



# **Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter**

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# **Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter**

## **U.S. Environmental Protection Agency**

National Center for Environmental Assessment  
Office of Research and Development  
and  
Health and Environmental Impacts Division  
Office of Air Quality Planning and Standards  
Office of Air and Radiation

Research Triangle Park, North Carolina

## **DISCLAIMER**

This draft integrated review plan for the national ambient air quality standards (NAAQS) for particulate matter (PM) is an informational document prepared for external review purposes and does not constitute U.S. Environmental Protection Agency policy. This plan, once finalized, will serve as a management tool for the U.S. Environmental Protection Agency's National Center for Environmental Assessment and the Office of Air Quality Planning and Standards. The approach described in the final plan may be modified to reflect information developed during the review of the PM NAAQS and to address advice and comments received from the Clean Air Scientific Advisory Committee and the public throughout this review. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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# 1 INTRODUCTION

2 The U.S. Environmental Protection Agency (EPA) is conducting a review of the existing  
3 air quality criteria for particulate matter (PM) and the primary (health-based) and secondary  
4 (welfare-based) national ambient air quality standards (NAAQS) for PM. The purpose of this  
5 document is to communicate the plan for reviewing the air quality criteria for PM associated  
6 with human health and welfare effects and the primary and secondary standards for PM.

7 This integrated review plan is a draft document and will be subject to consultation at a  
8 public meeting with the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science  
9 Advisory Board. Public comments are also being solicited on this draft document. For purposes  
10 of this review, the 7-member CASAC has been supplemented by additional scientific experts  
11 collectively referred to as the CASAC PM Review Panel (see Appendix A). The final integrated  
12 review plan will be informed by comments received from CASAC and the public.

13 This review will provide an integrative assessment of relevant scientific information on  
14 PM and will focus on the basic elements of the primary and secondary PM air quality standards:  
15 the indicator, averaging time, form,<sup>1</sup> and level. These elements, which serve to define each  
16 ambient air quality standard, must be considered collectively in evaluating the health protection  
17 afforded by the standard. The current standards use PM<sub>2.5</sub> and PM<sub>10</sub> as the indicators for fine and  
18 thoracic coarse particles, respectively.

19 This draft integrated review plan is organized into eight sections. Section 1 presents  
20 background information on the review process, the legislative requirements for the review of the  
21 NAAQS, and past reviews of the NAAQS for PM. Section 2 presents the proposed review  
22 schedule. Section 3 presents a set of policy-relevant questions that will serve to focus this  
23 review on the critical scientific and policy issues. Sections 4 through 8 discuss the planned  
24 scope and organization of the key assessment documents, the planned approaches for preparing  
25 the documents, specific monitoring issues, and plans for scientific and public review of the  
26 documents. As the assessments proceed, the plan described here may be modified to reflect  
27 information received during the review process.

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<sup>1</sup> The "form" of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard.

## 1.1 OVERVIEW OF THE NAAQS REVIEW PROCESS

The Agency has recently decided to make a number of changes to the process for reviewing the NAAQS (described at <http://www.epa.gov/ttn/naaqs/>). In making these changes, the Agency consulted with CASAC, which provides advice to the Administrator on key elements of NAAQS reviews, and the public. This new process, which is being applied to the current review of the NAAQS for PM, contains four major components. Each of these components is described in this section.

The first component of the review process is the development of an integrated review plan. This plan will specify the schedule for the review, the process for conducting the review, and the key policy-relevant science issues that will guide the review.

The second component of the review process is a science assessment. Under the new process, a concise synthesis of the most policy-relevant science will be compiled into an Integrated Science Assessment (ISA), which will be informed by input from CASAC, outside scientists, and the public. The ISA for this review of the air quality criteria for PM will critically evaluate and integrate scientific information on the health and welfare effects associated with exposure to PM in the ambient air. It will focus on scientific information that has become available since the last review and will reflect the current state of knowledge on the most relevant issues pertinent to the review of the primary and secondary PM NAAQS. The ISA will be supported by more detailed information about the scientific literature, which will be compiled into a series of annexes. The ISA and its annexes will replace the Air Quality Criteria Document (AQCD) from previous PM NAAQS reviews.

The third component of the review process is a risk/exposure assessment, which will be informed by input from CASAC, outside scientists, and the public. This assessment will develop, as appropriate, quantitative estimates of human exposures and/or risks associated with current ambient levels of PM, with levels that just meet the current standards, and with levels that just meet possible alternative standards. EPA will prepare a concise risk/exposure assessment report that focuses on key results, observations, and uncertainties.

The fourth component of the revised process is a policy assessment/rulemaking. Under the new process, a staff paper, such as that prepared in previous NAAQS reviews, will not be prepared. Rather, the Agency's views on policy options will be published in the Federal Register as an advance notice of proposed rulemaking (ANPR). The ANPR will present a policy

1 assessment and will be accompanied by supporting documents, such as air quality analyses and  
2 technical support documents, as appropriate. Taking into account CASAC advice and  
3 recommendations as well as public comment on the ANPR, the Agency will publish a proposed  
4 rule, to be followed by a public comment period. Taking into account comments received on the  
5 proposed rule, the Agency will issue a final rule to complete the rulemaking process.

## 6 **1.2 LEGISLATIVE REQUIREMENTS**

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

15 Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate  
16 “primary” and “secondary” NAAQS for pollutants listed under section 108. 42 U.S.C. § 7409  
17 (a). Section 109(b) (1) defines a primary standard as one “the attainment and maintenance of  
18 which in the judgment of the Administrator, based on such criteria and allowing an adequate  
19 margin of safety, are requisite to protect the public health.”<sup>2</sup> 42 U.S.C. § 7409(b)(1). A  
20 secondary standard, as defined in section 109(b)(2), must “specify a level of air quality the  
21 attainment and maintenance of which, in the judgment of the Administrator, based on such  
22 criteria, is required to protect the public welfare from any known or anticipated adverse effects  
23 associated with the presence of [the] pollutant in the ambient air.”<sup>3</sup> 42 U.S.C. § 7409(b)(2).

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<sup>2</sup> 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, 91<sup>st</sup> Cong., 2d Sess. 10 (1970)].

<sup>3</sup> 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.”



1           The requirement that primary standards include an adequate margin of safety was  
2 intended to address uncertainties associated with inconclusive scientific and technical  
3 information available at the time of standard setting. It was also intended to provide a reasonable  
4 degree of protection against hazards that research has not yet identified. See *Lead Industries*  
5 *Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980), cert. denied, 449 U.S. 1042 (1980);  
6 *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981), cert. denied, 455  
7 U.S. 1034 (1982). Both kinds of uncertainties are components of the risk associated with  
8 pollution at levels below those at which human health effects can be said to occur with  
9 reasonable scientific certainty. Thus, in selecting primary standards that include an adequate  
10 margin of safety, the Administrator is seeking not only to prevent pollution levels that have been  
11 demonstrated to be harmful but also to prevent lower pollutant levels that may pose an  
12 unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

13           In selecting a margin of safety, the EPA considers such factors as the nature and severity  
14 of the health effects involved, the size of sensitive population(s) at risk, and the kind and degree  
15 of the uncertainties that must be addressed. The selection of any particular approach to  
16 providing an adequate margin of safety is a policy choice left specifically to the Administrator’s  
17 judgment. See *Lead Industries Association v. EPA*, supra, 647 F.2d at 1161-62.

18           In setting standards that are “requisite” to protect public health and welfare, as provided in  
19 section 109(b), EPA’s task is to establish standards that are neither more nor less stringent than  
20 necessary for these purposes. In so doing, EPA may not consider the costs of implementing the  
21 standards. See generally *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472,  
22 475-76 (2001).

23           Section 109(d)(1) requires that “not later than December 31, 1980, and at 5-year  
24 intervals thereafter, the Administrator shall complete a thorough review of the criteria  
25 published under section 108 and the national ambient air quality standards . . . and shall make  
26 such revisions in such criteria and standards and promulgate such new standards as may be  
27 appropriate . . . .” 42 U.S.C. § 7409(d)(1). Section 109(d)(2) requires that an independent  
28 scientific review committee “shall complete a review of the criteria . . . and the national primary  
29 and secondary ambient air quality standards . . . and shall recommend to the Administrator any  
30 new . . . standards and revisions of existing criteria and standards as may be appropriate . . . .”

1 42 U.S.C. § 7409(d)(2). Since the early 1980's, this independent review function has been  
2 performed by CASAC of EPA's Science Advisory Board.

### 3 **1.3 HISTORY OF REVIEWS OF THE NAAQS FOR PM**

4 Particulate matter is the generic term for a broad class of chemically and physically  
5 diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of  
6 sizes. Particles originate from a variety of anthropogenic stationary and mobile sources as well  
7 as from natural sources. Particles may be emitted directly or formed in the atmosphere by  
8 transformations of gaseous emissions such as sulfur oxides (SO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>), and  
9 volatile organic compounds (VOC). The chemical and physical properties of PM vary greatly  
10 with time, region, meteorology, and source category, thus complicating the assessment of health  
11 and welfare effects.

12 EPA first established NAAQS for PM in 1971 (36 FR 8186, April 30, 1971), based on  
13 the original criteria document (DHEW, 1969). The reference method specified for determining  
14 attainment of the original standards was the high-volume sampler, which collects PM up to a  
15 nominal size of 25 to 45 micrometers (µm) (referred to as total suspended particulates or TSP).  
16 The primary standards (measured by the indicator TSP) were 260 µg/m<sup>3</sup>, 24-hour average, not to  
17 be exceeded more than once per year, and 75 µg/m<sup>3</sup>, annual geometric mean. The secondary  
18 standard was 150 µg/m<sup>3</sup>, 24-hour average, not to be exceeded more than once per year.

19 In October 1979 (44 FR 56731), EPA announced the first periodic review of the air  
20 quality criteria and NAAQS for PM, and significant revisions to the original standards were  
21 promulgated in 1987 (52 FR 24634, July 1, 1987). In that decision, EPA changed the indicator  
22 for particles from TSP to PM<sub>10</sub>, the latter including particles with a mean aerodynamic diameter<sup>4</sup>  
23 less than or equal to 10 µm, which delineated that subset of inhalable particles small enough to  
24 penetrate to the thoracic region (including the tracheobronchial and alveolar regions) of the  
25 respiratory tract (referred to as thoracic particles). EPA also revised the level and form of the  
26 primary standards by (1) replacing the 24-hour TSP standard with a 24-hour PM<sub>10</sub> standard of  
27 150 µg/m<sup>3</sup> with no more than one expected exceedence per year; and (2) replacing the annual

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<sup>4</sup>The more precise term is 50 percent cut point or 50 percent diameter (D<sub>50</sub>). This is the aerodynamic particle diameter for which the efficiency of particle collection is 50 percent. Larger particles are not excluded altogether, but are collected with substantially decreasing efficiency and smaller particles are collected with increasing (up to 100 percent) efficiency.

1 TSP standard with a PM<sub>10</sub> standard of 50 µg/m<sup>3</sup>, annual arithmetic mean. The secondary  
2 standard was revised by replacing it with 24-hour and annual standards identical in all respects to  
3 the primary standards. The revisions also included a new reference method for the measurement  
4 of PM<sub>10</sub> in the ambient air and rules for determining attainment of the new standards. On  
5 judicial review, the revised standards were upheld in all respects. *Natural Resources Defense*  
6 *Council v. Administrator*, 902 F. 2d 962 (D.C. Cir. 1990, cert. denied, 498 U.S. 1082 (1991).

7 In April 1994, EPA announced its plans for the second periodic review of the air quality  
8 criteria and NAAQS for PM, and promulgated significant revisions to the NAAQS in 1997 (62  
9 FR 38652, July 18, 1997). In that decision, EPA revised the PM NAAQS in several respects.  
10 While EPA determined that the PM NAAQS should continue to focus on particles less than or  
11 equal to 10 µm in diameter (PM<sub>10</sub>), EPA also determined that the fine and coarse fractions of  
12 PM<sub>10</sub> should be considered separately. The EPA added new standards, using PM<sub>2.5</sub> as the  
13 indicator for fine particles (with PM<sub>2.5</sub> referring to particles with a nominal mean aerodynamic  
14 diameter less than or equal to 2.5 µm), and using PM<sub>10</sub> as the indicator for purposes of regulating  
15 the coarse fraction of PM<sub>10</sub> (referred to as thoracic coarse particles or coarse-fraction particles;  
16 generally including particles with a nominal mean aerodynamic diameter greater than 2.5 µm  
17 and less than or equal to 10 µm, or PM<sub>10-2.5</sub>). The EPA established two new PM<sub>2.5</sub> standards: an  
18 annual standard of 15 µg/m<sup>3</sup>, based on the 3-year average of annual arithmetic mean PM<sub>2.5</sub>  
19 concentrations from single or multiple community-oriented monitors; and a 24-hour standard of  
20 65 µg/m<sup>3</sup>, based on the 3-year average of the 98<sup>th</sup> percentile of 24-hour PM<sub>2.5</sub> concentrations at  
21 each population-oriented monitor within an area. Also, EPA established a new reference method  
22 for the measurement of PM<sub>2.5</sub> in the ambient air and adopted rules for determining attainment of  
23 the new standards. To continue to address thoracic coarse particles, EPA retained the annual  
24 PM<sub>10</sub> standard, while revising the form, but not the level, of the 24-hour PM<sub>10</sub> standard to be  
25 based on the 99<sup>th</sup> percentile of 24-hour PM<sub>10</sub> concentrations at each monitor in an area. The EPA  
26 revised the secondary standards by making them identical in all respects to the primary  
27 standards.

28 Following promulgation of the 1997 PM NAAQS, petitions for review were filed by a  
29 large number of parties, addressing a broad range of issues. In May 1999, a three-judge panel of  
30 the U.S. Court of Appeals for the District of Columbia Circuit issued an initial decision that  
31 upheld EPA's decision to establish fine particle standards, holding that "the growing empirical

1 evidence demonstrating a relationship between fine particle pollution and adverse health effects  
2 amply justifies establishment of new fine particle standards." *American Trucking Associations v.*  
3 *EPA* , 175 F. 3d 1027, 1055-56 (D.C. Cir. 1999) (rehearing granted in part and denied in part,  
4 195 F. 3d 4 (D.C. Cir. 1999)), affirmed in part and reversed in part, *Whitman v. American*  
5 *Trucking Associations*, 531 U.S. 457 (2001). The Panel also found "ample support" for EPA's  
6 decision to regulate coarse particle pollution, but vacated the 1997 PM<sub>10</sub> standards, concluding  
7 that EPA had not provided a reasonable explanation justifying use of PM<sub>10</sub> as an indicator for  
8 coarse particles. 175 F. 3d at 1054-55. Pursuant to the court's decision, EPA removed the  
9 vacated 1997 PM<sub>10</sub> standards from the Code of Federal Regulations (CFR) (69 FR 45592, July  
10 30, 2004) and deleted the regulatory provision (at 40 CFR 50.6(d)) that controlled the transition  
11 from the pre-existing 1987 PM<sub>10</sub> standards to the 1997 PM<sub>10</sub> standards (65 FR 80776, December  
12 22, 2000). The pre-existing 1987 PM<sub>10</sub> standards remained in place. *Id.* at 80777.

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

23 Both sides filed cross appeals on these issues to the United States Supreme Court, and  
24 the Court granted *certiorari*. In February 2001, the Supreme Court issued a unanimous decision  
25 upholding EPA's position on both the constitutional and cost issues. *Whitman v. American*  
26 *Trucking Associations*, 531 U.S. 457, 464, 475-76. On the constitutional issue, the Court held  
27 that the statutory requirement that NAAQS be "requisite" to protect public health with an  
28 adequate margin of safety sufficiently guided EPA's discretion, affirming EPA's approach of  
29 setting standards that are neither more nor less stringent than necessary. The Supreme Court  
30 remanded the case to the Court of Appeals for resolution of any remaining issues that had not  
31 been addressed in that court's earlier rulings. *Id.* at 475-76. In March 2002, the Court of

1 Appeals rejected all remaining challenges to the standards, holding under the traditional standard  
2 of judicial review that EPA's PM<sub>2.5</sub> standards were reasonably supported by the administrative  
3 record and were not "arbitrary and capricious" *American Trucking Associations v. EPA*, 283 F.  
4 3d 355, 369-72 (D.C. Cir. 2002).

5 In October 1997, EPA published its plans for the third periodic review of the air quality  
6 criteria and NAAQS for PM (62 FR 55201, October 23, 1997), including the 1997 PM<sub>2.5</sub>  
7 standards and the 1987 PM<sub>10</sub> standards. After CASAC and public review of several drafts, EPA's  
8 National Center for Environmental Assessment finalized the Air Quality Criteria Document for  
9 Particulate Matter (henceforth, the "Criteria Document") in October 2004 (U.S. EPA, 2004).  
10 A second draft Staff Paper, based on the final Criteria Document, was released at the end of  
11 January 2005, and was reviewed by CASAC and the public at a meeting held in April 2005. The  
12 CASAC's advice and recommendations to the Administrator, based on its review of the second  
13 draft Staff Paper, were further discussed during a public teleconference held in May 2005 and  
14 were provided in a June 6, 2005 letter to the Administrator (Henderson, 2005a). The final Staff  
15 Paper, issued in June, 2005, took into account the advice and recommendations of CASAC and  
16 public comments received on the earlier drafts of this document. The Administrator  
17 subsequently received additional advice and recommendations from the CASAC, specifically on  
18 potential standards for thoracic coarse particles in a teleconference on August 11, 2005, and in a  
19 letter to the Administrator dated September 15, 2005 (Henderson, 2005b). The final Staff Paper  
20 was reissued in December 2005 to add CASAC's final letter as an attachment (U.S. EPA, 2005).

21 On December 20, 2005, EPA announced its proposed decision to revise the NAAQS for  
22 PM (71 FR 2620, January 17, 2006) (hereafter "proposal"). In the proposal, EPA identified  
23 proposed revisions, based on the air quality criteria for PM, and solicited public comments on  
24 alternative primary and secondary standards. EPA proposed to revise the level of the 24-hour  
25 PM<sub>2.5</sub> standard to 35 µg/m<sup>3</sup> to provide increased protection against health effects associated with  
26 short-term PM<sub>2.5</sub> exposures, including premature mortality and increased hospital admission and  
27 emergency room visits and to retain the level of the annual PM<sub>2.5</sub> standard at 15 µg/m<sup>3</sup>,  
28 continuing protection against health effects associated with long-term exposure including  
29 premature mortality and development of chronic respiratory disease. With regard to the primary  
30 standards for PM<sub>10</sub>, EPA proposed to revise the 24-hour PM<sub>10</sub> standard in part by establishing a  
31 new indicator for thoracic coarse particles (particles generally between 2.5 and 10 µm in

1 diameter, PM<sub>10-2.5</sub>), qualified so as to include any ambient mix of PM<sub>10-2.5</sub> that was dominated by  
2 resuspended dust from high density traffic on paved roads and PM generated by industrial  
3 sources and construction sources, and proposed to exclude any ambient mix of PM<sub>10-2.5</sub> that was  
4 dominated by rural windblown dust and soils and PM generated by agricultural and mining  
5 sources. The EPA proposed to set a PM<sub>10-2.5</sub> standard at a level of 70 µg/m<sup>3</sup> to continue to  
6 provide a level of protection against health effects associated with short-term exposure  
7 (including hospital admissions for cardiopulmonary diseases, increased respiratory symptoms  
8 and possibly premature mortality) generally equivalent to the level of protection provided by the  
9 existing 24-hour PM<sub>10</sub> standard. Also, EPA proposed to revoke, upon finalization of a primary  
10 24-hour standard for PM<sub>10-2.5</sub>, the 24-hour PM<sub>10</sub> standard as well as the annual PM<sub>10</sub> standard.  
11 EPA proposed to revise the secondary standards by making them identical to the suite of  
12 proposed primary standards for fine and coarse particles, providing protection against PM-related  
13 public welfare effects including visibility impairment, effects on vegetation and ecosystems, and  
14 materials damage and soiling. EPA also solicited comment on adding a new sub-daily PM<sub>2.5</sub>  
15 secondary standard to address visibility impairment in urban areas. CASAC provided additional  
16 advice to EPA in a letter to the Administrator requesting reconsideration of CASAC's  
17 recommendations for both the primary and secondary PM<sub>2.5</sub> standards as well as standards for  
18 thoracic coarse particles (Henderson, 2006a).

19 On September 21, 2006, EPA announced its final decisions to revise the primary and  
20 secondary NAAQS for PM to provide increased protection of public health and welfare,  
21 respectively (71 FR 61144, October 17, 2006). With regard to the primary and secondary  
22 standards for fine particles, EPA revised the level of the 24-hour PM<sub>2.5</sub> standard to 35 µg/m<sup>3</sup>,  
23 retained the level of the annual PM<sub>2.5</sub> annual standard at 15 µg/m<sup>3</sup>, and revised the form<sup>5</sup> of the  
24 annual PM<sub>2.5</sub> standard by narrowing the constraints on the optional use of spatial averaging.  
25 With regard to the primary and secondary standards for PM<sub>10</sub>, EPA retained the 24-hour PM<sub>10</sub>

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<sup>5</sup> When EPA sets NAAQS, it also must specify the air quality statistics that the Agency will use to determine whether an area is meeting the standards. These statistics are known as the "form of the standard" and are derived separately for each standard. The current forms for the PM<sub>2.5</sub> and PM<sub>10</sub> NAAQS are as follows:

**24-hour PM<sub>2.5</sub> standard** - 98th percentile of 24-hour PM<sub>2.5</sub> concentrations in a year, averaged over three years

**Annual PM<sub>2.5</sub> standard** - three-year average of the annual average PM<sub>2.5</sub> concentrations; revisions in 2006 limited the conditions under which some areas may average measurements from multiple community-oriented monitors to determine compliance (see 71 FR 61165-61167, October 17, 2006)

**24-hour PM<sub>10</sub> standard** – not to be exceeded more than once per year on average over a three year period

1 standard at  $150 \mu\text{g}/\text{m}^3$  and revoked the annual standard because available evidence generally did  
2 not suggest a link between long-term exposure to current ambient levels of coarse particles and  
3 health or welfare effects. Following the final decision, CASAC, in a letter to the Administrator,  
4 provided recommendations concerning the final PM NAAQS (Henderson, 2006b).

5 The revisions to the PM NAAQS also included a new reference method (Federal  
6 reference method or FRM) for the measurement of  $\text{PM}_{10-2.5}$  in the ambient air. Although the  
7 standards for thoracic coarse particles do not use a  $\text{PM}_{10-2.5}$  indicator, the new FRM for  $\text{PM}_{10-2.5}$   
8 will provide a basis for approving Federal Equivalent Methods (FEMs) and promote the  
9 gathering of scientific data to support future reviews of the PM NAAQS. One of the reasons for  
10 not finalizing a  $\text{PM}_{10-2.5}$  standard in 2006 was the limited body of evidence on health effects  
11 associated with thoracic coarse particles from studies that use  $\text{PM}_{10-2.5}$  measurements of ambient  
12 thoracic coarse particle concentrations. With an FRM, researchers will likely include  $\text{PM}_{10-2.5}$   
13 measurements of thoracic coarse particles in health studies either by directly using the FRM or  
14 by utilizing approved FEMs.

#### 15 **1.4 SCOPE OF THE CURRENT REVIEW**

16 In the last PM NAAQS review, EPA focused on particle mass and primarily  
17 distinguished between two categories of particle pollution based on size (i.e., fine- and thoracic  
18 coarse-fraction particles), and conducted parallel evaluations of the available scientific evidence  
19 relating to each category. The importance of specific PM components and sources was evaluated  
20 within the context of this basic size differentiation. In that review, it was determined that size-  
21 fractionated particle mass, rather than particle composition, remained the most appropriate  
22 approach for addressing ambient PM. Building upon the last review, EPA plans to continue to  
23 review the scientific evidence available based on particle size, considering fine and coarse-  
24 fraction particles separately. Within this basic structure, EPA will evaluate relevant scientific  
25 evidence on specific PM components and sources.

26 In considering what components of PM are relevant to the review of the primary PM  
27 NAAQS, EPA notes that the health effects associated with particulate species of nitrogen and  
28 sulfur oxides were considered within the context of the last PM NAAQS review. Building upon  
29 the last review, EPA plans to continue to include these particles in this review of the health  
30 effects of ambient particles. In addition, EPA has separate efforts under way to review the

1 current NO<sub>2</sub> and SO<sub>2</sub> primary NAAQS focusing on the gaseous species of nitrogen and sulfur  
2 oxides.<sup>6</sup>

3 In the last review of the suite of primary PM standards, EPA focused on evidence of  
4 health effects associated with daily and long-term (months to years) exposures to particles,  
5 specifically premature mortality, aggravation of respiratory and cardiovascular disease (as  
6 indicated by increased hospital admission and emergency department visits), changes in lung  
7 function and increased respiratory symptoms, as well as new evidence for more subtle indicators  
8 of cardiovascular health. In this review, EPA will integrate these previous findings with the  
9 results of new studies on these health endpoints and, to the extent data are available, on  
10 additional endpoints of concern (e.g., developmental, reproductive, systemic effects). Evidence  
11 of health effects associated with peak PM exposures (less than 24-hours) will also be considered.

12 Susceptible or vulnerable subpopulations that were considered to be at greater risk to  
13 effects associated with PM exposures in the last review included individuals with pre-existing  
14 heart and lung diseases, older adults, and children. In this review, EPA will integrate the  
15 previous understanding of sensitive subpopulations with new evidence on these and possibly  
16 additional sensitive subpopulations (e.g., fetuses, neonates).

17 In the last review of the suite of secondary standards, EPA focused on evaluating  
18 visibility impairment associated with aerosol compounds present in ambient air, selecting PM<sub>2.5</sub>  
19 as the appropriate indicator for the standard. Other welfare effects including effects on climate  
20 change processes, vegetation, and ecosystems as well as materials damage and soiling related to  
21 both fine and coarse particles were considered to a lesser extent. In this review, EPA will  
22 continue to focus the assessment of welfare effects on visibility-related impacts associated with  
23 fine particles. This review will include consideration of the impacts on visibility impairment  
24 related to the mixture of aerosol compounds in ambient air including nitrates and sulfates. In  
25 addition, drawing on the information in the ISA, EPA will again consider other welfare effects in  
26 this review, for example, climate-related effects and/or welfare effects associated with deposition  
27 of specific particles (e.g., ecotoxicity of heavy metals). In a separate effort, EPA has recently  
28 initiated a joint review of the nitrogen dioxide (NO<sub>2</sub>) and sulfur dioxide (SO<sub>2</sub>) secondary

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<sup>6</sup>Please see [http://www.epa.gov/ttn/naaqs/standards/nox/s\\_nox\\_index.html](http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_index.html) for more information on the review of the primary NO<sub>2</sub> NAAQS and [http://www.epa.gov/ttn/naaqs/standards/so2/s\\_so2\\_index.html](http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_index.html) for more information on the review of the primary SO<sub>2</sub> NAAQS.



1 NAAQS.<sup>7</sup> That review will consider gaseous and particulate species of NO<sub>x</sub> and SO<sub>x</sub> with  
2 respect to acidification effects on ecosystems and will focus on the ecosystem-related welfare  
3 effects that result from the deposition of these pollutants and transformation products in the gas-  
4 phase, rather than on the effects of particulate NO<sub>x</sub> and SO<sub>x</sub> that remain in the atmosphere.

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<sup>7</sup> Please see <http://www.epa.gov/ttn/naaqs/standards/no2so2sec/index.html> for more information on the NO<sub>x</sub>/SO<sub>x</sub> Secondary NAAQS review.

## 2 REVIEW SCHEDULE

Table 2-1 outlines the schedule under which the Agency will conduct this review. Consistent with this schedule, in June 2007, EPA's National Center for Environmental Assessment in Research Triangle Park, NC (NCEA-RTP) announced the initiation of the current periodic review of the air quality criteria for PM and the PM<sub>2.5</sub> and PM<sub>10</sub> NAAQS and issued a call for information in the Federal Register (72 FR 35462, June 28, 2007). Also, as an initial step in the new NAAQS review process described in Section 1.1 above, EPA invited a wide range of external experts as well as EPA staff, representing a variety of areas of expertise (e.g., epidemiology, human and animal toxicology, statistics, risk/exposure analysis, atmospheric science) to participate in two workshops: (1) Workshop to Discuss Policy-Relevant Science to Inform EPA's Integrated Plan for the Review of the Primary PM NAAQS (conducted July 11-13, 2007 in Research Triangle Park, NC) and (2) Workshop to Discuss Policy-Relevant Science to Inform EPA's Integrated Plan for the Review of the Secondary PM NAAQS (conducted July 16, 2007 in Chapel Hill, NC) (72 FR 34003 and 34005, June 20, 2007). These workshops provided an opportunity for the participants to broadly discuss the key policy issues around which EPA would structure the PM NAAQS review and to discuss the most meaningful new science that would be available to inform our understanding of these issues. Based in part on the workshop discussions, EPA has developed this draft integrated review plan outlining the schedule, the process, and the key policy-relevant science issues that will guide the evaluation of the air quality criteria for PM and the review of the primary and secondary PM NAAQS.

<b>Table 2-1. Proposed Schedule for Development of Revised PM Integrated Science Assessment (ISA) and Review of PM<sub>2.5</sub> and PM<sub>10</sub> NAAQS</b>		
<b>Stage of Review</b>	<b>Major Milestone</b>	<b>Draft Target Dates</b>
Integrated Plan	Literature Search	Ongoing
	Federal Register Call for Information	June 2007
	Workshops on Science/Policy Issues	July 2007
	Prepare Draft Integrated Review Plan	October 2007
	CASAC Consultation	November 2007
	Prepare Final Integrated Review Plan	December 2007
Science Assessment	Prepare First Draft ISA	August 2008
	CASAC/Public Review of First Draft ISA	October 2008
	Prepare Second Draft ISA	March 2009
	CASAC/Public Review of Second Draft ISA	May 2009
	Prepare Final ISA	September 2009
Risk/Exposure Assessments	Prepare Draft Scope and Methods Plan	September 2008
	CASAC Consultation on Scope and Methods Plan	October 2008
	Prepare First Draft Risk/Exposure Assessments	April 2009
	CASAC/Public Review of First Draft Risk/Exposure Assessments	May 2009
	Prepare Second Draft Risk/Exposure Assessments	November 2009
	CASAC/Public Review of Second Draft Risk/Exposure Assessments	January 2010
	Prepare Final Risk/Exposure Assessments	March 2010
Policy Assessment/ Rulemaking	Advance Notice of Proposed Rulemaking (ANPR)	June 2010
	CASAC Review/Public Comment on ANPR	August 2010
	Proposed Rulemaking	January 2011
	Final Rulemaking	October 2011

### 3 KEY POLICY-RELEVANT ISSUES

The key policy-relevant issues to be addressed in this review are presented below as a series of policy-relevant questions that will frame our approach to determining whether the current primary and secondary NAAQS for PM should be retained or revised. The ISA, risk/exposure assessment, and visibility and other welfare-related assessment to be conducted in this review will provide the basis for addressing these questions. The answers to these questions, and the resulting conclusions regarding the corresponding policy-relevant issues, will inform the policy assessment/rulemaking that will lead to the decision of whether to retain or revise the current 24-hour and annual primary and secondary standards for PM<sub>2.5</sub> and the 24-hour primary and secondary standards for PM<sub>10</sub>.

In the last PM NAAQS review, EPA focused on particle mass and primarily distinguished between two categories of particle pollution based on size (i.e., fine- and coarse-fraction particles), and conducted parallel evaluations of the available scientific evidence relating to each category. The importance of specific PM components and sources was evaluated within the context of this basic size differentiation. In this review, EPA will consider the extent to which new information has become available to assess and determine how particle pollution is defined. Specific characteristics to consider will include particle size/mass, composition, and sources/environments (e.g., urban and rural areas).

#### 3.1 ISSUES TO BE CONSIDERED IN THE CURRENT REVIEW OF THE PRIMARY PM NAAQS

The first step in reviewing the adequacy of the current primary PM standards is to consider whether the available body of scientific evidence, assessed in the ISA and addressed in the air quality and risk/exposure assessments, supports or calls into question the scientific conclusions reached in the last review regarding health effects related to exposure to fine and thoracic coarse particles in the ambient air. This evaluation of the available scientific evidence will focus on policy-relevant issues by addressing a series of questions including the following:

- Has new information altered the scientific support for the occurrence of health effects following short- and/or long-term exposure to levels of fine and thoracic coarse particles found in the ambient air?
- Has new information altered conclusions from previous reviews regarding the plausibility of adverse health effects associated with PM exposures?

- 1       ▪ What evidence is available from recent studies focused on specific components or  
2       sources of PM to inform our understanding of the nature of PM exposures that are linked  
3       to various health outcomes?
- 4       ▪ To what extent is key scientific evidence becoming available to improve our  
5       understanding of the health effects associated with various time periods of PM exposures,  
6       including not only daily and chronic (months to years) exposures, but also peak PM  
7       exposures (less than 24-hour)? To what extent is critical research becoming available  
8       that could improve our understanding of the relationship between various health  
9       endpoints and different lag periods (e.g., single day, multi-day distributed lags)?
- 10      ▪ What data are available to improve our understanding of spatial and/or temporal  
11      heterogeneity of exposures to PM and its components?
- 12      ▪ At what levels of PM exposure do health effects of concern occur? Is there evidence for  
13      the occurrence of adverse health effects at levels of PM lower than those observed  
14      previously? If so, at what levels and what are the important uncertainties associated with  
15      that evidence?
- 16      ▪ Do risk/exposure estimates suggest that exposures of concern for PM-induced health  
17      effects will occur with current ambient levels of PM or with levels that just meet the  
18      current standards? If so, are these risks/exposures of sufficient magnitude such that the  
19      health effects might reasonably be judged to be important from a public health  
20      perspective? What are the important uncertainties associated with these risk/exposure  
21      estimates?
- 22      ▪ To what extent is key evidence becoming available that could inform our understanding  
23      of subpopulations that are particularly sensitive to PM exposures? Specifically, is there  
24      new or emerging evidence on health effects beyond cardiovascular and respiratory  
25      endpoints (e.g., systemic effects, developmental effects) that suggest additional sensitive  
26      subpopulations should be given increased focus in this review (e.g., fetuses, neonates)?
- 27      ▪ To what extent have important uncertainties identified in the last review been reduced  
28      and/or have new uncertainties emerged?

29  
30       Drawing upon the evidence and analyses presented in the ISA and risk/exposure  
31      assessment, EPA will evaluate whether revisions to the current suite of primary PM standards

1 might be appropriate and, if so, how these standards might be revised. Specifically, EPA will  
2 evaluate how the scientific evidence informs decisions regarding the basic elements of the  
3 NAAQS: indicator, averaging time, level, and form. These elements will be considered  
4 collectively in evaluating the health protection afforded by the current or any alternative  
5 standards considered. Specific policy-relevant questions that will be addressed include:

- 6     ▪ Do the evidence, the air quality assessment, and the risk/exposure assessment provide  
7         support for considering different pollutant indicators for fine and thoracic coarse  
8         particles? Specifically, is there evidence to support continuing to maintain the basic mass  
9         size-fraction approach used in the last review or does the evidence support an alternative  
10        approach for defining particle pollution, including other size fractions, specific  
11        components, specific source-related mixtures, and/or indicators other than mass?
- 12    ▪ Do the evidence, the air quality assessment, and the risk/exposure assessment provide  
13        support for considering different averaging times?
- 14    ▪ What range of levels is supported by the evidence, the air quality assessment, and the  
15        risk/exposure assessments? What are the uncertainties and limitations in the evidence  
16        and the assessments?
- 17    ▪ What is the range of forms supported by the evidence, the air quality assessment, and the  
18        risk/exposure assessments? What are the uncertainties and limitations in the evidence  
19        and the assessments?

### 20 **3.2 ISSUES TO BE CONSIDERED IN THE CURRENT REVIEW OF THE** 21 **SECONDARY PM NAAQS**

22        The first step in reviewing the adequacy of the current secondary PM standards is to  
23        consider whether the available body of scientific evidence, assessed in the ISA and addressed in  
24        the air quality and visibility and other welfare-related effects assessment, supports or calls into  
25        question the scientific conclusions reached in the last review regarding visibility impairment and  
26        climate-related effects associated with ambient PM and other welfare-related effects associated  
27        with exposures to deposited fine and/or coarse particles. This evaluation of the available  
28        scientific evidence will focus on policy-relevant issues by addressing a series of questions  
29        including the following:

- 1       ▪ What new evidence is available on the relationship between PM mass/size fraction and/or  
2       specific PM components and visibility impairment and climate-related and other welfare  
3       effects?
- 4       ▪ To what extent has key scientific evidence now become available to improve our  
5       understanding of the nature and magnitude of visibility, climate, and ecosystem responses  
6       to PM and the variability associated with those responses (including ecosystem type,  
7       climatic conditions, environmental effects and interactions with other environmental  
8       factors and pollutants)?
- 9       ▪ At what levels of ambient PM do visibility impairment and/or environmental effects of  
10      concern occur? Is there evidence for the occurrence of adverse visibility and other  
11      welfare-related effects at levels of PM lower than those observed previously? If so, at  
12      what levels and what are the important uncertainties associated with the evidence?
- 13      ▪ Do the analyses suggest that PM-induced visibility impairment and/or other welfare-  
14      effects will occur with current ambient levels of PM or with levels that just meet the  
15      current standards? If so, are these effects of sufficient magnitude such that these effects  
16      might reasonably be judged to be important from a public welfare perspective? What are  
17      the uncertainties associated with these estimates?
- 18      ▪ To what extent have important uncertainties identified in the last review been reduced  
19      and/or have new uncertainties emerged?

20           Drawing upon the evidence and analyses presented in the ISA and visibility and other  
21 welfare-related assessments, EPA will evaluate whether revisions to the current suite of  
22 secondary PM standards might be appropriate and, if so, how these standards might be revised.  
23 Specifically, EPA will evaluate how the scientific evidence informs decisions regarding the  
24 basic elements of the NAAQS: indicator, averaging time, level, and form. These elements will  
25 be considered collectively in evaluating the welfare protection afforded by the current or any  
26 alternative standards considered. Specific policy-relevant questions that will be addressed  
27 include:

- 28      ▪ Do the evidence, the air quality assessment and the visibility and other welfare-related  
29      assessments provide support for considering different pollutant indicators or averaging  
30      times? What are the uncertainties and limitations in the evidence and the assessments?

- 1       ▪ What range of levels is supported by the evidence, the air quality assessments, and the  
2       visibility and other welfare-related assessments? What are the important uncertainties  
3       associated with that evidence?
- 4       ▪ What is the range of forms supported by the evidence, the air quality assessment, and the  
5       visibility and other welfare-related assessments? What are the uncertainties and  
6       limitations in the evidence and the assessments?



## 4 SCIENCE ASSESSMENT

### 4.1 SCOPE AND ORGANIZATION

The science assessment for PM will consist of the ISA and its supporting annexes. The ISA will critically evaluate and integrate the scientific information on exposure, health, and welfare effects associated with PM in ambient air. The annexes, which will summarize relevant studies, will provide a detailed basis for developing the ISA. The annexes will include scientific evidence in the discipline areas of epidemiology, toxicology, and dosimetry as well as human exposure and atmospheric science relevant to the review of the primary PM NAAQS. The annexes will also include scientific evidence related to welfare effects categories, including visibility impairment, effects on soils, animals, and vegetation related to or associated with deposition of particulate metals, and the relationship of PM to climate that are relevant to the review of the secondary PM NAAQS. The ISA will draw from this evidence and synthesize the current state of knowledge on the most relevant issues pertinent to the review of the NAAQS for PM. Information from other scientific fields will be integrated into the health and welfare effects evidence if it contributes to a better understanding of population exposure and/or risk or to a better understanding of the nature, sources, distribution, measurement, and/or concentrations of PM in ambient air. The ISA discussions will be designed to focus on the key policy-relevant questions described in Section 3 of this document.

The focus of the ISA will be on literature not included in the previous review of the air quality criteria for PM. Key findings and conclusions from the 2004 Air Quality Criteria Document (AQCD, U.S. EPA, 2004) for PM will be briefly summarized at the beginning of the ISA. Also included in the ISA will be information on studies included in the 2006 Provisional Assessment of Recent Studies on Particulate Matter (U.S. EPA, 2006a). This document presented findings of EPA's survey and provisional assessment of studies relevant to assessing the health effects of PM that were published too recently to be included in the 2004 PM AQCD.

The results of new studies will be integrated with previous findings. Important older studies will be more specifically discussed if they are open to reinterpretation in light of newer data. Generally, only information that has undergone scientific peer review and that has been published (or accepted for publication) in the open literature will be considered. Emphasis will

1 be placed on studies conducted at or near PM concentrations found in ambient air. However, in  
2 recognition of the fact that toxicologic studies do not necessarily reflect effects in the most  
3 sensitive populations, studies at higher exposure levels will be included when they provide  
4 information relevant to previously unreported effects, evidence of the potential mechanism for an  
5 observed effect, or information on exposure-response relationships.

## 6 **4.2 ASSESSMENT APPROACH**

### 7 **Introduction**

8 The EPA's National Center for Environmental Assessment in Research Triangle Park  
9 (NCEA-RTP) is responsible for preparing the ISA and its annexes for PM. Expert authors  
10 include EPA staff with an extensive base of knowledge in their respective fields and extramural  
11 scientists contracted to the EPA.

### 12 **Literature Search**

13 The NCEA-RTP will use a systematic approach to identify relevant studies for  
14 consideration. A Federal Register notice (72 FR 35462, June 28, 2007) was published to  
15 announce the initiation of this review and request information from the public. An initial  
16 publication base will be established by searching MEDLINE, Toxfile, Pascal, Biosis, and  
17 Embase using as key words the terms particulate, particle, PM, PM<sub>2.5</sub>, PM<sub>10</sub>, coarse, fine,  
18 ultrafine, carbon black, ROFA, oil fly ash, CAPS, diesel, metals associated with PM, elemental  
19 carbon, organic carbon, nitrate, sulfate, traffic, visibility, light extinction, and soot. As  
20 appropriate, the search strategy will be reexamined and modified to enhance identification of  
21 pertinent published papers. Additional papers will be identified for inclusion in the publication  
22 base in several ways. First, EPA staff will review pre-publication tables of contents for journals  
23 in which relevant papers may be published. Second, expert Section authors will be charged with  
24 independently identifying relevant literature. Finally, additional publications that may be  
25 pertinent will be identified by both CASAC and the public during the external review process.  
26 The studies identified will include research published or accepted for publication by a date  
27 determined to be as inclusive as possible given the relevant target dates in the PM NAAQS  
28 review schedule. Some additional studies, published after that date, may also be included if they  
29 provide new information that impacts one or more key scientific issues. The combination of

1 these approaches should produce the comprehensive collection of pertinent studies needed to  
2 form the basis of the ISA.

### 3 **Criteria for Study Selection**

4 In selecting epidemiologic studies for the present assessment, EPA will consider whether  
5 a given study contains information on (1) short- or long-term exposures at or near ambient levels  
6 of PM; (2) health effects of specific PM components or mixtures related to PM sources (e.g.,  
7 motor vehicle emissions, combustion-related particles); (3) health endpoints that repeat or extend  
8 findings from earlier assessments as well as those not previously extensively researched; (4)  
9 populations that are susceptible and/or vulnerable to PM exposures<sup>8</sup>; (5) multiple pollutant  
10 analyses and other approaches to address issues related to potential interactions (e.g., are there  
11 synergistic effects of PM with other pollutants), confounding (e.g., is PM associated with health  
12 endpoints independent of copollutants, and effect modification (e.g., is the effect of PM on health  
13 endpoints modified by the presence of copollutants); and/or (6) important methodological issues  
14 (e.g., lag of effects, model specifications, thresholds, mortality displacement) related to PM  
15 exposure effects. Among the epidemiologic studies, particular emphasis will be focused on  
16 those relevant to standard setting in the United States. Specifically, studies conducted in the U.S.  
17 or Canada will be generally accorded more emphasis than those from other geographic regions,  
18 as the potential impacts of different health care systems and the underlying health status of  
19 populations need to be accounted for in the assessment. In addition, emphasis will be placed on  
20 discussion of (1) new, multi-city studies that employ standardized methodological analyses for  
21 evaluating PM effects, provide overall estimates for effects based on combined analyses of  
22 information pooled across cities, and examine results for consistency across cities; (2) new  
23 studies that provide quantitative effect estimates for populations of interest; and (3) studies that  
24 regard PM as a component of a complex mixture of air pollutants and thus give consideration to  
25 the levels of other copollutants, correlate PM levels with these copollutants, and include  
26 multipollutant analyses in the study design.

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<sup>8</sup> *Susceptibility* refers to innate (e.g., genetic or developmental) or acquired (e.g., age, disease, or smoking) factors that make individuals more likely to experience effects with exposure to PM. *Vulnerability* refers to PM-related effects due to factors including socioeconomic status (e.g., reduced access to health care) or particularly elevated exposure levels.

1 A set of explicit criteria will also be used to select toxicologic studies for the present  
2 assessment. The selection of research evaluating controlled exposures to laboratory animals will  
3 focus primarily on those studies conducted at or near ambient PM concentrations and those  
4 studies that approximate expected human dose conditions in terms of concentration, size  
5 distributions, and duration, which will depend on the toxicokinetics and biological sensitivity of  
6 the particular laboratory animals examined. For example, rodents typically require PM  
7 concentrations greater than ambient to mimic retention of particles in the lung in terms of mass  
8 or surface area per lung area equivalent to humans. Additionally, animal researchers must limit  
9 the number of animals used in experimental protocols, and thus must use higher concentrations  
10 to observe effects. Thus, animal toxicology experiments, by necessity, are carried out at greater-  
11 than-ambient concentrations. In discussing the mechanisms of PM toxicity, studies conducted  
12 under atmospherically-relevant conditions will be emphasized, but studies at higher  
13 concentrations also will be considered when these studies provide useful information to inform  
14 our understanding of species-to-species differences and potential differences in sensitivity  
15 between healthy individuals and especially susceptible human populations. Another  
16 consideration in evaluating PM studies using animals is the use of inhalation vs. instillation  
17 exposures. All else being equal, those studies using inhalation exposures will be given greater  
18 emphasis than those using instillation exposures because inhalation studies better simulate  
19 human exposure to PM. However, instillation studies must be used when assessing the effects of  
20 thoracic coarse particles in rodents.

21 For research evaluating controlled human exposures to PM, emphasis will be placed on  
22 studies that: (1) investigate effects both on healthy populations and on potentially susceptible  
23 populations such as asthmatics or diabetics, particularly studies where subjects serve as their own  
24 control to compare responses following PM exposure and sham exposure and where responses in  
25 susceptible individuals are compared with those in age-matched healthy controls; (2) address  
26 issues such as dose-response or time-course of responses; (3) investigate exposure to PM  
27 separately and in combination with other pollutants such as O<sub>3</sub> and NO<sub>2</sub>; (4) include control  
28 exposures to filtered air; and (5) have sufficient sample size to assess findings adequately.

29 For evaluation of welfare effects research, emphasis shall be placed on (1) recent U.S.  
30 studies; (2) studies that evaluate effects at realistic ambient levels; and (3) studies that consider

1 PM as a component of a complex mixture of air pollutants. Studies conducted in other countries  
2 that contribute significantly to the knowledge base will be included in the assessment.

3 These criteria provide benchmarks for evaluating various studies and for focusing on the  
4 highest quality studies in assessing the body of health and welfare effects evidence. Detailed  
5 critical analysis of all PM health and welfare effects studies, especially in relation to the above  
6 considerations, is beyond the scope of this document. Of most relevance for evaluation of  
7 studies is whether they provide useful qualitative or quantitative information on exposure-effect  
8 or exposure-response relationships for effects associated with current ambient air concentrations  
9 of PM likely to be encountered in the United States.

## 10 **Quality Assurance**

11 Important quality assurance measures will be incorporated from the start of the current  
12 PM review. EPA uses an NCEA-RTP Plan for Information Search which details an approach to  
13 gathering the scientific information, usually found in peer-reviewed journal articles, books, and  
14 reports. Additionally, NCEA has Data Quality Objectives which identify inputs to the science  
15 assessment and provide quality assurance (QA) instruction for researchers citing secondary  
16 information.

## 17 **Content and Organization of the ISA**

18 The organization of the ISA for PM will be consistent with that used in the recent draft  
19 ISAs for Nitrogen Oxides and Sulfur Oxides (U.S. EPA 2007 a, b). The ISA will contain  
20 information relevant to considering whether it is appropriate to retain or revise the current  
21 standards. Taking into consideration the broad policy-relevant questions outlined in Section 3,  
22 the policy-relevant questions that will guide development of the ISA are related to two  
23 overarching issues. The first issue is whether new evidence reinforces or calls into question the  
24 scientific evidence presented and evaluated in the last PM NAAQS review. The second issue is  
25 whether uncertainties from the last review have been addressed and/or whether new uncertainties  
26 have emerged. Specific questions related to the review of the scientific literature for PM that  
27 stem from these issues will guide the content of the ISA. These questions were derived from the  
28 previous review of the PM NAAQS, as well as from discussions of new scientific evidence that  
29 occurred at two recent EPA workshops as outlined in Section 2 above. These questions are listed  
30 below by topic area.

1 **Source to Dose**

2 Air Quality and Atmospheric Chemistry: The ISA will present and evaluate data related to  
3 ambient concentrations of PM and its components; sources leading to the presence of PM in the  
4 atmosphere; and chemical reactions that determine the formation, transformation, and lifetime of  
5 PM in the atmosphere.

- 6       ▪ The ISA will evaluate studies of commercial samplers to determine whether they  
7       meet size selection performance standards. Specifically, what are the strengths and  
8       weaknesses of various methods for measuring PM? To what extent are these methods  
9       subject to interference from gas-phase pollutants or other gas- or aerosol-phase  
10      substances? Are new research methods available to understand the spatial and  
11      temporal distribution of different sizes and/or components of PM?
- 12      ▪ Based on recent air quality and emissions data, what are the current emissions and  
13      ambient concentrations of PM? What spatial and temporal patterns can be seen in the  
14      air quality data for PM? What new information is available on PM components (both  
15      primary and secondary particles) and mixtures of particles found in various regions of  
16      the country? How do particles in urban areas differ from those emitted or formed in  
17      rural areas?
- 18      ▪ Using air quality and emissions data on PM and precursor gases, together with  
19      atmospheric chemical-transport models, what are the likely policy-relevant  
20      background<sup>9</sup> concentrations of PM?
- 21      ▪ Because the regulatory ambient monitoring networks typically provide PM  
22      concentrations only once in every three or six days, are there other techniques that  
23      can augment ambient monitoring data to define better the range of concentrations and  
24      the spatial and temporal variability of PM over the U.S.? How useful are satellite  
25      retrievals and three-dimensional chemical transport models for understanding  
26      processes and spatial and temporal variations? Can satellite data be used on a regular  
27      basis to improve the characterization of PM emissions?

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<sup>9</sup> "Policy-relevant background" has been defined as the PM concentrations that would be observed in the U.S. in the absence of anthropogenic emissions of directly emitted PM particles and PM precursors (e.g., VOC, NO<sub>x</sub>, and SO<sub>x</sub>) in the U.S., Canada, and Mexico.

- 1       ▪ The ISA will also evaluate new information on specific PM components that merit  
2 attention including information on the spatial and temporal heterogeneity of PM  
3 components. Participants from the July 2007 Primary PM NAAQS workshop  
4 identified elemental carbon, organics, nickel, vanadium, sulfates, and products of  
5 photochemically oxidized organics as PM components that should be given greater  
6 attention in this review.
  
- 7       ▪ The ISA will assess new evidence on the characterization of particles from various  
8 sources, including primary and secondary particles, and the methods used to  
9 characterize particle sources. The ISA will discuss the utility of source  
10 apportionment modeling techniques in determining exposure surrogates for  
11 epidemiology.

12 Human Exposure: The ISA will evaluate the factors that influence exposure to PM and the  
13 uncertainties associated with extrapolation from ambient concentrations to personal exposures to  
14 PM of ambient origin, particularly in the context of interpreting results from epidemiologic  
15 studies. The issues of uncertainty differ by the exposure period of interest. Short-term exposure  
16 studies (e.g., population-level studies using time-series analyses, field/panel studies) rely on  
17 temporal variation in exposure while long-term exposure studies (e.g., longitudinal cohort  
18 studies) rely on spatial variability of exposure. The ISA will consider the available information  
19 on differential exposures to fine and coarse particles and particle characteristics such as chemical  
20 composition, size, surface area, and source.

- 21       ▪ Are new data available that classify PM exposure according to PM characteristics  
22 such as chemical constituents, size fraction, surface area, and source?
  
- 23       ▪ What new data are available on the relationship between exposures to PM  
24 components, size fractions, and sources? What data exist on relationships between  
25 PM exposure and exposure to gaseous co-pollutants?
  
- 26       ▪ What are the uncertainties when extrapolating between stationary PM monitoring  
27 instruments and personal exposure to PM of ambient origin, especially for susceptible  
28 subpopulations? Issues include measurement error in outdoor ambient monitors, the  
29 use of centralized monitors for estimating community concentrations, and the use of  
30 centralized monitors as a surrogate for personal exposure to PM of ambient origin.

- 1           ▪ What do measurements of ambient concentrations of PM represent? To what extent  
2           do they provide an estimate of ambient exposures for health studies, an indicator of  
3           personal exposure to PM, and/or an indicator of exposure to other pollutants or  
4           pollutant mixtures?
- 5           ▪ What data are available to interpret peak, short-term, and long-term PM exposures?  
6           This includes such information as air exchange rates, indoor sources, distance to  
7           highways, and methods for measuring personal exposures to ambient PM. Is this  
8           information available classified by PM characteristic (e.g., size, chemical  
9           composition)?
- 10          ▪ How do modeled predictions of PM concentrations compare with monitoring results?  
11          Do quality assurance (QA) checks suggest that modeling is accurate? How do the  
12          models perform at the tails of the distribution, in high concentrations areas and near  
13          roadways?

#### 14   **Health Effects**

15           The ISA will evaluate the literature related to cardiovascular, respiratory, and other health  
16           effects associated with short and/or long term exposures to PM. This will include evaluation of  
17           mortality and morbidity effects. Other health effects that may be evaluated include reproductive,  
18           developmental, and neurological outcomes. Health effects that occur following short- and/or  
19           long-term exposures to PM will be evaluated in epidemiologic, human clinical, and toxicologic  
20           studies.

21           For a given type of health outcome, the ISA will evaluate the strength, robustness and  
22           consistency of the findings from the different disciplines. The health findings will be further  
23           integrated, using the toxicologic and human clinical studies to assess biologic plausibility and  
24           mechanistic evidence for the epidemiology findings. A key focus of the integration of health  
25           evidence will be on the attribution of health effects to exposure to different size classes,  
26           components or characteristics of PM. Thus, the integrative synthesis of coherence and  
27           plausibility in the health evidence for effects (e.g., respiratory morbidity with short-term  
28           exposure) will focus on findings for various PM indices, to the extent that information is  
29           available. Efforts will be directed at identifying the lower levels at which effects are observed  
30           and at determining concentration-response relationships for various PM sizes and components.



1 The ISA will evaluate the scientific evidence on the occurrence of health effects from long-term  
2 or short-term exposure to PM at ambient levels that are lower than previously observed. The  
3 ISA will also assess the evidence for uncertainties related to these associations and information  
4 on the public health impacts related to ambient PM exposure. The evaluation will also focus on  
5 which exposure time windows are most strongly associated with effects, for both short-term and  
6 long-term exposures.

7 Short-Term Exposure:

- 8       ▪ What new evidence is available on associations between PM and mortality (total,  
9       respiratory or cardiovascular)?
- 10       ▪ How do results of recent studies expand current understanding of the relationship  
11       between acute exposure to PM and respiratory effects, such as lung function changes,  
12       lung inflammation, and host defense against infectious disease? What new evidence is  
13       available on the potential clinical relevance of these effects?
- 14       ▪ To what extent does new evidence from studies of hospital admissions or emergency  
15       department visits support previous findings regarding respiratory effects of PM? Is  
16       there evidence of coherence and plausibility for effects of different PM sizes or  
17       characteristics on the respiratory system?
- 18       ▪ What new evidence is available on PM-related effects on the cardiovascular system?  
19       Which electrocardiogram changes may be indicative of an adverse response to PM  
20       and which populations may be particularly susceptible to these effects? What do  
21       studies of heart rate variability tell us? Do these effects appear to be reversible and to  
22       what extent? How does PM affect vascular and endothelial function and through  
23       which pathways? The ISA will evaluate evidence from studies of hospitalization or  
24       emergency department visits for cardiovascular diseases, and the extent to which  
25       there is evidence of coherence or plausibility for effects of different PM sizes or  
26       characteristics on the cardiovascular system.
- 27       ▪ To what extent does exposure to PM contribute to health effects in the renal, hepatic,  
28       nervous, or other systems?

- 1           ▪ What is the nature of health effects in persons exposed to multipollutant mixtures that
- 2            contain PM in comparison to exposure to PM alone?
- 3           ▪ What biomarkers of early effect may be used in the assessments?

4 Long-Term Exposure:

- 5           ▪ How do results of recent studies expand current understanding of the relationships
- 6            between acute, repeated exposure to PM and lung function or lung function
- 7            development?
- 8           ▪ Can long-term exposures to PM result in chronic effects manifested as permanent
- 9            lung tissue damage, reduction in baseline lung function, or impaired lung function
- 10           development? To what extent does long-term PM exposure promote development of
- 11           asthma or chronic lung or cardiovascular disease? What is the relationship between
- 12           long-term PM exposure and shortening of human life span via promotion of such
- 13           diseases?
- 14           ▪ To what extent does the evidence indicate that long-term exposure to PM can increase
- 15           the incidence of cancer, or have mutagenic or genotoxic effects? How does PM
- 16           affect the developing fetus or infant?
- 17           ▪ What new studies are investigating measures of cardiovascular disease development
- 18           with chronic PM exposure? What evidence exists that demonstrates a link between
- 19           long-term PM exposure and atherosclerosis development or progression? Can long-
- 20           term exposure to PM result in chronic effects manifested as permanent cardiovascular
- 21           tissue damage or reductions in baseline cardiac function? What is the role of
- 22           systemic inflammation in initiating these effects?
- 23           ▪ The ISA will also assess the evidence from studies linking long-term exposure to PM
- 24           with mortality from cardiovascular and respiratory diseases or cancer.

25 Causality: The ISA will evaluate the evidence for and against a causal relationship between

26 observed health outcomes and PM exposures, focusing on different size classes, components

27 and/ or characteristics of PM, to the extent possible. Biologic plausibility and coherence of the

28 evidence will be key considerations in drawing conclusions about causality. The ISA will place

29 emphasis on epidemiologic studies conducted at or near typical ambient levels, except regarding

1 evidence of biological plausibility and mechanisms, as these may only be observable in animal  
2 or human exposure study populations at higher levels than they might be observed in susceptible  
3 human populations. The ISA will also assess information available from “intervention” studies  
4 regarding the health impacts of decreases in ambient levels of PM that is relevant to the  
5 evaluation of causality in PM-health outcome relationships.

6 Uncertainties: The ISA will evaluate uncertainty in the scientific data, particularly in relation to  
7 observed epidemiologic findings.

- 8       ▪ How does confounding by coexposure to other pollutants (e.g., O<sub>3</sub>, NO<sub>2</sub>, SO<sub>2</sub>, and  
9       CO) and meteorological factors influence the uncertainty of the evidence base for  
10      both short- and long-term PM exposures?
- 11      ▪ To what extent are the observed health effects associations attributable to PM versus  
12      the pollutant mixtures that PM may be representing? For example, what is the  
13      possibility that PM ambient concentrations may serve as a surrogate for personal  
14      exposure to mixtures or sources, such as motor vehicle exhaust?
- 15      ▪ What are the uncertainties due to other confounding or effect modification factors in  
16      epidemiologic studies (e.g., demographic and lifestyle attributes, socioeconomic  
17      status, genetic susceptibility factors, occupational exposure, and medical care)?
- 18      ▪ What are the shapes of the concentration-response models (e.g., linear vs. threshold  
19      models) and how do they influence public health impacts?
- 20      ▪ What uncertainties surround the evidence for long-term effects such as life shortening  
21      and development/progression of disease?
- 22      ▪ How do the findings of the available studies improve our understanding of exposure  
23      error? What evidence is newly available on the uncertainties related to statistical  
24      model specification and how can it be used to assess the influence of these  
25      uncertainties on the outcome of epidemiologic studies?

26 Biological Mechanisms of Action: The ISA will evaluate the data examining mechanisms for  
27 the health outcomes associated with exposure to PM.

- 28      ▪ Is there new information related to the pathways and biological mechanism(s) of  
29      action for PM of different size classes or characteristics?

- 1       ▪ What are the potential mechanisms of response to PM, with a focus on  
2       physical-chemical particle characteristics, response pathway(s), oxidative stress, and  
3       exposure-dose-response relationships?
- 4       ▪ What are the inherent interspecies differences in sensitivity to PM and in PM  
5       dosimetry in different regions of the respiratory tract? How does dosimetry differ  
6       based upon particle size?
- 7       ▪ What are the interspecies differences in basic mechanisms of lung injury and repair  
8       and cardiovascular responses?
- 9       ▪ What PM reaction products can be found in the respiratory tract cells, tissues, or  
10      fluids as biomarkers of PM exposure?
- 11      ▪ Are there interactions between PM components that increase bioavailability, such as  
12      sulfate increasing the bioavailability or activity of iron or other transition metals?
- 13      ▪ What are the mechanisms and time-courses of PM-induced cellular and tissue injury,  
14      repair, and remodeling?
- 15      ▪ Which PM-induced health effects are sufficiently characterized to be quantitatively  
16      compared across species?

17 Susceptible and Vulnerable Populations<sup>10</sup>: The ISA will examine health outcome data to identify  
18 specific groups that are more susceptible and/or vulnerable to the adverse effects of PM exposure  
19 than normal healthy adults (e.g., patients with COPD, children, and asthmatics). The host and  
20 environmental factors that are responsible for differential susceptibility to PM will be  
21 investigated.

- 22      ▪ What do controlled human exposure, animal toxicologic, and epidemiologic studies  
23      indicate regarding the relationship between acute exposures to PM and health effects  
24      of concern in healthy individuals and in those individuals with preexisting diseases  
25      (e.g., asthma, COPD, cardiovascular diseases)? What other medical conditions (e.g.,

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<sup>10</sup> *Susceptibility* refers to innate (e.g., genetic or developmental) or acquired (e.g., age, disease, or smoking) factors that make individuals more likely to experience effects with exposure to PM. *Vulnerability* refers to PM-related effects due to factors including socioeconomic status (e.g., reduced access to health care) or particularly elevated exposure levels.

1 diabetes, metabolic syndrome) are identified as increasing susceptibility to PM  
2 effects? What are the pathways and mechanisms through which PM may be acting  
3 for these groups? What is the nature and time-course of the development of effects in  
4 healthy persons and in persons with pre-existing disease (e.g., asthma, heart disease)?

- 5 ■ The ISA will assess new evidence on the extent to which children and older adults are  
6 more sensitive than the general population to effects from PM exposure?
- 7 ■ The ISA will evaluate the extent to which susceptibility to the effects of short-term  
8 PM exposure is associated with long-term PM susceptibility.
- 9 ■ What evidence is available regarding susceptibility of other subgroups, such as those  
10 based on gender or on genetic makeup, on PM-induced responses?
- 11 ■ What host and environmental factors (e.g., demographic, socioeconomic, and genetic)  
12 are associated with susceptibility and/or vulnerability to short- and long-term  
13 exposure to PM?
- 14 ■ New evidence will be evaluated regarding population groups with potentially greater  
15 vulnerability to effects of PM, such as those populations living near roads or in other  
16 areas with increased exposures.
- 17 ■ What information is available on exposure of sensitive and vulnerable populations to  
18 PM and its components?

19 Public Health Impact: The ISA will present concepts related to the potential for defining adverse  
20 health effects. To accomplish this, the implications for public health of different health effects  
21 will be discussed. This will include, as available, estimates of the numbers of people in specific  
22 at-risk populations groups (e.g., asthmatics, diabetics, older adults, children).

### 23 **Ecological and Welfare Effects**

24 Visibility: The ISA will summarize long-known information needed for placing current  
25 information in context. Previous evaluations have indicated that anthropogenic sulfate and  
26 nitrate particles are responsible for most of the regional haze in the eastern U.S. while the largest  
27 haze contributors in the West are anthropogenic nitrates and organics, either directly emitted or  
28 formed secondarily from other emissions. Additional sources of regional haze (e.g., dust, smoke,

1 sea salt) have anthropogenic, biogenic, and geogenic sources that vary in strength and  
2 significance by region. The ISA will evaluate newly available evidence, summarizing the recent  
3 important policy-relevant findings and will include sections for aerosol/optical characteristics,  
4 spatial/temporal trends, and causes of haze.

- 5       ▪ The ISA will present the relationship between visibility impacts and PM and will  
6       include definitions and metrics and algorithms to estimate haze from PM species  
7       levels.
- 8       ▪ The ISA will include a section on aerosol/optical characteristics that presents details  
9       of the size-resolved chemistry, transformation relationships and effects, and the  
10      algorithms used to estimate haze from particulate data taken in the regulatory  
11      measurement networks.
- 12      ▪ Other findings to be included in the ISA will be spatial patterns (e.g., the Midwest  
13      nitrate bulge in the U.S. and enhancement of sulfate concentrations in the eastern  
14      U.S.), urban excess above remote-area background, seasonal patterns, and multiyear  
15      trends, including descriptions of the roles of emissions changes and annual  
16      meteorology in helping determine those trends.
- 17      ▪ The ISA will discuss results of valuation studies that evaluate the extent to which air  
18      pollution-related visibility impairment may be considered to be adverse.

19  
20 Non-nutrient Ecosystem and Environmental Effects. Discussions will include issues of non-  
21 nutrient (N and S) particle chemistry/composition (e.g., cations, trace metals, semi-volatile  
22 organics); associated size fraction, and magnitude and rates of wet and dry deposition across the  
23 landscape. Both direct and indirect secondary welfare effects will be discussed in the ISA,  
24 including effects on vegetation, soils, waters and wildlife (e.g., bioaccumulation) as described in  
25 the phytotoxicology and ecotoxicology literature (focusing on copper, mercury, other trace  
26 metals). Soiling and materials damage will also be discussed. Nutrient N and S ecosystem  
27 effects will be addressed in the concurrent review of NO<sub>2</sub> and SO<sub>2</sub> secondary NAAQS.<sup>11</sup>  
28

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<sup>11</sup> Please see <http://www.epa.gov/ttn/naaqs/standards/no2so2sec/index.html> for more information on the NO<sub>2</sub>/SO<sub>2</sub> Secondary NAAQS review.

1 Effects of PM on Climate: The ISA will present information on temperature effects related to  
2 the various components of PM. Also addressed will be aerosol size/effect dependencies (e.g.,  
3 cloud formation and precipitation) and aerosol constituent/effect dependencies (e.g., black  
4 carbon vs. SO<sub>4</sub>).

5  
6 Effects of Climate on PM: The ISA will review information on the role of future predicted  
7 climate change in altering the emissions, transport and transformation, and fate of PM in the U.S.  
8 Additionally, information on the feedbacks to climate from primary and secondary PM in the  
9 U.S. will be collected and assessed.

## 10 **Outline and Annexes**

11 In addition to these major research areas and specific questions pertaining to each area, a  
12 broader question is how to organize this complex information. A draft outline is attached in  
13 Appendix B which details a high-level organizational strategy for the ISA.

14 The ISA will be supplemented by a series of annexes, which will be focused on  
15 accomplishing two goals. The first goal will be to identify scientific research that is relevant to  
16 informing key policy-relevant issues. The second goal will be to produce a base of evidence  
17 containing all of the publications relevant to the PM review. The annexes will provide  
18 information on (1) the chemistry, physics, sources, emissions, and measurement of PM; (2)  
19 environmental concentrations and human exposure to PM; (3) dosimetry; (4) toxicologic studies  
20 of PM health effects in laboratory animals and *in vitro* systems; (5) human clinical studies  
21 examining health effects following controlled exposure to PM; (6) epidemiologic studies of  
22 health effects from short- and long-term exposure to PM; (7) environmental studies on visibility,  
23 material damage, and ecosystem stress; and (8) climate change related to PM. More detailed  
24 information on various methods and results for the health and environmental studies will be  
25 summarized in tabular form in the annexes. These tables will generally be organized to include  
26 information about (1) concentrations, size fractions and components of PM and related averaging  
27 times; (2) description of study methods used; (3) results and comments; and (4) quantitative  
28 outcomes for PM measures. Additionally, annexes will contain background material on  
29 legislative requirements, the NAAQS review process, and the history of earlier PM reviews.

30

1 **4.3 SCIENTIFIC AND PUBLIC REVIEW**

2 Drafts of the ISA will be reviewed by the CASAC PM Review Panel and made available  
3 for public comment. The annexes to the ISA will also be made available to CASAC in order to  
4 assist with their review; however, the panel will not be specifically charged with reviewing the  
5 annexes. The CASAC PM Review Panel will review the first draft ISA and discuss their  
6 comments in a public meeting announced in the Federal Register. Based on CASAC’s past  
7 practice, EPA anticipates that key CASAC advice and recommendations for revision of the first  
8 draft ISA will be summarized by the CASAC Chair in a letter to the EPA Administrator. In  
9 revising the first draft ISA, EPA will take into account any such recommendations. EPA will  
10 also consider comments received from CASAC or from the public at the meeting itself and any  
11 written public comments. EPA will prepare a second draft ISA for CASAC review and public  
12 comment. The CASAC PM Review Panel will review the second draft ISA and discuss their  
13 comments in a public meeting announced in the Federal Register. Again, based on CASAC’s  
14 past practice, EPA anticipates that key CASAC advice and recommendations for revision of the  
15 second draft ISA will be summarized by the CASAC Chair in a letter to the EPA Administrator.  
16 In finalizing the ISA, EPA will take into account any such recommendations. EPA will also  
17 consider comments received from CASAC or from the public at the meeting itself and any  
18 written public comments. After appropriate revision, the final document will be made publicly  
19 available on an EPA website and in hard copy. A notice announcing the availability of the final  
20 ISA will be published in the Federal Register. In addition, the final ISA will be placed in the  
21 rulemaking docket.



# 5 HUMAN HEALTH ASSESSMENT

## 5.1 OVERVIEW

Characterizing health risks for the current review of the primary NAAQS for PM will include conducting air quality analyses to support quantitative risk and/or exposure assessments in specific locations as well as putting the results into a broader public health perspective. These assessments will be designed to estimate human exposures and to characterize the potential health risks that are associated with current ambient levels, with ambient levels simulated to just meet the current standards, and with ambient levels simulated to just meet alternative standards that may be considered. As part of such analyses, explicit and, where possible, quantitative characterizations of the uncertainties associated with the air quality analyses, as well as risk and exposure estimates will be developed. In addition, information on baseline incidence rates for specific health effects endpoints will be considered in the analyses.

The major components of the risk characterization (e.g., air quality analyses, quantitative exposure assessment, quantitative health risk assessment, broad health risk characterization) are outlined below and will be described in greater detail in a Scope and Methods Plan. Preparation of this detailed plan is underway and coincides with the development of the first draft ISA to facilitate the integration of policy-relevant science into both documents. In particular, the availability of air quality and concentration-response data will impact the type of risk and exposure assessments that will be developed.

An important issue associated with conducting human health assessments is the characterization of uncertainty and variability. *Uncertainty* refers to the lack of knowledge regarding both the actual values of model input variables (parameter uncertainty) and the physical systems or relationships (model uncertainty – e.g., the shapes of concentration-response relationships). *Variability* refers to the heterogeneity in a population of variable of interest that is inherent and cannot be reduced through further research.

## 5.2 OVERVIEW OF HEALTH RISK ASSESSMENT FROM PRIOR REVIEW

In the last PM NAAQS review, EPA conducted a quantitative health risk assessment for selected health endpoints to provide additional information and insights that could help inform

1 decisions on the standards. The limitations of such an assessment were clearly articulated.<sup>12</sup>  
2 EPA did not conduct an exposure assessment for that review. The approach used to develop  
3 quantitative risk estimates associated with exposures to PM<sub>2.5</sub> was built upon the more limited  
4 risk assessment conducted during the review completed in 1997. The expanded and updated  
5 assessment conducted in the review completed in 2006 included estimates of risks of mortality  
6 (total non-accidental, cardiovascular, and respiratory), morbidity (hospital admissions for  
7 cardiovascular and respiratory causes), and respiratory symptoms (not requiring hospitalization)  
8 associated with recent short-term (daily) ambient PM<sub>2.5</sub> levels and risks of total,  
9 cardiopulmonary, and lung cancer mortality associated with long-term exposure to PM<sub>2.5</sub> in a  
10 number of example urban areas.<sup>13</sup>

11 The EPA recognized that there were many sources of uncertainty and variability inherent  
12 in the inputs to this assessment and that there was a high degree of uncertainty in the resulting  
13 PM<sub>2.5</sub> risk estimates. Such uncertainties generally related to a lack of clear understanding of a  
14 number of important factors, including, for example, the shape of concentration-response  
15 functions, particularly when effect thresholds could neither be discerned nor determined not to  
16 exist; issues related to selection of appropriate statistical models for the analysis of the  
17 epidemiologic data; the role of potentially confounding and modifying factors in the  
18 concentration-response relationships; issues related to simulating how PM<sub>2.5</sub> air quality  
19 distributions would likely change in any given area upon meeting a particular standard, since  
20 strategies to reduce emissions had not yet been defined; and whether there would be differential  
21 reductions in the many components within PM<sub>2.5</sub> and, if so, whether this would result in  
22 differential reductions in risk. While some of these uncertainties were addressed quantitatively  
23 in the form of estimated confidence ranges around central risk estimates, other uncertainties and  
24 the variability in key inputs were not reflected in these confidence ranges, but rather were  
25 addressed through separate sensitivity analyses or characterized qualitatively (U.S. EPA, 2005,  
26 Section 4; Abt Associates, 2005)

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<sup>12</sup> 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.

<sup>13</sup> The risk assessment was discussed in the Staff Paper (EPA, 2005, Section 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).

1           The concentration-response relationships used in the assessment were based on findings  
2 from human epidemiologic studies that relied on fixed-site, population-oriented, ambient  
3 monitors as a surrogate for actual ambient PM<sub>2.5</sub> exposures. The risk assessment included a  
4 series of base case estimates that, for example, included various cutpoints intended as surrogates  
5 for alternative assumed population thresholds. In its review of the Staff Paper and quantitative  
6 risk assessment, the CASAC Panel commented that, for the purpose of estimating public health  
7 impacts, it “favored the primary use of an assumed threshold of 10 µg/m<sup>3</sup>,” 24-hour average, and  
8 that “a major research need is for more work to determine the existence and level of any  
9 thresholds that may exist or the shape of nonlinear concentration-response curves at low levels of  
10 exposure that may exist” (Henderson, 2005a). Other uncertainties were addressed in various  
11 sensitivity analyses (e.g., the use of single- versus multi-pollutant models, use of single- versus  
12 multi-city models, use of a distributed lag model) and had a more moderate and often variable  
13 impact on the risk estimates in some or all of the cities.

14           Key observations and insights from the PM<sub>2.5</sub> risk assessment, together with important  
15 caveats and limitations, were discussed in Section II.B of the 2006 proposal notice (71 FR 2637  
16 to 2641, January 17, 2006). In general, estimated risk reductions associated with going from just  
17 meeting the current suite of PM<sub>2.5</sub> standards to just meeting alternative suites of annual and 24-  
18 hour standards for all the various assumed cutpoints showed patterns of increasing estimated risk  
19 reductions as either the annual or 24-hour standard, or both, were reduced over the range  
20 considered in the assessment, and the estimated percentage reductions in risk were strongly  
21 influenced by the assumed cutpoint level (see U.S. EPA, 2005, Figures 5-1, 5-2, 5A-1, and 5A-  
22 2).

23           The general overview and discussion of key components of the risk assessment used to  
24 develop risk estimates for PM<sub>2.5</sub> presented above is also applicable to the risk assessment done  
25 for PM<sub>10-2.5</sub> as part of the last review. However, the scope of the risk assessment for PM<sub>10-2.5</sub> was  
26 much more limited than that for PM<sub>2.5</sub>, reflecting the much more limited body of epidemiologic  
27 evidence and air quality information available for PM<sub>10-2.5</sub>. As discussed in Section 4 of the  
28 Staff Paper (U.S. EPA, 2005), the PM<sub>10-2.5</sub> risk assessment included risk estimates for just three  
29 urban areas for two categories of health endpoints related to short-term exposure to PM<sub>10-2.5</sub>:  
30 hospital admissions for cardiovascular and respiratory causes, and respiratory symptoms.

1 Estimates of hospital admissions attributable to short-term exposure to PM<sub>10-2.5</sub> were  
2 developed for Detroit (cardiovascular and respiratory admissions) and Seattle (respiratory  
3 admissions), and estimates of respiratory symptoms were developed for St. Louis. While one of  
4 the goals of the PM<sub>10-2.5</sub> risk assessment was to provide estimates of the risk reductions  
5 associated with just meeting alternative PM<sub>10-2.5</sub> standards, EPA concluded that the nature and  
6 magnitude of the uncertainties and concerns associated with this portion of the risk assessment  
7 weighed against use of these risk estimates as a basis for recommending specific standard levels  
8 (U.S. EPA, 2005, p. 5-69). These uncertainties and concerns were summarized in the proposal  
9 notice (see FR 71 2662, January 17, 2006) and discussed more fully in the Staff Paper (U.S.  
10 EPA, 2005, Section 4) and associated technical support document (Abt Associates, 2005).

### 11 **5.3 CURRENT AIR QUALITY CHARACTERIZATION**

12 Air quality analyses are required to conduct both exposure and health risk assessments for  
13 NAAQS reviews. These analyses will build upon the analyses included in the ISA and include  
14 consideration of: (1) summaries of recent air quality data, (2) estimates of policy-relevant  
15 background (PRB) concentrations, and 3) air quality simulation procedures that modify recent air  
16 quality data to reflect changes in the distribution of air quality estimated to occur at some  
17 unspecified time in the future when an area just meets a given set of NAAQS. In this review, air  
18 quality analyses will be conducted to support quantitative risk and/or exposure assessments for  
19 specific locations. Air quality analyses also will be conducted to place the results of the  
20 quantitative risk/exposure assessments into a broader public health perspective.

21 As part of these analyses, it will be necessary to adjust recent PM air quality data to  
22 simulate just meeting the current suite and any alternative suites of PM standards. In the last  
23 review, EPA used a proportional rollback approach (U.S. EPA, 2005, section 4.3.1.2). EPA will  
24 consider alternative air quality simulation procedures for use in this current review, and will  
25 evaluate candidate procedures for simulating changes in PM air quality likely to result from just  
26 meeting the current or alternative suites of standards based on analyzing changes in PM levels  
27 that have been observed historically and/or analyzing changes in PM levels predicted by air  
28 quality models. EPA will consider factors which may influence the concentration distributions  
29 such as potential source concentrations, as well as the influence of local and regional pollution.  
30 In this review, EPA also will examine current techniques that may be used to assess the

1 variability and uncertainty of the simulated change in concentrations likely to result from just  
2 meeting the current or alternative standards.

### 3 **5.4 CURRENT HUMAN POPULATION EXPOSURE ASSESSMENT** 4 **APPROACH**

5 As part of the last PM NAAQS review, EPA did not conduct an exposure assessment. For  
6 this review, EPA is considering conducting a quantitative exposure assessment. This assessment  
7 would build upon the information presented in the ISA and include discussions of factors that  
8 affect exposure to ambient PM and the use of fixed site measurements of ambient PM  
9 concentrations as a surrogate for population exposure in epidemiologic studies. There are two  
10 specific purposes that such an assessment would serve: (1) providing insight on population  
11 exposures with respect to informing the interpretation of available epidemiologic studies; and (2)  
12 assessing population exposures above benchmark levels of concern, and possibly providing input  
13 to quantitative risk assessments based on evidence from clinical studies.<sup>14</sup>

14 Performing an exposure analysis will be helpful for identifying the various personal and  
15 building-related factors which may be responsible for some of the differences observed in  
16 epidemiologic studies of ambient PM. Exposure-related factors may contribute to city-to-city  
17 differences (mostly seen in time-series studies) in the reported PM concentration-response  
18 functions or in the results from intra-urban studies (e.g., cohort studies of long-term exposures to  
19 PM). Thus, an important reason for conducting an exposure assessment for PM would be to shed  
20 some light on these issues and attempt to examine and quantify uncertainties in the existing PM  
21 epidemiology literature. EPA will consider modeling specific locations and time periods which  
22 coincide with epidemiologic studies, if evidence indicates that such an analysis would prove to  
23 be useful.

24 An exposure assessment addressing the second purpose would be designed to estimate  
25 population exposures to ambient PM<sub>2.5</sub> and PM<sub>10-2.5</sub> in a number of generally representative  
26 urban areas across the U.S. These areas would be selected to represent a variety of populations,  
27 geographic areas, climates, and patterns of PM air quality levels. In addition, selection criteria  
28 might include consideration of locations of critical PM field and epidemiologic studies used to  
29 support the planned quantitative risk assessment. The exposure periods to be modeled would, at

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<sup>14</sup> At this time, based on discussions at the July 2007 Workshop, EPA staff are unaware of any results from human clinical studies that would provide the basis for exposure-response functions that could inform a quantitative risk assessment..

1 a minimum, encompass the most recent 3-year period for which air quality data are available.  
2 EPA is considering developing exposure estimates for the general population as well as for  
3 selected sensitive subpopulations (e.g., children, children with asthma or diabetes, adults over 70  
4 years of age, individuals with pre-existing heart or respiratory conditions). The areas, time  
5 periods, and populations modeled will depend on the availability of data and time and resource  
6 constraints.

7 A quantitative exposure assessment would take into account factors including the  
8 magnitude and duration of PM exposures and the frequency of repeated peak exposures.  
9 Estimates could be developed for several measures of exposure to various levels of PM<sub>2.5</sub> and/or  
10 PM<sub>10-2.5</sub> air quality, including estimates of the number of people exposed one or more times at or  
11 above a given PM concentration, and estimates of person-occurrences which accumulate  
12 occurrences of specific exposure conditions over all people in the population of interest.

13 EPA is considering developing estimates for population exposures associated with  
14 current PM<sub>2.5</sub> and PM<sub>10-2.5</sub> levels and with meeting the current PM<sub>2.5</sub> standards and potential  
15 alternative PM<sub>2.5</sub> standards. These exposure estimates could provide information on population  
16 exposures exceeding levels of concern that may be identified for various health endpoints.  
17 Exposure estimates may be used as an input to the quantitative risk assessment if health  
18 endpoints are identified in the ISA for which there are exposure-response functions.

19 Planning for conducting an exposure assessment will include building upon the  
20 information presented in the ISA and its annexes. This includes information on atmospheric  
21 chemistry and components of PM, air quality data, factors that influence exposures, human  
22 exposures, and information on sensitive subpopulations. EPA currently is considering  
23 conducting an exposure assessment that will focus primarily on ambient PM<sub>2.5</sub>, but will consider,  
24 to the extent relevant information is available, exposures associated with ambient PM<sub>10-2.5</sub> as  
25 well. EPA currently believes that exposure modeling for PM<sub>10-2.5</sub> would likely be significantly  
26 more uncertain than for PM<sub>2.5</sub>, primarily due to the limitations of the spatial coverage of  
27 available ambient PM<sub>10-2.5</sub> data.

## 28 **The Population Exposure Model**

29 If an exposure assessment is conducted, EPA is considering using the Air Pollutants  
30 Exposure (APEX) model (Richmond et al., 2002; U.S. EPA, 2006 b, c). APEX has its origins in

1 the NAAQS Exposure Model (NEM) which was developed in the early 1980's (McCurdy,  
2 1994), has been continually improved since then, and was recently used during EPA's ozone  
3 NAAQS review. APEX, also referred to as the Total Risk Integrated Methodology/Exposure  
4 (TRIM.Expo) model, is a Monte Carlo simulation model that simulates a large number of  
5 randomly sampled individuals within a metropolitan area to represent area-wide population  
6 exposures. APEX simulates the movements of individuals through time and space and their  
7 exposure to a given pollutant in indoor, outdoor, and in-vehicle microenvironments. The model  
8 stochastically generates simulated individuals using census-derived probability distributions for  
9 demographic characteristics. A large number of simulated individuals are modeled, and  
10 collectively they represent a random sample of the study area population.

11 Drawing on information from the ISA, EPA will consider specific microenvironments  
12 that could be evaluated in a quantitative exposure assessment for PM. The development of  
13 appropriate distributions representing variability and uncertainty in various model inputs (e.g.,  
14 air exchange rates, decay rates, indoor source emissions, and physiological parameters) will be a  
15 key aspect of this modeling effort. APEX employs a flexible approach for simulating  
16 microenvironmental concentrations, where the user can define the microenvironments to be  
17 modeled and their characteristics. Using input from the ISA, EPA will consider specific  
18 microenvironments that could be evaluated in a quantitative exposure assessment.

19 In considering conducting an exposure assessment, EPA plans to review the  
20 methodologies, inputs and results of other inhalation exposure modeling assessments to help  
21 inform the development of inputs for APEX and to understand the most significant uncertainties  
22 involved in estimating PM<sub>2.5</sub> exposures. PM exposure modeling studies to be reviewed would  
23 include exposure modeling of Philadelphia using the Stochastic Human Exposure and Dose  
24 Simulation model (SHEDS) (Burke et al., 2001) and the recent studies by McBride et al., 2007;  
25 Cressie et al., 2007; Issarayangyun and Greaves, 2007; Hertel et al., 2006; Klepeis and Nazaroff,  
26 2006; Fryer et al., 2006; Wilson and Zawar-Reza, 2006; Georgopoulos et al., 2005; Wu et al.,  
27 2005; Gulliver and Briggs, 2005; Marshall et al., 2005, as well as additional studies identified in  
28 the ISA.

29  
30  
31

## 1 **Uncertainty and Variability**

2           The primary difficulty in performing an exposure modeling uncertainty analysis is the  
3 quantitative characterization of the uncertainties of the model inputs and model formulation.  
4 Information about the variability of model inputs or the variability and uncertainty combined is  
5 often available, but it is usually difficult to estimate the uncertainty separately from the  
6 variability. In considering the use of APEX for a PM exposure assessment, EPA will consider  
7 the availability of information to provide reasonable distributions or ranges for the uncertainties  
8 of all of the model inputs. EPA will build upon the APEX exposure modeling uncertainty  
9 analysis conducted in support of the review of the ozone NAAQS (Langstaff, 2007), as well as  
10 an uncertainty analysis using SHEDS (Burke et al., 2001), improving on their distributions of  
11 variability and uncertainty where data are available to do so and extending the analysis of model  
12 formulation uncertainty.

13           Once estimates of the uncertainty of the model inputs have been developed, one can  
14 propagate these uncertainties through the model to quantify the resultant uncertainty of the  
15 model predictions. The APEX uncertainty methodology incorporates a 2-stage Monte Carlo  
16 modeling approach that explicitly characterizes and models the variability and uncertainty in  
17 inputs and outputs. Essentially, this approach entails performing thousands of model runs with  
18 model inputs randomly sampled from specified distributions reflecting variability and  
19 uncertainty of the model inputs. This 2-dimensional Monte Carlo method allows for the separate  
20 characterization of the variability and uncertainty in the model results (Morgan and Henrion,  
21 1990).

## 22 **5.5 CURRENT HEALTH RISK ASSESSMENT APPROACH**

23           The goals of a PM health risk assessment are: (1) to provide estimates of the potential  
24 magnitude of mortality and/or selected morbidity health effects in the population associated with  
25 recent ambient PM<sub>2.5</sub> and PM<sub>10-2.5</sub> levels and with meeting the current suite of PM standards and  
26 any alternative standards that might be considered in specific urban areas, (2) to develop a better  
27 understanding of the influence of various inputs and assumptions on the risk estimates; and (3) to  
28 gain insights into the distribution of risks and patterns of risk reduction and uncertainties in those  
29 risk estimates. The approach to the current health risk assessment will build upon the methods



1 developed and insights gained from the risk assessment completed for the last review. Several  
2 key considerations in planning for the health risk assessment are discussed below.

3 EPA is proposing to focus the quantitative risk assessments primarily on fine particles  
4 (PM<sub>2.5</sub>), but will consider, to the extent relevant information is available, risks associated with  
5 PM<sub>10-2.5</sub> in the ambient air, as well as risks associated with specific PM components. For PM<sub>2.5</sub>,  
6 EPA is proposing to focus the risk assessment on the most important health effect endpoints  
7 from the standpoint of public health significance and for which the weight of the evidence  
8 supports the judgment that the effect category is likely caused by exposure to PM<sub>2.5</sub> either alone  
9 and/or in combination with other pollutants.

10 The risk and exposure assessments will draw upon the information presented in the ISA  
11 and its annexes. This includes information on atmospheric chemistry and components of PM, air  
12 quality, human exposure, the impact of local source emissions, and health effects of concern. In  
13 particular, the availability of air quality, concentration-response, and baseline incidence rate data  
14 will impact the type of risk assessments that will be performed.

### 15 **Air Quality Considerations**

16 As described in Section 5.3 above, air quality inputs are required to conduct the health  
17 risk assessment including: (1) recent air quality data for PM<sub>2.5</sub> and PM<sub>10-2.5</sub> from suitable  
18 monitors for each selected location, (2) estimates of PRB concentrations for each location, and 3)  
19 simulated air quality that reflects changes in the distribution of PM air quality estimated to occur  
20 when an area just meets a given set of PM standards. While incremental risk reductions do not  
21 require estimates of PRB, estimates of the risks remaining upon meeting the current or potential  
22 alternative standards, do require EPA to estimate PRB. Both kinds of risk estimates are  
23 considered relevant to inform the EPA Administrator's decision on the adequacy of a given  
24 standard. The approach to estimating PRB for PM<sub>2.5</sub> and PM<sub>10-2.5</sub> for use in conducting the  
25 health risk assessment will be informed by the discussion and evaluation contained in the draft  
26 ISA and will build on the approach used in the previous review (Langstaff, 2004, 2005). The  
27 proposed approach for the current review will be discussed further in the Scope and Methods  
28 plan. EPA considerations with respect to exploring alternative air quality simulation procedures  
29 are discussed above in Section 5.3 and will be discussed in more detail in the Scope and Methods  
30 plan.

1 **Concentration-Response Functions**

2 As noted above, the health risk assessment conducted in this review will build on the  
3 approach developed and applied in the last review. EPA will rely on a weight-of-evidence  
4 approach, as provided in the ISA, based on evaluation of new and prior epidemiologic studies  
5 including identification of relevant concentration-response functions that characterize the  
6 relationships between short- and long-term PM exposures and health outcomes, particularly  
7 those conducted at or near current ambient concentrations. Quantitative relationships provided  
8 in the specific studies or derived from the data presented in the epidemiologic studies describe  
9 the change in concentration (generally based on ambient fixed-site monitors) associated with a  
10 change in health response. These concentration-response relationships will be combined with air  
11 quality data, baseline incidence data, and population data to develop population health risk  
12 estimates.

13 Epidemiologic studies typically provide estimated concentration-response relationships  
14 based on data collected in real-world settings. Ambient PM<sub>2.5</sub> and PM<sub>10-2.5</sub> concentrations are  
15 typically measured as the area-wide average of monitor-specific measurements, although  
16 personal exposures are occasionally measured. Common health responses for PM<sub>2.5</sub> have  
17 included associations with respiratory symptoms in asthmatic children, asthma emergency  
18 department visits, respiratory related hospital admissions and premature mortality. EPA will  
19 consider the type of health response function(s) available and the availability of ambient PM<sub>2.5</sub>  
20 and PM<sub>10-2.5</sub> concentration data to characterize public health risks. EPA considers that these  
21 analyses are most appropriately applied in areas where the specific epidemiologic studies were  
22 performed. It should be noted that a risk characterization based on epidemiologic studies also  
23 requires baseline incidence rates and population data for the specific locations evaluated in the  
24 risk assessment.

25 EPA plans to develop concentration-response relationships for health effects associated  
26 with short- and long-term exposures to PM<sub>2.5</sub> and to a lesser extent, associated with short-term  
27 exposures to PM<sub>10-2.5</sub> exposures based on recently conducted and previous epidemiologic studies  
28 presented in the ISA. EPA will also consider the scientific evidence presented in the ISA to  
29 determine if sufficient exposure-response data from controlled clinical studies are available to  
30 characterize health risks based on these studies.

## 1 **Uncertainty and Variability**

2 In the health risk assessment developed for the review completed in 2006, staff  
3 recognized that there were many sources of uncertainty and variability in the inputs to the  
4 assessment and that there was a high degree of uncertainty in the resulting risk estimates. The  
5 principle uncertainty, statistical uncertainty surrounding the estimated  $PM_{2.5}$  and  $PM_{10-2.5}$   
6 coefficients in concentration-response functions, was addressed quantitatively in the last review.  
7 Additional uncertainties were addressed through sensitivity analyses and/or qualitatively.

8 A persistent issue raised in CASAC and public review of the quantitative risk assessment  
9 was the desire to provide a more comprehensive characterization of the most significant  
10 uncertainties impacting the health risk estimates. For the current health risk assessment, EPA is  
11 considering the use of, at a minimum, a similar approach to that used in the prior assessment to  
12 characterize uncertainties in the risk estimates. In addition, EPA is considering the feasibility of  
13 conducting an expert elicitation to characterize and quantify the most important sources of  
14 uncertainty. As part of EPA's final regulatory impact analysis for the PM NAAQS review  
15 completed in 2006, EPA conducted a study of the concentration-response relationship between  
16 changes in  $PM_{2.5}$  exposures and mortality using formally elicited expert judgments (IEC, 2006).  
17 The goal of the study was to elicit, from a sample of health experts, probabilistic distributions  
18 describing uncertainty in estimates of the reduction in mortality among the adult U.S. population  
19 resulting from reductions in ambient annual average  $PM_{2.5}$  levels. These distributions were  
20 obtained through a formal interview protocol using methods designed to elicit subjective expert  
21 judgments.

22 The full-scale expert elicitation study involved personal interviews with twelve health  
23 experts who have conducted research on the relationship between  $PM_{2.5}$  exposures and mortality  
24 (IEC, 2006; Roman et al., submitted). These experts were selected through a peer-nomination  
25 process and included experts in epidemiology, toxicology, and medicine. The elicitation  
26 interview consisted of a protocol of carefully structured questions, both qualitative and  
27 quantitative, about the nature of the  $PM_{2.5}$ -mortality relationship. The questions requiring  
28 qualitative responses probed experts' beliefs concerning key evidence and critical sources of  
29 uncertainty and enabled them to establish a conceptual basis supporting their quantitative  
30 judgments. Questions covered topics such as potential biological mechanisms linking  $PM_{2.5}$   
31 exposures with mortality; the role of study design in capturing PM/mortality effects; key

1 scientific evidence on the magnitude of the PM/mortality relationship; sources of potential error  
2 or bias in epidemiological results; the likelihood of a causal relationship between PM<sub>2.5</sub> and  
3 mortality, and the shape of the concentration-response function.

4 As noted above, EPA is considering the feasibility and value of conducting an expert  
5 elicitation as part of the current PM health risk assessment to improve the quantitative  
6 characterization of the most significant uncertainties associated with the risk assessment. Factors  
7 that will be weighed in making a decision on whether or not to proceed with such an assessment  
8 include the perceived value of the project in informing the Administrator's decision in view of  
9 the considerable resources and effort required to carry out such an assessment and the time  
10 constraints for developing the risk assessment.

11 The prior risk assessment incorporated some of the variability in key inputs to the  
12 assessment by using location-specific inputs (e.g., location-specific concentration-response  
13 functions, baseline incidence rates, population data, and air quality data). In the last review, nine  
14 urban areas were included in the health risk assessment to provide some sense of the variability  
15 in the risk estimates across the U.S. For the current review, EPA is considering extending the  
16 risk assessment to a broader range of urban areas to provide greater coverage of additional  
17 regions of the country where significant PM exposures occur. EPA will consider the feasibility  
18 of developing concentration-response relationships that can be applied on a regional basis. It is  
19 very likely that the geographic (and population) coverage will vary for different health endpoint  
20 categories due to data limitations (e.g., the availability of hospital admission baseline incidence  
21 data is more limited than mortality baseline incidence data).

## 22 **5.6 BROADER RISK CHARACTERIZATION**

23 Beyond the quantitative risk/exposure assessments conducted for this review, EPA will  
24 consider ways to put the results of those assessments into a broader context. Specifically, EPA  
25 will explore analyses that would complement quantitative risk/exposure assessments conducted  
26 for a limited number of locations and selected health endpoints to better characterize the nature,  
27 magnitude, extent, variability, and uncertainty of the public health impacts associated with PM  
28 exposures on a broader scale. EPA will consider how additional analyses could be used to  
29 inform our understanding of:

- 30 ■ Additional health endpoints not considered in the quantitative risk assessment;

- 1       ▪ Additional locations not evaluated in the quantitative risk/exposure assessment to inform
- 2       a broader understanding of public health impacts;
- 3       ▪ Regional differences in PM risks taking into consideration the following factors:
- 4       - variations in individual and/or population susceptibility including consideration of
- 5       population demographics;
- 6       - variations in exposures;
- 7       - variations in particle size, composition, and/or levels; and
- 8       - impacts of potential effect modifiers (e.g., weather).

## 9       **5.7 SCIENTIFIC AND PUBLIC REVIEW**

10       A draft of the Scope and Methods Plan for the risk/exposure assessment will be submitted

11       to CASAC for consultation and will be provided to the public for comment. The CASAC PM

12       Review Panel will discuss their comments on the draft Scope and Methods Plan in a public

13       meeting that will be announced in the Federal Register. In conducting the risk/exposure

14       assessment, EPA will take into account comments received from CASAC or from the public at

15       the meeting itself and in any written comments. EPA will prepare two drafts of the risk/exposure

16       assessment for CASAC review and public comment. The CASAC PM Review Panel will review

17       each draft risk/exposure assessment and discuss their comments in two public meetings to be

18       announced in the Federal Register. Based on CASAC’s past practice, EPA anticipates that key

19       CASAC advice and recommendations for revision of the draft risk/exposure assessment will be

20       presented in letters to the EPA Administrator. EPA will also consider comments received from

21       CASAC or from the public at the meetings themselves and any written public comments. In

22       finalizing the risk/exposure assessment, EPA will take into account any such comments and

23       recommendations. After appropriate revision, the final risk/exposure assessment document will

24       be made publicly available on an EPA website and in hard copy. A notice announcing the

25       availability of the final document will be published in the Federal Register. In addition, the final

26       risk/exposure assessment document will be placed in the rulemaking docket.

# 6 VISIBILITY AND OTHER WELFARE-RELATED ASSESSMENTS

## 6.1 OVERVIEW

The assessments conducted in this review of the secondary PM NAAQS will focus primarily on visibility-related issues, with special emphasis on addressing those issues remaining at the conclusion of the last review associated with urban visibility impairment (see Section 6.2 below). In addition, depending on the nature of the information described in the ISA, there may also be opportunity to conduct limited assessment(s) on the potential for phyto- or eco-toxic related welfare impacts from the deposition of particulate or aerosol heavy metal compounds, or on the magnitude and associated benefits of materials damage from soiling. Though understanding and characterizing the potential climate/PM-related feedbacks and interactions that might occur under various alternative PM air quality scenarios is an important policy issue, we do not anticipate there will be sufficient information available to support quantitative analyses related to this public welfare effect in this review.

The major components of the visibility-related and other welfare-related assessments are outlined below and will be described in greater detail in a Scope and Methods Plan. Preparation of this detailed plan is underway and coincides with the development of the first draft ISA to facilitate the integration of policy-relevant science into both documents.

## 6.2 OVERVIEW OF VISIBILITY-RELATED ASSESSMENT FROM PRIOR REVIEW

EPA has long recognized that impairment of visibility is an important effect of PM on public welfare, and that it is experienced throughout the U.S. in urban areas as well as in remote Class I areas<sup>15</sup> (62 FR 38680, July 18, 1997). Visibility is an important welfare effect because it has direct significance to people's enjoyment of daily activities in all parts of the country. Individuals value good visibility for the sense of well-being it provides them directly, both in places where they live and work, and in places where they enjoy recreational opportunities.

Visibility can be defined as the degree to which the atmosphere is transparent to visible light. Visibility conditions are determined by the scattering and absorption of light by particles

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<sup>15</sup> Class I areas: as defined by the Clean Air Act, include national parks greater than 6,000 acres, wilderness areas and national memorial parks greater than 5,000 acres, and international parks that existed as of August 1977.

1 and gases, from both natural and anthropogenic sources. Visibility is often described in terms of  
2 visual range, light extinction, or deciviews.<sup>16</sup> The classes of fine particles principally responsible  
3 for visibility impairment are sulfates, nitrates, organic matter, elemental carbon, and soil dust.  
4 Fine particles are more efficient per unit mass at scattering light than coarse particles. The  
5 scattering efficiency of certain classes of fine particles, such as sulfates, nitrates, and some  
6 organics, increases as relative humidity rises because these particles can absorb water and grow  
7 to sizes comparable to the wavelength of visible light. In addition to limiting the distance that  
8 one can see, the scattering and absorption of light caused by air pollution can also degrade the  
9 color, clarity, and contrast of scenes.

## 10 **Air Quality Analyses**

11 In the last review, EPA summarized information on the general types of visibility  
12 impairment: local visibility impairment manifested as an urban haze, sometimes referred to as a  
13 “brown cloud” and regional haze generally resulting from pollutant emissions from a multitude  
14 of sources located across a broad geographic region. In addition, EPA conducted analyses  
15 evaluating trends and conditions in Class I and non-urban areas, visibility conditions in urban  
16 areas, and approaches for evaluating public perceptions of visibility impairment and judgments  
17 about the acceptability of varying degrees of impairment. Key insights and observations from  
18 the visibility assessment were discussed in Section IV.A of the 2006 proposal notice (see 71 FR  
19 2675 to 2681, January 17, 2006). In the last review, EPA concluded that fine particle mass  
20 concentrations could be used as a general surrogate for visibility impairment (U.S. EPA, 2005,  
21 Section 2.8.1). EPA also concluded that the available data on visibility conditions indicated that  
22 urban areas generally have higher loadings of PM<sub>2.5</sub> and, thus, higher visibility impairment than  
23 monitored Class I areas. EPA recognized that the Regional Haze Program (64 FR 35713; July 1,  
24 1999), implemented under sections 169A and 169B of the CAA, addressed all human-caused  
25 visibility in Class I areas and that the Clean Air Interstate Rule (CAIR) (70 FR 25162; May 12,  
26 2005) would result in improvements to visual air quality, particularly in eastern Class I and non-

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<sup>16</sup> Visual range can be defined as the maximum distance at which one can identify a black object against the horizon sky. It is typically described in kilometers or miles. Light extinction is the sum of light scattering and absorption by particles and gases in the atmosphere. It is typically expressed in terms of inverse megameters (Mm<sup>-1</sup>), with larger values representing poorer visibility. The deciview metric describes perceived visual changes in a linear fashion over its entire range, analogous to the decibel scale for sound.

1 urban areas. Therefore, the visibility-related assessments conducted in the last review focused  
2 primarily on evaluating visibility impairment in urban areas.

3 In evaluating correlations between urban visibility and PM<sub>2.5</sub> mass, EPA considered that  
4 direct relationships existed between measured ambient pollutant concentrations and their  
5 contributions to light extinction and thus to visibility impairment. The contribution of each PM  
6 constituent to total light extinction was derived by multiplying the constituent concentration by  
7 its extinction efficiency to calculate a "reconstructed" light extinction.<sup>17</sup> For certain fine particle  
8 constituents, extinction efficiencies increased significantly with increases in relative humidity.  
9 As a consequence, while higher PM<sub>2.5</sub> mass concentrations generally indicated higher levels of  
10 visibility impairment, it was not as precise a metric as the light extinction coefficient.  
11 Nonetheless, by using historic averages, regional estimates, and actual day-specific, component-  
12 specific ambient measurements of PM<sub>2.5</sub> total mass, reasonable estimates of light extinction from  
13 PM mass concentrations were developed.

14 In an effort to characterize urban visibility, EPA analyzed the available data on PM<sub>2.5</sub>  
15 ambient air concentrations primarily in urban areas. The national data base of PM<sub>2.5</sub> ambient air  
16 concentrations had expanded greatly since the 1997 PM<sub>2.5</sub> NAAQS had been promulgated and  
17 included 24-hour measurements of total PM<sub>2.5</sub> mass, continuous measurements of hourly (total)  
18 PM<sub>2.5</sub> mass, and 24-hour duration PM<sub>2.5</sub> chemical speciation (component) measurements. These  
19 data allowed for analyses that explored factors that have historically complicated efforts to  
20 address visibility impairment nationally, including regional differences related to levels of  
21 primarily fine particles and to relative humidity. The analyses showed a consistently high  
22 correlation between visibility, in terms of reconstructed light extinction,<sup>17</sup> and PM<sub>2.5</sub>  
23 concentrations (daily, hourly, and block hourly) for urban areas in a number of regions across the  
24 U.S. and, more generally, in the eastern and western U.S. The correlations in urban areas were  
25 generally similar in the East and West, in sharp contrast to the East/West differences observed in  
26 rural areas.

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<sup>17</sup> Extinction efficiencies vary by type of constituent and have been obtained for typical atmospheric aerosols by a combination of empirical approaches and theoretical calculations. As discussed in the Staff Paper, EPA's guidance for tracking progress under the Regional Haze Program specified an algorithm for calculating total light extinction as a function of the major fine particle components (U.S. EPA, 2005, Section 2.8.1). "Reconstructed" light extinction simply refers to the calculation of PM-related light extinction by the use of that formula.



1 While the average daily relative humidity levels were generally higher in the East than in  
2 the West, in both regions relative humidity levels were appreciably lower during daylight as  
3 compared to nighttime hours. The reconstructed light extinction coefficient, for a given mass  
4 and concentration, increased sharply as relative humidity rose. Thus, with lower relative  
5 humidity levels, visibility impacts related to East/West differences in average relative humidity  
6 were minimized during daylight hours, when relative humidity is generally lower.

7 Both 24-hour and shorter-term daylight hour averaging periods were considered in  
8 evaluations of correlations between  $PM_{2.5}$  concentrations in urban areas and visibility in eastern  
9 and western areas, as well as nationwide. Clear and similarly strong correlations were found  
10 between visibility and 24-hour average  $PM_{2.5}$  in eastern, western, and all urban areas (U.S. EPA,  
11 2005, Figure 6-3). Somewhat stronger correlations were observed between visibility and  $PM_{2.5}$   
12 concentrations averaged over certain sub-daily (e.g., a 4-hour) time periods (U.S. EPA, 2005,  
13 Figure 6-5). The correlations between visibility and  $PM_{2.5}$  concentrations during daylight hours  
14 in urban areas were relatively more reflective of  $PM_{2.5}$  mass rather than relative humidity effects,  
15 in comparison to correlations based on a 24-hour averaging time.

## 16 **Surveys of Public Perception**

17 In the last review, EPA considered survey research on public awareness of visual air  
18 quality. The importance of visual air quality to public welfare across the country had been  
19 demonstrated by a number of studies designed to quantify the benefits (or willingness to pay)  
20 associated with potential improvements in visibility (Chestnut and Dennis, 1997; Chestnut and  
21 Rowe, 1991). These economic benefits may include the value of improved aesthetics during  
22 daily activities (e.g., driving or walking, daily recreations), for special activities (e.g., visiting  
23 parks and scenic vistas, hiking, hunting), and for viewing scenic photography. They may also  
24 include the value of improved road and air safety, and/or preservation of the resource for its own  
25 sake.

26 EPA considered new methods and tools that had been developed to communicate and  
27 evaluate public perceptions of varying visual effects associated with alternative levels of  
28 visibility impairment relative to varying pollution levels and environmental conditions. New  
29 survey methods have been applied and evaluated in various studies, such as those done in  
30 Denver, Phoenix, and the Lower Fraser Valley in British Columbia. These methods were

1 intended to assess public perceptions in focus group sessions as to the acceptability of varying  
2 levels of visual air quality, considered in these studies to be an appropriate basis for developing  
3 goals and standards for visibility protection. In the last review, EPA conducted a pilot study in  
4 Washington D.C. in order to test both the session design and survey questions that would  
5 potentially be used in the broader focus group effort (Abt Associates, 2001). Even with  
6 variations in each study's approaches, the public perception survey methods used for the Denver,  
7 Phoenix, and British Columbia studies produced reasonably consistent results from location to  
8 location, with each study indicating that a majority of participants found visual ranges within  
9 about 40 to 60 km to be acceptable.

10         These public perception studies used images of urban and distant scenic views under  
11 different visibility conditions together with survey techniques designed to elicit judgments from  
12 members of the public about the acceptability of differing levels of visual air quality. Images  
13 used were either photographs or computer simulations using the WinHaze program. The  
14 WinHaze program is a sophisticated visual air quality image modeling program for personal  
15 computers that used simplified algorithms based on a sophisticated modeling technique (Air  
16 Resource Specialists, 2003). A base photographic image captured the cleanest air quality  
17 conditions possible for a given site and then digitized the photograph to assign an optical density  
18 to each pixel. Using the digital imaging information, combined with the physical and optical  
19 properties of assumed alternative aerosol mixes, WinHaze generated a series of images that  
20 showed the impact of various levels of ambient aerosol on the visual quality of the scene. The  
21 WinHaze simulation technique had the advantage that it could be done for any location as long  
22 as a very clear base photo was available. By using the same base picture in all images, in effect,  
23 this approach standardized the perception of the images and enabled researchers to avoid  
24 potentially biased responses that might occur if different pictures of the same scene were used.  
25 An alternative approach could use actual photographs of the site of interest at different ambient  
26 pollution levels. However, EPA did not consider this alternative approach because long-term  
27 photo archives of this type existed for only a few cities.

28         Information on the pilot project was presented in the preliminary draft Staff Paper (US  
29 EPA, 2001) to elicit CASAC and public comment on the use of this type of approach to help  
30 inform EPA's review of the secondary PM NAAQS, and, more specifically, to elicit comments  
31 on various aspects of the survey methodology used in the pilot project. The project was

1 premised on the view that public perceptions of and judgments about the acceptability of  
2 visibility impairment in urban areas are relevant factors in assessing what constitutes an adverse  
3 level of visibility impairment in the context of this NAAQS review. EPA received general  
4 support for the use of this type of approach, and also received advice from members of CASAC  
5 as to how the survey methodology could be improved. At that time, EPA staff expressed the  
6 intention of refining the approach based on that advice, and preparing a revised methodology  
7 document for additional review by CASAC and the public prior to conducting a more extensive  
8 survey that could appropriately inform this review. Resource constraints prevented this work  
9 from being conducted in the last review.

### 10 **6.3 CURRENT VISIBILITY AND OTHER WELFARE-RELATED** 11 **ASSESSMENT APPROACH**

12 To help inform the overarching policy-relevant question regarding the adequacy of the  
13 current suite of secondary standards in protecting the public welfare from any known or  
14 anticipated adverse effects associated with the presence of PM in the ambient air, EPA will look  
15 to the following types of assessments.

#### 16 **Urban Visibility**

17 As indicated in Section 6.2 above, the last review expanded consideration of the public  
18 welfare effect of visibility impairment beyond areas traditionally identified for protection (e.g.,  
19 federally designated Class I areas) to include urban areas. In this review, EPA has identified  
20 several issues specific to visibility impairment in urban or suburban areas. In order to progress  
21 the assessment of urban visibility impairment, EPA plans to address the following issues:

- 22 ■ Refining the algorithms relating light extinction to PM species concentrations originally  
23 developed for rural/remote sites using IMPROVE data to be more applicable to urban  
24 areas using data being collected by the new PM speciation network.
- 25 ■ Exploring different ways to characterize the relationship between light extinction and PM  
26 concentrations, which is a function of PM component concentrations and relative  
27 humidity.

28  
29 In addition to the above issues, both the Administrator and the CASAC panel observed in  
30 the last review that one of the key limitations to selecting an appropriate level of PM<sub>2.5</sub> that  
31 would afford the requisite protection against visibility impairment in urban areas was the limited

1 number of cities for which information of this nature (e.g., public perceptions of adverse impacts  
2 on visibility in urban settings) was available. In this review, EPA will consider the  
3 appropriateness of building on and expanding the pilot study evaluating public perceptions of  
4 and judgments about the acceptability of visibility impairment in urban areas conducted for the  
5 last review (see Section 6.2 above) so the results of a more extensive survey can be used to help  
6 inform this or future reviews of the PM secondary standards. For this to be realized, a number of  
7 different issues and challenges must be addressed. These include:

- 8     ▪ Identifying new literature that addresses methods for characterizing the value of visibility  
9       and assessing which approach(es) are potentially appropriate for use in the NAAQS  
10      review process. This effort could potentially be expanded to incorporate literature that  
11      includes information on how the psychological value of visual air quality, stress and  
12      human behavior are related and how those qualitative aspects are or could be included.
- 13     ▪ Expanding the characterization of perceptions of visibility impairment to include urban  
14      areas having sight paths to fixed scenic elements that are too short to be sensitive to  
15      changes in haze by exploring alternative ways to communicate change (e.g., based on  
16      changes in sky color and the appearance of clouds in the sky). Several methods are  
17      available to represent different levels of visual air quality (see discussion of the EPA pilot  
18      study above, Abt Associates, 2001).
- 19     ▪ Expanding the characterization of perceptions of adversity for urban areas with non-  
20      traditional views<sup>18</sup> as described above by developing new or modifying existing survey  
21      techniques to elicit information about what constitutes an acceptable versus unacceptable  
22      degradation of the scene (e.g., clouds against a blue sky).

### 23 **Other Welfare Effects**

24       There are several new or expanded sources of speciated PM data that might lend  
25 themselves to further analysis with respect to the welfare effects associated with deposition of  
26 heavy metals to vegetation and ecosystems, deposition of fine and coarse particles onto man-  
27 made structures, and the potential localized impacts of aerosol pollution on downwind  
28 precipitation patterns and trends. These new data sources include the urban PM speciation

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<sup>18</sup> Photographic views for urban areas traditionally are taken from an elevated vantage point near the edge of the city with the city skyline shown against distant mountains in the background. In areas where such distant views are not readily available, it is not clear at this time what could substitute for distant scenic elements.

1 network and data from assessments being conducted by state-run regional planning organizations  
2 (RPOs) in conjunction with fulfilling the requirements of the Regional Haze Rule. EPA will  
3 therefore investigate these and any other additional sources of information identified in the ISA  
4 and associated annexes and consider whether additional welfare effects assessments are  
5 appropriate.

#### 6 **6.4 SCIENTIFIC AND PUBLIC REVIEW**

7 A draft of the Scope and Methods Plan for the visibility and other welfare-related  
8 assessments will be submitted to CASAC for consultation and will be provided to the public for  
9 comment. The CASAC PM Review Panel will discuss their comments on the draft Scope and  
10 Methods Plan in a public meeting that will be announced in the Federal Register. In conducting  
11 the visibility and other welfare-related assessments, EPA will take into account comments  
12 received from CASAC or from the public at the meeting itself and in any written comments.  
13 EPA will prepare two drafts of the visibility and other welfare-related assessments for CASAC  
14 review and public comment. The CASAC PM Review Panel will review each draft visibility and  
15 other welfare-related assessment and discuss their comments in two public meetings to be  
16 announced in the Federal Register. Based on CASAC's past practice, EPA anticipates that key  
17 CASAC advice and recommendations for revision of the draft risk/exposure assessment will be  
18 presented in letters to the EPA Administrator. EPA will also consider comments received from  
19 CASAC or from the public at the meetings themselves and any written public comments. In  
20 finalizing the visibility and other welfare-related assessments, EPA will take into account any  
21 such comments and recommendations. After appropriate revision, the final visibility and other  
22 welfare-related assessment document will be made publicly available on an EPA website and in  
23 hard copy. A notice announcing the availability of the final document will be published in the  
24 Federal Register. In addition, the final visibility and welfare-related assessment document will  
25 be placed in the rulemaking docket.

# 7 AMBIENT AIR MONITORING

## 7.1 OVERVIEW

The PM monitoring networks provide data for a wide variety of purposes as part of an iterative process in managing air quality. These include: (1) determining compliance with the NAAQS; (2) characterizing air quality status; (3) supporting air quality analyses used to conduct assessments of exposure, health risks, and welfare effects; (4) developing and evaluating emissions control strategies; and (5) measuring overall progress for the air pollution control program.

Federal rules that regulate ambient monitoring programs are found in 40 CFR parts 50, 53 and 58. As noted below in Section 7.2, EPA amended these regulations in 2006, in part, to support changes necessary for implementation of the revised PM NAAQS. EPA expects to follow a similar process during this review, with the development of a complementary rulemaking effort, if appropriate, to support monitoring rule changes associated with any revisions to the PM NAAQS. Potential monitoring rule changes include the Federal Reference Methods (FRMs) that exist as appendices to part 50, the procedures for approval of Federal Reference and Federal Equivalent Methods (FEMs) contained in part 53, and the rules applicable to ambient monitoring network planning and operations that are the basis for part 58 and appendices A through E.

## 7.2 HISTORICAL PERSPECTIVE

As a result of the 1987 standard for PM<sub>10</sub>, EPA and its state/local partners implemented the first size-selective PM monitoring network in 1990 with the establishment of a PM<sub>10</sub> network consisting of mainly high-volume samplers. Approximately 1,000 PM<sub>10</sub> samplers remain in operation to assess mass concentrations across the U.S., although some divestment in the network is expected as thoracic coarse particle monitoring methods transition to PM<sub>10-2.5</sub> sampling. After setting the first PM<sub>2.5</sub> NAAQS in 1997, EPA implemented a PM<sub>2.5</sub> network consisting of ambient air monitoring sites with mass and/or chemical speciation measurements. Within the PM<sub>2.5</sub> network, there are approximately 900 FRM filter-based samplers that provide 24-hour PM<sub>2.5</sub> mass concentration data and about 600 continuous PM<sub>2.5</sub> mass monitors that provide hourly data on a near real-time basis. Due to the complex nature of fine particles, EPA implemented the Chemical Speciation Network (CSN) to better understand the components of

1 fine particle mass at selected locations. Chemical speciation measurements are made at 54  
2 “Speciation Trends Network (STN)” sites that are intended to remain in operation indefinitely  
3 and about 150 other, potentially less permanent sites used to support State Implementation Plan  
4 (SIP) development and other monitoring objectives.<sup>19</sup> In addition, specific components of fine  
5 particles are measured through the Interagency Monitoring of Protected Visual Environments  
6 (IMPROVE) monitoring program<sup>20</sup> which supports regional haze characterization and tracks  
7 changes in visibility in Class I areas as well as many other rural and some urban areas. Together,  
8 the IMPROVE and CSN data provide chemical species information for fine particles that are  
9 critical for use in health and epidemiologic studies to help inform reviews of the PM NAAQS.

10 EPA recently made changes to the NAAQS-related monitoring regulations. Specifically,  
11 the general monitoring network design requirements for the minimum number of ambient air  
12 monitors were modified to focus more on populated areas with air quality problems and to  
13 significantly reduce the requirements for criteria pollutant monitors that have measured ambient  
14 air concentrations well below the applicable NAAQS. A number of the changes related  
15 specifically to monitoring PM<sub>2.5</sub>, including revisions to the requirements for reference and  
16 equivalent method determinations (including specifications and test procedures) for fine particle  
17 monitors. These regulations also added a requirement for a new multi-pollutant monitoring  
18 network called National Core (NCore) and revised certain provisions regarding monitoring  
19 network descriptions and periodic assessments, quality assurance, and data certifications (71 FR  
20 61236, October 17, 2006).

21 In the last review, EPA promulgated a new FRM for the measurement of PM<sub>10-2.5</sub> in  
22 ambient air. Although the standard for thoracic coarse particles does not use a PM<sub>10-2.5</sub> indicator,  
23 a new FRM for PM<sub>10-2.5</sub> was developed to provide a basis for approving FEMs and promote the  
24 gathering of scientific data to support future reviews of the PM NAAQS. The new PM<sub>10-2.5</sub> FRM  
25 – or an approved FEM, if available - is to be implemented at required NCore stations by January  
26 1, 2011. Despite this long period of implementation, there are already a number of collocated

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<sup>19</sup> See <http://www.epa.gov/ttn/amtic/speciepg.html> for more information on the PM<sub>2.5</sub> speciation monitoring program.

<sup>20</sup> Recognizing the importance of visual air quality, Congress included legislation in the 1977 Clean Air Act to prevent future and remedy existing visibility impairment in Class I areas. To aid the implementation of this legislation, the IMPROVE program was initiated in 1985 and substantially expanded in 2000-2003. This program implemented an extensive long term monitoring program to establish the current visibility conditions, track changes in visibility and determine causal mechanism for the visibility impairment in the National Parks and Wilderness Areas. For more information see <http://www.epa.gov/ttn/amtic/visdata.html>.

1 PM<sub>10</sub> and PM<sub>2.5</sub> low-volume FRMs operating across the country that are essentially providing  
2 the PM<sub>10-2.5</sub> FRM measurement now. There is currently no chemical speciation network for  
3 characterizing the specific components of thoracic coarse particles. EPA is developing an  
4 implementation plan for a thoracic coarse particle speciation network as PM<sub>10-2.5</sub> at about 75  
5 locations that will be part of the NCore monitoring stations.

### 6 **7.3 MONITORING ISSUES TO BE CONSIDERED IN THE CURRENT** 7 **REVIEW OF THE PM NAAQS**

8 This review of the PM NAAQS will explore a number of policy-relevant issues  
9 associated with measuring and characterizing fine and thoracic coarse particles in ambient air.  
10 EPA will draw upon the information presented in the ISA to inform the evaluation of appropriate  
11 ambient monitoring methods and network design for PM, including considering the available  
12 information on probe and siting criteria that could best support the current or alternative PM  
13 standards.

#### 14 **Network Design**

15 Monitoring sites must represent ambient air (e.g., that portion of the atmosphere, external  
16 to buildings, to which the general public has access). The minimum number of required monitors  
17 for PM is stated in 40 CFR part 58, Appendix D, Network Design Criteria for Ambient Air  
18 Quality Monitoring. EPA negotiates with States to determine the total number of monitors  
19 needed to represent an area's air quality. The total number is typically greater than the basic rule  
20 requirements. It should be noted that although monitors are often sited with the intention to  
21 represent an area of a certain geographic scale, in general, a monitor need not be representative  
22 of the ambient air quality across an area of any specific size to be eligible for comparison to most  
23 NAAQS. The current monitoring requirements for the PM<sub>2.5</sub> NAAQS are an exception. Data  
24 from a PM<sub>2.5</sub> monitor can be compared to the NAAQS only if its location is "population-  
25 oriented."<sup>21</sup> Consequently, the existing PM monitoring network is primarily designed to be  
26 "population-oriented."

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<sup>21</sup> As defined in 40 CFR part 58.1, "Population-oriented monitoring sites" apply to residential areas, commercial areas, recreational areas, industrial areas, and other areas where a substantial number of people may spend a significant fraction of their day. Also, note Subpart D of 40 CFR part 58, Special considerations for data comparisons to the NAAQS.



1 Network design issues related to population exposure that will be considered in this  
2 review are reflected in the following questions:

- 3 ■ Is there a need to define more quantitative criteria for population-oriented exposure (e.g.,  
4 minimum population density requirements, proximity to closest residences or work areas)  
5 than is currently provided in the 40 CFR part 58?
- 6 ■ Is there evidence to support expanding the network from being mainly based on monitors  
7 representing community-wide air quality to also consider "hot-spot" monitoring where  
8 ambient concentrations are potentially higher? As an example, sites that represent  
9 populations that reside near roadways (e.g., an environmental justice community with a  
10 middle-scale<sup>22</sup> or micro-scale<sup>23</sup> location for protection against acute exposures to fine  
11 particles).
- 12 ■ Is there new evidence to support a network expansion to improve the characterization of  
13 ambient PM concentrations in additional areas such as remote areas that are not  
14 considered "population-oriented?" In what ways could this information be used to assess  
15 potential health and/or welfare effects in these areas?

16  
17 Additional PM<sub>10-2.5</sub> network design issues that will be considered in this review are  
18 reflected in the following questions:

- 19 ■ What factors should be considered in identifying the size (number of monitors,  
20 geographic distribution) of a PM<sub>10-2.5</sub> mass and speciation monitoring network (including  
21 consideration of the NCore network requirements) that would be sufficient to  
22 characterize levels across urban and rural areas?
- 23 ■ What additional sampling and statistical techniques (e.g., saturation sampling) are  
24 available to help determine the minimum number of PM<sub>10-2.5</sub> monitors needed across an  
25 urban area to adequately assess issues of spatial and temporal variability?
- 26 ■ What are the appropriate monitor placement criteria for thoracic coarse particle  
27 characterization of PM<sub>10-2.5</sub>, including the distance relative to sources, measurement

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<sup>22</sup> A middle scale-sized area is one in which there are significant differences in concentrations between locations that are 100 meters to 500 meters apart, and generally are areas that are impacted by nearly adjacent (but not immediately adjacent) sources, such as industrial sites, roadways, or construction sites.

<sup>23</sup> A micro-scale environment is one in which there are significant differences in concentrations between locations that are 10 meters to 100 meters apart, and generally are areas that are impacted by immediately adjacent sources such as industrial sites, roadways, or construction sites.

1 scale, and inlet height? Should data from PM<sub>10-2.5</sub> monitors located nearly adjacent to  
2 sources (micro-scale) be excluded from comparison with a potential NAAQS?

### 3 **Sampling Methods**

4 Federal Reference Methods (FRMs) provide the methodological basis for comparison to  
5 the NAAQS and also serve as the “gold-standard” for the comparison of other methods being  
6 reviewed for potential approval as equivalent methods. FEMs for PM are largely continuous  
7 monitors that can provide data for multiple monitoring objectives (e.g., an approved continuous  
8 PM method would provide hourly data that would be more cost effective for daily sampling and  
9 also provide data for reporting the Air Quality Index). For PM methods, only PM<sub>10</sub> currently has  
10 approved continuous FEM monitors.

11 Policy-relevant issues that will be considered in this review to inform the selection of  
12 monitoring methods are reflected in the following questions:

- 13 ■ To what extent do the variations in PM<sub>10</sub> sampling architecture used in FRM and FEM  
14 sampling heads lead to significant changes in measured PM<sub>10</sub> in areas affected by high  
15 concentrations of particles greater than 10 microns in size relative to each other and to the  
16 required performance specifications in 40 CFR part 53?
- 17 ■ In 2006, EPA considered, but did not adopt, a sub-daily PM<sub>2.5</sub> secondary NAAQS to  
18 protect against visibility-related impairment in urban areas. Have new data altered  
19 previous conclusions about using continuous PM<sub>2.5</sub> monitoring methods capable of  
20 providing hourly time resolution to support a potential sub-daily standard and/or other  
21 metrics (e.g., light scattering) that may be considered? What method(s) should be  
22 considered as the reference method?
- 23 ■ What new information is available to inform options and technologies for sampling and  
24 analysis of components of thoracic coarse particles? Speciation monitoring of PM<sub>10-2.5</sub> is  
25 required in some areas as part of the NCore monitoring network that must be  
26 implemented by 2011. What operational experiences learned in the PM<sub>2.5</sub> speciation  
27 network can be useful in the evaluation of sampler design and laboratory analysis  
28 methods being considered for PM<sub>10-2.5</sub> filters?

- 1       ▪ In addition to PM<sub>10-2.5</sub> monitoring being implemented as part of NCore, what other PM
- 2       and PM precursor-related measurements (e.g., ammonia, true NO<sub>2</sub>, nitric acid) should be
- 3       considered for incorporation into these multi-pollutant monitoring stations?
- 4       ▪ Is new technology available to advance ambient monitoring methods for ultra-fine
- 5       particles (particles less than 100 nanometers in diameter) from being research-only
- 6       instruments to being field-ready techniques that can be operated within conventional
- 7       monitoring networks?
- 8       ▪ To what extent should sample volume measurement<sup>24</sup> be consistent across the various
- 9       PM methods? Is there evidence to support modifying the PM<sub>10</sub> FRM to operate at local
- 10      rather than standard conditions?

## 11   **Data Reporting and Assessments**

12           In the 2006 revisions to the PM<sub>2.5</sub> FRM reporting requirements, EPA reduced the data

13   reporting requirements associated with the PM<sub>2.5</sub> FRM to decrease the data management burden

14   for monitoring agencies. EPA also added a requirement for submission of data on PM<sub>2.5</sub> field

15   blank mass in addition to PM<sub>2.5</sub> filter-based measurements. Reporting requirements will be the

16   same for PM<sub>10-2.5</sub> monitoring data. Quality assurance (QA) and network assessments are also an

17   important part of evaluating and confirming that the data from the monitoring networks continue

18   to meet the data needs. States conduct in-depth network assessments intended to ensure that

19   future gaps between data needs and monitoring operations are identified and filled in a timely

20   manner. Network assessments are required every 5 years, with the next one due by July 1, 2010.

21   As part of the QA framework, EPA establishes data quality objectives (DQOs) so that data can

22   be used effectively in making decisions regarding attainment of the NAAQS. DQOs for PM<sub>2.5</sub>

23   and PM<sub>10-2.5</sub> monitoring data have been developed. Regular data quality assessments are

24   performed to determine if the data are continually meeting the specified DQOs.

25           Data reporting and assessment issues that will be considered in this review are reflected

26   in the following questions:

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<sup>24</sup>The current PM<sub>10</sub> FRM requires operation and data reporting on a standard temperature and pressure basis, (measurements adjusted to 25 degrees C and 1 atmosphere). The current PM<sub>2.5</sub> and PM<sub>10-2.5</sub> FRMs are required to operate on a local (actual) temperature and pressure basis to better represent conditions of actual measurement and population exposure. Significant differences can occur between PM measurements calculated on standard conditions versus local conditions in some circumstances (e.g., high elevation monitoring sites).

- 1 • What has been learned from the analysis of PM<sub>2.5</sub> filter blank mass data that was newly  
2 required to be reported to the Air Quality System (AQS) in the 2006 revisions to  
3 monitoring regulations? To what extent should the blank data be considered in this  
4 review of the PM<sub>2.5</sub> NAAQS?
- 5 • An increase in the number of low volume PM<sub>10</sub> samplers is expected with the transition  
6 to PM<sub>10-2.5</sub> measurement and the desire of monitoring agencies to deploy more automated  
7 (sequential) filter-based samplers into the networks. Does an analysis of precision and  
8 bias data sets from high-volume and low-volume PM<sub>10</sub> samplers demonstrate a  
9 significant advantage for low-volume samplers to the extent that the phase-out of high-  
10 volume samplers PM<sub>10</sub> should be considered?
- 11 • What new assessments of PM<sub>2.5</sub> data should be considered to evaluate the performance of  
12 newer, continuous FEMs and Approved Regional Methods (ARMs) in comparison to the  
13 FRM? What should be the consequences of identifying a poor comparison between an  
14 approved FEM or ARM versus a collocated FRM?
- 15 • In anticipation of the use of hourly continuous PM<sub>2.5</sub> data to help inform consideration of  
16 a potential sub-daily secondary NAAQS, should FEM approval regulations (40 CFR part  
17 53) and/or ambient monitoring quality assurance regulations (40 CFR part 58, Appendix  
18 A) be modified to specifically require quantitative assessment of sub-daily data (e.g.,  
19 precision assessment of hourly data)?

## 8 POLICY ASSESSMENT/ RULEMAKING

Based on the information in the ISA, the risk/exposure assessment, and the visibility/welfare-related assessment, the Agency will develop an ANPR that reflects EPA's initial views regarding the need to retain or revise the NAAQS for PM<sub>2.5</sub> and PM<sub>10</sub>. In doing so, the Agency will consider the policy-relevant questions outlined in Section 3 including the fundamental questions associated with the adequacy of the current standards and consideration of alternative standards in terms of the specific elements of the standards: indicator, averaging time, level, and form.

The ANPR will identify conceptual evidence-based and risk/exposure-based approaches for reaching public health policy judgments. It will discuss the implications of the science and risk/exposure assessments for the adequacy of the current standards, and it will present risk/exposure information associated with alternative standards under consideration. The ANPR will also describe a range of policy options for standard setting including a description of the underlying interpretations of the scientific evidence and risk/exposure information that might support such alternative standards and that could be considered by the Administrator in making decisions for the suite of PM standards.

The use of an ANPR will provide an opportunity for CASAC and the public to evaluate the policy options under consideration and to offer comments and recommendations to inform the development of a proposed rule. Taking into account CASAC advice and recommendations and public comment on the ANPR, the Agency will publish a proposed rule. This proposal will be followed by a public comment period. Taking into account comments received on the proposed rule, the Agency will then issue a final rule to complete the rulemaking process. Monitoring rule changes associated with any revisions to the PM standards as outlined in Section 7 will be developed, if necessary, in conjunction with this NAAQS rulemaking.

## 9 REFERENCES

- 1
- 2 Abt Associates (2001). Assessing Public Opinions on Visibility Impairment Due to Air  
3 Pollution: Summary Report. Prepared for EPA Office of Air Quality Planning and  
4 Standards; U.S. Environmental Protection Agency, Contract No. 68-D-98-001. Bethesda,  
5 Maryland. January 2001.
- 6 Abt Associates (2005). Particulate Matter Health Risk Assessment for Selected Urban Areas.  
7 Final Report. Bethesda, MD. Prepared for the Office of Air Quality Planning and  
8 Standards, U.S. Environmental Protection Agency, Contract No. 68-D-03-002. EPA  
9 452/R-05-007A. Available: [http://www.epa.gov/ttn/naaqs/standards/pm/s\\_pm\\_cr\\_td.html](http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_td.html).
- 10
- 11 Air Resource Specialists, Inc. (2003) WinHaze Air Quality Modeler, version 2.9.0. Available  
12 from <http://www.air-resource.com/whatsnew.htm>
- 13 Burke J.M., Zufall M.J. and Özkaynak H (2001). A population exposure model for particulate  
14 matter: case study results for PM<sub>2.5</sub> in Philadelphia, PA. *J Expos Anal Environ Epidemiol*  
15 2001: 11: 470–489.
- 16 Cressie, Noel, Bruce E. Buxton, Catherine A. Calder, Peter F. Craigmile, Crystal Dong, Nancy J.  
17 McMillan, Michele Morara, Thomas J. Santner, Ke Wang, Gregory Young and Jian Zhang  
18 (2007). From sources to biomarkers: A hierarchical Bayesian approach for human  
19 exposure modeling. *Journal of Statistical Planning and Inference*, Volume 137, Issue 11,  
20 Pages 3361-3379.
- 21 DEHW (1969). Air Quality Criteria for Particulate Matter. U. S. Department of Health,  
22 Education, and Welfare. Public Health Service, Environmental Health Service, National  
23 Air Pollution Control Administration, Washington, D.C. January 1969.
- 24 Fryer, Michael, Chris D. Collins, Helen Ferrier, Roy N. Colvile and Mark J. Nieuwenhuijsen  
25 (2006). Human exposure modelling for chemical risk assessment: a review of current  
26 approaches and research and policy implications. *Environmental Science & Policy*,  
27 Volume 9, Issue 3, Pages 261-274.
- 28 Georgopoulos, P.G., Wang, S., Vyas, V.M., Sun, Q., Burke, J.M., Vedantham, R., McCurdy, T.,  
29 and Özkaynak, H (2005). A source-to-dose assessment of population exposures to fine PM  
30 and ozone in Philadelphia, PA, during a summer 1999 episode. *J Expos Anal Environ*  
31 *Epidemiol* 15: 439–457
- 32 Gulliver, John and David J. Briggs (2005). Time-space modeling of journey-time exposure to  
33 traffic-related air pollution using GIS. *Environmental Research*, Volume 97, Issue 1, Pages  
34 10-25.
- 35
- 36 Henderson, R. (2005a). EPA's Review of the National Ambient Air Quality Standards for  
37 Particulate Matter (Second Draft PM Staff Paper, January 2005): A review by the  
38 Particulate Matter Review Panel of the EPA Clean Air Scientific Advisory Committee.  
39 June 6, 2005. Available: <http://www.epa.gov/sab/pdf/casac-05-007.pdf>.
- 40

1 Henderson, R. (2005b). Clean Air Scientific Advisory Committee (CASAC) Review of the EPA  
2 Staff Recommendations Concerning a Potential Thoracic Coarse PM Standard in the  
3 Review of the National Ambient Air Quality Standards for Particulate Matter: Policy  
4 Assessment of Scientific and Technical Information (Final PM OAQPS Staff Paper,  
5 EPA-452/R-05-005). September 15, 2005. Available:  
6 <http://www.epa.gov/sab/panels/casacpmpanel.html>.  
7

8 Henderson, R. (2006a). Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific  
9 Advisory Committee to the Honorable Stephen L. Johnson, Administrator, US EPA.  
10 Clean Air Scientific Advisory Committee Recommendations Concerning the Proposed  
11 National Ambient Air Quality Standards for Particulate Matter. March 21, 2006.  
12 Available: <http://www.epa.gov/sab/pdf/casac-ltr-06-002.pdf>  
13

14 Henderson, R. (2006b). Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific  
15 Advisory Committee to the Honorable Stephen L. Johnson, Administrator, US EPA.  
16 Clean Air Scientific Advisory Committee Recommendations Concerning the Final  
17 National Ambient Air Quality Standards for Particulate Matter. September 29, 2006.  
18 Available: <http://www.epa.gov/sab/pdf/casac-ltr-06-003.pdf>  
19

20 Hopke, P. (2002). Letter from Dr. Philip Hopke, Chair Clean Air Scientific Advisory Committee  
21 to Honorable Christine Todd Whitman, Administrator, U.S. EPA. Final advisory review  
22 report by the CASAC PM Review Panel on the proposed particulate matter risk  
23 assessment. May 23, 2002. Available: <http://www.epa.gov/sab/pdf/casacadv02002.pdf>.

24 IEC (2006). Expanded Expert Judgment Assessment of the Concentration-Response  
25 Relationship Between PM<sub>2.5</sub> Exposure and Mortality. Final Report. Prepared for the  
26 Office of Air Quality Planning and Standards, U.S. EPA, RTP, NC 27711 by Industrial  
27 Economics, Incorporated, Cambridge, MA. September 21, 2006.

28 Issarayangyun, Tharit and Stephen Greaves (2007). Analysis of minute-by-minute exposure to  
29 fine particulates inside a car - A time-series modelling approach. Transportation Research  
30 Part D: Transport and Environment, Volume 12, Issue 5, July 2007, Pages 347-357.

31 Klepeis, Neil E. and William W. Nazaroff (2006). Modeling residential exposure to secondhand  
32 tobacco smoke, Atmospheric Environment, Volume 40, Issue 23, Pages 4393-4407.

33 Langstaff, J. (2004). OAQPS Staff Memorandum to PM NAAQS Review Docket (OAR-2001-  
34 0017). Subject: A Methodology for Incorporating Short-term Variable Background  
35 Concentrations in Risk Assessment. December 17, 2004. Available:  
36 [http://www.epa.gov/ttn/naaqs/standards/pm/s\\_pm\\_cr\\_td.html](http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_td.html).

37 Langstaff, J. (2005). OAQPS Staff Memorandum to PM NAAQS Review Docket (OAR-2001-  
38 0017). Subject: Estimation of Policy-Relevant Background Concentrations of Particulate  
39 Matter. January 27, 2005. Available:  
40 [http://www.epa.gov/ttn/naaqs/standards/pm/s\\_pm\\_cr\\_td.html](http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_td.html)  
41

42 Langstaff, J. (2007). Analysis of Uncertainty in Ozone Population Exposure Modeling.

1 January 31, 2007. Memo to the Ozone NAAQS Review Docket. EPA-HQ-OAR-2005-  
2 0172-0174.

3 Marshall, J.D., T.E. McKone, and W.W. Nazaroff (2005). Inhalation of Primary Motor Vehicle  
4 Emissions: Effects of Urban Population and Land Area, *Atmospheric Environment*, 39(2):  
5 283-295.

6 McBride, Sandra J., Ron W. Williams and John Creason (2007). Bayesian hierarchical modeling  
7 of personal exposure to particulate matter. *Atmospheric Environment*, Volume 41, Issue  
8 29, Pages 6143-6155.

9 McCurdy, T. (1994). Human Exposure to Ambient Ozone, Chapter 4 in *Tropospheric Ozone:  
10 Human Health and Agricultural Impacts*. Ed. David J. MacKee. CRC Press.

11 Morgan and Henrion (1990). *Uncertainty: A Guide to Dealing with Uncertainty in Qualitative  
12 Risk and Policy Analysis*. Cambridge University Press.

13 Richmond H., Palma, T, Langstaff, J., McCurdy, T., Glenn, G., Smith, L. (2002). Further  
14 Refinements and Testing of APEX (3.0): EPA's population exposure model for criteria and  
15 air toxic inhalation exposures. Joint meeting of the International Society of Exposure  
16 Analysis and International Society of Environmental Epidemiology, Vancouver, CAN.  
17 August 11-15, 2002.

18 Roman, H.A., Walker, K.D., Gettleman, T, Conner, L., Richmond, H.M., Hubbell, B.J., Kinney,  
19 P.L. (in press). An Expert Judgment Assessment of the Mortality Impact of Changes in  
20 Ambient Fine Particulate Matter in the U.S. Industrial Economics, Inc., Cambridge, MA;  
21 U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards;  
22 Columbia University Mailman School of Public Health.

23 U.S. EPA (2001). Review of the National Ambient Air Quality Standards for Particulate Matter:  
24 Policy Assessment of Scientific and Technical Information, Preliminary Draft OAQPS  
25 Staff Paper. Research Triangle Park, NC 27711: Office of Air Quality Planning and  
26 Standards. June 2001.

27 U.S. EPA (2002). Consolidated Human Activities Database (CHAD) Users Guide. Database  
28 and documentation available at: <http://www.epa.gov/chadnet1/>  
29

30 U.S. EPA (2004). Air Quality Criteria for Particulate Matter. National Center for Environmental  
31 Assessment, Office of Research and Development, U.S. Environmental Protection  
32 Agency, Research Triangle Park, NC 27711; report no. EPA/600/P-99/002aF and  
33 EPA/600/P-99/002bF. October 2004. Available:  
34 [http://www.epa.gov/ttn/naaqs/standards/pm/s\\_pm\\_cr\\_cd.html](http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_cd.html)  
35

36 U.S. EPA (2005). Review of the National Ambient Air Quality Standards for Particulate Matter:  
37 Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper.  
38 Research Triangle Park, NC 27711: Office of Air Quality Planning and Standards; report  
39 no. EPA EPA-452/R-05-005a. December 2005.  
40 Available: [http://www.epa.gov/ttn/naaqs/standards/pm/s\\_pm\\_cr\\_sp.html](http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_sp.html)  
41



- 1 U.S. EPA (2006a). Provisional Assessment of Recent Studies on Health Effects of Particulate  
2 Matter Exposure. National Center for Environmental Assessment, Office of Research  
3 and Development, U.S. Environmental Protection Agency, Research Triangle Park, NC  
4 27711; report no. EPA/600/R-06/063. July 2006. Available:  
5 [http://www.epa.gov/ttn/naaqs/standards/pm/s\\_pm\\_cr\\_td.html](http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_td.html)
- 6 U.S. EPA (2006b). Total Risk Integrated Methodology (TRIM) - Air Pollutants Exposure Model  
7 Documentation (TRIM.Expo / APEX, Version 4) Volume I: User's Guide. OAQPS, U.S.  
8 Environmental Protection Agency, Research Triangle Park, NC. June 2006. Available at:  
9 [http://www.epa.gov/ttn/fera/human\\_apex.html](http://www.epa.gov/ttn/fera/human_apex.html)
- 10 U.S. EPA (2006c). Total Risk Integrated Methodology (TRIM) - Air Pollutants Exposure Model  
11 Documentation (TRIM.Expo / APEX, Version 4) Volume II: Technical Support Document.  
12 OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, NC. June 2006.  
13 Available at: [http://www.epa.gov/ttn/fera/human\\_apex.html](http://www.epa.gov/ttn/fera/human_apex.html)
- 14 U.S. EPA (2007a). Integrated Science Assessment for Oxides of Nitrogen – Health Criteria (First  
15 External Review Draft). U.S. Environmental Protection Agency, Research Triangle Park,  
16 NC, EPA/600/R-07/093. Available at:  
17 <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=181712>
- 18 U.S. EPA (2007b). Integrated Science Assessment (ISA) for Sulfur Oxides – Health Criteria  
19 (First External Review Draft). U.S. Environmental Protection Agency, Research Triangle  
20 Park, NC, EPA/600/R-07/108. Available at:  
21 <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=182057>
- 22 Wilson, J. Gaines and Peyman Zawar-Reza (2006). Intraurban-scale dispersion modelling of  
23 particulate matter concentrations: Applications for exposure estimates in cohort studies,  
24 Atmospheric Environment, Volume 40, Issue 6, Pages 1053-1063.
- 25 Wu, Chang-Fu, Ralph J. Delfino, Joshua N. Floro, Penelope J.E. Quintana, Behzad S. Samimi,  
26 Michael T. Kleinman, Ryan W. Allen and L.-J. Sally Liu (2005). Exposure assessment  
27 and modeling of particulate matter for asthmatic children using personal nephelometers.  
28 Atmospheric Environment, Volume 39, Issue 19, Pages 3457-3469.

1 **APPENDIX A**

2 **U.S. EPA SCIENCE ADVISORY BOARD**

3 **CLEAN AIR SCIENTIFIC ADVISORY**

4 **COMMITTEE MEMBERS**

5 FISCAL YEAR 2007

6  
7 The Clean Air Scientific Advisory Committee (CASAC) has a statutorily mandated  
8 responsibility to review and offer scientific and technical advice to the Administrator on the air  
9 quality criteria and regulatory documents that form the basis for the national ambient air quality  
10 standards (NAAQS), which currently include standards for lead (Pb), particulate matter (PM),  
11 ozone (O<sub>3</sub>), carbon monoxide (CO), nitrogen dioxide (NO<sub>2</sub>) and sulfur dioxide (SO<sub>2</sub>).

12 To perform such reviews, in each case the Committee forms a review panel consisting of  
13 CASAC members augmented by selected consultants with expertise in scientific or technical  
14 areas pertinent to the given pollutant or pollutant class under review.

15 **CHAIR**

16 Dr. Rogene Henderson  
17 Lovelace Respiratory Symposium  
18 Lovelace Respiratory Research Institute  
19 Albuquerque, NM 87185

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22 Robert A. Plane Professor  
23 Department of Chemical Engineering  
24 Clarkson University  
25 Potsdam, NY 13699

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31 **TO BE DETERMINED**

1 **SCIENCE ADVISORY BOARD STAFF**

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3 Mr. Fred A. Butterfield, III  
4 Designated Federal Officer  
5 Clean Air Scientific Advisory Committee  
6 Science Advisory Board (1400A)  
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# **APPENDIX B**

## **PARTICULATE MATTER INTEGRATED SCIENCE ASSESSMENT - PROPOSED OUTLINE**

### **1. INTRODUCTION**

DOCUMENT DEVELOPMENT

ORGANIZATION OF THE DOCUMENT

### **2. SOURCE TO DOSE**

INTRODUCTION

ATMOSPHERIC CHEMISTRY, PHYSICS, SOURCES, EMISSIONS

MEASUREMENT TECHNIQUES AND CONCENTRATIONS

ISSUES ASSOCIATED WITH EVALUATING EXPOSURE TO PM

GENERAL CONSIDERATIONS FOR PERSONAL EXPOSURES

indoor sources, penetration of ambient PM indoors

PERSONAL EXPOSURE AND AMBIENT CONCENTRATION

EXPOSURE MEASUREMENT ERROR

DOSIMETRY OF INHALED PM –deposition, clearance, overload, modeling

### **3. INTEGRATED HEALTH EFFECTS OF PM EXPOSURE**

POTENTIAL MECHANISMS OF INJURY/MODES OF ACTION

MORBIDITY ASSOCIATED WITH SHORT-TERM EXPOSURE

Cardiovascular effects - by endpoint, then type of PM, then by discipline

Respiratory effects - by endpoint, then type of PM, then by discipline

Other system effects - by endpoint, then type of PM, then by discipline

MORTALITY ASSOCIATED WITH SHORT-TERM EXPOSURE

Multi-city studies and meta-analyses, risk estimates, confounding,  
cause-specific mortality

MORBIDITY ASSOCIATED WITH LONG-TERM EXPOSURE

Cardiovascular effects - by endpoint, then type of PM, then by discipline

Respiratory effects - by endpoint, then type of PM, then by discipline

Adverse birth outcomes

Cancer incidence, mutagenicity, genotoxicity

Other effects - by endpoint, then type of PM, then by discipline

#### MORTALITY ASSOCIATED WITH LONG-TERM EXPOSURE

US and European studies, estimations of exposure, summary of risk

### **4. PUBLIC HEALTH IMPLICATIONS OF PM**

#### ENVIRONMENTAL CONCENTRATIONS –

Ambient air quality data

Spatial and temporal variability

Policy-relevant background

#### HUMAN EXPOSURES

SUSCEPTIBLE AND VULNERABLE POPULATIONS- pre-existing disease, age, high-exposure groups, genetic factors, SES, potential numbers of people

#### C-R FUNCTION AND THRESHOLD

#### HETEROGENEITY IN EFFECTS FROM EXPOSURE TO PM

POTENTIAL PUBLIC HEALTH IMPACTS – adversity of effects, numbers of persons in susceptible populations

### **5. WELFARE EFFECTS OF PM**

#### VISIBILITY

organics, metrics, Regional Haze Rule, aerosol/optical characteristics, spatial patterns, seasonal patterns, multiyear trends

#### ECOLOGICAL AND ENVIRONMENTAL EFFECTS

ecosystem effects, deposition, direct and indirect ecosystem stress, ecotoxicology, nutrient cycling

#### EFFECTS OF PM ON CLIMATE

#### EFFECTS OF CLIMATE ON PM

### **6. PUBLIC WELFARE IMPLICATIONS OF PM**

## **7. FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS**

### **SUMMARY OF KEY FINDINGS - SOURCE TO DOSE**

Atmospheric science, exposure assessment

### **SUMMARY OF KEY FINDINGS - HEALTH EFFECTS**

2004 Findings, new findings

### **SUMMARY OF KEY FINDINGS – ENVIRONMENTAL EFFECTS**

### **CONCLUSIONS**

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United States  
Environmental Protection  
Agency

Office of Air Quality Planning and Standards  
Health and Environmental Impacts Division  
Research Triangle Park, NC

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