulting in less precision for estimated effect estimates for the individual cities and increased potential variability in results (EPA, 2004, p. 9–40). Overall, the Criteria document concluded that ''[f]ocusing on the studies with the most precision, it can be concluded that there is much consistency in epidemiologic evidence regarding associations between short-term and long-term exposures to fine

[16] In the HEI Review Panel commentary on the results of the NMMAPS multi-city analyses, the Panel stated that the results did not show a confounding effect of other pollutants, observing that the PM_{10} effects on mortality were not changed by addition of either O_3, SO_2, NO_2 or CO to the models (HEI, 2000, p. 77).

[17] The correlation coefficients between concentrations of $PM_{2.5}$ and the noted co-pollutants in these studies were high; the coefficient with CO in Los Angeles was 0.58, and the coefficients with O_3 were 0.58 and 0.72 in Montreal and Toronto, respectively.

particles and cardiopulmonary mortality and morbidity.'' (EPA, 2004, p. 9–47).

(4) The form of concentration-response relationships (e.g., linear, sigmoid) and the potential existence of thresholds was one of the important research questions remaining in the previous review. The Criteria Document recognized that it is reasonable to expect that there likely are biologic thresholds for different health effects in individuals or groups of individuals with similar innate characteristics and health status (EPA, 2004, Section 9.2.2.5). Individual thresholds would presumably vary substantially from person to person due to individual differences in genetic-level susceptibility and pre-existing disease conditions (and could even vary from one time to another for a given person). Thus, it would be difficult to detect a distinct threshold at the population level, below which no individual would experience a given effect, especially if some members of a population are unusually sensitive even down to very low concentrations. The person-to-person difference in the relationship between personal exposure to PM of ambient origin and the concentration observed at a monitor may also add to the variability in observed concentration-response relationships, further obscuring potential population thresholds within the range of observed concentrations (CD, p. 9–43, 9–44).

Several new epidemiologic studies have used different modeling methods to address this question, and most have been unable to detect threshold levels in the relationship between short-term PM exposure (generally using PM_{10}) and mortality; in fact, one single-city analysis suggests that statistical methods would allow detection of a threshold in the epidemiologic data if a clear threshold existed. However, a few analyses in individual cities have provided suggestions of some potential threshold levels, generally at fairly low ambient concentrations. One single-city study used $PM_{2.5}$ and $PM_{10-2.5}$ measurements in Phoenix and reported that there was suggestive evidence of a threshold for the association between mortality and short-term exposure to $PM_{2.5}$ in the range of 20–25 $\mu g/m^3$ (Smith et al., 2000; EPA, 2004, p. 8–322).

The shape of the concentration-response function for long-term exposure to $PM_{2.5}$ with mortality was evaluated using data from the ACS cohort. In the ACS reanalysis, the authors report that the concentration-response functions for $PM_{2.5}$ and all-cause and cardiopulmonary mortality demonstrate near-linear increasing trends through the range of particle levels observed in the fine particle cohort (Krewski, p. 160). However, the HEI Review Committee concluded that these results show no clear evidence either for or against overall linearity (Krewski, p. 265). In the extended ACS study, the authors reported that the associations for all-cause, cardiovascular and lung cancer mortality ''were not significantly different from linear associations'' (Pope, et al., 2002).

Thus, evaluation of the health effects data summarized in the Criteria Document provides no evidence to support selecting any particular population threshold for $PM_{2.5}$. The Staff Paper also recognized, however, that it is reasonable to expect that, for individuals, there may be thresholds for specific health responses and that it is possible that such thresholds exist toward the lower end of these ranges (or below these ranges) but cannot be detected due to variability in susceptibility across a population. Even in those few studies with suggestive evidence of such thresholds, the potential thresholds are at fairly low concentrations (EPA, 2004, sections 8.4.7 and 9.2.2.5).

(5) Few studies are available that assess the extent to which reductions in ambient PM actually lead to reductions in health effects attributable to PM. As discussed in sections 8.2.3.4 and 9.2.2.6 of the Criteria Document, several epidemiologic studies were done in the Utah Valley area over a time period when a major source of PM was closed, resulting in markedly decreased PM_{10} concentrations. An epidemiologic study reported that respiratory hospital admissions decreased during the plant closure time period (EPA, 2004, p. 8–131; Pope et al., 1989). Newly available controlled human exposure and animal toxicology studies, using particles extracted from stored PM_{10} sampling filters from the Utah Valley, have shown inflammatory responses that are greater with extracts of particles collected during the time period of source operation than when the source was closed, suggesting that the PM from the steel mill was more harmful than other ambient PM on an equal mass basis (EPA, 2004, p. 9–73). Epidemiologic studies in Dublin, Ireland and Hong Kong also provides evidence for reduced relative risks for mortality when PM (measured as BS or PM_{10}) and SO_2 were reduced as the result of interventions aimed at reducing air pollution. The Criteria Document concluded that this small group of studies add further support to the results of the hundreds of other epidemiologic studies linking ambient PM exposure to an array of health effects, and provide strong evidence that reducing emissions of PM and gaseous pollutants has beneficial public health impacts (EPA, 2004, p. 9–45 to 9–46).

(6) Several issues related to fine particle exposure time periods were assessed in the Criteria Document, as summarized in section 3.6.5 of the Staff Paper. As discussed above in this section, these include the exposure time periods used in long-term exposure studies as well as health outcome associations with very short time periods (e.g., 2-hour average). An additional issue is the time period (''lag'') between fine particle exposure and health outcome that is reported in short-term exposure study results. In these epidemiologic studies, associations are often tested for a range of lag periods, for example, with PM concentrations from the same day as the effect, and one or more days preceding the effect. In evaluating these results, it is important to consider the pattern of results that is seen across the series of lag periods. If there is an apparent pattern of results across the different lags, with positive associations reported for a series of consecutive lag periods, then selecting the single-day lag with the largest effect from a series of positive associations is likely to underestimate the overall effect size, since single-day lag effect estimates do not fully capture the risk that may be distributed over adjacent or other days (EPA, 2004, sections 8.4.4 and 9.2.2.4). For many epidemiologic studies, the authors have reported just such a pattern of associations across several consecutive lag periods (EPA, 2004, p. 8–279). However, if there is no apparent pattern or reported effects vary across lag days, any result for a single day may well be biased (CD, p. 9–42).

Some new studies have used a ''distributed lag'' model approach, that captures an effect of PM over a series of days following exposure.[18] Where effects are found for a series of lag periods, a distributed lag model will more accurately characterize the effect estimate size. A number of recent studies that have investigated associations with distributed lags provide effect estimates for health responses that persist over a period of time (days to weeks) after the exposure period. Effect estimates from distributed lag models are thus often, but not always, larger in size that those for single-day lag periods (EPA, 2004, p. 8–281).

[18] The available studies have generally used PM_{10}, but not $PM_{2.5}$ or $PM_{10-2.5}$.

The Criteria Document concludes that it is likely that the most appropriate lag period for a study will vary depending on the health outcome and the specific pollutant under study. For example, for a health outcome such as a delayed asthma response, the lag period of a day or several days might be expected between exposure and outcome; however, some cardiovascular responses might be expected to occur within a very short time period (e.g., an hour) after exposure (EPA, 2004, p. 8–279). As shown in Figures 8–24 to 8–28, the Criteria Document notes a pattern of stronger associations between PM_{10} and mortality or cardiovascular hospitalization with shorter lag periods (e.g., same-day or 1-day lagged PM_{10}). For other effects, however, such as respiratory symptoms, asthma emergency department visits or hospitalization, stronger effects were reported with PM concentrations averaged over several days (EPA, 2004, pp. 8–273 to 8–279). Thus, the Criteria Document concludes that one would expect to see different best-fitting lags for different health effects, based on potentially different biological mechanisms as well as individual variability in responses (EPA, 2004, p. 8–342). For some health outcomes, it is reasonable to expect associations to be observed with PM exposures on the same day or with very short lag periods, but not longer lag periods. In other cases, multi-day average exposure periods or distributed lag models would more appropriately estimate potential PM-related health risks.

(7) Looking more broadly to integrate epidemiologic evidence with that from exposure-related, dosimetric and toxicologic studies, EPA has considered the coherence of the evidence and the extent to which the new evidence provides insights into mechanisms by which PM, especially fine particles, may be affecting human health. Progress made in gaining insights into potential mechanisms lends support to the biologic plausibility of results observed in epidemiologic studies. For cardiovascular effects, the convergence of important new epidemiologic and toxicologic evidence (especially from studies using concentrated ambient particles) builds support for the plausibility of causal associations, especially between fine particles and physiological endpoints indicative of increased risk of cardiovascular disease and changes in cardiac rhythm. This finding is supported by new cardiovascular effects research focused on fine particles that has notably advanced our understanding of potential mechanisms by which $PM_{2.5}$ exposure, especially in susceptible individuals, could result in changes in cardiac function or blood parameters that are risk factors for cardiovascular disease. For respiratory effects, toxicologic studies have provided evidence that supports plausible biologic pathways for fine particles, including inflammatory responses, increased airway responsiveness, or altered responses to infectious agents. Further, coherence across a broad range of cardiovascular and respiratory health outcomes is supported by evidence from epidemiologic and toxicologic studies done in the same location, for example, in the series of studies conducted in or evaluating ambient PM from Boston and the Utah Valley (EPA, 2004, 7–42 to 43, 7–46 to 47, and 9–45). Toxicologic studies have suggested that some combustion-related particles, including particles from wood burning and diesel engine exhaust, but not others such as coal fly ash, may have carcinogenic effects (EPA, 2004, Section 7.8.4). This evidence supports the plausibility of the observed relationship between fine particles and lung cancer mortality. Evidence for PM-related infant mortality and developmental effects poses an emerging concern, but the current information is still very limited in support of the plausibility of potential ambient PM relationships. More generally, toxicologic animal studies often test effects of exposures to individual chemical components, and thus the physical and chemical characteristics may differ from those of particles in ambient air to which humans are exposed. These and other differences in toxicologic and epidemiologic study designs complicate the assessment of coherence in results from across disciplines (EPA, 2004, section 9.2.3.1; Schlesinger and Cassee, 2003).

Overall, the Criteria Document finds that much more evidence is now available related to the coherence and plausibility of effects than in the last review. For short-term exposures, integration of evidence from epidemiologic and toxicologic studies indicates both coherence and plausibility of effects on the cardiovascular and respiratory systems, especially for fine particles (EPA, 2004, p. 9–79). There is evidence supporting coherence and plausibility for the observed associations between long-term exposures to fine particles and lung cancer mortality (EPA, 2004, p. 9–78).

(8) In summary, as discussed in the Staff Paper (section 3.5) and the Criteria Document (section 9.2.2), the extensive body of epidemiologic evidence now available continues to support likely causal associations between $PM_{2.5}$ and a broad range of mortality and morbidity health outcomes based on an assessment of the strength of the evidence, including the strength and robustness of reported associations and the consistency of the results. While the limitations and uncertainties in the available evidence suggest caution in interpreting the epidemiologic studies at the lower levels of air quality observed in the studies, the evidence now available provides strong support that both short-term and long-term exposures to fine particles are plausibly associated with a broad range of effects on the respiratory and cardiovascular systems. The Criteria Document concludes: ''the epidemiological evidence continues to support likely causal associations between $PM_{2.5}$ and PM_{10} and both mortality and morbidity from cardiovascular and respiratory diseases, based on an assessment of strength, robustness, and consistency in results.'' (EPA, 2004, p. 9–48). In its integrative assessment, the Criteria Document finds that health evidence from various disciplines provides a strong and coherent basis for concluding that both short-term and long-term exposure to fine particles is associated with health effects ranging from subtle changes in lung function to premature mortality.

4. Sensitive Subgroups for $PM_{2.5}$-Related Effects

As described in the PM Criteria Document, the term susceptibility refers to innate (e.g., genetic or developmental) or acquired (e.g., personal risk factors, age) factors that make individuals more likely to experience effects with exposure to pollutants. A number of population subgroups have been identified as potentially susceptible to health effects as a result of PM exposure, including people with existing heart and lung diseases, including diabetes, and older adults and children. In addition, new attention has been paid to the concept of some population groups having increased vulnerability to pollution-related effects due to factors such as socioeconomic status or factors that result in particularly elevated exposure levels, such as residence near sources such as roadways (EPA, 2004, p. 9–81).

A good deal of evidence indicates that people with existing heart or lung diseases are more susceptible to PM-related effects. In addition, new studies have suggested that people with diabetes, who are at risk for cardiovascular disease, may have

increased susceptibility to PM exposures. As discussed in Section 9.2.4.1 of the Criteria Document, this body of evidence includes findings from epidemiologic studies that associations with mortality or morbidity are greater in those with preexisting conditions, as well as evidence from toxicologic studies using animal models of cardiopulmonary disease. In addition, dosimetric evidence indicates that deposition of particles is increased, and can be focused in ''hot spots'' in the respiratory tract, in people with chronic respiratory diseases.

Two age groups, older adults and the very young, are also potentially at greater risk for PM-related effects. Epidemiologic studies have generally not shown striking differences between adult age groups. However, some epidemiologic studies have suggested that serious health effects, such as premature mortality, are greater among older populations (EPA, 2005a, p. 8–328). In addition, preexisting respiratory or cardiovascular conditions are more prevalent in older adults than younger age groups; thus there is some overlap between potentially susceptible groups of older adults and people with heart or lung diseases.

Epidemiologic evidence has reported associations with emergency hospital admissions for respiratory illness and asthma-related symptoms in children. Several factors may make children susceptible to PM-related effects, including the greater ventilation rate per kilogram body weight in children, greater prevalence of chronic asthma, and the fact that children are more likely to be active outdoors and thus have greater exposures. In addition, there is a more limited body of new evidence from epidemiologic studies for potential PM-related health effects in infants, using various PM indicators. Results from this body of evidence, though mixed, are suggestive of possible effects; more research is needed to further elucidate the potential risks of PM exposure for these health outcomes (EPA, 2004, p. 8–222).

In summary, there are several population groups that may be especially susceptible or vulnerable to PM-related effects. These groups include those with preexisting heart and lung diseases, older adults and children. Emerging evidence indicates that people from lower socioeconomic strata or who have particularly elevated exposures may be more vulnerable to PM-related effects.

5. $PM_{2.5}$-Related Impacts on Public Health

As just discussed, there are several population groups that may be especially susceptible or vulnerable to effects from exposure to PM. These population subgroups, such as young children or older adults, and people with pre-existing heart or lung diseases, constitute a large portion of the U.S. population. For example, approximately 22 million people, or 11 percent of the U.S. population, have received a diagnosis of heart disease, about 20 percent of the population has hypertension and about 9 percent of adults and 11 percent of children in the U.S. have been diagnosed with asthma. In addition, about 26 percent of the U.S. population is under 18 years of age,[19] and about 12 percent is 65 years of age or older (EPA, 2004, Table 9–4). EPA recognizes that combining fairly small risk estimates and small changes in PM concentrations with large groups of the U.S. population would result in large public health impacts.

One issue that is important for interpreting the public health implications of the associations reported between mortality and short-term exposure to PM is whether mortality is occurring only in very frail individuals (sometimes referred to as ''harvesting''), resulting in loss of just a few days of life expectancy. A number of new analyses assess the likelihood of such ''harvesting'' occurring in the short-term exposure studies. Overall, the Criteria Document concludes from the time-series studies that there appears to be no strong evidence to suggest that short-term exposure to PM is only shortening life by a few days (EPA, 2004, Section 8.4.10). In addition to the evidence from short-term exposure studies discussed above, one new report used the mortality risk estimates from the ACS prospective cohort study to estimate potential loss of life expectancy from PM-related mortality in a population. The authors estimated that the loss of population life expectancy associated with long-term exposure to $PM_{2.5}$ was on the order of a year or so (EPA, 2004, p. 8–334). The Criteria Document recognizes that these calculations were based on studies in adult populations, and potential population life shortening would be increased if the new, albeit limited, evidence from infant mortality studies was considered (EPA, 2004, p. 8–335). The Criteria Document also observes that the risk estimates reported for long-term fine particle exposures and lung cancer mortality are in about the same range as the risk seen for a nonsmoker living with a smoker (EPA, 2004, p. 9–94).

Large subgroups of the U.S. population are included in subpopulations considered to be potentially sensitive to effects related to fine particle exposures (EPA, 2004, section 9.2.5.1). While individual epidemiologic effect estimates 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, especially $PM_{2.5}$, can have substantial public health impacts (EPA, 2004, p. 9–93).

B. Quantitative Risk Assessment

This section discusses the approach used to develop quantitative risk estimates associated with exposures to $PM_{2.5}$ building upon a more limited risk assessment that was conducted during the last review.[20] At that time, EPA conducted a very limited risk assessment covering a portion of two cities (i.e., Philadelphia County and Southeast Los Angeles County) for which ambient $PM_{2.5}$ data were available. For short-term exposure mortality and morbidity health effects, the prior assessment relied on either pooled analyses that combined the results from several studies of individual cities or individual single- and multi-city studies, none of which included the two urban counties for which risks were estimated, to estimate concentration-response relationships for these two cities. EPA recognized that the lack of city-specific relative risks introduced substantial uncertainties in the risk estimates due to inherent differences (e.g., different population characteristics, PM size distributions) that might influence the concentration-response relationships. For long-term exposure mortality, the prior assessment relied on the concentration-response relationship reported in the original ACS study (Pope et al., 1995). Additional important uncertainties noted at the time of that assessment with respect to all health effects included: (1) The absence of clear evidence regarding mechanisms of

[19] Health studies that have suggested that children are susceptible to PM-related effects include varying age ranges, for example, for hospital admissions in children up to 18 years of age, or respiratory symptoms in panels of 4th and 5th grade children.

[20] The methodology, scope, and results from the risk assessment conducted in the last review are described in Chapter 6 of the 1996 Staff Paper (EPA, 1996b) and in several technical reports (Abt Associates, 1996; Abt Associates, 1997a,b) and publications (Post et al., 2000; Deck et al., 2001).

action for the various effects of interest, (2) uncertainties about the shape of the concentration-response relationships; and (3) concern about whether the use of ambient $PM_{2.5}$ fixed-site monitoring data adequately reflected the relevant population exposures to PM that are responsible for the reported health effects (61 FR 65650).

In light of the substantial uncertainties in the prior risk estimates, EPA placed greater weight on the overall conclusions derived from the health effect studies—that ambient PM was likely causing or contributing to significant adverse effects at levels below those permitted by the then-existing PM_{10} standards—than on the specific concentration-response functions and quantitative risk estimates derived from them. Nevertheless, EPA judged that the assessment provided reasonable estimates as to the possible extent of risk for those effects given the available information (62 FR at 38656).

1. Overview

The updated risk assessment conducted as part of this review includes estimates of (1) risks of mortality, morbidity, and symptoms associated with recent ambient $PM_{2.5}$ levels; (2) risk reductions and remaining risks associated with just meeting the current suite of $PM_{2.5}$ NAAQS; and (3) risk reductions and remaining risks associated with just meeting various alternative $PM_{2.5}$ standards in a number of example urban areas. This risk assessment is more fully described and presented in the Staff Paper (EPA, 2005a, Chapter 4) and in a technical support document, *Particulate Matter Health Risk Assessment for Selected Urban Areas* (Abt Associates, 2005a). The scope and methodology for this risk assessment were developed over the last few years with considerable input from the CASAC PM Panel and the public.[21] The information presented in these documents included specific criteria for the selection of health endpoints and studies to include in the assessment. It also addressed which alternative statistical models (e.g., for control of time-varying factors such as weather and for various lags) to include in the assessment, recognizing that some of the health studies presented results from a large number of alternative models. In an advisory letter sent by CASAC to the Administrator documenting its advice in May 2002 (Hopke, 2002), CASAC concluded that the general methodology and framework to be used in the assessment were appropriate.

The goals of the $PM_{2.5}$ risk assessment were: (1) To provide estimates of the potential magnitude of mortality and morbidity effects associated with current $PM_{2.5}$ levels, and with meeting the current suite of $PM_{2.5}$ NAAQS and alternative $PM_{2.5}$ standards, in specific urban areas; (2) to develop a better understanding of the influence of various inputs and assumptions on the risk estimates; and (3) to gain insights into the distribution of risks and patterns of risk reductions associated with meeting alternative suites of $PM_{2.5}$ standards. EPA recognizes that there are many sources of uncertainty and variability inherent in the inputs to this assessment and that there is a high degree of uncertainty in the resulting $PM_{2.5}$ risk estimates. While some of these uncertainties have been addressed quantitatively in the form of estimated confidence ranges around central risk estimates, other uncertainties and the variability in key inputs are not reflected in these confidence ranges, but rather have been addressed through separate sensitivity analyses or characterized qualitatively.

2. Scope and Key Components

The risk assessment estimates risks of various health effects associated with exposure to ambient $PM_{2.5}$ in nine urban areas selected to illustrate the public health impacts associated with a recent year of air quality and potential reductions in risk associated with just meeting the current suite of $PM_{2.5}$ standards and alternative suites of standards. The selection of urban areas was largely determined by identifying areas in the U.S. for which acceptable epidemiological studies were available that estimated concentration-response relationships for $PM_{2.5}$, which were then used in assessing the risks. Thus, unlike the prior risk assessment, the current risk assessment for short-term exposure mortality and morbidity health effects used concentration-response relationships reported in studies that included the urban areas for which risks were estimated. Based on a review of the evidence evaluated in the Criteria Document and Staff Paper, as well as the criteria discussed in Chapter 4 of the Staff Paper, the following broad categories of health endpoints were included in the risk assessment for $PM_{2.5}$ associated with short-term exposure: Total (non-accidental), cardiovascular, and respiratory mortality; hospital admissions for cardiovascular and respiratory causes; and respiratory symptoms not requiring hospitalization. Also included in the $PM_{2.5}$ risk assessment were total, cardiopulmonary, and lung cancer mortality associated with long-term exposure.

The available long-term exposure mortality concentration-response functions are all based on cohort studies, in which a cohort of individuals is followed over time. Based on the evaluation contained in the Criteria Document and EPA's assessment of the complete data base addressing mortality associated with long-term exposure to $PM_{2.5}$, studies based on the following two cohorts were identified as being particularly relevant for the $PM_{2.5}$ risk assessment: (1) The Six Cities study cohort (referred to as Krewski et al. (2000)—Six Cities) and (2) the ACS cohort (referred to Krewski et al. (2000)—ACS), which includes a much larger number of individuals from many more cities. In addition, Pope et al. (2002) extended the follow-up period for the ACS cohort to sixteen years and published findings on the relation of long-term exposure to $PM_{2.5}$ and all-cause mortality as well as cardiopulmonary and lung cancer mortality (referred to as Pope et al. (2002)—ACS extended).[22]

The available short-term exposure morbidity and mortality concentration-response functions used in the risk assessment are all from time series studies. The risk assessment included only those health endpoints for which the the Criteria Document concluded that there is likely to be a causal relationship with short-term exposure to $PM_{2.5}$ based on the overall weight of the evidence from the collective body of available studies. Also, given the large number of endpoints and studies addressing $PM_{2.5}$-related effects, the assessment only included the more severe and better understood (in terms of health consequences) health effects. As noted above, in contrast to the prior risk assessment, the concentration-response functions used in this assessment for each urban area are

[21] In June 2001, OAQPS released a draft document, PM NAAQS Risk Analysis Scoping Plan (EPA, 2001), for CASAC consultation and public comment, which described staff's general plan for this assessment. In January 2002, OAQPS released a more detailed draft document, Proposed Methodology for Particulate Matter Risk Analyses for Selected Urban Areas (Abt Associates, 2002), for CASAC review and public comment, which described staff's plans to assess (a) $PM_{2.5}$-related risks for several health endpoints, including mortality, hospital admissions, and respiratory symptoms and (b) $PM_{10-2.5}$-related risks for hospital admissions and respiratory symptoms (as discussed below in Section III.B).

[22] The use of these particular cohort studies to estimate health risks associated with long-term exposure to $PM_{2.5}$ is consistent with the views expressed in the National Academy of Sciences (2002) report, ''Estimating the Public Health Benefits of Proposed Air Pollution Regulations,'' and the Science Advisory Board Clean Air Act Compliance Council review of the proposed methodology to estimate the health benefits associated with the Clean Air Act (SAB, 2004).

based on results of studies for that specific area or from a multi-city study that included that specific area.

The concentration-response relationships used in the assessment were based on findings from human 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 [23] or above various selected higher cutpoints intended as surrogates for alternative assumed population thresholds). 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 uncontrollable background PM concentrations. For the base case analyses, an estimate of the annual average background level was used, rather than a maximum 24-hour value, since estimated risks were aggregated for each day throughout the year.

In order to estimate the incidence of a particular health effect associated with recent conditions in a specific county or set of counties attributable to ambient $PM_{2.5}$ exposures in excess of background or various alternative cutpoints, as well as the change in incidence corresponding to a given change in $PM_{2.5}$ levels resulting from just meeting a specified set of alternative $PM_{2.5}$ standards, three elements are required. 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 concentrations; and (3) annual or seasonal baseline health effects incidence rates and population data, which are needed to provide an estimate of the annual or seasonal baseline incidence of health effects in an area before any changes in PM air quality.

The risk assessment for $PM_{2.5}$ included a series of base case analyses that characterized the uncertainty associated with the form of the concentration-response relationship drawn from the studies used in the assessment—this uncertainty had by far the greatest impact on estimated risks. Other uncertainties addressed in various sensitivity analyses (e.g., the use of single-versus multi-pollutant models, single-versus multi-city models, use of a distributed lag model, alternative assumptions about the relevant air quality for long-term exposure mortality, and alternative constant or varying background levels) all have a more moderate and often variable impact on the risk estimates in some or all of the cities.

In estimating health risks remaining upon just meeting the current and alternative $PM_{2.5}$ standards, the assessment includes a series of base cases, while noting that the confidence ranges in the estimates do not reflect all the identified uncertainties. As discussed above in section II.A.3, additional uncertainty for short-term exposure mortality is related to the use of alternative statistical models and methods to control for time-varying effects, such as weather or season, and to address alternative lag structures. To provide a consistent basis for comparison across studies and locations, the risk assessment used concentration-response functions based on the most common type of analysis (''generalized additive methods'') and on lag structures judged to be most appropriate for each specific health endpoint, as discussed in the Staff Paper (EPA, 2005a, p. 4–24). The risk assessment included a sensitivity analysis for one location where a wide array of statistical models and lags was reported in the health study for that location (Los Angeles, as reported in Moolgavkar, 2003). EPA recognizes that there is additional uncertainty associated with choices about appropriate modeling strategy (EPA, 2004, 8.4.2) and that this uncertainty is not included in the confidence ranges presented for the risk estimates.

As noted earlier, EPA recognizes that while there are likely biological thresholds in individuals for specific health endpoints, the available epidemiologic studies do not support or refute the existence of thresholds at the population level for either long-term or short-term $PM_{2.5}$ exposures within the range of air quality observed in the studies (EPA, 2004, 9.2.2.5). Thus, base case risks were estimated using not only the linear or log-linear concentration-response functions reported in the studies, but also using a series of modified linear functions, as discussed below, as surrogates for assumed non-linear functions that would reflect the possibility that thresholds may exist in the reported associations within the range of air quality observed in the studies.

For short-term exposure mortality and morbidity outcomes associated with $PM_{2.5}$, the initial base case includes linear or log-linear concentration-response models reported in the epidemiology studies which are applied down to the estimated policy-relevant background concentration level. Generally, the lowest measured concentrations in the short-term exposure studies were relatively near or below the estimated policy-relevant background levels such that little or no extrapolation was required beyond the range of data in the studies. In the case of the long-term exposure mortality studies for $PM_{2.5}$ that have been included in the risk assessment, the lowest measured levels were in the range 7.5 to 11 $\mu g/m^3$. For the initial base case scenario for this endpoint, the reported linear models were applied down to 7.5 $\mu g/m^3$, which is the lowest measured level reported in the long-term studies. Going down to an estimated policy-relevant background level for short-term exposure studies and to 7.5 $\mu g/m^3$ for long-term studies provides a consistent framework which facilitates comparison of risk estimates across urban locations within each group of studies and avoids significant extrapolation beyond the range of concentrations included in these studies.

Additional base case scenarios for both short- and long-term exposure health endpoints involved the use of alternative concentration-response functions that incorporated a modified linear slope with an imposed cutpoint (i.e., an assumed threshold). For mortality associated with short-term exposure, the base case analyses included risk estimates associated with cutpoints of 10, 15, and 20 $\mu g/m$. For mortality associated with long-term $PM_{2.5}$ exposure, cutpoints of 10 and 12 $\mu g/m^3$ were included. For the base case scenarios involving alternative cutpoints, the approach used to develop alternative functions incorporates a modified linear slope with an imposed cutpoint (i.e., an assumed population threshold) that is intended to reflect a

[23] Background PM concentrations used in the PM risk assessment were defined in Chapter 2 of the Staff Paper as the PM concentrations that would be observed in the U.S. in the absence of anthropogenic emissions of PM and its precursors in the U.S., Canada, and Mexico. For the initial base case risk estimates, the midpoints of the appropriate ranges of annual average estimates for $PM_{2.5}$ background presented in the Staff Paper were used (i.e., eastern values were used for eastern study locations and western values were used for western study locations). Estimated policy-relevant background concentrations are 3.5 $\mu g/m^3$ in eastern cities, and 2.5 $\mu g/m^3$ in western cities.

hypothetical inflection point in a typical non-linear, ''hockey-stick'' shaped function, below which there is little or no population response. More specifically, the slope of the concentration-response relationship has been adjusted assuming that the upward-sloping portion of the ''hockey stick'' would be the slope estimated in the original epidemiologic study adjusted by the inverse of the proportion of the range of PM levels observed in the study that was above the cutpoint. The Staff Paper concludes that this simple slope adjustment approach represents a reasonable approach to illustrating the potential impact of possible non-linear concentration-response relationships. In its review of the Staff Paper and risk assessment, the CASAC PM Panel commented that for the purpose of estimating public health impacts, it ''favored the primary use of an assumed threshold of 10 μg/m^3'' and that ''a major research need is for more work to determine the existence and level of any thresholds that may exist or the shape of nonlinear concentration-response curves at low levels of exposure that may exist'' (Henderson, 2005a).

3. Risk Estimates and Key Observations

In focusing on the five study areas that do not meet the current $PM_{2.5}$ standards based on 2001–2003 air quality data (Detroit, Los Angeles, Philadelphia, Pittsburgh, and St. Louis), the total mortality risk estimates associated with simulating air quality reductions to just meet the current $PM_{2.5}$ standards (based on associations with long-term $PM_{2.5}$ exposure, and using the lowest cutpoint of 7.5 μg/m^3) range from several hundred to over 1500 deaths per year, which translate into an incidence rate of approximately 16 to 35 deaths per year per hundred thousand population.[24] These estimated risks associated with long-term exposure represent approximately 2.6 to 3.2 percent of total mortality in those areas. Estimated risks associated with long-term exposure based on an assumed cutpoint of 10 μg/m^3 are roughly half as large as the estimates based on a cutpoint of 7.5 μg/m^3. In the same five areas, the estimates of mortality risk associated with short-term $PM_{2.5}$ exposure, based on a cutpoint equal to policy-relevant background or 10 μg/m, range from less than 20 percent to over 50 percent of the estimates associated with long-term exposure.[25]

Reductions in risk associated with simulating air quality to just meet a range of lower alternative annual and 24-hour $PM_{2.5}$ standards were also estimated in this assessment. The estimated risk reductions are depicted graphically in the Staff Paper (EPA, 2005a, Figures 5–1 and 5–2 and Figures 5A–1 and 5A–2), showing patterns of estimated risk reductions associated with alternative suites of standards for all the various assumed cutpoints. As would be expected, patterns of increasing estimated risk reductions are observed as either the annual or 24-hour standard, or both, are reduced over the range considered in this assessment, and the estimated percentage reductions in risk are strongly influenced by the assumed cutpoint level.

The discussion below highlights additional observations and insights from this $PM_{2.5}$ risk assessment, together with important caveats and limitations.

(1) With respect to short-term exposure mortality and morbidity, this risk assessment provides the basis for greater confidence in the results as compared to the prior assessment, given that studies are now available using $PM_{2.5}$ as the indicator in a much greater number of locations, and the assessment is able to use city-specific functions that are matched to the locations for which risks are estimated. This contrasts with the use of pooled concentration-response functions in the prior assessment which did not include studies for the specific cities included in that assessment. However, EPA recognizes that the confidence ranges, which only reflect uncertainty associated with the precision of the study (related to the population size and duration of the study), may be larger for the current risk estimates due to the use of concentration-response functions from smaller, city-specific studies now versus the use of concentration-response functions from pooled sets of studies that have greater statistical precision. Comparing the risk estimates for the only two specific locations that were included in both the prior and current assessments, the magnitude of the estimates associated with just meeting the current annual standard, in terms of percentage of total incidence, is similar in one of the locations (Philadelphia) and the current estimate is lower in the other location (Los Angeles).

(2) With respect to long-term exposure mortality risk estimates, the prior risk assessment focused on the estimates based on the original ACS study (Pope et al., 1995). Since that time additional cohort analyses have been published and evaluated in the Criteria Document. EPA has greater confidence in the current risk estimates for long-term exposure mortality, given the extensive review of these studies and the extension of the ACS study to additional years of data, as well as improvements in the statistical approach. However, ACS-based risk estimates remain sensitive to plausible changes in statistical model specifications. The choice of studies and concentration-response functions to use for the base case risk estimates is discussed in the Staff Paper (EPA, 2005a, p. 4–25) and risk assessment report (Abt Associates, 2005, pp.49–50) and is consistent with the advice provided by both the National Academy of Sciences and the Science Advisory board Clean Air Act Compliance Council (see footnote 22). At the same time, EPA recognizes that alternative statistical models were examined in the reanalysis of the ACS and Six-Cities studies, and that the uncertainty associated with model selection (such as multipollutant models and different effect estimates associated with different educational levels) is not reflected in the confidence ranges presented in this assessment. Thus, for long-term exposure mortality risk estimates there are additional unquantified uncertainties associated with a lack of understanding as to which statistical model best represents the actual concentration-response function. The relative risk estimates used in the current risk assessment from the ACS extended study are only slightly smaller (1.06 with 95 percent confidence interval of 1.02–1.11) compared to the original ACS study (1.07 with 95 percent confidence interval 1.04–1.10) used in the prior assessment. In terms of the magnitude of the risk estimates, the estimates in terms of percentage of total incidence are very similar for the two specific locations included in both the prior and current assessments.

(3) A fairly wide range of risk estimates are observed for $PM_{2.5}$-related morbidity and mortality risk associated with recent air quality across the urban areas analyzed. The impact of adding additional co-pollutants to the models was variable; sometimes there was relatively little difference, while in other cases there were larger differences. The wide variability in risk estimates associated with a recent year of air

[24] The full range of quantitative risk estimates associated with just meeting the current $PM_{2.5}$ standards are presented in Tables 4–9, 4–10, 4–12, and 4–13 in Chapter 4 of the Staff Paper.

[25] In some areas, the 95 percent confidence ranges associated with the risk estimates for short-term exposure (but not long-term exposure) extend to below zero, reflecting appreciably more uncertainty in estimates based on positive but not statistically significant associations.

quality is to be expected given the wide range of $PM_{2.5}$ levels across the urban areas analyzed and the variation observed in the concentration-response relationships obtained from the original epidemiologic studies. Among other factors, this variability may reflect differences in the mixture of components or sources of fine particles, populations, exposure considerations (e.g., degree of air conditioning use), differences in co-pollutants and/or other stressors, differences in study design, and differences related to exposure and monitor measurement error.

(4) The single most important factor influencing the quantitative estimates of risk is which of the alternative concentration-response functions included in this assessment are considered to best represent the unknown ''true'' concentration-response relationships. In comparison, the following uncertainties have only a moderate impact on the risk estimates in some or all of the cities: choice of an alternative estimated constant background level, use of a distributed lag model, and alternative assumptions about the relevant air quality for estimating exposure levels for long-term exposure mortality. Use of a distribution of daily background concentrations had very little impact on the risk estimates.

The overall pattern of risk associated with short-term $PM_{2.5}$ exposures across the distribution of $PM_{2.5}$ air quality, as typically observed in urban areas, is similar to that observed in the last review. That is, on an annual basis, the very highest days (which pose the greatest risk in terms of deaths per day) contribute less to the total annual health risk associated with short-term exposures than the middle of the distribution, due to the much greater number of days that occur in this part of the air quality distribution.

(5) Risk estimates associated with just meeting the current suite of $PM_{2.5}$ standards in five urban areas that do not meet the current $PM_{2.5}$ standards showed a wide range of $PM_{2.5}$-related risk estimates for short-term exposure mortality and morbidity. This is likely due, in large part, to differences in concentration-response relationships among single-location short-term exposure studies, differences in baseline incidence rates, and varying population sizes. Results of a sensitivity analysis which applied one multi-city concentration-response function to all five urban areas analyzed narrowed considerably the range of risk estimates when a risk metric was used that normalized for different population sizes. However, it is still unknown whether the wider range of estimates observed using single-city concentration-response functions reflect methodological differences between studies and/or real city-to-city differences related to exposure, population, composition of the particles, or other factors.

(6) For the risk estimates associated with just meeting the current suite of $PM_{2.5}$ standards and alternative suites of standards, the single most important factor influencing the short- and long-term exposure mortality and morbidity estimates is again which of the alternative concentration-response functions included in this assessment are considered to best represent the unknown ''true'' concentration-response relationships. Several additional sources of uncertainty are introduced into this portion of the risk assessment, including: (1) Uncertainty in the degree to which the pattern of air quality concentration reductions estimated for the risk assessment cities represents the distribution of actual PM concentration changes that would be observed in a given area (''rollback uncertainty'') and (2) uncertainty concerning the degree to which current PM risk coefficients may reflect contributions from other pollutants, or uncertainty concerning whether all of the constituents of $PM_{2.5}$ would be reduced in similar proportion to the reduction in $PM_{2.5}$ as a whole, and, if not, what impact this would have on estimated reductions in risk. For areas where the current annual standard is the controlling standard, one alternative approach to rolling back the distribution of daily $PM_{2.5}$ concentrations, in which the upper end of the distributions of concentrations was reduced by a greater amount than the rest of the distribution, had little impact on the risk estimates. This approach or alternative approaches to rolling back the distribution of daily concentrations may have a greater impact on the risk estimates in areas where the daily standard is the controlling standard.

(7) For the risk estimates associated with just meeting the current or alternative suites of $PM_{2.5}$ standards, there is a significant decrease in the mortality risk estimates based on short-term $PM_{2.5}$ exposure remaining as one considers alternative higher cutpoints. There also is a significant increase observed in the percent reduction in estimated risk upon just meeting alternative standards with higher alternative cutpoints. These findings are even more pronounced for the mortality risk estimates associated with long-term $PM_{2.5}$ exposure as higher alternative cutpoint levels are considered.

C. Need for Revision 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 advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the existing standards should be revised. Based on the information and conclusions presented in the Criteria Document, summarized above in section II.A., the Staff Paper concludes that the newly available information generally reinforces the associations between $PM_{2.5}$ and mortality and morbidity effects observed in the last review. While important uncertainties and research questions remain, much progress has been made in reducing some key uncertainties since the last review. The examination of specific components, properties, and sources of fine particles that are linked with health effects remains an important research need. Other important research needs include better characterizing the shape of concentration-response functions, including identification of potential threshold levels, and methodological issues such as those associated with selecting appropriate statistical models in time-series studies to address time-varying factors (such as weather) and other factors (such as other pollution variables), and better characterizing population exposures. Nonetheless, important progress has been made in advancing our understanding of potential mechanisms by which ambient $PM_{2.5}$, alone and in combination with other pollutants, is causally linked with cardiovascular, respiratory, and lung cancer associations observed in epidemiologic studies. In addition, health effects associations reported in epidemiologic studies have been found to be generally robust to confounding by co-pollutants, there is now greater confidence in the results of long-term exposure studies due to reanalyses and extensions of the critical studies, and there is an increased understanding of susceptible populations. Based on these considerations, the Staff Paper finds clear support in the available evidence for fine particle standards that are at least as protective as the current $PM_{2.5}$ standards (EPA, 2005a, p. 5–6).

Having reached this initial conclusion, the Staff Paper addresses the question of whether the available evidence supports consideration of standards that are more protective than the current $PM_{2.5}$ standards. In so doing, the Staff Paper considers whether there is now evidence (1) that statistically significant health effects associations

with short-term exposures to fine particles occur in areas that would likely meet the current $PM_{2.5}$ standards or (2) that such associations with long-term exposures to fine particles extend down to lower air quality levels than had previously been observed.[26] This takes into consideration the bases for the decisions made in 1997 in setting the current $PM_{2.5}$ standards. In generally considering what areas would likely meet the current $PM_{2.5}$ standards, the focus is principally on comparing the long-term average $PM_{2.5}$ level in an area with the level of the current annual $PM_{2.5}$ standard, since in 1997 that standard was set to be the ''generally controlling'' standard to provide protection against health effects related to both short- and long-term exposures to fine particles. In conjunction with such an annual standard, the current 24-hour standard was set to provide only supplemental protection against days with high peak $PM_{2.5}$ concentrations, localized ''hotspots,'' or risks arising from seasonal emissions that might not be well controlled by a national annual standard.

In first considering the available epidemiologic evidence related to short-term exposures, the Staff Paper focuses on specific epidemiologic studies that show statistically significant associations between $PM_{2.5}$ and health effects for which the Criteria Document judges associations with $PM_{2.5}$ to be likely causal (EPA, 2005a, section 5.3.1.1). Many more U.S. and Canadian studies are now available that provide evidence of associations between short-term exposure to $PM_{2.5}$ and serious health effects in areas with air quality at and above the level of the current annual $PM_{2.5}$ standard (15 μg/m3). Moreover, a few newly available short-term exposure mortality studies provide evidence of statistically significant associations with $PM_{2.5}$ in areas with air quality levels below the levels of the current $PM_{2.5}$ standards. In considering these studies, the Staff Paper focuses on those that include adequate gravimetric $PM_{2.5}$ mass measurements, and where the associations are generally robust to alternative model specification and to the inclusion of potentially confounding co-pollutants. Three such studies conducted in Phoenix (Mar et al., 2003), Santa Clara County, CA (Fairley, 2003) and eight Canadian cities (Burnett and Goldberg, 2003) report statistically significant associations between short-term $PM_{2.5}$ exposure and total and cardiovascular mortality in areas in which long-term average $PM_{2.5}$ concentrations ranged between 13 and 14 $\mu g/m^3$ and 98th percentile concentrations ranged between 32 and 59 $\mu g/m^3$.[27]

In also considering the new epidemiologic evidence available from U.S. and Canadian studies of long-term exposure to fine particles, the Criteria Document notes that new studies have built upon studies available in the last review and concludes that these studies have confirmed and strengthened the evidence of associations for both mortality and respiratory morbidity (EPA, 2004, section 9.2.3). For mortality, the Criteria Document places greatest weight on the reanalyses and extensions of the Six Cities and ACS studies, finding that these studies provide strong evidence for associations with fine particles (EPA, 2004, p. 9–34), notwithstanding the lack of consistent results in other long-term exposure studies. For morbidity, the Criteria Document finds that new studies of a cohort of children in Southern California have built upon earlier limited evidence to provide fairly strong evidence that long-term exposure to fine particles is associated with development of chronic respiratory disease and reduced lung function growth (EPA, 2004, pp. 9–33 to 9–34). In addition to strengthening the evidence of association, the new extended ACS mortality study observed statistically significant associations with cardiorespiratory mortality (including lung cancer mortality) across a range of long-term mean $PM_{2.5}$ concentrations that was lower than was reported in the original ACS study available in the last review.

Beyond the epidemiologic studies using $PM_{2.5}$ as an indicator of fine particles, a large body of newly available evidence from studies that used PM_{10}, as well as other indicators or components of fine particles (e.g., sulfates, combustion-related components), provides additional support for the conclusions reached in the last review as to the likely causal role of ambient PM, and the likely importance of fine particles in contributing to observed health effects. Such studies notably include new multi-city studies, intervention studies (that relate reductions in ambient PM to observed improvements in respiratory or cardiovascular health), and source-oriented studies (e.g., suggesting associations with combustion- and vehicle-related sources of fine particles). The Criteria Document also notes that new epidemiologic studies of asthma-related increased physicians visits and symptoms, as well as new studies of cardiac-related risk factors, suggest likely much larger public health impacts due to ambient fine particles than just those indexed by the mortality and morbidity effects considered in the last review (EPA, 2004, p. 9–94).

In reviewing this information, the Staff Paper recognizes that important limitations and uncertainties associated with this expanded body of evidence for $PM_{2.5}$ and other indicators or components of fine particles, noted above in section II.A.2, need to be carefully considered in determining the weight to be placed on the body of studies available in this review. For example, the Criteria Document notes that while PM-effects associations continue to be observed across most new studies, the newer findings do not fully resolve the extent to which the associations are properly attributed to PM acting alone or in combination with other gaseous co-pollutants, particularly SO_2, or to the gaseous co-pollutants themselves. The Criteria Document concludes, however, that overall the various approaches that have now been used to evaluate this issue substantiate that associations for various PM indicators with mortality and morbidity are generally robust to confounding by co-pollutants (EPA, 2004, p. 9–37).

While the limitations and uncertainties in the available evidence suggest caution in interpreting the epidemiologic studies at the lower levels of air quality observed in the studies, the Staff Paper concludes that the evidence now available provides strong support for considering fine particle standards that would provide increased protection beyond that afforded by the current $PM_{2.5}$ standards. The Staff Paper notes that a more protective suite of $PM_{2.5}$ standards would reflect the generally stronger and broader body of evidence of associations with mortality and morbidity now available in this review, both at levels

[26] In addressing this question, the Staff Paper first recognizes, as discussed above in section II.A.3, that although there are likely biologic threshold levels in individuals for specific health responses, the available epidemiologic evidence neither supports nor refutes the existence of thresholds at the population level for the effects of $PM_{2.5}$ on mortality across the range of concentrations in the studies, for either long-term or short-term $PM_{2.5}$ exposures (EPA, 2004, section 9.2.2.5).

[27] As noted in the Staff Paper, these studies were reanalyzed to address questions about the application of the statistical software used in the original analyses, and the study results from Phoenix and Santa Clara County were little changed in alternative models (Mar et al., 2003; Fairley, 2003), although Burnett and Goldberg (2003) reported that their results were sensitive to using different temporal smoothing methods. Two of these studies also reported significant associations with gaseous pollutants (Mar et al., 2003; Fairley, 2003), and the other study included multi-pollutant model results in reanalyses, reporting that associations with $PM_{2.5}$ remained significant with gaseous pollutants (Fairley, 2003).

below the current standards and extending to lower levels of air quality than in earlier studies, as well as increased understanding of possible underlying mechanisms.

In addition to this evidence-based evaluation, the Staff Paper also considers the extent to which health risks estimated to occur upon attainment of 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 Staff Paper first notes that the risk assessment addresses a number of key uncertainties through various base case analyses, as well as through several sensitivity analyses, as discussed above in section II.B. In considering the health risks estimated to occur upon attainment of the current $PM_{2.5}$ standards, the Staff Paper focuses in particular on a series of base case risk estimates, while recognizing that the confidence ranges in the selected base case estimates do not reflect all the identified uncertainties. These risks were estimated using not only the linear or log-linear concentration-response functions reported in the studies,[28] but also using alternative modified linear functions as surrogates for assumed non-linear functions that would reflect the possibility that thresholds may exist in the reported associations within the range of air quality observed in the studies. Regardless of the relative weight placed on the risk estimates associated with the concentration-response functions reported in the studies or with the modified functions favored by CASAC,[29] the risk assessment indicates the possibility that thousands of premature deaths per year would occur in urban areas across the U.S. upon attainment of the current $PM_{2.5}$ standards.[30] Beyond the estimated incidences of premature mortality, the Staff Paper also recognizes that similarly substantial numbers of incidences of hospital admissions, emergency room visits, aggravation of asthma and other respiratory symptoms, and increased cardiac-related risk are also likely in many urban areas, based on risk assessment results (EPA, 2005a, Chapter 4) and on the discussion related to this pyramid of effects in the Criteria Document (EPA, 2004, section 9.2.5). Based on these considerations, the Staff Paper concludes that the estimates of risks likely to remain upon attainment of the current $PM_{2.5}$ standards are indicative of risks that can reasonably be judged to be important from a public health perspective.

In considering available evidence, risk estimates, and related limitations and uncertainties, the Staff Paper concludes that the available information clearly calls into question the adequacy of the current suite of $PM_{2.5}$ standards and provides strong support for revising the current $PM_{2.5}$ standards to provide increased public health protection. Also taking into account these considerations, the CASAC advised the Administrator that a majority of CASAC Panel members were in agreement that the primary 24-hour and annual $PM_{2.5}$ standards ''should be modified to provide increase public health protection'' (Henderson, 2005a). The CASAC further advised that changes to either the annual standard or the 24-hour standard, or both, could be recommended, and expressed reasons that formed the basis for the consensus among the Panel members for placing more emphasis on lowering the 24-hour standard (Henderson, 2005a).[31]

In considering whether the suite of primary $PM_{2.5}$ standards should be revised to provide requisite public health protection, the Administrator has carefully considered the rationale and recommendations contained in the Staff Paper, the advice and recommendations from CASAC, and public comments to date on this issue. In so doing, the Administrator places primary consideration on the evidence obtained from the studies, and provisionally finds the evidence of serious health effects reported in short-term exposure studies conducted in areas that would attain the current standards to be compelling, especially in light of the extent to which such studies are part of an overall pattern of positive and frequently statistically significant associations across a broad range of studies that collectively represent a strong and robust body of evidence. As discussed in the Criteria Document and Staff Paper, the Administrator recognizes that much progress has been made since the last review in addressing some of the key uncertainties that were important considerations in establishing the current $PM_{2.5}$ standards. In considering the risk assessment presented in the Staff Paper, the Administrator notes that the assessment contained a sensitivity analysis but not a formal uncertainty analysis, making it difficult to use the risk assessment to form a judgment of the probability of various risk estimates. Instead, the Administrator views the risk assessment in light of his evaluation of the underlying studies. Seen in this light, the risk assessment informs the determination of the public health significance of risks to the extent that the evidence is judged to support an effect at a particular level of air quality. Based on these considerations, 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.

D. Indicator of Fine Particles

In 1997, EPA established $PM_{2.5}$ as the indicator for fine particles. In reaching this decision, the Agency first considered whether the indicator should be based on the mass of a size-differentiated sample of fine particles or on one or more components within the mix of fine particles. Secondly, in establishing a size-based indicator, a size cut needed to be selected that would appropriately distinguish fine particles from particles in the coarse mode.

In addressing the first question in the last review, EPA determined that it was appropriate to control fine particles as a group, as opposed to singling out any particular component or class of fine particles. Community health studies had found significant associations between various indicators of fine particles (including $PM_{2.5}$ or PM_{10} in areas dominated by fine particles) and health effects in a large number of areas that had significant mass contributions of differing components or sources of fine particles, including sulfates, wood smoke, nitrates, secondary organic compounds and acid sulfate aerosols. In addition, a number of animal

[28] As discussed above in section II.B.2, the reported linear or log-linear concentration-response functions were applied down to 7.5 $\mu g/m^3$ in estimating risk associated with long-term exposure (i.e., the lowest measured level in the extended ACS study), and down to the estimated policy-relevant background level in estimating risk associated with short-term exposure (i.e., 3.5 $\mu g/m^3$ for eastern urban areas and 2.5 $\mu g/m^3$ for western urban areas).

[29] The CASAC PM Panel generally favored the primary use of an assumed threshold of 10 $\mu g/m^3$ for the various concentration-response functions used in the risk assessment (Henderson, 2005a).

[30] The Staff Paper recognizes how highly dependent any specific risk estimates are on the assumed shape of the underlying concentration-response functions, noting nonetheless that mortality risks are not completely eliminated when current $PM_{2.5}$ standards are met in a number of example urban areas even using the highest assumed cutpoint levels considered in the risk assessment (EPA, 2005a, p. 5–15).

[31] Of the individual Panel members who submitted written comments expressing views on appropriate levels of the $PM_{2.5}$ standards, only one did not suppport changes to either the 24-hour or annual standard to provide additional public health protection (Henderson, 2005a). In written comments, the health scientists on the CASAC Panel did not agree on whether the annual standard should be lowered.

toxicologic and controlled human exposure studies had reported health effects associations with high concentrations of numerous fine particle components (e.g., sulfates, nitrates, transition metals, organic compounds), although such associations were not consistently observed. It also was not possible to rule out any component within the mix of fine particles as not contributing to the fine particle effects found in epidemiologic studies. For these reasons, EPA concluded that total mass of fine particles was the most appropriate indicator for fine particle standards rather than an indicator based on PM composition (62 FR 38667, July 18, 1997).

Having selected a size-based indicator for fine particles, the Agency then based its selection of a specific size cut on a number of considerations. In focusing on a size cut within the size range of 1 to 3 μm (i.e., the intermodal range between fine and coarse mode particles), the Agency noted that the available epidemiologic studies of fine particles were based largely on $PM_{2.5}$; only very limited use of PM_1 monitors had been made. While it was recognized that using PM_1 as an indicator of fine particles would exclude the tail of the coarse mode in some locations, in other locations it would miss a portion of the fine PM, especially under high humidity conditions, which would result in falsely low fine PM measurements on days with some of the highest fine PM concentrations. The selection of a 2.5 μm size cut reflected the regulatory importance that was placed on defining an indicator for fine particle standards that would more completely capture fine particles under all conditions likely to be encountered across the U.S., especially when fine particle concentrations are likely to be high, while recognizing that some small coarse particles would also be captured by $PM_{2.5}$ monitoring. Thus, EPA's selection of 2.5 μm as the size cut for the fine particle indicator was based on considerations of consistency with the epidemiologic studies, the regulatory importance of more completely capturing fine particles under all conditions, and the potential for limited intrusion of coarse particles in some areas; it also took into account the general availability of monitoring technology (62 FR 38668).

In this current review, the same considerations continue to apply for selection of an appropriate indicator for fine particles. As an initial matter, the available epidemiologic studies linking mortality and morbidity effects with short- and long-term exposures to fine particles continue to be largely indexed by $PM_{2.5}$. Some epidemiologic studies also have continued to implicate various components within the mix of fine particles that have been more commonly studied (e.g., sulfates, nitrates, carbon, organic compounds, and metals) as being associated with adverse effects (EPA, 2004, p. 9–31, Table 9–3). In addition, several recent studies have used $PM_{2.5}$ speciation data to evaluate the association between mortality and particles from different sources (Schwartz, 2003a; Mar et al., 2003; Tsai et al., 2000; EPA, 2004, section 8.2.2.5). Schwartz (2003a) reported statistically significant associations for mortality with factors representing fine particles from traffic and residual oil combustion that were little changed in reanalysis to address statistical modeling issues, and also an association between mortality and coal combustion-related particles that was reduced in size and lost statistical significance in reanalysis. In Phoenix, significant associations were reported between mortality and fine particles from traffic emissions, vegetative burning, and regional sulfate sources that remained unchanged in reanalysis models (Mar et al., 2003). Finally, a small study in three New Jersey cities reported significant associations between mortality and fine particles from industrial, oil burning, motor vehicle and sulfate aerosol sources, though the results were somewhat inconsistent between cities (Tsai et al., 2000).[32] No significant increase in mortality was reported with a source factor representing crustal material in fine particles (CD, p. 8–85). Recognizing that these three studies represent a very preliminary effort to distinguish effects of fine particles from different sources, and that the results are not always consistent across the cities, the Criteria Document found that these studies indicate that exposure to fine particles from combustion sources, but not crustal material, is associated with mortality (EPA, 2004, p. 8–77). Animal toxicologic and controlled human exposure studies have continued to link a variety of PM components or particle types (e.g., sulfates, notably primary metal sulfate emissions from residual oil burning, metals, organic constituents, bioaerosols, diesel particles) with health effects, though often at high concentrations (EPA, 2004, section 7.10.2). In addition, some recent studies have suggested that the ultrafine subset of fine particles (generally including particles with a nominal mean aerodynamic diameter less than 0.1 μm) may also be associated with adverse effects (EPA, 2004, pp. 8–67 to 68).

The Criteria Document recognizes that, for a given health response, some fine particle components are likely to be more closely linked with that response than others. The presumption that different PM constituents may have differing biological responses is toxicologically plausible and an important source of uncertainty in interpreting such epidemiologic evidence. For specific effects there may be stronger correlation with individual PM components than with aggregate particle mass. In addition, particles or particle-bound water can act as carriers to deliver other toxic agents into the respiratory tract, suggesting that exposure to particles may elicit effects that are linked with a mixture of components more than with any individual PM component (EPA, 2004, section 9.2.3.1.3).

Thus, epidemiologic and toxicologic studies have provided evidence for effects associated with various fine particle components or size-differentiated subsets of fine particles. The Criteria Document concludes: ''These studies suggest that many different chemical components of fine particles and a variety of different types of source categories are all associated with, and probably contribute to, mortality, either independently or in combinations'' (EPA, 2004, p. 9–31). Conversely, the Criteria Document provides no basis to conclude that any individual fine particle component cannot be associated with adverse health effects (EPA, 2005a, p. 5–17). In short, there is not sufficient evidence that would lead toward the selection of one or more PM components as being primarily responsible for effects associated with fine particles, nor is there sufficient evidence to suggest that any component should be eliminated from the indicator for fine particles. The Staff Paper continues to recognize the importance of an indicator that not only captures all of the most harmful components of fine particles (i.e., an effective indicator), but also emphasizes control of those constituents or fractions, including sulfates, transition metals, and organics that have been associated with health effects in epidemiologic and/or toxicologic studies, and is thus most likely to result in the largest risk reduction (i.e., an efficient indicator). Taking into account the above considerations, the Staff Paper concludes that it remains appropriate to

[32] More specifically, statistically significant associations were reported with factors representing fine particles from oil burning, industrial and sulfate aerosol sources in Newark and with particles from oil burning and motor vehicle sources in Camden, and no statistically significant associations were reported in Elizabeth.

control fine particles as a group; i.e., that total mass of fine particles is the most appropriate indicator for fine particle standards (EPA, 2005a, p. 5–17).

With regard to an appropriate size cut for a size-based indicator of total fine particle mass, the Criteria Document concludes that advances in our understanding of the characteristics of fine particles continue to support the use of particle size as an appropriate basis for distinguishing between these subclasses, and that a nominal size cut of 2.5 μm remains appropriate (EPA, 2004, p. 9–22). This conclusion follows from a recognition that within the intermodal range of 1 to 3 μm there is no unambiguous definition of an appropriate size cut for the separation of the overlapping fine and coarse particle modes. Within this range, the Staff Paper considered size cuts of both 1 μm and 2.5 μm. Consideration of these two size cuts took into account that there is generally very little mass in this intermodal range, although in some circumstances (*e.g.*, windy, dusty areas) the coarse mode can extend down to and below 1 μm, whereas in other circumstances (*e.g.*, high humidity conditions, usually associated with very high fine particle concentrations) the fine mode can extend up to and above 2.5 μm. The same considerations that led to the selection of a 2.5 μm size cut in the last review—that the epidemiologic evidence was largely based on $PM_{2.5}$ and that it was more important from a regulatory perspective to capture fine particles more completely under all conditions likely to be encountered across the U.S. (especially when fine particle concentrations are likely to be high) than to avoid some coarse-mode intrusion into the fine fraction in some areas—led to the same recommendation by the Staff Paper (EPA, 2005a, p. 5–18) and CASAC (Henderson, 2005a) in this review. In addition, the Staff Paper recognizes that particles can act as carriers of water, oxidative compounds, and other components into the respiratory system, which adds to the importance of ensuring that larger accumulation-mode particles are included in the fine particle size cut (EPA, 2005a, p. 5–18).

Consistent with the Staff Paper and CASAC recommendations, the Administrator proposes to retain $PM_{2.5}$ as the indicator for fine particles. Further, the Administrator provisionally concludes that currently available studies do not provide a sufficient basis for supplementing mass-based fine particle standards with standards for any specific fine particle component or subset of fine particles, or for eliminating any individual component or subset of components from fine particle mass standards. Addressing the current uncertainties in the evidence of effects associated with various fine particle components and types of source categories is an important element in EPA's ongoing PM research program.

The Administrator notes that some commenters have expressed views about the importance of evaluating health effect associations with various fine particle components and types of source categories as a basis for focusing ongoing and future research to reduce uncertainties in this area and for considering whether alternative indicator(s) are now or may be appropriate for standards intended to protect against the array of health effects that have been associated with fine particles as indexed by $PM_{2.5}$.[33] Information from such studies could also help inform the development of strategies that emphasize control of specific types of emission sources so as to address particles of greatest concern to public health. While recognizing that the studies evaluated in the Criteria Document provide some limited evidence of such associations that is helping to focus research activities, the Administrator solicits broad public comment on issues related to studies of fine particle components and types of source categories and their usefulness as a basis for consideration of alternative indicator(s) for fine particle standards. In general, comment is solicited on relevant new published research, recommendations for studies that would be appropriate for inclusion in future research activities, and approaches to assessing the available and future research results to determine whether alternative indicators for fine particles are warranted to provide effective protection of public health from effects associated with long- and short-term exposure to ambient fine particles.

More specifically, comment is also solicited on a number of related issues. One such issue is the extent to which reducing particular types of PM (differentiated by either size or chemistry) might alter the size and toxicity of remaining particles, and on the extent to which fine particles in urban and rural areas can be differentiated by size or chemistry. Another issue deals with assessment of human exposure and its relationship with pollution measurements at monitors (EPA, 2004, chapter 5); comment is solicited on the extent to which the latest scientific information can be used to improve our understanding of the relationship of monitored pollution levels to human exposure. Comment is also solicited on studies using concentrated ambient particles (CAPs) and their use in examining the toxicity of specific mixtures of pollutants or of particular source categories.

[33] Such comments have focused in part on newer studies that have become available since the close of the Criteria Document, which EPA intends to include in its assessment of potentially significant new studies discussed above in section I.D.

E. Averaging Time of Primary $PM_{2.5}$ Standards

In the last review, EPA established two $PM_{2.5}$ standards, based on annual and 24-hour averaging times, respectively (62 FR at 38668–70). This decision was based in part on evidence of health effects related to both short-term (from less than 1 day to up to several days) and long-term (from a year to several years) measures of PM. EPA noted that the large majority of community epidemiologic studies reported associations based on 24-hour averaging times or on multiple-day averages. Further, EPA noted that a 24-hour standard could also effectively protect against episodes lasting several days, as well as providing some degree of protection from potential effects associated with shorter duration exposures. EPA also recognized that an annual standard would provide effective protection against both annual and multi-year, cumulative exposures that had been associated with an array of health effects, and that a much longer averaging time would complicate and unnecessarily delay control strategies and attainment decisions. EPA considered the possibility of seasonal effects, although the very limited available evidence of such effects and the seasonal variability of sources of fine particle emissions across the country did not provide an adequate basis for establishing a seasonal averaging time.

In considering whether the information available in this review supports consideration of different averaging times for $PM_{2.5}$ standards, the Staff Paper concludes that the available information is generally consistent with and supportive of the conclusions reached in the last review to set $PM_{2.5}$ standards with both annual and 24-hour averaging times. In considering the new information, the Staff Paper makes the following observations (EPA, 2005a, section 5.3.3):

(1) There is a growing body of studies that provide additional evidence of effects associated with exposure periods shorter than 24-hours (*e.g.*, one to several hours) (EPA, 2004, section 3.5.5.1). While the Staff Paper concludes

that this information remains too limited to serve as a basis for establishing a shorter-than-24-hour fine particle primary standard at this time, it also noted that this information gives added weight to the importance of a standard with a 24-hour averaging time.

(2) Some recent PM_{10} studies have used a distributed lag over several days to weeks preceding the health event, although this modeling approach has not been extended to studies of fine particles (EPA, 2004, section 3.5.5). While such studies continue to suggest consideration of a multiple day averaging time, the Staff Paper notes that limiting 24-hour concentrations of fine particles will also protect against effects found to be associated with PM averaged over many days in health studies. Consistent with the conclusion reached in the last review, the Staff Paper concludes that a multiple-day averaging time would add complexity without providing more effective protection than a 24-hour average.

(3) While some newer studies have investigated seasonal effects (EPA, 2004, section 3.5.5.3), the Staff Paper concludes that currently available evidence of such effects is still too limited to serve as a basis for considering seasonal standards.

Based on the above considerations, the Staff Paper and CASAC (Henderson, 2005a) recommend retaining the current annual and 24-hour averaging times for $PM_{2.5}$ primary standards. The Administrator concurs with the staff and CASAC recommendations and proposes that averaging times for $PM_{2.5}$ standards should continue to include annual and 24-hour averages to protect against health effects associated with short-term (hours to days) and long-term (seasons to years) exposure periods.

F. Form of Primary $PM_{2.5}$ Standards

1. 24-Hour $PM_{2.5}$ Standard

In 1997 EPA established the form of the 24-hour $PM_{2.5}$ standard as the 98th percentile of the annual 24-hour concentrations at each population-oriented monitor within an area, averaged over three years (62 FR at 38671–74). EPA selected such a concentration-based form because of its advantages over the previously used expected-exceedance form.[34] A concentration-based form is more reflective of the health risk posed by elevated $PM_{2.5}$ concentrations because it 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 standard. Further, a concentration-based form better compensates for missing data and less-than-every-day monitoring; and, when averaged over 3 years, it has greater stability and, thus, facilitates the development of more stable implementation programs.[35] After considering a range of concentration percentiles from the 95th to the 99th, EPA selected the 98th percentile as an appropriate balance between adequately limiting the occurrence of peak concentrations and providing increased stability and robustness. Further, by basing the form of the standard on concentrations measured at population-oriented monitoring sites (as specified in 40 CFR part 58), EPA intended to provide protection for people residing in or near localized areas of elevated concentrations.

In this review, the Staff Paper concludes that it is appropriate to retain a concentration-based form that is defined in terms of a specific percentile of the distribution of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area, averaged over 3 years. This staff recommendation is based on the same reasons that were the basis for EPA's selection of this type of form in the last review. As to the specific percentile value to be considered, the Staff Paper took into consideration (1) the relative risk reduction afforded by alternative forms at the same standard level, (2) the relative year-to-year stability of the air quality statistic to be used as the basis for the form of a standard, and (3) the implications from a public health communication perspective of the extent to which either form allows different numbers of days in a year to be above the level of the standard in areas that attain the standard. Based on these considerations, the Staff Paper recommends either retaining the 98th percentile form or revising it to be based on the 99th percentile form, and notes that primary consideration should be given to the combination of form and level, as compared to looking at the form in isolation (EPA, 2005a, p. 5–44).

In considering the information provided in the Staff Paper, most CASAC Panel members favored continued use of the 98th percentile form because it is more robust than the 99th percentile form, such that it would provide more stability to prevent areas from bouncing in and out of attainment from year to year (Henderson 2005a). In recommending retention of the 98th percentile form, the CASAC Panel recognized that it is the link between the form and level of a standard that determines the degree of public health protection afforded by a standard.

In considering the available information and the Staff Paper and CASAC recommendations, the Administrator proposes that the form of the 24-hour standard should be based on the 98th percentile form. In so doing, the Administrator has focused on the relative stability of the 98th and 99th percentile forms as a basis for selecting the 98th percentile form, while 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.

2. Annual $PM_{2.5}$ Standard

In 1997 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 of the annual standard was intended to represent a relatively stable measure of air quality and to characterize area-wide $PM_{2.5}$ concentrations in conjunction with a 24-hour standard designed to provide adequate protection against localized peak or seasonal $PM_{2.5}$ levels. The current annual $PM_{2.5}$ standard level is to be compared to measurements made at the community-oriented monitoring site recording the highest level, or, if specific constraints are met, measurements from multiple community-oriented monitoring sites may be averaged (Part 50 App. N section 2.1(a) and (b) and Part 58 App. D at 2.8.1.6.1; 62 FR 38,672, July 18, 1997). Community-oriented monitoring sites were specified to be consistent with the intent that a spatially averaged annual standard protect those in smaller communities, as well as those in larger population centers. The constraints on allowing the use of spatially averaged measurements were intended to limit averaging across poorly correlated or widely disparate air quality values.[36] This approach was judged to be consistent with the epidemiologic studies on which the $PM_{2.5}$ standard

[34] The form of the 1987 24-hour PM_{10} standard is based on the expected number of days per year (averaged over 3 years) on which the level of the standard is exceeded; thus, attainment of the one-expected exceedance form is determined by comparing the fourth-highest concentration in 3 years with the level of the standard.

[35] See *American Trucking Associations* v. *EPA*, 283 F. 3d at 374–75 (legitimate for EPA to consider promotion of overall effectiveness of NAAQS implementation programs, including their overall stability, in setting a standard that is requisite to protect the public health).

[36] The current constraints include the criteria that the correlation coefficient between monitor pairs to be averaged be at least 0.6, and that differences in mean air quality values between monitors to be averaged not exceed 20 percent (Part 58 App. D at 2.8.1.6.1).

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, not localized ''hot spots'' (62 FR 38672). These criteria and constraints were intended to ensure that spatial averaging would not result in inequities in the level of protection afforded by the $PM_{2.5}$ standards (*Id.*).

In this review, there now exist much more $PM_{2.5}$ air quality data than were available in the last review. Consideration in the Staff Paper of the spatial variability across urban areas that is revealed by this new database has raised questions as to whether an annual standard that allows for spatial averaging, within currently specified or alternative constraints, would provide appropriate public health protection. Analyses in the Staff Paper to assess these questions, as discussed below, have taken into account both aggregate population risk across an entire urban area and the potential for disproportionate impacts on potentially vulnerable subpopulations within an area.

The effect of allowing the use of spatial averaging on aggregate population risk was considered in sensitivity analyses included in the health risk assessment (EPA, 2005a). In particular, analyses were done in several urban areas that compared estimated mortality risks based on calculating compliance with alternative standards (1) using air quality values from the highest community-oriented monitor in an area and (2) using air quality values averaged across all such monitors within the constraints allowed by the current standard.[37] As expected, estimated risks associated with long-term exposures remaining upon just meeting the current annual standard are greater when spatial averaging is used than when the highest monitor is used (*i.e.*, the estimated reductions in risk associated with just attaining the current or alternative annual standards are less when spatial averaging is used), as the use of the highest monitor leads to greater modeled reductions in ambient $PM_{2.5}$ concentrations.[38]

In considering the potential for disproportionate impacts on potentially vulnerable subpopulations, analyses were done to assess whether any such groups are more likely to live in census tracts in which the monitors recording the highest air quality values in an area are located. Data were obtained for demographic parameters measured at the census tract level, including education level, income level, and percent minority population. Data from the census tract in each area in which the highest air quality value was monitored were compared to the area-wide average value (consistent with the constraints on spatial averaging provided by the current standard) in each area. (Schmidt *et al.*, 2005). Recognizing the limitations of such cross-sectional analyses, the Staff Paper observes that the results suggest 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 percentage minority levels (EPA, 2005a, p. 5–41).[39] Noting the intended purposes of the form of the annual standard, as discussed above, the Staff Paper concludes that the existing constraints on spatial averaging may not be adequate to avoid substantially greater exposures in some areas, potentially resulting in disproportionate impacts on potentially vulnerable subpopulations.

In considering whether more stringent constraints on the use of spatial averaging may be appropriate, the Staff Paper presents results of an analysis of recent air quality data on the correlations and differences between monitor pairs in metropolitan areas across the country (Schmidt et al., 2005). For all pairs of $PM_{2.5}$ monitors, the median correlation coefficient based on annual air quality data is approximately 0.9, which is substantially higher than the current criterion for correlation of at least 0.6, which was met by nearly all monitor pairs. Similarly, the current criterion that differences in mean air quality values between monitors not exceed 20 percent was met for most monitor pairs, while the annual median and mean differences for all monitor pairs are 5 percent and 8 percent, respectively. This analysis also shows that in some areas with highly seasonal air quality patterns (e.g., due to seasonal wood smoke emissions), substantially lower seasonal correlations and larger seasonal differences can occur relative to those observed on an annual basis. This analysis provides some perspective on the constraints on spatial averaging that were put in place in the last review, before data were widely available on spatial distributions of $PM_{2.5}$ air quality levels, based on the extensive air quality data and related analyses that have become available since the last review.

In considering the results of the analyses discussed above, the Staff Paper concludes that it is appropriate to consider either eliminating the provision that allows for spatial averaging from the form of an annual $PM_{2.5}$ standard or revising the allowance for spatial averaging to be based on more restrictive criteria. More specifically, based on the analyses discussed above, the Staff Paper recommends consideration of revised criteria such that the correlation coefficient between monitor pairs to be averaged be at least 0.9, determined on a seasonal basis, with differences between monitor values not to exceed 10 percent (EPA, 2005a, p. 5–42).

In considering the Staff Paper recommendations based on the results of the analyses discussed above, and focusing on a desire to be consistent with the epidemiologic studies on which the $PM_{2.5}$ health effects are based and concern over the evidence of potential disproportionate impact on potentially vulnerable subpopulations, the Administrator proposes to revise the form of the annual $PM_{2.5}$ standard consistent with the Staff Paper recommendation to change the criteria for use of spatial averaging such that the correlation coefficient between monitor pairs must be at least 0.9, determined on a seasonal basis, with differences between monitor values not to exceed 10 percent. The Administrator also solicits comment on the other Staff Paper-recommended alternative of revising the form of the annual $PM_{2.5}$

[37] As discussed in the Staff Paper, section 4.2.2, the monitored air quality values were used to determine the design value for the annual standard in each area, as applied to a ''composite'' monitor to reflect area-wide exposures. Changing the basis of the annual standard design value from the concentration at the highest monitor to the average concentration across all monitors changes the ambient $PM_{2.5}$ levels that are needed to just meet the current or alternative annual standards. With averaging, less overall reduction in ambient $PM_{2.5}$ is needed to just meet the standards.

[38] For example, based on analyses conducted in three example urban areas, estimated mortality incidence associated with long-term exposure based on the use of spatial averaging is about 10 to over 40 percent higher than estimated incidence based on the use of the highest monitor (EPA, 2005a, p. 5–41).

[39] As summarized in section II.A.4 above, the Criteria Document notes that some epidemiologic study results, most notably the associations between mortality and long-term $PM_{2.5}$ exposure in the ACS cohort, have shown larger effect estimates in the cohort subgroup with lower education levels (EPA, 2004, p. 8–103). The Criteria Document also notes that lower education level can be a marker for lower socioeconomic status that may be related to increased vulnerability to the effects of fine particle exposures, for example, as a result of greater exposure to sources such as roadways. Lower education level may be associated with other potential risk factors, such as poorer health status or access to health care, that may also result in increased susceptibility to the effects of air pollution exposure (EPA, 2004, section 9.2.4.5)

standard to one based on the highest community-oriented monitor in an area, with no allowance for spatial averaging.

G. Level of Primary $PM_{2.5}$ Standards

In the last review, having concluded that both 24-hour and annual $PM_{2.5}$ standards were appropriate, EPA selected a level for each standard that was appropriate for the function to be served by such standard (62 FR 38652). As discussed above, EPA concluded at that time that the suite of $PM_{2.5}$ standards could most effectively and efficiently protect public health by treating the annual standard as the generally controlling standard for lowering both short- and long-term $PM_{2.5}$ concentrations.[40] In conjunction with such an annual standard, the 24-hour standard was intended to provide protection against days with high peak $PM_{2.5}$ concentrations, localized ''hotspots,'' and risks arising from seasonal emissions that would not be well controlled by an annual standard.[41]

In selecting the level for the annual standard in the last review, EPA used an evidence-based approach that considered the evidence from both short- and long-term exposure studies. The risk assessment conducted in the last review, while providing qualitative insights about the distribution of risks, was considered to be too limited to serve as a quantitative basis for decisions on the standard levels. In accordance with Staff Paper and CASAC views on the relative strengths of the short- and long-term exposure studies, greater emphasis was placed on the short-term exposure studies. In so doing, EPA first determined a level for the annual standard based on the short-term exposure studies, and then considered whether the long-term exposure studies suggested the need for a lower level. While recognizing that health effects could occur over the full range of concentrations observed in the studies, EPA concluded that the strongest evidence for short-term $PM_{2.5}$ effects occurs at concentrations near the long-term (e.g., annual) average in those studies reporting statistically significant health effects. Thus, in the last review, EPA selected a level for the annual standard that was below the lowest long-term average $PM_{2.5}$ concentration in a short-term exposure study that reported statistically significant health effects. Further consideration of the average $PM_{2.5}$ concentrations across the cities in the key long-term exposure studies available at that time did not provide a basis for establishing a lower annual standard level.

In this review, the approach used in the Staff Paper as a basis for staff recommendations on standard levels builds upon and broadens the general approach used by EPA in the last review. This broader approach reflects the more extensive and stronger body of evidence now available on health effects related to both short- and long-term exposure to $PM_{2.5}$, together with the availability of much more extensive $PM_{2.5}$ air quality data. This newly available information has been used to conduct a more comprehensive risk assessment for $PM_{2.5}$. As a consequence, the broader approach used in the Staff Paper discusses ways to take into account both evidence-based and quantitative risk-based considerations and places relatively greater emphasis on evidence from long-term exposure studies than was done in the last review.

Given the extensive body of new evidence based specifically on $PM_{2.5}$ that is now available, and the resulting broader approach presented in the Staff Paper, the Administrator considers it appropriate to use a different approach from that used in the last review to select appropriate standard levels. More specifically, the Administrator's proposal relies on an evidence-based approach that considers the much expanded body of evidence from short-term exposure $PM_{2.5}$ studies as the principal basis for selecting the level of the 24-hour standard and the stronger and more robust body of evidence from the long-term exposure $PM_{2.5}$ studies as the principal basis for selecting the level of the annual standard. In the Administrator's view, the very large number of health effect studies that are now available provide the most reliable basis for standard setting. With respect to the quantitative risk assessment, the Administrator recognizes that it rests on a more extensive body of data and is more comprehensive in scope than the assessment conducted in the last review, but is mindful that significant uncertainties continue to underlie the resulting risk estimates. Such uncertainties generally relate to a lack of clear understanding of a number of important factors, including for example: The shape of concentration-response functions, particularly when, as here, effect thresholds can neither be discerned nor determined not to exist; issues related to selection of appropriate statistical models for the analysis of the epidemiologic data; the role of potentially confounding and modifying factors in the concentration-response relationships; issues related to simulating how $PM_{2.5}$ air quality distributions will likely change in any given area upon attaining a particular standard, since strategies to reduce emissions are not yet defined; and whether there would be differential reductions in the many components within $PM_{2.5}$ and if so whether this would result in differential reductions in risk. In the case of fine particles, the Administrator recognizes that such uncertainties are likely to be unusually large due to the complexity in the composition of the mix of fine particles generally present in the ambient air. Further, in the Administrator's view, a risk assessment based on studies that do not resolve the issue of a threshold is inherently limited as a basis for standard setting, since it will necessarily predict that ever lower standards result in ever lower risks, which has the effect of masking the increasing uncertainty inherent as lower levels are considered. As a result, while the Administrator views the risk assessment as providing supporting evidence for the conclusion that there is a need to revise the current suite of $PM_{2.5}$ standards, he judges that it does not provide a reliable basis to determine what specific quantitative revisions are appropriate.

1. 24-Hour $PM_{2.5}$ Standard

Based on the approach discussed above, the Administrator has relied upon evidence from the short-term exposure $PM_{2.5}$ 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 Staff Paper of looking at the 98th percentile values in these studies. In so doing, the Administrator recognizes that these studies provide no evidence of clear effect thresholds or lowest-observed-effects levels. Thus, in focusing on 98th percentile values in these studies, the Administrator is seeking to establish a standard level that will require improvements in air quality generally in areas in which short-term exposure to $PM_{2.5}$ can reasonably be expected to be associated with serious

[40] In so doing, EPA noted that an annual standard would focus control programs on annual average $PM_{2.5}$ concentrations, which would generally control the overall distribution of 24-hour exposure levels, as well as long-term exposure levels, and would also result 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, 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).

[41] See also *American Trucking Associations* v. *EPA*, 283 F.3d at 373 (endorsing this reasoning).

health effects. While strategies that may be employed in the future to bring about such improvements in air quality in any particular area are not yet defined, most such strategies are likely to move the broad distribution of $PM_{2.5}$ air quality values in an area lower, resulting in reductions in risk associated with exposures to $PM_{2.5}$ levels across a wide range of concentrations.

Based on the information in the Staff Paper and a supporting staff memo,[42] the Administrator observes an overall pattern of statistically significant associations reported in studies of short-term exposure to $PM_{2.5}$ across a wide range of 98th percentile values. More specifically, there is a strong predominance of studies with 98th percentile values down to about 39 μg/m³ (in Burnett and Goldberg, 2003) reporting statistically significant associations with mortality, hospital admissions, and respiratory symptoms. For example, within this range of air quality, statistically significant associations were reported for mortality in the combined Six City study (and three of the individual cities within that study) (Klemm and Mason, 2003), the Canadian 8-City Study (Burnett and Goldberg, 2003), and in studies in Santa Clara County, CA (Fairley, 2003) and Philadelphia (Lipfert, 2000); for hospital admissions and emergency department visits in Seattle (Sheppard et al., 2003), Toronto (Burnett et al., 1997; Thurston et al., 1994), Detroit (Ito, 2003, for ischemic heart disease and pneumonia, but not for other causes), and Montreal (Delfino et al., 1998, 1997, for some but not all age groups and years); for respiratory symptoms in panel studies in a combined Six City study (Schwartz et al., 1994) and in two Pennsylvania cities (Uniontown in Neas et al., 1995; State College in Neas et al., 1996); and for lung function in Philadelphia (Neas et al., 1999).[43] Studies in this air quality range that reported positive but not statistically significant associations with mortality include studies in Detroit (Ito, 2003), Pittsburgh (Chock et al., 2000), and Montreal (Goldberg and Burnett, 2003).

Within the range of 98th percentile $PM_{2.5}$ concentrations of about 35 to 30 μg/m³, this strong predominance of statistically significant results is no longer observed. Rather, within this range, some studies report statistically significant results (Mar et al., 2003; Ostro et al., 2003), other studies report mixed results in which some associations reported in the study are statistically significant and others are not (Delfino et al., 1997; Peters et al., 2000),[44] and another study reports associations in two of six cities that are not statistically significant (Klemm and Mason, 2003). Further, the very limited number of studies in which the 98th percentile values are below this range do not provide a basis for reaching conclusions about associations at such levels (Stieb et al., 2000; Peters et al., 2001). Thus, in the Administrator's view, this body of evidence provides confidence that statistically significant associations are occurring down close to this range, and it provides a clear basis for concluding that this range represents a range of reasonable values and thus for selecting a 24-hour standard level from within this range. The Administrator further notes that focusing on the range of 35 to 30 μg/m³ is consistent with the interpretation of the evidence held by most CASAC Panel members as reflected in their recommendation to select a 24-hour $PM_{2.5}$ standard level within this range (Henderson, 2005a). The Administrator recognizes, however, the separate point that most CASAC Panel members favored the range of 35 to 30 μg/m³ for the 24-hour $PM_{2.5}$ standard in concert with an annual standard set in the range of 14 to 13 μg/m3 (Henderson, 2005a), as discussed in section II.G.2 below.

In considering what 24-hour standard is requisite to protect public health with an adequate margin of safety, the Administrator is mindful that this choice requires judgment based on an interpretation of the evidence that neither overstates nor understates the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. In the absence of evidence of any clear effect thresholds, the Administrator may select a specific standard level from within a range of reasonable values. In making this judgment, the Administrator notes that the general uncertainties related to the shape of the concentration-response functions and the selection of appropriate statistical models affect the likelihood that observed associations are causal down to the lowest concentrations in the studies. Further, and more specifically, the variation in results found in the short-term exposure studies in which the 98th percentile values were below 35 μg/m³ indicates an increase in uncertainty as to whether likely causal associations extend down below this level.

In considering the extent to which the quantitative risk assessment inform his selection of a 24-hour $PM_{2.5}$ standard, the Administrator recognizes that risk estimates based on simulating the attainment of standards set at lower levels within this range will inevitably suggest some additional reductions in risk at each lower standard level considered. However, these quantitative risk estimates largely depend upon assumptions made about the lowest level at which reported associations will likely persist and remain causal in nature. Thus, the Administrator is hesitant to use such risk estimates as a basis for proposing a standard level below 35 μg/m³, and instead prefers to rely on inferences that are based directly on the evidence in the studies themselves.

Taking the above considerations into account, the Administrator proposes to set the level of the primary 24-hour $PM_{2.5}$ standard at 35 μg/m³. In the Administrator's judgment, based on the currently available evidence, a standard set at this level would protect public health with an adequate margin of safety from serious health effects including premature mortality and hospital admissions for cardiorespiratory causes that are likely causally associated with short-term exposure to $PM_{2.5}$. This judgment by the Administrator appropriately considers the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes 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. Being mindful that the available evidence does not provide a basis for identifying a bright line within the range of 35 to 30 μg/m³ that clearly provides the appropriate degree of public health protection, the Administrator also

[42] As discussed in the Staff Paper (EPA, 2005a, p. 5–30) and supporting staff memo (Ross and Langstaff, 2005), staff focused on U.S. and Canadian short-term exposure $PM_{2.5}$ studies that had been reanalyzed as appropriate to address statistical modeling issues and considered the extent to which the reported associations are robust to co-pollutant confounding and alternative modeling approaches and the extent to which the studies used relatively reliable air quality data.

[43] Of the studies within this group that evaluated multipollutant associations, as discussed above in section II.A.3, the results reported in Fairley (2003), Sheppard et al. (2003), and Ito (2003) were generally robust to inclusion of gaseous co-pollutants, whereas the effect estimate in Thurston et al. (1994) was substantially reduced with the inclusion of O_3.

[44] For example, Delfino et al. (1997) report statistically significant associations between $PM_{2.5}$ and respiratory emergency department visits for elderly people (>64 years old), but not children (<2 years old) in one part of the study period (summer 1993) but not the other (summer 1992). Peters et al. (2000) report new findings of associations between fine particles and cardiac arrhythmia, but the Criteria Document observes that the strongest associations were reported for a small subset of the study population that had experienced 10 or more defibrillator discharges (EPA, 2004, p. 8–164).

solicits comment on selecting a lower level within this range.

Having reached this decision to propose a level of 35 μg/m^3 for the 24-hour $PM_{2.5}$ standard based on the approach to interpreting the available evidence described above, the Administrator recognizes that other approaches to selecting a standard level have been presented to the Agency. These other approaches reflect alternative views, principally expressed in public comments to date, as to the appropriate interpretation of the scientific evidence and the appropriate policy response in light of that interpretation. One such view focuses very strongly on the uncertainties inherent in the epidemiologic and toxicologic studies and the quantitative risk assessment as the basis for concluding that no change to the current 24-hour $PM_{2.5}$ standard of 65 μg/m^3 is warranted. Such commenters prefer greater weight, for example, on issues related to the sensitivity in the magnitude and statistical significance of relative risks reported in studies using different statistical models, noting that further research is needed to inform modeling strategies that will appropriately adjust for temporal trends and weather variables in time-series studies. Additional uncertainties arise from the potential confounding by co-pollutants, and the potential differential toxicity of components within the mix of fine particles. These commenters suggest that the magnitude of risks associated with fine particle exposures have decreased since the last review. Some such commenters also focus on considerations such as the absence of clear evidence from toxicologic studies and from studies focused on elucidating specific physiologic mechanisms by which $PM_{2.5}$ may be causing the observed effects. Such commenters recognize a need for a 24-hour $PM_{2.5}$ standard, but consider the evidence to be too uncertain overall to warrant any tightening of the standard and instead believe the appropriate policy response in light of this uncertainty is to retain the current level of the 24-hour standard.

Other commenters who also focus strongly on the uncertainties inherent in the epidemiologic and toxicologic studies and the quantitative risk assessment reach a somewhat different conclusion as to the appropriate policy response in light of these uncertainties. This group of commenters sees a basis for lowering the level of the 24-hour $PM_{2.5}$ standard, but does not believe that a level as low as 35 μg/m^3 is warranted. Such commenters note that while many of the studies within the range of air quality from approximately 39 μg/m^3 up to the level of the current standard of 65 μg/m^3 report statistically significant results, only a few such studies independently evaluated confounding by co-pollutants. This lack of a broader assessment of co-pollutants, together with other types of uncertainties as noted above, leads such commenters to conclude that a standard level selected from below this range is not warranted, and that the appropriate policy response is to select a standard level from within the range of about 40 to 65 μg/m^3.

In sharp contrast, others view the epidemiologic evidence and other health studies as strong and robust, and generally place much weight on the results of the quantitative risk assessment as a basis for concluding that a much stronger policy response is warranted, generally consistent with a standard level at or below 25 μg/m^3. While recognizing that important uncertainties are inherently present in both the evidence and estimated risks, these commenters generally support a view that such uncertainties warrant a highly precautionary policy response, particularly in view of the serious nature of the health effects at issue, and should be addressed by selecting a standard level that incorporates a large margin of safety.

The Administrator recognizes that these sharply divergent views on the appropriate level of the standard are based on very different interpretations of the science itself including its relative strengths and limitations and on very different judgments as to how such scientific evidence should be used in making policy decisions on proposed standards. Consistent with the goal of soliciting comments on a wide array of views, the Administrator also solicits broad public comment on these and other alternative approaches and on the related standard levels, such as levels from 35 μg/m^3 up to 65 μg/m^3 or from 30 μg/m^3 down to 25 μg/m^3, that commenters may believe are appropriate, along with the rationale supporting such approaches and levels. In addition, the Administrator solicits comments on issues related to the interpretation of relevant epidemiologic and toxicologic studies, including approaches to addressing uncertainties related to the sensitivity of results to alternative statistical modeling approaches, co-pollutant confounding, and the lack of a discernable threshold of effects, as well as approaches to more fully characterize uncertainties in quantitative risk assessments based on epidemiologic studies.

2. Annual $PM_{2.5}$ Standard

Based on the approach discussed at the beginning of this section, the Administrator has relied upon evidence from the long-term exposure $PM_{2.5}$ studies as the principal basis for selecting the level of the annual standard. In considering these studies as a basis for the level of an annual standard, the Administrator agrees with the focus in the Staff Paper of looking at the long-term mean $PM_{2.5}$ concentrations across the cities included in such studies. In so doing, the Administrator recognizes that these studies, like the short-term exposure studies, provide no evidence of clear effect thresholds or lowest-observed-effects levels. Thus, in focusing on the cross-city long-term mean concentrations in these studies, the Administrator is seeking to establish a standard level that will require improvements in air quality in areas in which long-term exposure to $PM_{2.5}$ can reasonably be expected to be associated with serious health effects.

Based on the characterization and assessment of the long-term exposure $PM_{2.5}$ studies presented in the Criteria Document and Staff Paper, the Administrator recognizes the importance of the validation efforts and reanalysis that have been done since the last review of the original Six Cities and ACS mortality studies. These new assessments provide evidence of generally robust associations and provide a basis for greater confidence in the reported associations than in the last review, for example, in the extent to which they have made progress in understanding the importance of issues related to co-pollutant confounding and the specification of statistical models. Consistent with the information available in the last review, these two key long-term exposure mortality studies reported long-term mean $PM_{2.5}$ concentrations across all the cities included in the studies of 18 and 21 μg/m^3, respectively. The Administrator also particularly recognizes the importance of the extended ACS mortality study, published since the last review, which provides new evidence of mortality related to lung cancer and further substantiates the statistically significant associations with cardiorespiratory-related mortality observed in the original studies. The Administrator notes that the statistically significant associations reported in the extended ACS study, in a large number of cities across the U.S., provide evidence of effects at a lower long-term mean $PM_{2.5}$ concentration (17.7 μg/m^3) than had been observed in the original study,

although the relative risk estimates are somewhat smaller in magnitude than those reported in the original study. The assessment in the Criteria Document of these mortality studies, taking into account study design, the strength of the study (in terms of statistical significance and precision of result), and the consistency and robustness of results, concludes that it would be appropriate to give the greatest weight to the reanalyses of the Six Cities and ACS studies, and in particular to the results of the extended ACS study (EPA, 2004, p. 9–33) in weighing the evidence of mortality effects associated with long-term exposure to $PM_{2.5}$. Consistent with that assessment, the Administrator places greatest weight on these studies as a basis for selecting the level of the annual $PM_{2.5}$ standard.

In addition to these mortality studies, the Administrator also recognizes the availability of relevant morbidity studies providing evidence of respiratory morbidity, including decreased lung function growth, in children with long-term exposure to $PM_{2.5}$. Studies conducted in the U.S. and Canada include the 24-city study considered in the last review and new studies of cohorts of children in southern California, in which the long-term mean $PM_{2.5}$ concentrations in all the cities included in the studies are approximately 14.5 and 15 $\mu g/m^3$, respectively. As discussed in section II.A. above, in the 24-city study, statistically significant associations were reported between long-term fine particle exposures and lung function measures at a single point in time, whereas positive but not statistically significant associations were reported with prevalence of several respiratory conditions. As interpreted in the last review, the results from the 24-city study are uncertain as to the extent to which the association extends below a long-term mean $PM_{2.5}$ concentration of approximately 15 $\mu g/m^3$. The new southern California children's cohort study provides evidence of important respiratory morbidity effects in children, including evidence for a new measure of morbidity, decreased growth in lung function. Reports from this study suggest that long-term $PM_{2.5}$ exposure is associated with decreases in lung function growth, as measured over a four-year follow-up period, although statistically significant associations are not consistently reported. The Administrator recognizes that these are important new findings, indicating that long-term $PM_{2.5}$ exposure may be associated with respiratory morbidity in children. However, the Administrator also observes this is the only study reporting decreased lung function growth, conducted in just one area of the country, such that further study of this health endpoint in other areas of the country would be needed to increase confidence in the reported associations. Thus, at this time, the Administrator provisionally concludes that this study provides an uncertain basis for establishing the level of a national standard.

As discussed in the Staff Paper (EPA, 2005a, p. 5–22), the Administrator generally agrees that it is appropriate to consider a level for an annual $PM_{2.5}$ standard that is below the averages of the long-term $PM_{2.5}$ concentrations across the cities in the key long-term exposure mortality studies, 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. The Administrator is mindful that considering what standard is requisite to protect public health with an adequate margin of safety requires policy judgments that neither overstate nor understate the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. The Administrator provisionally concludes that these key mortality studies, together with the morbidity studies, provide a basis for considering a standard level no higher than 15 $\mu g/m^3$. This level is somewhat below the long-term mean concentrations in the key mortality studies and consistent with the interpretation of the evidence from the morbidity studies discussed above. Further, in the Administrator's view, these studies do not provide a clear basis for selecting a level lower than the current standard of 15 $\mu g/m^3$.

In considering the extent to which the quantitative risk assessment can help to inform these judgments with regard to the annual $PM_{2.5}$ standard, the Administrator again recognizes that risk estimates based on simulating the attainment of standards set at lower levels, as expected, continue to suggest some additional reductions in risk at the lower standard level considered in the assessment, and that these estimates largely depend upon assumptions made about the lowest level at which reported associations will likely persist and remain causal in nature. Thus, the Administrator is again hesitant to use such risk estimates as a basis for proposing a lower annual standard level than 15 $\mu g/m^3$, the level that is based directly on the evidence in the studies themselves, as discussed above.

Taking the above considerations into account, the Administrator proposes to retain the level of the primary annual $PM_{2.5}$ standard at 15 $\mu g/m^3$. In the Administrator's judgment, based on the currently available evidence, a standard set at this level would be requisite to protect public health with an adequate margin of safety from serious health effects including premature mortality and respiratory morbidity that are likely causally associated with long-term exposure to $PM_{2.5}$. This judgment by the Administrator appropriately considers the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes 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.

In so doing, the Administrator recognizes that the CASAC Panel did not endorse retaining the annual standard at the current level of 15 $\mu g/m^3$ (Henderson, 2005a, p. 7). In weighing the recommendation of the CASAC Panel, the Administrator has carefully considered the stated reasons for it. In discussing its recommendation (Henderson, 2005a), the CASAC Panel first noted that changes to either the annual or 24-hour $PM_{2.5}$ standard, or both, could be recommended. Three reasons were then given for placing more emphasis on lowering the 24-hour standard than the annual standard: (1) The vast majority of studies indicating effects of short-term $PM_{2.5}$ exposure were carried out in settings in which $PM_{2.5}$ concentrations were largely below the current 24-hour standard level of 65 $\mu g/m^3$; (2) the amount of evidence on short-term exposure effects, at least as reflected by the number of reported studies, is greater than for long-term exposure effects; and (3) toxicologic findings are largely related to the effects of short-term, rather than long-term, exposures. In not endorsing the option of retaining the level of the current annual standard in conjunction with lowering the 24-hour standard, the CASAC Panel observed that some cities have relatively high annual $PM_{2.5}$ concentrations without much day-to-day variation and that such cities would only rarely exceed a 24-hour standard, even if it were set at a level below the current standard. In such a city, attaining a 24-hour standard would likely have minimal if any effect on the long-term mean $PM_{2.5}$ concentration and consequently would be less likely to reduce health effects associated with long-term exposures. These observations

were taken as an indication of the desirability of lowering the level of the annual $PM_{2.5}$ standard as well as that of the 24-hour standard. Based on these considerations and taking into account the results of the risk assessment, most CASAC Panel members favored setting an annual standard in the range of 14 to 13 $\mu g/m^3$, along with lowering the 24-hour standard (Henderson, 2005a).

In considering these views, the Administrator notes that the appropriateness of setting an annual standard that would lower annual $PM_{2.5}$ concentrations in cities across the country depends upon a policy judgment as to what annual level is required to protect public health with an adequate margin of safety from long-term exposures to $PM_{2.5}$ in light of the available evidence. In considering the evidence of effects associated with long-term $PM_{2.5}$ exposure as a basis for selecting an adequately health protective annual standard, as discussed above, the Administrator provisionally concludes that the evidence does not provide a basis for requiring annual levels below 15 $\mu g/m^3$. Thus, the Administrator agrees conceptually with the CASAC Panel that any particular 24-hour standard may not result in reductions in the level of long-term exposures to $PM_{2.5}$ in all areas with relatively higher than typical annual $PM_{2.5}$ concentrations and lower than typical ratios of peak-to-mean values. Further, the Administrator agrees that this general advice supports relying on the annual standard, and not the 24-hour standard, to achieve the appropriate level of protection from long-term exposures to $PM_{2.5}$. However, the Administrator does not believe that this advice necessarily translates into a reason for setting the annual $PM_{2.5}$ standard at a level below the current level of 15 $\mu g/m^3$. As discussed above, the Administrator believes the principal basis for selecting the appropriate level of an annual standard should be the evidence provided by the long-term studies, in conjunction with judgments concerning whether and over what range of concentrations reported associations are likely causal, and this evidence reasonably supports retaining the current level of the annual standard.

The Administrator places great importance on the advice of CASAC, and therefore solicits broad public comment on the range of 15 down to 13 $\mu g/m^3$, the low end of the range recommended by CASAC, for the level of the annual $PM_{2.5}$ standard as well as on the reasoning that formed the basis for that recommendation. A decision to select a standard from within this range would place greater weight on the strength of the associations reported in the key epidemiologic mortality and morbidity long-term exposure studies down to the lower part of the range of $PM_{2.5}$ concentrations observed across all the cities included in these studies. Such a standard could also reflect greater reliance on the results of the quantitative risk assessment that suggested increased reductions in risk associated with meeting an annual standard at such lower levels.

The Administrator recognizes that an even stronger view of the appropriate policy response to the currently available evidence has been expressed by some public commenters. These commenters have focused principally on the strength of the long-term exposure studies, including the new children's cohort study conducted in southern California, as well as on those results from the quantitative risk assessment that are based on the assumption that there is no threshold of effects down to the lowest levels observed in those studies. Such considerations generally have led these commenters to express views that support a highly precautionary policy response and the selection of a standard level that incorporates a large margin of safety, consistent with an annual $PM_{2.5}$ standard level of 12 $\mu g/m^3$. The Administrator recognizes that this view is based on a different interpretation of the science itself including its relative strengths and limitations and on different judgments as to how such scientific evidence should be used in making policy decisions on proposed standards. Consistent with the goal of soliciting comments on a wide array of views, the Administrator also solicits broad public comment on this alternative approach and on the related standard level of 12 $\mu g/m^3$.

The Administrator also recognizes a contrasting view as to the interpretation of and weight to be accorded to the results from the ACS-based studies (Pope et al., 1995; Krewski et al., 2000; Pope et al., 2002). In this view, the ACS-based studies are not sufficiently robust to support a policy response that would tighten the annual $PM_{2.5}$ standard based on the evidence. This view emphasizes the sensitivity of the results of these studies to plausible changes in model specification with regard to accounting for the geographical proximity of cities and the correlation of air pollutant concentrations within a region, effect modification by education level, and inclusion of SO_2 in the model. In this view, these sensitivities suggest potential confounding or effect modification that has not been taken into account. For example, concern has been raised about the sensitivity of results in the reanalysis of data from the ACS cohort study (Krewski et al., 2000) to inclusion of SO_2 in the models. As discussed in section II.A.2.b above, the reanalysis found that $PM_{2.5}$, sulfates, and SO_2 were each associated with mortality in single-pollutant models. However, in two-pollutant models with SO_2 and $PM_{2.5}$, the relative risk for $PM_{2.5}$ was substantially smaller and no longer statistically significant, whereas the effect estimates for SO_2 were not sensitive to inclusion of $PM_{2.5}$ or sulfates in two-pollutant models. In this view, the ACS-based risk estimates are more robust for SO_2 than for $PM_{2.5}$ or sulfates. In further extended analyses, Pope et al. (2002) reported that effect estimates were not highly sensitive to spatial smoothing approaches intended to address spatial autocorrelation, while findings of effect modification by education level were reaffirmed. Results of multi-pollutant models were not reported by Pope et al. (2002). Because the correlation coefficient between $PM_{2.5}$ and SO_2 was 0.50 in the ACS data, in this view it is plausible to believe that the independent effects of the two pollutants could be disentangled with additional study.

In this view, there is a separate but related concern that tightening the annual standard now, without a clear understanding of which specific PM-related pollutants are most toxic, will have very uncertain public health payoffs. In response to the advice of the National Research Council (NRC) and other scientists, the Agency is undertaking, as one of its higher priorities, a substantial research program to clarify which aspects of PM-related pollution are responsible for elevated risks of mortality and morbidity. For example, the Health Effects Institute has issued a request for applications to analyze the largest database on specific components of PM that has ever been assembled for public health and medical researchers. The time line for this multi-million dollar research program is well designed to inform the Agency's next periodic reevaluation of the primary ambient air quality standard for $PM_{2.5}$. In light of the degree of sensitivity of the ACS-based relative risk estimates to model specifications and the significant research underway, in this view, it would be wiser to consider modification of the annual standard with a fuller body of information in hand rather than initiate a change in the annual standard at this time.

The Administrator solicits comment on this view and on the issues raised in interpreting the results of the ACS-based

studies. For example, comment is solicited on the extent to which the associations reported in the ACS-based studies suggest that SO_2 should be considered as a surrogate for fine particles and/or the broader mix of air pollutants or as an independent pollutant exhibiting separate effects. Comment is also solicited on relevant research that would improve our understanding of issues related to model specification and alternative analytic approaches that would better inform judgments based on such epidemiologic studies in the future.

H. Proposed Decisions on Primary $PM_{2.5}$ Standards

For the reasons discussed above, and taking into account the information and assessments presented in the Criteria Document and Staff Paper, 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 24-hour $PM_{2.5}$ standard to 35 $\mu g/m^3$, and (2) the form of the annual $PM_{2.5}$ standard by changing the constraints on the use of spatial averaging to include the criterion that the minimum correlation coefficient between monitor pairs to be averaged be 0.9 or greater, determined on a seasonal basis, and the criterion that differences between monitor values not exceed 10 percent. Data handling conventions are specified in proposed revisions to Appendix N, as discussed in Section V below, and the reference method for monitoring PM as $PM_{2.5}$ is specified in proposed minor revisions to Appendix L, as discussed in Section VI below.

In recognition of alternative views of the science and the appropriate policy response based on the currently available information, the Administrator also solicits comments on (1) alternative levels of the 24-hour $PM_{2.5}$ standard within the range of 35 to 30 $\mu g/m^3$, and alternative approaches for selecting the level of the 24-hour $PM_{2.5}$ standard, and related levels (such as approaches that suggest retaining the current level of 65 $\mu g/m^3$, setting a level no higher than 25 $\mu g/m^3$, or setting a level within the range of 65 down to 35 $\mu g/m^3$); (2) alternative levels of the annual $PM_{2.5}$ standard below 15 $\mu g/m^3$ down to12 $\mu g/m^3$; (3) issues related to consideration of alternative indicators of fine particle components; and (4) an alternative form of the annual $PM_{2.5}$ standard based on the highest community-oriented monitor in an area. Based on the comments received and the accompanying rationales, the Administrator may adopt other standards within the range of the alternatives identified above in lieu of the standards he is proposing today.

The Administrator solicits comment on all aspects of this proposed decision. Comment is specifically invited on the methodology for evaluating the uncertainty and significance of risks to public health. The Administrator believes that it is important to further develop ways of addressing uncertainty when estimating such risk, recognizing the wide variety of information available in the underlying health effects and other studies. The Agency seeks comment on methods and approaches for conducting a more formalized uncertainty analysis. In addition, the Agency seeks comment on how to evaluate the results from a formalized uncertainty analysis or from the Staff Paper's risk assessment, which addresses multiple health effects across multiple populations, in the context of judging the public health importance of such risks and determining the requisite level of public health protection for the PM standards.

To address issues related to the transition from the current $PM_{2.5}$ standards to revised $PM_{2.5}$ standards, the Administrator intends to seek public comment on EPA's implementation plans for the revised $PM_{2.5}$ standards, including its plans for assuring an effective transition, as part of an advance notice of proposed rulemaking (ANPR) on NAAQS implementation that will be published in an early in 2006. In this ANPR, EPA will be discussing issues related to the timing and regulatory implications of this transition. The EPA intends to present and take comment on the need and potential approaches for revocation of the current 24-hour $PM_{2.5}$ standard, and on issues related to the establishment of no-backsliding requirements, such as those adopted by the Agency in 1997 with respect to the ozone NAAQS. The EPA also expects to address a variety of implementation issues concerning revised $PM_{2.5}$ standards in the ANPR. The ANPR will explain the designation process and its timing, and the timing of SIP submittals for both attainment and nonattainment areas. The EPA also expects to address issues regarding the attainment dates for areas designated nonattainment. The EPA will also discuss new source permitting requirements for both attainment and nonattainment areas, i.e., the PSD and Part D NSR programs. If the Administrator promulgates a revised $PM_{2.5}$ standard, EPA will determine the final implementation approach for that standard.

III. Rationale for Proposed Decisions on Primary PM_{10} Standards

This action presents the Administrator's proposed decisions on revision to the primary NAAQS for PM_{10}. The rationale for the proposed revisions of the primary PM_{10} NAAQS includes consideration of: (1) Evidence of health effects related to short- and long-term exposures to thoracic coarse particles; (2) insights gained from a quantitative risk assessment prepared by EPA; and (3) specific conclusions regarding the need for revisions to the current standards and the elements of PM_{10} standards (i.e., indicator, averaging time, form, and level) that, taken together, would be requisite to protect public health with an adequate margin of safety.

In developing this rationale, EPA has taken into account the information available from a growing, but still limited, body of evidence on health effects associated with thoracic coarse particles from studies that use $PM_{10-2.5}$ as a measure of thoracic coarse particles. The EPA has drawn upon an integrative synthesis of the body of evidence on associations between exposure to ambient thoracic coarse particles and a range of health endpoints (EPA, 2004, Chapter 9), focusing on those health endpoints for which the Criteria Document concludes that the associations are suggestive of possible causal relationships. In its policy assessment of the evidence judged to be most relevant to making decisions on elements of the standards, EPA has placed greater weight on U.S. and Canadian epidemiological studies using thoracic coarse particles measurements, since studies conducted in other countries may well reflect different demographic and air pollution characteristics.

While there is little question that particles in the thoracic coarse particle size range can present a risk of adverse effects to the most sensitive regions of the respiratory tract, the characterization of health effects attributable to various levels of exposure to ambient thoracic coarse particles is subject to uncertainties that are markedly greater than is the case for fine particles. As discussed below, however, there is a growing body of evidence available since the last review of the PM NAAQS, with important new information coming from epidemiologic, toxicologic, and dosimetric studies. Moreover, the newly available research studies have undergone intensive scrutiny through multiple layers of peer review and extended opportunities for public review and comment. While

important uncertainties remain, the review of the health effects information has been extensive and deliberate. In the judgment of the Administrator, this intensive evaluation of the scientific evidence has provided an adequate basis for proposing regulatory decisions at this time. This review also provides important input to EPA's research plan for improving our future understanding of the relationships between exposures to ambient thoracic coarse particles and health effects.

A. Evidence of Health Effects Related to Thoracic Coarse Particle Exposure

The first PM NAAQS (36 FR 8186) used an indicator based solely on a preexisting monitor for total suspended particles (TSP) that was not designed to focus on particles of greatest risk to health. In preparing for the initial review of those standards, EPA placed a major emphasis on developing a new indicator that considered the significant amount of evidence on particle size, composition, and relative risk of effects from penetration and deposition to the major regions of the respiratory tract (Miller et al., 1979). The development and assessment of these lines of evidence in the PM Criteria Document and PM Staff Paper published between 1979 and 1986 culminated in revised standards for PM that used PM_{10} as the indicator (52 FR 24634). The major conclusion from that review, which remained unchanged in the 1997 review, was that ambient particles smaller than or equal to 10 μm in aerodynamic diameter are capable of penetrating to the deeper ''thoracic'' [45] regions of the respiratory tract and present the greatest concern to health (61 FR 65648). While considerable advances have been made, the available evidence in this review continues to support the basic conclusions reached in the 1987 and 1997 reviews regarding penetration and deposition of fine and thoracic coarse particles. As discussed in the Criteria Document, both fine and thoracic coarse particles penetrate to and deposit in the alveolar and tracheobronchial regions. For a range of typical ambient size distributions, the total deposition of thoracic coarse particles to the alveolar region can be comparable to or even larger than that for fine particles. For areas with appreciable coarse particle concentrations, thoracic coarse particles would tend to dominate particle deposition to the tracheobronchial region for mouth breathers (EPA, 2004, p. 6–16). Deposition of particles to the tracheobronchial region is of particular concern with respect to aggravation of asthma.

In the last review, little new toxicologic evidence was available on potential effects of thoracic coarse particles and there were few epidemiologic studies that had included direct measurements of thoracic coarse particles. Evidence of associations between health outcomes and PM_{10} that were conducted in areas where PM_{10} was predominantly composed of thoracic coarse particles was an important part of the basis for reaching conclusions about the requisite level of protection provided against coarse particles for the final standards. The new studies available in this review include a number of epidemiologic studies that have reported associations with health effects using direct measurements of $PM_{10-2.5}$, as well as a number of new toxicologic studies.

This section outlines key information contained in the Criteria Document (Chapters 6–9 and the Staff Paper (Chapter 3) on known or potential effects associated with exposure to thoracic coarse particles and their major constituents. The information highlighted here summarizes: (1) New information available on potential mechanisms for health effects associated with exposure to thoracic coarse particles or their constituents; (2) the nature of the effects that have been associated with ambient thoracic coarse particles or their constituents; (3) an integrative assessment of the evidence on health effects related to thoracic coarse particles; (4) subpopulations that appear to be sensitive to effects of exposure to thoracic coarse particles; and (5) the public health impact of exposure to ambient thoracic coarse particles.

1. Mechanisms

As summarized above, the first review of the PM NAAQS found a strong basis for concluding that thoracic coarse particles could be plausibly linked to health effects. This was based on an integrated assessment of the physical and chemical characteristics of ambient coarse particles, the evidence regarding health effects that could be associated with deposition of coarse particulate substances in the different regions of the respiratory tract, and the relative potential for penetration and deposition of ambient distributions of coarse particles in the human respiratory tract (52 FR 24634). In the 1987 review, EPA found that occupational and toxicologic studies provided ample cause for concern related to higher levels of thoracic coarse particles. Such findings indicated that elevated levels of thoracic coarse particles were linked with effects such as aggravation of asthma and increases in upper respiratory illness, which was consistent with dosimetric evidence of enhanced deposition of thoracic coarse particles in the respiratory tract (61 FR 65649).

Toxicologic and controlled human exposure studies available in previous reviews have generally used particle exposures at levels higher than ambient levels, relying on various particle components or surrogates. Such studies reported some effects on the respiratory tract, indicative of inflammatory or irritant effects for particles in both the fine and thoracic coarse particle size range (EPA, 1982, chapters 12 and 13; EPA, 1996, chapters 10 and 11). As discussed above in section II.A, the results of numerous new toxicologic and controlled human exposure studies have implicated a number of potential mechanisms or pathways for effects associated with PM. Many of these studies have used particle exposures that are generally more relevant to studying the effects of fine particles than those of thoracic coarse particles. However, several studies, discussed more fully below, have suggested mechanisms or pathways for thoracic coarse particles to cause inflammatory and other effects on the respiratory system. This evidence generally supports previous conclusions that thoracic coarse particles can affect the respiratory system.

Some limited evidence is available from recent toxicologic studies on effects of exposure to thoracic coarse particles, specifically using $PM_{10-2.5}$, for either acute or chronic exposures (EPA, 2004, p. 9–55). This toxicologic evidence includes results from studies where respiratory cell cultures were exposed to ambient particles, thus providing insight into potential mechanisms for respiratory effects of thoracic coarse particles. The types of effects reported include inflammatory and allergic effects. For example, two recent studies report inflammatory responses in cells exposed to extracts of water-soluble and water-insoluble materials from thoracic coarse particles and fine particles collected in Chapel Hill, NC (Monn and Becker, 1999; Soukup and Becker, 2001). One study focused on water-soluble materials, and reported significant immune system effects with water-soluble extracts of ambient $PM_{10-2.5}$, in contrast to the lack of effects observed with extracts from

[45] The 'thoracic' regions of the respiratory tract are located in the chest (thorax) and are comprised of the tracheo-bronchial region with connecting airways and the alveolar, or gas-exchange region of the lung. For ease of communications, 'thoracic' particles penetrating to these regions are often called 'inhalable' particles.

ambient $PM_{2.5}$ as well as indoor-collected $PM_{10-2.5}$ and $PM_{2.5}$. The authors report that different components of $PM_{10-2.5}$ appeared to have different effects, with endotoxin implicated in inflammatory effects, while coarse particulate metals appeared to have a role in cytotoxicity effects (Monn and Becker, 1999). A followup study in the same laboratory (Soukup and Becker, 2001) reports that the insoluble materials from thoracic coarse particles resulted in several effects on immune system cells.[46] In this extract of thoracic coarse particles, endotoxin appeared to be the most pro-inflammatory component, but components other than endotoxin or metals appeared to contribute to other effects. Using particles collected in two urban areas in the Netherlands, Becker et al. (2003) reported that thoracic coarse particles, but not fine or ultrafine particles, resulted in effects related to inflammation and decreased pulmonary defenses. This small group of studies thus suggests that exposure to thoracic coarse particles may cause pro-inflammatory effects, as well as cytotoxicity and oxidant generation (EPA, 2004, section 7.4.2). While still limited, these emerging new studies provide additional insight into potential mechanisms for respiratory effects of thoracic coarse particles. The results also indicate that different health responses may be linked with different components of thoracic coarse particles.

In contrast, one recent study exposed human red blood cell cultures to ambient coarse particles collected in Italy and found only limited effects on blood cells (Diociaiuti et al., 2001). The addition of thoracic coarse particles that were collected in Italy to human respiratory tract cell cultures produced only limited evidence of carcinogenic effects; some response was seen with thoracic coarse particles but greater response was reported with fine particle exposures (Hornberg et al., 1998). These latter results are consistent with the evidence from epidemiologic studies, which provide no direct evidence for carcinogenicity of thoracic coarse particles.

As noted in past reviews (EPA, 1981b, 1996b), deposition of a variety of particle types in the tracheobronchial region, including resuspended urban dust and coarse-fraction organic materials, has the potential to affect lung function and aggravate symptoms, particularly in asthmatics. Of particular note are limited toxicologic studies that found urban road dust can produce cellular and immunological effects (e.g., Kleinman et al., 1995; Steerenberg et al., 2003). Road dust is a major source of thoracic coarse particles in urban areas and is therefore representative of the components expected to be found in resuspended thoracic coarse particles. In the 1996 Staff Paper, results from the study by Kleinman and colleagues (1995) were highlighted in which effects were observed in rats with inhalation exposure to road dust. These effects included changes in the structure of the rat airways as well as effects on immune cells. Higher concentrations of road dust were needed to cause effects, compared with exposures to fine particle components (e.g., sulfates, nitrates), in part because of the limited penetration of coarse-sized particles past the nose of the rats studied (EPA, 1996b, p. V–70).[47] Another study used a standard toxicologic approach to studying allergic responses, and the authors concluded that exposure to road tunnel dust particles resulted in greater allergy-related effects than did exposure to several other particle samples, including residual oil fly ash and diesel exhaust particles (Steerenberg et al., 2003).[48] In this study, the particles were collected in a road tunnel and placed directly in the animal respiratory tract, so differences in inhalability of larger particles in rodents was not an issue. In contrast, a number of studies have reported that Mt. St. Helens volcanic ash, which is generally in the size range of thoracic coarse particles, has very little toxicity in animal or in vitro toxicologic studies (EPA, 2004, p. 7–216).

The Criteria Document finds that the limited number of recent toxicologic studies using $PM_{10-2.5}$ provide some evidence that coarse fraction particle exposures can result in effects primarily linked to the respiratory system, related to inflammation or aggravation of allergic effects. Toxicologic studies have suggested potential pathways for effects from a few sources or components of thoracic coarse particles, such as road dust particles, metals or organic constituents. The need to better understand the relationship between different components or sources of thoracic coarse particles remains a key area of uncertainty with regard to the effects of thoracic coarse particles.

2. Nature of Effects

In the last review, EPA considered a substantial number of epidemiological studies using PM_{10}, which contains both fine and coarse particles, as a measure of exposure to PM. In many such studies in which fine and coarse particles occur at similar levels, it is difficult or impossible to determine whether fine and coarse particles both played major roles in the associations. Accordingly, considerable emphasis was placed on the more limited body of evidence from PM_{10} studies in locations where coarse particles were a much greater fraction of PM_{10} than were fine particles. These findings indicated that short-term exposure to thoracic coarse particles in such areas was linked with respiratory morbidity effects, such as aggravation of asthma, increases in respiratory symptoms and respiratory infections (62 FR 38677). The single available short-term exposure study that compared associations between mortality and fine and coarse particles reported a significant association between short-term exposure to $PM_{10-2.5}$ and mortality in one of six cities (Steubenville, OH). In this location, an unusually high correlation between high levels of fine and thoracic coarse particles suggested a common industrial source, and a clear conclusion about the relative contribution was not possible. The study found no association with thoracic coarse particles in a combined multi-city analysis (Schwartz et al., 1996; CD, p. 8–40 to 8–41).[49] No studies in the past review provided clear epidemiologic evidence of mortality or morbidity effects related to long-term exposure to $PM_{10-2.5}$. EPA observed that toxicologic studies offered some qualitative evidence suggesting the potential for effects on the respiratory system with long-term exposure to coarse particles or coarse particle constituents (62 FR 38678).

In this review, epidemiologic studies have continued to support a relationship between short-term exposure to thoracic coarse particles and respiratory morbidity, with effects ranging from increased respiratory symptoms to hospitalization for respiratory diseases. As discussed below, the new studies also suggest associations with effects on the cardiovascular system and possibly with

[46] Examples of such effects include cytokine production, decreased phagocytic ability and oxidant generation.

[47] The particles used in this study were collected by vacuum sweeping of freeway surfaces in California, and were generally 5 μm in diameter or lower (Kleinman et al., 1995).

[48] This approach, using ovalbumin-sensitized mice, is commonly used for comparing allergic potency of air pollutants. The authors also tested responses in an additional toxicologic model, based on pollen-sensitized rats, and reported responses only with diesel exhaust particles (Steerenberg et al., 2003, p. 1436).

[49] Note that in more recent reanalyses of this study to investigate statistical modeling issues, the association for Steubenville was not statistically significant in most models reported in the two reanalyses (Klemm and Mason, 2003; Schwartz, 2003a).

mortality. Figure 2 summarizes results from both multi-city and single-city epidemiologic studies using short-term exposures to $PM_{10-2.5}$, including all U.S. and Canadian studies that used direct measurements of $PM_{10-2.5}$[50] and for which effect estimates and confidence intervals were reported. Consistent with the presentation of fine particle study results in Figure 1, the central effect estimate is indicated by a diamond for each study result, with the vertical bar representing the 95 percent confidence interval around the estimate. The results of these epidemiologic studies are discussed below.

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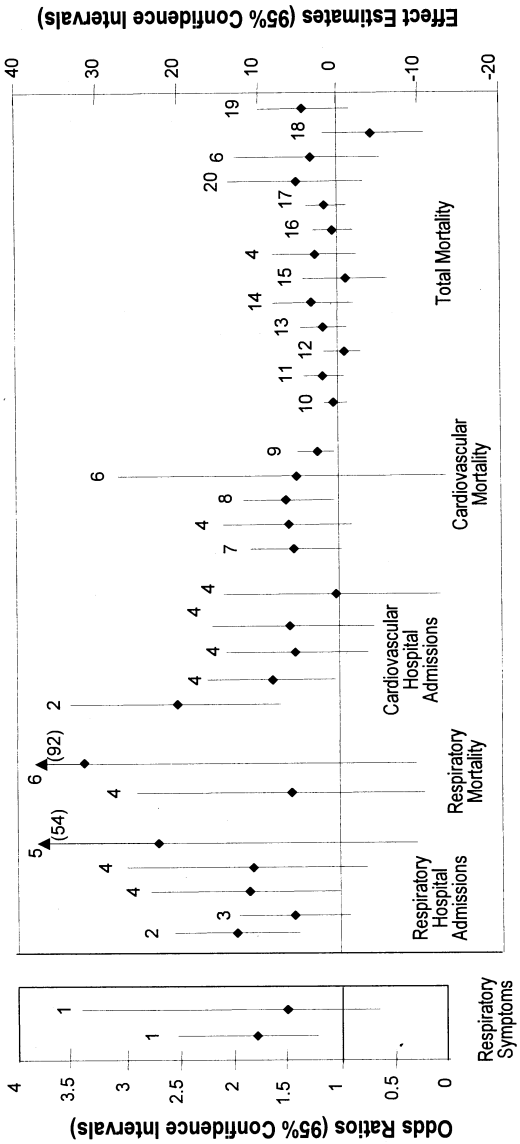

Figure 2. Effect estimates for associations between short-term exposure to $PM_{10-2.5}$ and mortality or morbidity health outcomes in U.S. and Canadian Studies; multi-city studies noted by bold text below.

1. Schwartz and Neas (2000), 6 U.S. cities
2. Burnett et al. (1997), Toronto
3. Sheppard et al. (2003), Seattle
4. Ito (2003), Detroit
5. Thurston et al. (1994), Toronto
6. Fairley (2003), Santa Clara County
7. Lipfert et al. (2000), Philadelphia
8. Mar et al. (2003), Phoenix
9. Ostro et al. (2003), Coachella Valley
10. Klemm and Mason (2003), 6 U.S. cities
11. Burnett and Goldberg (2003), 8 Canadian cities
12. Klemm and Mason (2003), St. Louis
13. Klemm and Mason (2003), Boston
14. Klemm and Mason (2003), Kingston-Harriman
15. Klemm and Mason (2003), Portage
16. Chock et al. (2000), Pittsburgh (< 75 y.o.)
17. Chock et al. (2000), Pittsburgh (75+ y.o.)
18. Klemm and Mason (2003), Topeka
19. Klemm and Mason (2003), Steubenville
20. Klemm and Mason (2000), Atlanta

Results presented are from time-series studies that did not use generalized additive models or were reanalyzed using general linear models. For consistency across studies, effect estimates are from single-pollutant, general linear models, based on an increment of 25 $\mu g/m^3$ $PM_{10-2.5}$, and have been plotted in order of decreasing study power, using as an indicator the natural log of the product of the number of study days and number of health events per day. Results for studies of respiratory symptoms are presented as odds ratios; an odds ratio of 1.0 is equivalent to no effect, and thus is presented as equivalent to the zero effect estimate line.

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a. Effects Associated With Short-Term Exposure to Thoracic Coarse Particles

The discussion below focuses first on evidence related to respiratory morbidity effects, since information available in the previous review provided plausible evidence that short-term exposure to thoracic coarse particles was associated with such effects. This is followed by a discussion of new findings on potential cardiovascular effects of thoracic coarse particles, as well as new evidence from studies of mortality.

i. Morbidity

(a) Effects on the Respiratory System

Evidence available in the last review suggested that aggravation of asthma

[50] All epidemiologic studies discussed below included measurements of thoracic coarse particles either through monitors that collected thoracic coarse particles separately (e.g., dichotomous monitors) or using data from side-by-side (co-located) monitors for fine particles and PM_{10}. Investigators have sometimes also used prediction models to ''fill'' or estimate PM concentrations where measurements are not available (most often where data are collected less frequently than daily). In one particular study in Coachella Valley, measurements were made of fine and thoracic coarse particle concentrations for two and a half years. The investigators predicted $PM_{10-2.5}$ concentrations for a longer time series, based on a ten-year data set for PM_{10} for use in the health study (Ostro et al., 2003).

and respiratory infections and symptoms were associated with PM_{10} in areas where thoracic coarse particles were a much greater fraction of PM_{10} than were fine particles, such as Anchorage, AK, and southeast Washington (62 FR 38679). Only one epidemiologic study had used $PM_{10-2.5}$ data; it reported a positive, but not statistically significant, association between respiratory hospital admissions and $PM_{10-2.5}$ in Toronto (Thurston et al., 1994).

Several new studies of respiratory symptoms and lung function have included both $PM_{10-2.5}$ and $PM_{2.5}$ data, and these results suggest a role for thoracic coarse particles as well as for fine particles in associations with respiratory symptoms (EPA, 2004, p. 8–311). In the Six Cities study, a statistically significant increase in cough for children was found with $PM_{10-2.5}$ but not with $PM_{2.5}$, while the reverse was true for lower respiratory symptoms. When both $PM_{10-2.5}$ and $PM_{2.5}$ were included in models, the effect estimates were reduced for each, but $PM_{10-2.5}$ retained significance in the association with cough and $PM_{2.5}$ retained significance in the association with lower respiratory symptoms (Schwartz and Neas, 2000).[51] Changes in lung function were evaluated in three cities in Pennsylvania, and in all three, short-term exposure to thoracic coarse particles was not significantly associated with peak flow rate, although some statistically significant associations were found with exposure to fine particles (EPA, 2004, p. 8–312).

Three new U.S. and Canadian epidemiologic studies have reported associations between short-term exposure to $PM_{10-2.5}$ with hospital admissions for respiratory diseases, including asthma, pneumonia and COPD (Burnett et al., 1997; Ito, 2003; Sheppard et al., 2003). As shown in Figure 2, the effect estimates for these associations are positive and some are statistically significant. In these associations with respiratory hospitalization, the risk estimates tend to fall in the range of 5 to 15 percent per 25 μg/m^3 $PM_{10-2.5}$ (EPA, 2004, p. 8–193).

Because fine particles and ozone, as well as other gaseous air pollutants, are known to cause respiratory effects, a key consideration for assessing this body of studies is assessment of potential confounding by these co-pollutants, as discussed in detail in Section 8.4.3 of the Criteria Document. The associations reported between respiratory hospital admissions and short-term exposure to $PM_{10-2.5}$ were largely unchanged in most cases when gaseous co-pollutants were included in the models (EPA, 2004, Figure 8–18; Burnett et al., 1997; Ito, 2003).[52] Few investigators have evaluated potential confounding of $PM_{10-2.5}$ effects with adjustment for $PM_{2.5}$ in multi-pollutant models. Only the study conducted in Detroit included such multi-pollutant models for respiratory hospitalization and was reanalyzed to address potential statistical modeling questions. In this study, the simultaneous consideration of $PM_{10-2.5}$ and $PM_{2.5}$ resulted in reduction in the size of the effect estimate, as well as loss of statistical significance, for both pollutants. The authors report that the correlation between the two pollutants was ''modest'' (correlation coefficient of 0.42) (Lippmann et al., 2000, p. 33). The results in this study vary by health outcome; for example, for pneumonia hospitalization, effect estimates for $PM_{2.5}$ were little changed but those for $PM_{10-2.5}$ decreased substantially in magnitude in two-pollutant models. In contrast, effect estimates for $PM_{2.5}$ with COPD hospitalization decreased dramatically, whereas those for $PM_{10-2.5}$ were only slightly decreased in size in two-pollutant models (Ito, 2003, pp. 152, 153).

Additional insight into the respiratory effects of coarse particles is provided by studies using PM_{10} in locations where thoracic coarse particles were a much greater fraction of PM_{10} than were fine particles. This review includes new PM_{10} studies in such relatively high coarse-fraction areas, such as Reno, NV and Anchorage, AK.[53] In these areas, statistically significant associations have been reported between PM_{10} and hospitalization for respiratory diseases (Chen et al., 2000) and outpatient medical visits for asthma (Choudhury et al., 1997). These findings support the evidence from the limited group of studies discussed above that have reported associations between measured $PM_{10-2.5}$ and respiratory morbidity.

Considering evidence from across a range of respiratory morbidity health outcomes, the Criteria Document concludes that the epidemiologic evidence indicates that both fine and thoracic coarse particles impact respiratory health (EPA, 2004, p. 8–311).

(b) Effects on the Cardiovascular System

Two new studies conducted in the U.S. and Canada have also reported associations between short-term exposure to $PM_{10-2.5}$ and hospital admissions for various cardiovascular diseases. The results of these studies are included in Figure 2, where it can be seen that the associations are generally positive and the results of the larger studies with more statistical power are statistically significant (Burnett et al., 1997, cardiovascular disease hospitalization; Ito, 2003, ischemic heart disease hospitalization). The excess risks for hospital admissions for cardiovascular diseases range from about 1 to 10 percent per 25 μg/m^3 $PM_{10-2.5,}$ as seen in the Detroit study (EPA, 2004, p. 8–310). In addition, a statistically significant association was reported between PM_{10} and increased hospitalization for cardiovascular diseases in Tucson, AZ, an urban area where thoracic coarse particles are a much greater fraction of PM_{10} than are fine particles (Schwartz, 1997).[54] The Criteria Document finds that associations between cardiovascular hospitalization and short-term $PM_{10-2.5}$ exposure were relatively unchanged when gaseous co-pollutants were included in the models (EPA, 2004, Figure 8–17; Burnett et al., 1997; Ito, 2003).[55] In assessing potential confounding between $PM_{2.5}$ and $PM_{10-2.5,}$ one new study in Detroit reported that simultaneous consideration of $PM_{10-2.5}$ and $PM_{2.5}$ resulted in a reduction in effect estimate

[51] The authors conclude that for acute asthma-related responses as well as daily mortality, fine particles are a stronger predictor of health response that are thoracic coarse particles (Schwartz and Neas, 2000, p. 8).

[52] More specifically, the effect estimates for associations between $PM_{10-2.5}$ and hospitalization for COPD and pneumonia in Detroit are largely unchanged with the addition of gaseous co-pollutants to the models, except in one case where the $PM_{10-2.5}$ effect estimate for COPD hospitalization is substantially reduced in size with the inclusion of O_3 in the model (Ito, 2003). Results for the study in Toronto also show relatively consistent effect estimate size for associations between $PM_{10-2.5}$ and respiratory hospitalization, except for the models including NO_2 and all four gaseous pollutants (Burnett et al., 1997).

[53] For example, Anchorage, AK and Reno, NV do not currently attain the PM_{10} 24-hour standard which is set at 150 μg/m^3. Based on 2002–2004 data, the 98th percentile $PM_{2.5}$ concentrations in these areas were 21 and 25 μg/m^3, respectively. As noted in the fine particle discussion above, no short-term exposure studies to date have shown statistically significant associations between fine particles and effects with 98th percentile values this low. This suggests that coarse particles either caused or contributed to the observed PM_{10} associations.

[54] Tucson currently attains the PM_{10} standard, and the 98th percentile 24-hour average concentrations reported for $PM_{2.5}$ are 15 and 17μg/m^3 at two monitoring sites in the area.

[55] The effect estimates for associations between $PM_{10-2.5}$ and hospitalization for ischemic heart disease and heart failure in Detroit are largely unchanged with the addition of gaseous co-pollutants to the models (Ito, 2003). Results presented for the study in Toronto also show relatively consistent effect estimate size for associations between $PM_{10-2.5}$ and cardiovascular hospitalization, except for the models including NO_2 and all four gaseous pollutants (Burnett et al., 1997).

size and a lack of statistical significance for both PM indicators (Ito, 2003). In the reanalysis for this study, for example, a significant association was reported between $PM_{10-2.5}$ and hospitalization for ischemic heart disease in a single-pollutant model, and in a two-pollutant model the effect estimates for $PM_{2.5}$ and $PM_{10-2.5}$ were both reduced in magnitude and neither remained statistically significant (Ito, 2003, pp. 152, 153).

Epidemiologic studies have also reported associations between short-term exposures to ambient PM (generally using PM_{10} or $PM_{2.5}$) and more subtle cardiovascular health outcomes (e.g., changes in heart rhythm or cardiovascular biomarkers) (EPA, 2004, p. 8–169). Only one of this new set of epidemiologic studies included $PM_{10-2.5}$, and no significant associations were reported between onset of myocardial infarction and short-term $PM_{10-2.5}$ exposures (EPA, 2005a, p. 8–165; Peters et al., 2001).

ii. Mortality

In the few epidemiologic studies available for the last review, only the Six City study summarized above evaluated the relationship between short-term exposure to $PM_{10-2.5}$ and mortality. That study provided a suggestion of a potential effect of thoracic coarse particles only in the city with the highest coarse and fine particle concentrations, but it was not possible to separate fine and thoracic coarse particle contributions.

As shown in Figure 2 for U.S. and Canadian studies, effect estimates for associations between mortality and short-term exposure to $PM_{10-2.5}$ are generally positive and similar in magnitude to those for $PM_{2.5}$ and PM_{10} though most are not statistically significant. In general, the confidence intervals (indicating uncertainty) are greater for associations between mortality and $PM_{10-2.5}$ than for associations with $PM_{2.5}$, as is apparent when directly comparing results from numerous studies as shown in Figure 8–5 of the Criteria Document (EPA, 2004, p. 8–61). In the same comparison, it can be seen that the size of the effect estimates for the associations are in the same range. In general, effect estimates are somewhat larger for respiratory and cardiovascular mortality than for total mortality. Two of the five effect estimates for cardiovascular mortality with short-term $PM_{10-2.5}$ exposure are positive and statistically significant (Mar et al., 2003; Ostro et al., 2003) while none of the effect estimates for total mortality reach statistical significance. The new studies include a multi-city study that uses data from the eight largest Canadian cities and reported associations between total mortality and $PM_{10-2.5}$ as well as $PM_{2.5}$ and PM_{10}. The effect estimates were of similar magnitude for each PM indicator (Burnett and Goldberg, 2003), but the association with $PM_{10-2.5}$ did not reach statistical significance. The magnitude of the effect estimates for $PM_{10-2.5}$ are similar to those for $PM_{2.5}$, generally falling in the range of 3 to 8 percent for cardiovascular mortality per 25 $\mu g/m^3$ $PM_{10-2.5}$.

Potential confounding by co-pollutant gases has been assessed in some of these mortality studies. As shown in Figures 8–16 through 8–18 of the Criteria Document, the associations reported with $PM_{10-2.5}$ are generally unchanged in effect size when co-pollutant gases are included in multi-pollutant models. The evidence available on potential confounding between $PM_{2.5}$ and $PM_{10-2.5}$ is limited, but the Criteria Document includes results from two studies that showed effects of the two PM indicators to be relatively independent in multi-pollutant models, however, these particular analyses were not included in reanalyses to address statistical modeling questions.[56]

iii. Effects of Thoracic Coarse Particle Components or Sources in Epidemiologic Studies

In considering the epidemiologic evidence on morbidity or mortality associations with short-term exposure to thoracic coarse particles, EPA recognizes that the issue of the relative toxicity of different PM components, discussed above in section II.A.1 for fine particles, is an important uncertainty for thoracic coarse particles as well. Several toxicologic studies, discussed above in section III.A.1, have reported evidence of effects with different components or sources of thoracic coarse particles. However, the available epidemiologic studies that have used $PM_{10-2.5}$ did not evaluate associations with specific components of thoracic coarse particles (EPA, 2004, section 8.2.2.5.2). As discussed in section II.A, several studies have reported that $PM_{2.5}$ from combustion-related sources is more strongly linked with mortality than $PM_{2.5}$ of crustal origin. However, these findings are not directly relevant to findings related to thoracic coarse particles. Combustion sources are a major contributor to $PM_{2.5}$ emissions, but not to emissions of $PM_{10-2.5}$, while crustal material is an important component of $PM_{10-2.5}$ but only a small portion of $PM_{2.5}$ (EPA, 2005a, Table 2–2).

One study that does have relevance to considering the effects of $PM_{10-2.5}$ from different sources assessed the contribution of dust storms to PM_{10}-related mortality. The authors focused on days when dust storms or high wind events occurred in Spokane, during which thoracic coarse particles from surrounding rural soils are the dominant fraction of PM_{10}. No evidence was reported of increased mortality on days with high PM_{10} levels related to these dust storms (average PM_{10} level was 221 $\mu g/m^3$ higher on dust storm days than on other study days) (Schwartz, et al., 1999), suggesting that $PM_{10-2.5}$ from wind-blown rural dust is also not likely associated with mortality.[57] EPA has also observed that the available epidemiologic studies using $PM_{10-2.5}$ have been conducted in urban areas, such as Phoenix, Detroit and Seattle. Coarse particles are generally not distributed over broad areas, but rather reflect contributions from more localized sources, thus it is more difficult than for fine particles to generalize the results of these studies to areas with other types of sources.

The Criteria Document finds that the new epidemiologic studies support the conclusions drawn in the previous review, and indicate that short-term exposure to thoracic coarse particles is likely associated with respiratory morbidity. The epidemiologic studies report statistically significant associations between short-term $PM_{10-2.5}$ exposure and outcomes ranging from respiratory symptoms to hospitalization for respiratory diseases (EPA, 2004, p. 8–312). A limited body of new

[56] One study was the Canadian 8-city study, in which multi-pollutant models included $PM_{2.5}$ and $PM_{10-2.5}$ and gaseous co-pollutants, with moderate reductions in the effect estimate size for both PM indicators (Burnett et al., 2000). Moolgavkar (2000) presented results of two-pollutant models for $PM_{2.5}$ and $PM_{10-2.5}$ with COPD hospitalization in Los Angeles, and again, effect estimates for both pollutants were generally reduced somewhat in size. The author also reports that associations with $PM_{10-2.5}$ were generally reduced in size and lost statistical significance in two-pollutant models including CO. These two studies were reanalyzed to address potential issues with statistical model specification, but these multi-pollutant model results were not included in the reanalysis reports.

[57] In addition, studies conducted in several areas in the western U.S. have reported that associations between PM_{10} and mortality or morbidity remained unchanged or became larger and more precise when days indicative of wind-blown dust or high PM_{10} concentration days were excluded from the analyses (Pope et al., 1999; Schwartz, 1997; Chen et al., 2000; Hefflin et al., 1994). This group of studies does not provide conclusive evidence of any effects or lack of effects associated with wind-blown dust or high concentration days, nor were the studies designed specifically for that purpose. The results do, however, indicate that associations between PM_{10} and health outcomes in these western areas are not overly influenced or ''driven by'' such days.

epidemiologic evidence suggests that short-term exposure to thoracic coarse particles is associated with effects on the cardiovascular system. Finally, the Criteria Document finds that evidence from health studies on associations between short-term exposure to $PM_{10-2.5}$ and mortality is ''limited and clearly not as strong'' as evidence for associations with $PM_{2.5}$ or PM_{10} but nonetheless is suggestive of associations with mortality (EPA, 2004, p. 9–28, 9–32). As discussed briefly above, some epidemiologic evidence suggests that there are components of thoracic coarse particles (e.g., crustal material in non-urban areas) that are less likely to have adverse effects, at least at lower concentrations, than other components. Based on the epidemiologic evidence, the Criteria Document concluded that the limited body of evidence provided suggestive evidence for associations between throacic coarse particles and various mortality and morbidity effects ''in some locations'' (EPA, 2004, p. 8–338).

b. Effects Related to Long-Term Exposure to Thoracic Coarse Particles

In the last review, the available prospective cohort study results had shown no evidence of associations between long-term exposure to thoracic coarse particles and either mortality (Dockery et al., 1993; Pope et al., 1995) or morbidity (Dockery et al., 1996; Raizenne et al., 1996). As discussed above for $PM_{2.5}$, new studies available in this review include the reanalyses and extended analyses for the Six Cities and ACS cohort studies of mortality, and new analyses from the southern California children's cohorts of morbidity effects.

In both the reanalyses and extended analyses of the ACS cohort study, long-term exposure to $PM_{10-2.5}$ was not significantly associated with mortality (CD, p. 8–105; Krewski et al., 2000; Pope et al., 2002). Based on evidence from reanalyses and extended analyses using ACS cohort data, the Criteria Document concludes that the long-term exposure studies find no associations between long-term exposure to thoracic coarse particles and mortality (EPA, 2004, p. 8–307).

In the previous review, results from the Harvard 24-city study had shown associations between respiratory illness prevalence and decreased lung function in children with fine particles or fine particle indicators, but not with the larger size fractions (Dockery et al., 1996; Raizenne et al., 1996). Further EPA staff evaluation of the data from this study that suggested that lung function decrements were not associated with long-term exposure to thoracic coarse particles (EPA, 1996b, p. V–67a) . In this group of cities, mean thoracic coarse particle concentrations ranged from approximately 4 to 15 $\mu g/m^3$. Several new studies have used data from the Southern California children's cohorts, one of which included $PM_{10-2.5}$ data; in these cities, mean thoracic coarse particle concentrations ranged from 6 to 39 $\mu g/m^3$. In this study, decreases in several measures of lung function growth were associated with long-term exposure to $PM_{10-2.5}$ (as well as PM_{10} and $PM_{2.5}$) though not all associations reached statistical significance (Gauderman et al., 2000). Further, in analyses for a second cohort of children, no statistically significant associations were reported between lung function growth and long-term $PM_{10-2.5}$ exposure (Gauderman et al., 2002, p. 81). The correlation reported between $PM_{10-2.5}$ and $PM_{2.5}$ in this area was unusually high (r=0.76); in two-pollutant models, the authors observe that the effects reported with both pollutants were reduced in magnitude, and did not remain statistically significant, with somewhat larger reductions for $PM_{10-2.5}$ associations than for $PM_{2.5}$ (Gauderman et al., 2000, p. 1387). Thus, results from one children's cohort study provide no evidence of associations between long-term to exposure to $PM_{10-2.5}$ and respiratory morbidity, while findings from a more recent cohort study provide only very limited evidence for such effects. Overall, EPA finds that the available evidence provides little support to link long-term exposures to thoracic coarse particles with respiratory morbidity (EPA, 2004, p. 9–34).

3. Integration and Interpretation of the Health Evidence

As discussed in section II.A.3, the Criteria Document and Staff Paper focused on well-recognized criteria in evaluating the epidemiologic evidence, including the strength of associations; robustness of reported associations to the use of alternative model specifications, potential confounding by co-pollutants, and exposure misclassification related to measurement error; consistency of findings in multiple studies of adequate power, and in different persons, places, circumstances and times; and the nature of concentration-response relationships. These evaluations addressed key methodological issues that are relevant to interpretation of evidence from epidemiologic studies. Further, findings from epidemiologic studies were integrated with available experimental evidence (e.g., dosimetric and toxicologic), in considering the extent of coherence and biological plausibility of effects observed in epidemiologic studies. This integrative assessment formed the basis for the Criteria Document and Staff Paper to draw judgments about the extent to which causal inferences can be made about observed associations between health endpoints and thoracic coarse particles combination with other pollutants. The key elements of these evaluations are summarized below. Many of these issues are discussed in section II.A.3 above for fine particles, and are thus only briefly summarized here with regard to implications for thoracic coarse particles.

(1) Effect estimates from associations between short-term exposures to thoracic coarse particles and various health outcomes are generally small in size. The Criteria Document observes that the associations are similar in size to those reported for $PM_{2.5}$, but with less precision as the measurement error for $PM_{10-2.5}$ is greater than that for $PM_{2.5}$. Thus, the Criteria Document concludes that the magnitude of $PM_{10-2.5}$ associations is similar to those for fine particles, but the lesser precision of the associations reduces the strength of the evidence for thoracic coarse particles (EPA, 2004, p. 9–41).

(2) EPA has evaluated the robustness of epidemiologic associations in part by considering the effect of differences in statistical model specification, exposure error on PM-health associations, and potential confounding by co-pollutants.

Sensitivity to model specification was discussed above for fine particles, and, in general, similar conclusions apply to studies using $PM_{10-2.5}$. Section 8.4.2 of the Criteria Document discusses a series of reanalyses that address issues related to a specific type of statistical model (''generalized additive methods'') used in some recent epidemiologic studies. The results of the reanalyses showed little change in effect estimates for some studies; in others the effect estimates were reduced in size though it was observed that the reductions were often not substantial (EPA, 2004, p. 9–35). Overall, the Criteria Document concludes that associations between short-term exposure to PM and various health outcomes are generally robust to the use of alternative modeling strategies, recognizing that further evaluation of alternative modeling strategies is warranted. It was also observed that the results of reanalyses indicated that effect estimates were more sensitive to the modeling approach used to account for temporal effects and weather variables than to the specific model specifications, and thus

recommended further exploration of alternative modeling approaches for time-series analyses (EPA, 2004, pp. 8–236 to 8–237).

Recent epidemiologic studies have also evaluated the influence of exposure error on PM-health associations. This includes both consideration of error in measurements of PM, and the degree to which measurements from an individual monitor reflect exposures to the surrounding community. As discussed in section 8.4.5 of the Criteria Document, several studies have shown that fairly extreme conditions (e.g., very high correlation between pollutants and no measurement error in the ''false'' pollutant) are needed for complete ''transfer of causality'' of effects from one pollutant to another (EPA, 2004, p. 9–38). Exposure error is likely to be more important for associations with $PM_{10-2.5}$ than with $PM_{2.5}$, since there is generally greater error in $PM_{10-2.5}$ measurements, $PM_{10-2.5}$ concentrations are less evenly distributed across a community, and thoracic coarse particles are less likely to penetrate into buildings (EPA, 2004, p. 9–38). Thus, factors related to exposure error likely result in reduced precision for epidemiologic associations with $PM_{10-2.5}$.

There are two key implications of this uncertainty for this review. First, for an individual epidemiologic association, the increased uncertainty in measurements would tend to increase the standard error about the effect estimate, possibly reducing statistical significance of the findings. This would mean that a set of positive but generally not statistically significant associations between $PM_{10-2.5}$ and a health outcome could be reflecting a true association that is measured with error (EPA, 2004, p. 5–126). Second, this uncertainty about measurements is an important consideration in evaluating the air quality concentrations with which a statistical association is reported. The air quality levels reported in these studies, as measured by ambient concentrations at monitoring sites within the study areas, are not necessarily good surrogates for the population exposures that are likely associated with the observed effects in the study areas or that would likely be associated with effects in other urban areas across the country. The concentrations measured at one particular site may over-or under-estimate air quality levels in other parts of the area. In evaluating the air quality data from the locations in which epidemiologic associations were reported, as discussed in the Staff Paper and below in section III.G, examples of both cases are seen. For example, in Coachella Valley, mortality was statistically significantly associated with $PM_{10-2.5}$ measurements made at one site (Ostro et al., 2003), but these air quality measurements appear to represent concentrations on the high end of $PM_{10-2.5}$ levels for Coachella Valley communities. In contrast, statistically significant associations were reported with $PM_{10-2.5}$ measurements in Detroit (Ito, 2003), and in this case the data appear to represent concentrations on the low end of $PM_{10-2.5}$ levels for the Detroit area (EPA, 2005a, p. 5–65, 5–66).

Finally, some investigators have assessed the robustness of associations between health outcomes and short-term exposures to $PM_{10-2.5}$ in multi-pollutant models to potential confounding by the gaseous co-pollutants or fine particles. A high degree of correlation between the concentrations of thoracic coarse particles and other pollutants (either gaseous co-pollutants or fine particles) can make interpretation of the study results difficult. Multi-pollutant models including $PM_{10-2.5}$ and gaseous co-pollutants are included in Figures 8–16 through 8–18 of the Criteria Document, where it can be seen that associations with $PM_{10-2.5}$ are largely unchanged when gaseous co-pollutants are added to the models (EPA, 2004, section 8.4.3). Further, in the available epidemiologic studies, it can be seen that correlations between the gaseous co-pollutants (CO, NO_2, O_3, SO_2) and $PM_{10-2.5}$ concentrations are often lower than correlations between the gases and fine particles.[58] While recognizing that disentangling the effects attributable to various pollutants within an air pollution mixture is challenging, the Criteria Document concludes that effect estimates for associations between PM, including $PM_{10-2.5}$, and health endpoints are generally robust to confounding by gaseous co-pollutants (EPA, 2004, p. 9–37).

Less information is available from studies that specifically assessed potential confounding between fine and thoracic coarse particles, as noted above. The reported correlation coefficients between $PM_{10-2.5}$ and $PM_{2.5}$ are in the low to moderate range for most such studies, i.e., generally in a range of below 0.3 to 0.5, with some notably higher correlation coefficients reported in Phoenix (0.59) and Steubenville (0.69). As observed previously, one study in Detroit evaluated the effects of both $PM_{2.5}$ and $PM_{10-2.5}$ simultaneously where the correlation between the two pollutants was ''modest'' (correlation coefficient of 0.42). The authors report a reduction in coefficients for both $PM_{10-2.5}$ and $PM_{2.5}$ in associations with mortality and hospital admissions for respiratory or cardiovascular diseases (Ito, 2003, pp. 152–153); the degree of reduction in size varied for different health outcomes. Similarly, Schwartz and Neas (2000) report some reduction in effect estimate size for both $PM_{10-2.5}$ and $PM_{2.5}$ associations across six cities in two-pollutant models, but the association reported between $PM_{10-2.5}$ and cough remains statistically significant.[59] Two studies reported associations between $PM_{10-2.5}$ and mortality (Ostro et al., 2003, Coachella Valley; Mar et al., 2003, Phoenix); stronger associations were reported with $PM_{10-2.5}$ than $PM_{2.5}$ by Ostro et al., although the authors note the reduced sample size for $PM_{2.5}$ may have influenced the statistical power (Ostro et al., 2003). Both areas have relatively low fine particle concentrations, with 98th percentile $PM_{2.5}$ concentrations of about 32 $\mu g/m^3$ in Phoenix and 34 $\mu g/m^3$ in Coachella Valley, while the correlation coefficient reported between $PM_{2.5}$ and $PM_{10-2.5}$ was low in Coachella Valley (0.28) and fairly high in Phoenix (0.59). This limited body of evidence suggests that $PM_{10-2.5}$ and $PM_{2.5}$ have associations with health outcomes that are likely independent of one another, but further work is needed to help distinguish the contributions of thoracic coarse particles on health outcomes from those of fine particles.

Overall, the Criteria Document concludes that associations reported between health outcomes and short-term exposure to $PM_{10-2.5}$ are generally robust to the use of alternative modeling strategies, to adjustment for the potential confounding effects of gaseous co-pollutants, and in terms of exposure error (EPA, 2004, p. 9–46). However, the remaining uncertainties are larger in assessing the degree to which effects observed with thoracic coarse particle exposures are independent from effects of fine particles. In addition, in interpreting the results of epidemiologic studies, it is difficult to determine how well $PM_{10-2.5}$ concentrations measured at ambient monitoring stations

[58] For example, from the studies included in Figures 8–16 through 8–18, correlation coefficients reported in Detroit between $PM_{10-2.5}$ and the four gaseous co-pollutants ranged from 0.13 to 0.32, whereas the correlation coefficients between $PM_{2.5}$ and the gaseous co-pollutants range from 0.38–0.49 (Ito, 2003).

[59] The correlation coefficients between $PM_{10-2.5}$ and $PM_{2.5}$ range from 0.23 to 0.45 in five of the six cities (Boston, Knoxville, Portage, Topeka, and St. Louis), with a correlation coefficient of 0.69 in Steubenville.

characterize the magnitude of population exposures to thoracic coarse particles.

(3) In assessing consistency in effect estimates, the epidemiologic study results suggest that effect estimates may differ from one location to another, but the extent of variation is not clear. For example, in one multi-city study, some limited evidence was reported in the reanalysis to address model specification issues that suggested some heterogeneity among the 8 largest Canadian cities for associations with $PM_{10-2.5}$, although there had been no evidence of heterogeneity in initial study findings (Burnett and Goldberg, 2003; EPA, 2004, p. 9–39). As was observed for fine particles, there are a number of factors that would be likely to cause variation in PM-health outcomes in different populations and geographic areas. The Criteria Document discusses such factors, including the mix of PM sources and composition, the mix of other gaseous pollutants, geographic features that would affect the spatial distribution of ambient PM, and population characteristics that affect susceptibility or exposure levels (EPA, 2004, p. 9–41). In addition, the use of data collected on a 1-in-6 or 1-in-3 day schedule results in reduced statistical power, resulting in less precision for estimated effect estimates for the individual cities and increased potential variability in results (EPA, 2004, p. 9–40). Overall, the Criteria Document concludes that there is some consistency in effect estimates for hospitalization for respiratory and cardiovascular causes with short-term exposure to thoracic coarse particles, though fewer studies are available on which to make such an assessment than are available for fine particles (EPA, 2004, p. 9–47).

(4) Of the group of new epidemiologic studies that have evaluated the shape of concentration-response functions, many (generally using PM_{10}) have been unable to detect threshold levels in the relationship between short-term PM exposure and mortality. One single-city study used $PM_{10-2.5}$ and $PM_{2.5}$ measurements in Phoenix and reported that there was no indication of a threshold in the association between $PM_{10-2.5}$ and mortality (Smith et al., 2000; EPA, 2004, p. 8–322). However, a few analyses have provided suggestions of some potential threshold levels, generally at fairly low ambient concentrations. Thus, the Criteria Document concludes that the evidence did not support selecting any particular population threshold for $PM_{10-2.5}$, recognizing that there may be thresholds for specific health responses in individuals, and that it is possible that such thresholds exist toward the lower end of the range of air quality measurements in the health studies, but cannot be detected due to variability in susceptibility across a population. Even in those few studies with suggestive evidence of such thresholds, the potential thresholds are at fairly low concentrations (EPA, 2004, sections 8.4.7 and 9.2.2.5).

(5) Several issues related to exposure time periods were assessed in the Criteria Document, as summarized in section 3.6.5 of the Staff Paper. One key issue is the lag period between thoracic coarse particle exposure and health outcome in short-term exposure studies. In many epidemiologic studies, the authors have reported a pattern of positive associations across several consecutive lag periods for thoracic coarse particles, such that an effect estimate for any individual lag day for thoracic coarse particles likely underestimates the magnitude of the PM-health response. A number of recent studies that have investigated associations with distributed lags provide effect estimates for health responses that persist over a period of time (days to weeks) after the exposure period and the effect estimates are often, but not always, larger in size that those for single-day lag periods; however, available studies have generally not included $PM_{10-2.5}$ (EPA, 2004, p. 8–281). As reported for fine particles, the Criteria Document concludes that it is likely that the most appropriate lag period for a study will vary, depending on the health outcome and the specific pollutant under study. (EPA, 2004, p. 8–279).

(6) In integrating evidence from across scientific disciplines, the Criteria Document and Staff Paper observed that the body of epidemiologic evidence on thoracic coarse particles is smaller than that for fine particles and the evidence available from toxicologic studies is also more limited. The clearest case for a causal relationship for coarse particles is for effects on the respiratory system. The epidemiologic results showing respiratory effects is consistent with the assessment of regional particle penetration and deposition, as well the observations from more limited toxicologic studies. The fractional deposition of elevated coarse particle concentrations is significant in the tracheobronchial region, which is particularly sensitive in asthmatic individuals. From the limited number of toxicologic studies using $PM_{10-2.5}$, as noted above in section III.A.1, there is some evidence that exposure to thoracic coarse particles results in respiratory-related effects such as inflammation or oxidative stress. In addition, allergic adjuvant effects were linked with road dust exposures. These findings are generally consistent with epidemiologic evidence linking $PM_{10-2.5}$ with respiratory morbidity, such as increased respiratory symptoms and hospitalization for respiratory diseases such as asthma or COPD.

The evidence is less coherent for effects on the cardiovascular system. Some epidemiologic studies have reported significant associations with hospital admissions for cardiovascular diseases, and associations reported with cardiovascular mortality are positive and some are statistically significant (see Figure 2). However, the very limited available evidence from toxicologic studies or epidemiologic studies on more subtle cardiovascular effects has not provided evidence that demonstrates plausible mechanisms or pathways for these effects.

Based on an integrative assessment of the evidence, the Criteria Document concludes that this growing but still limited body of health evidence is suggestive of causality in associations between short-term (but not long-term) exposures to thoracic coarse particles and health effects, particularly for associations with respiratory morbidity.

(7) In summary, based on the available evidence and the evaluation of that evidence in the Criteria Document and Staff Paper, the Criteria Document concludes that the body of evidence on effects related to exposure to thoracic coarse particles is less strong than that for fine particles, but provides suggestive evidence of causality for short-term exposure to $PM_{10-2.5}$ and morbidity, including hospitalization for respiratory diseases, increased respiratory symptoms and decreased lung function, and possibly mortality (EPA, 2004, pp. 9–79, 9–80). The Staff Paper recognizes, however, that the substantial uncertainties associated with this limited body of evidence suggest that it should be interpreted with a high degree of caution (EPA, 2005a, p. 5–70).

4. Sensitive Subgroups for Effects of Thoracic Coarse Particle Exposure

As described in section II.A.4, there are several population groups that may be susceptible or vulnerable to PM-related effects. These groups include those with preexisting lung diseases, such as asthma, and children and older adults. Emerging evidence indicates that people from lower socioeconomic strata or who have particularly elevated exposures may be more vulnerable to PM-related effects. However, the available evidence does not generally

allow distinctions to be drawn between the PM indicators, in terms of which groups might have greater susceptibility or vulnerability to $PM_{2.5}$ or $PM_{10-2.5}$ (EPA, 2005a pp. 3–35 to 36).

5. Impacts on Public Health From Thoracic Coarse Particle Exposure

While recognizing that the health evidence regarding effects of thoracic coarse particles is more limited, the Criteria Document has concluded that the evidence suggests causal associations between short-term exposure to thoracic coarse particles and morbidity effects, such as respiratory symptoms or hospital admissions for respiratory diseases, and possibly mortality. As observed above, the potentially susceptible populations for such effects include people with preexisting respiratory diseases, including asthma, and children and older adults. In focusing on respiratory effects likely associated with $PM_{10-2.5}$, it can be observed that population groups with respiratory diseases such as asthma or COPD include tens of millions of people (EPA, 2004; Tables 9–4 and 9–5). Considering the magnitude of these subpopulations and risks identified in health studies, the Criteria Document concludes that exposure to thoracic coarse particles can have an important public health impact.

B. Quantitative Risk Assessment

The general overview and discussion of key components of the risk assessment used to develop risk estimates for $PM_{2.5}$ presented in section II.B above is also applicable to the assessment done for $PM_{10-2.5}$ in this review. However, the scope of the risk assessment for $PM_{10-2.5}$ is much more limited than that for $PM_{2.5}$, reflecting the much more limited body of epidemiologic evidence and air quality information available for $PM_{10-2.5}$. As discussed in chapter 4 of the Staff Paper, the $PM_{10-2.5}$ risk assessment includes risk estimates for just three urban areas for two categories of health endpoints related to short-term exposure to $PM_{10-2.5}$: hospital admissions for cardiovascular and respiratory causes and respiratory symptoms.

Consistent with the approach used in the $PM_{2.5}$ risk assessment, discussed above in section II.B, $PM_{10-2.5}$-related health risks attributable to anthropogenic sources and activities (i.e., risk associated with concentrations above background or above various selected higher cutpoints intended as surrogates for alternative assumed population thresholds) were estimated by using the reported linear or log-linear concentration-response functions from epidemiologic studies and available air quality data from the locations in which the studies had been conducted. A series of base case analyses were conducted, using the same assumed cutpoints as were used in the assessment of short-term exposures to $PM_{2.5}$.

Estimates of hospital admissions attributable to short-term exposure to $PM_{10-2.5}$ have been developed for Detroit (cardiovascular and respiratory admissions) and Seattle (respiratory admissions), and estimates of respiratory symptoms have been developed for St. Louis.[60] Base case estimates of respiratory-related hospital admissions under recent air quality levels in Detroit are on the order of several hundred admissions per year across the range of assumed cutpoints considered in this assessment. The Detroit estimates are roughly one to two orders of magnitude greater than the range of estimated asthma-related admissions in Seattle, which can be attributed in part to differences in baseline risks related to respiratory-related health endpoints as well as to differences in $PM_{10-2.5}$ air quality levels in these two areas. More specifically, recent (e.g., 2001-2003) $PM_{10-2.5}$ concentrations are substantially higher in Detroit, where the current 24-hour PM_{10} standard is not met, than they are in Seattle (where the 24-hour PM_{10} design value is well below the level of the current PM_{10} standard). In considering risk estimates for respiratory symptoms in St. Louis, the number of days of cough in children living in St. Louis associated with recent $PM_{10-2.5}$ levels range from approximately 27,000 days per year[61] at the lowest assumed cutpoint to almost 3,000 days per year at the highest assumed cutpoint. For the same time period, $PM_{10-2.5}$ air quality levels in St. Louis are high, where, like Detroit, the current 24-hour PM_{10} standard is not met.

While one of the goals of the $PM_{10-2.5}$ risk assessment was to provide estimates of the risk reductions associated with just meeting alternative $PM_{10-2.5}$ standards, the nature and magnitude of the uncertainties and concerns associated with this portion of the risk assessment weigh against use of these risk estimates as a basis for recommending specific standard levels (EPA, 2005a, p. 5–69). These uncertainties and concerns include, but are not limited to the following:

(1) As noted above in section II.A and discussed more fully below in section III.G, the $PM_{10-2.5}$ levels measured at ambient monitoring sites in recent years may be quite different from the levels used to characterize exposure in the original epidemiologic studies based on monitoring sites in different location, thus possibly over- or underestimating population risk levels.

(2) There is greater uncertainty about the reasonableness of the use of proportional rollback to simulate just meeting alternative $PM_{10-2.5}$ standards in any urban area relative to that for $PM_{2.5}$ due to the limited availability of historic $PM_{10-2.5}$ air quality data.

(3) The locations used in the $PM_{10-2.5}$ risk assessment are not representative of urban areas in the U.S. that experience the most significant 24-hour peak $PM_{10-2.5}$ concentrations, and thus, observations about relative risk reductions associated with alternative standards may not be relevant to the areas expected to have the greatest health risks associated with elevated ambient $PM_{10-2.5}$ levels.

(4) The health effects database that supplies the concentration-response relationships used in the $PM_{10-2.5}$ risk assessment is much smaller than that available for $PM_{2.5}$, which limits EPA's ability to evaluate the robustness of the risk estimates for the same health endpoints across different locations.

C. Need for Revision of the Current Primary PM_{10} Standards

The initial issue to be addressed in the current review of the primary PM_{10} standards is whether, in view of the advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the existing standards should be revised. The Staff Paper addresses this question by first considering the conclusions reached in the last review, the subsequent litigation of that decision, and the nature of the new information available in this review.

In 1997, in conjunction with establishing new $PM_{2.5}$ standards, EPA concluded that continued protection against potential effects associated with thoracic coarse particles in the size range of 2.5 to 10 μm was warranted based on particle dosimetry, toxicologic information, and limited epidemiologic evidence (62 FR 38,677). This information indicated that thoracic coarse particles can deposit in the sensitive regions of the lung of most concern (e.g., the tracheobronchial and alveolar regions, which together make

[60] Quantitative risk estimates associated with recent air quality levels for these three cities are presented in Figures 4–11 and 4–12 in Chapter 4 of the Staff Paper.

[61] This represents roughly 1100 days of cough per 100,000 people in the general population, of which approximately 12 percent are children.

up the thoracic region),[62] and that they can be expected to aggravate effects in individuals with asthma and contribute to increased upper respiratory illness (62 FR 38,666–8).

Further, EPA decided that the new function of PM_{10} standard(s) would be to provide such protection against effects associated with particles in this narrower size range between 2.5 to 10 μm. Although some consideration had been given to a more narrowly defined indicator that did not include fine particles (e.g., $PM_{10-2.5}$), EPA decided that it was more appropriate to continue to use PM_{10} as the indicator for standards to control thoracic coarse particles. 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} in areas where the coarse fraction was the dominant fraction of PM_{10}, namely two studies conducted in areas that substantially exceeded the 24-hour PM_{10} standard (62 FR 38,679). The decision also reflected the fact that there were only very limited ambient air quality data then available specifically on thoracic coarse particles, in contrast to the extensive monitoring network already in place for PM_{10}. In essence, EPA concluded at that time that it was appropriate to continue to control thoracic coarse particles, but that the only information available upon which to base such standards was indexed in terms of PM_{10}.

In subsequent litigation regarding the 1997 PM NAAQS revisions, however, the court held in part that PM_{10} is a ''poorly matched indicator'' for thoracic coarse particles in the context of a rule that also includes $PM_{2.5}$ standards because PM_{10} includes $PM_{2.5}$. *American Trucking Associations* v. *EPA*, 175 F.3d. at 1054. Although the court found ''ample support'' (*id.*) for EPA's decision to regulate thoracic coarse particles, it vacated the 1997 revised PM_{10} standards for that reason. The result of subsequent EPA actions, discussed above in section I.C, is that the 1987 PM_{10} standards remain in place (65 FR 80776, 80777, Dec. 22, 2000) and the present review is consequently of those 1987 standards.

In this review, the Staff Paper focuses on the information now available from a growing, but still limited, body of evidence on health effects associated with thoracic coarse particles from studies that use $PM_{10-2.5}$ as the measure of thoracic coarse particles. In addition, there is now much more information available to characterize air quality in terms of $PM_{10-2.5}$ than was available in the last review.[63] In considering this information, the Staff Paper finds that the major considerations that formed the basis for EPA's 1997 decision to retain PM_{10} as the indicator for thoracic coarse particles, rather than a more narrowly defined indicator that does not include fine particles, no longer apply. More specifically, the continued use of PM_{10} as an indicator for standards intended to protect against health effects associated with thoracic coarse particles is no longer appropriate since information is now available that supports the use of a more directly relevant indicator, $PM_{10-2.5}$. Further, continuing to rely principally on health effects evidence indexed by PM_{10} to determine the appropriate averaging time, form, and level of a standard is no longer necessary or appropriate since a number of more directly relevant studies, indexed by $PM_{10-2.5}$, are also now available. Thus, separate from any legal considerations, the Staff Paper concludes it is appropriate to revise the current PM_{10} standards in part by revising the indicator for thoracic coarse particles, and by basing any such revised standard principally on the currently available evidence and air quality information indexed by $PM_{10-2.5}$, but also considering evidence from studies using PM_{10} in locations where $PM_{10-2.5}$ is the predominant fraction (EPA, 2005a, section 5.4.1).

Recognizing that dosimetric evidence formed the principal basis for the initial establishment of the PM_{10} indicator in 1987, and supported the decision in 1997 to retain the PM_{10} indicator, the Staff Paper also considers whether currently available dosimetric evidence continues to support the basic conclusions reached in those reviews of the standards. In particular, consideration is given to available information about patterns of penetration and deposition of thoracic coarse particles in the sensitive thoracic region of the lung and to whether an aerodynamic size of 10 μm remains a reasonable separation point for particles that penetrate and potentially deposit in the thoracic regions. The Staff Paper concludes that while considerable advances have been made in understanding particle dosimetry, the available evidence continues to support those basic conclusions from past reviews. More specifically, both fine particles, indexed by $PM_{2.5}$, and thoracic coarse particles, indexed by $PM_{10-2.5}$, penetrate to and deposit in the thoracic regions. Further, for a range of typical ambient size distributions, the total deposition of thoracic coarse particles to the alveolar region can be comparable to or even larger than that for fine particles (EPA, 2004, p. 6–16).

Beyond the dosimetric evidence, as noted in past reviews (EPA, 1981b, 1996b), toxicologic studies show that the deposition of a variety of particle types in the tracheobronchial region, including resuspended urban dust and coarse-fraction organic materials, has the potential to affect lung function and aggravate respiratory symptoms, particularly in asthmatics. Of particular note are limited toxicologic studies that found urban road dust can produce cellular and immunological effects (e.g., Kleinman, et al., 1995; Steerenberg et al., 2003).[64] In addition, some very limited in vitro toxicologic studies show some evidence that coarse particles may elicit pro-inflammatory effects (EPA, 2004, section 7.4.4). Further, the Staff Paper assessment of the physicochemical properties and occurrence of ambient coarse particles suggests that both the chemical makeup and the spatial distribution of coarse particles are likely to be more heterogeneous than for fine particles (EPA, 2005a, chapter 2). In particular, as discussed below in section III.D, coarse particles in urban areas can contain all of the components found in more rural areas, but be contaminated by a number of additional materials, from motor vehicle-related emissions to metals and transition elements associated with industrial operations. The Staff Paper concludes that the weight of the dosimetric, limited toxicologic, and atmospheric science evidence, taken together, lends support to the plausibility of the $PM_{10-2.5}$-related effects reported in urban epidemiologic studies, and provides support for retaining some standard for thoracic coarse particles so as to continue programs to protect public health from such effects (EPA, 2005a, p. 5–49).

The available epidemiologic evidence, discussed above in section III.A, includes studies of associations between short-term exposure to thoracic coarse particles, indexed by $PM_{10-2.5}$, and

[62] EPA further concluded at that time that the risks of adverse health effects associated with deposition of particles in the thoracic region are ''markedly greater than for deposition in the extrathoracic (head) region,'' and that risks from extrathoracic deposition are ''sufficiently low that particles which deposit only in that region can safely be excluded from the standard indicator'' (62 FR 38,666).

[63] Coarse particle concentrations from EPA's monitoring network are currently determined using a difference method in locations with same-day data from co-located PM_{10} and $PM_{2.5}$ FRM monitors.

[64] The Criteria Document notes that toxicologic studies, in general, use exposure concentrations that are generally much higher than ambient concentrations (EPA, 2004, p. 9–51).

health endpoints, as well as evidence from PM_{10} studies conducted in areas in which the coarse fraction is dominant. More specifically, several U.S. and Canadian studies now provide evidence of associations between short-term exposure to $PM_{10-2.5}$ and various morbidity endpoints. Three such studies conducted in Toronto (Burnett et al., 1997), Seattle (Sheppard et al., 2003), and Detroit (Ito, 2003) report statistically significant associations between short-term $PM_{10-2.5}$ exposure and respiratory- and cardiac-related hospital admissions, and a fourth study (Schwartz and Neas, 2000) conducted in six U.S. cities including Boston, St. Louis, Knoxville, Topeka, Portage, and Steubenville reports statistically significant associations across these six areas with respiratory symptoms in children. These studies were mostly done in areas in which $PM_{2.5}$, rather than $PM_{10-2.5}$, is the larger fraction of ambient PM_{10}, and they are not representative of areas with relatively high levels of thoracic coarse particles (EPA, 2005a, p. 5–49).

In evaluating the epidemiologic evidence from health studies on associations between short-term exposure to $PM_{10-2.5}$ and mortality, the Criteria Document concluded that such evidence was ''limited and clearly not as strong'' as that for associations with $PM_{2.5}$ or PM_{10} but nonetheless was suggestive of associations with mortality (EPA, 2004, p. 9–28, 9–32). Statistically significant mortality associations were reported in short-term exposure studies conducted in areas with relatively high $PM_{10-2.5}$ concentrations, including Phoenix (Mar et al., 2003), Coachella Valley, CA (Ostro et al., 2003), and in the initial analysis of data from Steubenville (as part of the Six Cities study, Schwartz et al., 1996), although in a reanalysis of this study, the results were generally not statistically significant (Klemm and Mason, 2003). In areas with lower $PM_{10-2.5}$ concentrations, no statistically significant associations were reported with mortality, though most were positive.

The Staff Paper also considers relevant epidemiologic studies indexed by PM_{10} that were conducted in areas where the coarse fraction of PM_{10} is typically much greater than the fine fraction. Such studies include findings of associations between short-term exposure to PM_{10} and hospitalization for cardiovascular diseases in Tucson, AZ (Schwartz, 1997), hospitalization for COPD in Reno/Sparks, NV (Chen et al., 2000), and medical visits for asthma or respiratory diseases in Anchorage, AK (Gordian et al., 1996; Choudhury et al., 1997). In addition, a number of epidemiologic studies have reported significant associations with mortality, respiratory hospital admissions and respiratory symptoms in the Utah Valley area (e.g., Pope et al., 1989; 1991; 1992). This group of studies provides additional supportive evidence for associations between short-term exposure to thoracic coarse particles and health effects, particularly morbidity effects, generally in areas not meeting the PM_{10} standards (EPA, 2005a, p. 5–50).[65]

In contrast to the findings from the short-term exposure studies discussed above, available epidemiologic studies do not provide evidence that long-term exposure to thoracic coarse particles is associated with mortality or morbidity (EPA, 2005a, p. 3–25). More specifically, no association is found between long-term exposure to thoracic coarse particles and mortality in the reanalyses and extended analysis of the ACS cohort (EPA, 2005a, p. 8–307). Further, little evidence is available on potential respiratory and cardiovascular morbidity effects of long-term exposure to thoracic coarse particles (EPA, 2005a, p. 3–23–24).

Taken together, the Staff Paper concludes that the health evidence, including dosimetric, toxicologic and epidemiologic study findings, supports retaining some standard to protect against effects associated with short-term exposure to thoracic coarse particles. However, the substantial uncertainties associated with this limited body of epidemiologic evidence on health effects related to exposure to $PM_{10-2.5}$, including the difficulty in separating the effects of fine and thoracic coarse particles, suggest a high degree of caution in interpreting this evidence, especially at the lower levels of ambient particle concentrations in the morbidity studies discussed above (EPA, 2004, p. 5–50).

Beyond this evidence-based evaluation, the Staff Paper also considers the extent to which $PM_{10-2.5}$-related health risks estimated to occur at current levels of ambient air quality may be judged to be important from a public health perspective, taking into account key uncertainties associated with the estimated risks. Consistent with the approach used to address this issue for $PM_{2.5}$-related health risks, discussed above in section II.B, the Staff Paper considers the results of a series of base case analyses that reflect in part the uncertainty associated with the form of the concentration-response functions drawn from the studies used in the assessment. In this assessment, which is much more limited than the risk assessment conducted for $PM_{2.5}$, health risks were estimated for three urban areas by using the reported linear or log-linear concentration-response functions as well as modified functions that incorporate alternative assumed cutpoints as surrogates for potential population thresholds (discussed above in section III.B). In considering the risk estimates from this limited assessment, and recognizing the very substantial uncertainties inherent in basing an assessment on such limited information, the Staff Paper concludes that the results for the two areas in the assessment that did not meet the current PM_{10} standards are indicative of risks that can reasonably be judged to be important from a public health perspective, in contrast to the appreciably lower risks estimated for the area that did meet the current standards (EPA, 2005a, p. 5–52).

The Staff Paper recognizes the substantial uncertainties associated with the limited available epidemiologic evidence and the inherent difficulties in interpreting the evidence for purposes of setting appropriate standards for thoracic coarse particles. Nonetheless, in considering the available evidence, the public health implications of estimated risks associated with current levels of air quality, and the related limitations and uncertainties, the Staff Paper concludes that this information supports (1) revising the current PM_{10} standards in part by revising the indicator for thoracic coarse particles, and (2) consideration of a standard that will continue to provide public health protection from short-term exposure to thoracic coarse particles of concern that have been associated with morbidity effects and possibly mortality at current levels in some urban areas (EPA, 2005a, p. 5–52).

In CASAC's review of these Staff Paper recommendations, there was general concurrence among CASAC Panel members that there is a need to revise the current PM_{10} standards and establish a primary standard specifically targeted to address particles in the size range of 2.5 to 10 μm (Henderson, 2005b). In making this recommendation, CASAC indicated its agreement with the summary of the scientific data regarding the potential adverse health effects from exposures to thoracic coarse particles in

[65] Based on recent air quality data, as well as the summary information provided for PM concentrations used in the studies, the existing PM_{10} standards are not met in any of these study cities except Tucson, AZ. Based on 2002–2004 air quality data, the 98th percentile $PM_{2.5}$ concentrations in three of these areas range from 15 to 25 $\mu g/m^3$, while in Utah Valley the concentrations range from 37 to 54 $\mu g/m^3$.

section 5.4 of the Staff Paper upon which the EPA staff recommendations were based.

In considering whether the primary PM_{10} standards should be revised, the Administrator has carefully considered the rationale and recommendations contained in the Staff Paper, the advice and recommendations of CASAC, and public comments to date on this issue. The Administrator provisionally concludes that the health evidence, including dosimetric, toxicologic and epidemiologic study findings, supports retaining a standard to protect against effects associated with short-term exposure to thoracic coarse particles. Further, the Administrator believes that the new evidence on health effects from studies that use $PM_{10-2.5}$ as a measure of thoracic coarse particles, together with the much more extensive data now available to characterize air quality in terms of $PM_{10-2.5}$, provide an appropriate basis for revising the current PM_{10} standards in part by revising the indicator to focus more narrowly on particles between 2.5 and 10 μm. The Administrator also notes that the need for a standard for thoracic coarse particles has already been upheld based upon evidence of health effects considerably more limited than now available. *American Trucking Associations* v. *EPA*, 175 F. 3d at 1054. Based on these considerations, the Administrator provisionally concludes that the current suite of PM_{10} standards should be revised, and that the revised standard(s) should provide more targeted protection from short-term exposure to those thoracic coarse particles that are of concern to public health.

D. Indicator of Thoracic Coarse Particles

In considering an appropriate indicator for a standard intended to afford protection from health effects associated with exposure to thoracic coarse particles of concern, the Staff Paper starts by making the following observations:

(1) The most obvious choice for a thoracic coarse particle standard is the size-differentiated, mass-based indicator used in the epidemiologic studies that provide the most direct evidence of such health effects, $PM_{10-2.5}$.

(2) The upper size cut of a $PM_{10-2.5}$ indicator is consistent with dosimetric evidence that continues to reinforce the finding from past reviews that an aerodynamic size of 10 μm is a reasonable separation point for particles that penetrate to and potentially deposit in the thoracic regions of the respiratory tract.

(3) The lower size cut of such an indicator is consistent with the choice of 2.5 μm as a reasonable separation point between fine and coarse fraction particles.

(4) Further, the limited available information is not sufficient to define an indicator for thoracic coarse particles solely in terms of metrics other than size-differentiated mass, such as specific chemical components.

(5) The available epidemiologic evidence for effects of $PM_{10-2.5}$ exposure is quite limited and is inherently characterized by large uncertainties, reflective in part of the more heterogeneous nature of the spatial distribution and chemical composition of thoracic coarse particles and the more limited and generally uncertain measurement methods that have historically been used to characterize their ambient concentrations.

In evaluating relevant information from atmospheric sciences, toxicology, and epidemiology related to thoracic coarse particles, the Staff Paper notes that there appears to be clear distinctions between (1) the character of the ambient mix of particles generally found in urban areas as compared to that found in nonurban and, more specifically, rural areas, and (2) the nature of the evidence concerning health effects associated with thoracic coarse particles generally found in urban versus rural areas. Based on such information, and on specific initial advice from CASAC (Henderson, 2005a), the Staff Paper considers a more narrowly defined indicator for thoracic coarse particles that focuses on the mix of such particles that is characteristic of that generally found in urban areas where thoracic coarse particles are strongly influenced by traffic-related or industrial sources. In so doing, the Staff Paper focuses on comparing the potential health effects associated with thoracic coarse particles in urban and rural settings, as discussed below.

Atmospheric science and monitoring information indicates that exposures to thoracic coarse particles tend to be higher in urban areas than in nearby rural locations. Further, the mix of thoracic coarse particles typically found in urban areas contains a number of contaminants that are not commonly present to the same degree in the mix of natural crustal particles that is typical of rural areas. The elevation of $PM_{10-2.5}$ levels in urban locations as compared to those at nearby rural sites suggests that sources located within urban areas are generally the cause of elevated urban concentrations; conversely, $PM_{10-2.5}$ concentrations in such urban areas are not largely composed of particles blown in from more distant regions (EPA, 2005a, sections 2.4.5 and 5.4.2.1). Important sources of thoracic coarse particles in urban areas include dense traffic that suspends significant quantities of dust from paved roads, as well as industrial and combustion sources and construction activities that contribute to ambient coarse particles both directly and through deposition to soils and roads (EPA, 2005a, Table 2–2). It follows that the mix of thoracic coarse particles in urban areas would differ in composition from that in rural areas, being influenced to a relatively greater degree by components from urban mobile and stationary source emissions.

While detailed composition data are more limited for $PM_{10-2.5}$ than for $PM_{2.5}$, available measurements from some areas as well as studies of road dust components do show a significant influence of urban sources on both the composition and mass of thoracic coarse particles generally found in urban areas. Although crustal elements and natural biological materials represent a significant fraction of thoracic coarse particles in urban areas, both their relative quantity and character may be altered by urban sources. For example, in industrial cities, primary particle emissions from industrial sources and resuspended road dust can increase the relative amount of iron in the mix of $PM_{10-2.5}$, one of the metals that has been noted as being of some interest in the studies of mechanisms of toxicity for PM, as well as other industrial process-related and potentially toxic materials such as nickel, cadmium, and chromium (EPA, 2005a, p. 5–54). Traffic-related activities can also grind and resuspend vegetative materials into forms not as common in more natural areas (Rogge et al., 1993). Studies of urban road dusts find that levels of a variety of components are increased from traffic as well as from other anthropogenic urban sources, including products of incomplete combustion (e.g. polycyclic aromatic hydrocarbons) from motor vehicle emissions and other sources, brake and tire wear, rust, salt and biological materials (EPA, 2004, p. 3D–3). Limited ambient coarse fraction composition data from various comparisons find that metals and sometimes elemental carbon contribute a greater proportion of thoracic coarse particle mass in urban areas than in nearby rural areas. In addition, while large uncertainties exist in emissions inventory data, the Staff Paper observes that major sources of $PM_{10-2.5}$ emissions in the urban counties in which epidemiologic studies have been conducted are paved roads and ''other''

sources (largely construction), and that such areas also have larger contributions from industrial emissions, whereas unpaved roads and agriculture are the main sources of $PM_{10-2.5}$ emissions outside of urban areas.

Toxicologic studies, although quite limited, support the view that thoracic coarse particles from sources common in urban areas are of greater concern than uncontaminated materials of geologic origin. One major source of thoracic coarse particles in urban areas is paved road dust; the Criteria Document discusses results from a recent toxicologic study in which road tunnel dust particles had greater allergic adjuvant activity than several other particle samples (Steerenberg et al., 2003; EPA, 2004, pp. 7–136, 137). This study supports evidence available in the last review regarding potential effects of road dust particles (EPA, 1996b, p. V–70). In contrast, a number of studies have reported that Mt. St. Helens volcanic ash, an example of natural crustal material of geologic origin, has very little toxicity in animal or in vitro toxicologic studies (EPA, 2004, p. 7–216).

A few toxicologic studies have used ambient thoracic coarse particles from urban/suburban locations ($PM_{10-2.5}$), and the results suggest that effects can be linked with several components of $PM_{10-2.5}$. These in vitro toxicologic studies linked thoracic coarse particles with effects including cytotoxicity, oxidant formation, and inflammatory effects (EPA, 2005a, sections 3.2 and 5.4.1). These studies suggest that several components (e.g., metals, endotoxin, other materials) may have roles in various health responses but do not suggest a focus on any individual component.

Although largely focused on undifferentiated PM_{10}, the series of epidemiologic observations and toxicologic experiments related to the Utah Valley suggest that directly emitted (fine and coarse) and resuspended (coarse) urban industrial emissions are of concern. Of particular interest are area studies spanning a 13-month period when a major source of PM_{10} in the area, a steel mill, was not operating. Observational studies found that respiratory hospital admissions for children were lower when the plant was shut down (Pope et al., 1989). More recently, a set of toxicologic and controlled human exposure studies have used particles extracted from filters from ambient PM_{10} monitors from periods when the plant did and did not operate. In both human volunteers and animals, greater lung inflammatory responses were reported with particles collected when the source was operating, as compared to the period when the plant was closed (EPA, 2004, p. 9–73). In addition, in some studies it was suggested that the metal content of the particles was most closely related to the effects reported (EPA, 2004, p. 9–74). While peak days in the Utah Valley occur in conditions that enhance fine particle concentrations, over the long run, over half of the PM_{10} was in the coarse fraction. The aggregation of particles collected on the filters during the study period reflect this long-term composition and represent the kinds of industrial components that would be incorporated in road dusts in the area.

Epidemiologic studies that have examined exposures to thoracic coarse particles generally found in urban environments, together with studies that have taken into account exposures to natural crustal materials typical of rural areas, generally support the view that the mix of thoracic coarse particles generally found in urban areas is of concern to public health, in contrast to natural crustal dusts of geologic origin. With respect to the urban results, several recent studies have shown associations between $PM_{10-2.5}$ and health outcomes in a few sites across the U.S. and Canada. Associations have been reported with morbidity in a few urban areas, some of which had relatively low $PM_{10-2.5}$ concentrations. For mortality, statistically significant associations have been reported only for two urban areas that have notably higher ambient $PM_{10-2.5}$ concentrations. These associations are with short-term exposures to aggregated $PM_{10-2.5}$ mass, and no epidemiologic evidence is available on associations with different components or sources of $PM_{10-2.5}$. However, these studies have all been conducted in urban areas of the U.S., and thus reflect effects associated with the ambient mix of thoracic coarse particles generally present in urban environments.

In contrast, recent evidence from epidemiologic studies has suggested that mortality and possibly other health effects are not associated with thoracic coarse particles from dust storms or other such wind-related events that result in suspension of natural crustal materials of geologic origin. The clearest example is provided by a study in Spokane, WA, which specifically assessed whether mortality was increased on dust-storm days using case-control analysis methods. The average PM_{10} level was more than 200 $\mu g/m^3$ higher on dust storm days than on control days, and the authors report no evidence of increased mortality on these specific days (Schwartz et al., 1999). One caveat of note is the possibility that people may reduce their exposure to ambient particles on the most dusty days (e.g., Gordian et al., 1996; Ostro et al., 2000). Nevertheless, these studies provide no suggestion of significant health effects from uncontaminated natural crustal materials that would typically form a major fraction of coarse particles in non-urban or rural areas.

Beyond the urban and rural distinctions discussed above, the Staff Paper also considers the extent to which there is evidence of effects with exposure to the ambient thoracic coarse particles in communities predominantly influenced by agricultural or mining sources.[66] For example, in the last review, EPA considered health evidence related to long-term silica exposures from mining activities, but found that there was a lack of evidence that such emissions contribute to effects linked with ambient PM exposures (EPA, 1996b, p. V–28). Similarly in this review, there is an absence of evidence related to such community exposures. While crustal and organic dusts generated from agricultural activity can include a variety of biological materials, and some occupational studies discussed in the Criteria Document report effects at occupational exposure levels (EPA, 2004, Table 7B–3, p. 7B–11), such studies do not provide relevant evidence for effects at much lower levels of community exposures. Further, it is unlikely that such sources contribute to the effects that have been observed in the recent urban epidemiologic studies.

The Criteria Document concludes its integrated assessment of the effects of natural crustal materials as follows:

> Certain classes of ambient particles appear to be distinctly less toxic than others and are unlikely to exert human health effects at typical ambient exposure concentrations (or perhaps only under special circumstances). For example, particles of crustal origin, which are predominately in the coarse fraction, are relatively non-toxic under most circumstances, compared to combustion-related particles (such as from coal and oil combustion, wood burning, etc.) However, under some conditions, crustal particles may become sufficiently toxic to cause human health effects. (EPA, 2004, p. 8–344)

The Staff Paper assessment of the available evidence relevant to the appropriate scope of an indicator for coarse particles can be summarized as follows. Ambient concentrations of thoracic coarse particles generally

[66] Mining sources are intended to include all activities that encompass extraction and/or mechanical handling of natural geologic crustal materials.

reflect contributions from local sources, and the limited information available from speciation of thoracic coarse particles and emissions inventory data indicate that the sources of thoracic coarse particles in urban areas generally differ from those found in nonurban areas. As a result, the mix of thoracic coarse particles people are typically exposed to in urban areas can be expected to differ appreciably from the mix typically found in non-urban or rural areas. Ambient $PM_{10-2.5}$ exposure is associated with health effects in studies conducted in urban areas, and the limited available health evidence more strongly implicates the ambient mix of thoracic coarse particles that is dominated by traffic-related and industrial sources than that from uncontaminated soil or geologic sources. The limited evidence does not support either the existence or the lack of causative associations for community exposures to thoracic coarse particles from agricultural or mining industries. Given the apparent differences in composition and in the epidemiologic evidence, the Staff Paper concludes that it is not appropriate to generalize the available evidence of associations with health effects that have been related to thoracic coarse particles generally found in urban areas and apply it to the mix of particles typically found in nonurban or rural areas (EPA, 2005a, p. 5–57).

Collectively, this evidence suggests that a more narrowly defined indicator for thoracic coarse particles should be considered that would protect public health against effects that have been linked with the mix of thoracic coarse particles generally present in urban areas. Such an indicator would be principally based on particle size, but also reflect a focus on the mix of thoracic coarse particles that is generally present in urban environments and the sources that principally generate that mix. The Staff Paper recommends consideration of thoracic coarse urban particulate matter[67] as an indicator for a thoracic coarse particle standard, referring to the mix of airborne particles between 2.5 and 10 μm in diameter that are generally present in urban environments, which, as discussed above, are principally comprised of resuspended road dust typical of high traffic-density areas and emissions from industrial sources and construction activities (EPA, 2005a, p. 5–54, 5–57–58). The Staff Paper concludes that such an indicator would more likely be an effective indicator for standards to protect against health effects that have been associated with thoracic coarse particles than a more broadly focused $PM_{10-2.5}$ indicator. This indicator would also be consistent with an appropriately cautious interpretation of the epidemiologic evidence that does not potentially over-generalize the results of the limited available studies.

In conjunction with this recommendation of an indicator defined in terms of the mix of thoracic coarse particles that are generally present in urban areas, the Staff Paper also discusses the importance of a monitoring network designed so as to be consistent with the intent of such an indicator and that would facilitate implementation of such a standard. EPA has historically used implementation policies to address elevations in thoracic coarse particle levels that may occur in urban areas as a result of dust storms or other such events for which this staff-recommended indicator is not intended to apply. Both new criteria for monitor network design and revised natural/exceptional events policies should work in concert with a revised thoracic coarse particle indicator to ensure the most effective application of a thoracic coarse particle standard.

In its review of the Staff Paper recommendation for a thoracic coarse particle indicator (Henderson, 2005b), the CASAC generally agreed that ''thoracic coarse particles in urban areas can be expected to differ in composition from those in rural areas;'' that ''coarse particles in urban or industrial areas are likely to be enriched by anthropogenic pollutants that tend to be inherently more toxic than the windblown crustal material which typically dominates coarse particle mass in arid rural areas;'' and that ''evidence of associations with health effects related to urban coarse-mode particles would not necessarily apply to non-urban or rural coarse particles.'' Further, most CASAC Panel members concurred that ''the current scarcity of information on the toxicity of rural dusts makes it necessary'' for EPA to base its standard for thoracic coarse particles ''on the known toxicity of urban-derived coarse particles.'' While most Panel members concurred with the thoracic coarse particle indicator recommended in the Staff Paper, a few members recommended specifying a $PM_{10-2.5}$ indicator in conjunction with monitoring network design criteria and natural/exceptional events policies that would emphasize urban influences. In either case, CASAC indicated that the intent of any such indicator should be to ''provide protection against those components of $PM_{10-2.5}$ that arise from anthropogenic activities occurring in or near urban and industrial areas.''

In considering an appropriate indicator for a standard intended to afford protection from health effects associated with exposure to thoracic coarse particles of concern, the Administrator has carefully considered the rationale and recommendations contained in the Staff Paper, the advice and recommendations from CASAC, and public comments to date on this issue. In so doing, the Administrator believes, despite the substantial limitations and uncertainties in the relevant information available, that it is appropriate to propose a new indicator for such particles at this time. Further, the Administrator believes that any such indicator should be defined not only by particle size, to generally include those particles between 2.5 and 10 μm in diameter, but also by qualifications that narrow the scope of the indicator. In considering an indicator that is intended to focus on the mix of thoracic coarse particles generally present in urban environments and commonly derived from sources typically found in urban environments, consistent with Staff Paper and CASAC recommendations, the Administrator notes that identifying it as an ''urban'' thoracic coarse particle indicator could be misconstrued as meaning that the standard is limited to certain geographic locations and, thus, not a national standard. To avoid this semantic problem, the Administrator has sought to define the indicator in a way that more clearly focuses on the nature of the mix of thoracic coarse particles intended to be included and the sources that principally generate that mix, rather than just where they are found, and that also explicitly focuses on what would be excluded from such an indicator. In so doing, the Administrator intends the proposed indicator to be equivalent to the one recommended in the Staff Paper and endorsed by CASAC, but to do so in a manner that will be more clearly understood and less likely to be misinterpreted.

Taking into account the considerations discussed above, the Administrator proposes to establish a new indicator for thoracic coarse particles in terms of $PM_{10-2.5}$, the definition of which includes qualifications that identify both the mix of such particles that are of concern to public health, and are thus included in the indicator, and those for which currently available information is not sufficient to infer a public health concern, and are thus excluded. More specifically, the proposed $PM_{10-2.5}$ indicator is qualified so as to include any ambient mix of $PM_{10-2.5}$ that is

[67] The acronym ''$UPM_{10-2.5}$'' is used in the Staff Paper to refer to this indicator.

dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and excludes any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. In short, the indicator is not defined by nor limited to any specific geographic area, but includes the mix of $PM_{10-2.5}$ in any location that is dominated by these sources.

With the indicator as defined above, each area in the country would fall into one or the other of these two categories: (1) Either the majority of the ambient mix of $PM_{10-2.5}$ in an area is resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, or (2) the majority of the ambient mix is rural windblown dust and soils and PM generated by agricultural and mining sources. The indicator would apply when $PM_{10-2.5}$ generated by one or more of these named sources in the first category constitutes a majority of the ambient mix of $PM_{10-2.5}$. The EPA recognizes that in many cases it will be clear which of these two categories applies, while in other cases it may be difficult to determine the appropriate category. As described in more detail in the preamble to EPA's proposed monitor network design rule, published elsewhere in today's **Federal Register**, the proposed minimum monitor siting criteria would provide guidance on distinguishing between areas where the mix of $PM_{10-2.5}$ of concern would likely be dominated by the named sources in the first category and those areas where it would not. Consequently, all $PM_{10-2.5}$ captured by a monitor that is properly sited in light of the indicator described above, as discussed in the proposed monitoring rule, would be considered in applying the standard, since the monitor would be capturing the mix of ambient $PM_{10-2.5}$ covered by the proposed indicator. As such, the proposed indicator does not present the type of over-inclusion or under-inclusion problems noted by the court with respect to a PM_{10} indicator (see *American Trucking Associations* v. *EPA*, 175 F.3d at 1054), since the application of the proposed indicator would result in compliance being based on measurement of the mix of ambient $PM_{10-2.5}$ at which the standard is directed.

The regulation for the proposed thoracic coarse particle indicator states that ''[a]gricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting this standard.'' This proposed language reflects that the information supporting the proposed standard for thoracic coarse particles does not support extending controls to thoracic coarse particles from agricultural, mining sources, and other similar sources of crustal material. This statement in the regulations therefore is designed to make clear that there is no need nor basis to control these sources to obtain the public health benefits intended by the proposed indicator.

Although the Administrator believes that an indicator qualified through reference to these categories and named sources appropriately identifies the ambient mixes that the epidemiologic studies indicate are of concern to public health, he solicits comment as to whether there may be other classes of sources which should also be included or excluded from the indicator. More generally, comment is also solicited on the approach of defining the indicator in terms of both particle size and categories of named sources.

The Administrator recognizes that the proposed indicator, which includes considerations beyond particle size in its definition, represents a shift in the way in which PM indicators have been defined historically, and thus poses new challenges in ensuring a common understanding of how it can be appropriately and consistently implemented in areas across the country. In the Administrator's view, the application of this proposed indicator in conjunction with the proposed monitoring network design criteria, published elsewhere in today's **Federal Register**, and proposed rules for the treatment of air quality data influenced by exceptional events that will be published in the near future, will facilitate appropriate and consistent implementation.

E. Averaging Time of Primary $PM_{10-2.5}$ Standard

In the last review, EPA retained both 24-hour and annual PM_{10} standards to provide protection against the known and potential effects of short- and long-term exposures to thoracic coarse particles (62 FR at 38,677–79). That decision was based in part on qualitative considerations related to the expectation that deposition of thoracic coarse particles in the respiratory system could aggravate effects in individuals with asthma. In addition, quantitative support for retaining a 24-hour standard came from limited epidemiologic evidence suggesting that aggravation of asthma and respiratory infection and symptoms may be associated with daily or episodic increases in PM_{10}, where dominated by thoracic coarse particles including fugitive dust. The decision to retain an annual standard as well was generally based on considerations of the plausibility of the potential build-up of insoluble thoracic coarse particles in the lung after long-term exposures to high levels of such particles.

New information available in this review on thoracic coarse particles, discussed above, includes several epidemiologic studies that report statistically significant associations between short-term (24-hour) exposure to $PM_{10-2.5}$ and various morbidity effects and mortality. With regard to long-term exposure studies, while one recent study conducted in southern California reported a link between reduced lung function growth and long-term exposure to $PM_{10-2.5}$ and $PM_{2.5,}$ other such studies reported no associations (EPA, 2005a, p. 3–19, 3–23–24). Thus, the Criteria Document concludes that the available evidence does not suggest an association with long-term exposure to $PM_{10-2.5}$ (EPA, 2004, p. 9–79).

Based on these considerations, the Staff Paper concludes that the newly available evidence continues to support a 24-hour averaging time for a standard intended to control thoracic coarse particles, based primarily on evidence suggestive of associations between short-term (24-hour) exposure and morbidity effects and, to a lesser degree, mortality. Noting the absence of evidence judged to be suggestive of an association with long-term exposures, the Staff Paper concludes that there is no quantitative evidence that directly supports an annual standard, while recognizing that it could be appropriate to consider an annual standard to provide a margin of safety against possible effects related to long-term exposure to thoracic coarse particles that future research may reveal. The Staff Paper observes, however, that a 24-hour standard that would reduce 24-hour exposures would also likely reduce long-term average exposures, thus providing some margin of safety against the possibility of health effects associated with long-term exposures (EPA, 2005a, p. 5–61).

Based on its review of the Staff Paper, CASAC recommends retention of a 24-hour averaging time and agrees that an annual averaging time for $PM_{10-2.5}$ is not currently warranted (Henderson, 2005b). Based on these considerations, the Administrator concurs with staff and CASAC recommendations, and provisionally concludes that the newly available evidence continues to support a 24-hour averaging time for a $PM_{10-2.5}$ standard, based primarily on evidence suggestive of associations between

short-term (24-hour) exposure and morbidity effects and, to a lesser degree, mortality. Further, the Administrator agrees that an annual $PM_{10-2.5}$ standard is not warranted at this time. Thus, the Administrator proposes to revoke the annual PM_{10} standard and is not proposing an annual $PM_{10-2.5}$ standard.

F. Form of Primary $PM_{10-2.5}$ Standard

For reasons similar to those discussed above in section II.F.2 on the form of the 24-hour $PM_{2.5}$ standard, the Staff Paper also recommends consideration of either the 98th or 99th percentile form for a 24-hour $PM_{10-2.5}$ standard. The relative year-to-year stability of the air quality statistic to be used as the basis for the form of a $PM_{10-2.5}$ standard is of particular importance for a $PM_{10-2.5}$ standard, since the nature and magnitude of the uncertainties in the risk assessment conducted for thoracic coarse particles weighed against considering risk estimates as a basis for comparing alternative combinations of specific forms and levels of standards.

In considering the information provided in the Staff Paper, CASAC strongly recommends use of the 98th percentile form because it is more statistically robust than the 99th percentile form, together with the use of a three-year average of this statistic (Henderson 2005b). In making this recommendation, CASAC notes that the use of this statistic will tend to minimize ''measurement error and spatial variability, which are larger for coarse-mode particles than for fine PM'' as well as ''the influence in arid areas of occasional but extreme excursion contributions from rural, coarse-mode dust sources that are thought to be inherently less toxic than coarse-mode particles heavily enriched with urban source contaminants'' (Henderson, 2005b).

In considering the available information, the Administrator concurs with the CASAC recommendation and proposes that the form of the 24-hour $PM_{10-2.5}$ standard be based on the annual 98th percentile statistic, averaged over three years.

G. Level of Primary $PM_{10-2.5}$ Standard

In considering the available evidence on associations between short-term $PM_{10-2.5}$ concentrations and morbidity and mortality effects as a basis for setting a 24-hour standard for thoracic coarse particles, the Staff Paper focuses on relevant U.S. and Canadian epidemiologic studies, as discussed above in section II.A. As an initial matter, the Staff Paper recognizes that these individual short-term exposure studies provide no evidence of clear population thresholds, or lowest-observed-effects levels, in terms of 24-hour average concentrations. As a consequence, this body of evidence is difficult to translate directly into a specific 24-hour standard that would protect against the range of effects that have been associated with short-term exposures.

In considering the evidence, the Staff Paper notes the significant uncertainties and the limited nature of the available evidence. In examining the available evidence to identify a basis for a range of standard levels that would be appropriate for consideration, the Staff Paper focuses on the upper end of the distributions of daily $PM_{10-2.5}$ concentrations in the relevant studies in terms of the 98th and 99th percentile values.[68]

In looking first at the morbidity studies that report statistically significant associations with respiratory- and cardiac-related hospital admissions in Toronto (Burnett et al., 1997), Seattle (Sheppard et al., 2003), and Detroit (Ito, 2003), the 98th percentile values reported in these studies range from approximately 30 to 36 $\mu g/m^3$. To provide some perspective on these $PM_{10-2.5}$ levels, the Staff Paper notes that the level of the 24-hour PM_{10} standard was exceeded only on a few occasions during the time periods of the studies in Detroit and Seattle.[69] In looking also at the mortality studies that report statistically significant and generally robust associations with short-term exposures to $PM_{10-2.5}$ in Phoenix (Mar et al., 2003) and Coachella Valley, CA (Ostro et al., 2003), the reported 98th percentile values were approximately 70 and 107 $\mu g/m^3$, respectively. These studies were conducted in areas with air quality levels that did not meet the current PM_{10} standards. In addition, a statistically significant association was reported between $PM_{10-2.5}$ and mortality in Steubenville as part of the original Six Cities study (Schwartz et al., 1996), although in more recent reanalyses, the association did not remain statistically significant in most models (Schwartz, 2003a; Klemm and Mason, 2003)—the $PM_{10-2.5}$ concentrations in this eastern city were fairly high, with a reported 98th percentile value of 53 $\mu g/m^3$. In contrast to the statistically significant mortality associations with $PM_{10-2.5}$ reported in these studies, the Staff Paper notes that no such associations were reported in a number of other studies, including those in the five other cities that were part of the Six Cities study (Boston, St. Louis, Knoxville, Topeka, and Portage), Santa Clara County, CA, Detroit, Philadelphia, and Pittsburgh. With the exception of Pittsburgh, these cities had much lower 98th percentile $PM_{10-2.5}$ values, ranging from 18 to 49 $\mu g/m^3$. Thus, in mortality studies that reported statistically significant associations, the reported 98th percentile $PM_{10-2.5}$ values were all above 50 $\mu g/m^3$, whereas in the mortality studies that reported no statistically significant associations, the reported 98th percentile $PM_{10-2.5}$ values were generally below 50 $\mu g/m^3$.

In looking more closely at air quality data used in the morbidity and mortality studies discussed above, however, the Staff Paper recognizes that the uncertainty related to exposure measurement error associated with using ambient concentrations to represent area-wide population exposure levels can be potentially quite large. For example, in looking specifically at the Detroit study, the Staff Paper notes that the $PM_{10-2.5}$ air quality values were based on air quality monitors located in Windsor, Canada. While the study authors concluded that these monitors were appropriate for use in exploring the association between air quality and hospital admissions in Detroit, a close examination of air quality levels at Detroit and Windsor sites in recent years led to the conclusion that the statistically significant, generally robust association with hospital admissions in Detroit likely reflects population exposures that may be appreciably higher in the central city area, but not necessarily across the broader study area, than would be estimated using data from the Windsor monitors (EPA, 2005a, p. 5–64).

The EPA staff also looked more specifically at the Coachella Valley mortality study (Ostro et al., 2003), in which data were used from a single monitoring site in one city, Indio, within the study area where daily measurements were available. A close examination of air quality levels across the Coachella Valley suggests that while the association of mortality with $PM_{10-2.5}$ measurements made at the Indio site was statistically significant, a portion of the study population would have been expected to experience appreciably lower ambient exposure levels. In contrast to the Detroit study, air quality data used in the mortality

[68] This examination of the evidence is based on air quality information and analyses presented in two staff memos which were part of the materials reviewed by CASAC (Ross and Langstaff, 2005; Ross, 2005).

[69] As shown in air quality data trends reports: for Seattle, 1997 Air Quality Annual Report for Washington State, p. 17, at *http://www.ecy.wa.gov/pubs/97208.pdf*; for Detroit, Michigan's 2003 Annual Air Quality Report, p. 46, at *http://www.deq.state.mi.us/documents/deq-aqd-air-reports-03AQReport.pdf.*

study conducted in Coachella Valley appear to represent concentrations on the high end of $PM_{10-2.5}$ levels for Coachella Valley communities. On the other hand, a close examination of the air quality data used in the other studies discussed above generally shows less disparity between air quality levels at the monitoring sites used in the studies and the broader pattern of air quality levels across the study areas than that described above in the Detroit and Coachella Valley studies.

This close examination of air quality information generally reinforces the view that exposure measurement error is potentially quite large in these $PM_{10-2.5}$ studies. As a consequence, the air quality levels reported in these studies, as measured by ambient concentrations at monitoring sites within the study areas, are not necessarily good surrogates for population exposures that are likely associated with the observed effects in the study areas or that would likely be associated in other urban areas across the country. The Detroit example suggests that population exposures were probably appreciably underestimated in the Detroit morbidity study, such that the observed effects are likely associated with higher $PM_{10-2.5}$ levels than reported. In contrast, the Coachella Valley mortality study provides an example in which population levels were probably appreciably overestimated, such that the observed effects may well be associated with lower $PM_{10-2.5}$ levels than reported. At relatively low levels of air quality, population exposures implied by these studies as being associated with the observed effects likely become more uncertain, suggesting a high degree of caution in interpreting the group of morbidity studies as a basis for identifying a standard level that would protect against the observed effects.

Taking into account this close examination of the studies, the Staff Paper concludes that this evidence suggests that EPA could consider a standard for urban thoracic coarse particles at a $PM_{10-2.5}$ level at least down to 50 $\mu g/m^3$, in conjunction with a 98th percentile form. This view takes into account the conclusion that this evidence is particularly uncertain as to population exposures, especially from the morbidity studies reporting effects at relatively low concentrations, as well as the general lack of evidence of associations from the group of mortality studies with reported concentrations below these levels.

Another view that reflects a more cautious or restrained approach to interpreting the limited body of $PM_{10-2.5}$ epidemiologic evidence would be to judge that the uncertainties in this whole group of studies as to population exposures that are associated with the observed effects are too large to use the reported air quality levels directly as a basis for setting a specific standard level. Such a judgment would be consistent with concluding that these studies, together with other dosimetric and toxicologic evidence, provide support for retaining standards for thoracic coarse particles at some level to protect against the morbidity and mortality effects observed in the studies, regardless of whether an associated population exposure level can be clearly discerned from the studies.

Based on this more cautious approach, the Staff Paper concludes that it would be reasonable to interpret the available epidemiologic evidence more qualitatively. Considering the available evidence in this way leads to the following observations:

(1) The statistically significant mortality associations with short-term exposure to $PM_{10-2.5}$ reported in the Phoenix and Coachella Valley studies were observed in areas that did not meet the current PM_{10} standards.

(2) The statistically significant morbidity associations with short-term exposure to $PM_{10-2.5}$ reported in the Detroit and Seattle studies were observed in areas that exceeded the level of the current 24-hour PM_{10} standard on just a few occasions during the time periods of the studies.

(3) All but one of the statistically significant morbidity and mortality associations with short-term exposure to PM_{10} reported in areas in which the thoracic coarse particle fraction of PM_{10} was much greater than was the fine fraction (including Reno/Sparks, NV, Tucson, AZ, Anchorage, AK, and the Utah Valley area) were observed in areas that did not meet the current PM_{10} standards.

Based on these considerations, the Staff Paper finds 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 standards, but have not been associated with air quality levels that would generally meet the current standards, and morbidity effects have been associated with air quality levels that exceeded the current standards only a few times. Further, the Staff Paper finds little basis for concluding that a greater degree of protection is warranted in light of the very high degree of uncertainty in the relevant population exposures implied by the morbidity studies. The Staff Paper concludes, therefore, that it is reasonable to interpret the available evidence as supporting consideration of a short-term standard for thoracic coarse particles, so as to provide generally ''equivalent'' protection to that afforded by the current PM_{10} standards, recognizing that no one $PM_{10-2.5}$ level will be strictly equivalent to a specific PM_{10} level in all areas (EPA, 2005a, p. 5–67). Such a standard would likely provide protection against morbidity effects especially in urban areas where, unlike the study areas, PM_{10} is generally dominated by coarse-fraction rather than fine-fraction particles. Such a standard would also likely provide protection against the more serious, but more uncertain, $PM_{10-2.5}$-related mortality effects generally observed at somewhat higher air quality levels.

To identify a range of levels for consideration for a 24-hour $PM_{10-2.5}$ standard, based on the indicator proposed above and set so as to afford generally ''equivalent'' protection as the current PM_{10} standards, the Staff Paper presents the results of analyses of relevant data on $PM_{10-2.5}$ and PM_{10} 24-hour average concentrations.[70] In one such analysis of 205 monitoring sites (Schmidt et al., 2005),[71] a $PM_{10-2.5}$ level of approximately 60 $\mu g/m^3$, in terms of a 98th percentile form, would be roughly equivalent on average across the U.S. to the current PM_{10} standard level of 150 $\mu g/m^3$, in terms of the current one-expected-exceedance form.[72] While noting appreciable variability in the estimated point of equivalence across individual sites, these levels of approximate average equivalence are quite consistent across each of the five regions in which all of the areas that do not meet the current PM_{10} standards are located (including the southern California, southwest, northwest, upper mid-west, and southeast regions). Notably different average equivalence

[70] Consistent with $PM_{10-2.5}$ monitoring network design criteria discussed in section 5.4.2.2 of the Staff Paper, monitors included in this analysis are those in CBSAs with at least 100,000 population and in census block groups with a population density of at least 500, and that also had 3 years of complete data in each quarter for both PM_{10} and $PM_{10-2.5}$ (EPA, 2005a, p. 5–67).

[71] These analyses were based on collocated PM_{10} and $PM_{10-2.5}$ data, and used linear regression methods to predict $PM_{10-2.5}$ concentrations (98th percentile form) equivalent to the 24-hour PM_{10} standard level of 150 $\mu g/m^3$ (one expected exceedence form) at a national and at regional levels.

[72] Across the U.S., the 95 percent confidence intervals around these point estimates are approximately ± 3 $\mu g/m^3$, while region-specific intervals are approximately ± 10 $\mu g/m^3$ in the five regions in which all of the areas that do not meet the current PM_{10} standards are located (EPA, 2005a, p. 5–68).

levels were observed in the other two regions, i.e., approximately 40 μg/m^3 in the northeast and over 70 μg/m^3 in the industrial mid-west.

Another such analysis was based on comparing the number of areas, and the population in those areas, that would likely not meet a specific $PM_{10-2.5}$ standard, set at a given level and form, with the same measures in areas that do not meet the current PM_{10} standards. This analysis, based on 2001 to 2003 data, provides some rough indication of the breadth of protection potentially afforded by alternative standards. The results of this analysis indicate that a $PM_{10-2.5}$ standard of about 70 or 65 μg/m^3, 98th percentile form, would impact approximately the same number of counties or number of people, respectively, as would the current PM_{10} standards.[73]

In considering the relevant dosimetric, toxicologic, and epidemiologic evidence, related limitations and uncertainties, and analyses of relevant air quality information, the Staff Paper concludes that it is appropriate to consider a 24-hour $PM_{10-2.5}$ standard in the range of 50 to 70 μg/m^3, with a 98th percentile form.[74] The lower end of this range is based on a close examination of the air quality patterns related to the limited number of relevant epidemiologic studies. The upper part of this range is based on a more cautious approach to interpreting the available information and reflects a generally ''equivalent'' degree of protection to that afforded by the current PM_{10} standards. The upper end of this range is also below the 98th percentile $PM_{10-2.5}$ concentrations in the two mortality studies that reported statistically significant associations. Consideration of a generally ''equivalent'' $PM_{10-2.5}$ standard would reflect a judgment that while the epidemiologic evidence supports establishing a short-term standard for urban thoracic coarse particles at such a generally ''equivalent'' level, the evidence concerning air quality levels of thoracic coarse particles in the studies is not strong enough to provide a basis for changing the level of protection generally afforded by the current PM_{10} standards.

Based on its review of the Staff Paper, there was general agreement among the CASAC Panel members that the Staff Paper-recommended range of 50 to 70 μg/m^3, with a 98th percentile form, for a 24-hour $PM_{10-2.5}$ standard was reasonably justified. Most CASAC Panel members favored levels at the upper end of that range, while several members supported the lower end of the range (Henderson, 2005b). Because of the significant uncertainties resulting from the limited number of studies to date in which $PM_{10-2.5}$ has been measured and the potentially large exposure measurement errors in such studies, the CASAC Panel did not generally support a level below the Staff Paper-recommended range.

In considering an appropriate level for a 24-hour $PM_{10-2.5}$ standard intended to afford requisite protection of public health from health effects associated with exposure to thoracic coarse particles of concern, the Administrator has carefully considered the rationale and recommendations contained in the Staff Paper, the advice and recommendations of CASAC, and public comments to date on this issue. Taking these considerations into account, the Administrator proposes to set the level of the primary 24-hour $PM_{10-2.5}$ standard at 70 μg/m^3. In the Administrator's provisional judgment, based on the currently available evidence, a standard set at this level would be requisite to protect public health with an adequate margin of safety from the morbidity and possibly mortality effects that have been associated with short-term exposures to thoracic coarse particles of concern. This proposed standard is expected to have the most impact in areas that do not meet the current 24-hour PM_{10} standard.

In reaching this judgment, the Administrator recognizes that the epidemiologic evidence on morbidity and possible mortality effects related to $PM_{10-2.5}$ exposure is very limited at this time, and that there are potentially quite large uncertainties inherent in interpreting the available evidence for $PM_{10-2.5}$ as compared with the evidence related to fine particles. For example, $PM_{10-2.5}$ concentrations can vary substantially across a metropolitan area and thoracic coarse particles are less able to penetrate into buildings than fine particles; thus, the ambient concentrations reported in epidemiologic studies may not well represent area-wide population exposure levels. It may also be difficult to disentangle effects associated with $PM_{10-2.5}$ and $PM_{2.5}$ in epidemiologic studies. Further, the Administrator is mindful that considering what standard is requisite to protect public health with an adequate margin of safety requires judgments that neither overstate nor understate the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. Thus, the Administrator provisionally concludes that the selection of a level that provides generally equivalent protection to that provided by the current PM_{10} standards is an appropriate policy response to the very limited body of evidence that is available at this time. The EPA intends to address the considerable uncertainties in the currently available information on thoracic coarse particles as part of the Agency's ongoing PM research program.

The Administrator also recognizes that there is no one level for a $PM_{10-2.5}$ standard that would be equivalent to the current PM_{10} standards in every area across the country, and that there are likely additional approaches to identifying a generally equivalent standard level beyond those approaches considered in the Staff Paper upon which the proposed level is based. Thus, the Administrator also solicits comment on alternative approaches to identifying a generally ''equivalent'' standard level. While proposing to set the $PM_{10-2.5}$ standard at a level that is generally equivalent to the 1987 PM_{10} standard, the Administrator solicits comment on whether it would be more appropriate to set the $PM_{10-2.5}$ standard at a level that is generally equivalent to the PM_{10} standard set in 1997.

Having decided to propose the 24-hour $PM_{10-2.5}$ standard described above, the Administrator recognizes that there are important views on the information relating to the effects of coarse fraction PM that warrant consideration. For example, an alternative interpretation of the available health evidence presented in the Criteria Document and the Staff Paper questions the conclusions about $PM_{10-2.5}$ associations drawn from one-pollutant models. This interpretation of the available epidemiological evidence suggests that the results from one-pollutant $PM_{10-2.5}$ models are confounded by fine particles and gaseous co-pollutants.

The key $PM_{10-2.5}$ epidemiologic results discussed in the Criteria Document and

[73] As shown in Tables 5B–2(a) and (b) of the Staff Paper, there are 585 counties with PM_{10} monitoring sites used in determining compliance with the PM_{10} standards, whereas only 309 of those counties have monitor sites that would be included in the monitoring network design criteria discussed in section 5.4.2.2 of the Staff Paper. Of these 309 counties, 259 have PM_{10} and $PM_{10-2.5}$ air quality data that meet the data completeness criteria defined for this analysis, which are somewhat less restrictive than the criteria that were applied in the regression analysis described above.

[74] Beyond looking directly at the relevant epidemiologic evidence and related air quality information, the Staff Paper also considers the extent to which the $PM_{10-2.5}$ risk assessment, discussed above in section III.B, can help inform consideration of alternative 24-hour $PM_{10-2.5}$ standards. The Staff Paper concludes that the nature and magnitude of the uncertainties and concerns associated with this portion of the risk assessment weigh against use of these risk estimates as a basis for recommending specific standard levels (EPA, 2005a, p. 5–69).

Staff Paper are drawn from one-pollutant models; i.e., $PM_{10-2.5}$ is the only variable used in the statistical model reflecting exposure to air pollution. There are four studies cited in these documents as being suggestive of a statistically significant role for $PM_{10-2.5}$ in the reported associations: Ito (2003), Burnett et al. (1997), Mar et al. (2003), and Ostro et al. (2003). However, there is strong evidence that adverse health effects similar to those observed in these studies, including both cardiovascular and/or respiratory health effects are associated with exposure to $PM_{2.5}$. The authors of several of these studies focus on fine particles (and in some cases one or more of the gaseous pollutants) as playing an important role in ''explaining'' the association between PM and various health endpoints. For example, in these key epidemiologic studies, the correlation coefficients between $PM_{2.5}$ and $PM_{10-2.5}$ concentrations range from moderate to high (i.e., 0.4 to 0.7), which increases the likelihood that associations between health effects and $PM_{10-2.5}$ identified in one-pollutant models may instead simply reflect the effects of exposure to $PM_{2.5}$ rather than independent health effects. With the positive correlations between pollutants and similar health effects, it generally would be appropriate for any assessment of the effect of exposure to $PM_{10-2.5}$ to control for exposure to the $PM_{2.5}$.

In this light, it is important to review how the authors of the four key $PM_{10-2.5}$ epidemiology studies have accounted for co-pollutants in their analysis. Ito (2003) noted significant estimates of the health effects of associations in one-pollutant models, but in a two-pollutant model with $PM_{2.5}$ the $PM_{10-2.5}$ associations lost statistical significance. Burnett et al. (1997) concluded that the effect of $PM_{10-2.5}$ in a one-pollutant model could be explained by gaseous co-pollutants. Mar et al. (2003) found $PM_{10-2.5}$ to be positively associated with adverse health effects in a one-pollutant model, but also found similar associations with a range of other air pollutants. In addition, Mar et al. (2003) noted that even though all PM mass metrics included in the study were associated with an excess risk of cardiovascular death, the strongest associations were with $PM_{2.5}$, followed by PM_{10} and $PM_{10-2.5}$. Ostro et al. (2003) used a one-pollutant model to estimate the association between $PM_{10-2.5}$ on mortality using an effectively linear construct of PM_{10} (as observed in Indio, CA) to represent $PM_{10-2.5}$ for the entire study area. By using such a construct of PM_{10}, the estimated associations simply reflect a PM_{10} association (i.e., the construct does not provide additional information on the effect of $PM_{10-2.5}$). Moreover, roughly 75 percent of the cardiovascular mortality in this study occurred in or near Palm Springs, CA and PM characteristics differ significantly between Palm Springs and Indio (e.g., average PM_{10} concentrations are roughly 30 percent lower in Palm Springs and $PM_{2.5}$ represents a higher fraction of PM_{10}, with a correlation coefficient between $PM_{2.5}$ and $PM_{10-2.5}$ of 0.46 in Palm Springs). Thus, the Ostro et al. (2003) study suggests a positive association between PM_{10} monitored in Indio and mortality in Palm Springs, but some view this study as offering little basis for attributing significant mortality association to $PM_{10-2.5}$ as observed in either city.

The Criteria Document and Staff Paper also present and discuss other epidemiology studies in support of the proposal for both the $PM_{2.5}$ and $PM_{10-2.5}$ standards (as shown in Figure 2 and discussed in Section III.A above): Burnett (1997), Fairley (2003), Ito (2003), Lipfert et al (2000), Mar et al (2003), Moolgavkar (2000), Sheppard et al (2003), Thurston et al (1994), Burnett (2000, 2003), Klemm and Mason (2003), and Schwartz and Neas (2000). However, these studies report positive, statistically significant associations with $PM_{2.5}$ that are more consistent and robust than the associations thus far identified for $PM_{10-2.5}$. Indeed, several of these and other studies that specifically considered $PM_{10-2.5}$, but did not find statistically significant associations, including Schwartz et al (1996), Thurston et al. (1994), Sheppard et al. (2003), Fairley (2003), Schwartz et al (1996) and Lipfert et al. (2000). With respect to mortality effects in the Six-City study, Schwartz et al. (1996) concluded that the PM associations (in the six metropolitan areas—including Steubenville) were specifically associated with $PM_{2.5}$, with little additional contribution from the $PM_{10-2.5}$. Sheppard et al. (2003) noted that bias in model selection and reporting can result in inflated excess risk estimates for PM. Fairley (1999) noted that $PM_{10-2.5}$ effects become negative and insignificant when modeled jointly with $PM_{2.5}$. Lipfert et al. (2000) showed insignificant effects for $PM_{10-2.5}$ in one- and two-pollutant models with O_3. The authors also caution against drawing causal interpretations from results when comparing health effects from one region in a metropolitan area to air quality observations in another region. In addition, several of these studies also report positive, statistically significant associations with one or more of the gaseous pollutants. Both Thurston et al. (1994) and Burnett et al. (1997) reported substantial confounding with gaseous co-pollutants in Toronto, and Thurston et al. (1994, p. 282) reported that ''it seems clear that these apparent associations were merely a statistical by-product of interpollutant confounding resulting from the shared day-to-day variations in dispersion conditions.'' In addition, Burnett et al. (2000) concluded that gaseous pollutants played an important role in explaining the effect of urban air pollution on health. Similarly, Moolgavkar (2000) concludes that gases were more strongly associated with respiratory effects than PM in Los Angeles.

Taken as a whole, evidence from $PM_{10-2.5}$ epidemiologic studies could be interpreted to suggest that one-pollutant $PM_{10-2.5}$ models suffer from bias due to omitting co-pollutants in the statistical model, especially given the much stronger evidence (discussed above) that these effects are associated with exposure to $PM_{2.5}$. As noted by many of the aforementioned authors, while significant health associations may be noted for coarse fraction PM in one-pollutant models, the actual association may be insignificant from zero due to confounding co-pollutants. Of course, the Administrator must conclude in the final rule that the evidence about the health effects of $PM_{10-2.5}$ is sufficiently robust to finalize a standard for $PM_{10-2.5}$.

The Administrator, recognizing notably large uncertainties in the underlying evidence and information that formed the basis for this proposal as well as the challenges associated with moving toward a new $PM_{10-2.5}$ indicator and a related new monitoring network, solicits comment on this and other alternative interpretations of the available health evidence and alternative policy responses. Several such alternative interpretations and policy responses are discussed below.

(1) In light of the large uncertainties in the evidence and the challenges of moving to a new indicator, and provisionally recognizing the need for a standard to provide a requisite level of protection from the risks associated with thoracic coarse particles, the Administrator also believes it appropriate to consider a policy option that would retain the current 24-hour PM_{10} standard (with a one-expected-exceedance form), while addressing issues such as the appropriateness of the indicator and the level of the standard.

As discussed in section I.D, in response to a challenge to the 1997 standards for thoracic coarse PM, the

U.S. Court of Appeals for the District of Columbia vacated the Agency's 1997 PM_{10} standards. In its decision the Court noted that use of PM_{10} as an indicator to protect against the public health risks associated with thoracic coarse particles resulted in double regulation of $PM_{2.5}$, since this size fraction is both a component of PM_{10} and the subject of its own standard. The Court further reasoned that, since $PM_{2.5}$ concentrations vary from area to area, use of PM_{10} as a thoracic coarse particle indicator results in an arbitrary level of protection in public health from the risks associated with thoracic coarse particles on a national basis, as the level of protection would vary based on the concentration of $PM_{2.5}$ in an area. See *American Trucking Associations* v. *EPA*, 175 F.3d at 1054–55.

Under this option to retain the 24-hour PM_{10} standard, EPA would modify the standard to exclude the double-counted $PM_{2.5}$ contribution in circumstances where this could present a concern. First, there will be some areas that may be in nonattainment with the PM_{10} standard because, and only because, they are in nonattainment with the $PM_{2.5}$ standard. To remedy the double counting in this situation, EPA is requesting comment on subtracting from a daily measured PM_{10} concentration the value by which the concentration of $PM_{2.5}$ measured at a collocated monitor is in excess of 35 $\mu g/m^3$ (i.e., the proposed level for the 24-hour $PM_{2.5}$ standard). This adjustment would need to be made only on days when a 24-hour average PM_{10} concentration is measured in excess of 150 $\mu g/m^3$. In such a case, the amount by which the $PM_{2.5}$ concentration exceeds 35 $\mu g/m^3$ would be subtracted from the measured PM_{10} concentration. The EPA would then use this adjusted value in any comparison to the PM_{10} standard.

The second situation where the overlap between the $PM_{2.5}$ and PM_{10} standards may cause some concern is in areas where a daily $PM_{2.5}$ level is below 35 $\mu g/m^3$. In those areas, the level of the PM_{10} standard would allow a higher concentration of thoracic coarse particles before triggering an exceedance than it would in other areas. The EPA is requesting comment on not requiring any adjustment to the daily measured PM_{10} concentration in this situation, on the basis that any additional risk to public health that may be associated with this higher allowable concentration of thoracic coarse particles would reasonably be expected to present less concern from a public health perspective than would the otherwise allowable equivalent increase in the concentration of $PM_{2.5}$.

The EPA also believes that it would be appropriate in this option to focus the PM_{10} standard in a manner similar to that proposed above for the $PM_{10-2.5}$ standard. While the indicator would remain specified as PM_{10}, the focus would be on including only the mix of ambient thoracic coarse particles that are of concern to public health (and to exclude the mix for which information is not sufficient to infer a public health concern) and would be achieved in practice through the data handling requirements associated with the standard, which are linked to the proposed monitoring network design criteria (in the part 58 rule proposed elsewhere in today's **Federal Register**).

The EPA invites comment on whether this option would provide the requisite level of public health protection from risks associated with thoracic coarse particles. Given the difference in form between the 24-hour PM_{10} standard (one-expected-exceedance form) and the proposed $PM_{10-2.5}$ standard (98th percentile form), and the adjustments noted above, in practice there may not be an appreciable difference in the degree of public health protection afforded by this option relative to that afforded by the proposed $PM_{10-2.5}$ standard. The EPA invites comment on whether this approach addresses one of the concerns about use of a PM_{10} indicator for thoracic coarse particles noted by the Court in its ATA decision, namely that the level of public health protection from thoracic coarse particles in an area would vary depending on the relative proportions of fine and thoracic coarse particles, by recognizing that the PM_{10} indicator and standard would cover both fine and thoracic coarse particles.

With respect to revocation of the 1987 24-hour PM_{10} standard, under this option EPA would apply the same approach to revocation as that proposed below in section III.H. in conjunction with the proposed $PM_{10-2.5}$ standard. Since the 24-hour PM_{10} standard would be focused in basically the same manner as the proposed $PM_{10-2.5}$ standard, it would be appropriate to follow the same approach to revocation of the current 24-hour PM_{10} standard under this option as well.

The EPA solicits comment on all aspects of this approach, including views on whether a 24-hour PM_{10} standard revised as noted above would be requisite to protect public health from the risks associated with thoracic coarse particles, with an adequate margin of safety, as well as views on any legal, scientific, or policy issues associated with this alternative, and including comments on the consistency of this option with CASAC's recommendations. The EPA also solicits comment on whether a 98th percentile form should be considered for a 24-hour PM_{10} standard and on the appropriate level of such a standard.

(2) The Administrator recognizes that some commenters hold the view that the uncertainties that exist at the present time are so great that no standards for thoracic coarse particles are warranted. Some such commenters point to conclusions reached in the Staff Paper in part as a basis for their view, including, for example, the conclusion that the ''substantial uncertainties associated with this limited body of epidemiological evidence on health effects related to $PM_{10-2.5}$ * * * suggests a high degree of caution in interpreting this evidence * * *.'' (EPA 2005, pp. 5–50). This view generally places significant weight on the issue of confounding between $PM_{2.5}$ and $PM_{10-2.5}$ (discussed above in section III.A), with some commenters stating that the correlation coefficients between fine and thoracic coarse particle levels are modest to high for all studies for which such data are available, increasing the possibility that the positive association identified in the $PM_{10-2.5}$ one-pollutant models may instead reflect the effects of fine particles. Noting that the Staff Paper puts little weight on the health risk assessment because of the significant uncertainties in the underlying health studies, some commenters suggest that the risk assessment therefore does not provide a basis for determining whether the health effects possibly associated with $PM_{10-2.5}$ constitute a meaningful public health risk. Some commenters take the view that, based either on the studies or the risk assessment, the magnitude of the health effects possibly associated with $PM_{10-2.5}$ do not constitute a meaningful risk to public health. These commenters also maintain that significant uncertainty remains as to an appropriate level of a standard, even assuming that a meaningful public health risk exists. In consideration of these views, the Administrator also solicits comment on revoking the current 24-hour PM_{10} standard at this time (as well as the current annual PM_{10} standard, as proposed above), not adopting a thoracic coarse particle standard at this time, and taking into account any new relevant research that becomes available as a basis for considering a more targeted standard for thoracic coarse particles in the next periodic review of the PM NAAQS.

(3) In sharp contrast to the views noted above, another view that the Administrator takes note of would place greater weight on the available epidemiologic evidence as a basis for selecting a level down to 50 μg/m^3 or below and/or for selecting an unqualified $PM_{10-2.5}$ indicator. While recognizing that important uncertainties are present in the available evidence, this view would support incorporating a larger margin of safety consistent with a more highly precautionary policy response. In soliciting comments on a wide array of views, the Administrator solicits comment on this view and on standard levels that are consistent with this view.

H. Proposed Decisions on Primary $PM_{10-2.5}$ Standard

For the reasons discussed above, and taking into account the information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, and public comments to date, the Administrator proposes to revise the current primary PM_{10} standards. In particular, to provide more targeted protection from thoracic coarse particles that are of concern to public health, the Administrator proposes to establish a new indicator for thoracic coarse particles in terms of $PM_{10-2.5}$, the definition of which includes qualifications that identify both the mix of such particles that are of concern to public health, and are thus included in the indicator, and those for which currently available information is not sufficient to infer a public health concern, and are thus excluded. More specifically, the proposed $PM_{10-2.5}$ indicator is qualified so as to include any ambient mix of $PM_{10-2.5}$ that is 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. The Administrator proposes to replace the current primary 24-hour PM_{10} standard with a 24-hour standard defined in terms of this new $PM_{10-2.5}$ indicator and set at a level of 70 μg/m^3, which would generally maintain the degree of public health protection afforded by the current PM_{10} standards from short-term exposure to thoracic coarse particles of concern. The proposed new standard would be met at an ambient air quality monitoring site [75] when the 3-year average of the annual 98th percentile 24-hour average $PM_{10-2.5}$ concentration is less than or equal to 70 μg/m^3.[76] The Administrator also proposes to revoke and not replace the annual PM_{10} standard.

In recognition of alternative views of the currently available scientific information and the appropriate policy response to this information, the Administrator also solicits comments on (1) alternative approaches to selecting the level of a 24-hour $PM_{10-2.5}$ standard or to selecting an unqualified $PM_{10-2.5}$ indicator, and (2) alternative approaches to providing continued protection from thoracic coarse particles based on retaining the current 24-hour PM_{10} standard. Alternatively, the Administrator also solicits comment on revoking and not replacing the 24-hour PM_{10} standard. Based on the comments received and the accompanying rationale, the Administrator may adopt other standards within the range of the alternatives identified above in lieu of the standard he is proposing today.

The Administrator is also proposing to revoke the current annual PM_{10} standard upon promulgation of this rule. Further, if EPA finalizes a 24-hour primary $PM_{10-2.5}$ standard, the Administrator is proposing to revoke the current 24-hour PM_{10} standard everywhere except in areas where there is at least one monitor that is located in an urbanized area [77] with a minimum population of 100,000 people and that violates the 24-hour PM_{10} standard based on the most recent three years of data.

EPA specifically proposes that the 24-hour PM_{10} standard would be revoked in this rulemaking in all areas except the following:

1. Birmingham urban area (Jefferson County, AL)
2. Maricopa and Pinal Counties; Phoenix planning area (AZ)
3. Riverside, Los Angeles, Orange and San Bernardino Counties; South Coast Air Basin (CA)
4. Fresno, Kern, Kings, Tulare, San Joaquin, Stanislaus, Maderia Counties; San Joaquin Valley planning area (CA)
5. San Bernardino County (part); excluding Searles Valley Planning Area and South Coast Air Basin (CA)
6. Riverside County; Coachella Valley Planning Area (CA)
7. Simi Valley urban area (CA)
8. Lake County; Cities of East Chicago, Hammond, Whiting, and Gary (IN)
9. Wayne County (part) (MI)
10. St. Louis urban area (MO)
11. Albuquerque urban area (NM)
12. Clark County; Las Vegas planning area (NV)
13. Columbia urban area (SC)
14. El Paso urban area (including those portions in TX and those portions in NM)
15. Salt Lake County (UT)

A separate memorandum explaining the factual basis for our proposed determinations regarding each PM_{10} area where we are proposing to retain the current 24-hour standard is part of the administrative record for this proposed rule (Rosendahl, 2005).

In essence, we are proposing to retain the current 24-hour PM_{10} standard only in areas which could be in violation of the proposed $PM_{10-2.5}$ standard. While it is possible that some existing PM_{10} monitors may not be sited in accordance with all of the criteria for $PM_{10-2.5}$ monitor siting proposed elsewhere in today's **Federal Register** (see section IV.E.2.b.ii of the preamble to the proposed changes to Part 53/58), it is not possible for EPA to make a case-by-case assessment of monitor placement within each area at this time. Therefore, EPA believes that all areas with violating PM_{10} monitors located in urbanized areas with a minimum population of 100,000 people should be considered areas that may violate the $PM_{10-2.5}$ standard.

For those areas where we propose to retain the 24-hour PM_{10} standard which were previously designated nonattainment for PM_{10} or which are currently designated nonattainment for PM_{10}, EPA proposes, in the alternative, either that the standard would continue to apply in the entire attainment/nonattainment area, or that the area to which the standard would continue to apply should be limited to the urbanized area containing the violating monitor(s). For areas with violating monitor(s) which were never designated nonattainment, EPA proposes that the boundaries of the area to which the standard would continue to apply should be limited to the urbanized area containing the violating monitor(s). For

[75] Monitoring sites that are appropriate for determining compliance with this standard are those that are consistent with the proposed indicator. Guidance on this can be found in the proposed monitoring network design criteria published elsewhere in today's **Federal Register**.

[76] Data handling conventions are specified in a new proposed Appendix P, as discussed in Section V below, and the reference method for monitoring PM as $PM_{10-2.5}$ is specified in a new proposed Appendix L, as discussed in Section VI below.

[77] As defined by the U.S. Bureau of the Census, an urbanized area has ''a minimum residential population of at least 50,000 people'' and generally includes ''core census block groups or blocks that have a population density of at least 1,000 people per square mile and surrounding census blocks that have an overall density of at least 500 people per square mile.'' The Census Bureau notes that ''under certain conditions, less densely settled territory may be part of each UA.'' See *http://www.census.gov/geo/www/ua/ua_2k.html.*

all areas in which the 24-hour PM_{10} standard would be retained, EPA invites comments on the appropriate boundaries within which the standard should continue to apply.

Consistent with our request for comment in the Part 53/58 proposal, section IV.E.2.b.ii, on whether we should establish criteria for locating discretionary monitors appropriate for comparison with the proposed 24-hour $PM_{10-2.5}$ standard in locations other than urbanized areas with population of at least 100,000 people, we also request comment on whether the 24-hour PM_{10} standard should be retained in areas that are either urbanized areas with a population less than 100,000 people or non-urbanized areas (*i.e.* population less than 50,000) but where the majority of the ambient mix of $PM_{10-2.5}$ is generated by high density traffic on paved roads, industrial sources, and construction activities, and which have at least one monitor that violates the 24-hour PM_{10} standard. The EPA requests comment on the criteria that should be used to determine whether such an area with a violating monitor must retain the 24-hour PM_{10} standard. Such criteria could include whether the area has one (or more) industrial source(s) listed in either the National Emissions Inventory or the Toxics Release Inventory located within a certain radius of the violating monitor, and whether these sources are in industrial categories that do not include agricultural or mining sources. One approach to defining such categories would be to utilize the U.S. Census Bureau's North American Industry Classification System,[78] which defines separate classifications for agricultural and mining activities such as Crop Production (111), Animal Production (112), and Mining (112). The EPA requests comments on how this or another classification system, combined with information on the location of sources relative to the violating PM_{10} monitor, could be used to identify additional areas to which the 24-hour PM_{10} standard should continue to apply due to the presence of industrial sources. The EPA also requests comments on which areas would meet these criteria or other criteria that may be appropriate to determine in which, if any, areas the 24-hour PM_{10} standard should be retained, and the appropriate boundaries within which the standard should continue to apply for these areas. A more detailed example of criteria that could be used to identify areas to which the standard should continue to apply, along with a list of all areas with violating PM_{10} monitors that meet these criteria, are part of the administrative record for this proposed rule (Rosendahl, 2005). For all areas where the 24-hour PM_{10} standard would be retained under this proposal, we contemplate that the 24-hour PM_{10} standard would be revoked after designations are completed under a final 24-hour $PM_{10-2.5}$ standard.

The EPA also recognizes that it is possible that some areas for which we are proposing to retain the PM_{10} daily standard would, upon a case-specific investigation (see section IV.E.2.c of the Part 53/58 preamble), warrant revocation as not being an area where the ambient coarse PM mix is dominated by the type of coarse PM described by the proposed indicator. The EPA is not in a position to conduct such case-by-case evaluation for this proposal, but could address revocation in such situations in a future rulemaking. The EPA invites comment on this issue.

To address issues related to the transition from the current PM_{10} standards to a new $PM_{10-2.5}$ standard, the Administrator intends to seek public comment on EPA's plans for assuring an effective transition as part of an ANPR that EPA intends to issue by the end of January 2006. In the forthcoming ANPR dealing with transition issues, EPA intends to address, among other things, the timing for revocation of the PM_{10} standard in areas in which we are proposing to retain that standard, and the consequences of revoking the PM_{10} standards on the PM_{10} PSD program (including PM_{10} increments), on the PM_{10} nonattainment New Source Review (NSR) program, and on our existing policy of using PM_{10} as a surrogate for the $PM_{2.5}$ NSR program.

IV. Rationale for Proposed Decisions on Secondary PM Standards

The Criteria Document and Staff Paper examined the effects of PM on such aspects of public welfare as visibility, vegetation and ecosystems, materials damage and soiling, and climate change. The existing suite of secondary PM standards, which is identical to the suite of primary PM standards, includes annual and 24-hour $PM_{2.5}$ standards and annual and 24-hour PM_{10} standards. This existing suite of secondary standards is intended to address visibility impairment associated with fine particles and materials damage and soiling related to both fine and coarse particles. The following discussion of the rationale for the proposed decisions on secondary PM standards focuses on those considerations most influential in the Administrator's proposed decisions, first addressing visibility impairment followed by the other welfare effects considered in this review.[79]

A. Visibility Impairment

This section presents the rationale for the Administrator's proposed revision of the current secondary $PM_{2.5}$ standard to address PM-related visibility impairment. As discussed below, the rationale includes consideration of: (1) The latest scientific information on visibility effects associated with PM; (2) insights gained from assessments of correlations between ambient $PM_{2.5}$ and visibility impairment prepared by EPA staff; 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.

1. Visibility Impairment Related to Ambient PM

This section outlines key information contained in the Criteria Document and Staff Paper on: (1) The nature of visibility impairment, including trends in visual air quality and the characterization of current visibility conditions; (2) quantitative relationships between ambient PM and visibility; (3) the impacts of visibility impairment on public welfare; and (4) approaches to evaluating public perceptions and attitudes about visibility impairment.

a. Nature of Visibility Impairment

Visibility can be defined as the degree to which the atmosphere is transparent to visible light. Visibility conditions are determined by the scattering and absorption of light by particles and gases, from both natural and anthropogenic sources. Visibility is often described in terms of visual range, light extinction, or deciviews.[80] The classes of fine particles principally responsible for visibility impairment are sulfates, nitrates, organic matter, elemental carbon, and soil dust. Fine

[78] *http://www.census.gov/epcd/naics02/naicod02.htm#N21.*

[79] As noted in section I.A above, in establishing secondary standards that are requisite to protect the public welfare from any known or anticipated adverse effects, EPA may not consider the costs of implementing the standards.

[80] Visual range can be defined as the maximum distance at which one can identify a black object against the horizon sky. It is typically described in kilometers or miles. Light extinction is the sum of light scattering and absorption by particles and gases in the atmosphere. It is typically expressed in terms of inverse megameters (Mm^{-1}), with larger values representing poorer visibility. The deciview metric describes perceived visual changes in a linear fashion over its entire range, analogous to the decibel scale for sound.

particles are more efficient per unit mass at scattering light than coarse particles. The scattering efficiency of certain classes of fine particles, such as sulfates, nitrates, and some organics, increases as relative humidity rises because these particles can absorb water and grow to sizes comparable to the wavelength of visible light. In addition to limiting the distance that one can see, the scattering and absorption of light caused by air pollution can also degrade the color, clarity, and contrast of scenes.

Visibility impairment is manifested in two principal ways: As local visibility impairment and as regional haze. Local visibility impairment may take the form of a localized plume, a band or layer of discoloration appearing well above the terrain that results from complex local meteorological conditions. Alternatively, local visibility impairment may manifest as an urban haze, sometimes referred to as a ''brown cloud.'' A ''brown cloud'' is predominantly caused by emissions from multiple sources in the urban area and is not typically attributable to a single nearby source or to long-range transport from more distant sources. The second type of visibility impairment, regional haze, generally results from pollutant emissions from a multitude of sources located across a broad geographic region. Regional haze impairs visibility in every direction over a large area, in some cases over multi-state regions. It is regional haze that is principally responsible for impairment in national parks and wilderness areas across the country (NRC, 1993).

While visibility impairment in urban areas at times may be dominated by local sources, it often may be significantly affected by long-range transport of haze due to the multi-day residence times of fine particles in the atmosphere. Fine particles transported from urban and industrialized areas, in turn, may, in some cases, be significant contributors to regional-scale impairment in Class I areas [81] and other rural areas.

As discussed in the Staff Paper (EPA, 2004, section 6.2), in Class I areas, visibility levels on the 20 percent haziest days in the West are about equal to levels on the 20 percent best days in the East. Despite improvement through the 1990's, visibility in the rural East remains significantly impaired, with an average visual range of approximately 20 km on the 20 percent haziest days (compared to the naturally occurring visual range in the eastern U.S. of about 150 ± 45 km). In the rural West, the average visual range showed little change over this period, with an average visual range of approximately 100 km on the 20 percent haziest days (compared to the naturally occurring visual range in the western U.S. of about 230 ± 40 km).

In urban areas, visibility levels show far less difference between eastern and western regions. For example, the average visual ranges on the 20 percent haziest days in eastern and western urban areas are approximately 20 km and 27 km, respectively (Schmidt et al., 2005). Even more similarity is seen in considering 4-hour (12 to 4 p.m.) average $PM_{2.5}$ concentrations, for which the average visual ranges on the 20 percent haziest days in eastern and western urban areas are approximately 26 km and 31 km, respectively (Schmidt et al., 2005).

Data on visibility conditions indicate that urban areas generally have higher loadings of $PM_{2.5}$ and, thus, higher visibility impairment than monitored Class I areas. Since efforts are now underway to address all human-caused visibility in Class I areas through the regional haze program (EPA, 1999; 65 FR 35713), implemented under sections 169A and 169B of the CAA, and since the Clean Air Interstate Rule (CAIR) (70 FR 25162) is expected to result in improvements to visual air quality, particularly in eastern Class I and non-urban areas, new assessments included in the Staff Paper were primarily focused on visibility impairment in urban areas.

b. Correlations Between Urban Visibility and $PM_{2.5}$ Mass

Direct relationships exist between measured ambient pollutant concentrations and their contributions to light extinction and thus to visibility impairment. The contribution of each PM constituent to total light extinction is derived by multiplying the constituent concentration by its extinction efficiency to calculate a ''reconstructed'' light extinction.[82] For certain fine particle constituents, extinction efficiencies increase significantly with increases in relative humidity. As a consequence, while higher $PM_{2.5}$ mass concentrations generally indicate higher levels of visibility impairment, it is not as precise a metric as the light extinction coefficient. Nonetheless, by using historic averages, regional estimates, or actual day-specific measurements of the component-specific percentage of total mass, one can develop reasonable estimates of light extinction from PM mass concentrations. As discussed below, the Staff Paper concludes that fine particle mass concentrations can be used as a general surrogate for visibility impairment (EPA, 2005a, p. 2–74).

In an effort to better characterize urban visibility, the Staff Paper presents results of analyses of the extensive new data now available on $PM_{2.5}$ primarily in urban areas. This rapidly expanding national database includes federal reference method (FRM) [83] measurements of $PM_{2.5}$ mass, continuous measurements of hourly $PM_{2.5}$ mass, and $PM_{2.5}$ chemical speciation measurements. These data allowed for analyses that explored factors that have historically complicated efforts to address visibility impairment nationally, including regional differences related to levels of primarily fine particles and to relative humidity. These analyses show a consistently high correlation between visibility, in terms of reconstructed light extinction, and hourly $PM_{2.5}$ concentrations for urban areas in a number of regions across the U.S. and, more generally, in the eastern and western U.S. These correlations in urban areas are generally similar in the East and West, in sharp contrast to the East/West differences observed in rural areas.

While the average daily relative humidity levels are generally higher in the East than in the West, in both regions relative humidity levels are appreciably lower during daylight as compared to night time hours. The reconstructed light extinction coefficient, for a given mass and concentration, increases sharply as relative humidity rises. Thus, with lower relative humidity levels, visibility impacts related to East/West differences in average relative humidity are minimized during daylight hours, when relative humidity is generally lower.

Both 24-hour and shorter-term daylight hour averaging periods were

[81] There are 156 mandatory Class I Federal areas protected by the visibility provisions in sections 169A and 169B of the Act. These areas are defined in section 163 of the Act as those national parks exceeding 6000 acres, wilderness areas and memorial parks exceeding 5000 acres, and all international parks which were in existence on August 7, 1977.

[82] Extinction efficiencies vary by type of constituent and have been obtained for typical atmospheric aerosols by a combination of empirical approaches and theoretical calculations. As discussed in the Staff Paper, EPA's guidance for tracking progress under the regional haze program specifies an algorithm for calculating total light extinction as a function of the major fine particle components (EPA, 2005a, section 2.8.1). ''Reconstructed'' light extinction simply refers to the calculation of PM-related light extinction by the use of that formula.

[83] The $PM_{2.5}$ Federal Reference Method (FRM) monitoring network provides 24-hour average $PM_{2.5}$ concentrations.

considered in evaluations of correlations between $PM_{2.5}$ concentrations in urban areas and visibility in eastern and western areas, as well as nationwide. Clear and similarly strong correlations are found between visibility and 24-hour average $PM_{2.5}$ in eastern, western, and all urban areas (EPA, 2005a, Figure 6–3). Somewhat stronger correlations are observed between visibility and $PM_{2.5}$ concentrations averaged over a 4-hour time period (EPA, 2005a, Figure 6–5). The correlations between visibility and $PM_{2.5}$ concentrations during daylight hours in urban areas are relatively more reflective of $PM_{2.5}$ mass rather than relative humidity effects, in comparison to correlations based on a 24-hour averaging time.

c. Impacts of Urban Visibility Impairment on Public Welfare

EPA has long recognized that impairment of visibility is an important effect of PM on public welfare, and that it is experienced throughout the U.S. in urban areas as well as in remote Class I areas (62 FR 38680). Visibility is an important welfare effect because it has direct significance to people's enjoyment of daily activities in all parts of the country. Individuals value good visibility for the sense of well-being it provides them directly, both in places where they live and work, and in places where they enjoy recreational opportunities.

Survey research on public awareness of visual air quality using direct questioning typically reveals that 80 percent or more of the respondents are aware of poor visual air quality (Cohen et al., 1986). The importance of visual air quality to public welfare across the country has been demonstrated by a number of studies designed to quantify the benefits (or willingness to pay) associated with potential improvements in visibility (Chestnut and Dennis, 1997; Chestnut and Rowe, 1991). Economists have performed many studies in an attempt to quantify the economic benefits associated with improvements in current visibility conditions both in national parks and in urban areas (Chestnut and Dennis, 1997). These economic benefits may include the value of improved aesthetics during daily activities (e.g., driving or walking, daily recreations), for special activities (e.g., visiting parks and scenic vistas, hiking, hunting), and for viewing scenic photography. They may also include the value of improved road and air safety, and/or preservation of the resource for its own sake. As discussed in the Staff Paper and below, the value placed on protecting visual air quality is further demonstrated by the existence of a number of programs, goals, standards, and planning efforts that have been established in the U.S. and abroad to address visibility concerns in urban and non-urban areas.

Protection against visibility impairment in special areas is provided for in sections 169A, 169B, and 165 of the CAA, in addition to that provided by the secondary NAAQS. Section 169A, added by the 1977 CAA Amendments, established a national visibility goal to ''remedy existing impairment and prevent future impairment'' in 156 national parks and wilderness areas (Class I areas). The Amendments also called for EPA to issue regulations requiring States to develop long-term strategies to make ''reasonable progress'' toward the national goal. EPA issued initial regulations in 1980 focusing on visibility problems that could be linked to a single source or small group of sources. The 1990 CAA Amendments placed additional emphasis on regional haze issues through the addition of section 169B. In accordance with this section, EPA established the Grand Canyon Visibility Transport Commission (GCVTC) in 1991 to address adverse visibility impacts on 16 Class I national parks and wilderness areas on the Colorado Plateau. The GCVTC issued its recommendations to EPA in 1996, triggering a requirement in section 169B for EPA issuance of regional haze regulations.

EPA accordingly promulgated a final regional haze rule in 1999 (U.S. EPA, 1999; 65 FR 35713). Under the regional haze program, States are required to establish goals for improving visibility on the 20 percent most impaired days in each Class I area, and for allowing no degradation on the 20 percent least impaired days. Each state must also adopt emission reduction strategies which, in combination with the strategies of contributing States, assure that Class I area visibility improvement goals are met. The first State implementation plans are to be adopted in the 2003–2008 time period, with the first implementation period extending until 2018. Five multi-state planning organizations are evaluating the sources of $PM_{2.5}$ contributing to Class I area visibility impairment to lay the technical foundation for developing strategies, coordinated among many States, in order to make reasonable progress in Class I areas across the country.

A number of other programs, goals, standards, and planning efforts have also been established in the U.S. and abroad to address visibility concerns in urban and non-urban areas. These regulatory and planning activities are of interest because they are illustrative of the significant value that the public places on improving visibility, and because they have developed and applied methods for evaluating public perceptions and judgments about the acceptability of varying degrees of visibility impairment, as discussed below in the next section.

Several state and local governments have developed programs to improve visual air quality in specific urban areas, including Denver, CO; Phoenix, AZ; and, Lake Tahoe, CA. At least two States have established statewide standards to protect visibility. In addition, interest in visibility protection in other countries, including Canada, Australia, and New Zealand has resulted in various studies, surveys, and programs. Examples of these efforts are highlighted below.

In 1990, the State of Colorado adopted a visibility standard for the city of Denver. The Denver standard is a short-term standard that establishes a limit of a four-hour average light extinction level of 76 Mm^{-1} (equivalent to a visual range of approximately 50 km) during the hours between 8 a.m. and 4 p.m. (Ely et al., 1991). In 2003, the Arizona Department of Environmental Quality created the Phoenix Region Visibility Index, which focuses on an averaging time of 4 hours during actual daylight hours. This visibility index establishes visual air quality categories (i.e., excellent to very poor) and establishes the goals of moving days in the poor/very poor categories up to the fair category, and moving days in the fair category up to the good/excellent categories (Arizona Department of Environmental Quality, 2003). This approach results in a focus on improving visibility to a visual range of approximately 48–36 km. In 1989, the state of California revised the visibility standard for the Lake Tahoe Air Basin and established an 8-hour visibility standard equal to a visual range of 30 miles (approximately 48 km) (California Code of Regulations).

California and Vermont each have standards to protect visibility, though they are based on different measures. Since 1959, the state of California has had an air quality standard for particle pollution where the ''adverse'' level was defined as the ''level at which there will be * * * reduction in visibility or similar effects.'' California's general statewide visibility standard is a visual range of 10 miles (approximately 16 km) (California Code of Regulations). In 1985, Vermont established a state visibility standard that is expressed as a summer seasonal sulfate concentration of 2 $\mu g/m^3$, that equates to a visual range

of approximately 50 km. This standard was established to represent ''reasonable progress'' toward attaining the congressional visibility goal for the Class 1 Lye Brook National Wilderness Area, and applies to this Class 1 area and to all other areas of the state with elevations greater than 2500 ft.

Outside of the U.S., efforts have also been made to protect visibility. The Australian state of Victoria has established a visibility objective (State Government of Victoria, 1999 and 2000), and a visibility guideline is under consideration in New Zealand (New Zealand National Institute of Water & Atmospheric Research, 2000a and 2000b; New Zealand Ministry of Environment, 2000). A survey was undertaken for the Lower Fraser Valley in British Columbia, with responses from this pilot study being supportive of a standard in terms of a visual range of approximately 40 km for the suburban township of Chilliwack and 60 km for the suburban township of Abbotsford, although no visibility standard has been adopted for the Lower Fraser Valley at this time.

d. Approaches to Evaluating Public Perceptions and Attitudes

New methods and tools have been developed to communicate and evaluate public perceptions of varying visual effects associated with alternative levels of visibility impairment relative to varying pollution levels and environmental conditions. New survey methods have been applied and evaluated in various studies, such as those done in Denver, Phoenix, and the Lower Fraser Valley in British Columbia. These methods are intended to assess public perceptions as to the acceptability of varying levels of visual air quality, considered in these studies to be an appropriate basis for developing goals and standards for visibility protection. A pilot study was also conducted in Washington, DC by EPA staff.[84] Even with variations in each study's approaches, the public perception survey methods used for the Denver, Phoenix, and British Columbia studies produced reasonably consistent results from location to location, with each study indicating that a majority of participants find visual ranges within about 40 to 60 km to be acceptable.

These public perception studies use images of urban and distant scenic views under different visibility conditions together with survey techniques designed to elicit judgments from members of the public about the acceptability of differing levels of visual air quality. Images used are either photographs or computer simulations using the WinHaze program.[85] Examples of images that illustrate visual air quality in Denver, Phoenix, Washington, DC, and Chicago under a range of visibility conditions associated with a range of $PM_{2.5}$ concentrations are available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_sp.html* (labeled as Appendix 6A: Images of Visual Air Quality in Selected Urban Areas in the U.S.). These examples include simulated images for Denver, Phoenix, and Washington, DC, and photographs of Chicago.

Survey techniques were developed in conjunction with the Denver study and relied on citizen judgments of acceptable and unacceptable levels of visual air quality (Ely et al., 1991; EPA, 2005a, section 6.2.6.2). The studies in Phoenix and British Columbia, and the pilot study in Washington, DC used survey approaches based on that used in Denver. This approach involves conducting a series of meetings with civic and community groups to elicit individual ratings of a number of images of well-known local vistas having varying levels of visual air quality. Participants are told that the results are intended to provide input on setting a visibility standard, and they are asked to base their judgments on three factors: (1) The standard is for an urban area, not a pristine national park area where the standards might be more strict; (2) standard violations should be at visual air quality levels considered to be unreasonable, objectionable, and unacceptable visually; and (3) judgments of standard violations should be based on visual air quality only, not on any health effects that some may perceive as being linked with poor visual air quality. The Denver visibility survey process produced the following findings: (1) Individuals' judgments of an images's visual air quality and whether the image should be considered to violate a visibility standard are highly correlated with the group average; (2) when participants judged duplicate slides, group averages of the first and second ratings were highly correlated; and (3) group averages of visual air quality ratings and ''standard violations'' were highly correlated. The strong relationship of standard violation judgments with the visual air quality ratings is cited as the best evidence available from this study for the validity of this approach as input to a standard setting process (Ely et al., 1991).

The Denver visibility standard was established based on a 50 percent acceptability criterion. That is, under this approach, the standard was identified as the light extinction level that divides the images into two groups: those found to be acceptable and those found to be unacceptable by a majority of study participants. In fact, when researchers evaluated all citizen judgments made on all the photographic images at this level and above as a single group, more than 85 percent of the participants found visibility impairment at and above the level of the selected standard to be unacceptable.

Generally consistent results were found in the Phoenix study, which used simulated images from the WinHaze program. The study carefully selected participants to be demographically representative of the Phoenix population. The Phoenix survey demonstrates that the rating methodology developed for gathering citizen input for establishing the Denver visibility standard can be reliably transferred to another city while relying on updated imaging technology to simulate a range of visibility impairment levels. Similarly, the British Columbia study reinforces the conclusion that the methodology originally developed for the Denver standard setting process is a sound and effective one for obtaining public participation in a standard setting process (EPA, 2005a, p. 6–22).

2. Need for Revision of the Current Secondary PM Standards for Visibility Protection

The initial issue to be addressed in the current review of the secondary PM standards is whether, in view of the information now available, the existing secondary standards should be revised to provide requisite protection from PM-related adverse effects on visual air quality. As discussed in the Criteria Document and Staff Paper, while new research has led to improved understanding of the optical properties of particles and the effects of relative humidity on those properties, it has not changed the fundamental characterization of the role of PM, especially fine particles, in visibility impairment from the last review. However, extensive new information

[84] This small pilot study was briefly discussed in the preliminary draft staff paper (Abt Associates, 2001).

[85] The Criteria Document discusses methods available to represent different levels of visual air quality (EPA, 2004, p. 4–174). In particular, Molenar et al. (1994) describe a sophisticated visual air quality simulation technique, incorporated into the WinHaze program developed by Air Resources Specialists, Inc., which combined various modeling systems under development for the past 20 years to produce images that standardize non-pollution related effects on visibility so that perceptions of these images are not biased due to these other factors.

now available from visibility and fine particle monitoring networks has allowed for updated characterizations of visibility trends and current levels in urban areas, as well as Class I areas. As discussed above, these new data are a critical component of analyses that better characterize visibility impairment in urban areas and the relationships between visibility and $PM_{2.5}$ concentrations, finding that $PM_{2.5}$ concentrations can be used as a general surrogate for visibility impairment in urban areas.

Taking into account the most recent monitoring information and analyses, and recognizing that efforts are now underway to address all human-caused visibility impairment in Class I areas through the regional haze program implemented under sections 169A and 169B of the CAA, as discussed above, this review focuses on visibility impairment primarily in urban areas. In so doing, consideration is first given to the question of whether visibility impairment in urban areas allowed by the current 24-hour secondary $PM_{2.5}$ standard can be considered adverse to public welfare.

As discussed above, studies in the U.S. and abroad have provided the basis for the establishment of standards and programs to address specific visibility concerns in a number of local areas. These studies (e.g., in Denver, Phoenix, British Columbia) have produced reasonably consistent results in terms of the visual ranges found to be generally acceptable by the participants in the various studies, which ranged from approximately 40 to 60 km in visual range. Standards targeting protection within this range have also been set by the State of Vermont and by California for the Lake Tahoe area, in contrast to the statewide California standard that targets a visual range of approximately 16 km.

In addition to the information available from such programs, photographic representations (simulated images and actual photographs) of visibility impairment are available, as discussed above, to help inform judgments about the acceptability of varying levels of visual air quality in urban areas across the U.S. In considering these images for Phoenix, Washington, DC, and Chicago (for which $PM_{2.5}$ concentrations are reported), the Staff Paper observes that:

(1) At concentrations at or near the level of the current 24-hour $PM_{2.5}$ standard (65 $\mu g/m^3$), which equates to visual ranges roughly around 10 km, scenic views (e.g., mountains, historic monuments), as depicted in these images around and within the urban areas, are significantly obscured from view.

(2) Appreciable improvement in the visual clarity of the scenic views depicted in these images occurs at $PM_{2.5}$ concentrations below 35 to 40 $\mu g/m^3$, which equate to visual ranges generally above 20 km for the urban areas considered (EPA, 2005a, p. 7–6).

(3) Visual air quality appears to be good in these images at $PM_{2.5}$ concentrations generally below 20 $\mu g/m^3$, corresponding to visual ranges of approximately 25 to 35 km (EPA, 2005a, p. 7–8).

While being mindful of the limitations in using visual representations from a small number of areas as a basis for considering national visibility-based secondary standards, the Staff Paper nonetheless concludes that these observations, together with information from the analyses and other programs discussed above, support revising the current secondary $PM_{2.5}$ standards to improve visual air quality, particularly in urban areas. As discussed in the following sections, the Staff Paper recommends the establishment of a new short-term secondary $PM_{2.5}$ standard to provide increased and more targeted protection primarily in urban areas from visibility impairment related to fine particles (EPA, 2005a, p. 7–12). Based on its review of the Staff Paper, the CASAC advised the Administrator that most CASAC PM Panel members strongly supported the Staff Paper recommendation to establish a new, secondary $PM_{2.5}$ standard to protect urban visibility (Henderson, 2005a).[86] Most Panel members considered such a standard to be a reasonable complement to the Regional Haze Rules that protect Class I areas.

In considering whether the secondary PM standards should be revised to target PM-related visibility impairment primarily in urban areas, the Administrator has carefully considered the rationale and recommendation in the Staff Paper, the advice and recommendations from CASAC, and public comments to date on this issue. In so doing, the Administrator first recognizes that PM-related visibility impairment is principally related to fine particle levels, such that it is appropriate to focus in this review on the current secondary $PM_{2.5}$ standards to provide such targeted protection. The Administrator also recognizes that visibility is most directly related to instantaneous levels of visual air quality, such that it is appropriate to focus on a standard with a short-term averaging time (e.g., 24-hours or less). Thus, the Administrator has considered whether the current 24-hour secondary $PM_{2.5}$ standard should be revised to provide a requisite level of protection from visibility impairment, principally in urban areas, in conjunction with the regional haze program for protection of visual air quality in Class I areas. The Administrator observes that at concentrations at or near the level of the current 24-hour $PM_{2.5}$ standard (65 $\mu g/m^3$), corresponding to visual ranges of about 10 km, images of scenic views (e.g., mountains, historic monuments, urban skylines) around and within a number of urban areas are significantly obscured from view. Further, the Administrator notes the various State and local standards and programs that have been established protect visual air quality beyond the degree of protection that would be afforded by the current 24-hour secondary $PM_{2.5}$ standard. Based on all of the above considerations, the Administrator provisionally concludes that it is appropriate to revise the current 24-hour secondary $PM_{2.5}$ standard to provide requisite protection from visibility impairment principally in urban areas.

3. Indicator of PM for Secondary Standard To Address Visibility Impairment

As discussed in the Staff Paper, fine particles contribute to visibility impairment directly in proportion to their concentration in the ambient air. 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. In analyzing how well $PM_{2.5}$ concentrations correlate with visibility in urban locations across the U.S. (see EPA, 2005a, section 6.2.3), the Staff Paper concludes that the observed correlations are strong enough to support the use of $PM_{2.5}$ as the indicator for such standards. More specifically, clear correlations exist between 24-hour average $PM_{2.5}$ concentrations and reconstructed light extinction, which is directly related to visual range. These correlations are similar in the eastern and western regions of the U.S.. Further, these correlations are less influenced by relative humidity and more consistent across regions when $PM_{2.5}$ concentrations are averaged over shorter, daylight time periods (e.g., 4 to

[86] A dissenting view was expressed in one Panel member's invididual review comments to the effect that any urban visibility standard should be voluntary and locally adopted (Henderson, 2005a).

8 hours). Thus, the Staff Paper concludes that it is 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 of daylight hours. Based on its review of the Staff Paper, most CASAC PM Panel members endorsed a $PM_{2.5}$ indicator for a secondary standard to address visibility impairment.

The Administrator concurs with the EPA staff and CASAC recommendations, and concludes that $PM_{2.5}$ should be retained as the indicator for fine particles as part of a secondary standard to address visibility protection. In the Administrator's view, $PM_{2.5}$ is the appropriate indicator for any such standard, whether averaged over 24-hours or over a shorter, sub-daily time period.

4. Averaging Time of a Secondary $PM_{2.5}$ Standard for Visibility Protection

As discussed in the Staff Paper, averaging times from 24 to 4 hours have been considered for a standard to address visibility impairment. Within this range, as noted above, clear and similarly strong correlations are found between visibility and 24-hour average $PM_{2.5}$ concentrations in eastern and western areas, while somewhat stronger correlations are found with $PM_{2.5}$ concentrations averaged over a 4-hour time period. In general, correlations between $PM_{2.5}$ concentrations and light extinction are generally less influenced by relative humidity and more consistent across regions as shorter, sub-daily averaging times, within daylight hours from approximately 10 a.m. to 6 p.m., are considered. The Staff Paper concludes that an averaging time from 4 to 8 hours, generally within this daylight time period, should be considered for a standard to address visibility impairment.

In reaching this conclusion, the Staff Paper recognizes that the $PM_{2.5}$ Federal Reference Method (FRM) monitoring network provides 24-hour average concentrations, and, in some cases, on a third- or sixth-day sample schedule, such that implementing a standard with a less-than-24-hour averaging time would necessitate the use of continuous monitors that can provide hourly time resolution. Given that the data used in the analysis discussed above are from commercially available $PM_{2.5}$ continuous monitors, such monitors clearly could provide the hourly data that would be needed for comparison with a potential visibility standard with a less-than-24-hour averaging time.[87]

Most CASAC PM Panel members supported the Staff Paper recommendation of a sub-daily (4 to 8 daylight hours) averaging time, finding it to be an innovative approach that strengthens the quality of the $PM_{2.5}$ indicator by targeting the driest part of the day (Henderson, 2005a). In its advice to the Administrator, CASAC noted an indirect but important benefit to advancing EPA's monitoring program goals that would come from the direct use of hourly data from a network of continuous $PM_{2.5}$ mass monitors.

In considering the Staff Paper recommendation and CASAC's advice, the Administrator provisionally concludes that averaging times from 24 hours to 4 daylight hours would represent a reasonable range of choices for a standard to address urban visibility impairment. A 24-hour averaging time could be selected and applied based on the extensive data base currently available from the existing $PM_{2.5}$ FRM monitoring network, whereas a sub-daily averaging time would necessarily depend upon an expanded network of continuous $PM_{2.5}$ mass monitors. While the Administrator agrees that broader deployment of continuous $PM_{2.5}$ mass monitors is a desirable goal, working toward that goal does not depend upon nor provide a basis for setting a sub-daily standard. The Administrator believes that it is appropriate to evaluate averaging time in conjunction with reaching decisions on the form and level of a standard, as discussed below.

5. Elements of a Secondary $PM_{2.5}$ Standard for Visibility Protection

In considering $PM_{2.5}$ standards that would provide requisite protection against PM-related impairment of visibility primarily in urban areas, the Administrator has taken into account the results of public perception and attitude surveys 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 provide 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. In considering alternative forms for such standards, the Administrator has also taken into account the same general factors that were considered in selecting an appropriate form for the 24-hour primary $PM_{2.5}$ standard, as well as additional information on the percent of areas not likely to meet various alternative $PM_{2.5}$ standards, consistent with CASAC advice to consider such information (Henderson, 2005a).

In considering elements of a secondary $PM_{2.5}$ standard, the Administrator has looked to the rationale presented in the Staff Paper and to CASAC's advice and recommendations for such a standard. Based on photographic representations of varying levels of visual air quality, public perception studies, and local and State visibility standards, as discussed above, the Staff Paper concludes that 30 to 20 $\mu g/m^3$ $PM_{2.5}$ represents a reasonable range for a national visibility standard primarily for urban areas, based on a sub-daily averaging time. The upper end of this range is below the levels at which the illustrative scenic views are significantly obscured, and the lower end is around the level at which visual air quality generally appears to be good based on observation of the illustrative views. Analyses of 4-hour average $PM_{2.5}$ concentrations indicate that this concentration range can be expected generally to correspond to median visual ranges in urban areas within regions across the U.S. of approximately 25 to 35 km (see EPA, 2005a, Figure 7–1).[88] This range of visual range values is 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 Staff Paper concludes that a concentration-based percentile form is appropriate for the same reasons as discussed above in section II.F.1 (on the form of the 24-hour primary $PM_{2.5}$ standard). The Staff Paper also concludes that the upper end of the range of concentration percentiles should be consistent with the percentile used for the primary standard, which is proposed to be the 98th percentile, and that the lower end of the range should be the 92nd percentile, which represents the mean of the distribution

[87] Decisions as to which $PM_{2.5}$ continuous monitors are providing data of sufficient quality to be used in a sub-daily visibility standard would follow protocols for approval of Federal equivalent methods (FEMs) that can provide data in at least hourly intervals, as proposed in the revisions to Part 53, published elsewhere in today's **Federal Register**.

[88] The Staff Paper notes that a standard set at any specific $PM_{2.5}$ concentration will 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 (EPA, 2005a, p. 7–8).

of the 20 percent worst day, as targeted in the regional haze program (EPA, 2005a, p. 7–11 to 12).

In its letter to the Administrator (Henderson, 2005a), the CASAC PM Panel recognizes that it is difficult to select any specific level and form based on currently available information. Some Panel members felt that the range of levels recommended in the Staff Paper was on the high side, but recognized that developing a more specific (and more protective) level in future reviews would require updated and refined public visibility valuation studies, which CASAC strongly encouraged the Agency to support prior to the next review. With regard to the form of the standard, the recommendations in the final Staff Paper reflected CASAC's advice to consider percentiles in the range of the 92nd to the 98th percentile. Some Panel members recommend considering a percentile within this range in conjunction with a level toward the upper end of the range recommended in the Staff Paper.[89]

Based on the above considerations, the Administrator believes that it is appropriate to first consider the level of protection that would be afforded by the suite of primary $PM_{2.5}$ standards proposed today. The limited and uncertain evidence currently available for use in evaluating the appropriate level of protection suggests that a cautious approach is warranted in establishing a secondary standard. While significantly more information is available since the last review concerning the relationship between fine PM levels and visibility across the country, there is still little available information for use in making the relatively subjective value judgment needed in setting the secondary standard. Given this, it is appropriate to first evaluate the level of protection that the proposed primary standards would likely provide, and then determine whether the available evidence warrants adopting a standard with a different level, form, or averaging time. In comparing 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, the Administrator has looked to information on the predicted percent of areas not likely to meet various alternative secondary and primary $PM_{2.5}$ standards (EPA, 2005a, Tables 7A–1 and 5B–1(a)[90]). In so doing, the Administrator observes that the predicted percent of counties with monitors not likely to meet the proposed suite of primary $PM_{2.5}$ standards (i.e., a 24-hour standard set at 35 $\mu g/m^3$, with a 98th percentile form, and an annual standard of 15 $\mu g/m^3$) is somewhat higher (27 percent) than the predicted percent of counties with monitors not likely to meet a sub-daily secondary standard with an averaging time of 4 to 8 daylight hours, a level toward the upper end of the range recommended in the Staff Paper (e.g., up to 30 $\mu g/m^3$), and a form within the recommended range (e.g., around the 95th percentile) (24 percent). A similar comparison is seen in considering the predicted percentages of the population living in such areas.

The Administrator provisionally concludes that revising the current secondary $PM_{2.5}$ to be identical to the proposed suite of primary $PM_{2.5}$ standards is a reasonable policy approach to addressing visibility protection primarily in urban areas. Such an approach would result in improvements in visual air quality in as many or more urban areas across the country as would the alternative approach of setting a sub-daily standard consistent with that generally recommended by CASAC. Such an approach also takes into account the substantial limitations in the available hourly air quality data and in available studies of public perception and attitudes with regard to the acceptability of various degrees of visibility impairment in urban areas across the country. Given these limitations, the Administrator concludes, subject to consideration of public comment, that a secondary standard with a different averaging time, level, or form is not warranted, because the available evidence does not support a decision to achieve a level of protection different from that provided by the current primary standards, and because no change in averaging time, level, or form appears needed to achieve a comparable level of protection.

The Administrator believes that a secondary NAAQS should be considered 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 Class I areas across the country. Programs implemented to meet a national standard focused primarily on 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 rule established for protection of visual air quality in Class I areas. The Administrator further believes that the development of local programs continues to be an effective and appropriate approach to provide additional protection for unique scenic resources in and around certain urban areas that are particularly highly valued by people living in those areas. Based on these considerations, and taking into account the observations, analyses, and recommendations discussed above, the Administrator proposes to revise the current secondary $PM_{2.5}$ standards by making them identical in all respects to the proposed suite of primary $PM_{2.5}$ standards.

As discussed above, most CASAC PM Panel members strongly supported a sub-daily (4- to 8-hour averaging time) $PM_{2.5}$ standard. The Administrator places great importance on the advice of CASAC, and therefore solicits public comment on such a standard.

B. Other PM-Related Welfare Effects

This section presents the rationale for the Administrator's proposed revision of the current secondary PM standards to address PM-related effects other than visibility impairment, including vegetation and ecosystems, materials damage and soiling, and climate change. In considering the currently available evidence on each of these types of PM-related welfare effects, the Staff Paper notes that there is much information linking ambient PM to potentially adverse effects on materials and ecosystems and vegetation, and on characterizing the role of atmospheric particles in climatic and radiative processes. However, given the evaluation of this information in the Criteria Document and Staff Paper which highlighted the substantial limitations in the evidence, especially the lack of evidence linking various effects to specific levels of ambient PM, the Administrator provisionally concludes that the available evidence does not provide a sufficient basis for establishing distinct secondary standards for PM based on any of these effects alone.

[89] Some CASAC Panel members also recommend that such a standard be implemented in conjunction an ''exceptional events'' policy so as to avoid having non-compliance with the standard be driven by natural source influences such as dust storms and wild fires (Henderson, 2005a).

[90] The information in these Tables is based on analysis of 2001–2003 air quality data, including 562 counties with FRM monitors that met specific data completeness criteria for developing predicted percentages of counties not likely to meet the suite of primary $PM_{2.5}$ standards and 168 counties with continuous $PM_{2.5}$ monitors that met less restrictive data completeness criteria for developing predicted percentages for a 4-hour secondary $PM_{2.5}$ standard.

The Administrator has also addressed the question of whether reductions in PM likely to result from the current secondary PM standards, or from the range of proposed revisions to the primary PM standards, would provide requisite protection against any of these PM-related welfare effects. As discussed below, these considerations include the latest scientific information characterizing the nature of these PM-related effects and judgments as to whether revision of the current secondary standards are appropriate based on that information.

1. Nature of Effects

Particulate matter contributes to adverse effects on a number of welfare effects categories other than visibility impairment, including vegetation and ecosystems, soiling and materials damage and climate. These welfare effects result predominantly from exposure to excess amounts of specific chemical species, regardless of their source or predominant form (particle, gas or liquid). Reflecting this fact, the Criteria Document concludes that regardless of size fraction, particles containing nitrates and sulfates have the greatest potential for widespread environmental significance, while effects are also related to other chemical constituents found in ambient PM, such as trace metals and organics.[91] The following characterizations of the nature of these welfare effects are based on the information contained in the Criteria Document and Staff Paper.

a. Effects on Vegetation and Ecosystems

Potentially adverse PM-related effects on vegetation and ecosystems are principally associated with particulate nitrate and sulfate deposition. In characterizing such effects, it is important to recognize that nitrogen and sulfur are necessary and beneficial nutrients for most organisms that make up ecosystems, with optimal amounts of these nutrients varying across organisms, populations, communities, ecosystems and time scales. Therefore, it is impossible to generalize to all species in all circumstances as to the amount at which inputs of these nutrients or acidifying compounds become stressors. The Staff Paper recognizes that the public welfare benefits from the use of nitrogen (N) and sulfur (S) nutrients in fertilizers in managed agricultural and commercial forest settings. The focus of this review, therefore, is on identifying risks to sensitive species and ecosystems where unintentional additions of these atmospherically derived nutrient and acidifying compounds may be contributing to undesired change in the nation's ecosystems and resulting in adverse impacts on essential ecological attributes such as species shifts, loss of species richness and diversity, impacts on threatened and endangered species, and alteration of native fire cycles. In these cases, deposited particulate nitrate and sulfate are appropriately termed ecosystem ''stressors.''

i. Vegetation Effects

At current ambient levels, risks to vegetation from short-term exposures to dry deposited particulate nitrate or sulfate are low. However, when found in acid or acidifying deposition, such particles do have the potential to cause direct foliar injury. Specifically, the responses of forest trees to acid precipitation (rain, snow) include accelerated weathering of leaf cuticular surfaces, increased permeability of leaf surfaces to toxic materials, water, and disease agents; increased leaching of nutrients from foliage; and altered reproductive processes—all which serve to weaken trees so that they are more susceptible to other stresses (e.g., extreme weather, pests, pathogens). Acid deposition with levels of acidity associated with the foliar effects described above are currently found in some locations in the eastern U.S. (EPA, 2003). Even higher concentrations of acidity can be present in occult deposition (e.g. fog, mist or clouds) which more frequently impacts higher elevations. Thus, the risks of foliar injury occurring from acid deposition in some areas of the eastern U.S. is high. However, based on currently available information, the contribution of particulate sulfates and nitrates to the total acidity found at these locations is not clear.

ii. Ecosystem Effects

The N- and S-containing components of PM have been associated with a broad spectrum of terrestrial and aquatic ecosystem impacts that result from either the nutrient or acidifying characteristics of the deposited compounds.

Reactive nitrogen (Nr) is the form of N that is available to support the growth of plants and microorganisms. Since the mid-1960's, Nr creation through natural terrestrial processes has been overtaken by Nr creation as a result of human processes, and is now accumulating in the environment on all spatial scales—local, regional and global. Some Nr emissions are transformed into ambient PM and deposited onto sensitive ecosystems. Some of the most significant detrimental effects associated with excess Nr deposition are those associated with a syndrome known as ''nitrogen saturation.'' These effects include: (1) Decreased productivity, increased mortality, and/or shifts in terrestrial plant community composition, often leading to decreased biodiversity in many natural habitats wherever atmospheric Nr deposition increases significantly and critical thresholds are exceeded; (2) leaching of excess nitrate and associated base cations from terrestrial soils into streams, lakes and rivers and mobilization of soil aluminum; and (3) alteration of ecosystem processes such as nutrient and energy cycles through changes in the functioning and species composition of beneficial soil organisms (Galloway and Cowling 2002). Thus, through its effects on habitat suitability, genetic diversity, community dynamics and composition, nutrient status, energy and nutrient cycling, and frequency and intensity of natural disturbance regimes (fire), excess Nr deposition is having profound and adverse impact on the essential ecological attributes associated with terrestrial ecosystems. In the U.S., numerous forests now show severe symptoms of nitrogen saturation. For other forested locations, ongoing expansion in nearby urban areas will increase the potential for nitrogen saturation unless there are improved emission controls.

Excess nutrient inputs into aquatic ecosystems (e.g., streams, rivers, lakes, estuaries or oceans) either from direct atmospheric deposition, surface runoff, or leaching from nitrogen saturated soils into ground or surface waters can contribute to conditions of severe water oxygen depletion (hypoxia); eutrophication and algae blooms; altered fish distributions, catches, and physiological states; loss of biodiversity; habitat degradation; and increases in the incidence of disease. Estuaries are among the most intensely fertilized systems on Earth.

Reactive nitrogen moves from one environmental reservoir to another through a number of sequential environmental processes. Though strong correlation between the stressor and adverse environmental response exists in many locations, and N-addition studies have confirmed the relationship between stressor and response, the ability to determine the temporal and spatial distribution of environmental effects for a given input of Nr are extremely limited by the large uncertainties associated with the rates at which Nr cascades through and

[91] The Staff Paper notes that some of these other components are regulated under separate statutory authorities, e.g., section 112 of the CAA.

accumulates in various environmental reservoirs.

Acid and acidifying deposition is another significant source of stress to forest and aquatic ecosystems. It changes the chemical composition of soils by depleting the content of available plant nutrient cations such as calcium (Ca^{2+}), increasing the mobility of aluminum (Al), and increasing the S and N content (Driscoll et al., 2001).

Leaching of soil nutrients is often of major importance in cation cycles, and many forest ecosystems show a net loss of base cations. In sensitive forest soils, acid deposition leads to a shift in chemical speciation of Al from organic to inorganic forms that are toxic to terrestrial and aquatic biota, and increases inorganic Al mobilization and transport into surface waters. The toxic effect of Al on forest vegetation is attributed to its interference with plant uptake of essential nutrients, such as Ca and Mg. There are large variations in Al sensitivity among ecotypes, between and within species, due to differences in nutritional demands and physiological status, that are related to age and climate, and which change over time.

Acid deposition has been firmly implicated as a causal factor in the decline of red spruce in high elevation sites in the Northeast. Red spruce is valued commercially, for recreation and aesthetics, and as habitat for unique and endangered species. Dieback of red spruce trees has also been observed in mixed hardwood-conifer stands at relatively low elevations in the western Adirondack Mountains, where inputs of acid deposition are high. Exposure to acidic mist or cloud water reduces foliar calcium levels in red spruce needles, leading to increased susceptibility to freezing (winter injury). There is also the strong possibility that acid deposition altering of foliar calcium levels leading to reduced cold tolerance is not unique to red spruce but has been demonstrated in many other northern temperate forest tree species including yellow birch, white spruce, red maple, eastern white pine, and sugar maple. Less sensitive forests throughout the U.S. are experiencing gradual losses of base cation nutrients, which in many cases will reduce the quality of forest nutrition in the future (National Science and Technology Council, 1998).

Inputs of acid deposition to regions with base-poor soils have also resulted in the acidification of soil waters, shallow ground waters, streams, and lakes in a number of locations within the U.S. Acidification has marked effects on the trophic structure of surface waters. Decreases in pH and increases in Al concentrations contribute to declines in species richness and in the abundance of zooplankton, macroinvertebrates, and fish. Numerous studies have shown that decreases in pH result in decreases in fish species richness (the number of fish species in a water body) by eliminating acid-sensitive species including important recreational fishes plus ecologically important minnows that serve as forage for sport fishes.

Though significant decreases in sulfur emissions have occurred in the U.S. and Europe in recent decades, these decreases have not been accompanied by equivalent declines in net acidity related to sulfate in precipitation, and may have, to varying degrees, been offset by steep declines in atmospheric base cation concentrations over the past 10 to 20 years (Hedin et al., 1994; Driscoll et al. 2001). Projections made using an acidification model (PnET-BGC) [92] indicate that full implementation of the 1990 CAA Amendments will not afford substantial chemical recovery at Hubbard Brook Experimental Forest and at many similar acid-sensitive locations (Driscoll et al., 2001). Model calculations indicate that the magnitude and rate of recovery from acid deposition in the northeastern U.S. are directly proportional to the magnitude of emissions reductions. Model evaluations of policy proposals calling for additional reductions in utility SO_2 and NO_X emissions, year round emissions controls, and early implementation indicate greater success in facilitating the recovery of sensitive ecosystems (Driscoll et al., 2001).

Driscoll et al. (2001) envision a recovery process that will involve two phases: chemical and biological. Initially, a decrease in acid deposition following emissions controls will facilitate a phase of chemical recovery in forest and aquatic ecosystems. Recovery time for this phase will vary widely across ecosystems and will be a function of a number of factors. In most cases, it seems likely that chemical recovery will require decades, even with additional controls on emissions. The second phase in ecosystem recovery is biological recovery, which can occur only if chemical recovery is sufficient to allow survival and reproduction of plants and animals. The time required for biological recovery is uncertain. For terrestrial ecosystems, it is likely to be at least decades after soil chemistry is restored because of the long life of tree species and the complex interactions of soil, roots, microbes, and soil biota. For aquatic systems, research suggests that stream macroinvertebrate populations may recover relatively rapidly (approximately 3 years), whereas lake populations of zooplankton are likely to recover more slowly (approximately 10 years) (Gunn and Mills, 1998). Some fish populations may recover in 5 to 10 years after the recovery of zooplankton populations, perhaps sooner with fish stocking (Driscoll et al., 2001).

iii. Ecosystem Exposure to PM Deposition

In order to establish exposure-response profiles useful in ecological risk assessments, two types of monitoring networks need to be in place. First, a deposition network is needed that can track changes in deposition rates of PM stressors (nitrates/sulfates) occurring in sensitive or symptomatic areas/ecosystems. Secondly, a network or system of networks should be established that measures the response of key sensitive ecological indicators over time to changes in atmospheric deposition of PM stressors.

Data from existing deposition networks in the U.S. demonstrate that N and S compounds are being deposited in amounts known to be sufficient to affect sensitive terrestrial and aquatic ecosystems over time. Though the percentages of N and S containing compounds in PM vary spatially and temporally, nitrates and sulfates make up a substantial portion of the chemical composition of PM. In the future, speciated data from these networks may allow better understanding of the specific components of total deposition that are most strongly influencing PM-related ecological effects.

At this time, however, there are only a few sites where long-term monitoring of sensitive indicators of ecosystem response to excess nitrogen and/or acidic and acidifying deposition is taking place within the U.S. Because the complexities of ecosystem response make predictions of the magnitude and timing of chemical and biotic recovery uncertain, it is important that this type of long-term monitoring network be continued, and that biological monitoring be enhanced to support future evaluations of the response of forested watersheds and surface waters to a host of research and regulatory issues related to nutrient and acid and acidifying deposition.

[92] PnET–BGC is designed to simulate element cycling in forest and interconnected aquatic ecosystems. The model PnET is a simple, generalized, and well validated model that provides estimates of forest net primary productivity, nutrient uptake by vegetation, and water balances. Recently, PnEt was coupled with a soil model that simulates abiotic soil processes, resulting in a comprehensive forest-soil-water model, PnET–BGC (Driscoll et al., 2001).

iv. Critical Loads

The critical load (CL) has been defined as a ''quantitative estimate of an exposure to one or more pollutants below which significant harmful effects on specified sensitive elements of the environment do not occur according to present knowledge'' (Lokke et al., 1996). The concept is useful for estimating the amounts of pollutants that ecosystems can absorb on a sustained basis without experiencing measurable degradation. The estimation of ecosystem critical loads requires an understanding of how an ecosystem will respond to different loading rates in the long term and is a direct function of the level of sensitivity of the ecosystem to the pollutants in question and its ability to ameliorate pollutant stress.

The CL approach is very data-intensive, and, at the present time, there is a paucity of ecosystem-level data for most sites. However, for a limited number of areas which already have a long-term record of ecosystem monitoring, (e.g., Rocky Mountain National Park in Colorado and the Lye Brook Wilderness in Vermont), Federal Land Managers may be able to develop site specific CLs. More specifically, with respect to PM deposition, there are insufficient data for the vast majority of U.S. ecosystems that differentiate the PM contribution to total N or S deposition to allow for practical application of this approach as a basis for developing national standards to protect sensitive U.S. ecosystems from adverse effects related to PM deposition. Though atmospheric sources of Nr and acidifying compounds, including ambient PM, are clearly contributing to the overall excess load or burden entering ecosystems annually, insufficient data are available at this time to quantify the contribution of ambient PM to total Nr or acid deposition as its role varies both temporally and spatially along with a number of other factors. Thus, at the present time, a CL could not be developed that would address the portion of the total N or S input that is contributed by ambient PM.

b. Effects on Materials Damage and Soiling

As discussed in the Staff Paper, the effects of the deposition of atmospheric pollution, including ambient PM, on materials are related to both physical damage and impaired aesthetic qualities. The deposition of PM (especially sulfates and nitrates) 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 concrete and limestone. As noted in the last review, only chemically active fine-mode or hygroscopic coarse-mode particles contribute to these physical effects. In addition, the deposition of ambient PM can reduce the aesthetic appeal of buildings and culturally important articles 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. Available data indicate that particle-related soiling can result in increased cleaning frequency and repainting, and may reduce the useful life of the soiled materials. However, to date, no quantitative relationships between particle characteristics (e.g., concentrations, particle size, and chemical composition) and the frequency of cleaning or repainting have been established. Thus, the Administrator concludes that PM effects on materials can play no quantitative role in considering whether any revisions of the secondary PM standards are appropriate at this time.

c. Effects on Climate

As discussed in the Staff Paper, atmospheric particles can alter the earth's energy balance by both scattering and absorbing radiation transmitted through the earth's atmosphere. Most components of ambient PM (especially sulfates) scatter and reflect incoming solar radiation back into space, thus tending to have a cooling effect on climate. In contrast, some components of ambient PM (especially black carbon) absorb incoming solar radiation or outgoing terrestrial radiation, thus tending to have a warming effect on climate. Other impacts of atmospheric particles are associated with their role in affecting the radiative properties of clouds, through changes in the number and size distribution of cloud droplets (which can have an effect on the climate in either direction), and by altering the amount of ultraviolet solar radiation (especially UV–B) penetrating through the atmosphere to ground level, where it can exert a variety of effects on human health, plant and animal biota, and other environmental components.

The available information, however, provides no basis for estimating how localized changes in the temporal, spatial, and composition patterns of ambient PM likely to occur as a result of expected future emissions of particles and their precursor gases across the U.S., would affect local, regional, or global changes in climate or UV–B radiation penetration. Even the direction of such effects on a local scale remains uncertain. Moreover, similar concentrations of different particle components can produce opposite net effects, depending on other atmospheric parameters such as humidity. The Administrator thus concludes that, given this uncertainty, the potential indirect effects of ambient PM on public health and welfare, secondary to potential PM-related changes in climate and UV–B radiation, can play no quantitative role in considering whether any revisions of the primary or secondary PM standards are appropriate at this time.

2. Need for Revision of Current Secondary PM Standards To Address Other PM-Related Welfare Effects

In considering the currently available evidence on each type of PM-related welfare effects discussed above, the Administrator notes that there is much information linking the S- and N-containing components of ambient PM to potentially adverse effects on ecosystems and vegetation, materials damage and soiling, and on climatic and radiative processes. However, after reviewing the extent of relevant studies and other information provided since the 1997 review of the PM standards, which highlighted the substantial limitations in the evidence, especially with regard to the lack of evidence linking various effects to specific levels of ambient PM, the Administrator concurs with conclusions reached in the Staff Paper and by CASAC (Henderson, 2005a) that the available data do not provide a sufficient basis for establishing separate and distinct secondary PM standards based on any of these non-visibility PM-related welfare effects.

While recognizing that PM-related impacts on vegetation and ecosystems and PM-related soiling and materials damage are associated with chemical components in both fine and coarse-fraction PM, the Administrator provisionally concludes that sufficient information is not available at this time to consider either an ecologically based indicator or an indicator based distinctly on soiling and materials damage, in terms of specific chemical components of PM. Further, consistent with the rationale and recommendations in the Staff Paper, the Administrator agrees that it is appropriate to continue control of ambient fine and coarse-fraction particles, especially long-term deposition of particles such as particulate nitrates and sulfates that contribute to adverse impacts on vegetation and ecosystems and/or to

materials damage and soiling. The Administrator also agrees with the Staff Paper that the available information does not provide a sufficient basis for the development of distinct national secondary standards to protect against such effects beyond the protection likely to be afforded by the proposed suite of primary PM standards. In considering those proposed standards in combination, including the proposed more protective 24-hour standard for $PM_{2.5}$ and the proposed 24-hour standard for $PM_{10-2.5}$, which is intended to provide an equivalent degree of protection to the current PM_{10} standards in areas where the proposed $PM_{10-2.5}$ indicator applies (which tend to be more densely populated areas where materials damage would be of greater concern), the Administrator believes that this proposed suite of standards would afford at least the degree of protection as that afforded by the current secondary PM standards.

Finally, the Administrator believes, as noted above, that such standards should be considered in conjunction with the protection afforded by other programs intended to address various aspects of air pollution effects on ecosystems and vegetation, such as the Acid Deposition Program and other regional approaches to reducing pollutants linked to nitrate or acidic deposition. Based on these considerations, and taking into account the information and recommendations discussed above, the Administrator therefore proposes to revise the current secondary $PM_{2.5}$ and PM_{10} standards to address these other welfare effects by making them identical in all respects to the proposed suite of primary $PM_{2.5}$ and $PM_{10-2.5}$ standards.

C. Proposed Decisions on Secondary PM Standards

For the reasons discussed above, and taking into account the information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, and public comments to date, the Administrator proposes to revise the current secondary $PM_{2.5}$ and PM_{10} standards by making them identical in all respects to the proposed primary $PM_{2.5}$ and $PM_{10-2.5}$ standards to address PM-related welfare effects including visibility impairment, effects on vegetation and ecosystems, materials damage and soiling, and effects on climate change. In recognition of an alternative view expressed by most members of the CASAC PM Panel, the Administrator also solicits comments on a sub-daily (4- to 8-hour averaging time) $PM_{2.5}$ standard to address visibility impairment, within the range of 20 to 30 $\mu g/m^3$ and with a form within the range of the 92nd to 98th percentile. Based on the comments received and the accompanying rationale, the Administrator may adopt other standards within the range of alternatives identified above in lieu of the standards he is proposing today.

V. Interpretation of the NAAQS for PM

A. Proposed Amendments to Appendix N—Interpretation of the National Ambient Air Quality Standards for $PM_{2.5}$

The EPA is proposing to revise the data handling procedures for the annual and 24-hour primary $PM_{2.5}$ standards in appendix N to 40 CFR part 50. The proposed amendments to appendix N would detail the computations necessary for determining when the proposed primary and secondary $PM_{2.5}$ national ambient air quality standards (NAAQS) are met. The proposed amendments also would address data reporting, monitoring considerations, and rounding conventions. Key elements of the proposed revisions to appendix N are summarized below in sections V.A.1 through V.A.5 of this preamble.

1. General

Several new definitions would be added to section 1.0 and utilized throughout the appendix, most notably ones for ''design values''. Also, the 24-hour time would be clarified as representing ''local *standard* (word inserted) time''. This proposal reflects EPA's previous intent as well as majority practice, and also avoids ambiguity since local *clock* time varies according to daylight savings periods.

2. $PM_{2.5}$ Monitoring and Data Reporting Considerations

Two new sections would be added to appendix N to more specifically stipulate and highlight monitoring and data considerations. New section 2.0 would include statistical requirements for spatial averaging (which is part of the form of the current and proposed annual standard for $PM_{2.5}$). As explained in section II.F.2 above, we are proposing to tighten the constraints on use of spatial averaging to reflect enhanced knowledge of typical monitor correlation coefficients in metropolitan areas. As also set out in section II.F.2, the Administrator is further soliciting comment on the other staff-recommended alternative of revising the form of the annual $PM_{2.5}$ standard to one based on the highest community-oriented monitor in an area, with no allowance for spatial averaging.

New section 3.0 would codify aspects of raw data reporting and raw data time interval aggregation including specifications of number of decimal places. Previously, these reporting instructions resided only in associated guidance documents. Section 3.0 would also note the process for assimilating monitored concentration data from collocated instruments into a single ''site'' record; data for the site record would originate mainly from the designated ''primary'' monitor at the site location, but would be augmented with collocated Federal reference method (FRM) or Federal equivalent method (FEM) monitor data whenever valid data are not generated by the primary monitor. This procedure would enhance the opportunity for sites to meet data completeness requirements. This proposed language likewise would codify existing practice, since the technique was previously documented in guidance documentation and implemented as EPA standard operating procedure.

3. $PM_{2.5}$ Computations and Data Handling Conventions

The EPA is proposing a spatially-averaged annual mean as the form of the annual $PM_{2.5}$ standard and a 98th percentile concentration as the form of the 24-hour $PM_{2.5}$ standard. Although no actual computational change is proposed for a spatially-averaged annual mean, the proposed Appendix N now differentiates, in language and formulae, between a spatial average of more than one site and a spatial average of only one site. The intent of this change is to alleviate confusion caused by the current ''catch-all'' generic reference. The proposed revisions to appendix N would identify the NAAQS metrics and explain data capture requirements and comparisons to the standards for the annual $PM_{2.5}$ standard and the 24-hour standard (in sections 4.1, and 4.2, respectively); data rounding conventions (in section 4.3); and formulas for calculating the annual and 24-hour metrics (in sections 4.4 and 4.5, respectively).

With regard to the annual $PM_{2.5}$ standard, we are proposing to retain current data capture requirements for the annual standard with two exceptions. Current appendix N has reduced data capture requirements for years that exceed the level of the annual NAAQS; specifically, a minimum of 11 valid samples per quarter as opposed to a more stringent 75 percent (of scheduled samples) is currently considered sufficient in those instances where the annual mean exceeded the NAAQS level. See existing Part 50 App.

N 2.1(b). The EPA is proposing to also allow 11 or more samples per quarter as an acceptable minimum if the calculated annual standard design value exceeds the level of the standard. The EPA solicits comments on this proposed change.

A second proposed change in the data completeness requirements would incorporate data substitution logic for situations where the proposed 11 sample per quarter minimum is not met. Consistent with existing guidance and practice (implementing current App. N 2.1(c)), EPA proposes to incorporate the following requirement into appendix N: a quarter with less than 11 samples would be complete and valid if, by substituting a historically low 24-hr value for the missing samples (up to the 11 minimum), the results yield an annual mean, spatially averaged annual mean, and/or annual standard design value that exceeds the levels of the standard. The EPA proposes to implement this procedure for making comparisons to the NAAQS and not to permanently alter the reported data. The EPA considers this a very conservative means of inputing data (and increasing the opportunities for using monitoring data that otherwise are valid), but solicits comment on the proposed approach.

With regard to the 24-hour $PM_{2.5}$ standard, the proposed revisions to appendix N would include a special formula (Equation 6 in the proposed rule) for computing annual 98th percentile values when a site operates on an approved seasonal sampling schedule. This formula was previously stated only in guidance documentation (''Guideline on Data Handling Conventions for the PM NAAQS'', April 1999) but was utilized, where appropriate, in official OAQPS design value calculations. Seasonal sampling has traditionally been implemented in periods that do not divide months; this criterion is explicitly stated in the proposed amendments.

The proposed revisions to appendix N would also incorporate language explicitly stating that 98th percentiles (for both regular and seasonal sampling schedules) is to be based on the *applicable* number of samples rather than the *actual* number of samples. Both annual 98th percentile equations (proposed Equations 5 and 6) would now reflect this approach. To accommodate seasonal sampling, the calculation of ''annual applicable number of samples'' would be changed from the sum of the ''quarterly applicable number of samples'' to a sum of the ''monthly applicable number of samples''. The EPA welcomes comment on the ''applicable number of samples'' concept and calculation.

To simplify the regulatory language, another proposed change to appendix N would eliminate the equation computational examples. The EPA will provide extensive computational examples in forthcoming guidance documents.

4. Secondary Standard

The EPA is proposing that the secondary standards for $PM_{2.5}$ be the same as the primary standards. However, the Administrator is soliciting comment on the alternative of a distinct 4-hour secondary standard for visibility protection with a form of an annual percentile, in the range 92nd to 98th, for a 12 p.m. to 4 p.m. local standard time daily average, averaged over 3 years. The same basic data handling approach as used for the 24-hour 98th percentile primary standard would also be utilized for a 4-hour percentile-based secondary standard (should EPA ultimately adopt such a standard). For example, 75 percent of the hours in the averaging time (i.e., 3 hours) would be required to produce a valid daily measurement. Also, 75 percent capture of sample days in a quarter would always make a complete quarter and four complete quarters, a complete year. Reduced capture (i.e., as little as one sample per year) would also suffice for high concentration years or 3-year periods. However, the percentile computational variation permitted for seasonal sampling for the 24-hour 98th percentile would not be needed for the 4-hour 95th percentile since the predominant (if not only) monitoring instrument used for this standard would be a continuous $PM_{2.5}$ sampler and EPA expects these continuous instruments to operate throughout the entire year. For this same reason, distinction between *applicable* number of samples and *actual* number of samples would not be necessary.

5. Conforming Revisions

Terminology and data handling procedures associated with exceptional events would be revised to conform to rules which EPA plans to propose in the near future to implement the recent amendment to CAA section 319 (42 U.S.C. 7619) by section 6013 of the Safe, Accountable, Flexible Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) (PL 109–59). At this time, EPA is proposing to replace the term currently used in Appendix N.1.(b)—''uncontrollable or natural events''—with ''exceptional events,'' corresponding with the term used in the recent amendment. (Because this proposal would make only a semantic change to existing Appendix N, EPA believes the proposal is consistent with section 6013 (b) (4) of SAFETEA–LU, which provides that EPA shall continue to apply existing Appendix N of part 50 (among others) until the effective date of rules implementing the exceptional event provisions in amended section 319 of the CAA.)

B. Proposed Appendix P—Interpretation of the National Ambient Air Quality Standards for $PM_{10-2.5}$

The EPA is proposing to add appendix P to 40 CFR part 50 in order to add data handling procedures for the proposed 24-hour $PM_{10-2.5}$ standard. The proposed appendix P would detail the computations necessary for determining when the proposed $PM_{10-2.5}$ NAAQS is met. The proposed appendix also would address data reporting, sampling frequency considerations, and rounding conventions. The protocols described in proposed appendix P would mirror the general and 24-hour specific protocols proposed for the $PM_{2.5}$ NAAQS in appendix N of 40 CFR part 50. Key elements of the proposed appendix P are summarized below in sections V.B.1 through V.B.3 of this preamble.

1. General

Terms utilized throughout the proposed appendix would be defined in section 1.0.

2. $PM_{2.5}$ Data Reporting Considerations

Section 2.0 of the proposed appendix P would specify the input data to be used in the NAAQS computations. The section would address raw data reporting and raw data time interval aggregation (i.e., report/calculate to one decimal place, truncate additional digits). Section 2.0 would also note the process for assimilating monitored concentration data into a ''site'' record; data for the site record would originate mainly from the designated ''primary'' monitor at the site location, but would be augmented with collocated Federal reference method or Federal equivalent method monitor data whenever valid data are not generated by the primary monitor. This procedure would enhance the opportunity for sites to meet data completeness requirements.

3. $PM_{10-2.5}$ Computations and Data Handling Conventions

The EPA is proposing a site-based 98th percentile concentration as the form of the 24-hour $PM_{2.5}$. The proposed appendix P would explain data handling conventions and computations for the 24-hour primary (and secondary) $PM_{10-2.5}$ standards in section 3.1; data

rounding conventions in section 3.2; and sampling frequency considerations in section 3.3. The formulas used for calculating the 24-hour NAAQS metric would be specified in section 3.4.

The proposed appendix would include a special formula (Equation 2) for use in computing annual 98th percentile values when a site operates on an approved seasonal sampling schedule. The proposed appendix P also would incorporate language explicitly stating that 98th percentiles (for both regular and seasonal sampling schedules) is to be based on the *applicable* number of samples rather than *actual* number of samples. Both annual 98th percentile equations (Equations 1 and 2 of proposed appendix P) would reflect this approach. This approach parallels that proposed in appendix N for $PM_{2.5}$ described in V.A.3. above, and is based on the same considerations.

4. Exceptional Events

The EPA plans to use the terminology and adopt the data handling procedures associated with exceptional events consistent with rules which would implement the recent amendment to CAA section 319 discussed in section V.A.5 above. The EPA expects to propose such rules in the near future. In the present proposal, the term ''exceptional events'' is used, consistent with the term used in the recent amendment as well as the term EPA proposes to use in the parallel provision in Appendix N (see section V.A.5).

VI. Reference Methods for the Determination of Particulate Matter As $PM_{2.5}$ and $PM_{10\text{-}2.5}$

A. Proposed Appendix O: Reference Method for the Determination of Coarse Particulate Matter (as $PM_{10\text{-}2.5}$) in the Atmosphere

1. Purpose of the New Reference Method

The EPA is proposing a new Federal reference method (FRM) for the measurement of coarse particles (as $PM_{10\text{-}2.5}$) in ambient air for the purpose of determining attainment of the proposed new $PM_{10\text{-}2.5}$ standards. The FRM would also serve as the standard of comparison for determining the adequacy of alternative ''equivalent'' methods for use in lieu of the FRM. The method is described in a proposed new appendix O to 40 CFR part 50, where it would join other FRM (or measurement principles) specified for the other criteria pollutants.

2. Rationale for Selection of the New Reference Method

The proposed FRM for measuring $PM_{10\text{-}2.5}$ is based on the combination of two conventional low-volume methods, one for measuring PM_{10} and the other for measuring $PM_{2.5}$, and determining the $PM_{10\text{-}2.5}$ measurement by subtracting the $PM_{2.5}$ measurement from the concurrent PM_{10} measurement. The proposed $PM_{2.5}$ measurement method is identical to the $PM_{2.5}$ FRM currently specified in appendix L to 40 CFR part 50, and the proposed PM_{10} measurement method is similar, utilizing the same sampler but without the $PM_{2.5}$ particle size separator. (Both samplers use identical PM_{10} size-selective inlets.) Thus, this $PM_{10\text{-}2.5}$ FRM is based on the same aerodynamic particle size separation and filter-based, gravimetric technology that is also the basis for FRMs for $PM_{2.5}$ and (in a somewhat less rigorously specified form) for PM_{10}.

In selecting the FRM methodology, EPA's primary considerations were the ability of the method to provide: (1) Credible and reliable measurements of $PM_{10\text{-}2.5}$; (2) reliable assessment of the quality of monitoring data; and (3) a credible and practical reference standard of comparison for candidate alternative measurement methods to determine their qualification as equivalent methods. In concept, a direct method for measuring $PM_{10\text{-}2.5}$ would seem to be desirable for the FRM, rather than the indirect method proposed. The EPA tested and evaluated various types of direct measurement technology (Vanderpool et al., 2005), including other conventional, filter-based gravimetric methods. The results of these tests and other evaluations indicate that none of the available methods or alternative technologies was more suitable as a reference method for $PM_{10\text{-}2.5}$ than the method proposed.

Perhaps the most fundamental requirement for the $PM_{10\text{-}2.5}$ FRM is the capability of the method to measure the subject particulate matter with a high degree of fidelity and faithfulness to the definition of $PM_{10\text{-}2.5}$. In proposed appendix O, $PM_{10\text{-}2.5}$ is defined as the mass concentration of ambient particles in the coarse-mode fraction of PM_{10}, specifically the (nominal) size range of 2.5 to 10 micrometers. The lower and upper limits of this size range are formally defined by the existing FRMs for $PM_{2.5}$ (40 CFR part 50, appendix L) and for PM_{10} (40 CFR part 50, appendix J). In both cases, the particle sizes are defined in terms of aerodynamic size, not actual physical size. Further, the particle size limits are not simple step functions but instead are defined by the corresponding $PM_{2.5}$ and PM_{10} measurement methodologies, which have inherent size fractionation curves with characteristic shapes and cutoff sharpness. The proposed $PM_{10\text{-}2.5}$ FRM would utilize these same measurement methodologies to determine the $PM_{10\text{-}2.5}$ concentration as the difference between separate PM_{10} and $PM_{2.5}$ measurements, thereby preserving and replicating the same particular PM_{10} and $PM_{2.5}$ aerodynamic particle size limit characteristics previously established by the PM_{10} and $PM_{2.5}$ FRMs.

Also, the proposed $PM_{10\text{-}2.5}$ FRM utilizes the same conventional integrated-sample, filter-collection, and mass-based gravimetric measurement technology that has been chosen for all previous FRM for the various formal particulate matter indicators. This well-established and reliable technology provides a high degree of credibility in the $PM_{10\text{-}2.5}$ measurements, derived from its gravimetric basis and its extensive track record from wide utilization over many years in many government monitoring networks. Further, it allows for maximum compatibility and comparability among new and existing $PM_{10\text{-}2.5}$, PM_{10}, and $PM_{2.5}$ data sets and thus to much of the health effects data used as a basis for the proposed NAAQS. No costly studies are needed to assess the impact, effect, or degree of comparability of a new or changed measurement technology relative to previously acquired measurement data. Extensive wind tunnel tests have shown that the inlet, used on both the $PM_{2.5}$ and PM_{10} samplers, is capable of aspirating large particles efficiently, even at high wind speeds. The presence of $PM_{2.5}$ aerosols on the PM_{10} sample collection filter increases the adhesion of larger particles to the filter to minimize losses of large particles from the PM_{10} filters during handling and transport. Such losses can be a problem with filter samples collected with a virtual impactor-type sampler, where the $PM_{2.5}$ aerosols are not present on the $PM_{10\text{-}2.5}$ filter in sufficient quantities to eliminate loss of coarse mode particles.

An inherent advantage of a difference method is that some (additive) biases may be eliminated or substantially reduced by the subtraction. In the proposed $PM_{10\text{-}2.5}$ FRM, the two samplers and their operational procedures are very closely matched (except for the particle size separator) to take maximum advantage of this feature, which helps to compensate for the additional variability resulting from dual measurement systems. Although a difference method could produce negative measurements on occasion,

considerable field testing of the method indicates that negative readings are rare, due in substantial part to the excellent precision of the base methods (Vanderpool et al., 2005). Moreover, measured negative $PM_{10-2.5}$ concentrations, if observed, would likely occur only at low concentrations near the detection limit of the method and would thus be unlikely to adversely affect the accuracy of $PM_{10-2.5}$ attainment decisions based on the proposed 24-hour NAAQS.

The proposed method also has a number of secondary advantages. The samplers and operational procedures of the proposed FRM are similar to those of the $PM_{2.5}$ FRM and will be familiar to most State monitoring agencies. In fact, the nature of the method allows for the possibility of readily and economically obtaining $PM_{10-2.5}$ samplers (actually sampler pairs) by reconfiguring existing $PM_{2.5}$ samplers. $PM_{10-2.5}$ sampler pairs based on currently designated $PM_{2.5}$ FRM samplers could be quickly designated by EPA as $PM_{10-2.5}$ FRM, as no additional qualification testing would be required. Existing $PM_{2.5}$ FRM samplers can be easily reconfigured as $PM_{10-2.5}$ FRM sampler pairs by converting some of them to the special PM_{10} (PM_{10c}) samplers by simply replacing the WINS impactor with the specified straight downtube adaptor. Thus, the $PM_{10-2.5}$ method could be rapidly and economically implemented into new or existing monitoring networks to begin collection of $PM_{10-2.5}$ monitoring data expeditiously, with minimal requirements for operator retraining or pilot operational periods.

The proposed FRM provides readily accessible aerosol samples for subsequent chemical analyses, and the sampler's design allows use of a wide variety of filter materials including Teflon, quartz, nylon, and polycarbonate. Compared to $PM_{2.5}$, the chemical composition of coarse-mode aerosols has not yet been extensively evaluated. The ability of the proposed FRM to provide speciated analyses of coarse aerosol samples would be an important tool for the States during development of effective implementation plans.

In developing this new FRM for $PM_{10-2.5}$, EPA staff consulted with a number of individuals and groups in the monitoring community, including instrument manufacturers, academics, consultants, and experts in State and local agencies. The approach and key specifications of the method were submitted for peer review to the Clean Air Scientific Advisory Committee (CASAC) Ambient Air Monitoring and Methods Subcommittee, which held public meetings to discuss methods and related monitoring issues on July 22, 2004 and September 21 and 22, 2005. Comments on the proposed method were provided orally and in writing by Subcommittee members and by interested public entities. In a letter dated November 30, 2005 (Henderson, 2005c) forwarded by the CASAC to the Administrator, the CASAC provided its peer review consensus report stating that ''in general, the CASAC agrees that there are several important scientific or operational strengths of the proposed difference method $PM_{10-2.5}$ to be used as the FRM, while noting that there are several prominent weaknesses as well. Despite these weaknesses, no other better, currently available candidate FRM method has been identified.'' The CASAC report noted that ''A majority of the Subcommittee members expressed the opinion that the demonstrated data quality of the $PM_{10-2.5}$ difference method and its documented value in correlations with health effects data support its being proposed as the PM coarse FRM''. However, the CASAC also indicated that the proposed FRM should not be intended for extensive implementation in national monitoring networks. Instead, it should be used primarily as a benchmark for evaluating the performance of continuous as well as other direct-measuring, filter-based, integrated methods and determining their acceptability for use in routine monitoring of $PM_{10-2.5}$. As explained more fully below, this is the approach we intend to adopt for the national monitoring network.

3. Consideration of Other Methods for the Federal Reference Method

Other measurement technologies considered for the FRM include a variety of alternative integrated-sample, filter-based methods as well as various automated methods providing continuous or semi-continuous measurements of $PM_{10-2.5}$. One methodology that warranted particular consideration is integrated, filter sampling using a virtual impactor particle size separator (also known as a dichotomous fractionator). This technology provides for measuring $PM_{10-2.5}$ more directly than the proposed difference method and also provides associated $PM_{2.5}$ measurements, as well as PM_{10} measurements by addition. Like the proposed difference method, dichotomous samplers have been used in health studies that supported the basis for both the $PM_{2.5}$ and proposed $PM_{10-2.5}$ NAAQS. A dichotomous sampler can utilize the same PM_{10} sampler inlet, the same types of filters and filter processing, and similar quality assurance procedures as the proposed method. It also has a very important advantage in providing $PM_{10-2.5}$ filter samples for chemical analysis. Such ''speciation'' analysis is a critical tool used by States for developing effective $PM_{10-2.5}$ control strategies. Speciated $PM_{2.5}$ and $PM_{10-2.5}$ data have supported epidemiological studies used to develop associations between exposure to ambient particulate matter and increased mortality and morbidity (Dockery, et al., 1993, Schwartz, 1994). Collected speciated samples from dichotomous samplers can also be used to conduct toxicological studies of the adverse health effects of PM exposure as a function of particle size (Demokritou, et al., 2003).

However, some aspects of virtual impactor technology raise concerns regarding the technology's current suitability for use as a $PM_{10-2.5}$ reference method. Various versions of virtual impactors have been designed and used, but their particle size separation characteristics have not been fully evaluated and independently characterized as extensively as those of the proposed method, resulting in considerable uncertainty about their performance relative to the conventional low-volume $PM_{2.5}$ and PM_{10} FRMs. There is also concern about the impact and potential need to compensate for some inherent fine particle contamination on the $PM_{10-2.5}$ filter. For example, for a virtual impactor which employs a 10 to 1 total flow rate to coarse flow rate ratio, 10 percent of the fine particles deposit on the coarse filter. Following each sampling event, the presence of these fine particles must be accounted for during subsequent calculation of the $PM_{10-2.5}$ mass concentration. Depending upon the analyte of interest, the collected mass of the analyte, and the method detection limit of the analytical technique for that analyte, proper compensation for fine particle contamination will also need to be made when conducting speciation analysis of the coarse channel filter. Allen et al. (1999) also reported the tendency for some fraction (up to 16 percent) of coarse mode particles to penetrate to the fine channel filter and thus positively bias calculated $PM_{2.5}$ mass concentrations as well as concentrations of specific analytes. Because the level of coarse particle contamination depends upon the size distribution of the sampled aerosol and the physical nature of the coarse particles, this contamination cannot be accurately predicted and thus cannot be

accounted for during subsequent calculations.

Loss of particles within virtual impactors is also well documented (Forney et al., 1982, Chen et al., 1985, Loo and Cork, 1988, Li and Lundgren, 1997, Allen, et al., 1999, Kim and Lee, 2000) and can substantially bias measured mass and species concentrations. As reported by Loo and Cork (1988), losses up to 50 percent have been reported during laboratory calibration of various virtual impactor designs when using liquid calibration aerosols. Moreover, these losses cannot be predicted and are very sensitive to virtual impactor geometry and component misalignment. Unlike conventional impactors where internal particle loss can be readily minimized, the design of virtual impactors must be optimized to ensure that particle loss is sufficiently low to enable accurate mass and species measurements during field use.

In the proposed difference method, the high concentration of fine particles on the PM_{10} filter provides additional adhesive force for retaining large particles to the filter's surface. In the dichotomous sampler, however, the low concentration of fine particles on the coarse channel filter results in a significantly reduced adhesive force. If inertial forces (applied to the filter during its post-sampling handling and transport) are greater than the adhesive force, then coarse particles will be dislodged from the coarse channel filter and not be subsequently quantified. Depending upon the virtual impactor design, the nature of the collected aerosol, and the magnitude of the applied inertial force, large particle losses up to 50 percent have been documented (Dzubay and Barbour, 1983, Spengler and Thurston, 1983). As in the case of coarse particle intrusion into the fine channel, the magnitude of this measurement bias is variable and cannot be accurately predicted nor compensated for.

The CASAC, in their peer review report (Hendersen, 2005c) supports ''* * * the possibility of specifying more than one FRM for $PM_{10-2.5}$ (as it did for PM_{10}) , if one or more of the current or evolving dichotomous sampler designs shows reasonable agreement with the difference method (assuming filter-handling procedures can be developed to minimize losses of coarse-only particles prior to weighing).'' We agree that the filter-handling procedures need to be investigated in addition to other issues described above. Therefore, at this point we believe the proposed FRM, based on the difference method, offers less uncertainty in $PM_{10-2.5}$ measurements and is the more prudent choice for the reference method. However, CASAC and EPA are both interested in utilizing dichotomous samplers in support of other monitoring objectives, such as providing samples for chemical speciation analysis, once a number of issues are worked through. Therefore, the Agency wishes to solicit public comment regarding consideration of a $PM_{10-2.5}$ reference method or equivalent method based on the use of the virtual impactors to aerodynamically separate fine mode aerosols from coarse mode aerosols.

Concerns have been expressed to EPA regarding the fact that the size separation devices of both the $PM_{2.5}$ and PM_{10} FRMs, which are the basis of the proposed difference-based $PM_{10-2.5}$ FRM, have inherent size fractionation curves with characteristic shapes and cutoff sharpness rather than creating a perfectly sharp cutpoint at a specific aerodynamic particle size. For example, a portion of all ambient particles larger than 10 micrometers are included in the $PM_{10-2.5}$ sample, while some particles smaller than 10 micrometers are not. A larger effect on measured $PM_{10-2.5}$ will occur in environments with high concentrations of particles above 10 micrometers than in environments with low concentrations.

Some commenters who have been concerned about this aspect of the $PM_{2.5}$ and PM_{10} FRMs have supported the adoption of a $PM_{10-2.5}$ FRM that would directly measure the coarse fraction of particles. We invite comment on this topic, in the context of today's proposal for a $PM_{10-2.5}$ NAAQS and a FRM that would employ both $PM_{2.5}$ and PM_{10} size separators.

4. Consideration of Automated Methods for the Federal Reference Method

Other measurement technologies considered for the FRM included various types of automated analyzer methods that provide continuous or semi-continuous measurements of $PM_{10-2.5}$. Such methods are particularly desirable for use in $PM_{10-2.5}$ monitoring networks because they potentially offer substantially lower operational and maintenance costs, hourly averages or other short-term measurements in addition to 24-hour averages, and nearly real-time electronic, remote reporting of measurement data. However, recent field testing of many of these instruments (Vanderpool et al., 2005) indicated that none can yet achieve performance commensurate to that of the proposed method. The technologies employed by these methods usually represent a substantial, if not radical, departure from the well-characterized, conventional filter-collection and gravimetric determination. This departure raises inevitable questions of representativeness of particle size discrimination, treatment of volatile components, variability with differing site and climatic conditions, and the degree of comparability to conventionally obtained measurements. Also, since EPA is proposing a daily standard for $PM_{10-2.5}$, hourly measurements are not required to support such a standard, although they would be of value to more closely investigate impacts of sources and exceptional events.

Most, if not all, of these automated measurement technologies are proprietary. While that alone is not sufficient reason to preclude their consideration as FRM or as a ''reference measurement principle,'' it would be in the best interest of all stakeholders if multiple manufacturers could compete for this market. Adoption of the proposed FRM along with reasonable qualification requirements for equivalent methods leaves a fair and level playing field for any manufacturer to either produce the specified FRM samplers or to pursue the development and EPA approval of innovative new methods and technologies to strive for competitive marketing advantages.

5. Use of the Proposed Federal Reference Method

The EPA acknowledges that the proposed FRM is quite labor-intensive and has other disadvantages that make it less than ideal for routine use in large monitoring networks. At the same time, as just described, alternative, automated methods are under continuing research and development, and some may soon demonstrate adequate performance and comparability to the FRM for use in monitoring networks. Accordingly, and consistent with the recommendations of the CASAC (Hendersen, 2005c), EPA is providing for the possible designation of alternative methods as equivalent methods for $PM_{10-2.5}$, as set forth in proposed amendments to 40 CFR part 53 published elsewhere in this **Federal Register.** Under these proposed equivalent method provisions, EPA anticipates that alternative methods—particularly filter based, virtual-impactor samplers as well as self-contained, automated analyzers—can be designated as equivalent methods. The dichotomous samplers could potentially lead to better speciation data, while automated equivalent methods would ease the potential $PM_{10-2.5}$ monitoring burdens of monitoring agencies and would potentially provide substantial

monitoring advantages such as reduced operational cost, availability of 1-hour (or other less-than-24-hour) average concentration measurements, and near real-time telemetered monitoring data. As explained in the preamble to the proposed Part 58 rule, if such automated methods are designated as equivalent, they would likely be used predominantly for much of the required $PM_{10-2.5}$ network monitoring. The new $PM_{10-2.5}$ FRM would thus be used primarily as the reference standard for designating qualified equivalent methods and for quality assurance activities, but used only minimally for routine network monitoring.

Encouraging the further development of automated analyzers by providing for their designation as equivalent methods for $PM_{10-2.5}$ could eventually lead to commercial, direct-reading instruments that would meet multiple monitoring objectives better than the FRM proposed today. In that event, the Agency may consider adopting such an automated method for the FRM (or as a ''measurement principle and calibration procedure'') under the provisions of 40 CFR 53.16, ''Supersession of reference methods.''

6. Relationship of Proposed FRM to SAFETEA–LU Requirements

Section 6012 of the SAFETEA–LU in part requires the Administrator, within two years, to ''develop a Federal reference method to measure directly particles that are larger than 2.5 micrometers in diameter without reliance on subtracting from coarse particle measurements those particles that are equal to or smaller than 2.5 micrometers in diameter.'' We believe that our proposed action today is consistent with the goals of the new legislation, in that it actively promotes use of non-difference methods through the Part 53 equivalency designation process, and states our ultimate expectation that the monitoring network for $PM_{10-2.5}$ will utilize primarily non-difference method monitors. Furthermore, we are actively investigating the possibility that a dichotomous method could be an alternative FRM within the time frame prescribed by this Act. However, we are proposing a difference method as the FRM for $PM_{10-2.5}$, for the reasons explained above as we believe this is the only approach technically justified at this time. Since the new statutory language does not require that EPA promulgate a non-difference method as either the sole or alternative FRM, we believe this proposed approach is consistent with the express language of the provision as well as with its objectives.

7. Basic Requirements of the Proposed Federal Reference Method Sampler

The proposed $PM_{10-2.5}$ FRM ''sampler'' is actually a collocated pair of samplers, one for PM_{10} and one for $PM_{2.5}$, operated simultaneously. The $PM_{2.5}$ sampler is exactly as specified in the $PM_{2.5}$ FRM (appendix L to 40 CFR part 50). The operational and procedural requirements would be the same as those for $PM_{2.5}$ FRM measurements. $PM_{2.5}$ measurements obtained as part of $PM_{10-2.5}$ FRM measurements would be indistinguishable from conventional $PM_{2.5}$ FRM measurements and would be usable for any $PM_{2.5}$ monitoring purpose, provided they are sited at the appropriate spatial scale (e.g., neighborhood scale).

In contrast, the PM_{10} sampler of the $PM_{10-2.5}$ sampler pair would be required to be identical in design and construction to the $PM_{2.5}$ sampler, except that the $PM_{2.5}$ particle size separator (WINS impactor) would be removed from the sampler and replaced with a straight downtube, thereby converting it to a PM_{10} sampler. This PM_{10} sampler would have to meet the higher standards of manufacture and performance of appendix L to 40 CFR part 50 rather than the standards for conventional PM_{10} FRM samplers (which meet the lesser requirements of appendix J to 40 CFR part 50). Thus, PM_{10} measurements obtained as part of or incidental to the $PM_{10-2.5}$ FRM measurements must be distinguished from conventional PM_{10} measurements and need to be identified by a unique descriptor such as ''PM_{10c}.'' Since PM_{10c} measurements would meet a higher standard than conventional PM_{10} measurements, such measurements would also be acceptable for any conventional PM_{10} monitoring purpose. However, one subtle issue regarding conventional PM_{10} measurements and new PM_{10c} measurements needs clarification. Conventional PM_{10} measurement flow systems operate on conditions of standard temperature and pressure (STP). Flow systems for $PM_{2.5}$ and the new $PM_{10-2.5}$ FRM as proposed today and peer reviewed by the CASAC, all operate under conditions of actual local conditions.

$PM_{10-2.5}$ sampler pairs would be required to be specifically designated as $PM_{10-2.5}$ FRM samplers by EPA under amendments to 40 CFR 53 proposed elsewhere in this **Federal Register**. The two samplers of the $PM_{10-2.5}$ FRM sampler pair would be required to be of like manufacturer and of matched design and fabrication so that they are essentially identical, except that one would have a $PM_{2.5}$ particle size separator while the other would not. Either single-filter samplers or multiple-filter, sequential samplers could constitute a $PM_{10-2.5}$ sampler pair, as long as both were of the same type and design. For a manufacturer's sampler model that has already been designated as a $PM_{2.5}$ FRM, no further testing would be required for designation as a $PM_{10-2.5}$ FRM, although the sampler manufacturer would have to submit a formal application under 40 CFR part 53. Users could assemble their own $PM_{10-2.5}$ sampler pair using existing $PM_{2.5}$ samplers of the same model or design by converting one of the samplers to a PM_{10c} sampler, provided the specific sampler pair has been previously designated by the EPA as a $PM_{10-2.5}$ FRM under 40 CFR part 53.

Pairings of qualified $PM_{2.5}$ samplers that are dissimilar or have some minor design or model variations (and one sampler is converted to a PM_{10c} sampler) could be designated by the EPA as Class I equivalent methods under proposed amendments to 40 CFR part 53. Again, an application for an equivalent method determination for the sampler combination would have to be submitted to the EPA under 40 CFR part 53, and not all combinations would necessarily be designated without further testing. For example, supplemental test or operational performance information would likely be required for designation of a $PM_{10-2.5}$ sampler pair consisting of a single-filter sampler and a multiple-filter, sequential sampler. A pairing of dissimilar $PM_{2.5}$ samplers that has not been designated as a Class I equivalent method for $PM_{10-2.5}$ under 40 CFR part 53 could be considered by the EPA for approved use in $PM_{10-2.5}$ monitoring networks as a user modification under section 2.8 of appendix C to 40 CFR part 58.

8. Other Important Aspects of the Proposed Federal Reference Method Sampler

The proposed method would require that both samplers of the $PM_{10-2.5}$ sampler pair be located in close proximity and operated simultaneously. Operational procedures for both samplers of the pair would be similar or identical to those specified for $PM_{2.5}$ FRM, and both samplers should be operated, serviced, and maintained similarly. Quality assurance procedures would parallel those for the $PM_{2.5}$ FRM, although data quality assessment procedures would apply to the calculated $PM_{10-2.5}$ measurement data rather than (or in addition to) the individual PM_{10} and $PM_{2.5}$

measurements. The proposed sample period would be nominally 24 hours (±1 hour).

Expected performance of the $PM_{10-2.5}$ FRM—as measured by precision, lower concentration limit, and completeness—is similar to that of the $PM_{2.5}$ FRM, but may be somewhat inferior because of the dual measurement components. Precision, defined as a goal for acceptable measurement uncertainty, is given as 15 percent coefficient of variation, as assessed according to quality assurance procedures for $PM_{10-2.5}$ monitoring described in proposed revisions to appendix A of 40 CFR part 58, published elsewhere in this **Federal Register**.

The lower concentration limit proposed for the method is 3 $\mu g/m^3$. This value can vary with the level of quality control and precision achieved in implementing the method. It should not be interpreted as a specification but rather as a simple guide to the general significance of low-level measured concentrations. However, this proposed value may be used as a lower range limit for excluding low-concentration data from composite performance calculations that use percentages (where very low values in a denominator need to be avoided) or in types of statistical calculations of monitoring data that cannot accept zero or negative values (such as geometric distributions, where ½ of this lower concentration limit may be substituted for any measurements less than that value). Comments are solicited on the usefulness of this lower concentration limit, its value, or how its value should be established and interpreted.

B. Proposed Amendments to Appendix L—Reference Method for the Determination of Fine Particulate Matter (as $PM_{2.5}$) in the Atmosphere

In connection with the proposal of a new Federal reference method (FRM) for $PM_{10-2.5}$, EPA is proposing minor changes to the FRM for $PM_{2.5}$ in appendix L to 40 CFR part 50. These proposed changes are based on new test information and extensive operational experience with the $PM_{2.5}$ FRM acquired subsequent to its promulgation in 1997. Through the increased flexibility afforded by the proposed changes, significant improvements in the efficiency of the $PM_{2.5}$ method in monitoring network operations are expected without altering the performance of the method. In fact, the changes have already been implemented in the national $PM_{2.5}$ monitoring network through designated equivalent methods or duly approved user modifications. Further, the changes would also apply to the proposed $PM_{10-2.5}$ FRM, so the benefits would be realized for $PM_{10-2.5}$ measurements as well, and uniformity between the $PM_{2.5}$ FRM and the $PM_{2.5}$ portion of the $PM_{10-2.5}$ FRM would be maintained.

The most significant proposed change is the addition of an alternative $PM_{2.5}$ particle size separator. Since the promulgation of the $PM_{2.5}$ FRM in 1997, a new, very sharp cut cyclone separator (VSCC™) manufactured by BGI Incorporated, Waltham, MA has been shown to have performance equivalent to that of the originally specified separator (WINS impactor) (Kenny, et al., 2001; Kenny et al., 2004; EPA, 2002b). Although the original WINS impactor continues to show fully adequate performance in $PM_{2.5}$ samplers, the new VSCC provides the same level of performance and has a considerably longer service interval. Generally, the VSCC separator is also physically interchangeable with the WINS where both are manufactured for the same sampler. The proposed change would allow either the WINS or the VSCC separator to be used in a $PM_{2.5}$ FRM sampler. Currently, EPA has designated seven $PM_{2.5}$ samplers configured with VSCC separators as Class II equivalent methods.[93] Upon promulgation of this change to appendix L, those seven methods would be re-designated as $PM_{2.5}$ FRM.

Another minor change proposed for the $PM_{2.5}$ FRM (and, hence, also applicable to the proposed $PM_{10-2.5}$ FRM) would require an improved impactor oil for the $PM_{2.5}$ WINS impactor particle size separator. The new oil corrects an occasional problem of crystallization of the original oil during sampling in cold and damp weather and has been tested and approved as a national user modification (EPA, 2000b). Also, the time limit specified for sample filter retrieval time would be increased from 96 hours to 177 hours following the end of the sample period. This change would allow the filter to be retrieved by the morning of the eighth day after sampling to permit recovery of up to three samples from a sequential sampler operating on a 1-in-3 day sample schedule. Based on a study (Papp, et al., 2002) at six sampling sites, this change has already been approved as a national user modification (EPA, 2002a). An associated change to ease the filter retrieval burden on monitoring agencies would modify the current requirement that retrieved filters be weighed within 10 days after sampling, unless they are maintained at a temperature of 4°C or less at all times during transport. The filter recovery extension study (Papp, et al., 2002) showed that these limits can be relaxed somewhat (EPA, 2000a) to allow up to 30 days for weighing the filter if it is maintained below the average ambient temperature during the sampling period prior to the post-collection sample equilibration.

Finally, some of the sampler data output reporting requirements specified in Table L–1 of appendix L to 40 CFR part 50 (e.g. flow rate CV, sample volume, minimum and maximum temperature, minimum and maximum pressure) have been determined to be unnecessary to report to the Air Quality System, and the reporting requirement for these data would be deleted. These data will be retained and available at the monitoring agency, if needed.

[93] List of designated reference and equivalent methods available at *http://www.epa.gov/ttn/amtic/criteria.html.*

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether a regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

1. Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

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

3. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

4. Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

In view of its important policy implications and potential effect on the economy of over $100 million, this action has been judged to be an economically ''significant regulatory action'' within the meaning of the Executive Order. As a result, today's action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations

will be documented in the public record.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. There are no information collection requirements directly associated with the establishment of a NAAQS under section 109 of the CAA.

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

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

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 today's 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 today's 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

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or Tribal governments or the private sector. The rule imposes no new expenditure or enforceable duty on any State, local or Tribal governments or the private sector, and EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Furthermore, as indicated previously, in setting a NAAQS 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 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). Accordingly, EPA has determined that the provisions of sections 202, 203, and 205 of the UMRA do not apply to this proposed decision. 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, EPA has addressed unfunded mandates in the notice that announces the proposed revisions to 40 CFR part 58, and will, as appropriate, address unfunded mandates when it proposes any revisions to 40 CFR part 51.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that 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.''

This proposed rule does not have federalism implications. It will not have

substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in 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, EPA is mandated to establish NAAQS; however, CAA section 116 preserves the rights of States to establish more stringent requirements if deemed necessary by a State. Furthermore, this 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 E (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 rule.

However, as also noted in section E (above) on UMRA, EPA recognizes that States will have a substantial interest in this rule and any corresponding revisions to associated SIP requirements and air quality surveillance requirements, 40 CFR part 51 and 40 CFR part 58, respectively. Therefore, in the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

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

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This rule concerns the establishment of PM 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.

This proposed rule does not have Tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes, since Tribes are not obligated to adopt or implement any NAAQS. Thus, Executive Order 13175 does not apply to this rule.

Although Executive Order 13175 does not apply to this rule, EPA contacted tribal environmental professionals during the development of this rule. The EPA staff participated in the regularly scheduled Tribal Air call sponsored by the National Tribal Air Association during the summer and fall of 2005 as this proposal was under development. Also, EPA is sending notice and an opportunity for comment to Tribal Leaders within the lower 48 states. Specifically, EPA solicits additional comment on this proposed rule from Tribal officials.

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

Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rule is subject to Executive Order 13045 because it is an economically significant regulatory action as defined by Executive Order 12866, and we believe that the environmental health risk addressed by this action may have a disproportionate effect on children. The proposed NAAQS will establish uniform, national standards for PM pollution; these standards are designed to protect public health with an adequate margin of safety, as required by CAA section 109. However, the protection offered by these standards may be especially important for children because children, along with other sensitive population subgroups such as the elderly and people with existing heart or lung disease, are potentially susceptible to health effects resulting from PM exposure. Because children are considered a potentially susceptible population, we have carefully evaluated the environmental health effects of exposure to PM pollution among children. These effects and the size of the population affected are summarized in section 9.2.4 of the Criteria Document and section 3.5 of the Staff Paper, and the results of our evaluation of the effect of PM pollution on children are discussed in sections II.A, B, and C and III.A, B, and C of this preamble.

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

This proposed rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this rule is to establish NAAQS for PM. The rule does not prescribe specific pollution control strategies by which these ambient standards will be met. Such strategies will be developed by States on a case-by-case basis, and EPA cannot predict whether the control options selected by States will include regulations on energy suppliers, distributors, or users. Thus, EPA concludes that this rule is not likely to have any adverse energy effects and does not constitute a significant energy action as defined in Executive Order 13211.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer Advancement Act of 1995 (NTTAA), Public Law No. 104–113, § 12(d) (15 U.S.C. 272 note) directs 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 EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The proposed rule establishes requirements for environmental monitoring and measurement. Specifically, it would establish the FRM for $PM_{10-2.5}$ measurement (and slightly amend the FRM for $PM_{2.5}$). The FRM is the benchmark against which all ambient monitoring methods are measured. While the FRM is not a voluntary consensus standard, the proposed revisions to the FEM in 40 CFR part 53 do allow for the utilization of voluntary consensus standards if they meet the specified performance criteria.

To the extent feasible, 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. Nevertheless, our approach in the past has resulted in multiple brands of monitors qualifying as FRM for PM, and we expect this to continue. Also, the FRM described in this proposal and the equivalency criteria contained in the proposed revisions to 40 CFR part 53 do constitute performance based criteria for the instruments that will actually be deployed for monitoring $PM_{10-2.5}$. Therefore, for most of the measurements that will be made and most of the measurement systems that make them, EPA is not precluding the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the specified performance criteria.

The EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially applicable voluntary consensus standards and to explain 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, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' requires Federal agencies to consider the impact of programs, policies, and activities on minority populations and low-income populations. According to EPA guidance, agencies are to assess whether minority or low income populations face risks or a rate of exposure to hazards that are significant and that ''appreciably exceed or is likely to appreciably exceed the risk or rate to the general population or to the appropriate comparison group.'' (EPA, 1998)

In accordance with Executive Order 12898, the Agency has considered whether these proposals, if promulgated, may have disproportionate negative impacts on minority or low income populations. The Agency expects these proposals would lead to the establishment of uniform NAAQS for PM.

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List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated: December 20, 2005.

Stephen L. Johnson,

Administrator.

For the reasons set forth in the preamble, part 50 of chapter 1 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. Section 50.3 is revised to read as follows:

§ 50.3 Reference conditions.

All measurements of air quality that are expressed as mass per unit volume (*e.g.*, micrograms per cubic meter) other than for the particulate matter ($PM_{2.5}$ and $PM_{10-2.5}$) standards contained in §§ 50.7 and 50.13 shall be corrected to a reference temperature of 25 [deg] C and a reference pressure of 760 millimeters of mercury (1,013.2 millibars). Measurements of $PM_{2.5}$ and $PM_{10-2.5}$ for purposes of comparison to the standards contained in §§ 50.7 and 50.13 shall be reported based on actual ambient air volume measured at the actual ambient temperature and pressure at the monitoring site during the measurement period.

3. Section 50.6 is amended by adding new paragraphs (d) and (e) to read as follows:

§ 50.6 National primary and secondary ambient air quality standards for PM_{10}.

* * * * *

(d) The national primary and secondary 24-hour ambient air quality standards for particulate matter set forth in paragraph (a) of this section will no longer apply except in the following areas as of [effective date of final rule]:

(1) Birmingham urban area (Jefferson County, AL).

(2) Maricopa and Pinal Counties; Phoenix planning area (AZ).

(3) Riverside, Los Angeles, Orange and San Bernardino Counties; South Coast Air Basin (CA).

(4) Fresno, Kern, Kings, Tulare, San Joaquin, Stanislaus, Maderia Counties; San Joaquin Valley planning area (CA).

(5) San Bernardino County (part); excluding Searles Valley Planning Area and South Coast Air Basin (CA).

(6) Riverside County; Coachella Valley Planning Area (CA).

(7) Simi Valley urban area (CA).

(8) Lake County; Cities of East Chicago, Hammond, Whiting, and Gary (IN).

(9) Wayne County (part) (MI).

(10) St. Louis urban area (MO).

(11) Albuquerque urban area (NM).

(12) Clark County; Las Vegas planning area (NV).

(13) Columbia urban area (SC).

(14) El Paso urban area (including those portions in TX and those portions in NM).

(15) Salt Lake County (UT).

(e) The national primary and secondary annual ambient air quality standards for particulate matter set forth in paragraph (b) of this section will no longer apply in an area as of [effective date of final rule.]

4. A new § 50.13 is added, to read as follows:

§ 50.13 National primary and secondary ambient air quality standards for $PM_{2.5}$ and $PM_{10-2.5}$.

(a) The national primary and secondary ambient air quality standards for particulate matter are:

(1) 15.0 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:

(i) A reference method based on appendix L of this part and designated in accordance with part 53 of this chapter; or

(ii) An equivalent method designated in accordance with part 53 of this chapter.

(2)(i) 70 $\mu g/m^3$ 24-hour average concentration measured in the ambient air as $PM_{10-2.5}$ (particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers and greater than a nominal 2.5 micrometers) by either:

(A) A reference method based on appendix O of this part and designated in accordance with part 53 of this chapter; or

(B) An equivalent method designated in accordance with part 53 of this chapter.

(ii) The standard for $PM_{10-2.5}$ includes any ambient mix of $PM_{10-2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and

PM generated by industrial sources and construction sources, and excludes any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. Agricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting this standard.

(b) The annual primary and secondary $PM_{2.5}$ standards are met when the annual arithmetic mean concentration, as determined in accordance with appendix N of this part, is less than or equal to 15.0 $\mu g/m^3$.

(c) The 24-hour primary and secondary $PM_{2.5}$ standards are 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 $\mu g/m^3$. The 24-hour primary and secondary $PM_{10-2.5}$ standards are met when the 98th percentile 24-hour concentration, as determined in accordance with appendix P of this part, is less than or equal to 70 $\mu g/m^3$. ′

5. Appendix L to part 50 is amended by:

a. Revising section 1.1;

b. Revising the heading of section 7.3.4 and adding introductory text; revising paragraph (a) of section 7.3.4.3, adding section 7.3.4.4; and revising Table L–1 in section 7.4.19;

c. Revising section 8.3.6;

d. Revising the first sentence in section 10.10 and revising section 10.13; and

e. Revising reference 2 in section 13.0. The revisions and addition read as follows:

Appendix L to Part 50—Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere

1.0 *Applicability.*

1.1 This method provides for the measurement of the mass concentration of fine particulate matter having an aerodynamic diameter less than or equal to a nominal 2.5 micrometers ($PM_{2.5}$) in ambient air over a 24-hour period for purposes of determining whether the primary and secondary national ambient air quality standards for fine particulate matter specified in § 50.7 and § 50.13 of this part are met. The measurement process is considered to be nondestructive, and the $PM_{2.5}$ sample obtained can be subjected to subsequent physical or chemical analyses. Quality assessment procedures are provided in part 58, appendix A of this chapter, and quality assurance guidance are provided in references 1, 2, and 3 in section 13.0 of this appendix.

* * * * *

7.3 *Design specifications.* * * *

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7.3.4 *Particle size separator.* The sampler shall be configured with either one of the two alternative particle size separators described in this section 7.3.4. One separator is an impactor-type separator (WINS impactor) described in sections 7.3.4.1, 7.3.4.2, and 7.3.4.3 of this appendix. The alternative separator is a cyclone-type separator (VSCC™) described in section 7.3.4.4 of this appendix.

* * * * *

7.3.4.3 Impactor oil specifications:

(a) Composition. Dioctyl sebacate (DOS), single-compound diffusion oil.

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7.3.4.4 The cyclone-type separator is identified as a BGI VSCC™ Very Sharp Cut Cyclone particle size separator specified as part of EPA-designated equivalent method EQPM–0202–142 (67 FR 15567, April 2, 2002) and as manufactured by BGI Incorporated, 58 Guinan Street, Waltham, Massachusetts 20451.

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7.4.19 Data reporting requirements. * * *

TABLE L–1 TO APPENDIX L OF PART 50.—SUMMARY OF INFORMATION TO BE PROVIDED BY THE SAMPLER

Information to be provided	Appendix L section reference	Availability				Format	
		Anytime [1]	End of period [2]	Visual display [3]	Data output [4]	Digital reading [5]	Units
Flow rate, 30 second maximum interval	7.4.5.1	✔		✔	(*)	XX.X	L/min
Flow rate, average for the sample period	7.4.5.2	(*)	✔	(*)	✔	XX.X	L/min
Flow rate, CV, for sample period	7.4.5.2	(*)	✔	(*)	✔	XX.X	%
Flow rate, 5-min. average out of spsec. (FLAG [6])	7.4.5.2	✔	✔	✔	✔■	On/Off	
Sample volume, total	7.4.5.2	(*)	✔	✔	✔	XX.X	m^3
Temperature, ambient, 30-second interval	7.4.8	✔		✔		XX.X	°C
Temperature, ambient, min., max., average for the sample period.	7.4.8	(*)	✔	✔	✔■	XX.X	°C
Baro. pressure, ambient, 30-second interval	7.4.9	✔		✔		XXX	mm Hg
Baro. pressure, ambient, min., max., average for the sample period.	7.4.9	(*)	✔	✔	✔■	XXX	mm Hg
Filter temperature, 30-second interval	7.4.11	✔		✔		XX.X	°C
Filter temp. differential, 30-second interval, out of spec. (FLAG [6]).	7.4.11	(*)	✔	✔	✔■	On/Off	
Filter temp., maximum differential from ambient, date, time of occurrence.	7.4.11	(*)	(*)	(*)	(*)	X.X, YY/MM/DD HH.mm	°C Yr/Mon/Day Hrs.min
Date and Time	7.4.12	✔		✔		YY/MM/DD HH.mm	Yr/Mon/Day Hrs.min
Sample start and stop time settings	7.4.12	✔	✔	✔	✔	YY/MM/DD HH.mm	Yr/Mon/Day Hrs.min
Sample period start time	7.4.12		✔	✔	✔	YY/MM/DD HH.mm	Yr/Mon/Day Hrs.min
Elapsed sample time	7.4.13	(*)	✔	✔	✔	HH.mm	Hrs.min
Elapsed sample time, out of spec. (FLAG [6])	7.4.13		✔	✔	✔■	On/Off	
Power interruptions ≤1 min., start time of first 10	7.4.15.5	(*)	✔	(*)	✔	1HH.mm, 2HH.mm, etc* * *	Hrs.min
User-entered information, such as sampler and site identification.	7.4.16	✔	✔	✔	✔■	As entered	

✔ Provision of this information is required.

* Provision of this information is optional. If information related to the entire sample period is optionally provided prior to the end of the sample period, the value provided should be the value calculated for the portion of the sampler period completed up to the time the information is provided.

■ Indicates that this information is also required to be provided to the Air Quality System (AQS) data bank; see § 58.16 of this chapter. For ambient temperature and barometric pressure, only the average for the sample period must be reported.

1. Information is required to be available to the operator at any time the sampler is operating, whether sampling or not.

2. Information relates to the entire sampler period and must be provided following the end of the sample period until reset manually by the operator or automatically by the sampler upon the start of a new sample period.

3. Information shall be available to the operator visually.

4. Information is to be available as digital data at the sampler's data output port specified in section 7.4.16 of this appendix following the end of the sample period until reset manually by the operator or automatically by the sampler upon the start of a new sample period.

5. Digital readings, both visual and data output, shall have not less than the number of significant digits and resolution specified.

6. Flag warnings may be displayed to the operator by a single flag indicator or each flag may be displayed individually. Only a set (on) flag warning must be indicated; an off (unset) flag may be indicated by the absence of a flag warning. Sampler users should refer to section 10.12 of this appendix regarding the validity of samples for which the sampler provided an associated flag warning.

* * * * *

8.3 *Weighing procedure.*

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8.3.6 The post-sampling conditioning and weighing shall be completed within 240 hours (10 days) after the end of the sample period, unless the filter sample is maintained at temperatures below the average ambient temperature during sampling (or 4°C or below for average sampling temperatures less than 4°C) during the time between retrieval from the sampler and the start of the conditioning, in which case the period shall not exceed 30 days. Reference 2 in section 13.0 of this appendix has additional guidance on transport of cooled filters.

* * * * *

10.0 *$PM_{2.5}$ Measurement Procedure.*

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10.10 Within 177 hours (7 days, 9 hours) of the end of the sample collection period, the filter, while still contained in the filter cassette, shall be carefully removed from the sampler, following the procedure provided in the sampler operation or instruction manual and the quality assurance program, and placed in a protective container. * * *

* * * * *

10.13 After retrieval from the sampler, the exposed filter containing the $PM_{2.5}$ sample should be transported to the filter conditioning environment as soon as possible, ideally to arrive at the conditioning environment within 24 hours for conditioning and subsequent weighing. During the period between filter retrieval from the sampler and the start of the conditioning, the filter shall be maintained as cool as practical and continuously protected from exposure to temperatures over 25°C to protect the integrity of the sample and minimize loss of volatile components during transport and storage. See section 8.3.6 of this appendix regarding time limits for completing the post-sampling weighing. See reference 2 in section 13.0 of this appendix for additional guidance on transporting filter samplers to the conditioning and weighing laboratory.

* * * * *

13.0 *References.*

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2. Quality Assurance Guidance Document 2.12. Monitoring $PM_{2.5}$ in Ambient Air Using Designated Reference or Class I Equivalent Methods. U.S. EPA, National Exposure Research Laboratory. Research Triangle Park, NC, November 1988 or later edition. Currently available at: *http://www.epa.gov/ttn/amtic/pmqainf.html.*

* * * * *

6. 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. *General.*

(a) This appendix explains the data handling conventions and computations necessary for determining when the annual and 24-hour primary and secondary national ambient air quality standards (NAAQS) for $PM_{2.5}$ specified in § 50.7 and § 50.13 of this part are met. $PM_{2.5}$, defined as particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers, is 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. Data handling and computation procedures to be used in making comparisons between reported $PM_{2.5}$ concentrations and the levels of the $PM_{2.5}$ NAAQS are specified in the following sections.

(b) Data resulting from exceptional events, for example structural fires or high winds, may be given special consideration. In some cases, it may be appropriate to exclude these data in whole or part because they could result in inappropriate values to compare with the levels of the $PM_{2.5}$ NAAQS. In other cases, it may be more appropriate to retain the data for comparison with the levels of the $PM_{2.5}$ NAAQS and then for EPA to formulate the appropriate regulatory response.

(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.

Daily values for $PM_{2.5}$ refers to the 24-hour average concentrations of $PM_{2.5}$ calculated (averaged from hourly measurements) or measured from midnight to midnight (local standard time).

Designated monitors are those monitoring sites designated in a State or local agency PM Monitoring Network Description in accordance with part 58 of this chapter.

Design values are the metrics (i.e., statistics) that are compared to the NAAQS levels to determine compliance, calculated as shown in section 4 of this appendix:

(1) The 3-year average of annual means for a single monitoring site or a group of monitoring sites (referred to as the *''annual standard design value''*). If spatial averaging has been approved by EPA for a group of sites which meet the criteria specified in section 2(b) of this appendix and section 4.7.5 of appendix D of 40 CFR part 58, then 3 years of spatially averaged annual means will be averaged to derive the *annual standard design value* for that group of sites (further referred to as the *''spatially averaged annual standard design value''*). Otherwise, the annual standard design value will represent the 3-year average of annual means for a single site (further referred to as the *''single site annual standard design value''*).

(2) The 3-year average of annual 98th percentile 24-hour average values recorded at each monitoring site (referred to as the *''24-hour standard design value''*).

98th percentile is the daily value out of a year of $PM_{2.5}$ monitoring data below which 98 percent of all daily values fall.

Year refers to a calendar year.

2.0 *Monitoring Considerations.*

(a) Section 58.30 of this chapter specifies which monitoring locations are eligible for making comparisons with the $PM_{2.5}$ standards.

(b) To qualify for spatial averaging, monitoring sites must meet the criterion specified in section 4.7.5 of appendix D of 40 CFR part 58 as well as the following requirements:

(1) The annual mean concentration at each site shall be within 10 percent of the spatially averaged annual mean.

(2) The daily values for each site pair shall yield a correlation coefficient of at least 0.9 for each calendar quarter.

(3) All of the monitoring sites should principally be affected by the same major emission sources of $PM_{2.5}$. This can be demonstrated by site-specific chemical speciation profiles confirming all major component concentration averages to be within 10 percent for each calendar quarter.

(4) The requirements in paragraphs (b)(1) through (3) of this section shall be met for 3 consecutive years in order to produce a valid spatially averaged annual standard design value. Otherwise, the individual (single) site annual standard design values shall be compared directly to the level of the annual 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 a reduced frequency during a season of expected low concentrations (i.e., ''seasonal sampling''), are subject to the approval of EPA. Annual 98th percentile values are to be calculated according to equation 6 in section 4.5 of this appendix when a site operates on a ''seasonal sampling'' schedule.

3.0 *Requirements for Data Used for Comparisons With the $PM_{2.5}$ NAAQS and Data Reporting Considerations.*

(a) Except as otherwise provided in this appendix, only valid FRM/FEM $PM_{2.5}$ data required to be submitted to EPA's Air Quality System (AQS) shall be used in the design value calculations.

(b) $PM_{2.5}$ measurement data (typically hourly for continuous instruments and daily for filter-based instruments) shall be reported to AQS in micrograms per cubic meter (μg/m^3) to one decimal place, with additional digits to the right being truncated.

(c) Block 24-hour averages shall be computed from available hourly $PM_{2.5}$ concentration data for each corresponding day of the year and the result shall be stored in the first, or start, hour (i.e., midnight, hour '0') of the 24-hour period. A 24-hour average shall be considered valid if at least 75 percent (i.e., 18) of the hourly averages for the 24-hour period are available. In the event that less than all 24 hourly averages are available (i.e., less than 24, but at least 18), the 24-hour average shall be computed on the basis of the hours available using the number of available hours as the divisor (e.g., 19). 24-hour periods with seven or more missing hours shall be considered valid if, after substituting zero for all missing hourly concentrations, the 24-hour average concentration is greater than the level of the standard. The computed 24-hour average $PM_{2.5}$ concentrations shall be reported to one decimal place (the insignificant digits to the right of the third decimal place are truncated, consistent with the data handling procedures for the reported data).

(d) Except for calculation of spatially averaged annual means and spatially averaged annual standard design values, all other calculations shown in this appendix shall be implemented on a site-level basis. Site level data shall be processed as follows:

(1) The default dataset for a site shall consist of the measured concentrations recorded from the designated primary FRM/FEM monitor. The primary monitor shall be designated in the appropriate State or local agency PM Monitoring Network Description.

(2) Data for the primary monitor shall be augmented as necessary with data from collocated FRM/FEM monitors. If a valid 24-hour measurement is not produced from the primary monitor for a particular required sampling day, but a valid sample is generated by a collocated FRM/FEM instrument (and recorded in AQS), then that collocated value shall be considered part of the site data record. If more than one valid collocated FRM/FEM value is available, the average of those valid collocated values shall be used as the site value for the day.

4.0 *Comparisons with the $PM_{2.5}$ NAAQS.*

4.1 *Annual $PM_{2.5}$ NAAQS.*

(a) The annual $PM_{2.5}$ NAAQS is met when the annual standard design value is less than or equal to 15.0 micrograms per cubic meter (μg/m^3).

(b) For single site comparisons, 3 years of valid annual means are required to produce a valid annual standard design value. In the case of spatial averaging, 3 years of valid spatially averaged annual means are required to produce a valid annual standard design value. Designated sites with less than 3 years of data shall be included in annual spatial averages for those years that data completeness requirements are met. A year meets data completeness requirements when at least 75 percent of the scheduled sampling days for each quarter have valid data. However, years with high concentrations and at least 11 samples in each quarter shall be considered valid, notwithstanding quarters with less than complete data, if the resulting annual mean, spatially averaged annual mean concentration, or resulting annual standard design value concentration (rounded according to the conventions of section 4.3 of this appendix) is greater than the level of the standard. Furthermore, where the explicit 11 sample per quarter requirement is not met, the site annual mean shall still be considered valid if, by substituting a low value (described below) for the missing data in the deficient quarters (substituting enough to meet the 11 sample minimum), the computation still yields a recalculated annual mean, spatially averaged annual mean concentration, or annual standard design value concentration over the level of the standard. The low value used for this substitution test shall be the lowest reported value in the site data record for that calendar quarter over the most recent 3-year period. If an annual mean is deemed complete using this test, the original annual mean (without substituted low values) shall be considered the official mean value for this site, not the result of the recalculated test using the low values.

(c) The use of less than complete data is subject to the approval of EPA, which may consider factors such as monitoring site closures/moves, monitoring diligence, and nearby concentrations in determining whether to use such data.

(d) The equations for calculating the annual standard design values are given in section 4.4 of this appendix.

4.2 *24-Hour $PM_{2.5}$ NAAQS.*

(a) The 24-hour $PM_{2.5}$ NAAQS is met when the 24-hour standard design value at each monitoring site is less than or equal to 35 μg/m^3. This comparison shall be based on 3 consecutive, complete years of air quality data. A year meets data completeness requirements when at least 75 percent of the scheduled sampling days for each quarter have valid data. However, years with high concentrations shall be considered valid, notwithstanding quarters with less than complete data (even quarters with less than 11 samples), if the resulting annual 98th percentile value or resulting 24-hour standard design value (rounded according to the conventions of section 4.3 of this appendix) is greater than the level of the standard.

(b) The use of less than complete data is subject to the approval of EPA which may consider factors such as monitoring site closures/moves, monitoring diligence, and nearby concentrations in determining whether to use such data.

(c) The equations for calculating the 24-hour standard design values are given in section 4.5 of this appendix.

4.3 *Rounding Conventions.* For the purposes of comparing calculated values 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 $PM_{2.5}$ standard design values shall be rounded to the nearest 0.1 μg/m^3 (decimals 0.05 and greater are rounded up to the next 0.1, and any decimal lower than 0.05 is rounded down to the nearest 0.1).

(b) 24-hour $PM_{2.5}$ standard design values shall be rounded to the nearest 1 μg/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

$$\overline{X}_{q,y,s} = \frac{1}{n_q}\sum_{i=1}^{n_q} X_{i,q,y,s}$$

Where:

$\bar{x}_{q,\,y,\,s}$ = the mean for quarter q of year y for site s;

n_q = the number of monitored values in the quarter; and

$x_{i,\,q,\,y,\,s}$ = the i^{th} value in quarter q for year y for site s.

(b) Equation 2 of this appendix is then used to calculate the site annual mean:

Equation 2

$$\overline{X}_{y,s} = \frac{1}{4}\sum_{q=1}^{4} \overline{X}_{q,y,s}$$

Where:

$\bar{x}_{y,s}$ = the annual mean concentration for year y (y = 1, 2, or 3) and for site s; and

$\bar{x}_{q,y,s}$ = the mean for quarter q of year y for site s.

(c) If spatial averaging is utilized, the site-based annual means will then be averaged together to derive the spatially averaged annual mean using equation 3 of this appendix. Otherwise (i.e., for single site comparisons), skip to equation 4.b of this appendix.

Equation 3

$$\bar{x}_y = \frac{1}{n_s}\sum_{s=1}^{n_s}\bar{x}_{y,s}$$

Where:

$\bar{x}_y$ = the spatially averaged mean for year y,
$\bar{x}_{y,s}$ = the annual mean for year y and site s, and
n_s = the number of sites designated to be averaged.

(d) The annual standard design value is calculated using equation 4A of this appendix when spatial averaging and equation 4B of this appendix when not spatial averaging:

Equation 4A

When spatial averaging

$$\bar{\bar{x}} = \frac{1}{3}\sum_{y=1}^{3}\bar{x}_y$$

Equation 4B

When not spatial averaging

$$\bar{\bar{x}} = \frac{1}{3}\sum_{y=1}^{3}\bar{x}_{y,s}$$

Where:

$\bar{\bar{x}}$ = the annual standard design value (the spatially averaged annual standard design value for equation 4A of this appendix and the single site annual standard design value for equation 4B of this appendix); and
x_y = the spatially averaged annual mean for year y (result of equation 3 of this appendix) when spatial averaging is used, or
$\bar{x}_{y,s}$ = the annual mean for year y and site s (result of equation 2 of this appendix) when spatial averaging is not used.

(e) The annual standard design value is rounded according to the conventions in section 4.3 of this appendix before a comparison with the standard is made.

4.5 *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. Equation 5 of this appendix shall be used to compute annual 98th percentile values, except that where a site operates on an approved seasonal sampling schedule, equation 6 of this appendix shall be used instead. Seasonal sampling, when approved, will be implemented in periods of calendar quarters or months; seasonal sampling seasons shall not divide months. Calculations of all annual 98th percentile values are based on the *applicable* number of samples (as described below), rather than on the *actual* number of samples. For the 24-hour NAAQS, credit will not be granted for more samples than the maximum number of scheduled sampling days in the sampling period. For each month, the *applicable* number of samples is the lower of the *actual* number of samples and the scheduled number of samples. The applicable number of samples for a year is the sum of the twelve monthly ''applicable number of samples'; the applicable number of samples for a season is the sum of the corresponding monthly ''applicable number of samples''. 98th percentile values shall be calculated as in equations 5 or 6 of this appendix using the *applicable* number of samples for the year or season. [The *applicable number of samples* will determine how deep to go into the data distribution, but all samples (scheduled or not) will be considered when making the percentile assignment.]

(1) *Regular formula for computing annual 98th percentile values.* Sort all the daily values from a particular site and year by ascending value. (For example: (x[1], x[2], x[3], * * *, x[n]). In this case, x[1] is the smallest number and x[n] is the largest value.) The 98th percentile is determined from this sorted series of daily values which is ordered from the lowest to the highest number. Compute (0.98) × (an) as the number ''i.d'', where 'an' is the annual applicable number of samples, ''i'' is the integer part of the result, and ''d'' is the decimal part of the result. The 98th percentile value for year y, $P_{0.98,y}$, is calculated using equation 5 of this appendix:

Equation 5

$$P_{0.98,y} = X_{[j+1]}$$

Where:

$P_{0.98,y}$ = 98th percentile for year y;
x[i+1] = the (i+1)th number in the ordered series of numbers; and
i = the integer part of the product of 0.98 and an.

(2) *Formula for computing annual 98th percentile values when sampling frequencies are seasonal.* Calculate the annual 98th percentiles by determining the smallest measured concentration, x, that makes *W(x)* greater than 0.98 using equation 6 of this appendix:

Equation 6

$$W(x) = \frac{d_{High}}{d_{High}+d_{Low}}F_{High}(x) + \frac{d_{Low}}{d_{High}+d_{Low}}F_{Low}(x)$$

Where:

d_{High} = number of calendar days in the ''High'' season;
d_{Low} = number of calendar days in the ''Low'' season;
$d_{High} + d_{Low}$ = days in a year; and

$$F_a(x) = \frac{\text{number of samples in season a that are} \le x}{\text{applicable number of samples in season a}}$$

Such that ''a'' can be either ''High'' or ''Low'' ''x'' is the measured concentration; and ''$d_{High}/(d_{High} + d_{Low})$ and $d_{Low}/(d_{High} + d_{Low})$'' are constant and are called seasonal ''weights.''

(b) The 24-hour standard design value is then calculated by averaging the annual 98th percentiles using equation 7 of this appendix:

Equation 7

$$P_{0.98} = \frac{\sum_{y=1}^{3} P_{0.98,y}}{3}$$

(c) The 24-hour standard design value (3-year average 98th percentile) is rounded according to the conventions in section 4.3 of this appendix before a comparison with the standard is made.

7. Appendix O to part 50 is added to read as follows:

Appendix O to Part 50—Reference Method for the Determination of Coarse Particulate Matter as $PM_{10-2.5}$ in the Atmosphere

1.0 *Applicability and Definition.*

1.1 This method provides for the measurement of the mass concentration of coarse particulate matter ($PM_{10-2.5}$) in ambient air over a 24-hour period for purposes of determining whether the primary and secondary NAAQS for coarse particulate matter specified in § 50.13 of this chapter are met.

1.2 For the purpose of this method, $PM_{10-2.5}$ is defined as particulate matter having an aerodynamic diameter in the nominal range of 2.5 to 10 micrometers, inclusive.

1.3 For this reference method, $PM_{10-2.5}$ concentrations shall be measured as the arithmetic difference between separate but concurrent, collocated measurements of PM_{10} and $PM_{2.5}$, where the PM_{10} measurements are obtained with a specially approved sampler, identified as a ''PM_{10c} sampler,'' that meets more demanding performance requirements than conventional PM_{10} samplers described in appendix J of this part. Measurements obtained with a PM_{10c} sampler are identified as ''PM_{10c} measurements'' to distinguish them from conventional PM_{10} measurements obtained with conventional PM_{10} samplers. Thus, $PM_{10-2.5} = PM_{10c} - PM_{2.5}$.

1.4 The PM_{10c} and $PM_{2.5}$ gravimetric measurement processes are considered to be nondestructive, and the PM_{10c} and $PM_{2.5}$ samples obtained in the $PM_{10-2.5}$ measurement process can be subjected to subsequent physical or chemical analyses.

1.5 Quality assessment procedures are provided in part 58, appendix A of this chapter. The quality assurance procedures and guidance provided in reference 1 in section 13 of this appendix, although written specifically for $PM_{2.5}$, are generally applicable for PM_{10c}, and, hence, $PM_{10-2.5}$ measurements under this method, as well.

1.6 A method based on specific model PM_{10c} and $PM_{2.5}$ samplers will be considered a reference method for purposes of part 58 of this chapter only if:

(a) The PM_{10c} and $PM_{2.5}$ samplers and the associated operational procedures meet the requirements specified in this appendix and all applicable requirements in part 53 of this chapter, and

(b) The method based on the specific samplers and associated operational procedures has been designated as a reference method in accordance with part 53 of this chapter.

1.7 $PM_{10-2.5}$ methods based on samplers that meet nearly all specifications set forth in this method but have one or more significant but minor deviations or modifications from those specifications may be designated as ''Class I'' equivalent methods for $PM_{10-2.5}$ in accordance with part 53 of this chapter.

1.8 $PM_{2.5}$ measurements obtained incidental to the $PM_{10-2.5}$ measurements by this method shall be considered to have been obtained with a reference method for $PM_{2.5}$ in accordance with appendix L of this part.

1.9 PM_{10c} measurements obtained incidental to the $PM_{10-2.5}$ measurements by this method shall be considered to have been obtained with a reference method for PM_{10} in accordance with appendix J of this part, provided that:

(a) The PM_{10c} measurements are adjusted to EPA reference conditions (25°C and 760 millimeters of mercury), and

(b) Such PM_{10c} measurements are appropriately identified to differentiate them from PM_{10} measurements obtained with other (conventional) methods for PM_{10} designated in accordance with part 53 of this chapter as reference or equivalent methods for PM_{10}.

2.0 *Principle.*

2.1 Separate, collocated, electrically powered air samplers for PM_{10c} and $PM_{2.5}$ concurrently draw ambient air at identical, constant volumetric flow rates into specially shaped inlets and through one or more inertial particle size separators where the suspended particulate matter in the PM_{10} or $PM_{2.5}$ size range, as applicable, is separated for collection on a polytetrafluoroethylene (PTFE) filter over the specified sampling period. The air samplers and other aspects of this $PM_{10-2.5}$ reference method are specified either explicitly in this appendix or by reference to other applicable regulations or quality assurance guidance.

2.2 Each PM_{10c} and $PM_{2.5}$ sample collection filter is weighed (after moisture and temperature conditioning) before and after sample collection to determine the net weight (mass) gain due to collected PM_{10c} or $PM_{2.5}$. The total volume of air sampled by each sampler is determined by the sampler from the measured flow rate at local ambient temperature and pressure and the sampling time. The mass concentrations of both PM_{10c} and $PM_{2.5}$ in the ambient air are computed as the total mass of collected particles in the PM_{10} or $PM_{2.5}$ size range, as appropriate, divided by the total volume of air sampled by the respective samplers, and expressed in micrograms per cubic meter (μ/m^3)at local temperature and pressure conditions. The mass concentration of $PM_{10-2.5}$ is determined as the PM_{10c} concentration value less the corresponding, concurrently measured $PM_{2.5}$ concentration value.

2.3 Most requirements for $PM_{10-2.5}$ reference methods are similar or identical to the requirements for $PM_{2.5}$ reference methods as set forth in appendix L to this part. To insure uniformity, applicable appendix L requirements are incorporated herein by reference in the sections where indicated rather than repeated in this appendix.

3.0 *$PM_{10-2.5}$ Measurement Range.*

3.1 *Lower concentration limit.* The lower detection limit of the mass concentration measurement range is estimated to be approximately 3 $\mu g/m^3$, based on the observed precision of $PM_{2.5}$ measurements in the national $PM_{2.5}$ monitoring network, the probable similar level of precision for the matched PM_{10c} measurements, and the additional variability arising from the differential nature of the measurement process. This value is provided merely as a guide to the significance of low $PM_{10-2.5}$ concentration measurements.

3.2 *Upper concentration limit.* The upper limit of the mass concentration range is determined principally by the PM_{10c} filter mass loading beyond which the sampler can no longer maintain the operating flow rate within specified limits due to increased pressure drop across the loaded filter. This upper limit cannot be specified precisely because it is a complex function of the ambient particle size distribution and type, humidity, the individual filter used, the capacity of the sampler flow rate control system, and perhaps other factors. All PM_{10c} samplers are estimated to be capable of measuring 24-hour mass

concentrations of at least 200 μg/m^3 while maintaining the operating flow rate within the specified limits. The upper limit for the $PM_{10-2.5}$ measurement is likely to be somewhat lower because the $PM_{10-2.5}$ concentration represents only a fraction of the PM_{10} concentration.

3.3 *Sample period.* The required sample period for $PM_{10-2.5}$ concentration measurements by this method shall be at least 1,380 minutes but not more than 1,500 minutes (23 to 25 hours), and the start times of the $PM_{2.5}$ and PM_{10c} samples are within 10 minutes and the stop times of the samples are also within 10 minutes (see section 10.4 of this appendix). However, a $PM_{10-2.5}$ measured concentration where the actual sample period for PM_{10c} sample is less than 1,380 minutes, but the corresponding $PM_{2.5}$ sample period is at least 1,380 minutes, may be used as if it were a valid concentration measurement for the specific purpose of determining an exceedance of the NAAQS. For this purpose, the measured PM_{10c} concentration is determined as the PM_{10c} mass collected divided by the actual sampled air volume, multiplied by the actual number of minutes in the PM_{10c} sample period and divided by 1,440; the $PM_{10-2.5}$ concentration is then calculated as prescribed in section 12.4 of this appendix. This value represents the minimum nominal $PM_{10-2.5}$ concentration that could have been measured for the full sample period. Accordingly, if the value thus calculated is high enough to be an exceedance, such an exceedance would be a valid exceedance for the sample period. When reported to AQS, this data value should receive a special data qualifier code to identify it as having an insufficient sample period.

4.0 *Accuracy (bias).*

4.1 Because the size, density, and volatility of the particles making up ambient particulate matter vary over wide ranges and the mass concentration of particles varies with particle size, it is difficult to define the accuracy of $PM_{10-2.5}$ measurements in an absolute sense. Furthermore, generation of credible $PM_{10-2.5}$ concentration standards at field monitoring sites and presenting or introducing such standards reliably to samplers or monitors to assess accuracy is still generally impractical. The accuracy of $PM_{10-2.5}$ measurements is therefore defined in a relative sense as bias, referenced to measurements provided by other reference method samplers or based on flow rate verification audits or checks, or on other performance evaluation procedures.

4.2 Measurement system bias for monitoring data is assessed according to the procedures and schedule set forth in part 58, appendix A of this chapter. The goal for the measurement uncertainty (as bias) for monitoring data is defined in part 58, appendix A of this chapter as an upper 95 percent confidence limit for the absolute bias of 15 percent. Reference 1 in section 13 of this appendix provides additional information and guidance on flow rate accuracy audits and assessment of bias.

5.0 *Precision.*

5.1 Tests to establish initial measurement precision for each sampler of the reference method sampler pair are specified as a part of the requirements for designation as a reference method under part 53 of this chapter.

5.2 Measurement system precision is assessed according to the procedures and schedule set forth in appendix A to part 58 of this chapter. The goal for acceptable measurement uncertainty, as precision, of monitoring data is defined in part 58, appendix A of this chapter as an upper 95 percent confidence limit for the coefficient of variation (CV) of 15 percent. Reference 1 in section 13 of this appendix provides additional information and guidance on this requirement.

6.0 *Filters for PM_{10c} and $PM_{2.5}$ Sample Collection.* Sample collection filters for both PM_{10c} and $PM_{2.5}$ measurements shall be identical and as specified in section 6 of appendix L to this part.

7.0 *Sampler.* The $PM_{10-2.5}$ sampler shall consist of a PM_{10c} sampler and a $PM_{2.5}$ sampler, as follows:

7.1 The $PM_{2.5}$ sampler shall be as specified in section 7 of appendix L to this part.

7.2 The PM_{10c} sampler shall be of like manufacturer, design, configuration, and fabrication to that of the $PM_{2.5}$ sampler and as specified in section 7 of appendix L to this part, except as follows:

7.2.1 The particle size separator specified in section 7.3.4 of appendix L to this part shall be eliminated and replaced by a downtube extension fabricated as specified in Figure O–1 of this appendix.

7.2.2 The sampler shall be identified as a PM_{10c} sampler on its identification label required under § 53.9(d) of this chapter.

7.2.3 The average temperature and average barometric pressure measured by the sampler during the sample period, as described in Table L–1 of appendix L to this part, need not be reported to EPA's AQS data base, as required by section 7.4.19 and Table L–1 of appendix L to this part, provided such measurements for the sample period determined by the associated $PM_{2.5}$ sampler are reported as required.

7.3 In addition to the operation/instruction manual required by section 7.4.18 of appendix L to this part for each sampler, supplemental operational instructions shall be provided for the simultaneous operation of the samplers as a pair to collect concurrent PM_{10c} and $PM_{2.5}$ samples. The supplemental instructions shall cover any special procedures or guidance for installation and setup of the samplers for $PM_{10-2.5}$ measurements, such as synchronization of the samplers' clocks or timers, proper programming for collection of concurrent samples, and any other pertinent issues related to the simultaneous, coordinated operation of the two samplers.

7.4 Capability for electrical interconnection of the samplers to simplify sample period programming and further ensure simultaneous operation is encouraged but not required. Any such capability for interconnection shall not supplant each sampler's capability to operate independently, as required by section 7 of appendix L of this part.

8.0 *Filter Weighing.*

8.1 Conditioning and weighing for both PM_{10c} and $PM_{2.5}$ sample filters shall be as specified in section 8 of appendix L to this part. See reference 1 of section 13 of this appendix for additional, more detailed guidance.

8.2 Handling, conditioning, and weighing for both PM_{10c} and $PM_{2.5}$ sample filters shall be matched such that the corresponding PM_{10c} and $PM_{2.5}$ filters of each filter pair receive uniform treatment. The PM_{10c} and $PM_{2.5}$ sample filters should be weighed on the same balance, preferably in the same weighing session and by the same analyst.

8.3 Due care shall be exercised to accurately maintain the paired relationship of each set of concurrently collected PM_{10c} and $PM_{2.5}$ sample filters and their net weight gain data and to avoid misidentification or reversal of the filter samples or weight data. See Reference 1 of section 13 of this appendix for additional guidance.

9.0 *Calibration.* Calibration of the flow rate, temperature measurement, and pressure measurement systems for both the PM_{10c} and $PM_{2.5}$ samplers shall be as specified in section 9 of appendix L to this part.

10.0 *$PM_{10-2.5}$ Measurement Procedure.*

10.1 The PM_{10c} and $PM_{2.5}$ samplers shall be installed at the monitoring site such that their ambient air inlets differ in vertical height by not more than 0.2

meter, if possible, but in any case not more than 1 meter, and the vertical axes of their inlets are separated by at least 1 meter but not more than 4 meters, horizontally.

10.2 The measurement procedure for PM_{10c} shall be as specified in section 10 of appendix L to this part, with ''PM_{10c}'' substituted for ''$PM_{2.5}$'' wherever it occurs in that section.

10.3 The measurement procedure for $PM_{2.5}$ shall be as specified in section 10 of appendix L to this part.

10.4 For the $PM_{10-2.5}$ measurement, the PM_{10c} and $PM_{2.5}$ samplers shall be programmed to operate on the same schedule and such that the sample period start times are within 5 minutes and the sample duration times are within 5 minutes.

10.5 Retrieval, transport, and storage of each PM_{10c} and $PM_{2.5}$ sample pair following sample collection shall be matched to the extent practical such that both samples experience uniform conditions.

11.0 *Sampler Maintenance.* Both PM_{10c} and $PM_{2.5}$ samplers shall be maintained as described in section 11 of appendix L to this part.

12.0 *Calculations.*

12.1 Both concurrent PM_{10c} and $PM_{2.5}$ measurements must be available, valid, and meet the conditions of section 10.4 of this appendix to determine the $PM_{10-2.5}$ mass concentration.

12.2 The PM_{10c} mass concentration is calculated using equation 1 of this section:

Equation 1

$$PM_{10c} = \left(W_f - W_i\right)/V_a$$

Where:

PM_{10c} = mass concentration of PM_{10c}, $\mu g/m^3$;

W_f, W_i = final and initial masses (weights), respectively, of the filter used to collect the PM_{10c} particle sample, μg;

V_a = total air volume sampled by the PM_{10c} sampler in actual volume units measured at local conditions of temperature and pressure, as provided by the sampler, m^3.

Note: Total sample time must be between 1,380 and 1,500 minutes (23 and 25 hrs) for a fully valid PM_{10c} sample; however, see also section 3.3 of this appendix.

12.3 The $PM_{2.5}$ mass concentration is calculated as specified in section 12 of appendix L to this part.

12.4 The $PM_{10-2.5}$ mass concentration, in $\mu g/m^3$, is calculated using Equation 2 of this section:

Equation 2

$$PM_{10-2.5} = PM_{10c} - PM_{2.5}$$

13.0 *Reference.*

1. Quality Assurance Guidance Document 2.12. Monitoring $PM_{2.5}$ in Ambient Air Using Designated Reference or Class I Equivalent Methods. Draft, November 1998 (or later version or supplement, if available). Available at: *http://www.epa.gov/ttn/amtic/pgqa.html.*

14.0 *Figures.*

Figures O–1 is included as part of this appendix O.

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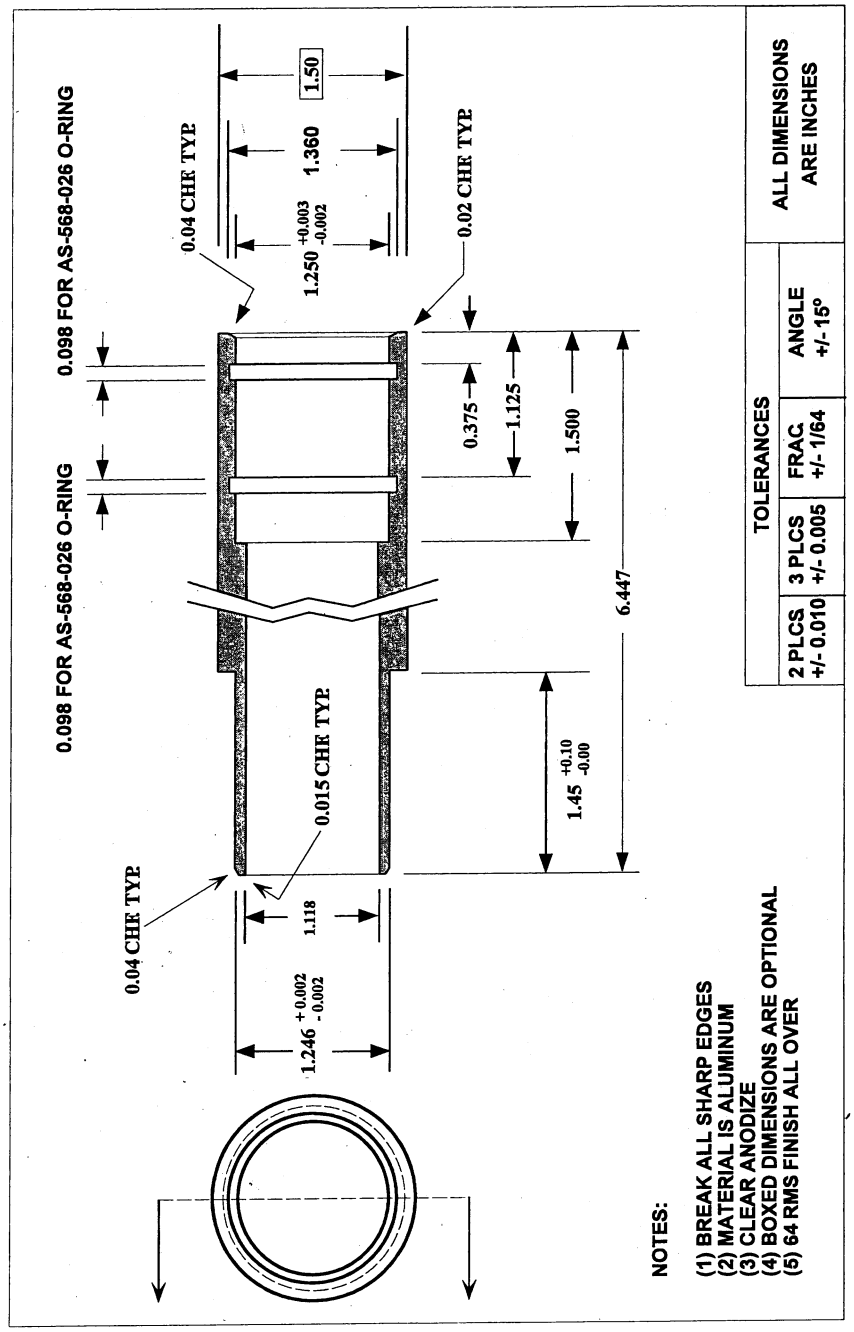

FIGURE O-1.DOWNTUBEEXTENSION

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8. Appendix P is added to part 50 to read as follows:

Appendix P to Part 50—Interpretation of the National Ambient Air Quality Standards for $PM_{10-2.5}$

1.0 *General.*

(a) This appendix explains the data handling conventions and computations necessary for determining when the 24-hour primary and secondary national ambient air quality standards (NAAQS) for $PM_{10-2.5}$ specified in § 50.13 of this part are met. $PM_{10-2.5}$, defined as particles with an aerodynamic diameter more than a nominal 2.5 micrometers and less than or equal to a nominal 10.0 micrometers, is measured in the ambient air by a Federal reference method (FRM) based on appendix O 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. Data handling and computation procedures to be used in making comparisons between reported $PM_{10-2.5}$ concentrations and the levels of the $PM_{10-2.5}$ NAAQS are specified in the following sections.

(b) Data resulting from exceptional events, for example structural fires or high winds, may require special consideration. In some cases, it may be appropriate to exclude these data in whole or part because they could result in inappropriate values to compare with the levels of the $PM_{10-2.5}$ NAAQS. In other cases, it may be more appropriate to retain the data for comparison with the levels of the $PM_{10-2.5}$ NAAQS and then allow EPA to formulate the appropriate regulatory response.

(c) The terms used in this appendix are defined as follows:

Daily values for $PM_{10-2.5}$ refers to the 24-hour average concentrations of $PM_{10-2.5}$ calculated (averaged) or measured from midnight to midnight (local standard time).

Designated monitors are those monitoring sites designated in a State or local agency PM

Monitoring Network Description in accordance with part 58 of this chapter.

Design values are the metrics that are compared to the NAAQS levels to determine compliance and are comprised of the 3-year average of annual 98th percentile 24-hour average values recorded at each monitoring location, are referred to as ''24-hour standard design values,'' and are calculated as shown in section 3 of this appendix.

Geographic area design value (e.g., one for a county or defined metropolitan area) is the highest valid site-level design value in that area.

98th percentile means the daily value out of a year of $PM_{10-2.5}$ monitoring data below which 98 percent of all values in the group fall.

Year refers to a calendar year.

2.0 *Requirements for data used for comparisons with the $PM_{10-2.5}$ NAAQS and data reporting considerations.*

(a) Appendix D to part 58 of this chapter specifies which monitors are eligible for making comparisons with the $PM_{10-2.5}$ standards.

(b) Except as otherwise provided in this appendix, only valid FRM/FEM $PM_{10-2.5}$ data required to be submitted to EPA's Air Quality System (AQS) shall be used in the design value calculations.

(c) Raw concentration data (typically hourly for automated continuous instruments and daily for manual, filter-based instruments) shall be reported to AQS in micrograms per cubic meter ($\mu g/m^3$) to one decimal place, with additional digits to the right being truncated.

(d) Block 24-hour averages shall be computed from available hourly $PM_{10-2.5}$ concentration data for each corresponding day of the year and the result shall be stored in the first, or start, hour (i.e., midnight, hour ''0'') of the 24-hour period. A 24-hour average shall be considered valid if at least 75 percent (i.e., 18) of the hourly averages for the 24-hour period are available. In the event that less than all 24 hourly averages are available (i.e., less than 24, but at least 18), the 24-hour average shall be computed on the basis of the hours available using the number of available hours as the divisor (e.g., 19). 24-hour periods with 7 or more missing hours shall be considered valid if, after substituting zero for the missing hourly concentrations, the 24-hour average concentration is greater than the level of the standard. The computed 24-hour average $PM_{10-2.5}$ concentrations shall be reported to one decimal place (the insignificant digits to the right of the third decimal place are truncated, consistent with the data handling procedures for the reported data).

(e) All calculations shall be implemented on a site-level basis. Site level data shall be processed as follows:

(1) The default dataset for a site shall consist of the measured concentrations recorded from the designated primary FRM/FEM monitor. The primary monitor shall be designated in the appropriate State or local agency PM Monitoring Network Description.

(2) Data for the primary monitor shall be augmented as necessary with data from collocated FRM/FEM monitors. If a valid 24-hour measurement is not produced from the primary monitor for a particular required sampling day, but a valid sample is generated by a collocated FRM/FEM instrument (and recorded in AQS), then that collocated value shall be considered part of the site data record. If more than one valid collocated FRM/FEM value is available, the average of those valid collocated values shall be used as the site value for the day.

3.0 *Comparisons with the $PM_{10-2.5}$ NAAQS.*

3.1 *24-Hour $PM_{10-2.5}$ NAAQS.*

(a) The 24-hour $PM_{10-2.5}$ NAAQS is met when the 24-hour standard design value at each monitoring site is less than or equal to 70 $\mu g/m^3$. This comparison shall be based on 3 consecutive, complete years of air quality data. A year meets data completeness requirements when at least 75 percent of the scheduled sampling days for each quarter have valid data. However, years or 3-year periods with high concentrations shall be considered valid, notwithstanding quarters with less than complete data (even quarters with less than 11 samples), if the resulting annual 98th percentile value or resulting 24-hour standard design value (rounded according to the conventions of section 3.2 of this appendix) is greater than the level of the standard.

(b) The use of less than complete data is subject to the approval of EPA, which may consider factors such as monitoring site closures/moves, monitoring diligence, and nearby concentrations in determining whether to use such data.

(c) The equations for calculating the 24-hour standard design values are given in section 3.4 of this appendix.

3.2 *Rounding Conventions.* For the purposes of comparing calculated values to the applicable level of the standard, it is necessary to round the final results of the calculations described in sections 3.4 of this appendix. 24-hour $PM_{10-2.5}$ standard design values shall be rounded to the nearest 1 $\mu g/m^3$ (decimals 0.5 and greater are rounded up to nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

3.3 *Sampling Frequency Considerations.* Section 58.12 of this chapter specifies the required minimum frequency of sampling for $PM_{10-2.5}$. Exceptions to the specified sampling frequencies, such as a reduced frequency during a season of expected low concentrations (i.e., ''seasonal sampling''), are subject to the approval of EPA. Annual 98th percentile values are to be calculated according to equation 2 in section 3.4 of this appendix when a site operates on a ''seasonal sampling'' schedule.

3.4 *Equations for the 24-Hour $PM_{10-2.5}$ NAAQS.*

(a) When the data for a particular site and year meet the data completeness requirements in section 3.1 of this appendix, calculation of the 98th percentile is accomplished by the steps provided in paragraphs (a) through (c) of this section. Equation 1 of this appendix shall be used to compute annual 98th percentile values, except that where a site operates on an approved seasonal sampling schedule, equation 2 of this appendix shall be used instead. Seasonal sampling, when approved, will be implemented in periods of calendar quarters or months; seasonal sampling seasons shall not divide months. Calculations of all annual 98th percentile values are based on the *applicable* number of samples (as described below), rather than on the *actual* number of samples. For the 24-hour NAAQS, credit will not be granted for more samples than the maximum number of scheduled sampling days in the sampling period. For each month, the applicable number of samples is the lower of the actual number of samples and the scheduled number of samples. The applicable number of samples for a year is the sum of the twelve monthly ''applicable number of samples;'' the applicable number of samples for a season is the sum of the corresponding monthly ''applicable number of samples.'' 98th percentile values shall be calculated as in equations 5 or 6 of this appendix using the applicable number of samples for the year or season. The applicable number of samples will determine how deep to go into the data distribution, but all samples (scheduled or not) will be considered when making the percentile assignment.

(1) *Regular formula for computing annual 98th percentile values.* Sort all the daily values from a particular site and year by ascending value. (For example: x[1], x[2], x[3], * * *, x[n]. In this case, x[1] is the smallest number and x[n] is the largest value.) The 98th percentile is determined from this sorted series of daily values. Compute (0.98) x (an) as the number ''i.d,'' where ''an'' is the applicable number of samples, ''i'' is the integer part of the result, and ''d'' is the decimal part of the result. The 98th percentile value for year y, $P_{0.98,y}$, is calculated using equation 1 of this appendix:

Equation 1

$$P_{0.98,y} = X_{[j+1]}$$

Where:

$P_{0.98,y}$ = 98th percentile for year y;

x[i+1] = the (i+1)th number in the ascending ordered series of numbers for year y; and

i = the integer part of the product of 0.98 and an.

(2) *Formula for computing annual 98th percentile values when sampling frequencies are seasonal.* Calculate the annual 98th percentiles by determining the smallest measured concentration, x, that makes *W(x)* greater than 0.98 using equation 2 of this appendix:

Equation 2

$$W(x) = \frac{d_{High}}{d_{High} + d_{Low}} F_{High}(x) + \frac{d_{Low}}{d_{High} + d_{Low}} F_{Low}(x),$$

Where:

d_{High} = number of calendar days in the ''High'' season;

d_{Low} = number of calendar days in the ''Low'' season;

$d_{High} + d_{Low}$ = days in a year); and

$$F_a(x) = \frac{\text{number of samples in season a that are} \leq x}{\text{applicable number of samples in season a}}$$

Such that ''a'' can be either ''High'' or ''Low;'' ''x'' is the measured concentration; and ''$d_{High}/(d_{High} + d_{Low})$ and $d_{Low}/(d_{High} + d_{Low})$'' are constant and are called seasonal ''weights.''

(b) The 3-year average 98th percentile (24-hour standard design value) is then calculated by averaging the annual 98th percentiles using equation 3 of this appendix:

Equation 3

$$P_{0.98} = \frac{\sum_{y=1}^{3} P_{0.98,y}}{3}$$

(c) The 24-hour standard design value (3-year average 98th percentile) is rounded according to the conventions in section 3.2 of this appendix before a comparison with the standard is made.

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