ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[EPA–HQ–OAR–2001–0017; FRL–8225–3]

RIN 2060–AI44

National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Based on its review of the air quality criteria and national ambient air quality standards (NAAQS) for particulate matter (PM), EPA is making revisions to the primary and secondary NAAQS for PM to provide increased protection of public health and welfare, respectively. With regard to primary standards for fine particles (generally referring to particles less than or equal to 2.5 micrometers (µm) in diameter, $PM_{2.5}$), EPA is revising the level of the 24-hour $PM_{2.5}$ standard to 35 micrograms per cubic meter (µg/m³) and retaining the level of the annual $PM_{2.5}$ standard at 15µg/m³. With regard to primary standards for particles generally less than or equal to 10µm in diameter (PM_{10}), EPA is retaining the 24-hour PM_{10} and revoking the annual PM_{10} standard. With regard to secondary PM standards, EPA is making them identical in all respects to the primary PM standards, as revised.

DATES: This final rule is effective on December 18, 2006.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2001–0017. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.* confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *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. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is 202–566–1741. The telephone number for the Public Reading Room is 202–566–1744.

The EPA Docket Center suffered damage due to flooding during the last week of June 2006. The Docket Center is continuing to operate. However, during the cleanup, there will be temporary changes to Docket Center telephone numbers, addresses, and hours of operation for people who wish to visit the Public Reading Room to view documents. Consult EPA's **Federal Register** notice at 71 FR 38147 (July 5, 2006) or the EPA Web site at *www.epa.gov/epahome/dockets.htm* for current information on docket status, locations and telephone numbers.

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I. Background

A. Summary of Revisions to the PM NAAQS

Based on its review of the air quality criteria and national ambient air quality standards (NAAQS) for particulate matter (PM), EPA is making revisions to the primary and secondary NAAQS for PM to provide increased protection of public health and welfare, respectively.

With regard to primary standards for fine particles (generally referring to particles less than or equal to 2.5 micrometers (μm) in diameter, $PM_{2.5}$), EPA is revising 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 retaining 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 is revising the form of the annual $PM_{2.5}$ standard with regard to the criteria for spatial averaging, such that averaging across monitoring sites is allowed if the annual mean concentration at each monitoring site is within 10 percent of the spatially averaged annual mean, and the daily values for each monitoring site pair yield a correlation coefficient of at least 0.9 for each calendar quarter.

With regard to primary standards for particles generally less than or equal to 10μm in diameter (PM_{10}), EPA is retaining the 24-hour PM_{10} standard to protect against the health effects associated with short-term exposure to coarse particles (including hospital admissions for cardiopulmonary diseases, increased respiratory symptoms and possibly premature mortality). Given that the available evidence does not suggest an association between long-term exposure to coarse particles at current ambient levels and health effects, EPA is revoking the annual PM_{10} standard.

With regard to secondary PM standards, EPA is revising the current 24-hour $PM_{2.5}$ secondary standard by making it identical to the revised 24-hour $PM_{2.5}$ primary standard, retaining the annual $PM_{2.5}$ and 24-hour PM_{10} secondary standards, and revoking the annual PM_{10} secondary standard. This suite of secondary PM standards is intended to provide protection against PM-related public welfare effects, including visibility impairment, effects on vegetation and ecosystems, and materials damage and soiling.

B. 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]

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 a background concentration level (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*

[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.''

Industries Association v. *EPA, supra,* 647 F.2d at 1161–62.

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 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).

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 in accordance with [the provisions in section 109(b) on primary and secondary standards].'' This includes the authority to modify or revoke a standard or standards, as appropriate under these provisions. 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.

C. Overview of Air Quality Criteria and Standards Review 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.

More specifically, the PM that is the subject of the air quality criteria and standards reviews includes both fine particles and thoracic coarse particles, which are considered as separate subclasses of PM pollution based in part on long-established information on differences in sources, properties, and atmospheric behavior between fine and coarse particles (EPA, 2005, 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, 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 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 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 aerodynamic diameter less than or equal to 2.5 µm), and using PM_{10} as the indicator for purposes of regulating the coarse fraction of PM_{10} (referred to as thoracic coarse particles or coarse-fraction particles; generally including particles with a nominal 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 µg/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 µg/m^3, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area. 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) (''ATA I'') rehearing granted in part and denied in part, 195 F.3d 4 (D.C. Cir. 1999) (''ATA II''), 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 that EPA's justification for the use of PM_{10} as an indicator for coarse particles was arbitrary. 175 F.3d at 1054–55. Pursuant to the court's decision, EPA removed the vacated 1997 PM_{10} standards from the 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 panel held (over one judge's dissent) 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 and D.C. Circuit precedent, 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 (2001). 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) (''*ATA III*'').

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. The approach in this review continues to address fine and thoracic coarse particles separately. This approach has been reinforced by new information that has advanced 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, 2004a, section 3.2.3). See also *ATA I,* 175 F. 3d at 1053–54, 1055–56 (EPA justified in establishing separate standards for fine and thoracic coarse particles).

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 and the broader scientific community 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. 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 (EPA, 2004a). 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 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). The final Staff Paper was reissued in December 2005 to add CASAC's final letter as an attachment (EPA, 2005).

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.

On December 20, 2005, EPA issued its proposed decision to revise the NAAQS for PM (71 FR 2620, January 17, 2006) (henceforth ''proposal''). In the proposal, EPA identified proposed revisions to the standards, based on the air quality criteria for PM, and to related data handling conventions and federal reference methods for monitoring PM. The proposal solicited public comments on alternative primary and secondary standards and related matters.

The EPA held several public hearings across the country to provide direct opportunities for public comment on the proposed revisions to the PM NAAQS. On March 8, 2006, EPA held three concurrent 12-hour public hearings in Philadelphia, PA; Chicago, IL; and San Francisco, CA. At these public hearings, EPA heard testimony

[3] The HEI is a non-profit, independent research institute jointly and equally funded by EPA and multiple industries that conducts research on the health effects of air pollution.

from 280 individuals representing themselves or specific interested organizations.

More than 120,000 comments were received from members of the public and various interested groups on the proposed revisions to the PM NAAQS by the close of the public comment period on April 17, 2006. CASAC provided additional advice to EPA in a letter to the Administrator requesting reconsideration of CASAC's recommendations for both the primary and secondary $PM_{2.5}$ standards as well as standards for thoracic coarse particles (Henderson, 2006). Major issues raised in the public comments are discussed throughout the preamble of this final action. A comprehensive summary of all significant comments, along with EPA's responses (henceforth ''Response to Comments''), can be found in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2001–0017).

In the proposal, EPA recognized that there were a number of new scientific studies on the health effects of PM that had been published recently and therefore were not included in the Criteria Document.[4] The EPA committed to conduct a review and assessment of any significant ''new'' studies, including studies submitted during the public comment period. The purpose of this review was to ensure that the Administrator was fully aware of the ''new'' science before making a final decision on whether to revise the current PM NAAQS. The EPA screened and surveyed the recent literature, including studies submitted during the public comment period, and conducted a provisional assessment (EPA, 2006a) that places the results of those studies of potentially greatest policy relevance in the context of the findings of the Criteria Document.

The provisional assessment found that the ''new'' studies expand the scientific information and provide important insights on the relationship between PM exposure and health effects of PM. The provisional assessment also found that ''new'' studies generally strengthen the evidence that acute and chronic exposure to fine particles and acute exposure to thoracic coarse particles are associated with health effects; some of the ''new'' epidemiologic studies report effects in areas with lower concentrations of $PM_{2.5}$ or $PM_{10-2.5}$ than those in earlier reports; ''new'' toxicology and epidemiologic studies link various health effects with a range of fine particle sources and components; and ''new'' toxicology studies report effects of thoracic coarse particles but do not provide evidence to support distinguishing effects from exposure to urban and rural particles. Further, the provisional assessment found that the results reported in the studies do not dramatically diverge from previous findings, and, taken in context with the findings of the Criteria Document, the new information and findings do not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the Criteria Document.

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

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

This decision is consistent with EPA's practice in prior NAAQS reviews. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria. See *e.g.*, 36 FR 8186 (April 30, 1971) (EPA based original NAAQS for six pollutants on scientific studies discussed in air quality criteria documents and limited consideration of comments to those concerning validity of scientific basis); 38 FR 25678, 25679–25680 (September 14, 1973) (EPA revised air quality criteria for sulfur oxides to provide basis for reevaluation of secondary NAAQS). This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the Act concerning CASAC review of air quality criteria. EPA has consistently followed this approach. 52 FR 24634, 24637 (July 1, 1987) (after review by CASAC, EPA issued a post-proposal addendum to the PM Criteria Document, to address certain new scientific studies not included in the 1982 Criteria Document); 61 FR 25566, 25568 (May 22, 1996) (after review by CASAC, EPA issued a post-proposal supplement to the 1982 Criteria Document to address certain new health studies not included in the 1982 Criteria Document or 1986 Addendum). The EPA recently reaffirmed this approach in its decision not to revise the ozone NAAQS in 1993, as well as in its final decision on the PM NAAQS in the 1997 review. 58 FR 13008, 13013–13014 (March 9, 1993) (ozone review); 62 FR 38652, 38662 (July 18, 1997) (The EPA conducted a provisional assessment but based the final PM decision on studies and related information included in the air quality criteria that had been reviewed by CASAC).

As discussed in EPA's 1993 decision not to revise the NAAQS for ozone, new studies may sometimes be of such significance that it is appropriate to delay a decision on revision of NAAQS and to supplement the pertinent air quality criteria so the new studies can be taken into account (58 FR at 13013–13014, March 9, 1993). In the present case, the provisional assessment of recent studies concludes that, taken in context, the new information and findings do not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the Criteria

[4] For ease of reference, these studies will be referred to as ''new'' studies or ''new'' science, using quotation marks around the word *new.* Referring to studies that were published too recently to have been included in the 2004 Criteria Document as ''new'' studies is intended to clearly differentiate such studies from those that have been published since the last review and are included in the 2004 Criteria Document (these studies are sometimes referred to as new (without quotation marks) or more recent studies, to indicate that they were not included in the 1996 Criteria Document and thus are newly available in this review).

Document. For this reason, reopening the air quality criteria review would not be warranted even if there were time to do so under the court order governing the schedule for this rulemaking. Accordingly, EPA is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review. The EPA will consider the newly published studies for purposes of decision making in the next periodic review of the PM NAAQS, which will provide the opportunity to fully assess them through a more rigorous review process involving EPA, CASAC, and the public.

In order to facilitate a comprehensive and timely review of the newly available science, the Administrator has directed EPA staff to begin the next review of the PM NAAQS immediately.[5]

D. 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 under sections 160–169 of the CAA (42 U.S.C. 7470–7479) for these pollutants. In addition, the Act provides for nationwide reductions in emissions of these and other air pollutants through related programs, such as 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 and off-highway engines 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. 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 also 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) have also helped reduce carbon and nitrates, both of which are components of $PM_{2.5}$. 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. 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 further 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 1997 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.

In 2005, 39 nonattainment areas were designated as not attaining the $PM_{2.5}$ standards established in 1997. SIPs for these areas are due in April 2008. Nonattainment areas are required to attain the standards as ''expeditiously as practicable'' based on implementation of federal measures already in place and the adoption of other reasonable control strategies for sources located in the nonattainment area and state. The presumptive timeframe for attainment is within five years of designation, although EPA may approve extended attainment dates of an additional one to five years for areas with more serious problems.

Modeling done by EPA indicates that by 2010, 18 of the 39 currently designated nonattainment areas are projected to come into attainment with those standards just based on regulatory programs already in place, including CAIR, the Clean Diesel Rules, and other Federal measures. Between 2010 and 2015, further reductions in PM concentrations in the eastern U.S. are projected due to existing federal programs alone, on the order of 0.5 to 1.5 $\mu g/m^3$. All areas in the eastern U.S. will have lower $PM_{2.5}$ concentrations in 2015 relative to present-day conditions. In most cases, the predicted improvement in $PM_{2.5}$ ranges from 10 percent to 20 percent.

E. Summary of Proposed Revisions to the PM NAAQS

For reasons discussed in the proposal, the Administrator proposed to revise the current primary and secondary $PM_{2.5}$ and PM_{10} standards. With regard to the primary $PM_{2.5}$ standards, the Administrator proposed to revise the level of the 24-hour $PM_{2.5}$ standard to 35

[5] The EPA has recently conducted a review of the process by which the Agency performs periodic NAAQS reviews to identify ways in which the process could be strengthened and streamlined (EPA, 2006b). The EPA intends to incorporate recommendations from the NAAQS process review into the next PM NAAQS review.

μg/m³, and to revise the form of the annual $PM_{2.5}$ standard by changing the constraints on the optional 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. Related revisions for $PM_{2.5}$ data handling conventions and for the reference method for monitoring PM as $PM_{2.5}$ were also proposed.

With regard to the primary PM_{10} standards, the Administrator proposed to revise the current standards to provide more targeted protection from thoracic coarse particles that are of concern to public health. In part, the Administrator proposed to establish a new indicator for thoracic coarse particles in terms of $PM_{10-2.5}$, the definition of which included qualifications that identified both the mix of such particles that were provisionally determined to be of concern to public health, and were thus included in the indicator, and those for which currently available information was provisionally determined to be insufficient as a basis from which to infer a public health concern, and were thus excluded. More specifically, the proposed $PM_{10-2.5}$ indicator was 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 to exclude 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 Administrator also proposed that agricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting the proposed standard. The Administrator proposed 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. The proposed new standard would be met at an ambient air quality monitoring site 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/m³, 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. Requirements for monitoring sites that would be appropriate for determining compliance with this proposed $PM_{10-2.5}$ standard were included as part of proposed revisions to EPA's ambient air monitoring regulations (see 71 FR 2710, 2736–2728 and 71 FR 2706–2707 (proposing to incorporate these requirements as part of the standard)). These proposed requirements included a five-part test for determining whether a potential monitoring site is suitable for comparison to the standard, all five parts of which had to be met. In summary, the suitability test included the following general provisions: a monitoring site must be within an urbanized area that has a population of at least 100,000 persons; the site must be within a block group with a population density greater than 500 people per square mile; the site must be a ''population-oriented'' site; the site may not be adjacent to a large emissions source or otherwise within the micro-scale environment affected by a large source; and, if the first four provisions are met, a site-specific assessment must show that the ambient mix of $PM_{10-2.5}$ sampled at the site would be dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and would not be dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. Related new $PM_{10-2.5}$ data handling conventions and a new reference method for monitoring PM as $PM_{10-2.5}$ were also proposed. The Administrator also proposed to revoke and not replace the annual PM_{10} standard.

With regard to the secondary $PM_{2.5}$ and PM_{10} standards, the Administrator proposed to revise the current 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.

F. Organization and Approach to Final PM NAAQS Decisions

This action presents the Administrator's final decisions on the review of the current primary and secondary $PM_{2.5}$ and PM_{10} standards. Primary standards for fine particles and for thoracic coarse particles are addressed below in sections II and III, respectively. Consistent with the decisions made by EPA in the last review and with the conclusions in the Criteria Document and Staff Paper, fine and thoracic coarse particles continue to be considered as separate subclasses of PM pollution. Secondary standards for fine and thoracic coarse particles are addressed below in section IV. Related data handling conventions and federal reference methods for monitoring PM are addressed below in sections V and VI, respectively.

Today's final decisions separately addressing fine and thoracic coarse particles are based on a thorough review in the Criteria Document of scientific information on known and potential human health and welfare effects associated with exposure to these subclasses of PM at levels typically found in the ambient air. These final decisions also take into account: (1) Staff assessments in the Staff Paper of the most policy-relevant information in the Criteria Document as well as a quantitative risk assessment based on that information; (2) CASAC advice and recommendations, as reflected in its letters to the Administrator, its 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 [6] (henceforth, ''CASAC Panel''); (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately; and (4) extensive public comments received on the proposed rulemaking.

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

A. Introduction

1. Overview

This section presents the Administrator's final decisions regarding the need to revise the current primary $PM_{2.5}$ NAAQS, and, more specifically, regarding revisions to the level of the 24-hour standard and to the form of the annual standard. As discussed more fully below, the rationale for the final decision on appropriate revisions to 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, are 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 on associations between exposure to

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

ambient fine particles and a broad range of health endpoints (EPA, 2004a, Chapter 9), focusing on those health endpoints for which the Criteria Document concluded 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 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, most generally with regard to whether observed associations are likely causal in nature and, if so, whether there are exposure levels below which such associations are no longer likely. As discussed below, an unprecedented amount of new research has been conducted since the last review, with important new information coming from epidemiologic, toxicologic, controlled human exposure, and dosimetric studies. Moreover, the newly available research studies evaluated in the Criteria Document have undergone intensive scrutiny through multiple layers of peer review, with extended opportunities for review and comment by CASAC and the public. 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 provides 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.

The health effects information and quantitative risk assessment were summarized in sections II.A and II.B of the proposal (71 FR 2626–2641) and are only briefly outlined below in sections II.A.2 and II.A.3. Subsequent sections of this preamble provide a more complete discussion of the Administrator's rationale, in light of key issues raised in public comments, for concluding that it is appropriate to revise the current primary $PM_{2.5}$ standards (section II.B), as well as a more complete discussion of the Administrator's rationale for retaining or revising the specific elements of the primary $PM_{2.5}$ standards, namely the indicator (section II.C); averaging time (section II.D); form (section II.E); and level (section II.F). A summary of the final decisions on revisions to the primary $PM_{2.5}$ standards is presented in section II.G.

2. Overview of Heath Effects Evidence

This section briefly outlines the information presented in Section II.A of the proposal on the health effects associated with exposure to 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 available since the last review 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 exposures to 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 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 particle levels and personal exposures to fine particles of ambient origin.

(5) New statistical approaches to addressing issues related to potential confounding by gaseous co-pollutants, possible thresholds for effects, and measurement error and exposure misclassification.[7]

(6) Efforts to evaluate the effects of fine particles from different sources (e.g., motor vehicles, coal combustion, vegetative burning, crustal[8]), using factor analysis or source apportionment methods with fine particle speciation data.

(7) 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 since the last review with findings from studies of 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.

Section II.A of the proposal provides a detailed summary of key information contained in the Criteria Document (EPA, 2004a, Chapters 6–9), and in the Staff Paper (EPA, 2005, Chapter 3), on the known and potential effects associated with exposure to fine particles including information on specific constituents and information on the effects of fine particles in combination with other pollutants that are routinely present in the ambient air

[7] ''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, 2004a, section 8.1.3.2; EPA, 2005, section 3.6.4). A ''threshold'' is a concentration below which it is expected that effects are not observed (EPA, 2004a, section 8.4.7; EPA, 2005, section 3.6.6). ''Gaseous co-pollutants'' generally refer to other commonly-occurring 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, 2004a, section 8.4.5; EPA, 2005, section 3.6.2)

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

(71 FR 2626–2637). The information highlighted there summarizes:

(1) Multiple biologic mechanisms that may be responsible for morbidity/mortality effects associated with exposure to ambient fine particles, including potential mechanisms or pathways related to direct effects on the respiratory system, systemic effects that are secondary to effects in the respiratory system including cardiovascular effects, or direct cardiovascular effects.

(2) The nature of the effects that have been reported to be associated with fine particle exposures including premature mortality, aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions and emergency department visits), changes in lung function and increased respiratory symptoms, as well as new evidence for more subtle indicators of cardiovascular health.

(3) An integrated evaluation of the health effects evidence, with emphasis on key issues raised in interpreting epidemiological studies, along with supporting evidence from experimental (e.g., dosimetric and toxicologic) studies.

(4) Sensitive or vulnerable subpopulations that appear to be at greater risk to such effects, including individuals with pre-existing heart and lung diseases, older adults, and children.

(5) Conclusions, based on the magnitude of these subpopulations and risks identified in health studies, that exposure to ambient fine particles can have substantial public health impacts.

3. Overview of Quantitative Risk Assessment

In addition to a comprehensive evaluation of the health effects evidence available in this review, EPA conducted a quantitative health risk assessment for selected health effects to provide additional information and insights that can help inform decision making on the NAAQS, while recognizing the limitations of such an assessment.[9] As discussed in section II.B of the proposal, the approach used to develop quantitative risk estimates associated with exposures to $PM_{2.5}$ was built upon the more limited risk assessment conducted during the last review (61 FR 65650). The expanded and updated assessment conducted in this review included estimates of risks of mortality (total non-accidental, cardiovascular, and respiratory), morbidity (hospital admissions for cardiovascular and respiratory causes), and respiratory symptoms (not requiring hospitalization) associated with recent short-term (daily) ambient $PM_{2.5}$ levels and risks of total, cardiopulmonary, and lung cancer mortality associated with long-term exposure to $PM_{2.5}$ in a number of example urban areas.[10]

The EPA recognized that there were many sources of uncertainty and variability inherent in the inputs to this assessment and that there was a high degree of uncertainty in the resulting $PM_{2.5}$ 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. While some of these uncertainties were addressed quantitatively in the form of estimated confidence ranges around central risk estimates, other uncertainties and the variability in key inputs were not reflected in these confidence ranges, but rather were addressed through separate sensitivity analyses or characterized qualitatively.

The concentration-response relationships used in the assessment were based on findings from human epidemiological studies that relied on fixed-site, population-oriented, ambient monitors as a surrogate for actual ambient $PM_{2.5}$ exposures. The risk assessment included a series of base case estimates that, for example, included various cutpoints intended as surrogates for alternative assumed population thresholds. In its review of the Staff Paper and risk assessment, the CASAC Panel commented that for the purpose of estimating public health impacts, it ''favored the primary use of an assumed threshold of 10 $\mu g/m^3$'' 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). Other uncertainties were addressed in various sensitivity analyses (e.g., the use of single-versus multi-pollutant models, use of single-versus multi-city models, use of a distributed lag model) and had a more moderate and often variable impact on the risk estimates in some or all of the cities.

Key observations and insights from the $PM_{2.5}$ risk assessment, together with important caveats and limitations, were discussed in section II.B of the proposal. In general, estimated risk reductions associated with going from just meeting the current suite of $PM_{2.5}$ standards to just meeting alternative suites of annual and 24-hour standards for all the various assumed cutpoints show patterns of increasing estimated risk reductions as either the annual or 24-hour standard, or both, were reduced over the range considered in this assessment, and the estimated percentage reductions in risk were strongly influenced by the assumed cutpoint level (see EPA, 2005, Figures 5–1, 5–2, 5A–1, and 5A–2). In 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, were very similar for mortality associated with long-term exposures. Current risk estimates for just meeting the current suite of $PM_{2.5}$ standards were similar in one of the locations (Philadelphia) and somewhat lower in the other location (Los Angeles) for mortality associated with short-term exposures.

B. Need for Revision of the Current Primary $PM_{2.5}$ Standards

1. Introduction

The initial issue to be addressed in the current review of the primary $PM_{2.5}$ standards is whether, in view of the advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the existing standards should be revised. As discussed in section II.A of the proposal (71 FR 2625–2637), the Staff Paper concluded, based on the information and

[9] The EPA continues to support the development and application of risk assessment methods with the goal of improving the characterization of risks and the communication of uncertainties in such risk estimates.

[10] The risk assessment was discussed in the Staff Paper (EPA, 2005, chapter 4) and presented more fully in a technical support document, Particulate Matter Health Risk Assessment for Selected Urban Areas (Abt Associates, 2005). The assessment scope and methodology were developed with considerable input from the CASAC Panel and the public, with CASAC concluding that the general assessment methodology and framework were appropriate (Hopke, 2002).

conclusions presented in the Criteria Document, that while important uncertainties and research questions remain, much progress has been made since the last review in reducing some key uncertainties related to our understanding of the scientific evidence. The newly available information generally reinforces and provides increased confidence in the likely causal nature of the associations between short- and long-term exposure to $PM_{2.5}$ and mortality and morbidity effects observed in the last review, and provides additional information to inform judgments as to the extent to which such associations likely remain at lower exposure levels within the range of ambient air quality.

The examination of short- and long-term exposures to specific components, properties, and sources of fine particles and mixtures of fine particles with gaseous co-pollutants that are linked with health effects, and the biological mechanisms underlying the observed linkages, remain important research needs. 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. Due to reanalyses and extensions of key long-term exposure studies, there is now greater confidence in the causal nature of associations with long-term exposures to fine particles than in the last review. There is also an increased understanding of the populations that are the most susceptible to $PM_{2.5}$-related effects. In addition, health effect associations reported in epidemiologic studies have been found to be generally robust to confounding by co-pollutants, especially for the more numerous short-term exposure studies. Further, while groups of commenters had differing views on the extent to which, if at all, newly available evidence increases confidence in associations between $PM_{2.5}$ and mortality and morbidity effects, and on the extent of progress that has been made in reducing uncertainties since the last review, virtually no commenters argued for any relaxation of the current $PM_{2.5}$ standards. Based on these considerations, EPA finds that overall the available evidence has increased the scientific basis supporting the health impacts of exposure to $PM_{2.5}$, and not lessened it, providing clear support for fine particle standards that are at least as protective as the current $PM_{2.5}$ standards.

Having reached this initial conclusion, EPA addresses the question whether the available evidence supports consideration of standards that are more protective than the current $PM_{2.5}$ standards. In considering this question, EPA first notes that the current standards were set as a suite that together would most effectively and efficiently protect the public against health effects related to both short- and long-term exposures to fine particles (62 FR at 38669). In so doing, the Agency set the annual standard to be the ''generally controlling'' standard for lowering both short- and long-term $PM_{2.5}$ concentrations. 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. As discussed below in section II.F, in considering what evidence to use as the basis for the 1997 annual standard, EPA placed greater emphasis on the short-term exposure studies, which were judged to be the strongest evidence at that time. The long-term exposure studies available at that time provided only supporting evidence for the annual standard, which was set primarily based on short-term exposure studies.

In addressing the question whether the evidence now available in this review supports consideration of standards that are more protective than the current $PM_{2.5}$ standards, the Staff Paper considered whether (1) 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) associations with long-term exposures to fine particles extend down to lower air quality levels than had previously been observed.[11]

In considering the available epidemiologic evidence in this review to address the question of whether more protective standards should be considered, the Staff Paper took a broader approach than was used in the last review. This approach reflects the more extensive and stronger body of evidence now available on health effects related to both short- and long-term exposure to $PM_{2.5}$, and places relatively greater emphasis on evidence from long-term exposure studies than was done in the last review. As discussed below in section II.F, this broader approach was used at the time of proposal to consider the much expanded body of evidence from short-term exposure studies as the principal basis for setting the 24-hour standard to protect against health effects associated with short-term exposures to $PM_{2.5}$, and to consider the stronger and more robust body of evidence from long-term exposure $PM_{2.5}$ studies as the principal basis for setting the annual standard to protect against health effects associated with long-term exposures to $PM_{2.5}$.

In first considering whether areas in which short-term exposure studies have been conducted would likely meet the current $PM_{2.5}$ standards, the focus is principally on comparing the long-term average $PM_{2.5}$ concentration in a study area with the level of the current ''generally controlling'' annual $PM_{2.5}$ standard. In considering the available epidemiologic evidence related to short-term exposures, the Staff Paper focused on specific epidemiologic studies that show statistically significant associations between $PM_{2.5}$ and health effects for which the Criteria Document judged associations with $PM_{2.5}$ to be likely causal (EPA, 2005, 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 $\mu g/m^3$). 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 focused on those that include adequate gravimetric $PM_{2.5}$ mass measurements, and noted where the associations are generally robust to alternative model specification and to the inclusion of potentially confounding co-pollutants. Three

[11] In addressing this question, the Criteria Document had recognized 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, 2004a, section 9.2.2.5).

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 or cardiovascular mortality in areas in which long-term average $PM_{2.5}$ concentrations ranged between 13 and 14 μg/m^3 and 98th percentile 24-hour concentrations ranged between 32 and 59 μg/m^3.[12]

In also considering the new epidemiologic evidence available from U.S. and Canadian studies of long-term exposure to fine particles, the Criteria Document noted that new studies have built upon studies available in the last review and concluded that these studies have confirmed and strengthened the evidence of associations for both mortality and respiratory morbidity (EPA, 2004a, section 9.2.3). For mortality, the Criteria Document placed 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, 2004a, p. 9–34), notwithstanding the lack of consistent results in other long-term exposure studies. For morbidity, the Criteria Document found 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, 2004a, pp. 9–33 to 9–34). In addition to strengthening the evidence of association, the new extended ACS mortality study (Pope *et al.*, 2002) 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} in areas where fine particles would likely dominate this measurement, 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 noted that new epidemiologic studies of asthma-related increased physician 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, 2004a, p. 9–94).

In reviewing this information, the Staff Paper recognized that important limitations and uncertainties associated with this expanded body of evidence for $PM_{2.5}$ and other indicators or components of fine particles 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 noted that although 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 or to the gaseous co-pollutants themselves. The Criteria Document concluded, however, that overall the newly available epidemiologic evidence, especially for the more numerous short-term exposure studies, substantiates that associations for various PM indicators with mortality and morbidity are robust to confounding by co-pollutants (EPA, 2004a, 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 concluded 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 noted 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 in short-term exposue studies at levels below the current standards and in long-term exposure studies that extend 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 considered 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, noted above in section II.A.3. In so doing, the Staff Paper first noted that the risk assessment addressed several key uncertainties through various base case analyses, as well as through sensitivity analyses, as noted above in section II.A.3 and discussed in section II.B of the proposal (71 FR 2637–2641). In considering the health risks estimated to occur upon attainment of the current $PM_{2.5}$ standards, the Staff Paper focused 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,[13] 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 (discussed above in section II.A.3), the risk assessment indicated the possibility that thousands of premature deaths per year would occur in urban areas across the U.S. upon attainment of the current $PM_{2.5}$

[12] 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 one of these studies included multi-pollutant model results in reanalyses, reporting that associations with $PM_{2.5}$ remained significant with gaseous pollutants (Fairley, 2003). The 98th percentile 24-hour concentrations were approximately 59 μg/m^3 in Fairley *et al.* (2003), 39 μg/m^3 in Burnett and Goldberg (2003), and 32 μg/m^3 in Mar *et al.* (2003).

[13] As noted in section II.B of the proposal, the reported linear or log-linear concentration-response functions were applied down to 7.5 μg/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 μg/m^3 for eastern urban areas and 2.5 μg/m^3 for western urban areas).

standards.[14] Beyond the estimated incidences of premature mortality, the Staff Paper also recognized 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, 2005, Chapter 4) and on the discussion related to this ''pyramid of effects'' in the Criteria Document (EPA, 2004a, section 9.2.5). Based on these considerations, the Staff Paper concluded 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 (EPA, 2005, section 5.3.1.).

In considering available evidence, risk estimates, and related limitations and uncertainties, the Staff Paper concluded 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 suite of $PM_{2.5}$ 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 increased 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).[15]

At the time of proposal, in considering whether the suite of $PM_{2.5}$ standards should be revised to provide requisite public health protection, the Administrator 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 placed primary consideration on the evidence obtained from the studies, and provisionally found 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 recognized that much progress has been made since the last review in addressing some of the key uncertainties that were important considerations in establishing the current suite of $PM_{2.5}$ standards. For example, progress made since the last review provides increased confidence in the long-term exposure studies as a basis for considering whether any revision of the annual standard is appropriate and increased confidence in the short-term exposure studies as a basis for considering whether any revision of the 24-hour standard is appropriate.[16] In considering the risk assessment presented in the Staff Paper, the Administrator noted 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 viewed 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 concluded that the current $PM_{2.5}$ 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.

2. Comments on the Need for Revision

General comments based on relevant factors that either support or oppose any change to the current suite of $PM_{2.5}$ primary standards are addressed in this section. Comments on specific short- and long-term exposure studies that relate to consideration of the appropriate levels of the 24-hour and annual $PM_{2.5}$ standards are addressed below in sections II.F.1 and II.F.2, respectively. General comments based on implementation-related factors that are not a permissible basis for considering the need to revise the current standards are addressed in the Response to Comments document.

Many public comments received on the proposal asserted that the current $PM_{2.5}$ standards are insufficient to protect public health with an adequate margin of safety and revisions to the standards are appropriate. Among those calling for revisions to the current standards are medical groups, including the American Medical Association, the American Thoracic Society, the American Academy of Pediatrics, and the American College of Cardiology, as well as medical doctors and academic researchers. For example, the American Medical Association stated that PM air pollution is ''a national public health problem'' and supported more stringent standards based on studies that provide evidence of associations between $PM_{2.5}$ and serious health effects in areas with $PM_{2.5}$ concentrations that are below the 1997 standards. Other medical associations offered the following views in support of more protective standards:

> As professional organizations that represent physicians treating patients with diseases either caused by or exacerbated by air pollution, we are keenly aware of the impact air quality has on the individual health of our patients. As such we are committed to supporting a standard for PM that is protective of the health of vulnerable populations including children, seniors and patients with respiratory and cardiac conditions * * *. In short, a significant body of research has described potential mechanisms for and the range of health effects caused by PM air pollution. The undersigned physician organizations find the body of scientific evidence to be rigorous, comprehensive and compelling enough to justify a significant tightening of the existing NAAQS PM standards. [American Thoracic Society et al.]

In a letter signed from environmental health researchers and physicians, similar conclusions were drawn:

> More than 2,000 peer-reviewed studies have been published since 1996 * * *. These studies, as discussed and interpreted in the 2004 EPA Criteria Document, validate earlier epidemiologic studies linking both acute and chronic fine particle pollution with serious morbidity and mortality. The newer research has also expanded the list of health effects associated with PM, and has identified health effects at lower exposure levels than

[14] The Staff Paper recognized 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, 2005, p. 5–15).

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

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

previously reported. In fact, the science is now sufficiently strong that it is appropriate to conclude that $PM_{2.5}$ is causally associated with numerous adverse health effects in humans, at exposure levels far below the current standards. [Schwartz *et al.*, 2005]

Similar conclusions were also reached in comments by many national, state, and local public health organizations, including, for example, the American Lung Association, the American Heart Association, the American Cancer Society, the American Public Health Association, and the National Association of Local Boards of Health, as well as in letters to the Administrator from EPA's advisory panel on children's environmental health (Children's Health Protection Advisory Committee, 2005, 2006). All of these medical and public health commenters stated that the current $PM_{2.5}$ standards need to be revised, and that even more protective standards than those proposed by EPA are needed to protect the health of sensitive population groups. Many individual commenters also expressed such views.

State and local air pollution control authorities who commented on the $PM_{2.5}$ standards supported revision of the suite of current $PM_{2.5}$ standards, as did the National Tribal Air Association. The State and Territorial Air Pollution Program Administrators and the Association of Local Air Pollution Control Officials (STAPPA/ALAPCO) urged that EPA revise the $PM_{2.5}$ standards in accordance with the recommendations of CASAC. Each of the individual State environmental/public health agencies that commented on the $PM_{2.5}$ standards supported revisions to the current standards, with most supporting standards consistent with CASAC's recommendations. The Northeast States for Coordinated Air Use Management (NESCAUM) argued for even more stringent revisions to the standards.

The commenters noted above primarily based their views on the body of evidence assessed in the Criteria Document, finding it to be stronger and more compelling than in the last review. These commenters generally placed much weight on CASAC's interpretation of the body of available evidence and the results of EPA's risk assessment, both of which formed the basis for CASAC's recommendation to revise the $PM_{2.5}$ standards to provide increased public health protection was based.

Some of these commenters specifically mentioned the independent reanalysis of the original ACS and Six Cities long-term exposure studies conducted by HEI (Krewski *et al.*, 2000) that concluded that the original data were of high quality, the original results could be fully replicated, and the results were robust to alternative model specifications. Some also mentioned the ACS extended study (Pope *et al.*, 2002) and the Southern California children's cohort study (Gauderman *et al.*, 2002) as providing evidence of mortality and morbidity effects associated with long-term exposures to $PM_{2.5}$ at lower levels than had previously been studied. A number of short-term exposure studies were also cited by some of these commenters as providing evidence of mortality and morbidity effects at levels well below the level of the current 24-hour $PM_{2.5}$ standard. In addition, many of these commenters generally concluded that progress had been made in reducing many of the uncertainties identified in the last review and in better understanding mechanisms by which $PM_{2.5}$ may be causing the observed health effects.

Some of these commenters also noted the results of EPA's risk assessment, concluding that it showed that the risks estimated to remain when the current standards are met are large and important from a public health perspective and warrant increased protection. Some of these commenters expressed the view that $PM_{2.5}$-related risks are likely larger than those estimated in EPA's risk assessment, in part because EPA based its risk assessment on the ACS extended study which had greater exposure measurement error than other studies, leading to an underestimate of the relative risk, and because EPA incorporated an assumed ''cutpoint'' in its assessment that is not supported by studies that find no evidence of a threshold.

In general, all of these commenters agreed on the importance of results from the large body of scientific studies reviewed in the Criteria Document and on the need to revise the suite of $PM_{2.5}$ standards as articulated in EPA's proposal, while generally differing with EPA's proposed judgments about the extent to which the standards should be revised based on this evidence. The EPA generally agrees with these commenters' conclusion regarding the need to revise the current suite of $PM_{2.5}$ standards. The scientific evidence noted by these commenters was generally the same as that assessed in the Criteria Document and the Staff Paper, and EPA agrees that this evidence provides a basis for concluding that the current $PM_{2.5}$ standards, taken together, are not adequately protective of public health. For reasons discussed below in section II.F, however, EPA disagrees with aspects of these commenters' views on the level of protection that is appropriate and supported by the available scientific information.

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

Another group of commenters representing industry associations and businesses opposed revising the current $PM_{2.5}$ standards. These views are most extensively presented in comments from the Utility Air Regulatory Group (UARG), representing a group of electric generating companies and organizations and several national trade associations, and from Pillsbury, Winthrop, Shaw and Pittman (Pillsbury *et al.*) on behalf of 19 industry and business associations (including, for example, the Alliance of Automobile Manufacturers, the American Iron and Steel Institute, the National Association of Manufacturers, the American Petroleum Institute, and the U.S. Chamber of Commerce).

These and other commenters in this group generally mentioned many of the same studies that were cited by the commenters who supported revising the standards, as well as other studies, but highlighted different aspects of these studies in reaching substantially different conclusions about their strength and the extent to which progress has been made in reducing uncertainties in the evidence since the last review. These commenters generally expressed the view that the current standards provide the requisite degree of public health protection. They then considered whether the evidence that has become available since the last review has established a more certain risk or a risk of effects that are significantly different in character to those that provided a basis for the current standards, or whether the evidence demonstrates that the risk to public health upon attainment of the current standards would be greater than was understood when EPA established the current standards in 1997.

In supporting their view that the present suite of primary $PM_{2.5}$ standards continues to provide the requisite public health protection and should not be revised, UARG and others generally stated: (1) That the effects of concern have not changed significantly since 1997; (2) that the uncertainties in the underlying health science are as great or greater than in 1997; (3) that the estimated risk upon attainment of the current $PM_{2.5}$ standards has decreased since 1997; and (4) that ''new'' studies not included in the Criteria Document continue to increase uncertainty about possible health risks associated with exposure to $PM_{2.5}$. These comments are discussed in turn below.

(1) In asserting that effects of concern have not changed significantly since 1997, some of these commenters stated that more subtle physiological changes in the cardiovascular system are the only type of new PM-related effect identified in this review. They stated that such subtle effects are far less serious than the cardiovascular effects such as aggravation of cardiovascular disease that had been considered in the last review. The EPA disagrees with the assertion that subtle changes in the cardiovascular system are the only type of new PM-related effect identified in this review. Further, EPA believes that evidence of physiological changes in the cardiovascular system is important in that it increases confidence in inferences about the causal nature of the associations between fine particles and cardiovascular-related mortality and hospital admissions.

As discussed in the Criteria Document (EPA, 2004a, p. 9–75), epidemiologic studies published since the last review have expanded upon and extended the evidence examining possible links between long-term exposures to fine particles and increased risk of lung cancer incidence and mortality, which was considered to be insufficient to support such a linkage in the last review. In this review, however, the epidemiologic evidence now available ''support(s) an association between long-term exposure to fine particles and lung cancer mortality; and the new toxicological studies provide credible evidence for the biological plausibility of these associations'' (EPA, 2004a, p. 9–76). More specifically, the Criteria Document highlighted ''the newer results of the extension of the ACS study analyses (that include more years of participant follow-up and address previous criticisms of the earlier ACS analyses), which indicate that long-term ambient PM exposures are associated with increased risk of lung cancer. That increased risk appears to be in about the same range as that seen for a nonsmoker residing with a smoker, with any consequent life-shortening due to lung cancer'' (EPA 2004a, p. 9–94).

In addition, as noted earlier, the Criteria Document identified increased nonhospital medical visits (physician visits) and aggravation of asthma associated with short-term exposure to $PM_{2.5}$ as being newly identified effects since the last review, and concluded that findings of such effects ''suggest likely much larger health impacts and costs to society due to ambient PM than just those indexed either by just hospital admissions/visits and/or mortality.'' *Id.* Further, the Criteria Document (EPA, 2004a, p. 9–79) noted that there may be PM-related health effects in infants and children, although only very limited evidence of such effects exists.

(2) In asserting that the uncertainties in the underlying health science are as great or greater than in 1997, commenters in this group variously discussed a number of issues including: The lack of demonstrated mechanisms by which $PM_{2.5}$ may be causing mortality and morbidity effects; uncertainty in the shape of the concentration-response functions; the potential for co-pollutant confounding; uncertainty in the role of individual constituents of fine particles; and the sensitivity of epidemiological results to statistical model specification. Each of these issues is addressed below. In summary, these commenters concluded that the substantial uncertainties present in the last review have not been resolved, that a previously unrecognized sensitivity to model specification has been newly identified, and/or that the uncertainty about the possible health risks associated with $PM_{2.5}$ exposure has not diminished. As discussed below, although EPA agrees that important uncertainties remain, and that future research directed toward addressing these uncertainties is warranted, EPA believes that overall uncertainty about possible health risks associated with both short- and long-term $PM_{2.5}$ exposure has diminished since the last review. As noted above, the greater confidence in short-term exposure studies supports the Administrator's increased reliance on those studies as the basis for the 24-hour standard, and greater confidence in long-term exposure studies supports the Administrator's increased reliance on those studies as the basis for the annual $PM_{2.5}$.[17]

With regard to the issue of mechanisms, these commenters noted that although EPA recognizes that new evidence is now available on potential mechanisms and plausible biological pathways, the evidence still does not resolve all questions about how $PM_{2.5}$ at ambient levels could produce the effects in question in this review. They further assert that even if more recent information has advanced our understanding of such mechanisms, it would not justify revision of the standard. The EPA notes that in the last review, the Agency 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, upon which the standards were based. Since the last review, there has been a great deal of research directed toward advancing our understanding of biologic mechanisms. While this research has not resolved all questions, and further research is warranted, it has provided important insights as discussed in section II.A.1 of the proposal (71 FR 2626–2627). As noted there, the findings from this new research 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. The Criteria Document (EPA, 2004a, p. 7–206) concluded: ''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 biological responses are produced by PM whether it is composed of a single component or a complex mixture.'' Further, EPA believes that progress made in gaining insights into potential mechanisms lends support to the biologic plausibility of results observed in epidemiologic studies (71 FR 2636). The mechanistic evidence now available, taken together with newly available epidemiologic evidence, increases the Agency's confidence that observed associations are causal in nature, such that the risks of health effects attributed to short- and long-term exposure to $PM_{2.5}$, acting alone and/or in combination with gaseous co-pollutants, are now more

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

certain than was understood in the last review.

With regard to uncertainty in concentration-response functions, these commenters concluded that ''because the actual shape of this function remains unknown, this uncertainty has not been reduced since 1997'' (UARG, p. 17). The EPA notes that, in contrast to the last review when few studies had quantitatively assessed the form of the concentration-response function or the potential for a threshold, several new studies available in this review have used different methods to examine this question, and most have been unable to detect threshold levels in time-series mortality studies. The Criteria Document (EPA, 2004a, p. 9–44) recognized that in multi-city and most single-city time-series studies, statistical tests comparing linear and various nonlinear or threshold models have not shown statistically significant distinctions between them; where potential threshold levels have been suggested in single-city studies, they are at fairly low levels (*Id.* at p. 9–45). Further, the shape of concentration-response functions for long-term exposure to $PM_{2.5}$ was evaluated using data from the ACS cohort, with the HEI reanalysis finding near-linear increasing trends through the range of particle levels observed in this study, and the extended ACS study reporting that the various mortality associations were not significantly different from linear (71 FR 2635).[18] However, EPA agrees that uncertainties remain in our understanding of the shape of concentration-response functions, and, consistent with the conclusion in the Criteria Document, has concluded that the available evidence does not either support or refute the existence of population thresholds for effects associated with short- or long-term exposures to PM across the range of concentrations in the studies. Even while recognizing that uncertainties remain, EPA believes that our understanding of this issue for both short- and long-term exposure studies has been advanced since the last review.

With regard to co-pollutant confounding, these commenters asserted that EPA has been ''dismissive'' of this issue in assessing the epidemiologic evidence of associations between PM and mortality and morbidity endpoints (UARG, p. 18). These commenters asserted that EPA has inappropriately concluded that PM-related mortality and morbidity associations are generally robust to confounding, which is one of the criteria considered in drawing inferences about the extent to which observed statistical associations are likely causal in nature. The commenters focused on an examination of the extent to which statistically significant $PM_{2.5}$ associations based on one-pollutant models in a number of time-series studies, and in an analysis of associations with long-term exposures in the ACS cohort studies, often did not remain statistically significant in two-pollutant models.

In general, EPA does not believe that the examination of this issue put forward by these commenters reflects the complexities inherent in assessing the issue of co-pollutant confounding. As discussed in the proposal (71 FR 2634) and more fully in the Criteria Document (EPA, 2004a, section 8.4.3; chapter 9, section 9.2.2.2.2), although multi-pollutant models may be useful tools for assessing whether gaseous co-pollutants may be *potential* confounders, such models cannot determine whether in fact they are. Interpretation of the results of multi-pollutant models is complicated by correlations that often exist among air pollutants, by the fact that some pollutants play a role in the atmospheric reactions that form other pollutants such as secondary fine particles, and by the inherent statistical power of the studies in question. While single-city multi-pollutant models have received a great deal of attention during this review, the Criteria Document also noted several other approaches to examining the question, including a more careful examination of personal exposures to PM and co-pollutants, the use of factor or principal component analyses, and the use of intervention studies (EPA, 2004a, pp. 8–245 to 8–246). The Criteria Document also recognized that it is important to consider the issue of potential co-pollutant confounding in the context of the more recent evidence available about the biological plausibility of associations between the various pollutants and health outcomes, model specification, and exposure error (EPA, 2004a, p. 8–254).

An example of other approaches to examining potential co-pollutant confounding is the study of personal exposure to fine particles and co-pollutant gases done in Baltimore (Sarnat *et al.*, 2001). This study found that day-to-day variations in monitored ambient gases were not associated with day-to-day changes in personal exposures to those gases, but they were associated with day-to-day changes in personal exposure to $PM_{2.5}$. One reasonable interpretation of this study is that for cities like Baltimore, changes in model results when ambient gases are included in multi-pollutant models may stem from such gases being surrogates for exposures to particles and not confounders at all.

The broader examination of this issue in the Criteria Document included a focus on evaluating the stability of the size of the effect estimates in time-series studies using single- and multi-pollutant models, as illustrated in Figures 8–16 through 8–19 (EPA, 2004a, pp. 8–248 to 8–251). This examination found that for most time-series studies, there was little change in effect estimates based on single- and multi-pollutant models, although recognizing that in some cases, the PM effect estimates were markedly reduced in size and lost statistical significance in models that included one or more gaseous pollutants. The Criteria Document also noted that PM and the gaseous co-pollutants were often highly correlated, and it is generally the case that high correlations existed between pollutants where PM effect estimates were reduced in size with the inclusion of gaseous co-pollutants. With regard to the analysis of multiple pollutants from the ACS cohort, it is important to note that the effects estimates for fine particles actually increased in two pollutant models that incorporated CO, NO_2, and ozone, and were reduced only for models that incorporated SO_2. The Criteria Document recognized, however, that SO_2 is a precursor for fine particle sulfates, which complicates the interpretation of multi-pollutant model results, and that mortality may be associated with not only $PM_{2.5}$ but also with other components of the mix of ambient pollutants in this long-term exposure study.

Far from being dismissive, EPA has examined this issue in detail based on the much more extensive body of relevant evidence available in this review. This Criteria Document concluded that ''the most consistent findings from amidst the diversity of multi-pollutant evaluation results for different sites is [sic] that the PM signal most often comes through most clearly.'' (EPA, 2004a, p. 8–254.) While acknowledging that these analyses have not fully disentangled the relative role of co-pollutants, EPA believes that this examination provides greater confidence than in the last review that

[18] In assessing such uncertainties in this review relative to the last review, EPA notes that in the last review the level of uncertainty associated with long-term exposure studies was such that they were not relied on as the primary basis for the annual standard. In the last review, relative risk estimates from long-term exposure studies were deemed ''highly uncertain'' (62 FR 38668) and health effects from long-term exposure were characterized as ''potentially independent'' (*Id.*) from those associated with short-term exposure.

observed effects can be attributed to short- and long-term exposures to $PM_{2.5}$, alone and in combination with other pollutants, while recognizing that potential confounding by co-pollutants remains a very challenging issue to address, even with well-designed studies.

With regard to questions about the role of individual constituents within the mix of fine particles, these commenters pointed out that EPA recognized this issue as an important uncertainty in the last review and did so again in this review. These commenters then expressed the view that such continued uncertainty provides no grounds for reconsidering the Agency's 1997 conclusion that the current $PM_{2.5}$ standards provide the requisite protection. As a general matter, EPA agrees that although new research directed toward this question has been conducted since the last review, important questions remain and the issue remains an important element in the Agency's ongoing research program. The EPA does not agree, however, that continued uncertainty with regard to the relative toxicity of components within the mix of fine particles, in and of itself, provides grounds for not revising the suite of $PM_{2.5}$ standards. Rather, the full body of health effects evidence that has become available since the last review provides a basis for concluding that additional public health protection is warranted to protect against health effects that have been associated with exposure to fine particles measured as $PM_{2.5}$ mass.

At the time of the last review, the Agency 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. This distinction was based largely on epidemiologic evidence of health effects using various indicators of fine particles in a large number of areas that had significant contributions of differing components or sources of fine particles, together with some limited experimental studies that provided some evidence suggestive of health effects associated with high concentrations of numerous fine particle components. In this review, as discussed in section II.D of the proposal (71 FR 2643–2645) and below in section II.C, while most epidemiologic studies continue to be 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, 2004a, p. 9–31, Table 9–3). In addition, several recent epidemiologic studies included in the Criteria Document have used $PM_{2.5}$ speciation data to evaluate associations between mortality and fine particles from different sources, and some toxicologic studies have provided evidence for effects associated with various fine particle components or size-differentiated subsets of fine particles.

The available information continues to suggest that many different chemical components of fine particles and a variety of different types of source categories are all associated with, and probably contribute to, effects associated with $PM_{2.5}$. Consequently, there continues to be no basis to conclude that any individual fine particle component cannot be associated with adverse health effects (EPA, 2005, p. 5–17). This information is relevant to the Agency's decision to retain PM2.5 as the indicator for fine particles (as discussed below in section II.C). The EPA also believes that it is relevant to the Agency's conclusion as to whether revision of the suite of $PM_{2.5}$ standards is appropriate. Furthermore, while there remains uncertainty about the role and relative toxicity of various components of fine PM, the current evidence continues to support the view that fine particles should be addressed as a group for purposes of public health protection, and the remaining uncertainty does not call for delaying any increase in public health protection that other evidence indicates may be warranted.

With regard to the sensitivity of epidemiologic associations to the use of different statistical models and different approaches to model specification used by researchers, these commenters identified this issue of model sensitivity as an area in which uncertainty in interpreting epidemiologic evidence has increased since the last review. Comments from UARG, Pillsbury *et al.*, the Annapolis Center and others pointed to examples where individual study results are sensitive to the use of alternative models, and to reviews that recommend further exploration of this issue in future research, as a basis for asserting that current modeling approaches are too uncertain to use the available epidemiologic studies as a basis for revising the current $PM_{2.5}$ standards. The EPA agrees that recent work on model sensitivity has raised new concerns and the Agency has given much attention to this issue. In so doing, EPA recognizes, as does the HEI and other researchers, that there is no clear consensus at this time as to what constitutes appropriate control of weather and temporal trends in time-series studies, and that no single statistical modeling approach is likely to be most appropriate in all cases (EPA 2004a, p. 8–238).

While recognizing the need for further research on this issue, EPA believes that the body of time-series epidemiologic studies considered in this review [19] provides an appropriate basis for informing the Agency's decisions on whether to revise the 24-hour $PM_{2.5}$ standard, consistent with the conclusion of the HEI review panel (''* * * the revised findings will continue to help inform regulatory decisions regarding PM.'' HEI, 2003; EPA, 2004a, p. 8–237). More specifically, as discussed in the proposal (71 FR 2633–2634), the recent time-series epidemiologic studies evaluated in the Criteria Document have included some degree of control for variations in weather and seasonal variables. However, 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, 2004a, 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.

The HEI commentary also reached several other relevant conclusions about the reanalysis of time-series studies: upon reanalysis, the PM effect persisted in the majority of studies; in some of the large number of studies in which the PM effect persisted, the estimates of PM effects were substantially reduced; in the few studies in which further sensitivity analyses were performed, some showed marked sensitivity of the PM effect estimate to the degree of smoothing and/or the specification of

[19] As discussed in section II.A.2.a of the proposal (71 FR 2629–2630, 2633), this body of studies includes those that did not use generalized additive models or were reanalyzed to address problems with applications of statistical software used in a number of important studies, as noted above in section I.C.

weather; and, in most studies, parametric smoothing approaches used to obtain correct standard errors of the PM effect estimates produced slightly larger standard errors than with the use of generalized additive models. However, the impact of these larger standard errors on the level of statistical significance of the PM effect was minor (EPA, 2004a, pp. 8–237 to 8–238). 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, 2004a, pp. 8–340, 8–341).

For long-term exposure to fine particles, the reanalysis and extended analyses of data from prospective cohort studies 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 the extended analysis, Krewski *et al.* (2000) did identify model sensitivities related to education level and spatial patterns in the data (*e.g.*, correlations in air pollutant concentrations between cities within a region of the country). However, these model sensitivities do not invalidate the findings of statistically significant associations between long-term exposure to $PM_{2.5}$ and mortality. For example, while the association was stronger for the subset of the ACS cohort with the least education, there was an association with cardiorespiratory mortality in the entire population.[20]

In considering these issues related to uncertainties in the underlying health science, on balance, EPA believes that the available evidence interpreted in light of these remaining uncertainties does provide increased confidence relative to the last review in the reported associations between short- and long-term $PM_{2.5}$ exposures and mortality and morbidity effects, alone and in combination with other pollutants, and generally supports stronger inferences as to the causal nature of the associations. The EPA also believes that this increased confidence, when taken in context of the entire body of available health effects evidence and in light of the evidence from short-term exposure studies of associations observed in areas meeting the current suite of $PM_{2.5}$ standards, adds support to its conclusion that the current suite of $PM_{2.5}$ standards needs to be revised to provide increased public health protection. This increased confidence also adds support to the Administrator's decision to place greater reliance on the long-term exposure studies as the basis for the annual $PM_{2.5}$ standard and to place greater reliance on the short-term exposure studies as the basis for the 24-hour $PM_{2.5}$ standard.

(3) In asserting that the estimated risk upon attainment of the current $PM_{2.5}$ standards has decreased since 1997 (UARG, p. 23), these commenters compared results of EPA's risk assessment done in the last review with those from the Agency's risk assessment done as part of this review, and they concluded that risks upon attainment of the current $PM_{2.5}$ standards ''are almost surely far below those that were predicted in 1997'' (UARG, p. 25). These commenters used this conclusion as the basis for a claim that there is no reason to revise the current $PM_{2.5}$ standards. In particular, UARG and other commenters claimed that based on this purported reduction in risk estimates EPA cannot reconcile a decision to provide a greater level of health protection now than that afforded by the current standards with the ''not lower or higher than is necessary'' standard articulated by the Supreme Court in *Whitman*.

The EPA believes that this claim is fundamentally flawed for three reasons, as discussed in turn below: (i) It mischaracterizes the use of the quantitative risk assessment in the 1997 rulemaking; (ii) it is factually incorrect in comparing the quantitative risks estimated in 1997 with those estimated in the current rulemaking; and (iii) it fails to take into account that with similar risks, increased certainty in the risks presented by $PM_{2.5}$ implies greater concern than in the last review.

First, this claim mischaracterizes EPA's use of the risk assessment in 1997 in part by not recognizing that the illustrative risk assessment conducted for portions of two cities (Philadelphia and Los Angeles) in the last review was only used qualitatively to assess the need to revise the then-current PM_{10} standards. The EPA used the 1997 risk assessment estimates to confirm the conclusions drawn primarily from the epidemiological studies that ambient $PM_{2.5}$ levels allowed under the then current PM_{10} standards presented a serious public health problem. EPA did not use it as a basis for selecting the level of the 1997 PM standards. See 62 FR at 38656, 65; *ATA III*, 283 F. 3d at 373–74 (noting that EPA did not base the level of the standards on the numerical results of the risk assessment). In so doing, the Administrator concurred with CASAC's judgment that the quantitative risk estimates at the time were too uncertain for EPA to rely on in deciding the appropriate levels for the $PM_{2.5}$ NAAQS. Therefore, the final decision on the level of the NAAQS was not based on the absolute or relative risk reductions estimated in the quantitative risk assessment. Instead, the decision was based on a direct assessment of the available epidemiological studies and the concentration levels observed in urban areas examined in the studies where statistically significant effects had been observed. Since EPA did not rely on the 1997 quantitative risk estimates in setting the level of the 1997 standards, the 1997 estimates associated with those levels do not represent a decision on a requisite level of quantified risk from PM exposure, and therefore do not support the argument that a lower estimated risk is more than is necessary to provide the requisite level of protection. As a result, the suggested quantitative comparison between the 1997 estimates and the current estimates of risks at the levels of the current standards is not an appropriate basis for determining whether the current suite of $PM_{2.5}$ standards needs to be revised.

Second, EPA relies on the current risk estimates associated with meeting the current standards in a qualitative manner, as in 1997, to inform the conclusions drawn primarily from the epidemiological studies on whether ambient $PM_{2.5}$ levels allowed under the current suite of $PM_{2.5}$ standards present a serious public health problem warranting revision of the suite of $PM_{2.5}$ standards. The 1997 estimate of these risks, or any comparison of the 1997 risk estimates to the current estimates, are irrelevant for that purpose, as the 1997 estimates reflect an outdated analysis that has been updated in this review to reflect the current science.

Further, even if the 1997 and current risk assessments were legitimately comparable for decision-making purposes, it would still be factually

[20] More specifically, 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).

incorrect to conclude that EPA accepted significantly greater risk in 1997 than is now estimated to be associated with the 1997 standards based on the most recent risk assessment. It is important to note that a very large proportion of the quantitative risks estimated in 1997 and today comes from long-term exposure mortality. The primary estimates from the current risk assessment (which assume a potential threshold of 10 µg/m³, as recommended by CASAC) result in residual risks in terms of percent of total incidence that are about the same in the current review as they were in the last review for both Philadelphia and Los Angeles.

Third, it is important to take into account EPA's increased level of confidence in the associations between short- and long-term $PM_{2.5}$ exposures and mortality and morbidity effects. In comparing the scientific understanding of the risk presented by exposure to $PM_{2.5}$ between the last and current reviews, one must examine not only the quantitative estimate of risk from those exposures (*e.g.* the numbers of premature deaths or increased hospital admissions at various levels), but also the degree of confidence that the Agency has that the observed health effects are causally linked to $PM_{2.5}$ exposure at those levels. As documented in the Criteria Document and the recommendations and conclusions of CASAC, EPA recognizes significant advances in our understanding of the health effects of $PM_{2.5}$, based on reanalyses, extended analyses and new epidemiology studies, new human and animal studies documenting effects of concentrated ambient particles, new laboratory studies identifying and investigating biological mechanisms of PM toxicity, and new studies addressing the utility of using ambient monitors to assess population exposures to particles of outdoor origin. As a result of these advances, EPA is now more certain that fine particles, alone or in combination with other pollutants, present a significant risk to public health at levels at or above the range of levels that the Agency had considered for these standards in 1997. From this more comprehensive perspective, since the risks presented by $PM_{2.5}$ are more certain and the overall current quantitative risk estimates are about the same as in 1997, $PM_{2.5}$-related risks are now of greater concern than in the last review.

In sum, quantitative risk estimates were not a basis for EPA's decision in setting a level for the $PM_{2.5}$ standards in 1997, and they do not set any quantified ''benchmark'' for the Agency's decision to revise the $PM_{2.5}$ standards at this time. In any case, there is not a significant difference in the risk estimates from 1997 to now. Finally, EPA believes that confidence in the causal relationships between short- and long-term exposures to fine particles and various health effects has increased markedly since 1997. Therefore, similar or even somewhat lower quantitative risk estimates today would not be a basis to conclude that no revision to the suite of $PM_{2.5}$ standards is ''requisite'' to protect public health with an adequate margin of safety.

(4) Some of these commenters also identified ''new'' studies that were not included in the Criteria Document as showing ''continued erosion of the hypothesis that there is a causal connection between fine PM mass and health effects'' and further supporting ''the conclusion that more stringent $PM_{2.5}$ standards are not justified'' (Pillsbury *et al.*, p. 14). As discussed above in section I.C, EPA notes that, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review, and will consider newly published studies for purposes of decision making in the next PM NAAQS review. Nonetheless, in provisionally evaluating commenters' arguments (see Response to Comments document), EPA notes that its provisional assessment of ''new'' science found that such studies did not materially change the conclusions in the Criteria Document.

3. Conclusions Regarding the Need for Revision

Having carefully considered the public comments, as discussed above, the Administrator believes the fundamental scientific conclusions on the effects of $PM_{2.5}$ reached in the Criteria Document and Staff Paper, discussed above in section II.B.1, remain valid. In considering whether the suite of primary $PM_{2.5}$ standards should be revised, the Administrator places primary consideration on the evidence obtained from the epidemiologic studies, and finds the evidence of serious health effects reported in short-term exposure studies conducted in areas that would meet the current suite of $PM_{2.5}$ 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. The Administrator believes that this literature collectively represents a strong and generally robust body of evidence of serious health effects associated with both short- and long-term exposures to $PM_{2.5}$. Further, the Administrator believes that the increased confidence in the evidence of health effects associated with long-term exposure to $PM_{2.5}$ supports relying on long-term exposure studies as the basis for setting the annual standard in this review. This is in contrast to 1997 when EPA relied primarily on evidence from the then-available short-term exposure studies as the primary basis for setting the annual standard. As discussed in the Criteria Document and Staff Paper, the Administrator believes that much progress has been made since the last review in reducing some of the major uncertainties that were important considerations in establishing the current suite of $PM_{2.5}$ standards.

Extensive critical review of this body of evidence, the quantitative risk assessment, and related uncertainties during the criteria and standards review process, including review by CASAC and the public of the basis for EPA's proposed decision to revise the suite of primary $PM_{2.5}$ standards, has identified a number of issues about which different reviewers disagree and for which additional research is warranted. Nonetheless, on balance, the Administrator believes that the remaining uncertainties in the available evidence do not diminish confidence in the associations between serious mortality and morbidity effects and exposure to fine particles, in particular as reported in peer-reviewed short-term exposure studies at levels allowed by the current standards. In this regard, the Administrator agrees with CASAC and the majority of public commenters that revision of the current suite of $PM_{2.5}$ standards to provide increased public health protection is both appropriate and necessary. Based on these considerations, the Administrator concludes that the current suite of primary $PM_{2.5}$ standards, taken together, is not sufficient and thus not requisite to protect public health with an adequate margin of safety, and that revision is needed to provide increased public health protection.

It is important to note that this conclusion, and the reasoning on which it is based, do not address the question of what specific revisions are appropriate. That requires looking specifically at the current indicator, averaging time, form, and level of the 24-hour and annual $PM_{2.5}$ standards, and evaluating the evidence relevant to determining whether any of those elements should be revised. The analyses discussed above concerning the need to revise the current standards go no further than determining whether the evidence, taken as a whole, indicates that greater public health protection is needed than that provided by the current suite of $PM_{2.5}$ standards.

C. Indicator for 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. Second, 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 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).

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, 2004a 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, 2003; Mar *et al.*, 2003; Tsai *et al.*, 2000; EPA, 2004a, section 8.2.2.5). Schwartz (2003) 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).[21] 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).[22] No significant increase in mortality was reported with a source factor representing crustal material in fine particles (EPA, 2004a, 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, 2004a, 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, 2004a, section 7.10.2). In addition, some recent studies have suggested that the ultrafine subset of fine particles (generally including particles with a nominal aerodynamic diameter less than 0.1 µm) may also be associated with adverse effects (EPA, 2004a, pp. 8–67 to 8–68).

The Criteria Document recognized 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

[21] Mar *et al.* (2000) noted that sulfate alone in a single-pollutant model was not associated with cardiovascular mortality, but that the sulfate "factor," which was so associated, contained elevated levels of lead and bromine. The authors state that the health association with the sulfate (S) factor "may be reflective of the contribution of Pb [lead] and Br [bromine] to the S factor." Mar *et al.* (2003) did not provide information about single-pollutant analysis of sulfate or about contribution of Pb and Br to the S factor.

[22] 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.

exposure to particles may elicit effects that are linked with a mixture of components more than with any individual PM component (EPA, 2004a, 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 concluded: ‘‘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, 2004a, p. 9–31). Conversely, the Criteria Document provided no basis to conclude that any individual fine particle component cannot be associated with adverse health effects (EPA, 2005, 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 continued 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 concluded that it remains appropriate to control fine particles as a group; i.e., that total mass of fine particles is the most appropriate indicator for fine particle standards (EPA, 2005, p. 5–17).

With regard to an appropriate size cut for a size-based indicator of total fine particle mass, the Criteria Document concluded 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, 2004a, p. 9–22). This conclusion followed 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 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 in the Staff Paper (EPA, 2005, p. 5–18), which was endorsed by CASAC in its recommendations for $PM_{2.5}$ standards (Henderson, 2005a, p. 6). In addition, the Staff Paper recognized 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, 2005, p. 5–18).

Consistent with the Staff Paper and CASAC recommendations, the Administrator proposed to retain $PM_{2.5}$ as the indicator for fine particles. Further, the Administrator provisionally concluded 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.

In so doing, the Administrator also noted that some commenters had 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 $PM_{2.5}$. 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 provided some limited evidence of such associations that is helping to focus research activities, the Administrator solicited 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 was 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 (71 FR at 2645). More specifically, the proposal solicited comment on a number of related issues, including the extent to which reducing particular types of PM (differentiated by either size or chemistry) might alter the size and toxicity of remaining particles; the extent to which fine particles in urban and rural areas can be differentiated by size or chemistry; 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; and on studies using concentrated ambient particles (CAPs) and their use in examining the toxicity of specific mixtures of pollutants or of particular source categories.

The EPA received comparatively few public comments on issues related to the indicator for fine particles.[23] Public comments from all major public and private sector groups received on the proposal were overwhelmingly in favor of EPA's proposal to retain $PM_{2.5}$ as the indicator for fine particles. Commenters who supported retaining $PM_{2.5}$ as an indicator argued that current scientific evidence does not identify specific components or sources of concern and therefore, that a mass-based indicator remains the appropriate indicator for fine particles (Engine Manufacturers Association; American Lung Association *et al.*). Some commenters emphasized the need to conduct additional research to more fully

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

understand the effect of specific PM components and/or sources on public health. For example, the Electric Power Research Institute highlighted specific new research studies that had been completed since the close of the Criteria Document addressing issues related to fine particle components and source apportionment, and noted its ongoing research on component-related health effects that includes coordinated epidemiology, toxicology, and exposure assessment studies. The Administrator recognizes the work of the Electric Power Research Institute and agrees that additional research is important to improve future understanding of the role of specific fine particle components and/or sources of fine particles. The Administrator also recognizes the ongoing efforts of HEI to conduct additional multidisciplinary research targeted at expanding the available data on the health effects associated with specific PM components (HEI, 2005).

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

D. 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 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. The 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. The 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. The 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 supported consideration of different averaging times for $PM_{2.5}$ standards, the Staff Paper concluded 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 made the following observations (EPA, 2005, 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, 2004a, section 3.5.5.1). While the Staff Paper concluded 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, 2004a, section 3.5.5). While such studies continue to suggest consideration of a multiple day averaging time, the Staff Paper noted 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 concluded 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, 2004a, section 3.5.5.3), the Staff Paper concluded 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, p. 6) recommended retaining the current annual and 24-hour averaging times for $PM_{2.5}$ primary standards. The Administrator concurred with the staff and CASAC recommendations and proposed 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.

The EPA received very limited public comment on the issue of averaging time for the $PM_{2.5}$ primary standards. A group of public health and environmental organizations agreed that ''the EPA has selected the appropriate averaging times for the fine particle standards'' (American Lung Association *et al.*).

Having considered the public comments on this issue, the Administrator concurs with the recommendations presented in the Staff Paper and recommendations made by CASAC (Henderson, 2005a) and concludes, as proposed, that it is appropriate to retain the current annual and 24-hour averaging times for the primary $PM_{2.5}$ standards to protect against health effects associated with short-term and long-term exposure periods.

E. 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 38671–74). EPA found that, as compared to an exceedance-based form used in earlier PM standards, 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. 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 concluded 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 was 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 recommended either retaining the 98th percentile form or revising it to be based on the 99th percentile form, and noted that primary consideration should be given to the combination of form and level, as compared to looking at the form in isolation (EPA, 2005, p. 5–44).

In considering the information provided in the Staff Paper, most CASAC Panel members favored continued use of the 98th percentile for a concentration-based form because it is more robust than the 99th percentile, such that it would provide more stability to prevent areas from moving 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 the standard affords.

In considering the available information and the Staff Paper and CASAC recommendations, the Administrator proposed to retain the form for the 24-hour standard. In so doing, the Administrator 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.

None of the public commenters raised objections to continuing the use of a concentration-based form for the 24-hour standard. Many of the individuals and groups who supported a more stringent 24-hour $PM_{2.5}$ standard noted above in Section II.B, however, recommended a more restrictive concentration-based percentile form, specifically a 99th percentile form. The limited number of these commenters who provided a specific rationale for this recommendation generally expressed their concern that the 98th percentile form could allow too many days where concentrations exceeded the level of the standard, and thus fail to adequately protect public health. The EPA received comparatively few public comments from State and local air pollution control authorities and tribal organizations on the form of the 24-hour $PM_{2.5}$ standard. Of the limited number of state air pollution control authorities that commented on the form of the 24-hour $PM_{2.5}$ standard, all supported retaining the 98th percentile form. Of the limited number of local air pollution control authorities and tribal organizations that commented on the form of the 24-hour $PM_{2.5}$ standard, some supported retaining the 98th percentile form while others supported the 99th percentile form. Beyond their support for retaining the current 24-hour $PM_{2.5}$ standard, which has a 98th percentile form, commenters representing industry associations and businesses provided no specific comments regarding the form of the 24-hour $PM_{2.5}$ standard.

The EPA notes that the viewpoints represented in this review are similar to comments submitted in the last review and through various NAAQS reviews. The EPA recognizes that the selection of the appropriate form includes maintaining adequate protection against peak 24-hour values while also providing a stable target for risk management programs, which serves to provide for the most effective public health protection in the long run.[24] Nothing in the commenters' views has provided a reason to change the Administrator's previous conclusion regarding the appropriate balance represented in the proposed form of the 24-hour $PM_{2.5}$ standard. Therefore, the Administrator concurs with CASAC recommendations and concludes that it is appropriate to retain the 98th percentile form for the 24-hour $PM_{2.5}$ standard.

In reaching this conclusion, EPA also recognizes that several states that otherwise supported EPA's proposal to retain the 98th percentile form of the 24-hour $PM_{2.5}$ standard raised concerns regarding a technical problem associated with a potential bias in the method used to calculate the 98th percentile concentration for this form. NESCAUM, in particular, noted that ''the existing and proposed methodology yields a lower (*i.e.*, less stringent) value on average for a 1 in 3 day frequency sample data-set compared to a daily sample data-set by approximately 1 μg/m ^{3}'' (NESCAUM, p. 3), and recommended revisions to the methodology such that ''the calculation becomes insensitive to data capture rate or sampling frequency'' (NESCAUM, Attachment A, p.7). Another state commenter suggested the issue could be addressed by ''the addition of language that requires areas that are near the daily NAAQS to continue to use every day FRM/FEM sampling'' (Delaware Department of Natural Resources, p. 4). The EPA agrees with these commenters that the potential bias in calculating the design value of the 24-hour $PM_{2.5}$ standard is a concern. To reduce this bias, EPA had proposed to increase the sampling frequency for monitoring sites that were within 10 percent of the standard to 1 in 3 day sampling (Part 58 section 12(d)(1)). The EPA is persuaded by these comments that it is appropriate to adjust the proposed sampling frequency requirements in order to further reduce this bias. Accordingly, EPA is modifying the final monitoring requirements such that areas that are within 5 percent of the standard will be required to increase the frequency of sampling to every day (Part 58 section 12(d)(1).[25]

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 Appendix N section 1.0(c) and 2.1(a) and (b) and Part 58 Appendix D section 2.8.1.6.1; 62 FR 38672). Community-oriented monitoring sites were specified to be consistent with the intent that a spatially averaged annual standard protect persons living in smaller communities, as well as those in larger population centers. The constraints on allowing the use of spatially averaged measurements were

[24] See *ATA III,* 283 F. 3d at 374–375 which concludes it is 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.

[25] See final rulemaking notice regarding revisions to ambient air monitoring requirements, elsewhere in today's **Federal Register**.

intended to limit averaging across poorly correlated or widely disparate air quality values.[26] This approach was judged to be consistent with the short-term epidemiologic studies on which the annual $PM_{2.5}$ standard was primarily based, in which air quality data were generally averaged across multiple monitors in an area or were taken from a single monitor that was selected to represent community-wide exposures, 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 exists a much larger set of $PM_{2.5}$ air quality data than was available in the last review. Consideration in the Staff Paper of the spatial variability across urban areas that is revealed by this new data base 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, took 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, 2005, section 4.4.3.2). In particular, this included analyses of 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 on spatial averaging allowed by the current standard.[27] As expected, estimated risks associated with long-term exposures that remain 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.[28]

In considering the potential for disproportionate impacts on potentially vulnerable subpopulations, EPA assessed whether any such groups are more likely than the general population to live in census tracts in which the monitors recording the highest air quality values in an area are located. Data used in this analysis included demographic parameters measured at the census 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 observed 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 percentages of minority populations (EPA, 2005, p. 5–41).[29] Noting the intended purposes of the form of the annual standard, as discussed above, the Staff Paper concluded 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 these potentially vulnerable subpopulations.

In considering whether more stringent constraints on the use of spatial averaging may be appropriate, the Staff Paper presented results of an analysis of recent air quality data which assessed 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 (in Appendix D of Part 58, section 2.8.1.6.1) of a minimum correlation of at least 0.6, which was met by nearly all monitor pairs. The current criterion that differences in mean air quality values between individual monitors and the corresponding multi-site spatial average not exceed 20 percent on an annual basis also was met for most monitor pairs, while the actual annual median and mean differences for all monitor pairs were 5 percent and 8 percent, respectively. This analysis also showed 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 provided some perspective on the constraints on spatial averaging that were adopted in the last review before data were widely available on spatial distributions of $PM_{2.5}$ air quality levels.

In considering the results of the analyses discussed above, the Staff Paper concluded 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 narrowing the constraints on spatial averaging to be based on more restrictive criteria. More specifically, based on the analyses discussed above, the Staff Paper recommended 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, and annual mean differences between individual monitors and corresponding spatial averages not exceed 10 percent (EPA, 2005, p. 5–42).[30]

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[26] 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 and that areas in which monitoring results may be averaged should principally be affected by the same major emission source of $PM_{2.5}$ (Part 58 App. D section 2.8.1.6.1).

[27] As discussed in the Staff Paper (EPA, 2005; 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 amount of reduction in $PM_{2.5}$ levels that is 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.

[28] 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 more than 40 percent higher than estimated incidence based on the use of the highest monitor (EPA, 2005, p.5–41).

[29] As summarized in section II.A.4 of the proposal, the Criteria Document notes that some epidemiologic study results, most notably the associations between total 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, 2004a, 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 from proximity to sources such as roadways and industry, as well as other factors such as poorer health status and access to health care (EPA, 2004a, section 9.2.4.5).

[30] In CASAC's review of the Second Draft Staff Paper, most of the members of the CASAC Review Panel found the fine particle sections to be ''generally well-written and scientifically well-reasoned'' but, beyond their recommendation that the primary $PM_{2.5}$ standards should be strengthened, CASAC provided no specific

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 proposed to revise the form of the annual $PM_{2.5}$ standard consistent with the Staff Paper recommendation to change two of 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 (71 FR 2647). The Administrator also solicited comment on the other Staff Paper-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 (*Id.* at 2647–48).

Relatively few public comments were received on the form of the annual $PM_{2.5}$ standard. Of the commenters noted above in Section II.B who supported a more stringent annual $PM_{2.5}$ standard, those who commented on the form of the annual $PM_{2.5}$ standard argued that the EPA analyses described above demonstrated that the current form of the standard results in uneven public health protection leading to disproportionate impacts on potentially vulnerable subpopulations, and thus a change in the form of the standard is needed. However, these commenters argued that the proposed modifications to the spatial averaging criteria were not stringent enough and, in order to reduce the possibility of pollution hotspots and disproportionate impacts, especially in areas meeting the annual $PM_{2.5}$ standard, spatial averaging should be eliminated (American Lung Association *et al.*, 2006, pp. 44–47; Schwartz, 2005, p. 2). Of the commenters noted above in Section II.B who supported retaining the current annual $PM_{2.5}$ standard, those who commented specifically on the form of the standard supported retaining the current spatial averaging criteria. These views are most extensively presented in comments from UARG who argued that changes to the spatial averaging criteria, effectively increasing the stringency of the standard, are not needed as the current standards provide the requisite degree of public health protection (UARG, 2006. pp. 33–36). In addition, one state air pollution control agency supported a more stringent level for the annual $PM_{2.5}$ standard in the range recommended by CASAC but also supported retaining the option for spatial averaging for the form of the standard arguing that ''rarely is one monitor representative of an entire nonattainment area'' especially in the western U.S. (Utah Department of Environmental Quality, 2006, p. 2).

The Administrator emphasizes that the intent of the current spatial averaging criteria, as defined in 1997 based on a limited set of $PM_{2.5}$ air quality data, was to ensure that spatial averaging would not result in inequities in the level of protection provided by the $PM_{2.5}$ standards against health effects associated with short- and long-term exposures to $PM_{2.5}$. Based on the analyses described above (Schmidt *et al.*, 2005), which are based on the much larger set of air quality data that has become available since the last review, EPA now believes that tighter constraints on spatial averaging are necessary to address concerns over potential disproportionate impacts on the populations that EPA has identified as being potentially vulnerable to $PM_{2.5}$-related health effects. The EPA believes that current information and analyses indicate that application of the current form has the clear potential to result in disproportionate impacts on potentially vulnerable subpopulations in some areas. The EPA recognizes that the proposed constraints have the potential to increase the stringency of the annual $PM_{2.5}$ standard in some areas in which a State might choose to use spatial averaging. The EPA believes that in such cases this increased stringency is warranted so as to address possible disproportionate impacts on potentially vulnerable populations and more generally to avoid inequities across all population groups. The EPA disagrees with those commenters who support eliminating spatial averaging altogether. The EPA believes that the proposed narrowing of the spatial averaging criteria will adequately address the concerns about disproportionate impact raised by some commenters, as analyzed in the Staff Paper, by substantially reducing the amount of spatial variation in long-term ambient levels that will be allowed to be averaged together in determining compliance with the standard. Therefore, the Administrator concludes that the current form of the standard should be retained with the proposed modifications. The form of the annual $PM_{2.5}$ standard is retained as an annual arithmetic mean, averaged over 3 years; however, the following two aspects of the spatial averaging criteria are narrowed: (1) The annual mean concentration at each site shall be within 10 percent of the spatially averaged annual mean, and (2) the daily values for each monitoring site pair shall yield a correlation coefficient of at least 0.9 for each calendar quarter.

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

In the last review, having concluded that it was appropriate to establish both 24-hour and annual $PM_{2.5}$ standards, EPA selected a level for each standard that was appropriate for the function to be served by each (62 FR 38674, 38676–77). As noted 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.[31] 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.[32]

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 by EPA 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, EPA placed greater emphasis 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

comments regarding the form of the annual standard (Henderson, 2005a, pp. 1–2).

[31] 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).

[32] *See also ATA III,* 283 F.3d at 373 (endorsing this reasoning).

strongest evidence for short-term $PM_{2.5}$ effects occurs for air quality distributions with long-term 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 somewhat 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 built upon and broadened the general approach used by EPA in the last review. This broader approach reflected 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 was used to conduct a more comprehensive risk assessment for $PM_{2.5}$. As a consequence, the broader approach used in the Staff Paper discussed ways to take into account both evidence-based and quantitative risk-based considerations and placed 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 considered it appropriate to use a somewhat different evidence-based approach from that used in the last review to propose appropriate standard levels. In the Administrator's view, the very large numbers of $PM_{2.5}$ health effect studies that now make up the available body of evidence provide the most reliable basis for determining the level of the standards. More specifically, EPA's proposal relied on an evidence-based approach that considered 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, with such standard aimed at protecting against health effects associated with short-term exposures to $PM_{2.5}$. Likewise, the stronger and more robust body of evidence from the long-term exposure $PM_{2.5}$ studies was considered as the principal basis for selecting the level of the annual standard, with such standard aimed at protecting against health effects associated with long-term exposures to $PM_{2.5.}$

With respect to the quantitative risk assessment, the Administrator recognized at proposal 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 was 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 recognized that for purposes of developing quantitative risk estimates such uncertainties are likely to amplified by the complexity in the composition of the mix of fine particles generally present in the ambient air. Further, in the Administrator's view, this risk assessment, which is based on studies that do not resolve the issue of a threshold, has important limitations as a basis for standard setting, since if no threshold is assumed the assessment necessarily predicts that ever lower standards result in ever lower risks. This has the effect of masking the increasing uncertainty in the risk estimates that exists as lower levels are considered, even when a range of assumed thresholds is included. As a result, at the time of proposal the Administrator viewed 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, but he judged that it did not provide an appropriate basis to determine what specific quantitative revisions are appropriate.

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

Based on the approach discussed above, the Administrator relied upon evidence from the short-term exposure $PM_{2.5}$ studies as the principal basis for selecting the proposed level of the 24-hour standard. In considering these studies as a basis for the level of a 24-hour standard, and having provisionally selected a 98th percentile form for the standard, the Administrator agreed with the focus in the Staff Paper of looking at the 98th percentile values in these studies. In so doing, the Administrator recognized 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 was seeking to establish a standard level that will require improvements in air quality generally in areas in which the distribution of daily short-term exposure to $PM_{2.5}$ can reasonably be expected to be associated with serious health effects. Although future air quality improvement strategies in any particular area are not yet defined, most such strategies are likely to move a 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 in a supporting staff memorandum,[33] the Administrator observed an overall pattern of statistically significant associations reported in studies of short-term exposure to $PM_{2.5}$ across a wide range of 24-hour average 98th percentile values. More specifically, the Administrator observed a strong predominance of studies with 98th percentile values down to about 39 μg/m^3 (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 Cities study (and three of four individual cities within that study [34]) (Klemm and Mason, 2003), the Canadian 8-City Study (Burnett and Goldberg, 2003), and in studies in Santa Clara County, CA

[33] As discussed in the Staff Paper (EPA, 2005, 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 are based on relatively reliable air quality data. Additional air quality data used in this analysis were documented in another staff memo (Ross and Langstaff, 2006) that was placed in the docket during the public comment period.

[34] Of the four cities in this study that were within this range of air quality, statistically significant results were reported for Boston, St. Louis, and Knoxville, but not for Steubenville.

(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 heart failure [35] and pneumonia, but not for other causes), and Montreal (Delfino *et al.*, 1998,[36] for some but not all age groups and years); and for respiratory symptoms in panel studies in a combined Six Cities study (Schwartz *et al.*, 1994, as reanalyzed in Schwartz and Neas, 2000) and in two Pennsylvania cities (Uniontown in Neas *et al.*, 1995; State College in Neas *et al.*, 1996).[37] Studies in this air quality range that reported positive but not statistically significant associations include mortality studies in Detroit (Ito, 2003), Pittsburgh (Chock *et al.*, 2000), Steubenville (Klemm and Mason, 2003), and Montreal (Goldberg and Burnett, 2003), and a study of lung function in Philadelphia [38] (Neas *et al.*, 1999).

Within the range of 24-hour average 98th percentile $PM_{2.5}$ concentrations of about 35 to 30 μg/m³, the Administrator no longer observed this strong predominance of statistically significant results. Rather, within this range, one study reports statistically significant results (Mar *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),[39] and other studies report associations that are not statistically significant (Ostro, 2003; [40] two individual cities within Klemm and Mason, 2003). Further, the Administrator concluded that the very limited number of studies in which the 98th percentile values are below this range (Stieb *et al.*, 2000; Peters *et al.*, 2001) do not provide a basis for reaching conclusions about associations at such levels. Thus, in the Administrator's view, this body of evidence provided confidence that statistically significant associations are occurring down close to this range, and it provided a clear basis for provisionally concluding that this range represents a range of reasonable values for a 24-hour standard level. The Administrator further noted 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, p. 7). The Administrator recognized, 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 (*Id.*), as discussed in section II.F.2 below.

At proposal, in considering what level would be appropriate for a 24-hour standard, the Administrator was 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 effects thresholds, EPA may select a specific standard level from within a range of reasonable values. In making this judgment, the Administrator noted that the general uncertainties related to the shape of the concentration-response functions and to 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 indicated an increase in uncertainty as to whether likely causal associations extend down below this level (71 FR 2649).

In considering the extent to which the quantitative risk assessment should inform EPA's selection of a 24-hour $PM_{2.5}$ standard, the Administrator recognized 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 was hesitant to use such risk estimates as a basis for proposing a specific standard level, particularly one below 35 μg/m³, and instead preferred to base the decision on level directly on the evidence in the studies themselves (71 FR 2649).

Taking the above considerations into account, the Administrator proposed to set the level of the primary 24-hour $PM_{2.5}$ standard at 35 μg/m³.[41] In the Administrator's judgment at that time, 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 appropriately considered the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognized that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

At the time of proposal, the Administrator recognized that sharply divergent views on the appropriate level of this standard had been presented to EPA as part of the NAAQS review process, and solicited comment on a wide range of standard levels and alternative approaches to characterizing and addressing scientific uncertainties. One such alternative view focused 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/m³ was warranted. In sharp contrast, others viewed the epidemiologic evidence and other health studies as strong and robust, and generally placed 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/m³. As discussed below, the same sharply divergent views were generally repeated in comments on the proposal by the two distinct groups of commenters identified in section II.B.2 above.

In considering comments received on the proposal, the Administrator first notes that CASAC provided additional recommendations concerning the

[35] The proposal incorrectly listed this as an association with ischemic heart disease.

[36] The proposal incorrectly included Delfino *et al.*, 1997 here as well as correctly including it in the next lower air quality range.

[37] Of the studies within this group that evaluated multi-pollutant associations, as discussed above in section II.A.3, the results reported in Fairley (2003), Sheppard (2003), and Ito (2003) were generally robust to inclusion of gaseous co-pollutants.

[38] The proposal incorrectly identified this as a statistically significant association.

[39] 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, 2004a, p. 8–164).

[40] The proposal incorrectly identified this as a statistically significant association.

[41] As noted above, the proposed form of the 24-hour standard was the same as the current standard.

proposed PM standards in a letter to the Administrator (Henderson, 2006, p. 2), noting that members of the CASAC PM Panel were generally pleased that the proposed 24-hour $PM_{2.5}$ primary standard was within the range that had previously been recommended by most members. Further, the Panel recognized that the proposed choice of the high end of the recommended range was a policy judgment. A number of commenters, including many States and Tribes, who supported the proposed level generally placed great weight on the recommendation of CASAC.

Many more commenters expressed disagreement with the proposed level. As noted above, these commenters generally fell into two distinct groups that expressed sharply divergent views on their interpretations of the science (in some cases taking into consideration ''new'' science not included in the Criteria Document), on the appropriate policy response based on the science, and on how the quantitative risk assessment should factor into a decision on the standard level.

In interpreting the available scientific information, including consideration of ''new'' science, and advocating a policy response based on the science, one group of commenters focused strongly on the uncertainties they saw in the scientific evidence as a basis for concluding that no change to the current level of the 24-hour $PM_{2.5}$ standard was warranted. This group included virtually all commenters representing industry associations and businesses. In commenting on the proposed level, these commenters most generally relied on the same arguments presented above in section II.B.2 as to why they believed it was inappropriate for EPA to make any revisions to the suite of primary $PM_{2.5}$ standards. That is, they asserted that the health effects of concern associated with short-term exposure to $PM_{2.5}$ have not changed significantly since 1997; that the uncertainties in the underlying time-series epidemiologic studies are as great or greater than in 1997; that the estimated risk upon attainment of the current $PM_{2.5}$ standards is lower now than it was when the $PM_{2.5}$ standards were set in 1997; and that ''new'' science not included in the Criteria Document continues to increase uncertainty about possible health risks associated with exposure to $PM_{2.5}$. These general comments are addressed above in section II.B.2.

In more specific comments, UARG and other commenters in this group called into question EPA's rationale for the proposed level of 35 μg/m³. In so doing, these commenters primarily relied on an examination of this rationale included in an attachment to UARG's comments as the basis for concluding that the available studies do not support EPA's view of the overall pattern of statistically significant associations in studies of short-term exposure to $PM_{2.5}$ across a wide range of 98th percentile $PM_{2.5}$ values. This examination of such studies concluded that there is no consistent pattern of associations at levels up to (and above) the 65 μg/m³ 98th percentile level of the current standard. This examination was based on an individual consultant's ranking of a set of short-term exposure studies by what is characterized as the ''overall significance'' of each study's results. A number of studies were included in this examination that EPA did not include in looking at the pattern of associations.

In considering the approach used in this examination, EPA concludes that the categorical rankings were inappropriately defined in a very restrictive way that overly emphasized certain studies based on selection criteria that favored multi-pollutant models and alternative model specifications, which had the effect of dismissing statistically significant results in some studies. This conclusion reflects EPA's consideration of these issues as presented above in section II.B.2. As noted there, EPA believes in the importance of a comprehensive evaluation that considers and weighs a variety of evidence, including biological plausibility of associations between the various pollutants and health outcomes, and focuses on the stability of the size of the effect estimates in time-series studies using both single- and multi-pollutant models, rather than just looking at statistical significance in a large number of alternative models and using it simplistically to delineate between real and suspect associations. In addition, the examination included several studies that, for a variety of reasons, EPA does not believe are appropriate for such an analysis. The inclusion of such studies, many of which had low statistical power, served to dilute the pattern of associations seen in studies considered by EPA as providing a more appropriate basis for this type of examination.

Further, even if this examination were to be accepted at face value, it still would support a distinction between the patterns of associations above and below the proposed level, in that over half of the cited studies with 98th percentile values above 35 μg/m³ were characterized as being of overall or mixed significance, and more than half of the cited studies with 98th percentile values below 35 μg/m³ were characterized as having no overall significant association. After fully considering this examination of patterns of study results, the Administrator believes that the observations of patterns of study results presented earlier in this section remain valid.[42]

The other group of commenters, including many medical groups, numerous physicians and academic researchers, many public health organizations, some States, and a large number of individual commenters, viewed the epidemiologic evidence and other health studies as strong and robust and expressed the belief that a much stronger policy response is warranted, generally consistent with a standard level at or below 25 μg/m³. Some of these commenters generally expressed the view that the level of the standard should be set below the lowest level observed in any of the studies that report any statistically significant association. Some also expressed the view that important uncertainties inherently present in the evidence 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.

More specifically, American Lung Association *et al.* and other commenters noted three studies included in the Criteria Document with 98th percentile values below 35 μg/m³, including a mortality study in Phoenix (Mar *et al.*, 2000; reanalyzed in Mar *et al.*, 2003) with a 98th percentile value of 32 μg/m³, a study of emergency department visits in Montreal (Delfino *et al.*, 1997) with a 98th percentile value of 31 μg/m³, and a study of increase in myocardial infarction in Boston (Peters *et al.*, 2001) with a 98th percentile value of 28 μg/m³. Further, these commenters expressed the view that EPA's proposed approach to selecting a level of the 24-hour $PM_{2.5}$ standard is fundamentally flawed because it ''relies unreasonably on point estimates of statistical significance at various concentrations, rather than on trends, and because it completely fails to consider issues of statistical power'' (American Lung Association *et al.*, p. 57). In addition, these commenters found EPA's justification for the proposed level to be ''simply irrational'' in that it ''essentially fabricates uncertainty'' as a basis for avoiding setting a standard that

[42] The EPA's consideration of this examination is discussed more fully in the Response to Comments document.

the evidence ''clearly indicates is necessary'' (*Id.*).

In considering these comments, the Administrator first notes that he generally agrees with CASAC's view that selecting a level within the range of 30 to 35 μg/m³ is a public health policy judgment and that the science does not dictate the selection of any specific level within this range. The Administrator also believes that this policy judgment should take into consideration the important uncertainties that remain in issues that are central to interpreting these types of time-series epidemiologic studies. While the Administrator believes that progress has been made since the last review in addressing key uncertainties, as discussed above in section II.B.2, EPA and the scientific community, including CASAC and the National Research Council (NRC), recognize that important uncertainties remain that warrant further research (*e.g.*, see NRC, 2004). Thus, the Administrator does not agree that the Agency is ''fabricating'' uncertainties that do not exist. More specifically, in considering the studies cited in these comments as a basis for a standard level below 35 μg/m³, the Administrator continues to believe that it is necessary to consider not only the results of these studies and the inherent uncertainties in such studies, but also the pattern of results from other studies with similar air quality values. In so doing, EPA notes that the statistically significant results in Peters *et al.* (2001) were uniquely associated with 1 to 2 hour lag times, but not with 24-hour average $PM_{2.5}$ concentrations, such that it would provide a very tenuous basis for the level of a 24-hour average national standard. While the studies in Phoenix and Montreal do provide some evidence of statistically significant associations within the range of 30 to 35 μg/m³, several other studies within this range of air quality that generally have somewhat greater statistical power and narrower confidence ranges do not provide such evidence. In making the public health policy judgment inherent in selecting a standard level, the Administrator believes that it is necessary to weigh the evidence and related uncertainties against the requirement that the standard is to be neither more nor less stringent than necessary to protect public health with an adequate margin of safety. See *NRDC* v. *EPA*, 902 F. 2d 962, 971 (D.C. Cir. 1990) (in considering level of a NAAQS, EPA is required to take into account all of the relevant studies in the record and rationally determine what weight to give each study); *API* v. *Costle*, 665 F. 2d 1176, 1187 (DC Cir. 1981) (same). In so doing, the Administrator does not agree that this evidence presented by American Lung Association *et al.* warrants a level below 35 μg/m³.

These commenters also identified several ''new'' studies in support of their arguments for a lower level. As noted above, as in past NAAQS reviews, EPA is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review, and will consider the newly published studies for purposes of decision making in the next PM NAAQS review. Nonetheless, in provisionally evaluating commenters' arguments (see Response to Comments document), EPA notes that its provisional assessment of ''new'' science found that such studies did not materially change the conclusions in the Criteria Document.

With regard to the other studies, EPA notes that neither the Vancouver nor the Atlanta studies found statistically significant associations with $PM_{2.5}$, and that the Atlanta and California studies were conducted in areas with 98th percentile $PM_{2.5}$ values well above the proposed level. Thus, EPA concludes that, taken at face value, these studies would provide no basis for the commenters' claim that they would require a lower standard level than one based on the science included in the Criteria Document.

With regard to considering how the quantitative risk assessment should factor into a decision on the standard level, EPA notes that both groups of commenters generally consider the risk assessment in their comments on the standard level, but they reach diametrically opposed conclusions as to what standard level is supported by the assessment. The general views of both groups on the implications of the risk assessment are presented above in section II.B.2, with one group arguing that it supports a decision not to revise either of the current $PM_{2.5}$ standards, and the other group arguing that it supports a decision to revise both $PM_{2.5}$ standards. More specifically, some of the medical/environmental health commenters consider the magnitude of risk estimated to remain upon meeting the proposed 24-hour standard as a strong reason to select a lower level. These commenters generally assert that the risks are likely even higher than EPA's primary estimates, in part because EPA incorporated a surrogate threshold of 10 μg/m³ even though there is no clear evidence of a threshold in the relevant time-series studies. On the other hand, the industry/business commenters generally assert that the risks are likely lower than EPA's primary estimates, in part because EPA did not base its primary estimates on an assessment that included all statistical model results presented in the studies. Having considered comments based on the quantitative risk assessment from both groups of commenters, the Administrator finds no basis to change the position on the risk assessment that was taken at the time of proposal. That is, as discussed above, while the Administrator recognizes that the risk assessment rests on a more extensive body of data and is more comprehensive in scope than the assessment conducted in the last review, he is mindful that significant uncertainties continue to underlie the resulting quantitative risk estimates. Further, in the Administrator's view, as noted above in this section, this risk assessment, which is based on studies that do not resolve the issue of a threshold, has important limitations as a basis for standard setting in this review, since if no threshold is assumed the assessment necessarily predicts that ever lower standards result in ever lower risks. This has the effect of masking the increasing uncertainty that exists as lower levels are considered, even when a range of assumed thresholds are considered. As a result, the Administrator judges that the quantitative risk assessment does not provide an appropriate basis for selecting the level of the 24-hour $PM_{2.5}$ standard.

After carefully taking the above comments and considerations into account, the Administrator has decided 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 will 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 $PM_{2.5}$. A standard set at a higher level would not likely result in improvements in air quality in areas across the country in which short-term exposure to $PM_{2.5}$ can reasonably be expected to be associated with serious health effects. A standard set at a lower level would only result in significant further public health protection if, in fact, there is a continuum of health risks down to the lower end of the ranges of air quality observed in the key epidemiologic studies and if the reported associations are, in fact, causally related to $PM_{2.5}$ at those lower levels. Based on the pattern of results observed in the available evidence, the Administrator is not prepared to make those assumptions. Taking into account the uncertainties that remain in interpreting the available epidemiologic studies, the likelihood of obtaining benefits to public health decreases at lower levels while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to reduce risks to public health increases. On balance, the Administrator does not believe that a lower standard is necessary to provide the requisite degree of public health protection. 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.

2. Annual $PM_{2.5}$ Standard

Based on the approach discussed above at the beginning of section II.F, at the time of proposal the Administrator relied upon evidence from the long-term exposure $PM_{2.5}$ studies as the principal basis for selecting the proposed level of the annual standard. In considering these studies as a basis for the level of an annual standard, the Administrator agreed with the evidence-based focus in the Staff Paper of looking at the long-term mean $PM_{2.5}$ concentrations across the cities included in such long-term studies. In so doing, the Administrator recognized 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 was 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 $PM_{2.5}$ exposure studies presented in the Criteria Document and Staff Paper, in the proposal the Administrator recognized the importance of the validation efforts and reanalyses 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/m³, respectively. The Administrator also particularly recognized 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.[43] The Administrator noted 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/m³) 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 robustness of results, concluded 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, 2004a, 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 placed greatest weight on these studies as a basis for selecting the proposed level of the annual $PM_{2.5}$ standard.

In addition to these mortality studies, the Administrator also recognized 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-Cities study considered in the last review and more recent 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 µg/m³, respectively. As discussed in section II.A. of the proposal (71 FR at 2632), in the 24 Cities 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 generally not statistically significant associations were reported with prevalence of several respiratory conditions. As interpreted in the last review, the results from the 24-Cities study are uncertain as to the extent to which the association extends below a long-term mean $PM_{2.5}$ concentration of approximately 15 µg/m³. The more recent 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 recognized 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 observed that 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, the Administrator provisionally concluded that this study provides an uncertain basis for establishing the level of a national standard (*Id.* at 2651).

The Administrator generally agreed that, as discussed in the Staff Paper (EPA, 2005, p. 5–22), it was 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 was mindful that considering what standard is requisite to protect public health with an adequate margin of safety requires public health policy judgments that neither overstate nor understate the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. The Administrator provisionally concluded that these key mortality studies, together

[43] In the extended ACS study, significant lung cancer associations were found for those with high school education or less, but not for those with better than a high school education. When data are combined for all education levels, a significant association is found.

with the morbidity studies, provide a basis for considering a standard level no higher than 15 μg/m³. 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 provisional view, these studies did not provide an appropriate basis for selecting a level lower than the current standard of 15 μg/m³.

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 recognized 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 levels 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 was again hesitant to use such risk estimates as a basis for proposing a lower annual standard level than 15 μg/m³, the level that is based directly on the evidence in the studies themselves, as discussed above.

Taking the above considerations into account, the Administrator proposed to retain the level of the primary annual $PM_{2.5}$ standard at 15 μg/m³. In the Administrator's judgment at that time, 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 considered the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognized that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

At the time of proposal, the Administrator recognized that the CASAC Panel did not endorse retaining the annual standard at the current level of 15 μg/m³ (Henderson, 2005a, p. 7). In weighing the recommendation of the CASAC Panel, the Administrator carefully considered CASAC's stated rationale. 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. The Panel then gave three reasons 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 μg/m³; (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 presented in the Staff Paper 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 indicate the desirability of lowering the level of the annual $PM_{2.5}$ standard as well as that of the 24-hour standard, so as to ensure that revisions to the standards achieve appropriate reductions in long-term exposures. 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 μg/m³, along with lowering the 24-hour standard (Henderson, 2005a, p. 7).

In considering these views, the Administrator noted 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 concluded that the evidence did not provide a basis for requiring annual levels below 15 μg/m³. Thus, the Administrator agreed 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 (71 FR 2652). Further, the Administrator agreed that this general advice supported 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 did not believe that this advice necessarily translated into a reason for setting the annual $PM_{2.5}$ standard at a level below the current level of 15 μg/m³. As discussed above, the Administrator believed that 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 the reported associations are likely causal, without reliance on the risk assessment, and that this evidence reasonably supported retaining the current level of the annual standard (*Id.*).

Reflecting the great importance that EPA places on the advice of CASAC, the Administrator solicited broad public comment on the range of 15 down to 13 μg/m³ the low end of the range recommended by CASAC for the level of the annual $PM_{2.5}$ standard, and on the reasoning that formed the basis for that recommendation. The Administrator recognized that a decision to select a standard in this range below 15 μg/m³ 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 (*Id.*).

At the time of proposal, the Administrator also recognized that sharply divergent views on the appropriate level of this standard had been presented to EPA as part of the NAAQS review process, and solicited comments on a wider range of levels, down to 12 μg/m³ on alternative views of the appropriate interpretation of the epidemiologic evidence and related uncertainties, and on relevant research that would improve our understanding of key issues and analytic approaches to better inform policy judgments in the future. As was the case with the 24-hour $PM_{2.5}$ standard, the same sharply divergent views were again expressed by the two distinct groups of commenters identified above in section II.B.2, as discussed below.

In considering comments received on the proposal, the Administrator first notes that CASAC requested that EPA reconsider its proposed decision on the level of the annual $PM_{2.5}$ standard and set the level within the range that CASAC had previously recommended, 13 to 14 μg/m³ (Henderson, 2006, p. 1).[44] In so doing, CASAC reiterated and elaborated on the scientific basis for its earlier recommendation (Henderson, 2006, pp. 3–4), which included consideration of the Agency's risk assessment (as ''the primary means of determining the effects on risk of changes in the 24-hour and annual $PM_{2.5}$ standards in concert'') as well as the observations that ''a lower daily $PM_{2.5}$ concentration limit alone cannot be relied on to provide protection against the adverse effects of higher annual average concentrations,'' that ''there is evidence that effects of long-term $PM_{2.5}$ concentrations occur at or below the level of the current standard,'' and that ''short-term effects of $PM_{2.5}$ persist in cities with annual $PM_{2.5}$ concentrations below the current standard'' down to approximately 13 μg/m³ (*e.g.*, Burnett and Goldberg, 2003; Mar *et al.*, 2003; and Lipsett *et al.*, 1997). The CASAC concluded:

> In summary, the epidemiologic evidence, supported by emerging mechanistic understanding, indicates adverse effects of $PM_{2.5}$ at current annual average levels below 15 μg/m³. The PM Panel realized the uncertainties involved in setting an appropriate, health-protective level for the annual standard, but noted that the uncertainties would increase rapidly below the level of 13 μg/m³. That is the basis for the PM Panel recommendation of a level at 13–14 μg/m³ (Henderson, 2006, p. 4).

In response to CASAC's request for reconsideration, the Administrator has carefully considered its stated views and the scientific basis for the range it recommended. As an initial matter, the Administrator notes that CASAC's recommendation to lower the level of the annual standard was based in large measure on the results of the Agency's risk assessment, which examined changes in both the 24-hour and annual standard levels in concert. In considering this information qualitatively, as discussed above in section II.B, the Administrator believes that the estimates of risks likely to remain upon attainment of the current suite of $PM_{2.5}$ standards are indicative of risks that can reasonably be judged to be important from a public health perspective, and thus support revision of the current suite of standards. In addressing what revisions to the current suite of $PM_{2.5}$ standards are appropriate, the Administrator has determined that the evidence of health effects associated with short-term exposure to $PM_{2.5}$ is such that it is appropriate to lower the level of the 24-hour $PM_{2.5}$ standard (as discussed in section II.F.1 above). However, as discussed more fully above, the Administrator also believes that this risk assessment has important limitations as a basis for setting a standard level in this review, in part because the available studies do not resolve questions related to potential effect thresholds and because of other important uncertainties noted above in section II.A.3. As a result, the Administrator judges that the quantitative risk assessment does not provide an appropriate basis for selecting the level of either the 24-hour or the annual $PM_{2.5}$ standard. Thus, the Administrator more heavily weighs the implications of the uncertainties associated with the Agency's quantitative risk assessment than CASAC apparently does, and disagrees with CASAC that the risk assessment results appropriately serve as a primary basis for a decision on the level of the annual $PM_{2.5}$ standard.

The CASAC also considered the evidence from specific short-term exposure studies as part of the basis for its recommendation for a lower annual standard level, pointing to studies indicating that effects from short-term exposure of $PM_{2.5}$ persist in cities with annual $PM_{2.5}$ concentrations below the current standard. While the Administrator does not disagree with CASAC's factual statements regarding the findings of the studies of short-term exposure effects, he believes that, based on the evidence available in this review, it is more appropriate to consider the short-term exposure studies as a basis for the level of the 24-hour standard and to consider the long-term exposure studies as a basis for the level of the annual standard. The Administrator recognizes that the Agency used available short-term exposure studies as the primary basis for setting the level of a ''generally controlling'' annual standard in the last review, with the purpose that the annual standard would provide protection against both short-term exposures and long-term exposures, but notes that such a public health policy choice was made primarily because the short-term exposure studies were judged to be the strongest evidence available at that time and the evidence from long-term exposure studies was judged to be too limited to serve as other than a secondary consideration in setting the level of the annual standard. See 62 FR 38675 n. 41 and 38676. In this review, however, the bodies of evidence for both short- and long-term exposures have been substantially extended and strengthened, such that each $PM_{2.5}$ standard can appropriately be evaluated based on the most directly relevant body of scientific studies, and can be focused on providing protection from the health risks evaluated in that body of scientific studies. The Administrator continues to believe, consistent with the evidence-based approach presented in the Staff Paper, that using evidence of effects associated with periods of exposure that are most closely matched to the averaging time of each standard is the most appropriate public health policy approach to evaluating the scientific evidence in selecting the level of each standard, with each standard designed to provide protection from the health risks associated with exposures reflecting that averaging time. Thus, the Administrator believes that the 24-hour standard should be set so as to provide an appropriate degree of protection from health effects associated with short-term exposures to $PM_{2.5}$, and the annual standard should be set so as to provide an appropriate degree of protection from health effects associated with long-term exposures to $PM_{2.5}$. In determining the level of each standard, the Administrator believes it is appropriate to rely on the short-term studies for purposes of determining the level of the 24-hour standard, and the long-term studies for purposes of determining the level of the annual standard.[45] Therefore, the Administrator does not believe that evidence from short-term exposure studies is an appropriate basis for selecting any different level of the annual standard in this review than that selected based on the long-term exposure evidence. The EPA has instead

[44] Two PM Panel members did not agree with the views of the majority, expressing the view that there was an adequate scientific basis to choose an annual $PM_{2.5}$ standard level within the range of 12 to 15 μg/m³ and that the choice of a specific level within that range was a policy decision (Henderson, 2006, p. 6).

[45] This is consistent with the approach taken in the Staff Paper, sections 5.3.4.1 and 5.3.5.1, for evaluating the evidence-based considerations related to setting the standards. The CASAC's letter of June 6, 2005 states that the Second Draft of the Staff Paper was ''Scientifically well-reasoned,'' with the exception of a section not relevant to the fine PM (Henderson, 2005a, pp. 1–2). The CASAC's general view thus includes this evidence-based approach presented in the Staff Paper.

evaluated these short-term exposure studies in the context of determining the appropriate level for the 24-hour standard.

Finally, CASAC also expressed the view that there is evidence that effects of long-term $PM_{2.5}$ concentrations occur at or below the level of the current standard. While the Administrator agrees that any such evidence would be directly relevant to his decision on the level of the annual $PM_{2.5}$ standard, CASAC did not provide any specific information as to what studies it felt provided such evidence nor the considerations that played a role in its interpretation of the studies, including its assessment of the uncertainties inherent in any such studies.[46] As discussed below, the Administrator has considered the available studies of long-term exposure to $PM_{2.5}$, together with the uncertainties inherent in that body of evidence, to reach his final decision on the level of the annual standard. However, since CASAC did not provide any more specific statements as to its assessment of such mortality or morbidity studies, the Administrator cannot determine in what ways his judgments about that evidence may differ from CASAC's views.[47] Lacking such specific statements to support CASAC's view that there is evidence that effects of long-term $PM_{2.5}$ concentrations occur at or below the level of the current standard, the Administrator cannot discern a clear line of scientific reasoning that would preclude the current level of 15 μg/m³ from being a reasonable policy choice based on the most relevant available evidence on the health effects of long-term exposures to $PM_{2.5}$.

As noted above, EPA received other comments on the proposal from two distinct groups of commenters. One group that included virtually all commenters representing industry associations and businesses agreed with the Agency's proposed decision not to revise the level of the annual $PM_{2.5}$ standard. The other group of commenters included many medical groups, numerous physicians and academic researchers, many public health organizations, many States, and a large number of individual commenters. They strongly disagreed with the Agency's proposed decision and argued that EPA should lower the level of the annual $PM_{2.5}$ standard. While some of these commenters felt that the level should be set within the range recommended by CASAC, most such commenters advocated a level of 12 μg/m³. These commenters largely based their views on the same general considerations put forward by CASAC as a basis for its recommendation to lower the level of the annual $PM_{2.5}$ standard. To the extent that these commenters, like CASAC, relied upon the Agency's risk assessment or the evidence from short-term exposure studies as a basis for their views, their comments are addressed above. Comments that address how specific long-term $PM_{2.5}$ exposure studies should be considered as a basis for the level of the annual $PM_{2.5}$ standard are addressed below.

A few commenters offered detailed comments on the key long-term exposure $PM_{2.5}$ mortality studies discussed in the proposal, including the original analyses and reanalyses of the ACS and Six Cities cohorts and the extended ACS cohort study. In general, some medical/public health/researcher/State commenters expressed the view that EPA has downplayed the results of these studies to the extent that they provide evidence of effects below the level of the current standard. For example, American Lung Association *et al.* and Schwartz (2006) asserted that the ACS cohort study and the HEI reanalysis provide direct evidence of premature mortality associated with annual exposures below 15 μg/m³ based on plots of the concentration-response function between long-term exposure to $PM_{2.5}$ and risk of dying across 50 U.S. metropolitan areas that show no substantial deviation from linear, non-threshold relationships down through levels well below 15 μg/m³. These commenters did not, however, discuss the uncertainties inherent in this type of epidemiologic study or the implications of these uncertainties on their interpretation of the results.

In contrast, some industry/business commenters (*e.g.*, Pillsbury *et al.;* Annapolis Center; UARG) emphasized that uncertainties remain in interpreting these studies with regard to issues such as potential confounding by co-pollutants, especially SO_2, modeling to address spatial correlations in the data, and effect modification by education level or socioeconomic status. In addition, some industry/business commenters raised additional questions about the appropriate interpretation of these key studies in light of other studies, which EPA did not rely on, that provided either mixed or no evidence of $PM_{2.5}$-mortality associations, and in light of their view that the studies that EPA relied on report implausibly large effect estimates.

In considering these commenters' sharply divergent assessments of the key mortality studies, the Administrator continues to believe that these studies provide strong evidence of an association between long-term exposure to $PM_{2.5}$ and mortality. However, the Administrator believes that the remaining uncertainties weigh against reaching the conclusion that the level of the annual $PM_{2.5}$ standard should be lowered on the basis of these studies. In reaching this conclusion, the Administrator notes that even though the long-term average $PM_{2.5}$ concentration across the cities in the extended ACS study (17.7 μg/m³) is lower than in the original study (21 μg/m³), the level of the current standard is still appreciably below the long-term average of the extended ACS study and that of the Six Cities study (18 μg/m³). In commenting on alternative approaches to interpreting the study results as a basis for setting a standard level, American Lung Association *et al.* expressed the view that the level of the standard should more appropriately be based on the concentration that is one standard deviation below the cross-city long-term average in each relevant long-term exposure study. In considering such an approach, the Administrator notes that while that approach would by definition lead to a more precautionary standard, there is no basis for concluding that it is a more scientifically defensible approach or that it is more appropriate in this case where a number of key uncertainties in the evidence remain to be addressed in future research, and where the basic decision is a judgment by the Administrator as to what level is neither more nor less stringent than is necessary to protect public health with an adequate margin of safety. The Administrator continues to believe that it is reasonable to base the decision on the standard level on long-term average $PM_{2.5}$ concentrations in the key long-term exposure studies, because 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 (71 FR 2651).

Both groups of commenters also identified several ''new'' mortality studies not included in the Criteria Document in support of their various views. As noted above in Section I.C, as in past NAAQS reviews, EPA is basing

[46] The EPA does not believe that CASAC based this statement on the evidence it cites concerning effects associated with the long-term means of the short-term studies. These studies address effects from short-term exposures, and do not address effects from long-term exposures.

[47] The CASAC did express the view that although the ''new'' scientific literature that was not included in the Criteria Document appears to support its findings, that literature was not needed to support its recommendation of a lower annual standard level (Henderson, 2006, p. 6).

the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review, and will consider the newly published studies for purposes of decision making in the next PM NAAQS review. Nonetheless, in provisionally evaluating commenters' arguments (see Response to Comments document), EPA notes that its provisional assessment of ''new'' science found that such studies did not materially change the conclusions in the Criteria Document.

Some commenters who supported a lower annual standard level also asserted that EPA failed to adequately consider long-term exposure $PM_{2.5}$ morbidity studies, especially studies of effects in children. For example, the Children's Health Protection Advisory Committee and other commenters noted that studies by Razienne *et al.* (1996) and Gauderman *et al.* (2002, 2004) showed effects on children's lung function at long-term cross-city average $PM_{2.5}$ concentrations of 14.5 μg/m^3 and 15 μg/m^3, respectively. The proposal notice included a careful discussion of the 24-Cities study (Razienne *et al.*, 1996) and the earlier Southern California children's health study (Gauderman *et al.*, 2000, 2002), studies which were included in the Criteria Document,[48] and explained the basis for the Administrator's provisional conclusion that these studies provide an uncertain basis for establishing the level of a national standard (71 FR 2651). These commenters offered no information that would change the Administrator's judgment with regard to these studies.[49] In addition, the Children's Health Advisory Committee also cited several studies of ''traffic-related'' pollution (van Vliet *et al.*, 1997; Brunekreef *et al.*, 1997; Kim *et al.*, 2004 [50]) as showing associations between fine particles and adverse respiratory outcomes, including asthma in children who live near major roadways, with mean annual average fine particle concentrations near and below 15 μg/m^3.

In considering these comments, EPA first notes that studies of traffic-related pollution generally do not disentangle potential effects of fine particles from those of other traffic-related pollutants, and thus provide an uncertain basis for establishing the level of a $PM_{2.5}$ standard. Further, two of the studies cited by this commenter are ''new'' studies not included in the Criteria Document. As discussed above in section I.C, EPA is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review, and will consider the newly published studies for purposes of decision making in the next PM NAAQS review.

The CARB and some other commenters who supported a lower annual standard level discussed the rationale used by the CARB in deciding to set the State's annual $PM_{2.5}$ standard at a level of 12 μg/m^3. Some of these commenters also pointed to the World Health Organization's annual $PM_{2.5}$ guideline value of 10 μg/m^3 in support of their view that the scientific evidence supports an annual $PM_{2.5}$ standard in the U.S. at a level no higher than 12 μg/m^3. In considering these comments, the Administrator notes that his decision is constrained by the provision of the CAA that requires that the NAAQS be requisite to protect public health with an adequate margin of safety. This requires that his judgment is to be 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. This is not the same legal framework that governs the standards set by the State of California or the guidelines established by a working group of scientists within the World Health Organization.[51] Thus, the Administrator does not agree that the California standard or the WHO guideline provide an appropriate basis for setting the level of the annual $PM_{2.5}$ NAAQS in the U.S.

The Administrator further stresses, as explained at proposal, that he is placing the greatest weight in determining the level of the annual standard on the long-term means of the levels associated with mortality effects in the two key long-term studies in the record, the ACS and Six Cities studies (71 FR at 2651). The ACS and Six Cities studies are the two key long-term studies in this review, taking into account both ''study design, strength of the study (in terms of statistical significance and precision of result), and the consistency and robustness of results'' (71 FR 2651), and also the comprehensive reanalyses of these studies, which involved replication, validation, and sensitivity analyses. These reanalyses replicated the original results and confirmed the associations noted in the original studies (EPA 2005, p. 3–17). The Administrator has taken into account all the relevant studies but in evaluating the strengths and weaknesses of the various studies has determined that the greatest weight should be placed on these key studies, as compared to other studies, in determining the level of the annual standard. As discussed above, the level of the current annual standard is appropriate as it is appreciably below the long-term average of these key studies. This standard is also basically at the same level as the long-term average in the two morbidity studies, the 24 Cities study and the Southern California children's cohort study. These morbidity studies provide an uncertain basis for setting the level of the national standard, and, therefore, in the judgment of the Administrator do not warrant setting a lower level for the annual standard than the level warranted based on the key mortality studies.[52]

After carefully taking the above comments and considerations into account, the Administrator has decided to retain the level of the primary annual $PM_{2.5}$ standard at 15 μg/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 $PM_{2.5}$. A standard set at a lower level would only result in significant further public health protection if, in fact, there is a continuum of health risks in areas with long-term average $PM_{2.5}$ concentrations that are well below the cross-city long-term average concentrations observed in

[48] The Gaudermann *et al.* (2004) study cited by these commenters is a ''new'' study, and EPA's provisional consideration of this study is discussed in the Response to Comments document.

[49] The Administrator notes that CASAC's letter of March 21, 2006 did not note any objection to his views on these morbidity studies as discussed in the proposal, or provide any reason to reconsider such views (Henderson, 2006).

[50] Kim *et al.* (2004) is a ''new'' study and EPA's provisional consideration of this study is discussed in the Response to Comments document.

[51] For example, the California statute does not refer to setting a standard that is ''requisite'' to protect, as that term is used in the CAA, and California, unlike EPA, may take economic impacts into consideration in setting air quality standards. In addition, as with the WHO guidelines, the standards appear to be more in the nature of goals as compared to binding requirements that must be met.

[52] The EPA is not required to base the level of the standard on either the highest or lowest level from any one study. Rather, the Administrator must ''make an informed judgment based on available evidence.'' *American Petroleum Inst* v. *Costle*, 665 F. 2d at 1187; *NRDC* v. *EPA,* 902 F. 2d at 971. Such an informed judgment can result in higher levels than shown in some of the studies in the record. See, e.g. *NRDC* v. *EPA*, 902 F. 2d at 971 (upholding 1987 PM_{10} annual standard selected from ''near the middle of the 'range of interest' ''); *API* v. *Costle*, 665 F. 2d at 1187 (upholding 1979 hourly standard for ozone selected at level higher than a number of studies in the record).

the key epidemiologic studies and if the reported associations are, in fact, causally related to $PM_{2.5}$ at those lower levels. Based on the available evidence, the Administrator is not prepared to make these assumptions. As was the case in considering the 24-hour $PM_{2.5}$ standard, taking into account the uncertainties that remain in interpreting the available long-term exposure epidemiologic studies, the likelihood of obtaining benefits to public health decreases with a standard set below the current level, while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to reduce risks to public health increases. On balance, the Administrator does not believe that a lower standard is needed to protect public health with an adequate margin of safety. 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.

G. Final 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, including its request to reconsider parts of the proposal, and public comments received on the proposal, the Administrator is revising the current primary $PM_{2.5}$ standards. The suite of standards as revised will provide increased protection from the health risks associated with exposure to $PM_{2.5}$, and in the judgment of the Administrator will be requisite to protect public health with an adequate margin of safety.

Specifically, the Administrator is making the following revisions:

(1) The level of the primary 24-hour $PM_{2.5}$ standard is revised to 35 $\mu g/m^3$.

(2) The form of the primary annual $PM_{2.5}$ standard is revised with regard to the criteria for spatial averaging, such that averaging across monitoring sites is allowed if the annual mean concentration at each monitoring site is within 10 percent of the spatially averaged annual mean, and the daily values for each monitoring site pair yield a correlation coefficient of at least 0.9 for each calendar quarter. Data handling conventions for the revised standards are specified in revisions to Appendix N, as discussed below in section V, and minor revisions to the reference method for monitoring PM as $PM_{2.5}$ are specified in Appendix L, as discussed below in section VI.

In a related rule on ambient air monitoring regulations (40 CFR Parts 53 and 58) published elsewhere in today's **Federal Register**, EPA is revising the requirements for reference and equivalent method determinations for fine particle monitors, monitoring network descriptions and periodic assessments, quality assurance, and data certification.

Issues related to the implementation of revised $PM_{2.5}$ standards are discussed below in section VII. The EPA plans to propose related revisions to the Air Quality Index for $PM_{2.5}$ at a later date.

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

A. Introduction

1. Overview

This section presents the Administrator's final decisions on the review of the primary NAAQS for PM_{10}. The rationale for the final decisions on 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 standards for thoracic coarse particles (*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, 2004a, 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 epidemiologic studies using thoracic coarse particle 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 at sufficient exposure levels, 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 summarized 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 provides an adequate basis for making final regulatory decisions at this time.

In addition, this review has already provided important input to EPA's research and monitoring plans for improving our future understanding of the relationships between exposures to ambient thoracic coarse particles and health effects. As discussed in the proposal, the epidemiological evidence available in this review is almost entirely based on measurements of undifferentiated $PM_{10-2.5}$ mass, without regard to the composition of thoracic coarse particles. Yet both fundamental toxicological considerations and the limited data available on this issue strongly suggest that the health effects could vary significantly depending upon the composition of the ambient coarse particle mix. The goal of the Agency's research and monitoring programs going forward is to provide scientific advances that will enable future PM NAAQS reviews to make more informed decisions that will provide more effective and efficient protection against the effects of those coarse particles and related source emissions that prove to be of concern to public health.

The health effects information and human risk assessment were summarized in sections III.A and III.B of the proposal and are only briefly outlined in subsections III.A.2 and 3 below. Subsequent sections provide a more complete discussion of the Administrator's rationale, in light of key issues raised in public comments, for his decision to retain the current 24-hour primary PM_{10} standard and to revoke the current annual PM_{10} standard. Specifically, these sections present a more complete discussion of the Administrator's rationale regarding the need to maintain protection against the health effects of coarse particles (section III.B) as well as the rationale for the decisions regarding specific elements of the primary PM_{10} standards including indicator (section III.C); and averaging time, level and form (section III.D).

2. Overview of Health Effects Evidence

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'' [53] 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, 2004a, 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 EPA's basis for reaching conclusions about the requisite level of protection from coarse particles provided by the final standards. The new studies available in this review include epidemiologic studies that have reported associations with health effects using direct measurements of $PM_{10-2.5}$, as well as new dosimetric and toxicologic studies.

Section III.A of the proposal further 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 there includes:

(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 short-term exposures to ambient thoracic coarse particles, particularly in urban and industrial settings, including aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions), increased respiratory symptoms in children, and premature mortality.

(3) An integrative assessment of the evidence on health effects related to thoracic coarse particles, with an emphasis on the key issues raised in assessing the available community-based epidemiologic studies, including alternative interpretations of the evidence, both for individual studies and the evidence as a whole.

(4) Subpopulations that appear to be sensitive to effects from exposure to thoracic coarse particles, specifically including individuals with preexisting lung diseases such as asthma, and children and older adults.

(5) Conclusions, based on the magnitude of these subpopulations and risks identified in health studies conducted in urban and industrial areas, that exposure to ambient thoracic coarse particles can have an important public health impact.

The summary of the health effects evidence related to ambient coarse particles in the proposal will not be repeated here. The EPA emphasizes that the final decisions on these standards take into account the more comprehensive and detailed discussions of the scientific information on these issues contained in the Criteria Document and Staff Paper, which were reviewed by the CASAC and the public. For reasons summarized in section I.C above, EPA is not relying on studies published after completion of the Criteria Document as a basis for reaching final decisions on these standards.

3. Overview of 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.A 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.

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.[54] 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, 2005, p. 5–69).

[53] 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 communication, ''thoracic'' particles penetrating to these regions are often called ''inhalable'' particles.

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

These uncertainties and concerns are summarized in section III.B of the proposal and discussed more fully in the Staff Paper (Chapter 4) and the technical support document (Abt Associates, 2005).

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

As presented in the proposal, taking into account both the nature of recent scientific evidence and legal considerations, this review of the primary PM_{10} standards has focused on whether to revise the indicator for thoracic coarse particles, and on the appropriate level, form and averaging time for any revised indicator. The basis for reaching a final decision on the indicator, as well as other facets of the standards, is presented below in sections III.C and III.D. This section provides an overview of the considerations that led to the Administrator's provisional conclusion, at the time of proposal, that it would be appropriate to revise the PM_{10} standards by adopting a new indicator ($PM_{10-2.5}$).[55] The section then presents a summary of public comments concerning whether the available evidence supports retention, revision, or revocation of standards to protect against exposure to thoracic coarse particles. For the reasons discussed below, the Administrator has concluded, consistent with CASAC and Staff Paper recommendations and conclusions drawn at the time of proposal, that continued protection against health effects associated with short-term exposure to thoracic coarse particles is requisite. However, EPA notes that, having considered the issues raised in extensive public comment on the proposal, the Administrator's final decision differs from that in the proposal regarding whether it is appropriate to revise the indicator in order to retain protection from coarse particles. This section, and the subsequent section on indicator, outline the rationale presented at the time of the proposal, and then describe how the Administrator has reached a different conclusion in his final decision.

1. Overview of the Proposal

The initial issue addressed in the current review of the primary PM_{10} standards was whether, in view of the advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the current standards should be revised. The Staff Paper addressed 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 from studies that measured PM_{10} in areas where coarse particles were likely to dominate the distribution (62 FR 38677). This information indicated that thoracic coarse particles can deposit in those regions of the lung of most concern (*i.e.*, the tracheobronchial and alveolar regions, which together make up the thoracic region),[56] and that they can be expected to aggravate effects in individuals with asthma and contribute to increased upper respiratory illness (62 FR 38666–8).

Further, EPA decided that the new function of PM_{10} standard(s) would be to provide such protection against effects associated with particles in the 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 38679). The decision also reflected the fact that there were only very limited ambient air quality data then available specifically on thoracic coarse particles (*i.e.* $PM_{10-2.5}$), 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 U.S. Court of Appeals (D.C. Circuit) held in part that EPA had not provided a reasonable explanation justifying use of PM_{10} as an indicator for thoracic coarse particles. *ATA I*, 175 F.3d at 1054–55. Although the court found ''ample support'' (*id.* at 1054) for EPA's decision to regulate thoracic coarse particles, it vacated the 1997 revised PM_{10} standards. 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 focused on the recent information available in the Criteria Document 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. In considering this information, the Staff Paper found 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, staff concluded that the continued use of PM_{10} as an indicator for standards intended to protect against health effects associated with thoracic coarse particles was no longer necessary since the information available in the Criteria Document could support the use of a more directly relevant indicator, $PM_{10-2.5}$. Further, staff concluded that continuing to rely principally on health effects evidence indexed by PM_{10} to determine the appropriate averaging time, form, and level of a standard was no longer necessary or appropriate since a number of more directly relevant studies, indexed by $PM_{10-2.5}$, were available. Thus, the Staff Paper concluded that it was 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 $PM_{10-2.5}$ was the predominant fraction (EPA, 2005, section 5.4.1). As noted in the introduction to this section,

[55] The Administrator also proposed qualifications to the indicator, and corresponding revisions to the level and form of the 24-hour standard to provide protection that is generally equivalent to that afforded by the PM_{10} standard, and to revoke the annual PM_{10} standard.

[56] 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 38666).

having considered public comments on this issue, EPA has reached different conclusions regarding the appropriateness of revising the current indicator in this final decision; this is described in more detail below in section III.C.

Recognizing that dosimetric evidence formed the 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 considered whether currently available dosimetric evidence continues to support the basic conclusions reached in those reviews of the standards. In particular, consideration was 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 concluded 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 of fine particles (EPA, 2004a, p. 6–16).

Beyond the dosimetric evidence, as noted in past reviews (EPA, 1982, 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, especially 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).[57] In addition, some very limited *in vitro* toxicologic studies show some evidence that coarse particles may elicit pro-inflammatory effects (EPA, 2004a, 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, 2005, chapter 2). In particular, as discussed below in section III.C, coarse particles in urban areas can contain all of the components found in more rural areas, but can also 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 concluded 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 the urban epidemiologic studies discussed below, and provides support for retaining some standard for thoracic coarse particles so as to continue programs to protect public health from such effects (EPA, 2005, p. 5–49).[58]

The available epidemiologic evidence, discussed in section III.A of the proposal, includes studies of associations between short-term exposure to thoracic coarse particles, indexed by $PM_{10-2.5}$, and health endpoints. 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, 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 (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, 2005, 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, 2004a, 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),[59] and in the initial analysis of data from Steubenville (as part of the Six Cities study, Schwartz *et al.*, 1996; reanalysis, Schwartz, 2003). In a separate reanalysis of the Six Cities study, the $PM_{10-2.5}$ mortality association was not statistically significant for Steubenville (Klemm and Mason, 2003). In areas with lower $PM_{10-2.5}$ concentrations, including the remaining five cities in the Six Cities study, no statistically significant associations were reported with mortality, though most were positive.

The Staff Paper also considered 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, 1989 and 1991; Pope *et al.*, 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, 2005, p. 5–50).[60]

In contrast to the findings from the short-term exposure studies discussed above, available epidemiologic studies do not provide evidence that long-term community-level exposure to thoracic coarse particles is associated with mortality or morbidity (EPA, 2005, p. 3–25). More specifically, no association is

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

[58] Eventually, as a result of the data that will be gathered under EPA's new research and monitoring plan , the Agency may be able to further refine its regulation of coarse particles to better target those coarse particles of greatest concern to health.

[59] The Coachella Valley study, like the Seattle study noted above, is subject to additional measurement uncertainties because it used regression techniques to impute $PM_{10-2.5}$ concentrations; this approach fills in missing $PM_{10-2.5}$ data based on relationships developed using data from days when data are available for both PM_{10} and $PM_{2.5}$.

[60] 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 μg/m³, while in Utah Valley the concentrations range from 37 to 54 μg/m³.

found between long-term exposure to thoracic coarse particles and mortality in the reanalyses and extended analysis of the ACS cohort (EPA, 2005, p. 8–306–07). Further, little evidence is available on potential respiratory and cardiovascular morbidity effects of long-term exposure to thoracic coarse particles (EPA, 2005, p. 3–23–24).

The Staff Paper concluded that the available body of health evidence, including dosimetric, toxicologic and epidemiologic study findings, supports retaining a NAAQS that would continue to provide protection against the 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 $PM_{10-2.5}$ 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, 2005, p. 5–50).

Beyond this evidence-based evaluation, the Staff Paper also considered 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.A.3, the Staff Paper considered 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 summarized above in section III.A.3, which is much more limited than the risk assessment conducted for $PM_{2.5}$, health risks were estimated for three urban areas (Detroit, Seattle, and St. Louis) 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. 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 concluded 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, 2005, p. 5–52).

The Staff Paper recognized 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 concluded 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, 2005, p. 5–52).

In CASAC's review of these Staff Paper recommendations, there was unanimous agreement among CASAC Panel members that ''there was a need for a specific primary standard to address particles in the size range of 2.5 to 10 microns'' (Henderson, 2005b, p. 4). 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 section 5.4 of the Staff Paper upon which the EPA staff recommendations were based.

Unlike the case in the current $PM_{2.5}$ review, neither EPA staff nor CASAC concluded that it was necessary to revise the PM_{10} standards to provide additional health protection against coarse particles beyond that afforded by the current standards. Rather, as noted above, staff and CASAC found that the most recent scientific information suggested it was possible to move to a more direct measurement of thoracic coarse particles via a $PM_{10-2.5}$ indicator, and this was the major basis for recommending revisions to the current 24-hour PM_{10} standard. In considering what level of protection was appropriate, staff and CASAC recommended consideration of a range of levels for alternative 24-hour coarse particle standards, from levels which would be more stringent than the current 24-hour PM_{10} standard to a level that would provide protection that was roughly equivalent to that provided by the current 24-hour PM_{10} standard.

In considering whether the primary PM_{10} standards should be revised at the time of proposal, the Administrator considered the rationale and recommendations provided by the Staff Paper and CASAC, and the public comments received through the time of proposal. The Administrator provisionally concluded that the health evidence, including dosimetric, toxicologic and epidemiologic study findings, supported retaining a standard to provide continued protection against effects associated with short-term exposure to thoracic coarse particles. Further, the Administrator expressed the belief 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 $PM_{10-2.5}$, provided 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 noted that the need for a standard for thoracic coarse particles had already been upheld based upon evidence of health effects considerably more limited than now available. *ATA I*, 175 F.3d at 1054. Based on these considerations, the Administrator provisionally concluded that the current suite of PM_{10} standards should be revised, and that the revised standard(s) should be set at a level that would ensure an equivalent level of protection to the current suite of standards (71 FR 2665).

2. Comments on the Need for Revision

The vast majority of public comments on coarse particles raised issues related to the proposed revisions to the indicator for thoracic coarse standards, particularly the proposal to adopt a new $PM_{10-2.5}$ indicator that was qualified to focus on particles associated with particular types of emissions sources and to impose stringent monitor site-suitability criteria for NAAQS-comparable monitors. These comments are addressed below in section III.C. Comments more specific to the 24-hour and annual standards (*i.e.*, on averaging time, form, and level) are addressed below in section III.D. This section addresses those comments that, directly or indirectly, addressed the need to continue the kind of protection against coarse particles that is provided by the current PM_{10} standards.

A substantial majority of commenters supported the Administrator's provisional conclusion that it is necessary to maintain a standard to continue protection against the health effects associated with short-term exposure to thoracic coarse particles. Those advocating a coarse particle standard included public health organizations such as the American Lung Association, the American Heart

Association, and the American Cancer Society; environmental groups such as Environmental Defense, Earthjustice and Natural Resources Defense Council; the Children's Health Protection Advisory Committee, which provides the EPA Administrator with advice on children's health issues; all state and local air pollution control agencies commenting on the proposed coarse particle standard; and Tribal groups such as the National Tribal Caucus, the National Tribal Environmental Council, and numerous individual Tribes.

These commenters agreed with EPA that the currently available scientific evidence clearly supports the need to provide continued protection from health effects associated with coarse particle exposure. Citing the Criteria Document and the Staff Paper, those commenters providing a more detailed rationale stressed the availability of epidemiologic, toxicologic and dosimetric studies showing associations between thoracic coarse particles and multiple morbidity and mortality endpoints. Many of these commenters also cited CASAC's recommendation in favor of continued protection. Moreover, some of these commenters pointed to particular studies, such as Ito (2003), Mar *et al.* (2003) and Ostro *et al.* (2003), which they concluded show that coarse particles are associated with hospital admissions or mortality and that coarse particles may even have stronger effects than fine particles in some instances. Several also cited two recent independent reviews (Brunekreef and Forsberg, 2005; WHO, 2005) which considered many of the same scientific studies on the health effects of coarse particles that were included in the Criteria Document as support for separate standards for coarse particles, in addition to standards for fine particles.

In general, this body of commenters opposed revisions that they believed would reduce the level of protection provided by the current PM_{10} standards. For example, the comments of the American Lung Association and five environmental groups stated (American Lung Association *et al.*, p. 81):

> We strongly support the need for a coarse PM standard * * *. However, the coarse particle standard proposed by EPA is an egregious step backwards in protection of human health and welfare compared to the status quo * * *. If EPA feels it lacks adequate data to undertake the change in the coarse PM indicator to a $PM_{10-2.5}$ standard, without reducing current protections * * * then the Agency must retain the existing PM_{10} NAAQS.

Citing the more abundant evidence from studies focusing on short-term exposures, these commenters advocated maintaining a 24-hour standard for thoracic coarse particles, at a minimum. Several of them also recommended an annual standard for thoracic coarse particles to protect against possible long-term effects, despite a significantly more limited body of evidence (for specific comments on averaging time, see section III.D.1 below).

Many of these commenters, while recognizing that the epidemiologic evidence available to support specific coarse particle standards is weaker than that for fine particles, believed that the weight of evidence required revisions that provided a greater degree of protection, on a national basis, than that afforded by the current PM_{10} standards (for specific comments on level, see section III.D.2 below). Some commenters favoring a coarse particle standard supported their arguments by reference to emerging science from new toxicologic and epidemiologic studies that were not included in the Criteria Document. In general, however, these ''new'' studies were used in support of commenters' concerns about the proposal to qualify the indicator (discussed in section III.C.2 below), and not to support their comments on the need for coarse particle standards.

The EPA generally agrees with these commenters regarding the need to provide continued protection from short-term exposure to coarse particles that may be harmful. The scientific evidence cited by these commenters was generally the same as that discussed in the Criteria Document and the Staff Paper and the commenters' recommendations for retaining a coarse particle standard are broadly consistent with staff and CASAC recommendations on this issue. To the limited extent that some commenters cited ''new'' scientific studies in support of their arguments in favor of retaining a coarse particle standard, EPA notes that it is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review. Although EPA is not basing its final decisions in this review on such information, the Agency will consider the newly published studies for purposes of decision making in the next PM NAAQS review, as discussed above in section I.C. Nonetheless, in provisionally evaluating commenters' arguments concerning the need for revision to or elimination of the current standards, the Agency notes that its preliminary analysis suggests such studies would not materially change the conclusions in the Criteria Document.

In sharp contrast, a number of commenters, including virtually all of those representing industry associations and businesses, recommended revising the PM_{10} standards by revoking both the 24-hour and annual standards. These groups argued that the current body of scientific evidence is insufficient to justify either retaining the current PM_{10} standards or setting a revised standard for thoracic coarse particles at this time. These commenters included the National Cattlemen's Beef Association, the National Mining Association, the American Farm Bureau Federation, the Alliance of Automobile Manufacturers, the Engine Manufacturers Association, the National Association of Home Builders, and the Coarse Particle Coalition, which includes the National Stone, Sand and Gravel Association, the Industrial Minerals Association, the American Forest and Paper Association, the Portland Cement Association and the National Cotton Council. These commenters stressed the uncertainties, particularly those associated with interpreting the limited number of epidemiologic studies focusing on coarse particle health effects, and stated that EPA had failed to demonstrate that a coarse particle standard is necessary to protect public health. These commenters recommended deferring the decision on the appropriateness of setting a coarse particle standard pending additional monitoring and scientific research on health effects associated with exposure to coarse particles.

These commenters criticized the key epidemiologic studies cited by EPA, referring especially to the alternative interpretations of the evidence presented in the proposal and citing a review and critique of key studies prepared by an academic consultant. They also argued that all coarse particle epidemiologic studies are flawed to the extent that they rely on air quality data from central monitors in exposure assessments. Based on these arguments, the commenters asserted that EPA's risk assessment cannot be used to demonstrate that ambient coarse particles present a significant risk to public health, and therefore EPA cannot maintain the existing PM_{10} NAAQS or establish a revised NAAQS to address coarse particles. Each of these issues is further summarized and discussed below.

In discussing their disagreement with EPA's interpretation of four key epidemiologic studies (Ito, 2003; Burnett *et al.*, 1997; Mar *et al.*, 2003; Ostro *et al.*, 2003), these commenters placed significant weight on the alternative interpretations of these studies that EPA provided in the proposal to encourage additional public comment (71 FR 2671–72). In particular, they criticized EPA's reliance on the single pollutant models in these and other studies as biased because the models omit $PM_{2.5}$ and gaseous co-pollutants. The commenters argued that when $PM_{2.5}$ or gaseous co-pollutants were added to the underlying models, the effects associated with $PM_{10-2.5}$ lost statistical significance. These commenters also stated that EPA failed to consider and give appropriate weight to a significant number of studies which relied on larger and more powerful data sets, were of longer duration, and assessed $PM_{10-2.5}$ using multi-pollutant models, but did not find any statistically significant associations, including Schwartz *et al.* (1996), Thurston *et al.* (1994), Sheppard (2003), Fairley (2003), and Lipfert *et al.* (2000). They further summarized and attached a ''detailed review of the cited studies'' prepared by an academic consultant, which they stated reveals numerous deficiencies that undermine the use of these studies to support the proposed coarse particle standard or any alternative standard. Based on all of the above, one commenter claimed that a ''fair and sound'' assessment of evidence would not conclude coarse particles have effects at ambient concentrations (National Mining Association, p. 14).

The rationale for these commenters' conclusions, however, do not consider important aspects of the rationale for retaining coarse particle protection and are inconsistent with CASAC and other recent reviews of the scientific evidence. As summarized in section III.A of the proposal, the scientific evidence contained in the Criteria Document and Staff Paper, both of which have been reviewed and found acceptable for use in regulatory decision making by CASAC, supports the need for some standard to provide continued protection from coarse particles.[61] The alternative interpretation of the evidence espoused by these commenters essentially argues that it is more reasonable to presume that the positive results from one-pollutant $PM_{10-2.5}$ statistical models is the result of bias associated with omitting co-pollutants, especially $PM_{2.5}$, for which the evidence is much stronger. EPA does not accept this argument for both technical and public health policy reasons. The Criteria Document and Staff Paper explain the rationale for reliance on single pollutant models in these studies, while recognizing the significant uncertainties in the limited number of studies available (EPA, 2004, section 8.4.3; EPA, 2005, p. 3–46). These documents illustrate the results of a number of studies that examined co-pollutants (Figures 8–16 through 8–18 of the Criteria Document), where it can be seen that, in most cases, the inclusion of gaseous co-pollutants does little to change the effects estimate for $PM_{2.5}$, although in some cases it does. Recognizing the additional uncertainties in measuring coarse particles (as discussed below), these documents further note the importance of the relative consistency in the size of effects estimates for coarse particles as well as the pattern of generally positive associations, and the need for considering the results of recent statistically significant associations found in PM_{10} studies where it is reasonable to expect that the coarse fraction dominated the distribution. It would be unwise to presume, in the face of this evidence, that the single pollutant result for coarse particles is generally the result of omitted gases in the model.

EPA also believes that it is inappropriate to presume that coarse particle or PM10 associations in single or multi-pollutant models can be wholly explained by fine particles. In studies where $PM_{2.5}$ and $PM_{10-2.5}$ have similar effect estimates, it is difficult to determine whether one or both contribute to the result (*e.g.* EPA 2004a, p 8–61). The comparison of $PM_{2.5}$ and $PM_{10-2.5}$ is further complicated by the differential measurement error between the two pollutants, which is generally greater for coarse particles (as discussed below). When both pollutants have similar effect estimates, it is difficult to determine whether one or both contribute to the result (*e.g.* EPA, 2004a, p. 8–61). Some studies conducted in urban areas, however, have found significant associations for coarse particles, but not fine particles. The Criteria Document summarizes a case cross-over study (Lin *et al.*, 2002) conducted in Toronto, that found a significant association of $PM_{10-2.5}$ with asthma hospital admissions in children ages 6–12 that was robust to the inclusion of gaseous co-pollutants, but did not report significant associations for $PM_{2.5}$.[62] Three different studies used essentially the same air quality data set to examine coarse and fine particles in Phoenix (Mar *et al.*, 2000, 2003; Clyde, 2000; Smith *et al.*, 2000). All three studies found significant associations between mortality and $PM_{10-2.5}$, but only one found a significant association for $PM_{2.5}$ (EPA, 2004a, p. 8–57 to 66). Ito (2003) found a significant association in Detroit between hospital admissions for ischemic heart disease and exposure to coarse particles, but not fine particles. While all of these studies have limitations, it is difficult to ignore the fact that, despite the differential measurement error associated with coarse particles, a number of these studies find statistically significant associations for coarse particles, but not for fine particles. For these reasons, EPA believes that it would be inappropriate, based on the limited data currently available, to presume that all of the effects associated with coarse particles in single pollutant models are actually the result of confounding by fine particles.

It is also important to note that in the NAAQS reviews that concluded in 1987 and 1997, EPA found that the scientific evidence then available supported the need to continue regulation of thoracic coarse particles through appropriate NAAQS. This evidence included mechanistic considerations developed from particle dosimetry and toxicology, as well as an integrated assessment of particle composition and both community and occupational epidemiologic studies. By 1997, EPA judged the evidence to be strong enough to propose separate standards for fine and coarse particles. While the D.C. Circuit found problems with the indicator for thoracic coarse particles promulgated in 1997, the court upheld EPA's determination that a standard was needed (*ATA I*, 175 F.3d at 1054). In EPA's judgment, the more recent studies included in the 2004 Criteria Document, even with their recognized limitations, serve to add to, not reduce, the concern present in previous reviews over ambient exposures to coarse particles, particularly in urban areas.

The business and industry commenters also suggested that the epidemiologic studies were flawed by the reliance on data from central monitors to estimate community-level exposures to coarse fraction particles. According to these commenters, this would result in an overestimation of

[61] The Response to Comments document contains more detailed responses to the specific issues these commenters raise regarding the interpretation of the epidemiologic evidence, which is important in terms of the use of these studies for supporting a coarse standard (this section of the preamble) as well as their use in deciding upon an appropriate level of protection (section III.D.2 of this preamble).

[62] Unlike more commonly used time series studies, the design used in this study has the advantage of controlling for confounding by having each case serve as its own control. The Criteria Document notes limitations in available measurement information and adjustment for season that may have influenced the relative results for fine and coarse particles (EPA, 2004a, pp. 185–186).

exposure due to the significant spatial variability associated with coarse particle distributions. Such overestimation, in the commenters' view, would invalidate any statistical associations found between ambient data, as measured by the central monitors, and adverse health effects. The National Mining Association (p. 16–17), for example, noted:

The spatial variability of coarse PM renders even the few, limited, uncertain epidemiological studies that have been cited by EPA invalid, as well as imprecise * * *. Given that the purported associations between PM coarse and health effects is small to begin with, 71 FR at 2659, the logical conclusion should be that the lack of a demonstrable connection between the monitored ambient data and the level of exposure of the subject population is a fatal flaw that precludes reliance on the studies for any connection between PM coarse and health effects.

These commenters also provided supporting information regarding correlations among monitors and an air quality modeling analysis purporting to show that significant quantities of coarse particles cannot travel more than 1 kilometer from sources.[63]

The Criteria Document and Staff Paper contain detailed analyses of the spatial variability of coarse particle concentrations, as well as other issues that generally result in greater exposure measurement error for coarse particles as compared to fine particles (EPA, 2004a, p. 3–52–53, Appendix 3A; EPA, 2005, pp. 2–36–40, 2–70–73). While EPA agrees that coarse particle measurements from central monitors is subject to potentially large measurement error when used to reflect population exposures in epidemiologic studies, the Agency disagrees with the commenters' assessment of the direction of the resulting bias and with their conclusion that any statistically significant associations between centrally monitored air quality concentrations and adverse health effects measured in these studies are invalid as a result. This issue received substantial attention in the Criteria Document (EPA, 2004a, section 8.4.5). The Criteria Document concluded that such measurement errors are more likely to underestimate the strength and the significance of any association between coarse particles and any adverse health effects observed in the study (EPA, 2004a, pp. 5–126, 8–341). While the spatial variation of coarse particle data is larger than for fine particles, the Staff Paper notes that, on a day-to-day basis, coarse particle data from monitor sites within an urban area can be fairly well correlated, even when substantial differences exist in the absolute concentrations between the sites (EPA, 2005, p. 3–41). The signal that drives statistical associations between ambient concentrations and health effects in time-series studies is the day-to-day changes in concentration, not the absolute daily values. To the extent possible, EPA examined both the day-to-day correlations and annual averages in $PM_{10-2.5}$ taken from multiple monitors in key study locations, such as Detroit, Phoenix and Coachella Valley (Ross and Langstaff, 2005).[64]

In reacting to this issue in opposing comments, the California Air Resources Board similarly stated:

The current scientific consensus suggests that measurement of coarse particles will typically involve greater errors than that of fine particles. However we reject the * * * implication that therefore these studies are not reliable. In fact, the larger measurement error, which is likely to be random, would make it more difficult to find an association with mortality. It is well accepted in the epidemiological literature that such measurement error will tend to obscure a relationship between an exposure and a given health outcome, assuming that such a relationship exists. Therefore, the measurement error argument cannot be used to nullify an effect that has been observed. If anything, it is likely that the real effects are likely to be larger than those that were estimated. (CARB, p. 11)

The EPA agrees with CARB's analysis of the issue. Therefore, for the purposes of determining whether public health protection is warranted in light of the available evidence, EPA believes that it has interpreted the evidence from these epidemiologic studies correctly, and that despite the uncertainties, the evidence of statistically significant relationships between exposure to coarse particles and adverse health effects is sufficiently strong to support continued regulation of coarse particles.

Some commenters opposed to maintaining a coarse particle standard criticized EPA's risk assessment. These commenters stated that current short-term epidemiologic data are insufficient to serve as the basis for a scientifically sound quantitative risk assessment, without which, they claim, EPA lacks sufficient evidence to establish a standard based on those data. According to these commenters, while EPA may exercise its judgment about future risks and set standards that are preventive in nature, as long as an adequate scientific rationale is presented, the Agency does not have the authority to engage in ''crystal ball speculation'' in the absence of support in the record considered as a whole. (*See e.g.*, Coarse Particle Coalition, p. 8–9, citing *Lead Industries Assoc* v. *EPA*, 647 F. 2d 1130, 1146–7 (DC Cir. 1980), *NRDC* v. *EPA*, 902 F.2d 962, 968, 971 (D.C. Cir. 1990) and *Ethyl Corp.* v. *EPA*, 541 F.2d 1, 13 (D.C. Cir. 1976).) These commenters stated that the NAAQS must address only ''significant risk'', not any risk, and that EPA has failed to demonstrate that coarse particles pose a significant enough risk to human health to warrant a coarse particle standard.

The EPA disagrees on technical, policy, and legal grounds. For reasons specified in the proposal and summarized above, EPA believes that the available scientific evidence is more than adequate to support a decision to continue regulation of coarse particles under the NAAQS. Although the data are weaker than for fine particles and subject to greater measurement error, in several of the studies where comparisons are possible, the normalized relative risk estimates for coarse particles from the new urban/industrial-area studies that were included in the Criteria Document often fall into a similar range as those for fine particles (EPA, 2004a, p. 8–64; EPA, 2005, pp. 3–13 and 3–20). Furthermore, as summarized above, EPA did produce a risk assessment for thoracic coarse particles, which was reviewed by CASAC and included in the Staff Paper (EPA, 2005, Chapter 4). While the limited number of cities and the significant uncertainties noted in the risk assessment and the proposal limit their quantitative usefulness, EPA staff concluded that the risk assessment results for the two urban 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.

Furthermore, there is no requirement that EPA develop a ''scientifically sound quantitative risk assessment'' before adopting or revising a NAAQS (ATA III, 283 F.3d at 374), or that the Agency must demonstrate significant risk before promulgating a NAAQS.[65] EPA's reliance on evidence from peer-

[63] This issue is discussed in more detail in the Response to Comments document.

[64] In Phoenix, for example, two key sites were highly correlated with similar means. In Detroit/Windsor, correlations were moderate to good, but absolute values were significantly higher in Detroit (Ross and Langstaff, 2005).

[65] See *e.g., American Petroleum Inst.* v. *Costle*, 665 F. 2d at 1186–87: ''In setting margins of safety the Administrator need not regulate only the known dangers to health, but may ''err'' on the side of overprotection by setting a fully adequate margin of safety. Of course the Administrator's conclusions must be supported by the record, and he may not engage in sheer guesswork. Where the Administrator bases his conclusion as to an adequate margin of safety on a reasoned analysis and evidence of risk, the court will not reverse.''

reviewed scientific studies in this review, as well as its reliance on CASAC's unanimous recommendation that there is a need for a standard for thoracic coarse particles, cannot be considered ''crystal ball speculation.''

After careful consideration of all of these comments, EPA continues to believe 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. As noted above and summarized in section III.A of the proposal, there is a growing body of evidence suggesting causal associations between short-term exposure to thoracic coarse particles and morbidity effects, such as respiratory symptoms and hospital admissions for respiratory diseases, and possibly mortality. As summarized in the proposal (71 FR 2659), the available body of evidence also suggests there is a lack of such effects associated with long-term exposure to thoracic coarse particles. Considering the magnitude of the risks identified in health studies, and the size of potentially susceptible subpopulations such as people with preexisting respiratory diseases, including asthma, and children and older adults, EPA concludes that short-term exposure to thoracic coarse particles can have an important public health impact. The health evidence regarding effects of thoracic coarse particles is limited in some respects and still subject to significant uncertainty. The Administrator has concluded that it is a priority to establish a robust research program that will enable future PM NAAQS reviews to make more informed decisions that will provide more targeted protection against the effects only of those coarse particles and related source emissions that prove to be of concern to public health. 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 (*ATA I*, 175 F.3d at 1054).

In the judgment of the Administrator, it is appropriate at this time to retain a standard to address the known and potential public health risks associated with exposure to coarse particles. The Administrator's specific decisions regarding the indicator, averaging time, level and form of a standard for thoracic coarse particles are described below.

C. Indicator for Thoracic Coarse Particles

1. Introduction

As outlined above, at the time of proposal the Administrator judged it appropriate, based on an evaluation of the available scientific evidence, to propose a new indicator of thoracic coarse particles defined to include those particles between 2.5 and 10 μm in diameter, or $PM_{10-2.5}$, and qualified to focus on the mix of thoracic coarse particles generally present in urban environments. In making this determination, the Administrator relied heavily on key findings and observations from the Criteria Document and Staff Paper, and on recommendations from CASAC. The Staff Paper made the following general observations about the $PM_{10-2.5}$ indicator:

(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 also noted that there appear 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 non-urban 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.[66] Based on such information, and on specific initial advice from CASAC (Henderson, 2005a), the Staff Paper considered a more narrowly defined indicator for thoracic coarse particles that would focus on the mix of such particles that is characteristic of the mix generally found in urban areas where thoracic coarse particles are strongly influenced by traffic-related or industrial sources. In so doing, the Staff Paper focused on comparing the potential health effects associated with thoracic coarse particles in urban and rural settings, as discussed below.

The Staff Paper also noted that 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, 2005, 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, 2005, Table 2–2).

[66] In general, EPA believes it is appropriate to draw a distinction between two general types of ambient mixes of coarse particles: ''urban'' and ''non-urban''. The first term characterizes the mix in more heavily populated urban areas, where sources such as motor vehicles and industry contribute heavily to ambient coarse particle concentrations and composition. The term ''non-urban,'' on the other hand, encompasses mixes in a variety of other locations outside of urbanized areas, including mixes in rural areas which are likely to be dominated by natural crustal materials (and where urban types of sources are largely absent or, in the case of motor vehicles, are not present to the same degree). It should be noted that some types of sources are present in both urban and non-urban areas. Industrial sources, for example, are found in non-urban areas, though they are more commonly located in urban areas. Similarly, agricultural and mining sources are primarily non-urban sources, but may be found in or near urban areas as well.

The Staff Paper concluded that the mix of thoracic coarse particles in urban areas would likely 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 (EPA, 2005, 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, 2004a, p. 3D–3). Limited ambient coarse fraction composition data from various comparisons show 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 observed 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.

In the proposal, EPA also stated that 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 discussed results from a recent toxicologic study in which road tunnel dust particles had greater allergy-related activity than several other particle samples (Steerenberg *et al.*, 2003; EPA, 2004a, 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 uncontaminated natural crustal material of geologic origin, has very little toxicity in animal or *in vitro* toxicologic studies (EPA, 2004a, 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, 2005, sections 3.2 and 5.4.1). While these studies cannot be used for quantitative assessment of morbidity or mortality effects, they 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, 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, 2004a, 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, 2004a, 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 reflects this long-term composition and represent the kinds of industrial components that would be incorporated in road dusts in the area.

The Staff Paper also noted that 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, which includes PM from traffic and industrial sources.

The Staff Paper also pointed to other evidence from epidemiologic studies suggesting 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 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 dustiest 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 rural areas.

Beyond the urban and rural distinctions discussed above, the Staff Paper also considered the extent to which there is evidence of effects from exposure to the ambient thoracic coarse particles in communities predominantly influenced by agricultural or mining sources.[67] 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, 2004a, Table7B–3, p. 7B–11), such studies do not provide relevant evidence for effects at the much lower levels of community exposure. Further, it is unlikely that such predominantly non-urban sources contribute to the effects reported in the recent urban epidemiologic studies.

The Criteria Document concluded 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, 2004a, 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 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 non-urban 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 dominated by 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 concluded 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 non-urban or rural areas (EPA, 2005, p. 5–57). The Staff Paper concluded that the available evidence collectively 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 recommended consideration of thoracic coarse urban particulate matter ($UPM_{10-2.5}$) 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, 2005, p. 5–54, 5–57–58). The Staff Paper concluded 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 a 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 discussed the importance of a monitoring network designed to be consistent with the intent of such an indicator and to facilitate implementation of such a standard. It should be noted that EPA has historically used other implementation-related policies, specifically its guidelines regarding the handling of data affected by exceptional or natural events, 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 the staff-recommended indicator was not intended to apply. The Staff Paper recommended that 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, p. 4), 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 an unqualified $PM_{10-2.5}$ 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.’’

Based on these considerations, the Administrator proposed to establish a new indicator for thoracic coarse particles in terms of $PM_{10-2.5}$, 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

[67] As used in the Staff Paper, the term ‘‘mining sources’’ is intended to include all activities that encompass extraction and/or mechanical handling of natural geologic crustal materials. In the context of this rulemaking, neither mining nor agricultural sources are included in the more general category of ‘‘industrial sources.’’

by industrial sources and construction sources, and to exclude 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 (71 FR 2667–68). Furthermore, EPA proposed that ''[a]gricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting this standard'' (71 FR 2699). As summarized above in section I.E, the proposed standard also included specific monitor site-suitability requirements which any monitor would have to meet in order to be used for comparison to the NAAQS, including a requirement that such monitors be sited in urbanized areas with a minimum population of 100,000. These requirements were designed to ensure that the monitors were capturing the ambient mix of $PM_{10-2.5}$ dominated by the sources of concern.

Subsequent to the proposal, CASAC provided additional comments to the Administrator on the proposed indicator for thoracic coarse particles. In a letter dated March 21, 2006, the Committee stated that ''the PM Panel was pleased to see that the indicator for coarse thoracic particles of concern to public health took into account some of the various approaches that the PM Panel identified for consideration'' (Henderson 2006, p. 4). The CASAC reiterated its earlier statement that ''the current scarcity of information on the toxicity of rural dusts makes it necessary for the Agency to base its regulations on the known toxicity of urban-derived coarse particles.'' However, the Committee went on to say that ''the CASAC neither foresaw nor endorsed a standard that specifically exempts all agricultural and mining sources, and offers no protection against episodes of urban-industrial $PM_{10-2.5}$ in areas of populations less than 100,000.'' The Committee recommended the ''expansion of our knowledge of the toxicity of rural dusts rather than exempting specific industries (*e.g.* mining, agriculture)'' from control under the standard (*id* at 5).

2. Comments on Indicator for Thoracic Coarse Particles

The EPA received a large number of comments on its proposed decision with regard to the indicator of thoracic coarse particles which overwhelmingly opposed the proposed indicator. Few commenters unconditionally supported EPA's proposal to replace the PM_{10} indicator with a qualified $PM_{10-2.5}$ indicator that would provide targeted protection by including certain ambient mixes of thoracic coarse particles and excluding others. Support for the proposed approach came almost entirely from those industrial sectors whose sources were excluded from the proposed qualified $PM_{10-2.5}$ indicator (*i.e.*, agriculture and mining interests). While these commenters argued that EPA should not maintain any standard for thoracic coarse particles, they conditionally supported the qualified indicator if any standard were to be set. In contrast, all other commenters, including environmental and public health groups, State and local agencies, and industries not excluded from the proposed indicator (*e.g.*, transportation and construction), opposed the proposed qualified indicator. Representatives from a variety of groups who otherwise disagreed on various aspects of the proposed indicator commented on the need for additional research to address the uncertainties in the current body of evidence regarding coarse particles and health effects. In addition, a variety of commenters urged EPA to deploy additional $PM_{10-2.5}$ monitors in both urban and rural areas, consistent with the advice of CASAC, to provide a more robust and complete body of evidence regarding coarse particle effects.

Commenters conditionally supporting the proposal expressed the view that EPA should exclude non-urban wind-blown dust and soil from the $PM_{10-2.5}$ indicator. According to these commenters, ''such particles have been shown to be nontoxic, and the scientific studies show that they are not associated with adverse health effects' (American Farm Bureau Federation, p. 1). Furthermore, these commenters agreed with the proposed exclusion for agricultural and mining sources, stating that ''the preponderance of scientific evidence continues to demonstrate that fugitive dust from agricultural and mining operations presents no substantial health or welfare concerns' (National Mining Association, p. 1; see also National Cattlemen's Beef Association, p. 1). These commenters quoted extensively from the Criteria Document and Staff Paper, and made points that were in many cases conceptually similar to the arguments in these documents and in the proposal. These commenters also tended to argue that there is substantial scientific evidence showing an absence of health effects from rural particles.

These commenters cited differences in the composition of the mix of particles in urban areas versus the mix of particles in non-urban areas, which they stated is dominated by wind-blown soil fractions including silicates, primary organic materials including ground plant matter, residential wood smoke, and dust from unpaved roads. Though the coarse particle mix in urban areas also contains significant crustal materials, the commenters stated that it is contaminated by a wide variety of industrial and combustion-related byproducts, such as metals and organic materials (tire and brake wear, vehicle exhaust, industrial emissions, residential fuel combustion). These commenters noted that studies conducted in urban areas have linked health effects specifically to these urban-industrial contaminants. For example, the American Farm Bureau Federation cited the distinction between studies that found health effects related to traffic emissions in urban areas (Pearson *et al.*, 2000; Kramer *et al.*, 2000; and Lin *et al.*, 2002) and a study they suggested found a strong association between cardiovascular mortality and motor vehicle exhaust components, but a negative association between soil and total mortality (Mar *et al.*, 2000).[68] Some of these commenters argued that coarse mode particles, especially crustal coarse mode particles, are unlikely to serve as carriers of urban-area contaminants because they have less surface area, do not adsorb contaminants easily, and have short atmospheric residence times. These commenters conditionally agreed with EPA's proposed goal of focusing regulatory efforts on the sources known to be associated with toxic coarse particles, especially traffic (Coarse Particle Coalition). Some of these commenters cited new studies completed after the close of the Criteria Document as providing additional evidence of associations between traffic-related emissions and adverse health effects (*e.g.* Kim *et al.*, 2004; Ryan *et al.*, 2005; Garshick *et al.*, 2003; McDonald *et al.*, 2004; and Ostro *et al.*, 2006).

These commenters also stated that while urban contaminants may increase the toxicity of coarse particles, studies have demonstrated a lack of adverse effects associated with exposure to coarse particles in non-urban areas (*e.g.*, Buist *et al.* (1983) study of exposure to Mount St. Helens' ash among diabetic children). Furthermore, these commenters argued that studies have found a lack of effects associated with exposure to crustal materials in general. They cited the lack of an association between mortality and dust storms found in Schwartz *et al.* (1999) and also noted that studies such as the 6-city study by Laden *et al.* (2000) have found

[68] Commenters cite the original publication. In the subsequent reanalysis, the investigators report ''our original findings remained unchanged'' (Mar *et al.* 2003).

that crustal material, in both the fine and coarse fractions, is not associated with increased mortality. Thus, these commenters argued that there is sufficient evidence to show that crustal particulate matter is essentially benign and therefore should be excluded from the coarse particle indicator.

The EPA agrees with these commenters that the strongest available evidence relates to the toxicity of the ambient mix of coarse particles found in urban environments. The limited evidence available from epidemiologic and toxicologic studies indicates exposure to ambient thoracic coarse particulate in urban areas is associated with health effects, and the health evidence more strongly implicates coarse particles from urban types of sources such as resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources than coarse particles from uncontaminated soil or geologic sources. The EPA also agrees that there is far more evidence concerning health effects associated with thoracic coarse particles in urban areas than in non-urban areas. However, EPA disagrees with these commenters that there is sufficient evidence to demonstrate that there are no adverse health effects from community-level exposure to coarse particles in non-urban areas. Rather, the existing evidence is inconclusive with regard to whether or not community-level exposures to thoracic coarse particles are associated with adverse health effects in non-urban areas. However, EPA does agree with these commenters that additional research is needed to clarify this issue and to reduce some of the other uncertainties regarding the effects associated with coarse particles. As discussed above, the EPA is, in fact, expanding both its research and monitoring programs to collect additional evidence on the differences between coarse particles typically found in urban areas and those typically found in rural areas. Specifically, EPA notes that the Agency's National Center for Environmental Research recently issued a Request for Proposals on ''Sources, Composition, and Health Effects of Coarse Particulate Matter'' which is designed to (1) improve understanding of the type and severity of health outcomes associated with exposure to $PM_{10-2.5}$; (2) improve understanding of subpopulations that may be especially sensitive to $PM_{10-2.5}$ exposures including minority populations, highly exposed groups, and other susceptible groups; (3) characterize and compare the influence of mass, composition, source characteristics and exposure estimates in different locations and differences in health outcomes, including comparisons in rural and urban areas; and (4) characterize the composition and variability of $PM_{10-2.5}$ in towns, cities or metropolitan areas, including comparisons of rural and urban areas. In addition, as described in the final monitoring rule published elsewhere in today's **Federal Register**, EPA and the states will require measurement of $PM_{10-2.5}$ at 75 new multipollutant monitoring sites around the country. These sites will provide continuous measurements of mass as well as chemical speciation. EPA will locate 55 of these sites in urban areas and 20 in rural areas in order to gather information on the composition and transport of coarse particles in urban and rural areas. In addition, these monitors will employ the latest in speciation technology to advance the science so that future regulation will provide more targeted protection against the effects only of those coarse particles and related source emissions that prove to be of concern to public health.

In addition, EPA disagrees with these commenters that there is sufficient evidence to exclude crustal materials from the coarse particle indicator regardless of the degree of contamination. Although there is some evidence that coarse particles of natural geologic origin are relatively non-toxic in their uncontaminated form, the Criteria Document notes that such particles may become sufficiently ''contaminated by toxic trace elements or other components from previously deposited fine PM,'' to cause health effects (EPA, 2004a, 8–344). Indeed, the urban coarse PM associated with adverse health effects in the studies discussed above was, by mass, predominantly crustal in origin.[69] As noted in the proposal and in the response to these commenters on the need to maintain a coarse particle standard, EPA is aware of the studies that found no effects on mortality at lower coarse particle concentrations, but believes, consistent with the Staff Paper and Criteria Document conclusions, that the evidence is suggestive of a coarse particle effect in urban or industrial areas.[70] The EPA continues to believe that urban sources may significantly alter both the relative quantity and character of crustal and natural biological materials in ambient mixes in urban areas. As noted above in section III.C.1, metals and other contaminants such as elemental carbon tend to appear in higher concentrations in the urban $PM_{10-2.5}$ mix, and vegetative materials are ground and resuspended by traffic-related activities into forms not common outside urban areas.

In contrast to those few commenters who conditionally supported EPA's proposed indicator, the vast majority of commenters opposed one or more aspects of EPA's proposed indicator, including: (1) The basic decision to qualify the indicator to focus on particles associated with certain types of sources and to exclude other ambient mixes; and (2) the particular qualifications applied to the indicator, including the proposed siting requirements for coarse particle monitors suitable for comparison with the NAAQS and the proposed exclusion of agricultural, mining, and other similar sources from control under the standard. This large group of commenters advanced scientific as well as legal and policy arguments against drawing a distinction between particles typical of urban versus non-urban or rural areas. These commenters included public health groups such as the American Lung Association, the American Heart Association, the American Cancer Society, the American Diabetes Association, and the American Public Health Association, and environmental groups such as Earthjustice, Environmental Defense, and the Natural Resources Defense Council. It also included the State and Territorial Air Pollution Program

[69] The American Farm Bureau Federation's summary of the results of Mar *et al.* (2000), offered in support of their arguments about the lack of effect of soil or crustal materials, misses some important elements of the study results. A major finding of the original study as well as the reanalysis (Mar *et al.*, 2003) was an association between $PM_{10-2.5}$ particles and mortality. The analysis in this work that examined sources and components examined contributions to the effects of $PM_{2.5}$, not to $PM_{10-2.5}$. In the opinion of the authors, the factor commenters call motor vehicle exhaust ''probably represents the influence of motor vehicle exhaust and resuspended road dust'' (Mar *et al.*, 2000, p. 351). The negative association for ''soil'' in the fine fraction cited by the commenter was apparently related to problems in the $PM_{2.5}$ measurement. When the data were reassessed for the period with an improved sampler, the authors report that the association between soil and mortality was ''positive and significant at 0 days lag'' (ibid., p. 352).

[70] The Laden *et al.* (2000) study cited by commenters was reanalyzed in Schwartz (2003), with qualitatively similar findings. As in Mar *et al.* (2000, 2003), this study examined the associations of crustal materials in the fine particle fraction, in which they make up such a small fraction of fine mass that one of the six cities had to be excluded from the analysis (Laden *et al.*, 2000, p. 945). While this result does not provide any support for associations between coarse crustal materials and mortality, given the lower concentrations of coarse particles in five of the six cities and the lack of examination of coarse particle composition, the results are inconclusive with respect to the potential effects of higher concentrations of coarse particles.

Administrators and the Association of Local Air Pollution Control Officials (STAPPA/ALAPCO) and numerous individual State and local air pollution control agencies, as well as dozens of Tribes and Tribal organizations such as the National Tribal Caucus, the National Tribal Air Association and its parent organization, the National Tribal Environmental Council. In addition, a number of industry groups expressed opposition to the proposal to qualify the coarse particle indicator; in general, these comments came from groups representing industry categories that were not excluded from the proposed indicator, such as the Engine Manufacturers Association, the Alliance of Automobile Manufacturers, and the National Association of Home Builders. Though these industry commenters primarily argued against setting any coarse particle standard at this time, they stated that if a standard were to be adopted, scientific evidence did not support the proposal to qualify the indicator based on the mix of sources present.

Commenters opposed to a qualified coarse particle indicator advanced numerous scientific arguments to support their position. They criticized EPA's interpretation of key epidemiologic studies, such as Gordian *et al.* (1996), Choudhury *et al.* (1997), Ostro *et al.* (2003), Smith *et al.* (2000) and Mar *et al.* (2003), arguing that these studies linked thoracic coarse particles to adverse health effects in environments where crustal components formed a significant part of the ambient mix of $PM_{10-2.5}$. For example, commenters argued that the study conducted by Ostro *et al.* (2003) in Coachella Valley, which found statistically significant associations between exposure to coarse particles and mortality, provides direct evidence of harm from exposure to rural particles. These commenters also challenged the results of Schwartz *et al.* (1999), attributing the lack of statistically significant mortality results in that study to avoidance behavior (*i.e.*, people may stay inside during dust storms) and noting that the study might have drawn different conclusions if morbidity endpoints had been considered. In support of this argument, they pointed to Hefflin *et al.* (1994), which looked at hospitalizations for bronchitis and sinusitis during dust storms and did find a small increase in these effects in the same area.

In addition, a number of commenters, including States, researchers, environmental and public health groups, and industry commenters, cited studies of particle composition as showing that the coarse PM found in rural areas is commonly contaminated with the same toxic components as particles found in urban areas (*e.g.* Alaska Department of Environmental Conservation; American Lung Association; Engine Manufacturers Association; Veranth). Moreover, these commenters noted that rural dusts may contain additional toxic contaminants such as molds, fungi, endotoxins, pesticides, and carbonaceous compounds including polycyclic aromatic hydrocarbons (PAHs), all of which are associated with rural sources and have been shown to produce toxic effects (citing studies including: Monn and Becker 1999; Soukup and Becker 2001; Horvath *et al.*, 1996; Offenberg and Baker, 2000; Eleftheriadis and Colbeck, 2001). (See American Lung Association *et al.*, pp. 92–100.) In addition, some commenters pointed to studies of the composition of coarse particles in particular locations, such as Owens and Mono Lakes in California, as evidence of the dangerous nature of rural particles. Commenters noted that coarse particles from these areas are contaminated by heavy metals, arsenic, and other toxic contaminants, but would be excluded from the proposed indicator.

Commenters critical of the proposed decision to qualify the coarse particle indicator also stated that EPA had inappropriately relied on the relatively few studies involving exposure to crustal materials, especially the Mt. St. Helens' studies. These commenters expressed the view that EPA should not equate exposure to volcanic ash to exposure to coarse particles emitted from agricultural and mining industries. Commenters noted that volcanic ash lacks many of the organic components typical of rural coarse PM, including pesticides and PAHs. Commenters pointed to specific components of coarse particles emitted by agricultural or mining activities, including endotoxins, pesticides, and metals, that they claim are associated with adverse health effects. These commenters argued that coarse particles in rural and other non-urban areas are not generally ''uncontaminated materials of geologic origin'' or ''uncontaminated natural crustal dusts.'' They argued that some of the effects noted in epidemiologic studies of thoracic coarse particles, such as Mar *et al.* (2003), occurred in areas dominated by agricultural or mining dusts (Maricopa County Air Quality Department, p. 3–4). Some commenters also stated that EPA had not demonstrated or even claimed that coarse particles associated with agricultural and mining activities are harmless. Citing a long history of occupational studies documenting effects and EPA's statement in the proposal that ''in the 1987 review, EPA found that occupational and toxicological studies provided ample cause for concern related to higher levels of thoracic coarse particles' (71 FR 2654), these commenters urged EPA to give greater weight to the results of such studies.

A number of commenters opposing a qualified $PM_{10-2.5}$ indicator referenced ''new'' epidemiologic and toxicologic studies which were not included in the Criteria Document in support of their arguments in favor of an unqualified $PM_{10-2.5}$ indicator. Specifically, the commenters pointed to recent epidemiologic studies showing statistically significant adverse health effects from exposure to coarse particles of varying composition, such as one study that found an association between exposure to volcanic ash and wheeze and exercise-induced bronchoconstriction (Forbes *et al.*, 2003). In addition, commenters cited several ''new'' studies of health effects associated with exposure to coarse particles during Asian dust storms (Chen Y-S *et al.*, 2004; Chen and Yang, 2005; Yang C-Y *et al.*, 2005; Chang *et al.*, 2006). Commenters also pointed to ''new'' toxicologic studies such as Schins *et al.* (2004), Veranth (2004, 2006), Becker (2005), Labban *et al.* (2004, 2006), and Steerenberg *et al.* (2006), arguing that toxicological studies do not show consistent differences between urban and rural dusts.

In response to these commenters' first point regarding the epidemiologic studies that were included in the Criteria Document, EPA does not agree with the commenters that these epidemiologic studies provide direct evidence of harm from non-urban or rural crustal material. While EPA acknowledges that crustal particles may have dominated the ambient mix in some of the locations in which these studies were done, it is also the case that these areas are all urban, so the crustal materials in the ambient mix typically would be contaminated by metals, road dust, and other combustion byproducts. At the same time, EPA notes that CASAC cited the studies by Ostro *et al.* (2000, 2003) as suggestive of health effects associated with exposure to rural crustal materials: ''Little is known about the potential toxicity of rural dusts, although the 2000 and 2003 Coachella Valley, CA studies from Ostro *et al.* showed significant adverse health effects, primarily involving exposures to coarse-mode particles arising from crustal sources' (Henderson, 2005a, p. 4). Thus while EPA does not agree with these commenters that the epidemiologic studies demonstrate that non-urban or rural crustal particles are harmful, at the same time EPA believes the studies do raise credible concerns and suggest the need to be cautious in interpreting the epidemiologic and other evidence.

The EPA agrees with these commenters that the observations of Hefflin *et al.* (1994) suggest it is possible that the lack of mortality effects on dust storm days observed in Schwartz *et al.* (1999) may be due to avoidance behavior. As noted in the proposal (71 FR 2666), there is a possibility that people may reduce their exposure to ambient particles on the most dusty days. This argues for caution in interpreting the results of Schwartz *et al.* (1999) with regard to the potential health effects associated with exposure to natural crustal material.

The EPA acknowledges the limitations on the scientific evidence identified by these commenters regarding the differences in composition and toxicologic effects of urban and rural thoracic coarse particles. As noted in the Criteria Document and Staff Paper, there is clear evidence of toxicity of certain components of thoracic coarse particles, such as metals and endotoxins, as well as evidence that natural crustal materials of geologic origin, such as Mt. St. Helens volcanic ash, may have very little toxicity. There is largely an absence of evidence regarding the presence or absence of toxicologic effects associated with other types of coarse particles in non-urban areas. However, EPA agrees that thoracic coarse particles in non-urban areas may become contaminated with a wide variety of toxic materials (EPA, 2004a, p. 8–344). Clearly, however, crustal material associated with particular locations, such as the dry lakebeds of Owens and Mono Lakes, can be highly contaminated with metals, salts, and other toxic constituents. The EPA agrees with commenters that the potential toxicity of these components is well recognized; however, such locations tend to be isolated and not representative of other locations.

In response to other comments raised by this group of commenters, EPA continues to find it inappropriate to assume that effects observed in occupational studies should be considered representative of effects that would occur at community exposure levels. However, EPA agrees with commenters that the presence of occupational exposure studies demonstrating adverse effects lends further support to a cautious approach in considering revisions to the standards affording protection from thoracic coarse particles. Finally, to the extent that commenters cited new scientific studies that were not considered in the Criteria Document in support of their arguments against a qualified coarse particle indicator, EPA notes that as discussed above in section I.C, EPA it is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review, and will consider the newly published studies for purposes of decision making in the next PM NAAQS review.

Overall, the scientific evidence supports a conclusion that the risks of adverse health effects associated with thoracic coarse particles typically found in urban or industrial areas warrant targeted protection. Although the limited and inconclusive evidence does not support such a conclusion concerning thoracic coarse particles typically found in non-urban or rural areas, it supports a cautious approach concerning thoracic coarse particles. The EPA agrees with all the commenters who pointed to the need for additional research to strengthen the current body of evidence to reduce some of the uncertainties regarding the health effects associated with coarse particles.

In addition to their criticisms of the scientific basis for EPA's proposed indicator, commenters opposed to a qualified indicator also advanced legal and policy arguments against EPA's proposed approach. In particular, commenters criticized the proposal's provision that ''agricultural sources, mining sources, and other similar sources of crustal materials shall not be subject to control in meeting this standard'' (71 FR 2699); a large number of commenters expressed the view that the exclusion is flatly illegal, citing CAA section 101 (a) (3) and case law in support. These commenters also pointed to CASAC's March 21, 2006 letter to the Administrator which stated that EPA had misconstrued the finding of the Committee and that the proposed rule—particularly the source-category exclusions—was not consistent with the Committee's recommendations.

These commenters also stated that EPA had failed to demonstrate that its proposed qualified indicator would protect public health with an adequate margin of safety. Pointing again to the relative paucity of data regarding health effects associated with coarse particles of differing compositions, and the almost complete lack of evidence regarding health effects in rural areas, these commenters expressed the view that EPA must demonstrate affirmatively that the coarse particle standards will ensure an absence of adverse effects on sensitive individuals (American Lung Association, p. 82, citing *Lead Industries Ass'n* v. *EPA,* 647 F.2d 1130, 1153 (D.C. Cir. 1980) and *American Lung Ass'n* v. *EPA,* 134 F.3d 388, 389 (D.C. Cir. 1998)), and that in the absence of evidence, or in the face of significant uncertainty, the CAA requirement to provide an adequate margin of safety obligates EPA to regulate all coarse particles equally (*Lead Industries Ass'n* v. *EPA,* 647 F.2d 1154–55). Some of these commenters pointed to the DC Circuit Court's instruction in ATA III that ''[t]he Act requires EPA to promulgate protective primary NAAQS even where * * * the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree' '' (*ATA III,* 283 F.3d 355, 369 (quoting PM NAAQS, 62 FR 28653)).

Commenters also argued that, under the CAA, EPA is charged with setting ambient standards that are national in scope and application, and that the proposed qualified indicator fails this test. Citing *Whitman,* 531 U.S. at 473, some of these commenters stated that the proposed qualified indicator is a thinly veiled attempt to establish a coarse particle standard that only applies to urban areas, and that it denies citizens in non-urban areas adequate health protection. Several commenters, including numerous Tribes, argued that the qualified indicator, by virtue of depriving non-urban populations of protection from coarse particles, violated principles of environmental justice and the government's Trust Responsibility to Tribes.

Commenters pointed to other concerns as well, many of them focused on specific aspects of the proposed $PM_{10-2.5}$ indicator. First, some commenters stated that the proposed qualified indicator inadequately describes the substance(s) being regulated. These commenters argued that EPA is attempting to establish a composition-based indicator without being able to define adequately which particular chemical or physical components are associated with adverse health effects. Furthermore, commenters pointed out that the indicator was defined in large part through an implementation strategy—i.e. via the placement of monitors—rather than in scientific terms. The Alliance of Automobile Manufacturers expressed concern that the result would be that two sources of coarse particulate matter with similar composition that presumably produce similar health impacts would be ''given different regulatory treatment based merely on the non-scientific qualifiers established in EPA's indicator'' (Alliance of Automobile Manufacturers, p. 9).

In addition, some commenters pointed to a logical paradox inherent in the proposed $PM_{10-2.5}$ indicator, which is defined to include any ambient mix ''dominated by'' particles from particular types of sources. Commenters noted the potential for the same concentration of ''harmful'' coarse particles—*i.e.* particles from high-density traffic, industrial sources and construction sources—to be regulated differently in different locations depending on what percentage of the ambient mix it constitutes relative to ''crustal'' particles. These commenters stated that the coarse particle standard must provide a consistent level of protection from particles of concern, and that use of a 50 percent domination threshold would result in a variable level of protection from particles of concern.

The EPA also received an extremely large number of comments from diverse stakeholder groups—some of whom conditionally supported a qualified indicator—regarding perceived problems with implementing the proposed $PM_{10-2.5}$ indicator. Many commenters pointed out that EPA failed to specify which source types were included in the broad source category descriptions listed in the indicator. They requested further definition of what could be considered an ''agricultural source,'' a ''mining source,'' or ''other similar sources of crustal material'' (i.e. those sources that would be excluded from control under the proposed standard), and which ''industrial'' and ''construction'' sources were included in the indicator. Furthermore, some commenters inquired about the treatment of sources that were neither explicitly included in nor excluded from the proposed indicator, such as residential and commercial sources. In addition, commenters wondered how EPA or the States would make the determination that one set of sources was ''dominant,'' given the scarcity of knowledge about coarse particle emissions and air quality concentrations, and the lack of suitable source attribution techniques.

Commenters also objected to the proposed five-part test for siting NAAQS-comparable monitors, noting that as written, the monitor siting criteria arbitrarily would prohibit monitoring and regulation of coarse particles outside urbanized areas of 100,000 population, regardless of the presence of large or numerous sources of the types of coarse particles of concern or the nature of the ambient mix. Commenters pointed out that the monitor siting criteria, by virtue of their highly prescriptive role in defining where the pollutant can and cannot be measured, in essence define the indicator itself, and artificially narrow its scope such that in many instances, coarse particles of concern would not be covered by the indicator. These commenters argued that by failing to provide protection from coarse particles of concern in non-urban areas even though the composition of those particles may be identical to that of coarse particles found in large urban areas, the qualified indicator, as EPA proposed to implement it, would be under inclusive. Many Tribes and some other commenters raised concerns about the environmental justice implications of the proposal and stated that EPA had violated its Trust Responsibility toward Tribes, because Tribal lands would be virtually excluded from coverage under the proposed monitor siting criteria, regardless of the mix of particles present. Furthermore, numerous commenters stated that the siting criteria would be impossible to implement, so the criteria undermined the proposed standard on a practical level. Commenters particularly objected to the fifth part of the monitor-site suitability test, which as proposed would require an affirmative demonstration that the ambient mix at the site was dominated by sources of concern, even if all of the other four monitor site-suitability criteria were met. Commenters stated that this demonstration would be impossible to execute due to the lack of suitable data and techniques, undermining the siting of any NAAQS-comparable $PM_{10-2.5}$ monitors.

In response to these perceived problems with the proposed qualified indicator, commenters suggested a number of remedies. A few commenters, mostly industry representatives who preferred that no coarse particle standard be set at the current time, stated that if EPA does set a standard, it should be based on a qualified $PM_{10-2.5}$ indicator, but EPA should fix specific problematic aspects of the proposal (e.g. clarify the definition of included vs. excluded industries). Most commenters, including States, Tribes, and environmental and public health groups, urged EPA to adopt an unqualified $PM_{10-2.5}$ indicator to ensure adequate public health protection and to avoid some of their perceived legal and/or policy issues associated with the qualified indicator. A few of these commenters recommended that EPA utilize the Exceptional Events Rule, proposed on March 10, 2006 (71 FR 12592–12610), to exclude violations caused by rural windblown dust. According to these commenters, this would be consistent with historical practice, because in the past the Natural Events Policy has been applied in many instances to exclude data associated with dust storms and other events from consideration under the PM_{10} standard (see New Mexico Air Quality Bureau, p. 10).

Some commenters advocating an unqualified $PM_{10-2.5}$ indicator stated that, given the limitations on the scientific evidence, and in light of some of the other problems identified with the proposed qualified indicator, EPA should consider retaining the current PM_{10} standards to continue protection from coarse particles. They expressed particular concern about the absence of control in the interim period between the issuance of the final PM NAAQS rule (which as proposed would include the revocation of existing PM_{10} standards in almost all locations) and the completion of designations under a new $PM_{10-2.5}$ standard (which would require deployment of a new monitoring network followed by 3 years of data collection). A few of the commenters advocating the retention of the PM_{10} standards suggested that measurements of PM_{10} could be adjusted by subtracting out $PM_{2.5}$ to avoid double regulating the fine fraction, to satisfy a concern voiced by the D.C. Circuit in *ATA I* (*e.g.*, Alliance of Automobile Manufacturers; also some Tribes and States). Some Tribal, State and local commenters suggested that the 24-hour PM_{10} standard be retained permanently in all areas where the $PM_{10-2.5}$ standard did not apply by virtue of the monitoring requirements, which limited NAAQS-comparable monitors to sites that met the five-point site suitability test outlined in the monitoring rule.

While EPA proposed a qualified indicator that attempted to include certain ambient mixes of thoracic coarse particles and exclude others, EPA's evaluation of the large number of adverse comments received on the proposed qualified indicator has led it to the conclusion that significant caution is warranted in considering such revisions to the scope of the indicator affording public health protection from coarse particles. As discussed below, there are two main issues that arise from consideration of a qualified indicator for thoracic coarse particles: (1) The inability to effectively and precisely identify which coarse particles are included in the indicator and which are not; [71] and (2) the importance of providing some level of protection from exposure to all thoracic coarse particles while targeting protection at those kinds of thoracic coarse particles for which there is more evidence regarding adverse health effects.

As explained earlier in this section, EPA continues to believe that, from a scientific standpoint, it is appropriate to draw a distinction between the character of the ambient mix of thoracic coarse particles generally found in urban areas and that found in non-urban and, more specifically, rural areas, recognizing that the mix of coarse particles in urban areas is influenced to a relatively greater degree by components from urban mobile and stationary source emissions and that the evidence of health effects associated with exposure to these urban types of coarse particles should not be generalized to other types of coarse particles. In the presence of significant, though limited, evidence of effects in urban areas, it remains EPA's view that a targeted indicator that focuses control on areas with ambient mixes of coarse particles known to be associated with adverse health effects will provide the most certain and substantial public health benefits.

However, EPA also recognizes a number of flaws in the proposed qualified indicator, as noted by numerous commenters, most specifically the difficulties inherent in attempting to effectively and precisely identify the ambient mixes of concern. These include: (1) The artificial constraints on the reach of the indicator resulting from the application of quantitative monitor site-suitability criteria such as the requirement that NAAQS-comparable monitors can only be sited in urbanized areas with minimum 100,000 population even if there is an ambient mix of concern around such an area; and (2) the difficulties associated with attempting to determine with any precision which sources ''dominate'' the ambient mix of coarse particles in different locations.

The quantitative constraints in the monitor site-suitability criteria result in an under-inclusive indicator that fails to include all ambient mixes of concern. Smaller urban and/or industrial areas, for example, would not meet the proposed monitor siting criteria, but might have an ambient mix of concern. Consequently, EPA agrees with commenters that unless the constraints were changed, the proposed indicator would be under-inclusive. The EPA has considered several options to modify the quantitative criteria, including those discussed in the proposal (see Weinstock, 2006). For example, EPA evaluated different possible minimum population thresholds (e.g., 25,000 or 50,000 instead of 100,000) for areas eligible to site NAAQS-comparable monitors, and/or the possibility of adding additional criteria to include areas that do not meet a quantitative population threshold but are dominated by industrial or traffic-oriented sources. Each of these options, however, was found too inflexible to capture all relevant areas or too difficult to implement in practice. Thus, EPA believes that even a more complex set of quantitative criteria would fail to resolve the basic problem inherent in precisely identifying those ambient mixes to include and those to exclude. Based on the data available to us in this review, there still remains a clear risk of failing to capture all ambient mixes of concern, or of capturing ambient mixes that are intended to be excluded from the qualified indicator.

Moreover, as a general matter, the use of a qualified indicator without such objective monitor site-suitability criteria would still present serious problems because it is currently impossible to determine with any precision which sources ''dominate'' the ambient mix in many different locations. Although it may be easy in certain instances to identify an ambient mix dominated by urban and/or industrial sources, in many cases it would be difficult to determine whether that precise ambient mix presents the types of health risks identified in the epidemiologic and other studies. The EPA is currently unable to identify any set of objective criteria or techniques such as chemical air quality speciation or modeling that could be practically employed to ensure adequate inclusion of all areas with particles of concern, and exclusion of areas without such particles.

The EPA is also aware that the legal concerns raised by commenters with regard to the exemption of agricultural and mining sources from control under the standard, and the specific sections of the Clean Air Act that speak to this issue, would require careful consideration if the proposed qualified indicator were to be adopted. The logical paradox noted by commenters is also a flaw in the qualified indicator that would need to be resolved. It is another example of the lack of precision in the use of such a qualified indicator.

After careful consideration of the concerns raised by commenters and the options available, EPA now agrees with commenters that the proposed qualified indicator is fundamentally flawed, because it cannot effectively and precisely identify the ambient mixes of concern and because modifications to the indicator that could rectify this and other problems highlighted by the commenters have not been identified. At the present time, therefore, EPA believes that there is an inherent risk that a qualified indicator would not include all of the ambient mixes of concern which the indicator is intended to capture.

Furthermore, in light of the significant scientific uncertainty surrounding the health effects associated with different ambient mixes of coarse particles, EPA agrees with commenters that the proposed qualified indicator would be insufficiently protective and further concludes that, given the limitations on the evidence regarding the health risks associated with different ambient mixes, some protection from exposure to thoracic coarse particles is warranted in all areas. The EPA recognizes that additional data will be collected and analyzed that will be useful to inform the next review.

The EPA has already set out the reasons for providing protection from exposure to ambient mixes dominated by the types of thoracic coarse particles found in urban or industrial areas. With respect to other ambient mixes, some commenters have argued that the scientific evidence, including epidemiologic, dosimetric, toxicologic, and occupational studies, demonstrates that non-urban mixes of thoracic coarse particles are harmful, and therefore that EPA should maintain an unqualified indicator. Other commenters argue that the evidence demonstrates that non-urban mixes of thoracic coarse particles are benign and therefore EPA should retain a qualified indicator. The EPA disagrees with both of these views regarding the strength of the evidence. The existing evidence is inconclusive with regard to whether or not community-level exposures to thoracic coarse particles are associated with adverse health effects in non-urban areas. In light of this uncertainty and the need for caution in considering the evidence, and recognizing the large population groups potentially exposed to non-urban thoracic coarse particles and the nature and degree of the health effects at issue, it is the judgment of the Administrator that the proper response to this body of evidence is to provide some protection from thoracic coarse particles in all areas. Congress ''specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not

[71] These concerns apply both to defining the qualified indicator and implementing the standard.

yet been uncovered by research and effects whose medical significance is a matter of disagreement * * * Congress' directive to the Administrator to allow an ''adequate margin of safety'' alone plainly refutes any suggestion that the Administrator is only authorized to set primary air quality standards which are designed to protect against health effects that are known to be clearly harmful.'' *Lead Industries* v. *EPA,* 647 F.2d at 1154–55; see also *American Petroleum Inst.* v. *Costle,* 665 F.2d at 1186 (''in setting margins of safety the Administrator need not regulate only the known dangers to health'').

The Administrator has carefully reviewed the scientific evidence and recommendations contained in the Staff Paper, the advice and recommendations from CASAC, and the public comments received regarding the appropriate indicator for coarse particles. After doing so, the Administrator has decided that it would not be appropriate at this time to revise the indicator for coarse particles by adopting a qualified $PM_{10-2.5}$ indicator, either as proposed or with modifications. At the same time, the Administrator believes it is appropriate to target protection from thoracic coarse particles principally towards those types of coarse particles that have been demonstrated to be associated with significant adverse health effects, specifically urban and industrial ambient mixes of coarse particles.

In general, EPA believes these conclusions regarding the potential health effects associated with thoracic coarse particles, and the conclusion that an unqualified indicator that provides targeted protection is the most appropriate approach for regulating coarse particles, are consistent with views expressed by CASAC. In its June 6, 2005 letter, CASAC expressed the view that it was ''important to qualify the $PM_{10-2.5}$ standard by somehow allowing exceptions for regions where the coarse fraction was composed largely of material that was not contaminated by industrial- or motor vehicle traffic-associated sources. Options discussed by members of the Panel for attempting to achieve this approach included limiting the standard to cover ''all'' urban areas, the judicious siting of monitors with a focus on urban areas, or regulatory exceptions for regions where road dust is not an issue or where rural components dominate the source. *No single option was favored''* (Henderson, 2005a, p. 8, emphasis added). CASAC thus recognized that there were numerous ways to approach the need for targeted protection. In its September 2005 letter responding to the recommendations regarding a qualified $PM_{10-2.5}$ indicator in the final Staff Paper, the PM Panel noted that some members did not favor adoption of a qualified indicator. Moreover, CASAC clearly anticipated the difficulties associated with adopting a qualified $PM_{10-2.5}$ indicator:

> CASAC generally agrees with EPA staff conclusions that thoracic coarse particles in urban areas can be expected to differ in composition from those in 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 (although it is likely that there will be some overlap of the same contaminants in both areas). Most Panel members concurred that the current scarcity of information on the toxicity of rural dusts makes it necessary for the Agency to base its regulations on the known toxicity of urban-derived coarse particles, and that an urban coarse particle indicator should be specified as $UPM_{10-2.5}$. Other Panel members recommended specifying a national $PM_{10-2.5}$ standard accompanied by monitoring and exceptional-events guidance that emphasized urban influences. Some members also expressed concerns whether EPA would be able to specify a clear definition of ''urban'' to effectively determine in advance the specific conditions in which the standard would (and would not) apply. It is recognized that, as more information on the toxicity of rural dusts is acquired, the name and/or geographical focus of a coarse-particle indicator may need to be reconsidered* * *. There is a paucity of data currently available on health outcomes related to thoracic coarse particles in rural areas and limited information on the composition and toxicity of rural area coarse particles. (Henderson 2005b, p. 4)

CASAC also commented negatively on the proposed qualified indicator, raising concerns about the quantitative criteria for monitor siting and the source exclusions, as well as flagging the need for more information about health effects in non-urban areas (Henderson, 2006, p.4).

The comments and concerns expressed by CASAC are consistent with the difficulties EPA has encountered in attempting to craft a qualified indicator, and the Committee correctly anticipated these difficulties. Furthermore, CASAC's advice is generally consistent with the ultimate decision by the Administrator not to move to a qualified $PM_{10-2.5}$ indicator at present. The practical difficulties and imprecision associated with a qualified indicator, as well as the substantial scientific uncertainty regarding the health effects associated with different components and mixes of coarse particles, the large population groups potentially exposed to non-urban thoracic coarse particles and the nature and degree of the health effects at issue, have convinced the Administrator that it is inappropriate to adopt a qualified $PM_{10-2.5}$ indicator at this time. In the following section, EPA considers what indicator would most appropriately provide the type of targeted but comprehensive protection judged appropriate based on its review of the scientific evidence.

3. Decision Not To Revise PM_{10} Indicator

For reasons discussed in the previous section, in the view of the Administrator it is not appropriate to revise the PM_{10} indicator by replacing it with a qualified indicator for thoracic coarse particles at this time. Based on the scientific evidence already summarized, the Administrator believes it is necessary to maintain some protection from all ambient mixes of thoracic coarse particles, and also to have that level of protection reflect the varying degree of public health concern presented by the different ambient mixes of thoracic coarse particulate matter. This would mean allowing lower ambient concentrations of thoracic coarse particles in urban areas, where the evidence indicates the public health risks to be significant, and higher levels in non-urban areas where the public health concerns are less certain. The difficulty of the task is compounded because there presently is no means of achieving this objective by linking allowable concentrations to specific coarse particle chemical components. As CASAC noted, ''[s]ufficient data are lacking at the present time to set standards [for thoracic coarse particulate matter] based specifically on composition'' (Henderson 2005b, p. 5).

Given these objectives and constraints, EPA carefully considered various possibilities regarding the indicator for coarse particles, including adopting an unqualified $PM_{10-2.5}$ indicator, retaining the existing PM_{10} indicator, and/or retaining the PM_{10} indicator with adjustment to avoid double-counting the PM2.5 fraction. These options are discussed below.

a. Unqualified $PM_{10-2.5}$ Indicator. The EPA evaluated whether an unqualified $PM_{10-2.5}$ indicator would satisfy the goals for public health protection described above. However, if such an indicator were utilized as part of a standard with a single unvarying level, it would not reflect the critical difference in evidence regarding the relative public health risks associated with urban and non-urban thoracic coarse particles. If the level were selected to provide appropriate protection against effects associated with exposure to the ambient mixes typical of urban or industrial areas, the standard would likely be more stringent than necessary to protect against effects associated with exposure to the ambient mixes in non-urban areas. In the judgment of the Administrator, the evidence warrants a lower ambient concentration of ambient coarse particles in urban areas than in non-urban areas, where the coarse particles are typically from different sources and there is less evidence of public health risk. Conversely, if a less stringent level were adopted on the grounds that there is less certainty that the ambient mix in non-urban areas poses a health risk, then the standard would not provide sufficient protection from the ambient mix found in urban or industrial areas. In both instances the standard would not be requisite overall, *i.e.*, ''not lower or higher than is necessary,'' to protect the public health with an adequate margin of safety. *Whitman*, 531 U.S. at 476.

Arguably this dilemma could be resolved by adopting a standard based on a $PM_{10-2.5}$ indicator with a varying level depending on whether the area is urban or non-urban. However, determining appropriate levels for different kinds of ambient mixes is not feasible at this time. The EPA notes that given the variety of sources contributing to $PM_{10-2.5}$ concentrations in different locations, a wide variety of ''ambient mixes'' are likely to exist, greatly complicating the determination of the appropriate standard level for each location. There is a lack of evidence to support establishing specific quantitative distinctions in level based on variations in coarse particle composition and differential toxicity. In addition, there is insufficient evidence regarding coarse particle composition in different areas to allow for the proper assignment of different standard levels in different locations, and the technical capabilities necessary to make such determinations are currently lacking. Even if EPA tried to assign only two levels, urban and non-urban, the same problems identified earlier with respect to a qualified indicator would apply here, given the inability to effectively and precisely identify different ambient mixes. Therefore, EPA finds that the current state of the science does not provide an adequate basis upon which to establish a $PM_{10-2.5}$ standard with an appropriately varying level. As EPA's new research program produces speciated monitoring data, thereby improving scientific knowledge, revealing more specific and precise information about coarse particle composition and relative toxicity, and about the distribution of ambient coarse particle mixes of varying composition, it will be appropriate in a future review to revisit the option of a $PM_{10-2.5}$ standard with a variable level or a qualified indicator.

b. PM_{10} Indicator. An alternative approach would be to retain PM_{10} as an indicator. The EPA recognizes, as did many commenters, that the D.C. Circuit concluded that EPA's 1997 choice of PM_{10} as the indicator for coarse particles was arbitrary and capricious. *ATA I*, 175 F.3d at 1027, 1054–55. In that case, the court noted the tension between EPA's conclusion that coarse and fine particles are different kinds of particles and pose independent and distinct threats to public health, and its choice to address the public health risks associated with coarse particles indirectly, using an indicator for coarse particles that nonetheless includes both fine and coarse particles. Although EPA adopted PM_{10} as a ''surrogate for coarse fraction particles,'' the court also noted EPA's recognition ''that $PM_{10-2.5}$ would have served as a satisfactory coarse particle indicator.'' With this backdrop, the court evaluated EPA's three bases for selecting PM_{10} as the indicator: (a) That the two epidemiologic studies underlying the standards for coarse particles used PM_{10} rather than $PM_{10-2.5}$ as the indicator; (b) that the PM_{10} standards would work in conjunction with the $PM_{2.5}$ standards ''by regulating the portion of particulate pollution not regulated by the $PM_{2.5}$ standards''; and (c) that a nationwide monitoring network for PM_{10} already existed. *Id.* at 1054.

The court rejected the first two arguments for two interrelated reasons. First, use of PM_{10} as the indicator regulates both fine and coarse particles, contrary to EPA's argument that the PM_{10} indicator would work in conjunction with the $PM_{2.5}$ standard to regulate only the coarse particle fraction of PM_{10}. The court concluded: ''we cannot discern exactly how a PM_{10} standard, instead of a $PM_{10-2.5}$ standard, will work alongside a $PM_{2.5}$ standard to regulate only the coarse fraction of PM_{10}. EPA provides no explanation to aid us in understanding its decision.'' *Id.* at 1054. Second, because the PM_{10} indicator regulates both fine and coarse particles, the amount of coarse particles allowed ''will depend (quite arbitrarily) on the amount of $PM_{2.5}$ pollution in the air.'' *Id.* EPA failed to explain why this result was consistent with its argument that a PM_{10} indicator would increase the likelihood that the standard would achieve the desired level of protection from exposure to coarse particles. The resulting combination of $PM_{2.5}$ and PM_{10} standards would lead to double regulation of fine particles and the potential under-regulation of coarse particles, since the amount of allowable coarse particles would always depend on the amount of fine particles in the air. *Id.* The court rejected the third of EPA's arguments, the pragmatic, administrative convenience of using the existing monitoring network, on the grounds that only factors related to public health can be considered in establishing a NAAQS. *Id.* at 1054–55. In sum, the court rejected EPA's adoption of a PM_{10} indicator as arbitrary because of the inadequacy of the reasons provided by the Agency as support for the decision.

Based on the current review of the scientific evidence, EPA feels it is now appropriate to reconsider utilizing PM_{10} as an indicator for coarse particles. Unlike its view in 1997, EPA views $PM_{10-2.5}$ as an unsatisfactory indicator in this review, for the reasons described in the previous subsection. In addition, EPA is not maintaining, as it did in 1997, that a PM_{10} indicator will work in conjunction with the $PM_{2.5}$ standard to regulate coarse particles exclusively, nor is the Agency justifying its choice of the PM_{10} indicator on grounds of administrative convenience. Instead, after careful consideration, it is the view of the Administrator that the PM_{10} indicator will in fact provide the type of targeted protection from thoracic coarse particles which is justified by the emerging body of scientific evidence, that it will do so more effectively and more appropriately than all other indicators evaluated by EPA during the course of this review, and that the inclusion of $PM_{2.5}$ in the PM_{10} indicator does not over-regulate fine particles or under-regulate coarse particles.

To the contrary, the inclusion of $PM_{2.5}$ in the PM_{10} indicator plays two important roles in effectively providing the kind of targeted health protection called for under the current state of the science. Because the PM_{10} indicator includes both coarse PM (PM10–2.5) and fine PM (PM2.5), the concentration of PM10–2.5 allowed by a PM_{10} standard set at a single level declines as the concentration of $PM_{2.5}$ increases. Thus, the level of coarse particles allowed varies depending on the level of fine particles present. At the same time, $PM_{2.5}$ levels tend to be lower in rural areas and higher in urban areas. EPA, 2005, p. 2–54, and Figures 2–23 and 2–24 at pp. 2–52 and 2–53. Thus, to the extent that higher $PM_{2.5}$ levels lead to a lower allowable level of coarse particles in some areas compared to others, this will occur in precisely those locations—

i.e. urban or industrial areas—where the science has shown the strongest evidence of adverse health effects associated with exposure to coarse particles. The EPA's recent Particle Pollution Report (EPA, 2004b, Figure 5, p. 8) provides evidence that annual average concentrations of $PM_{2.5}$ in selected eastern and western urban areas consistently exceed the annual average levels of $PM_{2.5}$ in nearby rural areas. This means that a PM_{10} standard set at a single, unvarying level will permit, on average, lower levels of coarse particles in urban areas, where $PM_{2.5}$ concentrations tend to be higher. The varying levels of coarse particles allowed by a PM_{10} indicator will therefore target protection in urban and industrial areas where the evidence of adverse health effects associated with exposure to coarse particles is strongest. For the same reason, lower levels of $PM_{2.5}$ lead to a higher allowable level of coarse particles in non-urban areas, again an appropriate result given the inconclusive evidence of health risks associated with coarse particles in these areas. The varying amounts of coarse particles that are allowed in urban vs. non-urban areas under the 24-hour PM_{10} standard, based on the varying levels of $PM_{2.5}$ present, appropriately reflect the differences in the strength of evidence regarding coarse particle effects in urban and non-urban areas.[72]

This result is consistent with our current understanding of the strength of the evidence regarding the toxicity of different ambient mixes of thoracic coarse particles in urban and non-urban or rural areas, and also is in accord with our current understanding of the observed toxicity in urban and industrial areas. As noted in both the proposal and the Criteria Document, the observed toxicity of coarse particles in urban and industrial areas comes from the kind of coarse particles found in these environments, for example direct emissions from industrial sources or materials released to road dust from motor vehicles such as brake and tire wear, as well as from the contamination of coarse particles that can occur. This contamination can come from both mobile and stationary sources. In particular, specific components, such as byproducts of incomplete combustion (*e.g.* polycyclic aromatic hydrocarbons) most commonly emitted from motor vehicles and other sources in the form of $PM_{2.5}$, as well as metals and other contaminants emitted from other anthropogenic sources, appear in higher levels in urban areas (EPA, 2004a, p. 8–344; 71 FR 2665). Many of these contaminants in $PM_{10-2.5}$ come originally from fine particles, which may become attached in the atmosphere or be deposited and mixed into coarse materials on the ground. Thus the greater the concentration of $PM_{2.5}$, with higher levels typically found in urban areas, the greater the level of contamination of coarse particles by fine particles. This contamination increases the potential health risk posed by those coarse particles. For that reason, it is logical to allow lower levels of coarse particles when fine particle concentrations are high. In other words, inclusion of $PM_{2.5}$ in the PM_{10} indicator for purposes of coarse particle protection would appropriately reflect the contribution that contaminants emitted in fine particle form can make to the overall health risk posed by coarse particles.

Moreover, due to the contamination of $PM_{10-2.5}$ by $PM_{2.5}$, use of a PM_{10} indicator will not result in inappropriate double regulation of the $PM_{2.5}$ component. To the extent that use of a PM_{10} indicator would result in any reduction in $PM_{2.5}$ concentrations in an area, this would reduce the potential health risk from coarse particles in the area as well. There is no certainty that the contribution of $PM_{2.5}$ to the health risk associated with exposure to contaminated coarse particles would be appropriately addressed through the fine particle standards alone. Thus, to the extent that the inclusion of the $PM_{2.5}$ fraction in the PM_{10} indicator amounts to double regulation of $PM_{2.5}$, its inclusion is non-duplicative and reasonable: it ensures that this risk of contamination of coarse particles by $PM_{2.5}$ is addressed in the suite of fine and coarse PM standards.

Some commenters nonetheless maintained that the court's opinion in *ATA I* bars use of PM_{10} as an indicator for coarse particles, stressing the court's statement that ''[i]t is the very presence of a separate $PM_{2.5}$ standard that makes retention of the PM_{10} indicator arbitrary and capricious.'' 175 F. 3d at 1054. The EPA disagrees that the *ATA I* decision precludes use of a PM_{10} indicator. The court did not hold that it was unlawful *per se* to use PM_{10} as an indicator for thoracic coarse particles. Instead, the court noted two particular problems—the variable level of allowable concentrations of $PM_{10-2.5}$ and double regulation of $PM_{2.5}$—and found that EPA either failed to address these issues, or provided explanations that were inconsistent and unsupported. *Id.* In large part, the court's decision was an important factor in EPA's close evaluation and subsequent proposal of a qualified $PM_{10-2.5}$ indicator as part of this NAAQS review. See EPA, 2005, p. 1–5. However, EPA now believes that a qualified $PM_{10-2.5}$ indicator is inappropriate, and that an unqualified $PM_{10-2.5}$ indicator is more problematic and less effective than a PM_{10} indicator at providing the requisite level of protection from the varying risks associated with thoracic coarse particles. Indeed, for the reasons described above, PM_{10} is an effective indicator for targeting coarse particles because it provides the desired variability in allowable coarse particle concentrations.

Far from being arbitrary and capricious, inclusion of $PM_{2.5}$ serves two important functions: first, it is the mechanism that provides for the variation in allowable $PM_{10-2.5}$ concentrations, targeting lower allowable levels where there is greater public health concern; and second, to the extent that there is ''double regulation'' of $PM_{2.5}$ by virtue of its inclusion in the PM_{10} indicator (175 F.3d at 1054), regulation of $PM_{2.5}$ via this indicator serves valid, non-duplicative purposes in providing requisite protection from thoracic coarse particles. The EPA also notes that ''double regulation'' of a pollutant, in the context of multiple NAAQS standards, is neither impermissible nor even unusual. For example, there are both annual and 24-hour standards for $PM_{2.5}$, as well as both primary and secondary standards for $PM_{2.5}$. The key is that the different standards reasonably serve different purposes '' they are directed at different effects, or

[72] The EPA recognizes that this relationship is qualitative. That is, the varying coarse particle concentrations allowed under the PM_{10} standard do not precisely correspond to the variable toxicity of thoracic coarse particles in different areas. While currently available information does not allow any more precise adjustment for relative toxicity, EPA believes the standard will generally ensure that the coarse particle levels allowed will be lower in urban areas and higher in non-urban areas. While the allowable levels will vary with location due to differing levels of fine particles, that variability will ultimately be limited by implementation of the $PM_{2.5}$ standards. Areas that do not meet these standards are taking steps to reduce $PM_{2.5}$, Currently, the annual fine particle standard places limits on both the long- and short-term levels of fine particles in a number of cities, particularly in the east and in some California cities. In the long run, this will serve to make the ''headroom'' allowed for thoracic coarse particles (*i.e.* the allowable PM_{10} level minus the corresponding $PM_{2.5}$ concentration) more uniform among cities. The new 24-hour $PM_{2.5}$ standard of 35 µg/m³ will promote this same result. It should cause areas that now meet the annual $PM_{2.5}$ standard, but have high 24-hour $PM_{2.5}$ concentrations, to adopt additional controls, further reducing the variability in the ''headroom'' for allowable thoracic coarse particle concentrations. In combination with the annual standard, the revised 24-hour $PM_{2.5}$ standard thus will provide for more consistent allowable levels of thoracic coarse particles in cities under the PM_{10} standard.

are not inconsistent when directed at the same effect—as is the case here.

The EPA also recognizes that selection of PM_{10} as the indicator for thoracic coarse particles differs in some degree from the specific advice provided by CASAC to use a qualified $PM_{10-2.5}$ indicator directed at urban or industrial thoracic coarse particles (71 FR 2665). However, EPA believes that the PM_{10} indicator is consistent with the central thrust of CASAC's advice—to utilize an indicator directed at urban types of coarse particulate matter, given the known toxicity of these particles—because it would generally allow lower levels of $PM_{10-2.5}$ in urban areas. The EPA has also explained why it has rejected a qualified $PM_{10-2.5}$ indicator at this time, and notes that CASAC itself considered multiple ways to achieve some degree of targeted protection and voiced strong objections to the qualified $PM_{10-2.5}$ indicator which the Agency proposed (Henderson, 2006, p. 4). The EPA has carefully considered CASAC's views in making its decision, and believes the final decision is consistent with the critical part of CASAC's advice, *i.e.*, to focus the indicator (and standard) on the type of thoracic coarse particles known to be harmful, which are found in urban and/or industrial environments.

c. Unqualified PM_{10} Indicator, with Adjustment to the $PM_{2.5}$ Component. EPA also solicited comment on an approach that would use PM_{10} as an indicator but subtract out the amount of $PM_{2.5}$ in excess of the 24-hour daily standard for $PM_{2.5}$ to avoid the double regulation of $PM_{2.5}$ in the situations where this would have the most regulatory consequence (71 FR 2673). Specifically, this option would retain the indicator, form and level of the 1987 PM_{10} standard, but on days when the measured concentration of PM_{10} exceeds the level of the standard and the measured concentration of $PM_{2.5}$ exceeds the level of the daily $PM_{2.5}$ standard, the amount of $PM_{2.5}$ in excess of the daily $PM_{2.5}$ standard would be subtracted from the total PM_{10}. A few commenters, including certain industry commenters and several local agencies and Tribes, expressed conditional support for pursuing this approach: though they preferred either no coarse particle standard (in the case of industry commenters) or an unqualified $PM_{10-2.5}$ standard applied nationally (in the case of Tribes or local agencies), they suggested that an adjusted PM_{10} indicator would be an acceptable alternative. This alternative, like an unadjusted PM_{10} indicator, would allow variable ambient concentrations of coarse particles. The net result, however, would be that $PM_{10-2.5}$ levels would be allowed to increase relative to the current PM_{10} standard when $PM_{2.5}$ levels are highest. As explained above, this is the opposite result from that desired from a public health perspective. There should be less allowable coarse particulate matter as $PM_{2.5}$ levels increase because these are the conditions under which $PM_{10-2.5}$ tends to become more contaminated and therefore more harmful. Furthermore, it would essentially relax the level of protection afforded by the current 24-hour PM_{10} standard because it would allow higher total PM_{10} levels on days with high $PM_{2.5}$ levels. As explained below in section III.D.2, EPA believes it is important to maintain the current level of protection from health effects associated with exposure to thoracic coarse particles. For both of these reasons, therefore, EPA rejected this approach.

4. Conclusions Regarding Indicator for Thoracic Coarse Particles

After extensive evaluation of the evidence, the alternatives available to the Agency, the advice and recommendations of CASAC, and all of the public comments, EPA concludes that retaining the PM_{10} indicator will be more effective in providing targeted public health protection than all other options available and, based on the current state of the science, is the most appropriate indicator to protect against the health effects associated with exposure to thoracic coarse particles. Thus, in the judgment of the Administrator, it is appropriate to retain PM_{10} as the indicator for coarse particles at this time. The conclusions that led to this decision can be summarized as follows:

(1) All thoracic coarse particulate matter can deposit in the sensitive regions of the lung of most concern, the tracheobronchial and alveolar regions.

(2) It remains appropriate to provide, to the extent possible, targeted protection from thoracic coarse particles that have been demonstrated to be associated with significant adverse health effects. Urban or industrial ambient mixes of coarse particulate matter dominated by high density vehicular, industrial, and construction emissions are of greatest concern, and should be the focus of protection.

(3) The proposed qualified $PM_{10-2.5}$ indicator was beset by numerous problems. Possible modifications to the qualifications considered by EPA failed to resolve these problems, which stem from the basic inability at this time to effectively and precisely identify which ambient mixes are included in the indicator and which are not.

(4) The evidence of health effects associated with non-urban ambient mixes of coarse particles is limited and inconclusive: in general, the evidence does not demonstrate that community-level exposures in non-urban areas are associated with either the existence or absence of adverse health effects.

(5) In light of the entire body of evidence concerning thoracic coarse particles, and given the potentially serious nature of the health risks posed by at least some thoracic coarse particles and the potential size of the population exposed, it is appropriate to provide some protection for all types of thoracic coarse particles, consistent with the requirement of the Act to allow an adequate margin of safety.

With all of the foregoing considerations in mind, the Administrator judges it appropriate not to revise the current PM_{10} indicator at this time. In the view of the Administrator, the PM_{10} indicator provides the type of targeted variation in allowable coarse particle concentrations that is justified by the emerging body of scientific evidence, while providing some protection in all areas. A decision not to revise the PM_{10} indicator reflects an appropriately cautious approach in two respects. First, it ensures inclusion of all ambient mixes of coarse particles of known concern in the indicator; and second, it addresses the potential that additional scientific research may reveal that non-urban or rural ambient mixes of thoracic coarse particles present public health risks that the evidence does not clearly identify at this time. It is EPA's goal that its new research and speciated monitoring program will produce data to determine what effect differences in particle composition may have on health outcomes. Such results have the potential to provide the kind of certainty and specificity required for making future decisions on indicators for thoracic coarse particles that might incorporate qualifications, such as the proposed qualified indicator related to coarse particles from agriculture and mining.

D. Conclusions Regarding Averaging Time, Form, and Level of the Current PM_{10} Standards

1. Averaging Time

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 38677–79). 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, 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 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, 2005, p. 3–19, 3–23–24). Thus, the Criteria Document concluded that the available evidence does not suggest an association with long-term exposure to $PM_{10-2.5}$ (EPA, 2004a, p. 9–79).

Based on these considerations, the Staff Paper concluded 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 concluded 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 observed, 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, 2005, p. 5–61). Based on its review of the Staff Paper, CASAC recommended retention of a 24-hour averaging time and agreed that an annual averaging time is not currently warranted for the coarse particle standard (Henderson, 2005b, p.5).

The EPA received relatively few comments regarding the appropriate averaging time of the coarse particle standard. Most of those who did comment generally supported the retention of a 24-hour, but not annual, averaging time, as proposed. A few of the commenters who concurred with EPA's proposal to revoke the annual standard urged reconsideration of the appropriateness of an annual averaging time in the next PM NAAQS review. Several commenters, however, including a few States and several environmental and public health groups, urged EPA to retain an annual standard as well as a 24-hour standard. The American Lung Association, in particular, stated that EPA had inappropriately ignored evidence of long-term morbidity effects in several studies, including Gauderman *et al.* (2000, 2002) and Avol *et al.* (2001), and had also ignored substantial evidence from European studies as well as the recommendations for an annual PM_{10} standard made by a WHO working group. These commenters argued that an annual standard was requisite to protect public health with an adequate margin of safety.

EPA disagrees that it ignored the evidence that is relevant to evaluating the health effects associated with long-term exposure to thoracic coarse particles. The EPA's assessment, both in this review and the previous review, placed greatest weight on studies that measured $PM_{10-2.5}$ or on studies conducted in areas where it is reasonable to expect the PM_{10} measurements to be dominated by coarse particles (EPA, 2005). By contrast, these commenters have placed inappropriate reliance on studies that measured PM_{10}, and were conducted in Southern California cities (Gauderman *et al.*, 2000, 2002) or in European cities where it is not reasonable to assume that PM_{10} associations are dominated by coarse particles.[73] In such cases, it is difficult to draw meaningful conclusions about the relative role of coarse as opposed to fine particles. The WHO panel recommendations for PM_{10} limits cited by commenters also do not provide any independent scientific justification regarding the need for a separate long-term standard for coarse particles.[74]

The long-term exposure studies of mortality and morbidity that permit comparisons of fine and coarse particles continue to suggest that, at current ambient levels in the US, fine particles are associated with health effects and coarse particles are not.[75] The EPA believes that the $PM_{2.5}$ standards it is establishing in today's notice address the major risk suggested in the PM_{10} studies cited by commenters. To the extent that additional concerns may exist with regard to long-term exposures to coarse particles that have not been fully identified by scientific research, the Staff Paper notes that the short-term standard for coarse particles, which is generally controlling, has and will continue, as a practical matter, to limit such long-term exposures.[76]

After reviewing the available evidence, the Administrator concurs with staff and CASAC recommendations and concludes that the evidence continues to support a 24-hour averaging time for a coarse particle standard, based primarily on evidence suggestive of associations between short-term (24-hour) exposure and morbidity effects and, to a lesser degree, mortality. As noted above, a 24-hour standard would in effect also provide protection against any as yet unidentified potential effects of long-term exposure at ambient levels. Further, the Administrator concludes

[73] The only one of these studies (Gauderman *et al.*, 2000) to include measurements of coarse particles found an association between lung function growth for PM_{10}, $PM_{2.5}$, $PM_{10-2.5}$, NO_2, and acids. The authors were unable to cite any single pollutant as responsible for these results, but they chose not to include measures for coarse particles in their follow-up study (Gauderman *et al.*, 2002). As noted in the 1996 PM Staff Paper, the other major study of lung function and long-term air pollution in children found no associations with coarse particles (EPA, 1996, p. 5–67a).

[74] The WHO panel essentially developed their recommendations for PM_{10} standards by deriving a ratio of fine particles to PM_{10} and adjusting their recommended levels for $PM_{2.5}$ to derive an equivalent PM_{10} metric, for areas that do not yet have access to $PM_{2.5}$ monitors (WHO, 2005, p. 8).

[75] See EPA 2004a, pp. 8–306 to 307 (''no statistically significant associations have been reported between long-term exposure to coarse fraction particles and cause-specific mortality''); pp. 8–313 to 314 (''[t]he recent studies suggest that long-term exposure to fine particles is associated with development of chronic respiratory disease and reduced lung function growth; little evidence is available on potential effects of exposure to coarse fraction particles'').

[76] The Staff Paper analysis of PM_{10} air quality data indicates that the current 24-hour PM_{10} standard is ''controlling'' in virtually every area in the US; that is, virtually all areas that violate the PM_{10} standards violate the 24-hour PM_{10} standard. Some of them may violate the annual PM_{10} standard as well, but (depending on the year) few, if any, areas violate the annual PM without violating the 24-hour PM_{10} standard (EPA, 2005, p. 2–31 to 32). A supplemental analysis in the Response to Comments document shows that for 2003–2005, all of the areas that would violate the annual PM_{10} standard also violate the 24-hour standard.

that an annual coarse particle standard is not warranted at this time. Thus, the Administrator is retaining the 24-hour PM_{10} standard and revoking the annual PM_{10} standard.

2. Level and Form of the 24-Hour PM_{10} Standard

This section summarizes the major considerations that led to the proposed decision regarding the appropriate level and form for the 24-hour standard for thoracic coarse particles, summarizes and addresses public comments on the appropriate level of protection to be provided by the standard, and presents the Administrator's final conclusions regarding the level and form of the 24-hour standard. The proposed level and form for the 24-hour standard for thoracic coarse particles were based primarily on an assessment of studies that measured $PM_{10-2.5}$, as well as studies that measured PM_{10} in areas that were dominated by $PM_{10-2.5}$. Now that the Administrator has concluded that it is appropriate to retain PM_{10} as the indicator for thoracic coarse particles, rather than adopting a $PM_{10-2.5}$ indicator as proposed, the Administrator relied on this same body of studies as the principal basis for determining an appropriate level and form for a standard based on the PM_{10} indicator. Therefore, in this section EPA reviews the basis for its conclusions in the proposal, and then discusses how this evidence informs the choice of level and form for the 24-hour PM_{10} standard.

In considering the available evidence as a basis for setting a 24-hour standard for thoracic coarse particles, the Staff Paper focused on relevant U.S. and Canadian epidemiologic studies showing associations between short-term $PM_{10-2.5}$ concentrations and morbidity and mortality effects, as discussed above in section III.A. As an initial matter, the Staff Paper recognized 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 to coarse particles.

In considering the evidence, the Staff Paper noted 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 focused 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.[77]

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, 2003), and Detroit (Ito, 2003), the 98th percentile $PM_{10-2.5}$ 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 noted that the level of the 24-hour PM_{10} standard was exceeded on only a few occasions during the time periods of the studies in Detroit and Seattle.[78] In 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, as part of the Six Cities study, Schwartz *et al.* (1996 and reanalysis 2003a) reported a statistically significant association between $PM_{10-2.5}$ and mortality in Steubenville, where the $PM_{10-2.5}$ concentrations were fairly high, with a reported 98th percentile value of 53 $\mu g/m^3$, although in a second reanalysis, the association did not remain statistically significant (Klemm and Mason, 2003). On the other hand, the Staff Paper noted that no statistically significant mortality 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), and in 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 $\mu g/m^3$, and all in areas that exceeded the level of the daily PM_{10} standard, 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 examining the air quality data used in the key morbidity and mortality studies considered in the Staff Paper, EPA recognized 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 noted 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, 2005, p. 5–64).

The Staff Paper 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 suggested 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 study conducted in Coachella Valley appeared 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 showed 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.

The Staff Paper noted that this close examination of air quality information generally reinforced the view that exposure measurement error is potentially quite large in studies focusing on thoracic coarse particles. As

[77] 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).

[78] 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*.

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 with effects 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 $PM_{10-2.5}$ levels to which the study populations were exposed 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 become more uncertain, suggesting a high degree of caution in interpreting the air quality levels from the group of morbidity studies as a basis for identifying a standard level that would protect against the observed effects. See generally EPA, 2005, pp. 5–65–66.

Taking into account this close examination of the air quality data associated with health effects in these studies, the Staff Paper concluded 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 µg/m³, 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. *Id.* at p. 5–66.

The Staff Paper also outlined another view that reflected a more cautious or restrained approach to interpreting the limited body of $PM_{10-2.5}$ epidemiologic evidence. This approach would judge that the uncertainties as to population exposures associated with the observed effects in this whole group of studies were too large to permit direct use of the reported effects levels 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 concluded that it would be reasonable to interpret the available epidemiologic evidence more qualitatively. Considering the available evidence in this way led 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} that were reported in areas in which PM_{10} was dominated by the coarse particle 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. *Id.* at p. 5–67.

Based on these considerations, the Staff Paper found little basis for concluding that the degree of protection afforded by the current PM_{10} standards in urban areas is greater than warranted, since potential mortality effects have been associated with air quality levels not allowed by the current 24-hour standard, but have not been associated with air quality levels that would generally meet that standard, and morbidity effects have been associated with air quality levels that exceeded the current 24-hour standard only a few times. Further, the Staff Paper found 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 concluded, therefore, that it is reasonable to interpret the available evidence as supporting consideration of a short-term standard for urban thoracic coarse particles, so as to provide generally ''equivalent'' protection to that afforded by the current 24-hour PM_{10} standard, recognizing that no one $PM_{10-2.5}$ level will be strictly equivalent to a specific PM_{10} level in all areas (EPA, 2005, p. 5–67). Such a standard would likely provide protection against morbidity effects especially in those urban areas where, unlike several of 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 less certain, coarse-particle-related mortality effects observed in some studies, generally at somewhat higher concentrations.

The Staff Paper went on to consider what level for a 24-hour $PM_{10-2.5}$ standard for urban coarse particles would provide an equivalent level of protection to that afforded by the current 24-hour PM_{10} standard. This consideration of a $PM_{10-2.5}$ standard providing generally ''equivalent'' protection reflected a judgment that while the epidemiologic evidence supported 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 was not strong enough to provide a basis for changing the level of protection generally afforded by the current PM_{10} standards (EPA, 2005, pp. 5–68–69). The Staff Paper examined various approaches to providing this equivalent level of protection, including establishing a level of 70 µg/m³ (98th percentile form) for the qualified $PM_{10-2.5}$ standard (*Id.* at 5–67–68), which is what EPA proposed (71 FR 2671).

CASAC generally supported the Agency's proposed range of 50–70 µg/m³ (98th percentile) for the 24-hour $PM_{10-2.5}$ standard. As noted, the upper end of this range was based on EPA's assessment of a level for an urban coarse particle standard that would provide a generally equivalent level of protection to that afforded by the current PM_{10} standards. The lower end of the range was developed in consideration of an approach that would place greater weight on the effects levels reported in several studies with lower ambient coarse particle concentrations. The CASAC Panel noted that ''there was general agreement among Panel members that Agency staff had presented a reasonable justification for the ranges of levels proposed'' (Henderson 2005b, p. 6).

Relatively few public commenters addressed the issue of whether ''general equivalence'' was an appropriate goal for the level and form of the proposed coarse particle standard. Some commenters, particularly those industry commenters advocating that no coarse particle standard be adopted,[79] stated that seeking ''equivalence'' to the PM_{10} standard was fundamentally flawed because, in their view: (1) The level of the current PM_{10} standard was not based on coarse particle studies; (2) the proposed standard is not equivalent to the PM_{10} standard; and (3) the court had already declared any standard based directly or indirectly on PM_{10} to be invalid. The EPA agrees that the 1987 PM_{10} standards were designed to protect against the health effects of both fine and coarse particles, and based in part on epidemiological studies that variously measured particles both smaller and larger than PM_{10}. However, the arguments regarding the origin of the 1987 standards as well as commenters' claims about the basis for the PM_{10} standards promulgated in 1997 [80] are not relevant to the current review. In determining whether to revise the standards in this review, EPA has examined the degree of protection provided by the current 24-hour PM_{10} standard in light of the quantitative evidence from the expanded epidemiological data base that includes studies using direct $PM_{10-2.5}$ measurements as well as studies using PM_{10} measurements in areas where coarse particles dominate the distribution.

Because as discussed in section III.C.3 above, the Administrator has decided that it is appropriate to retain PM_{10} as the indicator for thoracic coarse particles, there can be no uncertainty as to whether the final standard is equivalent to the current standard, making the commenters' second point above moot. With regard to their third point, for reasons outlined in section III.C.3, EPA believes that it has addressed the concerns raised by the court regarding PM_{10} as an indicator, and in any case, the D.C. Circuit did not address the issue of the level of protection from thoracic coarse particles afforded by the 1997 or 1987 24-hour PM_{10} standard.

Other commenters, particularly environmental and public health groups, disagreed with EPA's proposal to seek an ''equivalent level of protection'' because they believe the scientific evidence mandates a lower level to protect against adverse health effects. These commenters cited studies reviewed in the Staff Paper and noted above, which they claimed showed significant associations between health effects and $PM_{10-2.5}$ concentrations at levels between 30–40 μg/m^3, and recent decisions by the European Union and the State of California to adopt 24-hour PM_{10} standards of 50 μg/m^3.

These commenters argued that, even considering EPA's analyses of the uncertainties in the relevant ambient concentration measurements, these studies, particularly those in Atlanta, Seattle, and Toronto and the six-cities study of respiratory symptoms in children (Schwartz and Neas, 2000), demonstrate the need for a more stringent level of protection than that provided by the current standards. These commenters also argued that EPA's approach to determining an equivalent level resulted in less protection than the current standard, even in urban areas. In addition, these commenters pointed to the study review conducted by Brunekreef and Forsberg (2005) and numerous ''new'' studies published too recently for inclusion in the Criteria Document such as Mar *et al.* (2004), Chen Y *et al.* (2005), and Lin *et al.* (2005), as supportive of lower levels.

As noted above, EPA has conducted a careful assessment of the studies cited by commenters [81] from the Staff Paper assessment but reaches substantially different conclusions about their implications for the level of a 24-hour standard for thoracic coarse particles. Based on that assessment, EPA staff recommended consideration of a range of levels for a 24-hour $PM_{10-2.5}$ standard extending from a level equivalent to the current PM_{10} standard down to a level of 50 μg/m^3, which is clearly above that suggested by these commenters. CASAC found general agreement that the ''staff had presented a reasonable justification'' for this range oflevels. While EPA strongly agrees that the available scientific evidence supports and requires maintaining the level of protection provided by the current 24-hour PM_{10} standard, the limited extent of epidemiological evidence as well as the unusually large uncertainties in measuring exposures to thoracic coarse particles, particularly at lower levels, argue for the more cautious interpretation advocated by EPA staff and CASAC. Because the Administrator has decided to continue the use of PM_{10} as the indicator for coarse particles, commenters' remaining concerns about whether the proposed levels for $PM_{10-2.5}$ are as protective as current standards are no longer relevant.

For reasons summarized in section II.F above, EPA does not believe that standards adopted by the State of California or, by extension, the European Union, which operates under a different legal and policy structure, provide a relevant guide for establishing U.S. National Ambient Air Quality Standards. While EPA agrees that the assessment of Brunekreef and Forsberg (2005) supports separate regulation of fine and coarse particles, these authors make no recommendations with respect to appropriate levels of protection. To the extent that commenters cited ''new'' studies in support of their argument for a more stringent standard to protect against health effects associated with exposure to coarse particles, EPA notes that as in past NAAQS reviews, it is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review, and will consider the newly published studies for purposes of decision making in the next PM NAAQS review, as discussed above in section I.C. As evidenced by the uncertainties found in the detailed assessment of key coarse particle studies in the Staff Paper, the kind of assessment and analysis provided by the formal criteria and standards review process is particularly crucial for coarse particle studies that may be relevant to selecting the level of the standard.

After considering the public comments on this issue, EPA continues to believe that the available evidence leads to the conclusion that the degree of protection afforded by the current 24-hour PM_{10} standard is requisite to protect public health with an adequate margin of safety. Having chosen to retain the current indicator for the standard (PM_{10}), and to retain the same degree of protection, it is still necessary to determine the appropriate form and level for the standard. In the context of proposing a standard based on a qualified $PM_{10-2.5}$ indicator, EPA proposed to change the form of the 24-hour standard from a one-expected

[79] As discussed in section III.B.2, these commenters call EPA's interpretation of the key studies discussed in this section into question. EPA's response to the criticisms of use of these studies for standard setting is summarized in section III.B.2 and presented in more detail in the Response to Comments document.

[80] Commenters also suggested that, in promulgating revised PM_{10} standards in 1997, EPA did not consider whether the level of the PM_{10} standards it promulgated was lower than necessary and did not base the levels on coarse particle health effects data. While EPA disagrees with both of these claims—for example, EPA relied on two PM_{10} studies done in areas dominated by coarse particles in selecting the level (62 FR 38679)—this argument is not relevant to this review.

[81] As detailed in the Response to Comment document, EPA had various reasons for not placing primary reliance on the reported air quality results in these studies for selecting a standard level. The Atlanta study (Tolbert *et al,* 2000), found a significant effect for PM_{10}, but not for coarse particles. Both the Six Cities children's diary study (Schwartz and Neas, 2000) and the Toronto hospital admissions study (Burnett *et al.,*, 1997) were conducted for a periods of less than one year, making it difficult to determine what peak value across all seasons in a year might represent exposures of concern.

exceedance form to a 98th percentile form. The 98th percentile form was intended to be consistent with the goal of providing protection equivalent to that afforded by the current 24-hour PM_{10} standard (71 FR at 2671; EPA, 2005, p. 5–68). The few commenters addressing the proposed form supported it, largely because the 98th percentile would provide a more stable statistical basis for making nonattainment determinations. However, some commenters objected to the 98th percentile form because they felt it was inappropriate to allow as many as 21 days over the level of the standard over the course of a three-year period. These commenters argued for a more restrictive form (generally 99th percentile) to ensure the protection of public health with an adequate margin of safety. The EPA notes that the current one-expected-exceedance form of the 24-hour PM_{10} standard allows only three days above the standard over a three-year period.

While EPA generally favors the concentration-based form for short-term standards for reasons noted above, EPA also notes that adopting such a form in this review without changing the level would result in a standard that would not provide the same protection as the current standard, and the level of the standard would have to be adjusted downward to achieve the desired protection. Given the overall decision to provide the same protection as the current standards, the Administrator concludes it is best to retain both the form and the level of the current primary 24-hour PM_{10} standard.

In conclusion, it is EPA's view, as expressed in the Staff Paper and proposal and supported by CASAC and by the available health effects evidence, that the level of protection afforded by the current 24-hour PM_{10} standard of 150 μg/m³, one-expected-exceedance form, continues to be appropriate for the types of thoracic coarse particles typically found in urban or industrial areas. As explained above, mortality effects observed in epidemiologic studies for coarse particles are generally associated with exposure levels that exceed the current standards, and morbidity effects are generally associated with exposure levels that exceeded the current standards on only a few occasions. This suggests the level of protection afforded by the current PM_{10} standards is not greater than warranted. Furthermore, the very high degree of uncertainty in the relevant population exposures implied by the morbidity studies suggests there is little basis for concluding at this time that a greater degree of protection is warranted.

Moreover, as explained above in section III.C.3.b, the PM_{10} indicator provides appropriate variation in allowable coarse particle concentrations in different areas based on the relative proportions of $PM_{2.5}$ and $PM_{10-2.5}$ in the ambient mix. In urban areas where $PM_{2.5}$ concentrations tend to be higher, the current 24-hour PM_{10} standard level of 150 μg/m³ will result in lower allowable levels of $PM_{10-2.5}$. In non-urban areas, the higher allowable levels of coarse particles provided by the current 24-hour PM_{10} standard will also provide appropriate protection of public health, given the body of evidence discussed above. The EPA therefore believes that the level of protection from coarse particles provided by the current 24-hour PM_{10} standard remains requisite to protect public health with an adequate margin of safety. Revising either the level or the form of this standard would alter the current level of protection and therefore would not be appropriate based on the scientific evidence available at this time.

Therefore, after considering the available scientific evidence, the rationale and recommendations contained in the Staff Paper, the advice and recommendations of CASAC, and the public comments received regarding the appropriate level and form for a 24-hour standard intended to afford requisite protection of public health from effects associated with exposure to coarse particles, the Administrator has determined to retain the current level of 150 μg/m³ for the 24-hour PM_{10} standard, and the current one-expected-exceedance form. In the Administrator's judgment, based on the currently available evidence, a standard set at this level remains 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 in urban or industrial areas, as well as to protect against the potential for risks from exposure to thoracic coarse particles in other areas. 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.

E. Final Decisions on Primary PM_{10} Standards

For the reasons discussed above in this section, 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 received on the proposal, the Administrator is retaining the current primary 24-hour PM_{10} standard at the level of 150 μg/m³, which is met when this level is not exceeded more than once per year on average over a three-year period measured at each monitor within an area. The Administrator also is revoking and not replacing the annual PM_{10} standard.

As discussed in more detail in section VI, EPA is promulgating a new reference method (FRM) for measurement of mass concentrations of $PM_{10-2.5}$ in the atmosphere. Although NAAQS for $PM_{10-2.5}$ have not been established by EPA, this new FRM will nevertheless be defined as the standard of reference for measurements of $PM_{10-2.5}$ concentrations in ambient air. This should provide a basis for approving Federal Equivalent Methods (FEMs) and promote the gathering of scientific data to support future reviews of the PM NAAQS. One of the reasons for not finalizing a $PM_{10-2.5}$ standard was the limited body of evidence on health effects associated with thoracic coarse particles from studies that use $PM_{10-2.5}$ measurements of ambient thoracic coarse particle concentrations. If an FRM is available, researchers will likely include $PM_{10-2.5}$ measurements of thoracic coarse particles in health studies either by directly using the FRM or by utilizing approved equivalent methods based on the FRM.

In addition, EPA published elsewhere in today's **Federal Register** a requirement for a new multi-pollutant monitoring network that takes an integrated approach to air quality measurements. One of the required measurements at these multi-pollutant monitoring stations is $PM_{10-2.5}$. The availability of an FRM, and subsequently approved equivalent methods for $PM_{10-2.5}$, will support State and local agencies' efforts to deploy robust methods at these monitoring stations for the measurement of thoracic coarse particles that do not include fine particles. These multi-pollutant monitoring stations will provide a readily available dataset at approximately 75 urban and rural locations for atmospheric and health researchers to compare particle and gaseous air pollutants.

Finally, the $PM_{10-2.5}$ FRM, by definition, provides a reference measurement. Because it is a filter based system, this method can itself be used to provide speciated data and EPA will be issuing guidance to ensure the use of a consistent national approach for speciated coarse particle monitors as soon as possible. The reference measurement from this instrument is also important in the development of alternative $PM_{10-2.5}$ speciation samplers. We will be developing dichotomous samplers to meet the requirements of SAFETEA–LU. Appropriate guidance to ensure that the use of a consistent national approach for speciated coarse particle monitors will be issued with this method. As discussed in more detail in the final monitoring rule published elsewhere in today's **Federal Register**, EPA is requiring the deployment of $PM_{10-2.5}$ speciation samplers at all 75 multi-pollutant monitoring stations. Such speciation monitoring will help States in developing SIPs and will address a key research need for thoracic coarse particles by providing a better understanding of the chemistry of the collected samples.

IV. Rationale for Final Decisions on Secondary PM Standards

This section presents the Administrator's final decisions regarding the review of the current secondary NAAQS for PM. 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. The existing suite of secondary standards is intended to address visibility impairment associated with fine particles,[82] and materials damage and soiling related to both fine and coarse particles. The following discussion of the rationale for the final decisions on revising the secondary PM standards focuses on those considerations most influential in the Administrator's decisions, first addressing visibility impairment as it relates to the $PM_{2.5}$ secondary standards and then addressing the other welfare effects as they relate to both the $PM_{2.5}$ and PM_{10} secondary standards. The other welfare effects considered in this review include effects on vegetation and ecosystems, materials damage and soiling, and climate change.[83]

Sections IV.A and IV.B of the proposal (71 FR 2675–2685) provide a detailed summary of key information contained in the Criteria Document (EPA, 2004a, Chapters 4 and 9) and in the Staff Paper (EPA, 2005, Chapters 6 and 7) on the known and potential welfare effects associated with PM, including PM-related visibility impairment and PM-related effects on vegetation and ecosystems, materials damage and soiling, and climate change, respectively. This information is only briefly outlined in subsections IV.A.1 and IV.B.1 below. Subsequent sections provide a more complete discussion of the Administrator's rationale, having considered the evidence in light of public comments and his final decisions on the primary standards for PM, for his decision to revise the current PM secondary standards by making them identical in all respects to the revised suite of primary PM standards.

A. Visibility Impairment

This section presents the rationale for the Administrator's decision to revise the current secondary $PM_{2.5}$ standards to address PM-related visibility impairment by setting secondary standards identical in all respects to the revised $PM_{2.5}$ primary standards. 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 of $PM_{2.5}$ on visual air quality.

1. Visibility Impairment Related to Ambient PM

Section IV.A.1 of the proposal (71 FR 2675–2678) outlined key information contained in the Criteria Document and Staff Paper relevant to considering visibility impairment that is related to ambient PM. The information highlighted there summarizes:

(1) The nature of visibility impairment, including trends in visual air quality and the characterization of current visibility conditions, with a particular focus on visibility impairment in urban areas.

(2) Direct, quantitative relationships that exist between ambient PM constituents and light extinction, and thus visibility impairment, based in part on analyses of the extensive new data now available on $PM_{2.5}$ concentrations, primarily in urban areas, 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.

(3) The impacts of urban visibility impairment on public welfare, based in part on valuation studies of benefits associated with improvements in visibility and in part on recognition of a number of programs, standards, and planning efforts to address visibility impairment, in the U.S. and abroad, that illustrate the value that the public places on improved visibility.

(4) Approaches to evaluating public perceptions and attitudes about visibility impairment, including new methods and tools that 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.

The summary of the evidence on visibility impairment related to ambient fine particles in the proposal will not be repeated here. The EPA emphasizes that the final decisions on the secondary standards take into account the more comprehensive and detailed discussions of the scientific information on visibility impairment contained in the Criteria Document and Staff Paper.

2. Need for Revision of the Current Secondary $PM_{2.5}$ Standards To Protect Visibility

In 1997, EPA decided to address the effects of PM on visibility by setting secondary standards identical to the suite of $PM_{2.5}$ primary standards, in conjunction with the future establishment of a regional haze program under sections 169A and 169B of the Act (62 FR 38679–83). In reaching this decision, EPA first concluded that PM, especially fine particles, impairs visibility in various locations across the country, including multi-state regions, urban areas, and remote Class I Federal areas (e.g., national parks and wilderness areas). The EPA also concluded that addressing visibility impairment solely through setting more stringent national secondary standards would not be an appropriate means to protect the public welfare from adverse impacts of PM on visibility in all parts of the country. As a consequence, EPA determined that an approach that combined national secondary standards with a regional haze program was the most appropriate and effective way to address visibility impairment (EPA 2005, p. 7–2).

As anticipated in the last review, EPA promulgated a regional haze program in 1999 (65 FR 35713). That program requires States to establish goals for improving visibility in Class I areas and

[82] The Administrator recognized in establishing the levels of the secondary standards for $PM_{2.5}$ that these standards would work "in conjunction with implementation of a regional haze program" under Section 169A to provide appropriate national protection against visibility impairment in both urban and non-urban areas (62 FR 38683).

[83] 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.

to adopt control strategies to achieve these goals. Since strategies to meet these goals are to reflect a coordinated approach among States, multi-state regional planning organizations have been formed and are now developing strategies, to be adopted over the next few years, that will make reasonable progress in meeting these goals.

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 from the last review of the role of PM, and especially fine particles, in visibility impairment. However, extensive new information from visibility and fine particle monitoring networks since the last review has allowed for updated characterizations of visibility trends and current levels in urban areas, as well as Class I areas. As discussed in section IV.A.1.b. of the proposal (71 FR 2676–2677), these new data were a critical component of analyses that better characterized visibility impairment in urban areas and the relationship between visibility and $PM_{2.5}$ concentrations, and led to the 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 focused on visibility impairment primarily in urban areas. In so doing, given the stronger link between visibility impairment and short-term $PM_{2.5}$ concentrations, EPA gave significant consideration 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 in section IV.A.1.c. of the proposal (71 FR 2677–2678), 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 spanned 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 in section IV.A.1.d of the proposal (71 FR 2678), 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 observed 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 (6 miles), 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, 2005, 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, 2005, p. 7–8).

While being mindful of the limitations inherent in using visual representations from a small number of areas as a basis for considering national visibility-based secondary standards, the Staff Paper nonetheless concluded 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 below, the Staff Paper recommended 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, 2005, 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 distinct secondary $PM_{2.5}$ standard to protect urban visibility (Henderson, 2005a).[84] Most Panel members considered such a standard to be a reasonable complement to the Regional Haze Rules that protect Class I areas.

In the proposal, the Administrator carefully considered the rationale and recommendations in the Staff Paper, the advice and recommendations from CASAC, and initial public comments on the issue of whether the secondary PM standards should be revised to provide increased PM-related visibility impairment primarily in urban areas. In so doing, the Administrator first recognized that PM-related visibility impairment is principally related to fine particle levels, such that it is appropriate to focus the review on whether the current secondary $PM_{2.5}$ standards should be revised. The Administrator also recognized that perception of visibility impairment is most directly related to instantaneous levels of visual air quality, such that in considering whether the current suite of secondary standards would provide the appropriate degree of protection, he first considered whether the current 24-hour secondary $PM_{2.5}$ standard provides an appropriate level of protection from visibility impairment, principally in urban areas.

In the proposal, the Administrator called attention to the Staff Paper finding that, at concentrations at or near the level of the current 24-hour $PM_{2.5}$ secondary standard (65 $\mu g/m^3$) visual ranges are degraded to a distance of about 10 km (6 miles) and 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 took note of the various State and local standards and programs that have been established to 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 concluded that it was appropriate to revise the current 24-hour secondary $PM_{2.5}$ standard to provide an appropriate level of protection from visibility impairment principally in urban areas, in conjunction with the regional haze

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

program for protection of rural air quality in Class I areas.

The majority of commenters who expressed an opinion on the secondary standards, including NESCAUM, STAPPA/ALAPCO, a number of individual States, Tribal associations, and local organizations, and combined comments from various environmental groups supported the position that the secondary $PM_{2.5}$ standards should be revised to increase protection against visibility impairment. A number of these commenters cited the studies and evidence in the PM Staff Paper, as well as the recommendations of CASAC, in support of their views that a more protective standard is warranted. NESCAUM noted that, though monitors in the northeast region do not exceed the current secondary $PM_{2.5}$ standards, their regional haze camera network (CAMNET) routinely documents extremely hazy days obscuring city skylines and views. NESCAUM stated that ''this shows that virtually all of $PM_{2.5}$ effects on visibility in the Northeast are occurring below the present secondary standard, justifying EPA's proposal to revise the existing standard to a more stringent level adequately protective of public welfare'' (NESCAUM, attachment C, p. C–1) In general, EPA agrees with these commenters that the more recent information on visibility values, photographic evidence, and air quality/visibility relationships supports the need to revise the current secondary $PM_{2.5}$ standards.

Other commenters, including UARG, American Public Power Association, and American Electric Power, opposed a revision to strengthen the secondary $PM_{2.5}$ standards at this time. UARG stated that:

> Because the record does not establish that the risks to public welfare from ambient $PM_{2.5}$ are greater, different in character, or more certain than was understood when the present standards were established, the Agency lacks a basis for revising its conclusion that those standards provide the requisite protection of public welfare. (UARG, p. 36).

UARG questioned the usefulness of the photographic images and urban studies of acceptable visibility highlighted in the proposal for determining appropriate levels of urban visibility. They further noted that, for most areas, the annual $PM_{2.5}$ standard would prevent any exceedances of 65 $\mu g/m^3$.

While, as summarized above, the key optical aspects of the relationship between fine particles and visibility have been established for a long time, EPA strongly disagrees that the more recent visibility-related evidence and analyses presented in the Criteria Document and Staff Paper provide no basis for considering more protective $PM_{2.5}$ standards. As discussed in the Staff Paper, one of the key issues in the last review was whether the differences in humidity between East and West complicated the establishment of a nationally uniform $PM_{2.5}$ secondary standard, even for urban areas (EPA, 2005, p. 7–3). With the substantial addition to the air quality and visibility data made possible by the national urban $PM_{2.5}$ monitoring networks, an analysis conducted for this review found that, in urban areas, visibility levels show far less difference between eastern and western regions on a 24-hour or shorter time basis than implied by the largely non-urban data available in the 1997 review (EPA, 2005, p. 7–5). Of equal importance, more recent studies of visibility values conducted for several urbanized areas have found results generally consistent with an earlier study done for the city of Denver. While such studies are still limited in number and subject to uncertainty, they suggest a remarkable consistency in public reaction to urban visibility impairment caused by fine particles (EPA 2005, p. 6–18 to 23).

Furthermore, staff and CASAC agreed on the utility of photographic evidence in characterizing the nature of particle-induced haze. At the level of the current 24-hour $PM_{2.5}$ standard, the potential subtleties associated with alternative photographic views alluded to by UARG would be obscured by the density of the accompanying haze, which would restrict the distance of the farthest discernable dark objects to only 6 miles and greatly reduce the contrast for objects at significantly shorter distances. Although, as suggested by these commenters, the annual standard serves to limit excursions above the level of the current 24-hour standard, particularly in eastern urban areas, continuation of the current 24-hr $PM_{2.5}$ standard would permit a large number of exceedances of this level especially in some western urban areas, even when the standard is just attained. In summary, contrary to the views of this set of commenters, EPA believes that the combination of new insights from air quality analyses, the standards and studies developed to address urban visibility in several areas, as well as an evaluation of the photographic evidence, supports the need to revise the current secondary $PM_{2.5}$ standards.

Having considered the evidence and analysis of visibility and fine particles in the Criteria Document and Staff Paper, the advice and recommendations of the CASAC, as well as the public comments on this issue, the Administrator concludes that it is appropriate to revise the current secondary $PM_{2.5}$ standards to provide increased protection from visibility impairment in urban areas. Consistent with the considerations and rationale summarized above and in the proposal, the Administrator believes that emphasis should be placed on revisions to the current 24-hour $PM_{2.5}$ standard that would provide an appropriate level of protection against visibility impairment principally in urban areas, in conjunction with the regional haze program for protection of visual air quality in Class I 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, 2005, section 6.2.3), the Staff Paper concluded 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 8 hours). Thus, the Staff Paper concluded 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 Panel members endorsed a $PM_{2.5}$ indicator for a secondary standard to address visibility impairment (Henderson, 2005a, p. 9).

The Administrator provisionally concurred with the EPA staff and CASAC recommendations, and proposed that $PM_{2.5}$ should be retained as the indicator for fine particles as part of a secondary standard to address visibility protection. No commenters disputed the appropriateness of continuing to use $PM_{2.5}$ as the indicator for fine particle secondary standards to address visibility impairment.

Having considered the scientific information discussed in the proposal and summarized above, as well as the recommendations of the staff and CASAC and the public comments on this issue, the Administrator concludes that $PM_{2.5}$ should be retained as the indicator for fine particles as part of a secondary standard to address visibility protection.

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 were considered for a revised standard to address visibility impairment. Within this range, clear and similarly strong correlations were found between visibility and 24-hour average $PM_{2.5}$ concentrations in eastern and western areas, while somewhat stronger correlations were found with $PM_{2.5}$ concentrations averaged over a 4-hour time period. In general, correlations between $PM_{2.5}$ concentrations and light extinction were found to be 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., were considered. The Staff Paper concluded 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 recognized 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 Staff Paper analysis discussed above were 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.

Most CASAC 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 for visibility effects by targeting the driest part of the day (Henderson, 2005a, p. 9). 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 concluded 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 agreed that broader deployment of continuous $PM_{2.5}$ mass monitors is a desirable goal, working toward that goal does not depend upon nor provide an appropriate basis for setting a sub-daily standard. The Administrator believed that it was appropriate to evaluate averaging time in conjunction with reaching decisions on the form and level of a standard. Public comments on these issues, as well as the rationale for the final decisions on averaging time, form, and level of the secondary standards, are presented in the following section.

5. Final Decisions on Secondary $PM_{2.5}$ Standards for Visibility Protection

In considering $PM_{2.5}$ standards that would provide an appropriate level of protection against PM-related impairment of visibility primarily in urban areas, the Administrator took into account the results of the 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. summarized in section IV.A.1 of the proposal. 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 took into account the same general factors that were considered in selecting an appropriate form for the 24-hour primary $PM_{2.5}$ standard (as discussed above in section II.E.1), 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, p. 10).

In considering the remaining elements of a secondary $PM_{2.5}$ standard (averaging time, form, and level) for purposes of the proposal, the Administrator 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 concluded 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, 2005, Figure 7–1).[85] 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 concluded that a concentration-based percentile form is appropriate for the same reasons as those discussed in section II.F.1 above (on the form of the 24-hour primary $PM_{2.5}$ standard). The Staff Paper also concluded that the upper end of the range of concentration percentiles should be consistent with the percentile used for the primary standard, which was 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 of the 20 percent most impaired days, as targeted in the regional haze program (EPA, 2005, p. 7–11 to 12).

In its advice to the Administrator, the CASAC Panel recognized that it is difficult to select any specific level and

[85] 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, 2005, p. 7–8).

form based on currently available information (Henderson, 2005a, p. 9). 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 recommended considering a percentile within this range in conjunction with a level toward the upper end of the range recommended in the Staff Paper.[86]

Based on the above considerations, for purposes of the proposal the Administrator believed that it was appropriate to first consider the level of protection that would be afforded by the proposed suite of primary $PM_{2.5}$ standards (71 FR 2681). The limited and uncertain evidence currently available for use in evaluating the appropriate level of protection suggested that a cautious approach was warranted in establishing a distinct secondary $PM_{2.5}$ standard to address visibility impairment. 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 selecting the appropriate degree of protection to be afforded by such a standard. Given this, the Administrator first evaluated the level of protection that the proposed primary $PM_{2.5}$ standards would likely provide, and then determined whether the available evidence warranted 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 looked to an analysis of the predicted percent of areas not likely to meet various alternative secondary and primary $PM_{2.5}$ standards (EPA, 2005, Tables 7A–1 and 5B–1(a)[87]). In so doing, the Administrator observed 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 μg/m³, with a 98th percentile form, and an annual standard of 15 μg/m³) was actually somewhat greater (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 daylight hours, a level toward the upper end of the range recommended in the Staff Paper (e.g., up to 30 μg/m³), and a form within the recommended range (e.g., around the 95th percentile) (24 percent). A similar comparison was seen in considering the predicted percentages of the population living in such areas.

Considering the evidence in light of these comparisons, the Administrator provisionally concluded that revising the current secondary 24-hour standard for $PM_{2.5}$ to be identical to the proposed revised primary $PM_{2.5}$ standard and retaining the current annual secondary $PM_{2.5}$ standard was a reasonable policy approach to addressing visibility protection primarily in urban areas. Consistent with CASAC's recommendation, the Administrator also solicited comment on a sub-daily (4- to 8-hour averaging time) secondary $PM_{2.5}$ standard.

In additional comments responding to EPA's proposed revision of the secondary $PM_{2.5}$ standards for visibility protection (71 FR 2675–2781), the CASAC requested that a sub-daily standard to protect visibility be favorably reconsidered (Henderson, 2006, p. 2). As noted above, most of the CASAC Panel recommended a sub-daily standard for $PM_{2.5}$ with a level in the 20 to 30 μg/m³ range for a four- to eight-hour (4–8 hr) mid-day time period with a 92nd to 98th percentile form. The CASAC members noted three cautions regarding the Agency's proposed reliance on a secondary $PM_{2.5}$ standard identical to the proposed 24-hour primary $PM_{2.5}$ standard (*Id.* at pp. 5–6):

(1) They noted that the $PM_{2.5}$ mass measurement is a better indicator of visibility impairment during daylight hours, when humidities are low; the sub-daily standard more clearly matches the nature of visibility impairment, whose adverse effects are most evident during the daylight hours; using a 24-hour standard as a proxy introduces error and uncertainty in protecting visibility; and sub-daily standards are used for other NAAQS and should be the focus for visibility.

(2) They noted that CASAC and its monitoring subcommittees have repeatedly commended EPA's initiatives promoting the introduction of continuous and near-continuous PM monitoring, and that expanded deployment of continuous $PM_{2.5}$ monitors is consistent with setting a sub-daily standard to protect visibility.

(3) They cautioned that the analysis showing a similarity between percentages of counties not likely to meet what they considered to be a lenient 4- to 8-hour secondary standard and a secondary standard identical to the proposed 24-hour primary standard is a numerical coincidence that is not indicative of any fundamental relationship between visibility and health.

The CASAC Panel further stated that ''visual air quality is substantially impaired at $PM_{2.5}$ concentrations of 35 μg/m³'' and that ''it is not reasonable to have the visibility standard tied to the health standard, which may change in ways that make it even less appropriate for visibility concerns.'' (*Id.* at p. 6.)

Many of the public commenters who supported a more stringent visibility standard also supported the more specific EPA staff and CASAC recommendations and urged EPA to adopt a sub-daily (4- to 8-hour averaging time) $PM_{2.5}$ standard to address visibility impairment, within the range of 20 to 30 μg/m³ and with a form within the range of the 92nd to 98th percentile. In general, these commenters based their recommendations on the same studies, analyses, and considerations presented in the Staff Paper and in section IV.A of the proposal.[88]

EPA agrees with several of the key technical points made in CASAC's original recommendations and their request for reconsideration. The Administrator recognizes that there is a significant body of data and information indicating that a sub-daily standard has

[86] Some CASAC Panel members also recommended that such a standard be implemented in conjunction with 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).

[87] 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.

[88] The American Lung Association *et al.* disagreed with the Administrator's view that the secondary standards should be focused primarily on providing protection in urban areas, with protection of Class I areas provided by the Regional Haze Rule. These commenters suggested that EPA should not rely on the regional haze program and must set national standards to protect all areas. As discussed in the Response to Comments document, EPA believes that this issue was settled in *ATA I.* (*See* 175 F.3d at 1056–1057.)

strong technical merit. The fine particle/visibility relationship is most consistent across regions for shorter averaging times during the daylight hours, when humidity tends to be lowest. The EPA also agrees that visibility impairment has the greatest impact on public welfare during the daylight hours, but notes that daylight is not limited to a four to eight hour period.

The Administrator believes, however, that it is appropriate to consider the protection the revised suite of primary $PM_{2.5}$ standards would provide against adverse effects on public welfare. The analysis summarized above found that the relative protection provided by the proposed primary standards was equivalent or more protective than several of the 4-hour secondary standard alternatives in the range recommended by the Staff Paper and CASAC. Given the limitations in the underlying studies and the subjective nature of the judgment required, the Administrator continues to believe that caution is warranted in establishing a distinct secondary standard for visibility impairment. Contrary to commenters who recommended a distinct standard providing greater protection, in this case, the Administrator does not believe that these studies warrant adopting a secondary standard that would provide either more or less protection against visibility impairment in urban areas than would be provided by secondary standards set equal to the proposed primary $PM_{2.5}$ standards. While EPA agrees that the use of 24-hour and annual averages will result in more variability in visibility across urban areas, as the Staff Paper notes, any $PM_{2.5}$ secondary standard would result in some variability in protection in different locations (EPA, 2005, p. 7–8).

While, as noted above and in the proposal, the Administrator agrees with CASAC's point that broader deployment of continuous $PM_{2.5}$ mass monitors is a desirable goal, working toward that goal does not depend upon nor provide an appropriate basis for setting a sub-daily standard. Moreover, pursuant to CASAC recommendations, EPA is today issuing modifications to the $PM_{2.5}$ reference and equivalent methods that will encourage the certification and deployment of more continuous monitors (in a separate document published in today's **Federal Register**). With respect to the third CASAC comment summarized above, EPA agrees that the result of the analysis showing a similarity in the percentages of counties not likely to meet the revised 24-hour primary $PM_{2.5}$ standard or a sub-daily standard set toward the upper end of the range of protectiveness recommended by CASAC is not indicative of any fundamental relationship between visibility and public health. However, EPA does not believe that this coincidental similarity weighs against considering making the secondary standard identical to the revised primary standard.

Having considered the evidence, the advice of CASAC, and public comments, the Administrator believes that revising the current secondary $PM_{2.5}$ standards to be identical to the revised suite of primary $PM_{2.5}$ standards adopted in today's notice is a reasonable policy approach to addressing visibility impairment primarily in urban areas. The current annual and revised 24-hour secondary $PM_{2.5}$ standards will 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 the upper portion of the ranges recommended by CASAC. This approach recognizes 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 believes that a distinct secondary standard with a different averaging time, level, or form is not warranted at this time, because the available evidence does not support a decision to achieve a level of protection different from that provided by the revised suite of primary standards, and because no further change in averaging time, level, or form appears needed to achieve a comparable level of protection. A decision in this review to make secondary standards equivalent in all respects to the primary standards, as revised, does not limit the ability of the Agency to establish a distinct secondary standard in the future if and when the underlying evidence indicates that it is appropriate. Further, the Administrator notes that continuing to advance the use of continuous $PM_{2.5}$ monitors is not dependant on establishing a sub-daily secondary $PM_{2.5}$ standard.

The Administrator believes that any secondary NAAQS for visibility protection 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 the national primary standards can be expected to improve visual air quality not just in urban areas but in surrounding non-urban areas as well; similarly, programs now being developed to address the requirements of the regional haze rule established for protection of visual air quality in Class I areas can be expected to improve visual air quality in surrounding areas as well. 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 highly valued by people living in those areas.

Based on all of the considerations discussed above, the Administrator concludes that it is appropriate to revise the current secondary $PM_{2.5}$ standards to be identical in all respects to the revised suite of primary $PM_{2.5}$ standards adopted in today's notice to provide an appropriate level of visibility protection primarily in urban areas.

B. Other PM-Related Welfare Effects

In considering the currently available evidence on non-visibility PM-related welfare effects, the Staff Paper noted that there was much information linking ambient PM to potentially adverse effects on vegetation and ecosystems and on materials damage and soiling, 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 concluded in the proposal that the available evidence did not provide a sufficient basis for establishing distinct secondary standards for PM based on any of these effects alone.

In the proposal, the Administrator also addressed the question whether reductions in PM likely to result from the current secondary PM standards, or from the range of revised primary PM standards, would provide appropriate protection against any of these PM-related welfare effects. As discussed below, these considerations included the latest scientific information characterizing the nature of these non-visibility PM-related effects and judgments as to whether revision of the current secondary standards is appropriate based on that information.

1. Evidence of Non-Visibility Welfare Effects Related to PM

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 concluded that regardless of size fraction, particles containing nitrates and sulfates have the greatest potential for widespread environmental significance. The nature of these welfare effects is discussed in the Criteria Document (Chapters 4 and 9) and Staff Paper (Chapter 6) and summarized in section IV.B.1 of the proposal. The information highlighted there includes:

(1) PM-related effects on vegetation, specifically those associated with excess levels of particulate nitrate and sulfate in acidifying deposition to foliage, leading to 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).

(2) PM-related effects on ecosystems, specifically those resulting from the nutrient or acidifying characteristics of deposited PM on both terrestrial and aquatic ecosystems, which contribute to adverse impacts on essential ecological attributes such as species shifts, loss of diversity, impacts to threatened and endangered species and alteration of native fire cycles.

(3) Characterization of ecosystem exposure to PM deposition, specifically the currently available deposition monitoring network and the lack of sufficient long-term monitoring of ecosystem response needed for PM-related ecological risk assessment.

(4) The critical loads concept and its applicability as an assessment tool in the context of the PM secondary NAAQS review.

(5) PM-related effects on materials, specifically the physical damage caused mainly by deposited particulate nitrates and sulfates and the impaired aesthetic qualities due to soiling caused mainly by particles consisting primarily of carbonaceous compounds.

(6) PM-related effects on climate, specifically through scattering and absorption of radiation by ambient particles, as well as effects on the radiative properties of clouds through changes in the number and size distribution of cloud droplets, and by altering the amount of ultraviolet solar radiation (especially UV–B) penetrating through the atmosphere to ground level.

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

At the time of proposal, in considering the currently available evidence on each type of PM-related welfare effects discussed above, the Administrator noted that there was much information linking the sulfur- and nitrogen-containing components of ambient PM to potentially adverse effects on ecosystems and vegetation, as well as links between PM and its constituents and materials damage and soiling, as well as climatic and radiative processes. However, after reviewing the extent of relevant studies and other information available 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 concurred with conclusions reached in the Staff Paper and by CASAC (Henderson, 2005a) that the available data do not provide a sufficient basis for establishing 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 concluded that sufficient information was 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 agreed that it was 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 agreed with the Staff Paper that the available information did not provide a sufficient basis for the development of distinct 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 was intended to provide an equivalent degree of protection to the current PM_{10} standards in areas where the proposed $PM_{10-2.5}$ indicator would apply (which tend to be more densely populated areas where materials damage would be of greater concern), the Administrator believed 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 believed 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 proposed 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.

In response to the proposal, in addition to their recommendation for a $PM_{2.5}$ secondary standard, CASAC recommended (Henderson, 2006, p. 4) ''that a secondary $PM_{10-2.5}$ standard be set at the same level as the primary PM coarse standard to protect against the various irritant, soiling and nuisance welfare or environmental effects of coarse particles. Since these effects are not uniquely related to urban sources or receptors, the standard should not be limited to urban areas.'' Only limited public comments were received on this aspect of the proposal.

In general, public comments relating to secondary standards and other welfare effects focused on issues related to the current secondary PM_{10} standards. Most of these commenters, including the groups who objected to the use of a qualified indicator for the primary thoracic coarse particle standard, argued that current levels of PM dust contribute or potentially contribute to nuisance, soiling, and irritant impacts on personal comfort and well being, especially in non-urban areas. The same commenters agreed with CASAC that, in the absence of a demonstration to the contrary, EPA is not justified in eliminating or reducing the level of protection to rural areas that is provided by the current suite of secondary standards. Most of these commenters recommended that EPA either retain the current PM_{10} secondary standard or replace it with a $PM_{10-2.5}$

standard set identical to the proposed primary standard without the proposed qualifications that limited application of the standard to urban areas.

A few commenters argued against retaining any secondary standard for coarse particles. Many of these same commenters argued that if EPA did set a secondary $PM_{10-2.5}$ standard, it should be set equal to the primary $PM_{10-2.5}$ standard because there was insufficient evidence to support adoption of a distinct secondary standard for $PM_{10-2.5}$ at this time. Furthermore, these commenters noted that in the proposal, EPA had correctly excluded from both primary and secondary standards ''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'' because these particles are nontoxic and generally settle quickly.

In reaching a final decision on the need to revise the PM secondary standards regarding these non-visibility related welfare effects, the Administrator has taken into account several key factors, including: (1) The latest scientific information on non-visibility welfare effects associated with PM, as previously described; (2) the post-proposal recommendations of CASAC, (3) comments received during the public comment period, and (4) the final decisions reached in today's notice on the primary standards for fine and coarse particles, as well as the decision presented above on secondary $PM_{2.5}$ standards to protect against visibility impairment. The Administrator notes that extending today's decision not to revise the current 24-hour primary PM_{10} standard to the secondary standard would be consistent with the recommendations of CASAC and would address the issues raised by the first group of commenters summarized above. Consistent with the assessment of the evidence in the Staff Paper and the CASAC recommendations, the Administrator disagrees with those who assert that no secondary standard is needed to protect against the welfare effects associated with coarse particles.

On the other hand, the Administrator does not believe that distinct secondary standards for fine or coarse particles are warranted for any of the effects considered in this section. The available evidence is not sufficient to support the selection of an ecologically based indicator or an indicator based distinctly on materials damage, soiling, irritant or nuisance effects, or other effects of PM. However, the Administrator recognizes that it is appropriate to continue control of ambient fine and coarse particles, especially long-term deposition of particles such as particulate nitrates and sulfates that contribute to the total input of nitrogen and sulfur to ecosystems that has been shown to adversely affect sensitive aquatic and terrestrial ecosystems, and/or particles that contribute to materials damage and soiling. The Administrator notes that setting the secondary PM standards identical to the revised suite of primary standards directionally improves the level of protection afforded vegetation, ecosystems, and materials. In addition, the Administrator continues to believe that the secondary NAAQS 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 the above considerations, the Administrator concludes that it is appropriate to address the other welfare effects summarized in this section by revising the current suite of $PM_{2.5}$ secondary standards, making them identical in all respects to the suite of primary $PM_{2.5}$ standards, while retaining the current 24-hour PM_{10} secondary standard and revoking the current annual PM_{10} secondary standard. For the reasons noted in section III.D.1 above, the 24-hour PM_{10} standard will provide adequate protection against the known and potential effects related to long-term PM_{10} concentrations.

C. Final 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 received on the proposal, the Administrator is revising the current secondary PM standards by making them identical in all respects to the suite of primary PM standards, as revised by today's action. In the Administrator's judgment, these standards, in conjunction with the regional haze program, will provide appropriate protection to address PM-related welfare effects, including visibility impairment, effects on vegetation and ecosystems, materials damage and soiling, and effects on climate change.

V. Interpretation of the NAAQS for PM

This section presents EPA's final decisions regarding the revision, addition, and/or revocation of appendices to 40 CFR Part 50 on interpreting the primary and secondary NAAQS for PM.

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

The EPA proposed to revise the data handling procedures in appendix N to 40 CFR Part 50 for the annual and 24-hour $PM_{2.5}$ standards (71 FR 2685–2686). The proposed amendments to appendix N detailed the computations necessary for determining when the proposed primary and secondary $PM_{2.5}$ NAAQS were met. The proposed amendments also addressed data reporting, monitoring considerations, and rounding conventions. Key elements of the proposed revisions to appendix N were presented in section V of the preamble to the proposed rule and are summarized below, together with EPA's final decisions on revisions to appendix N.

1. General

As proposed, EPA is adding several new definitions to section 1.0 and using these definitions throughout the appendix, most notably ones for ''design values.'' Also, the 24-hour sampling timeframe has been clarified as representing ''local *standard* (word inserted) time.'' This revision reflects EPA's previous intent as well as majority practice, and also avoids ambiguity since local *clock* time varies according to daylight savings periods. No opposing comments were received on these changes.

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

As proposed, two new sections are being added to appendix N to more specifically stipulate and highlight monitoring and data considerations (71 FR 2685). New section 2.0 includes statistical requirements for spatial averaging (which is part of the form of the annual standard for $PM_{2.5}$). As discussed in section II.F.2 above, EPA is tightening two of the constraints on the use of spatial averaging to provide an adequate margin of safety to susceptible subpopulations by reflecting enhanced knowledge of typical monitor relationships in metropolitan areas.

New section 3.0 to appendix N codifies 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 also notes 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 will enhance the opportunity for sites to meet data completeness requirements. This language likewise codifies existing practice, since the technique was previously documented in guidance documentation and implemented as EPA standard operating procedure. Commenters agreed that this was a valid approach and should be implemented.

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

As proposed, EPA is maintaining a spatially-averaged annual mean, with revisions to the criteria for when spatial averaging can be used (see section 1 above, as well as section II.E.2), as the form of the annual $PM_{2.5}$ standard and is retaining a 98th percentile concentration as the form of the 24-hour $PM_{2.5}$ standard. Although no actual computational change was proposed for a spatially-averaged annual mean, the proposed Appendix N differentiated, in language and formulae, between a spatial average of more than one site and a spatial average of only one site. We are adopting these changes throughout Appendix N as appropriate to alleviate confusion caused by the current ''catch-all'' generic reference (*i.e.*, ''spatial average'' or ''spatially averaged'') found throughout the existing Appendix N.

As proposed, appendix N identifies the NAAQS metrics and explains 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). A significant comment related to the 98th percentile formula and an associated bias for periodic sampling is discussed above in section II.E.1.

With regard to the annual $PM_{2.5}$ standard, EPA proposed to retain current data capture requirements with two exceptions. The current appendix N had reduced data capture requirements for years that exceeded 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) was considered sufficient in those instances where the annual mean exceeded the NAAQS level. See existing Part 50 App. N 2.1 (b). The EPA proposed 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 intent of this change was to prevent a site with a violating design value that is made up of one (or more) annual means under the level of the NAAQS from not being used for regulatory purposes just because one (or more) of the quarters of the year(s) under the NAAQS level has less than 75% data capture. One commenter voiced a general concern over the lack of uniformity in completeness criteria but the other commenters supported the change. Taking these comments into consideration, EPA is revising appendix N as proposed with regard to this issue.

A second proposed change in the data completeness requirements would incorporate data substitution logic for situations where the proposed 11 samples per quarter minimum is not met. Consistent with existing guidance and practice (implementing current App. N 2.1 (c)), EPA proposed to incorporate the following requirement into appendix N: a quarter with less than 11 samples would be complete and valid if, by substituting an 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 level of the standard. The EPA proposed to implement this procedure for making comparisons to the NAAQS and not to permanently alter the reported data. The EPA considered this a very conservative means of imputing data (and increasing the opportunities for using monitoring data that otherwise are valid), but solicited comment on the proposed approach. Several comments were received on this approach and the majority favored it. However, two commenters (NESCAUM and a constituent State) suggested a limit of one quarter (out of the 12 in a 3-year period) where the substitutions could be made. They suggested the limitation because they were concerned that the absence of a significant amount of data is an indication that site operator and/or equipment problems exist. The EPA shares this concern but observes that the method protocol itself guards against excessive utilization. The more missing values that are potentially substituted with the method effectively reduce the chance of a valid result (*i.e.*, a usable design value). Taking these comments into consideration, EPA is revising appendix N as proposed with regard to this issue.

With regard to the 24-hour $PM_{2.5}$ standard, EPA proposed to revise appendix N to include a special formula (Equation 6 in the proposed rule, 71 FR 2702) 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 (EPA, 1999) but was utilized, where appropriate, in official OAQPS design value calculations. No adverse comments were received on this addition.

The proposed revisions to appendix N also incorporated language explicitly stating that 98th percentiles (for both regular and seasonal sampling schedules) were to be based on the *applicable* number of samples rather than the *actual* number of samples. The EPA proposed that both annual 98th percentile equations (proposed Equations 5 and 6) would reflect this approach. The EPA acknowledges that it made an error in the placement of the ''applicable number of samples'' references into the denominator of the special seasonal 98th percentile formula (Equation 6) and has restored the equation to its original form. The EPA notes that the special season formula already takes into consideration oversampling in low periods. Furthermore, because the ''applicable number of samples'' was removed from the seasonal formula, there was no need to stipulate that ''seasons'' could not divide months; that proposed requirement was only necessary to accommodate the calculation of ''applicable number.''

The EPA solicited comment on the ''applicable number of samples'' concept and calculation and received several comments on the concept. One commenter endorsed it without discussion, one commenter did not object to it but noted that it was difficult to program, and another commenter thought that the concept unnecessarily complicates matters and favored the use of ''scheduled number of samples'' instead. Two commenters said that it would be an acceptable approach if it still permitted ''extra'' sampling at the end of a month to make up for missed samples. The EPA notes that it has never endorsed this ''extra'' sampling practice for the 24-hour $PM_{2.5}$ standard, so that the commenter's premise is incorrect. The EPA agrees with comments that expressed concerns about this calculation being too complicated and, therefore, has simplified the procedure in a manner that corresponds to the calculation of data capture. The applicable number of samples for a given year is now defined as simply the sum of the number of completed scheduled (''creditable'') samples for the year. The new appendix N defines the new term, ''creditable'' and describes its use in calculating data capture rates and ''applicable number.'' For sites that sample correctly (*i.e.* don't oversample at the end of the month), the simpler ''applicable number'' procedure will produce the same result as the proposed calculation.

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

4. Conforming Revisions

As proposed, EPA is revising terminology and data handling procedures associated with exceptional events to conform to rules which EPA proposed 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) (Pub. L. 109–59). The EPA proposed rules to address exceptional events on March 10, 2006 (71 FR 12592). The EPA is replacing 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 revision makes only a semantic change to existing appendix N, EPA believes the change is consistent with section 6013(b)(4) of SAFETEA–LU, which provided that EPA 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.)[89]

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

The EPA proposed 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. Since the current 24-hour PM_{10} standard is being retained and a $PM_{10-2.5}$ standard is not being implemented, the proposed new appendix P (on interpreting the proposed 24-hour $PM_{10-2.5}$ standard) is not being added.

[89] EPA will answer all comments raising substantive issues relating to the natural events policy when it finalizes the pending exceptional events proposal.

C. Amendments to Appendix K—Interpretation of the National Ambient Air Quality Standards for PM_{10}

Because the Administrator has decided to retain the current 24-hour PM_{10} standard but to revoke and not replace the annual PM_{10} standard, some changes are required to appendix K to 40 CFR Part 50 on interpreting the primary and secondary NAAQS for PM_{10}. The modifications principally entailed simply removing the obsolete annual standard related sections. However some typographical corrections were also made to some of the remaining sections related to the 24-hour standard; a spelling error was corrected and certain equal signs (=) were changed to plus signs (+) in the illustrative examples found in section 3 of the appendix in order to correct obvious mistakes in arithmetic. For readers' convenience, EPA is reprinting the entire Appendix K in the rule section of this notice, but is not reopening or reconsidering any parts of the Appendix except those discussed above.

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

A. Appendix O to Part 50—Reference Method for Determination of Coarse Particulate Matter as $PM_{10-2.5}$ in the Atmosphere

The EPA proposed a new reference method (FRM) for measuring mass concentrations of coarse particles ($PM_{10-2.5}$) in ambient air as a new Appendix O to 40 CFR part 50.71 FR 2703. Although this method can fulfill a variety of PM monitoring objectives, its primary purpose is to serve as the standard of comparison for determining the adequacy of alternative ''equivalent'' methods for use in lieu of the FRM. *Id.* at 2687–88. In conjunction with additional analysis, this method may be used to develop speciated data. The EPA expects to designate such alternative methods as equivalent methods (FEMs) under revised provisions of 40 CFR part 53, published elsewhere in today's **Federal Register**. The EPA is finalizing the FRM for $PM_{10-2.5}$, even though a NAAQS for $PM_{10-2.5}$ is not being adopted. An official FRM will be an important element in facilitating consistent research on $PM_{10-2.5}$ air quality and health effects and in promoting the commercial development of FEMs. In a separate final rule amending 40 CFR part 58 elsewhere in today's **Federal Register**, the EPA is promulgating a requirement that States deploy about 60 FRM or FEM $PM_{10-2.5}$ monitors as part of a new National Core (NCore) multi-pollutant monitoring stations. The EPA also plans to negotiate with some States for additional NCore stations which would include $PM_{10-2.5}$ monitors.

The $PM_{10-2.5}$ reference method is a difference method based on separate, concurrent measurements of PM_{10} and $PM_{2.5}$, with the $PM_{10-2.5}$ measurement being the result of subtraction of the $PM_{2.5}$ measurement from the corresponding PM_{10} measurement. The 24-hour integrated measurements are based on conventional, low-volume filter samples of particulate matter analyzed gravimetrically after a period of moisture and temperature equilibration. Although the component PM_{10} and $PM_{2.5}$ filter samples can be subsequently analyzed chemically, no actual, physically separated $PM_{10-2.5}$ sample is produced by the method for chemical species analysis. The EPA anticipates that one or more alternative methods that do provide $PM_{10-2.5}$ samples that are completely or nearly completely separated physically for species analysis (such as the dichotomous sampler method) will become available as an FEM.

The substantial advantages of the method and the rationale for its selection as the FRM for $PM_{10-2.5}$ are discussed in the proposal (71 FR 2687). In that discussion, EPA acknowledges that the method does not provide a direct measurement of $PM_{10-2.5}$, has some significant shortcomings, and likely will not ideally meet all needs for monitoring $PM_{10-2.5}$ in the ambient air. The EPA indicated that although the method is readily usable in routine monitoring networks, it is clearly less than optimally suited for such use. Instead, EPA expects that alternative FEMs that typically offer some substantial advantage or advantages over the FRM will become the principle methods deployed for routine monitoring. Further, EPA anticipates that self-contained, automated FEMs will become available to provide near real-time, hourly monitoring data availability and ease the monitoring burdens of monitoring agencies. Although the FRM will likely be used initially in monitoring applications because of its conventional nature and similarity to the widely used $PM_{2.5}$ FRM, ultimately its principle purpose will be as the standard of reference for determining the adequacy of alternative, candidate FEMs and for assessing the quality of $PM_{10-2.5}$ monitoring data obtained in monitoring networks, particularly networks using alternative FEMs. The FRM may thus be used on a voluntary basis by states wishing to deploy $PM_{10-2.5}$ monitors prior to the

January 1, 2011 deadline for operation of $PM_{10-2.5}$ monitors at NCore multi-pollutant sites (a requirement of the final rule amending 40 CFR part 58, elsewhere in today's **Federal Register**), although many of the required monitors operating at NCore sites in 2011 and beyond may be FEMs.

After considering alternative methodologies and weighing the various pros and cons of other methods, as also discussed in the proposal preamble, the EPA concluded that the proposed method is the best method currently available to serve these purposes, while also being readily usable for many initial monitoring applications. The Ambient Air Monitoring and Methods Subcommittee of the Clean Air Scientific Advisory Committee (CASAC) concurs with this assessment and approach, recommending that EPA adopt the difference method as the FRM, but that it ultimately be used primarily as a benchmark for evaluating the performance of continuous as well as other direct-measuring filter-based integrated methods (Henderson, 2005c).

Of the relatively few comments received on the proposed FRM, most raised concern about some of the same shortcomings of the method that had already been considered by EPA in selecting the method (and by the CASAC in concurring with EPA's approach). No comments presented any issues that resulted in any changes to the method. Thus, the FRM is being promulgated today (in Appendix O), with the only change being deletion of the reference to national ambient air quality standards in section 1.1 of the method, since the EPA is not using $PM_{10-2.5}$ as the indicator in the NAAQS addressing thoracic coarse particles.

One comment raised concern about the relationship of the new $PM_{10-2.5}$ FRM to the requirements of Section 6012 of the SAFETEA–LU, under which the EPA is 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.'' As discussed in the proposal preamble at 71 FR 2690, EPA believes that this FRM does not conflict with either the specific language or intent of the SAFETEA–LU Act. The new FRM, together with the additions to part 53 (published elsewhere in this **Federal Register**) that will allow designation of FEMs for monitoring $PM_{10-2.5}$, will provide a strong incentive to stimulate the further commercial development and refinement of new or existing methods for $PM_{10-2.5}$, most of which will not rely on subtraction of fine mode particle measurements from coarse mode particle measurements. Further, EPA is actively investigating the possibility that a dichotomous-based method might ultimately provide a more direct means of measuring the coarse fraction of PM_{10}. Within the time frame prescribed by the SAFETEA–LU, it appears very likely that at least one such method will be shown to achieve an adequate level of performance and may therefore be identified and utilized as a ''reference method''. The terms of the SAFETEA–LU Act do not require that the Agency promulgate a non-difference method as either the sole FRM or as an alternative FRM as specifically defined in part 53. Until such a new, more direct method is demonstrated to be suitable and adequate and becomes commercially available, the difference-based FRM of Appendix O provides a reliable, proven measurement method which can be successfully implemented immediately. The CASAC agreed that none of the direct sampling methods is presently sufficiently reliable for use as an FRM, Henderson, 2005c, but that suitable direct measurement methods could be developed quickly enough to become approved as equivalent methods in a planned monitoring network.

The salient technical aspects of the FRM are provided in the proposal preamble (71 FR 2690). The dual samplers specified in the FRM are essentially identical to the sampler specified in the $PM_{2.5}$ FRM (40 CFR part 50, appendix L) except for removal of the $PM_{2.5}$ WINS impactor particle separator from the sampler used for PM_{10}. Operational procedures and most other aspects are also similar or identical to those for the $PM_{2.5}$ FRM. One notable condition is that the PM_{10} sampler of the $PM_{10-2.5}$ FRM must meet the higher standards of performance and manufacture of appendix L rather than the somewhat lesser requirements for conventional PM_{10} samplers in 40 CFR part 50, appendix J. Thus, conventional PM_{10} FRM samplers will not be acceptable for use as part of a $PM_{10-2.5}$ FRM sampler pair. But both the PM_{10} and $PM_{2.5}$ component measurements obtained incidental to $PM_{10-2.5}$ measurements would be valid as PM_{10} or $PM_{2.5}$ measurements under the monitoring requirements of 40 CFR part 58, provided they are sited at the appropriate spatial scale. However, since such PM_{10} samplers meet higher standards of performance than conventional PM_{10} samplers, the measurements need to be differentiated from conventional PM_{10} measurements (*e.g.* by a descriptor such as PM_{10c}). Also, conventional PM_{10} measurements are reported based on standard temperature and pressure, whereas PM_{10c} measurements are reported based on actual local conditions of temperature and pressure.

The EPA designation of specific, commercial candidate $PM_{10-2.5}$ FRM samplers will be based on an application and on consideration in accordance with new or revised provisions of 40 CFR part 53, published elsewhere in this **Federal Register**. Since $PM_{2.5}$ FRM samplers have been in use for several years and are readily available, EPA designation of $PM_{10-2.5}$ FRM sampler models based on one or more currently available $PM_{2.5}$ sampler models is expected to occur soon after promulgation. The two samplers of the $PM_{10-2.5}$ FRM sampler pair would be required to be of the same make and model and matched design and fabrication so that they are essentially identical (except that one would not have a $PM_{2.5}$ particle separator). The samplers may be of either single-filter or multiple-filter (sequential-sample) design, as long as both are of the same type, design, and configuration. For a commercial sampler that has already been designated as a $PM_{2.5}$ FRM, no further testing under part 53 would be required for designation as a $PM_{10-2.5}$ FRM, although the sampler manufacturer would have to submit a formal, brief application under part 53. Users may assemble their own $PM_{10-2.5}$ sampler pair using existing $PM_{2.5}$ samplers of matched model or design by converting one of the samplers to a PM_{10c} sampler, provided that the specific sampler pair has been previously designated by the EPA as a $PM_{10-2.5}$ FRM under part 53.

A $PM_{2.5}$ sampler pair consisting of samplers that are slightly dissimilar or have some minor design or model variations (and one sampler is configured as a PM_{10c} sampler) may be considered for designation by EPA as a Class I FEM under revised part 53. An application for an FEM determination would need to be submitted under part 53, and some supplemental or special tests may be required. Also, a pairing of slightly dissimilar samplers that has not been designated by EPA as an FRM or Class I FEM may be considered for approved use in $PM_{10-2.5}$ monitoring networks as a user-modification of an FRM under section 2.8 of appendix C to 40 CFR part 58.

B. 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 FRM for $PM_{10-2.5}$, the EPA also proposed (71 FR 2691) minor technical changes to the FRM for $PM_{2.5}$ (40 CFR Part 50, appendix L). EPA is adopting these changes as proposed. These changes are to provide improvements in the efficiency of the method in monitoring network operations without altering the method's performance.

The most significant change is the addition of an alternative $PM_{2.5}$ particle size separator, specifically, a very sharp cut cyclone (VSCC™) manufactured by BGI Incorporated, Waltham, MA. FRM samplers now may be configured with either the original WINS impactor or the alternative cyclone separator, and existing FRM samplers may be retrofitted by users with the cyclone, if desired. Sampler users wishing to retrofit their samplers should contact the sampler manufacturer to obtain the correct BGI VSCC™ model along with the associated installation, operation, and maintenance instructions specific to the sampler model, and a new designated method label to be attached to the sampler. The seven sampler models configured with the BGI VSCC™ that have been designated as FEMs will be re-designated as reference methods, and owners of such sampler should contact the sampler manufacturer to receive a new reference method label for the sampler.

Another change is substitution of an improved type of impactor oil for the original $PM_{2.5}$ WINS particle size separator to correct an occasional cold-weather performance issue with the originally specified oil. Finally, minor increases in the time limits for sample retrieval and sample weighing were proposed, as were minor reductions in the sampler data output reporting requirements. Justifications for these changes are discussed in the proposal preamble. Of the very few comments received in connection with these proposed changes, all were supportive. Accordingly, the changes are adopted as proposed.

VII. Issues Related to Implementation of PM_{10} Standards

Issues related to implementation of the NAAQS are not relevant to the Administrator's decisions regarding whether it is appropriate to set or revise a standard. For this reason, EPA has not addressed implementation-related issues in preceding sections, nor has it addressed public comments regarding implementation. The EPA identified issues regarding transition to or implementation of the standards promulgated in this rule in an advance notice of proposed rulemaking (ANPR) on Transition to New or Revised Particulate Matter National Ambient Air Quality Standards (71 FR 6718–6729, February 9, 2006). In the ANPR, EPA solicited comment on a wide range of issues related to both the fine and coarse particle NAAQS, including the schedules for implementation of these standards and the requirements that would be applicable if any PM NAAQS were revoked. The public comment period for the ANPR ended on July 10, 2006. The EPA is currently reviewing the public comments received. In the near future, EPA intends to address, as necessary, issues such as designations, conformity, and new source review, related to implementation of today's final rule. In this section, EPA highlights a few issues that may arise as an immediate consequence of today's final decision to retain the 24-hour PM_{10} standards but revoke the annual PM_{10} standards, and restates existing policies and practices to address several concerns raised by commenters.

A. Summary of Comments Received on Transition

Many commenters, particularly State and local air pollution control agencies and Tribes, but also environmental and public health groups, voiced strong concerns about EPA's proposal to revoke current annual PM_{10} standards everywhere upon promulgation of this final rule, and to revoke, upon finalization of a primary 24-hour standard for $PM_{10-2.5}$, the current 24-hour PM_{10} standard everywhere except in 15 large urbanized areas (with population greater than 100,000) that have at least one monitor violating the 24-hour PM_{10} standard based on the most recent three years of air quality data. For these few areas, EPA proposed to retain the 24-hour PM_{10} standard until designations were completed under a final 24-hour $PM_{10-2.5}$ standard. While a few local government commenters recommended that one or another of the 15 areas be dropped from this list—i.e., recommended that the 24-hour PM_{10} standard should be retained in fewer locations—most commenters expressing views on transition suggested that EPA was being too hasty in dismantling existing PM_{10} protections. Pointing to long delays in the implementation timeline for the 1997 $PM_{2.5}$ standards due to litigation, such that designations were not completed for eight years after promulgation of the final rule, these commenters suggested that the 24-hour PM_{10} standard should remain in place everywhere until designations were complete under the 24-hour $PM_{10-2.5}$ standard, or even until $PM_{10-2.5}$ SIPs had been submitted by States. Some Tribal, State and local commenters suggested that the PM_{10} standard should be retained permanently in all areas where the $PM_{10-2.5}$ standard did not apply by virtue of the monitoring requirements, which limited NAAQS comparable monitors to sites that met the five-point site suitability test outlined in the monitoring rule. Other commenters maintained that EPA has no authority to revoke the PM_{10} standards or the specific pollution controls mandated in Title I Subpart 4 for PM_{10} nonattainment areas.[90]

The EPA notes that the Administrator's decision to retain the current 24-hour PM_{10} standard alleviates these concerns. Because the 24-hour PM_{10} standard is generally controlling, as described above in section III.D.2, retention of this standard ensures the continuation of existing public health protections. The EPA further believes that it has the legal authority to revoke the annual PM_{10} standard, and addresses this issue in detail in the Response to Comments document.

B. Impact of Decision on PM_{10} Designations

The EPA notes that because it is retaining the current 24-hour PM_{10} standards, new nonattainment designations for PM_{10} will not be required under the provisions of the Clean Air Act. As established in Section 107(d)(1) of the Act, the only time EPA is obligated to designate areas as attainment or nonattainment is after it promulgates or revises a NAAQS. Under an existing standard, all redesignations are at the Administrator's discretion: EPA has no legal obligation to redesignate an area even if a monitor should register a violation of that standard (see CAA Section 107(d)(3)). Thus, this final decision does not affect existing PM_{10} nonattainment designations. This is consistent with past practice. For example, when EPA decided not to revise the ozone standards in 1993 or the SO_2 standards in 1996, it did not revisit prior designations or designate any new areas as nonattainment. The EPA does regard air quality violations seriously, and does expect States to take actions to reduce

[90] These comments and EPA's responses to the issues raised by commenters are discussed in greater detail in the Response to Comments document.

air quality to healthy levels in any areas that are experiencing violations. However, EPA recognizes that there are other ways to address such violations besides redesignating an area as nonattainment. For example, EPA can work directly with a State and nearby industries to take appropriate actions to reduce emissions that are contributing to the violation. The EPA has worked in this way with States in the past. Of course, States may request redesignation of an area, either from nonattainment to attainment, or from attainment to nonattainment, based on the most recent air quality data available, if they choose to do so. In addition, both transportation and general conformity will continue to apply to all PM_{10} nonattainment and maintenance areas since no designations are changing. However, because EPA is revoking the annual PM_{10} standard in this final rule, after the effective date of this rule conformity determinations in PM_{10} areas will only be required for the 24-hour PM_{10} standard; conformity to the annual PM_{10} standard will no longer be required. The EPA will address specific conformity issues related to the revocation of the annual PM_{10} standard either in future guidance or in another public document. The EPA also notes that PSD increments and baseline years will not be affected by this decision.

The EPA is retaining the current 24-hour PM_{10} standards and revoking the annual PM_{10} standards. Today's rule does not change any existing guidance related to the PM_{10} NAAQS as it applies to the 24-hour PM_{10} standards, and to the extent that modifications to the existing guidance are needed in response to today's action, EPA will make such modifications in the near future.

As described in the revisions to Part 53/58 appearing elsewhere in today's **Federal Register**, EPA believes a reduction in the size of the existing monitoring networks for certain pollutants, including PM_{10}, for which the large majority of monitors record no NAAQS violations, is appropriate as a way to free up resources for higher priority monitoring objectives. The current minimum PM_{10} network requirements are based on the population of a metropolitan statistical area (MSA) and its historical PM_{10} air quality. This focus on larger urban areas is consistent with EPA's belief that it is appropriate to target an indicator for thoracic coarse particles toward urban and industrial areas, where the ambient mix of thoracic coarse particles is dominated by emissions from particular types of sources. See sections III.C.2 and III.C.3 above. To the extent that States and Tribes are considering reducing the total number of PM_{10} monitors deployed, EPA believes, consistent with the basis for retaining the 24-hour PM_{10} standard, that priority should be given to maintaining monitors sited in urban and industrial areas.

In addition, if States and Tribes are considering deploying new PM_{10} monitors, EPA recommends, again consistent with the basis for retaining the 24-hour PM_{10} standard, that those monitors be placed in areas where there are urban and/or industrial sources of thoracic coarse particles. Furthermore, consistent with the monitors used in studies that informed the Administrator's decision on the level of the standard (see section III.D above), EPA recommends that any new PM_{10} monitors be placed in locations that are reflective of community exposures at middle and neighborhood scales of representation, and not in source-oriented hotspots.

As summarized briefly above in section III.E and described in detail in section V.E.1 of the monitoring rule published elsewhere in today's **Federal Register**, EPA is also establishing requirements for a new multi-pollutant monitoring network that will include approximately 75 $PM_{10-2.5}$ monitors that will speciate according to the composition as well as size of the particles. These speciated $PM_{10-2.5}$ monitors are a critical part of EPA's research program on coarse particles, and will be sited in both urban and rural locations. It is EPA's expectation that these monitors will help alleviate the current deficit of information regarding the public health impacts of $PM_{10-2.5}$ mixes in different locations.[91]

C. Impact of Decision on State Implementation Plans (SIPs) and Control Obligations

The EPA's decision today to retain the PM_{10} NAAQS does not establish new legal obligations beyond those that already exist. Specifically, this final rule does not obligate States to revise SIPs or to create new obligations to control particular sources. In response to comments regarding potential impacts of any coarse particle standard on agricultural and mining sources, EPA notes that the NAAQS do not create emissions control obligations for individual sources or groups of sources. In this particular case, even if an individual source were shown to contribute to an exceedance of the 24-hour PM_{10} standard, this would not necessarily result in regulation of that source. Decisions about which sources to control are generally made by the State in the context of developing or revising SIPs. Given that the available evidence regarding adverse health effects associated with exposure to thoracic coarse particles is strongest with respect to urban and industrial ambient mixes of those particles, EPA encourages States to focus control programs on urban and industrial sources to the extent that those sources are contributing to air quality violations. This would help to ensure that resources expended on implementing the 24-hour PM_{10} standard realize the maximum public health and welfare benefits.

With regard to emissions of thoracic coarse particles from agricultural sources, EPA recognizes that the United States Department of Agriculture (USDA) has been working with the agricultural community to develop conservation systems and activities to control coarse particle emissions. Based on current ambient monitoring information, these USDA-approved conservation systems and activities have proven to be effective in controlling these emissions in areas where coarse particles emitted from agricultural activities have been identified as a contributor to violation of the NAAQS. The EPA concludes that where USDA-approved conservation systems and activities have been implemented, these systems and activities have satisfied the Agency's reasonably available control measure and best available control measure requirements. The EPA believes that in the future, when properly implemented, USDA-approved conservation systems and activities should satisfy the requirements for reasonably available control measures or best available control measures. The EPA will work with States to identify appropriate measures to meet their RACM or BACM requirements, including site-specific conservation systems and activities. The EPA will continue to work with USDA to prioritize the development of new conservation systems and activities;

[91] In addition, EPA notes that the Agency's National Center for Environmental Research recently issued a Request for Proposals on "Sources, Composition, and Health Effects of Coarse Particulate Matter" which is designed to (1) improve understanding of the type and severity of health outcomes associated with exposure to $PM_{10-2.5}$; (2) improve understanding of subpopulations that may be especially sensitive to $PM_{10-2.5}$ exposures including minority populations, highly exposed groups, and other susceptible groups; (3) characterize and compare the influence of mass, composition, source characteristics and exposure estimates in different locations and differences in health outcomes, including comparisons in rural and urban areas; and (4) characterize the composition and variability of $PM_{10-2.5}$ in towns, cities or metropolitan areas, including comparisons of rural and urban areas.

demonstrate and improve, where necessary, the control efficiencies of existing conservation systems and activities; and ensure that appropriate criteria are used for identifying the most effective application of conservation systems and activities.

The EPA does not construe the Clean Air Act (CAA) to require that the Agency make an independent determination as to whether a PSD increment is violated in any specific State or Tribal reservation. The EPA has the discretion to inquire into these matters and call for revisions to a State's SIP if an EPA investigation concluded with EPA finding that the PSD increment is being exceeded. The EPA's regulations at 40 CFR 51.166(a)(3) directs a state to make revisions to its SIP if EPA or a State finds such an exceedance. However, this regulation does not require that EPA conduct its own investigation and make such a finding in all cases where a State has completed a periodic review and submitted its findings to EPA. Oversight of this nature is a matter within EPA's discretion. Likewise, section 110(k)(5) of the Clean Air Act does not require that EPA periodically investigate and determine whether a SIP is sufficient to protect the PSD increments. The EPA has the discretion to decide when it is appropriate to exercise its oversight authority and inquire into these issues in a specific State or Tribal reservation. When EPA exercises this discretion and finds an exceedance of the increments or another SIP deficiency, EPA is then required to issue a SIP call under section 110(k)(5) of the CAA. However, the CAA affords EPA discretion on whether to make a determination that a state SIP is deficient. See, *New York Public Interest Research Group* v. *Whitman,* 321 F.3d 316, 331 (2d Cir. 2003) (considering analogous provision of the CAA addressing EPA oversight of state Title V operating permit programs).

D. Consideration of Fugitive Emissions for New Source Review (NSR) Purposes

Under the current NSR regulations, for purposes of determining whether a stationary source qualifies as a major stationary source, that source must include fugitive emissions in calculating the total amount of a pollutant directly emitted, or the potential to emit that pollutant, only if the source is associated with a source category listed by the Administrator pursuant to notice and comment rulemaking in accordance with Section 302(j) of the Clean Air Act (CAA). Agricultural and mining sources are generally not among those listed by the Administrator. Therefore, fugitive emissions from sources in these categories are generally not included in making major source determinations. However, the current NSR regulations require that once any source qualifies as a major stationary source, that source must count all fugitive emissions toward determining whether an emissions increase results in a major modification of that source regardless of whether the source is associated with a source category listed by the Administrator. On July 11, 2003, we received a petition for reconsideration of the current NSR regulations relating to whether fugitive emissions must be counted for purposes of determining whether a major modification occurs. In January 2004, we agreed to reconsider this issue, and we expect to propose changes to the existing regulations in the near future.

E. Handling of PM_{10} Exceedances Due to Exceptional Events

The EPA recognizes that PM_{10} exceedances may be caused, in whole or in part, by exceptional events, including natural events such as windstorms. In some of these instances, the PM_{10} exceedance(s) may also be associated with anthropogenic emissions that contribute to total PM_{10} concentrations. Under EPA's March 2006 *Proposed Rule on the Treatment of Data Influenced by Exceptional Events* (71 FR 12592–12610), and consistent with historical practice, an exceedance may be treated as an exceptional event even though anthropogenic sources such as agriculture and mining emissions contribute to the exceedance. (EPA's Exceptional Events Rule will be finalized in March 2007 and will discuss this issue in more detail.)

VIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under section 3(f)(1) of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is an ''economically significant regulatory action'' because it is likely to have an annual effect on the economy of $100 million or more. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action (Docket ID No. EPA–HQ–OAR–2001–0017).

In addition, EPA prepared a regulatory impact analysis (RIA) of the potential costs and benefits associated with this action, entitled ''Regulatory Impact Analysis for Particulate Matter National Ambient Air Quality Standards'' (September 2006). The RIA estimates the nationwide costs and monetized human health and welfare benefits of attaining two alternatives to the current suite of $PM_{2.5}$ NAAQS (15 μg/m^3 annual, 65 μg/m^3 daily). Specifically, the RIA compares the current standards to the proposed alternative of 15 μg/m^3 annual, 35 μg/m^3 daily and a tighter alternative of 14 μg/m^3 annual, 35 μg/m^3 daily. The RIA contains illustrative analyses that consider a limited number of emissions control scenarios that States and Regional Planning Organizations might implement to achieve the 1997 $PM_{2.5}$ NAAQS and these alternative $PM_{2.5}$ NAAQS. It calculates the incremental costs that might be incurred between the base year of 2015, which is the year by which States must all be in attainment with the 1997 $PM_{2.5}$ standards (15 μg/m^3 annual, 65 μg/m^3 daily), and 2020, which is the final date by which States would implement controls to attain the revised $PM_{2.5}$ standards.

As discussed above in section I.B, the Clean Air Act and judicial decisions make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although an RIA has been prepared, the results of the RIA have not been considered in issuing this final rule.

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 revisions to 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 EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. 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 final rule on small entities, EPA has concluded that this action will not have a significant economic impact on a substantial number of small entities. This 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 *ATA I* at 1044–45 (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities).

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 final 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 *ATA I* 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 final 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 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.''

At the time of proposal, EPA concluded that the proposed rule would not have federalism implications. The EPA stated that the proposed rule would 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. However, EPA recognized that States would 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 solicited comment on the rule from State and local officials at the time of proposal.

One commenter who opposed EPA's proposed decision on the standards for thoracic coarse particles stated that the decision violated E.O. 13132. The commenter argued that EPA's proposal to replace the PM_{10} standards with a new 24-hour $PM_{10-2.5}$ standard based on a qualified indicator would substantially impact CAA section 107 which establishes that the States have primary responsibility for implementation of the NAAQS. Specifically, the commenter stated that the proposed rule language establishing that ''agricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting this standard'' was a clear infringement upon States' authority with regard to implementation of the NAAQS. The EPA notes that in light of the final decision to retain the PM_{10} indicator, and the 24-hour PM_{10} NAAQS, the concern voiced by this commenter is no longer relevant. The final rule does not exclude any sources from control under the 24-hour PM_{10} standard.

Therefore, EPA concludes that this final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in 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 above in section E 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.

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.

Although EPA determined at the time of proposal that Executive Order 13175 did 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 the proposal was under development, as well as the call in the spring of 2006 during the public comment period on the proposed rule. The EPA sent individual letters to all federally recognized Tribes within the lower 48 states and Alaska to give Tribal leaders the opportunity for consultation, and EPA staff also participated in Tribal public meetings, such as the National Tribal Forum meeting in April 2006, where Tribes discussed their concerns regarding the proposed rule. Furthermore, the Administrator discussed the proposed PM NAAQS with members of the National Tribal Caucus and with leaders of individual Tribes during the spring and summer of 2006, in advance of his final decision.

During the course of these meetings and in written comments submitted to the Agency, Tribal commenters expressed significant concerns about the implications of the proposed rule for Tribes. In particular, Tribes strongly opposed the proposed qualified $PM_{10-2.5}$ indicator and the proposed monitor site-suitability requirements, especially the requirement that monitors used for comparison with the NAAQS be located within urbanized areas with a minimum population of 100,000. Tribal commenters pointed out that this would virtually exclude Tribes from applying the $PM_{10-2.5}$ standards because very few Tribal sites would meet this criterion. Tribes stated that EPA had violated its Trust Responsibility to Tribes in three ways. First, the commenters claimed that EPA had failed to engage in meaningful consultation with Tribal leaders regarding the proposed qualified $PM_{10-2.5}$ indicator and other aspects of the proposed rule. Second, commenters claimed that the proposed 24-hour $PM_{10-2.5}$ standard would have serious adverse impacts on the existing level of health protection for Tribes. Third, Tribal commenters objected to the proposed exclusion of ''agricultural sources, mining sources, and other similar sources of crustal material'' from the proposed $PM_{10-2.5}$ indicator; like States, Tribes felt this provision was illegal and Tribal commenters argued this violated Tribal sovereignty. The EPA notes that its final decision to retain the current 24-hour PM_{10} standard, for the reasons noted above in Section III, without any qualifications or changes to the monitor siting requirements, effectively resolves the concerns raised by these commenters.

EPA has determined that this final 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.

G. Executive Order 13045: Protection of Children From Environmental Health & 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 rule on children, and explain why the regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This 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 NAAQS constitute 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 and III of this preamble.

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

This 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 104–113, Section 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 final rule establishes requirements for environmental monitoring and measurement. Specifically, it establishes the FRM for $PM_{10-2.5}$ measurement (and slightly amends 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 equivalency criteria established 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 requirements utilize performance standards for some aspects of monitor design, multiple performance standards defined for many combinations of PM type, concentration, and environmental conditions would be required to be sure that monitors certified to purely performance-based standards actually performed similarly in the field, which would in turn require extensive testing of each candidate monitor design. 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 final rule and the equivalency criteria contained in the 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.

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 a risk or a rate of exposure to hazards that are significant and that ''appreciably exceeds 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 decisions may have disproportionate negative impacts on minority or low-income populations. This rule establishes uniform, national ambient air quality standards for particulate matter, and is not expected to have disproportionate negative impacts on minority or low income populations. The EPA notes that some commenters expressed concerns that EPA had failed to adequately assess the environmental justice implications of its proposed decisions, and that the proposed revisions to both the fine particle and coarse particle standards would violate the principles of environmental justice. In particular, numerous commenters criticized the proposed qualified $PM_{10-2.5}$ indicator, arguing that the exclusive urban focus of the indicator failed to protect large segments of the U.S. population (including Tribes and lower-income rural populations). The EPA believes that the final decision to retain the current nationally applicable 24-hour PM_{10} standard adequately addresses the concerns raised by these commenters, as discussed above in section III.

Further, some commenters were concerned that the proposed $PM_{2.5}$ standards would permit the continuation of disproportionate adverse health effects on minority and low-income populations because those populations are concentrated in urban areas where exposures are higher and are generally more susceptible (given lack of access to health care and prevalence of chronic conditions such as asthma). The EPA believes that the implications of the newly strengthened suite of $PM_{2.5}$ standards will reduce health risks precisely in the areas subject to the highest fine particle concentrations. Furthermore, the $PM_{2.5}$ NAAQS established in today's final rule are nationally uniform standards which in the Administrator's judgment protect public health with an adequate margin of safety. In making this determination, the Administrator expressly considered the available information regarding health effects among vulnerable and susceptible populations, such as those with preexisting conditions. Thus it remains EPA's conclusion that this rule is not expected to have disproportionate negative impacts on minority or low income populations.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective December 18, 2006.

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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: September 21, 2006.

Stephen L. Johnson,

Administrator.

■ For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

■ 1. The authority citation for part 50 continues to read as follows:

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

■ 2. Section 50.3 is revised to read as follows:

§ 50.3 Reference conditions.

All measurements of air quality that are expressed as mass per unit volume (*e.g.*, micrograms per cubic meter) other than for the particulate matter ($PM_{2.5}$) 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 $PM_{2.5}$ 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.

§ 50.6 [Amended]

■ 3. Section 50.6 is amended by removing and reserving paragraph (b).

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

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

(a) The national primary and secondary ambient air quality standards for particulate matter are 15.0 micrograms per cubic meter (µg/m³) annual arithmetic mean concentration, and 35 µg/m³ 24-hour average concentration measured in the ambient air as $PM_{2.5}$ (particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers) by either:

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

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

(b) The 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 µg/m³.

(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 µg/m³.

■ 5. Appendix K to Part 50 is revised to read as follows:

Appendix K to Part 50—Interpretation of the National Ambient Air Quality Standards for Particulate Matter

1.0 General

(a) This appendix explains the computations necessary for analyzing particulate matter data to determine attainment of the 24-hour standards specified in 40 CFR 50.6. For the primary and secondary standards, particulate matter is measured in the ambient air as PM_{10} (particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers) by a reference method based on appendix J of this part and designated in accordance with part 53 of this chapter, or by an equivalent method designated in accordance with part 53 of this chapter. The required frequency of measurements is specified in part 58 of this chapter.

(b) The terms used in this appendix are defined as follows:

Average refers to the arithmetic mean of the estimated number of exceedances per year, as per Section 3.1.

Daily value for PM_{10} refers to the 24-hour average concentration of PM_{10} calculated or measured from midnight to midnight (local time).

Exceedance means a daily value that is above the level of the 24-hour standard after rounding to the nearest 10 µg/m³ (*i.e.*, values ending in 5 or greater are to be rounded up).

Expected annual value is the number approached when the annual values from an increasing number of years are averaged, in the absence of long-term trends in emissions or meteorological conditions.

Year refers to a calendar year.

(c) Although the discussion in this appendix focuses on monitored data, the same principles apply to modeling data, subject to EPA modeling guidelines.

2.0 Attainment Determinations

2.1 24-Hour Primary and Secondary Standards

(a) Under 40 CFR 50.6(a) the 24-hour primary and secondary standards are attained when the expected number of exceedances per year at each monitoring site is less than or equal to one. In the simplest case, the number of expected exceedances at a site is determined by recording the number of exceedances in each calendar year and then averaging them over the past 3 calendar years. Situations in which 3 years of data are not available and possible adjustments for unusual events or trends are discussed in sections 2.3 and 2.4 of this appendix. Further, when data for a year are incomplete, it is necessary to compute an estimated number of exceedances for that year by adjusting the observed number of exceedances. This procedure, performed by calendar quarter, is described in section 3.0 of this appendix. The expected number of exceedances is then estimated by averaging the individual annual estimates for the past 3 years.

(b) The comparison with the allowable expected exceedance rate of one per year is made in terms of a number rounded to the nearest tenth (fractional values equal to or greater than 0.05 are to be rounded up; *e.g.*, an exceedance rate of 1.05 would be rounded to 1.1, which is the lowest rate for nonattainment).

2.2 Reserved

2.3 Data Requirements

(a) 40 CFR 58.12 specifies the required minimum frequency of sampling for PM_{10}. For the purposes of making comparisons with the particulate matter standards, all data produced by State and Local Air Monitoring Stations (SLAMS) and other sites submitted to EPA in accordance with the part 58 requirements must be used, and a minimum of 75 percent of the scheduled PM_{10} samples per quarter are required.

(b) To demonstrate attainment of the 24-hour standards at a monitoring site, the monitor must provide sufficient data to perform the required calculations of sections 3.0 and 4.0 of this appendix. The amount of data required varies with the sampling frequency, data capture rate and the number of years of record. In all cases, 3 years of representative monitoring data that meet the 75 percent criterion of the previous paragraph should be utilized, if available, and would suffice. More than 3 years may be considered, if all additional representative years of data meeting the 75 percent criterion are utilized. Data not meeting these criteria may also suffice to show attainment; however, such exceptions will have to be approved by the appropriate Regional Administrator in accordance with EPA guidance.

(c) There are less stringent data requirements for showing that a monitor has failed an attainment test and thus has recorded a violation of the particulate matter standards. Although it is generally necessary to meet the minimum 75 percent data capture requirement per quarter to use the computational equations described in section 3.0 of this appendix, this criterion does not apply when less data is sufficient to unambiguously establish nonattainment. The following examples illustrate how nonattainment can be demonstrated when a site fails to meet the completeness criteria. Nonattainment of the 24-hour primary standards can be established by the observed annual number of exceedances (*e.g.*, four observed exceedances in a single year), or by the estimated number of exceedances derived from the observed number of exceedances and the required number of scheduled samples (*e.g.*, two observed exceedances with every other day sampling). In both cases, expected annual values must exceed the levels allowed by the standards.

2.4 Adjustment for Exceptional Events and Trends

(a) An exceptional event is an uncontrollable event caused by natural sources of particulate matter or an event that is not expected to recur at a given location. Inclusion of such a value in the computation of exceedances or averages could result in inappropriate estimates of their respective expected annual values. To reduce the effect of unusual events, more than 3 years of representative data may be used. Alternatively, other techniques, such as the use of statistical models or the use of historical data could be considered so that the event may be discounted or weighted according to the likelihood that it will recur. The use of such techniques is subject to the approval of the appropriate Regional Administrator in accordance with EPA guidance.

(b) In cases where long-term trends in emissions and air quality are evident, mathematical techniques should be applied to account for the trends to ensure that the expected annual values are not inappropriately biased by unrepresentative data. In the simplest case, if 3 years of data are available under stable emission conditions, this data should be used. In the event of a trend or shift in emission patterns, either the most recent representative year(s) could be used or statistical techniques or models could be used in conjunction with previous years of data to adjust for trends. The use of less than 3 years of data, and any adjustments are subject to the approval of the appropriate Regional Administrator in accordance with EPA guidance.

3.0 Computational Equations for the 24-Hour Standards

3.1 Estimating Exceedances for a Year

(a) If PM_{10} sampling is scheduled less frequently than every day, or if some scheduled samples are missed, a PM_{10} value will not be available for each day of the year. To account for the possible effect of incomplete data, an adjustment must be made to the data collected at each monitoring location to estimate the number of exceedances in a calendar year. In this adjustment, the assumption is made that the fraction of missing values that would have exceeded the standard level is identical to the fraction of measured values above this level. This computation is to be made for all sites that are scheduled to monitor throughout the entire year and meet the minimum data requirements of section 2.3 of this appendix. Because of possible seasonal imbalance, this adjustment shall be applied on a quarterly basis. The estimate of the expected number of exceedances for the quarter is equal to the observed number of exceedances plus an increment associated with the missing data. The following equation must be used for these computations:

Equation 1

$$e_q = v_q \times \left(\frac{N_q}{n_q} \right)$$

Where:

e_q = the estimated number of exceedances for calendar quarter q;

v_q = the observed number of exceedances for calendar quarter q;

N_q = the number of days in calendar quarter q;

n_q = the number of days in calendar quarter q with PM_{10} data; and

q = the index for calendar quarter, q = 1, 2, 3 or 4.

(b) The estimated number of exceedances for a calendar quarter must be rounded to the nearest hundredth (fractional values equal to or greater than 0.005 must be rounded up).

(c) The estimated number of exceedances for the year, e, is the sum of the estimates for each calendar quarter.

Equation 2

$$e = \sum_{q=1}^{4} e_q$$

(d) The estimated number of exceedances for a single year must be rounded to one decimal place (fractional values equal to or greater than 0.05 are to be rounded up). The expected number of exceedances is then estimated by averaging the individual annual estimates for the most recent 3 or more representative years of data. The expected number of exceedances must be rounded to one decimal place (fractional values equal to or greater than 0.05 are to be rounded up).

(e) The adjustment for incomplete data will not be necessary for monitoring or modeling data which constitutes a complete record, i.e., 365 days per year.

(f) To reduce the potential for overestimating the number of expected exceedances, the correction for missing data will not be required for a calendar quarter in which the first observed exceedance has occurred if:

(1) There was only one exceedance in the calendar quarter;

(2) Everyday sampling is subsequently initiated and maintained for 4 calendar quarters in accordance with 40 CFR 58.12; and

(3) Data capture of 75 percent is achieved during the required period of everyday sampling. In addition, if the first exceedance is observed in a calendar quarter in which the monitor is already sampling every day, no adjustment for missing data will be made to the first exceedance if a 75 percent data capture rate was achieved in the quarter in which it was observed.

Example 1

a. During a particular calendar quarter, 39 out of a possible 92 samples were recorded, with one observed exceedance of the 24-hour standard. Using Equation 1, the estimated number of exceedances for the quarter is:

$e_q = 1 \times 92/39 = 2.359$ or 2.36.

b. If the estimated exceedances for the other 3 calendar quarters in the year were 2.30, 0.0 and 0.0, then, using Equation 2, the estimated number of exceedances for the year is 2.36 + 2.30 + 0.0 + 0.0 which equals 4.66 or 4.7. If no exceedances were observed for the 2 previous years, then the expected number of exceedances is estimated by: $(1/3) \times (4.7 + 0 + 0) = 1.57$ or 1.6. Since 1.6 exceeds the allowable number of expected exceedances, this monitoring site would fail the attainment test.

Example 2

In this example, everyday sampling was initiated following the first observed exceedance as required by 40 CFR 58.12. Accordingly, the first observed exceedance would not be adjusted for incomplete sampling. During the next three quarters, 1.2 exceedances were estimated. In this case, the estimated exceedances for the year would be 1.0 + 1.2 + 0.0 + 0.0 which equals 2.2. If, as before, no exceedances were observed for the two previous years, then the estimated exceedances for the 3-year period would then be $(1/3) \times (2.2 + 0.0 + 0.0) = 0.7$, and the monitoring site would not fail the attainment test.

3.2 Adjustments for Non-Scheduled Sampling Days

(a) If a systematic sampling schedule is used and sampling is performed on days in addition to the days specified by the systematic sampling schedule, e.g., during episodes of high pollution, then an adjustment must be made in the equation for the estimation of exceedances. Such an adjustment is needed to eliminate the bias in the estimate of the quarterly and annual number of exceedances that would occur if the chance of an exceedance is different for scheduled than for non-scheduled days, as would be the case with episode sampling.

(b) The required adjustment treats the systematic sampling schedule as a stratified sampling plan. If the period from one scheduled sample until the day preceding the next scheduled sample is defined as a sampling stratum, then there is one stratum for each scheduled sampling day. An average number of observed exceedances is computed for each of these sampling strata. With nonscheduled sampling days, the estimated number of exceedances is defined as:

Equation 3

$$e_q = \left(\frac{N_q}{m_q}\right) \times \sum_{j=1}^{m_q} \left(\frac{v_j}{k_j}\right)$$

Where:

e_q = the estimated number of exceedances for the quarter;

N_q = the number of days in the quarter;

m_q = the number of strata with samples during the quarter;

v_j = the number of observed exceedances in stratum j; and

k_j = the number of actual samples in stratum j.

(c) Note that if only one sample value is recorded in each stratum, then Equation 3 reduces to Equation 1.

Example 3

A monitoring site samples according to a systematic sampling schedule of one sample every 6 days, for a total of 15 scheduled samples in a quarter out of a total of 92 possible samples. During one 6-day period, potential episode levels of PM_{10} were suspected, so 5 additional samples were taken. One of the regular scheduled samples was missed, so a total of 19 samples in 14 sampling strata were measured. The one 6-day sampling stratum with 6 samples recorded 2 exceedances. The remainder of the quarter with one sample per stratum recorded zero exceedances. Using Equation 3, the estimated number of exceedances for the quarter is:

$$Eq = (92/14) \times (2/6 + 0 + . \ . \ .+ 0) = 2.19.$$

■ 6. 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;

■ c. Revising paragraph (a) of section 7.3.4.3:

■ d. Adding section 7.3.4.4;

■ e. Revising Table L–1 in section 7.4.19;

■ f. Revising section 8.3.6;

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

■ h. Revising reference 2 in section 13.0 to 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.

* * * * *

7.3.4 *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 * * *

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

* * * * *

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.

* * * * *

7.4.19 * * *

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 spec. (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

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

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
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.

* * * * *

8.3.6 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.

* * * * *

10.10 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.*

* * * * *

■ 7. 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, or by an Approved Regional Method (ARM) designated in accordance with part 58 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.

Creditable samples are samples that are given credit for data completeness. They include valid samples collected on required sampling days and valid ''make-up'' samples taken for missed or invalidated samples on required sampling days.

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) that are used in NAAQS computations.

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*'').

Extra samples are non-creditable samples. They are daily values that do not occur on scheduled sampling days and that can not be used as make-ups for missed or invalidated scheduled samples. Extra samples are used in mean calculations and are subject to selection as a 98th percentile.

Make-up samples are samples taken to supplant missed or invalidated required scheduled samples. Make-ups can be made by either the primary or the collocated instruments. Make-up samples are either taken before the next required sampling day or exactly one week after the missed (or voided) sampling day. Also, to be considered a valid make-up, the sampling must be administered according to EPA guidance.

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 among the 3-year period 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 $PM_{2.5}$. For example, this could 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/ARM $PM_{2.5}$ 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/m³) 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 additional digits to the right of the first 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/ARM monitor. The primary monitor shall be designated in the appropriate State or local agency PM Monitoring Network Description. All daily values produced by the primary sampler are considered part of the site record (i.e., that site's daily value); this includes all creditable samples and all extra samples.

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

(e) All daily values in the composite site record are used in annual mean and 98th percentile calculations, however, not all daily values are give credit towards data completeness requirements. Only ''creditable'' samples are given credit for data completeness. Creditable samples include valid samples on scheduled sampling days and valid make-up samples. All other types of daily values are referred to as ''extra'' samples.

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/m³).

(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. [Quarterly data capture rates (expressed as a percentage) are specifically calculated as the number of creditable samples for the quarter divided by the number of scheduled samples for the quarter, the result then multiplied by 100 and rounded to the nearest integer.] However, years with 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 daily 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/m³. 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 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 for comparisons to the NAAQS.

(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/m³ (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/m³ (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

4.4 Equations for the Annual $PM_{2.5}$ NAAQS.

(a) An annual mean value for $PM_{2.5}$ is determined by first averaging the daily values of a calendar quarter using equation 1 of this appendix:

Equation 1

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

Where:

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

n_q = the number of daily 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

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

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 for sites designated to be averaged that meet completeness criteria , and

n_s = the number of sites designated to be averaged that meet completeness criteria.

(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

$$\bar{x} = \frac{1}{3}\sum_{y=1}^{3} \bar{x}_y$$

Equation 4B

When not spatial averaging

$$\bar{x} = \frac{1}{3}\sum_{y=1}^{3} \bar{x}_{y,s}$$

Where:

$\bar{x}$ = 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

$\bar{x}_y$ = 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.

(1) *Regular formula for computing annual 98th percentile values.* Calculation of annual 98th percentile values using the regular formula (equation 5) will be based on the creditable number of samples (as described below), rather than on the actual number of samples. Credit will not be granted for extra (non-creditable) samples. Extra samples, however, are candidates for selection as the annual 98th percentile. [The creditable number of samples will determine how deep to go into the data distribution, but all samples (creditable and extra) will be considered when making the percentile assignment.] The annual creditable number of samples is the sum of the four quarterly creditable number of samples. 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) x (cn) as the number ''i.d,'' where 'cn' is the annual creditable 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

$$P_{0.98,y} = X_{[i+1]}$$

Where:

$P_{0.98,\ y}$ = 98th percentile for year y;

$x_{[i+1]}$ = the $(i+1)^{th}$ number in the ordered series of numbers;

i = the integer part of the product of 0.98 and cn.

(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}+ = days in a year; and d_{Low}

$$F_a(x) = \frac{\text{number of daily values in season a that are} \leq \times}{\text{number of daily values in season a}}$$

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.

■ 8. Appendix O is added to part 50 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. In conjunction with additional analysis, this method may be used to develop speciated data.

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 have 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 ($\mu g/m^3$)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/m³ 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).

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_{10}c 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

$$PM_{10c} = \frac{(W_f - W_i)}{V_a}$$

Where:

PM_{10c} = mass concentration of PM_{10c}, µg/m³;
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, m³.

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 μg/m³, 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: *www.epa.gov/ttn/amtic/pgqa.html.*

14.0 Figures

Figure O–1 is included as part of this appendix O.

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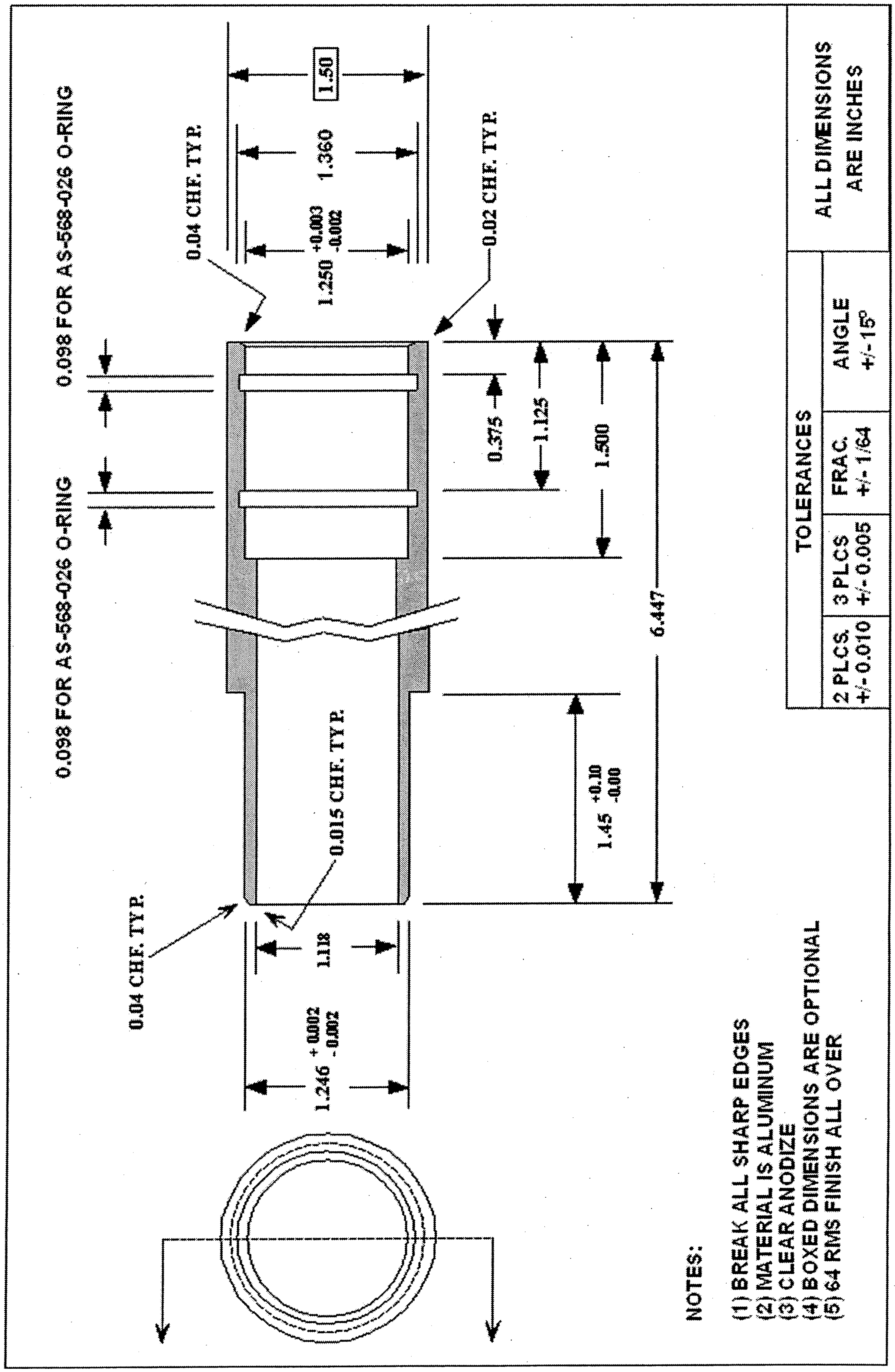

FIGURE O-1. DOWNTUBE EXTENSION

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