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 integrated review plan for the national ambient air quality standards (NAAQS) for particulate matter (PM) serves 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 this 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

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

This review will provide an integrative assessment of relevant scientific information on PM and will focus on the basic elements of the primary and secondary PM air quality standards: the indicator, averaging time, form,[1] and level. These elements, which serve to define each ambient air quality standard, must be considered collectively in evaluating the health protection afforded by the standard. The current standards use $PM_{2.5}$ and PM_{10} as the indicators for fine and coarse particles, respectively.

This integrated review plan is organized into eight sections. Section 1 presents background information on the recently revised NAAQS review process, the legislative requirements for the review of the NAAQS, past reviews of the NAAQS for PM, and the scope of the current review. Section 2 presents the current review schedule. Section 3 presents a set of key policy-relevant questions that will serve to focus this review on the critical scientific and policy issues. Sections 4 through 8 discuss the planned scope and organization of the key assessment documents, the planned approaches for preparing the documents, specific monitoring issues, and plans for scientific and public review of the documents.

EPA consulted with the Clean Air Scientific Advisory Committee (CASAC), an independent scientific advisory committee established under the Clean Air Act[2], on a draft of this document. This final integrated review plan reflects comments received from individual CASAC members as well as comments from the public.[3] As the assessments proceed, the plan described here may be modified to reflect information received during the review process and to

[1] 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.

[2] See http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommitteesSubcommittees/CASAC%20Particulate%20Matter%20Review%20Panel for a list of the CASAC PM Panel members.

[3] See http://yosemite.epa.gov/sab/sabproduct.nsf/76D069B8191381DA852573C500688E74/$File/EPA-CASAC-08-004-unsigned.pdf for more information on the CASAC comments submitted on the draft integrated review plan.

address additional advice and comments received from CASAC and from the public throughout this review.

1.1 OVERVIEW OF THE NAAQS REVIEW PROCESS

Since completion of the last PM NAAQS review, the Agency has made 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: an integrated review plan, a science assessment, a risk/exposure assessment, and a policy assessment/rulemaking. Each of these components is described in this section.

The review process starts with the development of an integrated review plan prepared jointly by EPA's National Center for Environmental Assessment (NCEA) within the Office of Research and Development (ORD) and EPA's Office of Air Quality Planning and Standards (OAQPS) within the Office of Air and Radiation (OAR). This document represents the current plan and specifies the schedule for the entire 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 the development of the science assessment, which consists of an Integrated Science Assessment (ISA) and supporting annexes. NCEA along with contracted support prepares these documents. The annexes will contain a comprehensive description and evaluation/assessment of the full breadth of the current scientific literature pertaining to known and anticipated effects on public health and welfare associated with the presence of PM in the ambient air, emphasizing the information that has become available since the last review in order to reflect the current state of knowledge. NCEA will then critically evaluate, integrate, and synthesize the most policy-relevant science from the annexes into an ISA. The ISA is intended to provide information useful in forming judgments about air quality indicator(s), form(s), averaging time(s) and level(s) for the primary and secondary PM NAAQS. Hence, the ISA and its associated annexes function in the new NAAQS review as the Air Quality Criteria Document (AQCD) did in previous reviews. The schedule includes production of a first and second draft ISA, both of which will undergo CASAC and public review prior to completion of the final ISA. Section 4 provides a more detailed description of the planned scope, organization and assessment approach for the annexes and ISA.

In the third component of the revised review process, the risk/exposure assessment, EPA's OAQPS plans to draw upon the information presented in the ISA to develop quantitative and qualitative estimates of the exposures and risks of adverse health and welfare effects associated with current ambient levels of PM, with levels that just meet the current standards, and with levels that just meet possible alternative standards. Sections 5 and 6 of this integrated plan contain more detail about possible approaches EPA could take in conducting the human health and visibility and other welfare-related assessments, respectively. Once the first draft ISA is complete, EPA will release separate draft Scope and Methods Plans for human health and visibility/other welfare-related assessments for CASAC and public review that describe the proposed scope of the analyses to be performed and the tools/methods that may be employed. Comments on the draft Scope and Methods Plans will be considered as EPA performs the actual analyses. The schedule includes production of first and second draft risk/exposure assessments, all of which will undergo CASAC and public review prior to completion of the final risk/exposure assessment reports that will focus on key results, observations, and uncertainties.

The fourth component of the revised process is a policy assessment/rulemaking. Under the revised NAAQS process, a policy assessment reflecting Agency views will be published in the Federal Register as an advance notice of proposed rulemaking (ANPR). The ANPR will be accompanied by supporting documents, such as air quality analyses and technical support documents, as appropriate. The ANPR will take the place of the Staff Paper prepared for previous NAAQS reviews. Taking into account CASAC advice and recommendations as well as public comment on the ANPR, the Agency will publish a proposed rule, to be followed by a public comment period. Taking into account comments received on the proposed rule, the Agency will issue a final rule to complete the rulemaking process.

1.2 LEGISLATIVE REQUIREMENTS

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list "air pollutants" that "in his judgment, may reasonably be anticipated to endanger public health and welfare" and whose "presence . . . in the ambient air results from numerous or diverse mobile or stationary sources" and to issue air quality criteria for those that are listed. 42 U.S.C. § 7408(a) & (b). Air quality criteria are intended to "accurately reflect the latest scientific knowledge

useful in indicating the kind and extent of identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in ambient air . . . ." 42 U.S.C. § 7408(b).

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants listed under section 108. 42 U.S.C. § 7409 (a). Section 109(b) (1) defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."[4] 42 U.S.C. § 7409(b)(1). A secondary standard, as defined in section 109(b)(2), must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is required to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air."[5] 42 U.S.C. § 7409(b)(2).

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

In selecting a margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to

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

[5] 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."

providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Association v. EPA*, supra, 647 F.2d at 1161-62.

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

Section 109(d)(1) requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate . . . ." 42 U.S.C. § 7409(d)(1). Section 109(d)(2) requires that an independent scientific review committee "shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate . . . ." 42 U.S.C. § 7409(d)(2). Since the early 1980's, this independent review function has been performed by CASAC.

1.3 HISTORY OF REVIEWS OF THE NAAQS FOR PM

Particulate matter is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes. Particles originate from a variety of anthropogenic stationary and mobile sources as well as from natural sources. Particles may be emitted directly or formed in the atmosphere by transformations of gaseous emissions such as sulfur oxides (SO_x), nitrogen oxides (NO_x), and volatile organic compounds (VOC). Examples of secondary particle formation include: (1) the conversion of sulfur dioxide (SO_2) to sulfuric acid (H_2SO_4) droplets that further react with gaseous ammonia (NH_3) to form various sulfate particles (e.g., ammonium sulfate, $(HNH_4)_2SO_4$, or ammonium bisulfate, NH_4HSO_4); (2) the conversion of nitrogen dioxide (NO_2) to nitric acid (HNO_3) vapor that reacts further with ammonia to form ammonium nitrate (NH_4NO_3) particles; and (3) reactions involving gaseous VOC yielding organic compounds with low ambient temperature (saturation) vapor pressures that nucleate or condense on existing particles to form secondary organic aerosol particles (U.S. EPA, 2004, Chapter 3). The chemical and physical

properties of PM vary greatly with time, region, meteorology, and source category, thus complicating the assessment of health and welfare effects. Table 1-1 summarizes the NAAQS that have been promulgated for PM to date. These reviews are briefly described below.

Table 1-1. Summary of National Ambient Air Quality Standards Promulgated for Particulate Matter 1971-2006[6]

Final Rule	Indicator	Ave. Time	Level	Form
1971 (36 FR 8186)	**TSP - Total Suspended Particles** ($\leq$ 25-45 μm)	**24-hour**	**260 μg/m^3** (primary) **150 μg/m^3** (secondary)	Not to be exceeded more than once per year
		Annual	**75 μg/m^3** (primary)	Annual average
1987 (52 FR 24634)	**PM_{10}**	**24-hour**	**150 μg/m^3**	Not to be exceeded more than once per year on average over a 3-year period
		Annual	**50 μg/m^3**	Annual arithmetic mean, averaged over 3 years
1997 (62 FR 38652)	**$PM_{2.5}$**	**24-hour**	**65 μg/m^3**	98th percentile, averaged over 3 years
		Annual	**15 μg/m^3**	Annual arithmetic mean, averaged over 3 years[7]
	PM_{10}	**24-hour**	**150 μg/m^3**	Initially promulgated 99th percentile, averaged over 3 years; when 1997 standards were vacated, the form of 1987 standards remained in place (not to be exceeded more than once per year on average over a 3-year period)
		Annual	**50 μg/m^3**	Annual arithmetic mean, averaged over 3 years
2006 (71 FR 61144)	**$PM_{2.5}$**	**24-hour**	**35 μg/m^3**	98th percentile, averaged over 3 years
		Annual	**15 μg/m^3**	Annual arithmetic mean, averaged over 3 years[8]
	PM_{10}	**24-hour**	**150 μg/m^3**	Not to be exceeded more than once per year on average over a 3-year period

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

[7] The level of the 1997 annual $PM_{2.5}$ standard was to be compared to measurements made at the community-oriented monitoring site recording the highest level, or, if specific constraints were met, measurements from multiple community-oriented monitoring sites could be averaged ("spatial averaging"). These criteria and constraints were intended to ensure that spatial averaging would not result in inequities in the level of protection afforded by the $PM_{2.5}$ standards. Community-oriented monitoring sites were specified to be consistent with the intent that a spatially averaged annual standard provide protection for persons living in smaller communities, as well as those in larger population centers.

[8] In the revisions to the PM NAAQS finalized in 2006, EPA tighten the constraints on the spatial averaging criteria by further limiting the conditions under which some areas may average measurements from multiple community-oriented monitors to determine compliance (see 71 FR 61165-61167, October 17, 2006)

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

In October 1979 (44 FR 56730, October 2, 1979), EPA announced the first periodic review of the air quality criteria and NAAQS for PM, and significant revisions to the original standards were promulgated in 1987 (52 FR 24634, July 1, 1987). In that decision, EPA changed the indicator for particles from TSP to PM_{10}, the latter including particles with a mean aerodynamic diameter[9] less than or equal to 10 μm, which delineated that subset of inhalable particles small enough to penetrate to the thoracic region (including the tracheobronchial and alveolar regions) of the respiratory tract (referred to as thoracic particles). EPA also revised the level and form of the primary standards by (1) replacing the 24-hour TSP standard with a 24-hour PM_{10} standard of 150 $\mu g/m^3$ with no more than one expected exceedence per year; and (2) replacing the annual TSP standard with a PM_{10} standard of 50 $\mu g/m^3$, annual arithmetic mean. The secondary standard was revised by replacing it with 24-hour and annual standards identical in all respects to the primary standards. The revisions also included a new reference method for the measurement of PM_{10} in the ambient air and rules for determining attainment of the new standards. On judicial review, the revised standards were upheld in all respects. *Natural Resources Defense Council v. Administrator*, 902 F. 2d 962 (D.C. Cir. 1990, cert. denied, 498 U.S. 1082 (1991).

In April 1994, EPA announced its plans for the second periodic review of the air quality criteria and NAAQS for PM, and promulgated significant revisions to the NAAQS in 1997 (62 FR 38652, July 18, 1997). In that decision, EPA revised the PM NAAQS in several respects. While EPA determined that the PM NAAQS should continue to focus on particles less than or

[9] The more precise term is 50 percent cut point or 50 percent diameter (D_{50}). 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.

equal to 10 μm in diameter (PM_{10}), EPA also determined that the fine and coarse fractions of PM_{10} should be considered separately. The Agency's decision to modify the standards was based on evidence that serious health effects were associated with short- and long-term exposure to fine particles in areas that met the existing PM_{10} standards. The EPA added new standards, using $PM_{2.5}$ as the indicator for fine particles (with $PM_{2.5}$ referring to particles with a nominal mean aerodynamic diameter less than or equal to 2.5 μm), and using PM_{10} as the indicator for purposes of regulating the coarse fraction of PM_{10} (referred to as thoracic coarse particles or coarse-fraction particles; generally including particles with a nominal mean aerodynamic diameter greater than 2.5 μm and less than or equal to 10 μm, or $PM_{10-2.5}$). The EPA established two new $PM_{2.5}$ standards: an annual standard of 15 $\mu g/m^3$, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors; and a 24-hour standard of 65 $\mu g/m^3$, based on the 3-year average of the 98^{th} percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area. Also, EPA established a new reference method for the measurement of $PM_{2.5}$ in the ambient air and adopted rules for determining attainment of the new standards. To continue to address thoracic coarse particles, EPA retained the annual PM_{10} standard, while revising the form, but not the level, of the 24-hour PM_{10} standard to be based on the 99^{th} percentile of 24-hour PM_{10} concentrations at each monitor in an area. The EPA revised the secondary standards by making them identical in all respects to the primary standards.

Following promulgation of the 1997 PM NAAQS, petitions for review were filed by a large number of parties, addressing a broad range of issues. In May 1999, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit issued an initial decision that upheld EPA's decision to establish fine particle standards, holding that "the growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects amply justifies establishment of new fine particle standards." *American Trucking Associations v. EPA* , 175 F. 3d 1027, 1055-56 (D.C. Cir. 1999) (rehearing granted in part and denied in part, 195 F. 3d 4 (D.C. Cir. 1999)), affirmed in part and reversed in part, *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001). The Panel also found "ample support" for EPA's decision to regulate coarse particle pollution, but vacated the 1997 PM_{10} standards, concluding that EPA had not provided a reasonable explanation justifying use of PM_{10} as an indicator for coarse particles. 175 F. 3d at 1054-55. Pursuant to the court's decision, EPA removed the

vacated 1997 PM_{10} standards. The pre-existing 1987 PM_{10} standards remained in place (65 FR 80776, December 22, 2000). The Court also upheld EPA's determination not to establish more stringent secondary standards for fine particles to address effects on visibility. 175 F. 3d at 1027.

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

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

In October 1997, EPA published its plans for the third periodic review of the air quality criteria and NAAQS for PM (62 FR 55201, October 23, 1997), including the 1997 $PM_{2.5}$ standards and the 1987 PM_{10} standards. After CASAC and public review of several drafts, EPA's NCEA finalized the Air Quality Criteria Document for Particulate Matter (henceforth, the "Criteria Document") in October 2004 (U.S. EPA, 2004). The final Staff Paper (U.S. EPA,

2005a), took into account the advice and recommendations of CASAC and public comments received on the earlier drafts of this document and presented additional advice and recommendations submitted by CASAC to the Administrator.

For the primary fine particle standards, most CASAC PM Panel members favored the option of revising the level of the 24-hour $PM_{2.5}$ standard in the range of 35 to 30 $\mu g/m^3$ with a 98^{th} percentile form, in concert with revising the level of the annual $PM_{2.5}$ standard in the range of 14 to 13 $\mu g/m^3$ (Henderson, 2005a). Most of the members of the CASAC PM Panel also strongly supported establishing a new, secondary $PM_{2.5}$ standard to protect urban visibility and recommended establishing a sub-daily (4- to 8-hour averaging time) $PM_{2.5}$ standard within the range of 20 to 30 $\mu g/m^3$ with a form within the range of the 92^{nd} to 98^{th} percentile (Henderson, 2005a). For thoracic coarse particles, there was general concurrence among CASAC PM Panel members to revise the PM_{10} standards by establishing a primary standard specifically targeted to address particles in the size range of 2.5 to 10 µm. The CASAC PM Panel was also in general agreement "that coarse particles in urban or industrial areas are likely to be enriched by anthropogenic pollutants that tend to be inherently more toxic than the windblown crustal material which typically dominates coarse particle mass in arid rural areas." Based on its review of the Staff Paper, there was general agreement among the CASAC PM Panel members that a 24-hour $PM_{10-2.5}$ standard with a level in the range of 50 to 70$\mu g/m^3$, with a 98^{th} percentile form, was reasonably justified and that a $PM_{10-2.5}$ standard with an annual averaging time was not warranted (Henderson, 2005b).

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

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

On September 21, 2006, EPA announced its final decisions to revise the primary and secondary NAAQS for PM to provide increased protection of public health and welfare, respectively (71 FR 61144, October 17, 2006). With regard to the primary and secondary standards for fine particles, EPA revised the level of the 24-hour $PM_{2.5}$ standard to 35 $\mu g/m^3$, retained the level of the annual $PM_{2.5}$ annual standard at 15 $\mu g/m^3$, and revised the form of the annual $PM_{2.5}$ standard by narrowing the constraints on the optional use of spatial averaging. With regard to the primary and secondary standards for PM_{10}, EPA retained the 24-hour PM_{10} standard at 150 $\mu g/m^3$ and revoked the annual standard because available evidence generally did not suggest a link between long-term exposure to current ambient levels of coarse particles and health or welfare effects.

The revisions to the PM NAAQS also included a new reference method (Federal reference method or FRM) for the measurement of $PM_{10-2.5}$ in the ambient air. Although the standards for thoracic coarse particles do not use a $PM_{10-2.5}$ indicator, the new FRM for $PM_{10-2.5}$

will provide a basis for approving Federal Equivalent Methods (FEMs) and promote the gathering of scientific data to support future reviews of the PM NAAQS. One of the reasons for not finalizing a $PM_{10-2.5}$ standard in 2006 was the limited body of evidence on health effects associated with thoracic coarse particles from studies that used $PM_{10-2.5}$ measurements of ambient thoracic coarse particle concentrations. With an FRM, researchers will likely include $PM_{10-2.5}$ measurements of thoracic coarse particles in health studies either by directly using the FRM or by utilizing approved FEMs.

1.4 SCOPE OF THE CURRENT REVIEW

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 thoracic 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 that review, it was determined that size-fractionated particle mass, rather than particle composition, remained the most appropriate approach for addressing ambient PM. Building upon the last review, EPA plans to continue to review the available scientific evidence based on particle size, considering fine and coarse-fraction particles separately. EPA will also consider the available scientific evidence for additional size fractions (e.g., ultrafine particles). Within this basic structure, EPA will evaluate relevant scientific evidence on specific components, sources, and environments (e.g., urban and non-urban environments).

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

Susceptible or vulnerable subpopulations that were considered to be at greater risk to effects associated with PM exposures in the last review included individuals with pre-existing

heart and lung diseases, older adults, and children. In this review, EPA will integrate the previous understanding of sensitive subpopulations with new evidence on these and possibly additional sensitive subpopulations (e.g., fetuses, neonates, genetically susceptible populations).

In the last review of the suite of secondary standards, EPA focused on quantitatively evaluating visibility impairment associated with aerosol compounds present in ambient air, selecting $PM_{2.5}$ as the appropriate indicator for the standard. Other welfare effects including effects on climate change processes, vegetation, and ecosystems as well as materials damage and soiling related to both fine and coarse particles were considered more qualitatively. In this review, EPA plans to continue to focus the assessment of welfare effects on visibility-related impacts associated with fine particles. This review will include consideration of the impacts on visibility impairment related to the mixture of aerosol compounds in ambient air including nitrates and sulfates. In addition, drawing on the information in the ISA, EPA will again consider other welfare effects in this review, for example, climate-related effects and/or welfare effects associated with deposition of specific particles (e.g., soiling, nuisance dust, materials damage, ecotoxicity of heavy metals).

1.5 LINKS TO OTHER NAAQS REVIEWS AND OTHER RELATED AGENCY ACTIVITIES

The Clean Air Act (CAA) calls for EPA to issue and periodically review air quality criteria and NAAQS for the "criteria" pollutants that now include PM, ozone (O_3), carbon monoxide (CO), sulfur oxides (SOx), nitrogen oxides (NOx), and lead (Pb). EPA is actively involved in reviewing all of these NAAQS at this time.[10] In addition to coordinating activities across NAAQS reviews, there are other specific Agency activities that will be taken into consideration during the review of the primary and secondary PM standards. These related activities are briefly described below.

Primary (Health-based) Standards

EPA will continue, as in previous NAAQS reviews, to evaluate the possible influence and interactions of other atmospheric pollutants (e.g., O_3, NOx, SOx, CO) in the interpretation of the role of PM in epidemiologic studies. In considering the relative importance of various key components of PM to the review of the primary PM NAAQS, EPA notes that the health effects associated with particulate species of nitrogen and sulfur oxides (e.g., nitrates and sulfates) were

[10] See http://www.epa.gov/ttn/naaqs/ for more information on the NAAQS reviews.

considered within the context of the last PM NAAQS review along with other key components such as elemental carbon (EC), organic carbon (OC), and metals. Building upon that review, EPA plans to continue to include these particulate species in this review of the health effects of ambient particles. In two other on-going NAAQS reviews, EPA is reviewing the current NO_2 and SO_2 primary NAAQS focusing on the gaseous species of nitrogen and sulfur oxides, respectively.[11]

Secondary (Welfare-based) Standards)

In reviewing the secondary PM NAAQS, EPA will continue to consider these standards in conjunction with the protection afforded by other programs intended to address visibility impairment, climate effects, and other welfare-related effects. As outlined in Section 1.4 above and discussed in more detail in Section 6, this review will focus on evaluating effects associated with aerosol compounds present in ambient air including nitrates and sulfates. In a separate effort, EPA has recently initiated a joint review of the NO_2 and SO_2 secondary NAAQS. That review will consider gaseous and particulate species of NOx and SOx with respect to acidification and eutrophication effects on ecosystems and will focus on the ecosystem-related welfare effects that result from the deposition of these pollutants and transformation products, rather than on the effects of particulate species of NOx and SOx that remain in the atmosphere.[12]

Visibility impairment is the most noticeable effect of fine particles present in the atmosphere. In the PM NAAQS review completed in 1997, EPA concluded that addressing visibility impairment solely through setting more stringent national secondary standards would not be an appropriate means to protect the public welfare from adverse impacts of PM on visibility in all parts of the country. As a consequence, EPA determined that an approach that combined national secondary standards with a regional haze program was the most appropriate and effective way to address visibility impairment (see 62 FR 38679-83, July 18, 1997). The Regional Haze Rule (64 FR 35714, July 1, 1999) recognizes that the pollutants that cause haze can be transported great distances so that the pollution that occurs in one State may contribute to

[11] See http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_index.html for more information on the primary NO_2 NAAQS review and http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_index.html for more information on the primary SO_2 NAAQS review.

[12] See http://www.epa.gov/ttn/naaqs/standards/no2so2sec/index.html for more information on the NO_2/SO_2 secondary NAAQS review.

impairment in Class I areas[13] elsewhere. In the PM NAAQS review completed in 2006, EPA recognized that the Regional Haze Program[14], implemented under sections 169A and 169B of the CAA, addressed all human-caused visibility impairment in Class I areas; therefore, the focus of the last PM NAAQS review was on visibility impairment primarily in urban areas. As described more fully in Section 6, EPA plans to continue this same focus in this review.

With respect to climate effects, changes in atmospheric concentrations of aerosols (particles) as well as greenhouse gases (GHGs), land-cover and solar radiation alter the energy balance of the climate system. Particles can have both direct and indirect effects on climatic processes. Direct effects are the result of the same processes responsible for visibility degradation, namely radiative scattering and absorption. However, while visibility impairment is caused by particle scattering in all directions, climate effects result mainly from scattering light away from the earth and into space. At the same time, absorption of either incoming solar radiation or outgoing terrestrial radiation by particles, primarily black carbon, results in an increase in the heating rate of the lower atmosphere. In addition to these direct radiative effects, particles can also have a number of indirect effects on climate related to their physical properties. The overall radiative and physical effects of particles, both direct and indirect, are not the simple sum of effects caused by individual classes of particles because interactions occur between particles and other atmospheric gases. The last review of the secondary PM NAAQS made clear that atmospheric particles play an important role in climatic processes, but that their role at the time of that review remained poorly quantified (US EPA, 2005a, p 6-55). As described in Section 6, in this review, EPA plans to continue to critically evaluate the scientific evidence for climate effects associated with particulate matter. The ISA will inform our understanding of PM-related effects on climate and this updated scientific evidence will be used to provide important input into broader Agency and inter-agency climate initiatives that are focused on slowing the growth of emissions affecting climate change, strengthening the scientific evidence and control technology options supporting policies on climate change, and enhancing international cooperation on activities related to climate issues.

[13] 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.

[14] See http://www.epa.gov/air/visibility/program.html for more information on EPA's Regional Haze Program.

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 $PM_{2.5}$ and PM_{10} 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-relevant 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 developed a 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. On November 30, 2007, CASAC held a teleconference with EPA to provide their comments on the draft integrated review plan (72 FR 63177, November 8, 2007). Public comments were also presented at that teleconference. This final integrated review plan incorporates comments received from CASAC and the general public on the draft plan.

Table 2-1. Proposed Schedule for Development of PM Integrated Science Assessment (ISA) and Review of $PM_{2.5}$ and PM_{10} NAAQS

Stage of Review	Major Milestone	Target Dates
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	March 2008
Science Assessment	Prepare First Draft ISA	September 2008
	CASAC/Public Review of First Draft ISA	December 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	October 2008
	CASAC Consultation on Scope and Methods Plan	December 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 and risk/exposure assessments 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 $PM_{2.5}$ and the 24-hour primary and secondary standards for PM_{10}.

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). This information will inform decisions related to whether sufficient evidence exists to warrant consideration of alternative indicators for PM, and, if appropriate, the development of new NAAQS.

3.1 ISSUES RELATED TO 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 key policy-relevant issues by addressing a series of questions including the following:

- Has new information altered the body of 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 exposures to $PM_{2.5}$, PM_{10}, $PM_{10-2.5}$, or alternative PM indicators that might be considered?
- What evidence is available from recent studies focused on specific size fractions, chemical components, sources, or environments (e.g., urban and non-urban areas) of PM to inform our understanding of the nature of PM exposures that are linked to various health outcomes?
- To what extent is key scientific evidence becoming available to improve our understanding of the health effects associated with various time periods of PM exposures, including not only short-term (daily or multi-day) and chronic (months to years) exposures, but also peak PM exposures (less than 24-hour)? To what extent is critical research becoming available that could improve our understanding of the relationship between various health endpoints and different lag periods (e.g., less than one day, single day, multi-day distributed lags)?
- What data are available to improve our understanding of spatial and/or temporal heterogeneity of PM exposures considering different size fractions and/or components?
- At what levels of PM exposure do health effects of concern occur? Is there evidence for the occurrence of adverse health effects at levels of PM lower than those observed previously? If so, at what levels and what are the important uncertainties associated with that evidence? What is the nature of the dose-response relationships of PM for the various health effects evaluated?
- What evidence is available linking particle number concentration with adverse health effects of ultrafine particles?
- Do risk/exposure estimates suggest that exposures of concern for PM-induced health effects will occur with current ambient levels of PM or with levels that just meet the current standards? If so, are these risks/exposures of sufficient magnitude such that the health effects might reasonably be judged to be important from a public health perspective? What are the important uncertainties associated with these risk/exposure estimates?

- To what extent is key evidence becoming available that could inform our understanding of subpopulations that are particularly sensitive or vulnerable to PM exposures[15]? In the last review, sensitive or vulnerable subpopulations that appeared to be at greater risk for PM-related effects included individuals with pre-existing heart and lung diseases, older adults, and children. Has new evidence become available to suggest additional sensitive subpopulations should be given increased focus in this review (e.g., fetuses, neonates, genetically susceptible subpopulations)?
- To what extent is key evidence becoming available to inform our understanding of populations that are particularly vulnerable to PM exposures? Specifically, is there new or emerging evidence to inform our understanding of geographical, spatial, SES, and environmental justice considerations?
- To what extent have important uncertainties identified in the last review been reduced and/or have new uncertainties emerged?
- To what extent is new information available to inform our understanding of non-PM-exposure factors that might influence the associations between PM levels and health effects being considered (e.g., weather-related factors; behavioral factors such as heating/air conditioning use; driving patterns; and time-activity patterns)?

Drawing upon the evidence and analyses presented in the ISA and risk/exposure assessment, EPA will evaluate whether revisions to the current suite of primary PM standards might be appropriate and, if so, how these standards might be revised. Specifically, EPA will evaluate how the scientific evidence informs decisions regarding the basic elements of the NAAQS: indicator, averaging time, level, and form. These elements will be considered collectively in evaluating the health protection afforded by the current or any alternative standards considered. Specific policy-relevant questions that will be addressed include:

- Do the evidence, the air quality assessment, and the risk/exposure assessment provide support for considering different pollutant indicators for fine and thoracic coarse particles? Specifically, is there evidence to support continuing to maintain the basic mass

[15] *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.

size-fraction approach used in the last review or does the evidence support an alternative approach for defining particle pollution, including other size fractions, specific components, specific source-related mixtures, specific environments (e.g., urban and non-urban environments) and/or indicators other than mass?

- Do the evidence, the air quality assessment, and the risk/exposure assessment provide support for considering different averaging times?
- What range of levels is supported by the evidence, the air quality assessment, and the risk/exposure assessments? What are the uncertainties and limitations in the evidence and the assessments?
- What is the range of forms supported by the evidence, the air quality assessment, and the risk/exposure assessments? What are the uncertainties and limitations in the evidence and the assessments?

3.2 ISSUES RELATED TO THE SECONDARY PM NAAQS

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

- What new evidence is available on the relationship between PM mass/size fraction and/or specific PM components and visibility impairment and climate-related and other welfare effects?
- To what extent has key scientific evidence now become available to improve our understanding of the nature and magnitude of visibility, climate, and ecosystem responses to PM and the variability associated with those responses (including ecosystem type, climatic conditions, environmental effects and interactions with other environmental factors and pollutants)?
- Do the evidence, the air quality assessment, and the risk/exposure assessment provide support for considering alternative averaging times?

- At what levels of ambient PM do visibility impairment and/or environmental effects of concern occur? Is there evidence for the occurrence of adverse visibility and other welfare-related effects at levels of PM lower than those observed previously? If so, at what levels and what are the important uncertainties associated with the evidence?
- Do the analyses suggest that PM-induced visibility impairment and/or other welfare-effects will occur with current ambient levels of PM or with levels that just meet the current standards? If so, are these effects of sufficient magnitude and/or frequency such that these effects might reasonably be judged to be important from a public welfare perspective? What are the uncertainties associated with these estimates?
- What new evidence and/or techniques are available to quantify the benefits of improved visibility and/or other welfare-related effects?
- To what extent have important uncertainties identified in the last review been reduced and/or have new uncertainties emerged?

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

- Do the evidence, the air quality assessment and the visibility and other welfare-related assessments provide support for considering different pollutant indicators or averaging times? What are the uncertainties and limitations in the evidence and the assessments?
- What range of levels is supported by the evidence, the air quality assessments, and the visibility and other welfare-related assessments? What are the important uncertainties associated with that evidence?
- What is the range of forms supported by the evidence, the air quality assessment, and the visibility and other welfare-related assessments? What are the uncertainties and 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 from the disciplines of epidemiology, toxicology, human clinical, 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, semi-volatiles, and organics 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 published since the last review of the air quality criteria for PM, and on key scientific evidence and science-policy issues raised during the last review. 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 remain definitive or are open to reinterpretation in light of newer data. Information that has undergone scientific peer review and

that has been published (or accepted for publication) in the open literature will be considered. Additionally, "gray literature," i.e., studies and reports from governmental agencies that have undergone sufficient quality assurance and/or peer review, may be included. Emphasis will be placed on studies conducted at or near PM concentrations found in ambient air. However, recognizing that toxicologic studies do not necessarily reflect effects in the most sensitive populations, studies at higher exposure levels will be included when they provide information relevant to previously unreported effects, evidence of the potential mechanism for an observed effect, or information on exposure-response relationships.

4.2 ASSESSMENT APPROACH

Introduction

The EPA's National Center for Environmental Assessment in Research Triangle Park (NCEA-RTP) is responsible for preparing the ISA and its annexes for PM. Expert authors include EPA staff with extensive knowledge in their respective fields and extramural scientists contracted to the EPA. A diagram showing the standard protocol for development of an ISA is shown in Figure 4.1. A complete description of the recently revised NAAQS process is addressed in Section 1.1.

Literature Search

The NCEA-RTP will use a systematic approach to identify relevant studies for consideration. A Federal Register notice (72 FR 35462, June 28, 2007) was published to announce the initiation of this review and request information from the public. An initial publication base will be established by searching MEDLINE, Toxfile, Pascal, Biosis, and Embase using as key words the terms particulate, particle, PM, $PM_{2.5}$, PM_{10}, coarse, fine, ultrafine, carbon black, ROFA, oil fly ash, CAPS, diesel, metals associated with PM, elemental carbon, organic carbon, nitrate, sulfate, oxidative potential, size distribution, bioaerosol, combustion, traffic, visibility, light extinction, ecosystem, climate, fly ash, aerosols, smoke, and soot. As appropriate, the search strategy will be reexamined and modified to enhance identification of pertinent published papers. Additional papers will be identified for inclusion in the publication base in several ways. First, EPA staff will review pre-publication tables of

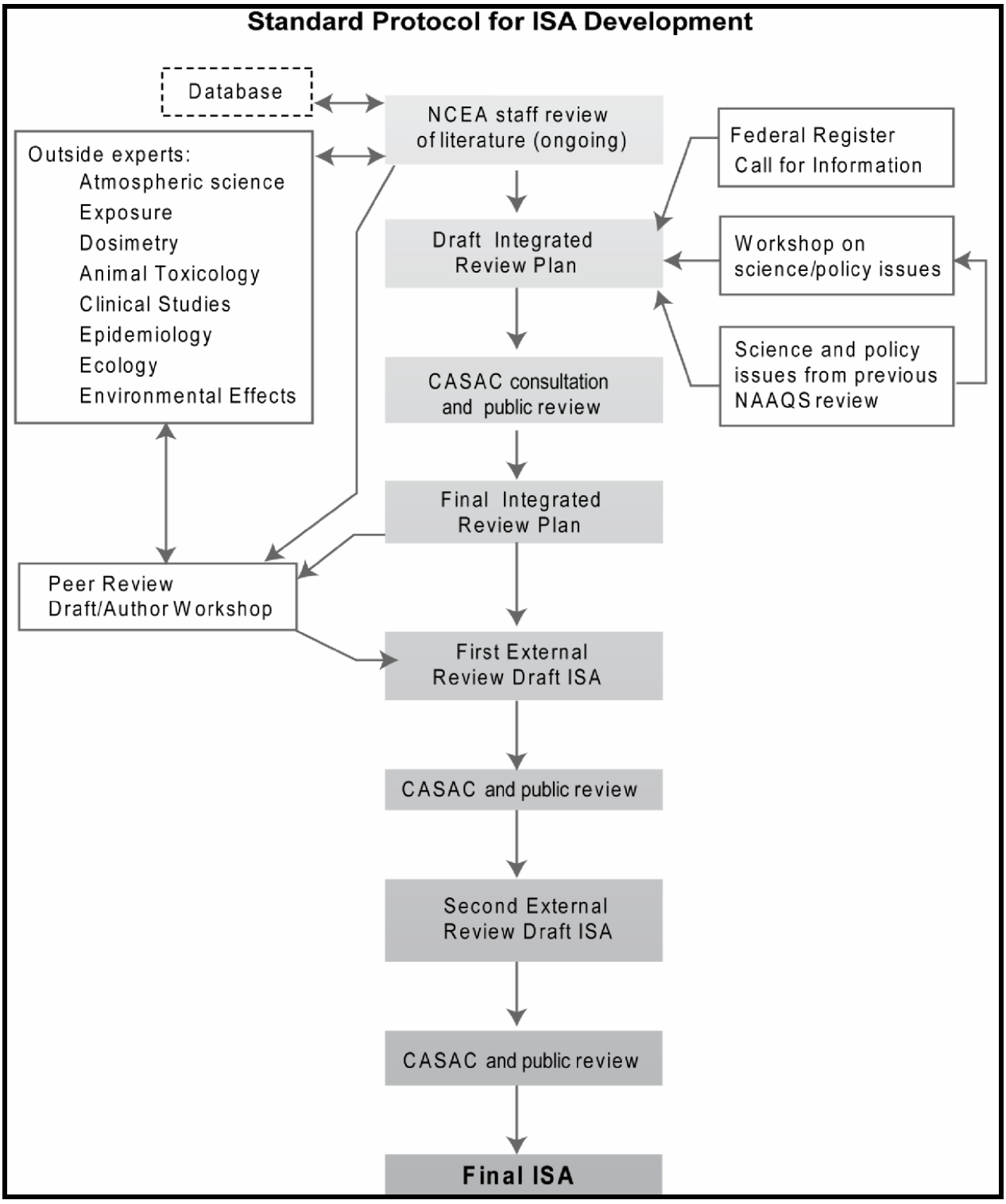

Figure 4.1 Standard protocol illustrating the steps involved in development of Integrated Science Assessments (ISAs)

contents for journals in which relevant papers may be published. Second, expert Section authors will be charged with independently identifying relevant literature. Finally, additional

publications that may be pertinent will be identified by both CASAC and the public during the external review process. The studies identified will include research published or accepted for publication by a date determined to be as inclusive as possible given the relevant target dates in the PM NAAQS review schedule. Some additional studies, published after that date, may also be included if they provide new information that impacts one or more key scientific issues. The combination of these approaches should produce the comprehensive collection of pertinent studies needed to form the basis of the ISA.

Criteria for Study Selection

In selecting epidemiologic studies for the present assessment, EPA will consider whether a given study contains information on (1) short- or long-term exposures at or near ambient levels of PM; (2) health effects of specific PM components or mixtures related to PM sources (e.g., motor vehicle emissions, combustion-related particles) and/or environments (e.g., urban, non-urban environments); (3) health endpoints that repeat or extend findings from earlier assessments as well as those not previously extensively researched; (4) populations that are susceptible and/or vulnerable to PM exposures; (5) issues related to potential confounding, and modification of effects; and/or (6) important methodological issues (e.g., lag of effects, model specifications, thresholds, mortality displacement) related to PM exposure effects. Among the epidemiologic studies, emphasis will be focused on those relevant to standard setting in the United States. Specifically, studies conducted in the U.S. or Canada will be generally accorded more emphasis than those from other geographic regions, as the potential impacts of different health care systems and the underlying health status of populations need to be accounted for in the assessment. However, informative studies conducted in other countries will be included, as appropriate. In addition, emphasis will be placed on discussion of (1) new, multi-city studies that employ standardized methodological analyses for evaluating PM effects, provide overall estimates for effects based on combined analyses of information pooled across cities, and examine results for consistency across cities; (2) new studies that provide quantitative effect estimates for populations of interest; and (3) studies that regard PM as a component of a complex mixture of air pollutants and thus give consideration to the levels of other copollutants, correlate PM levels with these copollutants, and include multipollutant analyses in the study design.

A set of explicit criteria will also be used to select toxicologic studies for the present assessment. The selection of research evaluating controlled exposures to laboratory animals will focus primarily on those studies conducted at or near ambient PM concentrations and those studies that approximate expected human dose conditions in terms of concentration, size distributions, and duration, which will depend on the toxicokinetics and biological sensitivity of the particular laboratory animals examined. For example, rodents typically require PM concentrations greater than ambient to mimic retention of particles in the lung in terms of mass or surface area per lung area equivalent to humans. Additionally, animal researchers are constrained by limited resources and thus cannot test hypotheses that require large numbers of animals exposed to ambient levels of PM over a prolonged time. Consequently, animals studies are typically used to acquire data relating to mechanisms and the exposures are purposefully high to assure a response. In discussing the mechanisms of PM toxicity, studies conducted under atmospherically-relevant conditions will be emphasized, but studies at higher concentrations also will be considered when these studies provide useful information to inform our understanding of species-to-species differences and potential differences in sensitivity between healthy individuals and especially susceptible human populations. Another consideration in evaluating PM studies using animals is the use of inhalation vs. lung instillation and other forms of dose administration. All else being equal, those studies using inhalation exposures will be given greater emphasis than those using instillation exposures because inhalation studies better simulate human exposure to PM. However, instillation studies must be used when assessing the effects of thoracic coarse particles in rodents. Studies will also be sought that reveal site-specific effects of PM exposure within the respiratory tract to determine the micro-domains of response and effect to better characterize non-pulmonary sequelae of exposure.

For research evaluating controlled human exposures to PM, emphasis will be placed on studies that: (1) investigate effects both on healthy populations and on potentially susceptible populations such as those with preexisting respiratory or cardiac disease such as asthma, diabetes, chronic obstructive pulmonary disease (COPD), ischemic heart disease (IHD), or congestive heart failure (CHF) (particularly studies where subjects serve as their own control to compare responses following PM exposure and sham exposure and where responses in susceptible individuals are compared with those in age-matched healthy controls); (2) address issues such as dose-response or time-course of responses; (3) investigate exposure to PM

separately and in combination with other pollutants such as O_3 and NO_2; (4) include control exposures to filtered air; and (5) have sufficient sample size to assess findings adequately.

For evaluation of welfare effects research, emphasis shall be placed on recent studies that: (1) evaluate effects at realistic ambient levels and (2) consider PM as a component of a complex mixture of air pollutants. Studies conducted both in the US and in other countries that contribute significantly to the knowledge base will be included in the assessment.

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

Quality Assurance

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

Content and Organization of the ISA

The organization of the ISA for PM will be consistent with that used in the recent draft ISAs for Nitrogen Oxides and Sulfur Oxides (U.S. EPA 2007 a, b). The ISA will contain information relevant to considering whether it is appropriate to retain or revise the current standards. Taking into consideration the broad policy-relevant questions outlined in Section 3, the policy-relevant questions that will guide development of the ISA are related to two overarching issues. The first issue is whether new evidence reinforces or calls into question the scientific evidence presented and evaluated in the last PM NAAQS review. The second issue is whether uncertainties from the last review have been addressed and/or whether new uncertainties have emerged. Specific questions related to the review of the scientific literature for PM that

stem from these issues will guide the content of the ISA. These questions were derived from the last review of the PM NAAQS, as well as from discussions of new scientific evidence that occurred at two recent EPA workshops as outlined in Section 2 above. These questions are listed below by topic area.

Source to Dose

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

- The ISA will evaluate studies of commercial samplers to determine whether they meet size selection performance standards. Specifically, what are the strengths and weaknesses of various methods for measuring PM?
- To what extent are these methods subject to positive or negative sampling artifacts or to interference from gas-phase pollutants or other gas- or aerosol-phase substances? Do potential sampling biases affect the magnitude or seasonal or diurnal patterns of specific aerosols or apparent source contributions? Are new research methods available to understand the spatial and temporal distribution of different sizes and/or components of PM?
- Based on recent air quality and emissions data, what are the current emissions and ambient concentrations of PM? What spatial and temporal patterns can be seen in the air quality data for PM and how do these relate to patterns of human exposure? What new information is available on PM components (both primary and secondary particles) and mixtures of particles found in various regions of the country? How do particles in urban areas differ from those emitted or formed in rural areas? How can sources such as resuspended road dust be characterized?

- Using air quality and emissions data on PM and precursor gases, together with atmospheric chemical-transport models, what are the likely policy-relevant background[16] concentrations of PM?
- Because the regulatory ambient monitoring networks typically provide PM concentrations only once in every three or six days, are there other techniques that can augment ambient monitoring data to better define the range of concentrations and the spatial and temporal variability of PM across the U.S.? How useful are satellite retrievals and three-dimensional chemical transport models for understanding processes and spatial and temporal variations? Can satellite data be used on a regular basis to improve the characterization of PM emissions? Could enhancements to the existing PM monitoring networks allow greater utility of satellite data?
- The ISA will also evaluate new information on specific PM components that merit attention including information on the spatial and temporal heterogeneity of PM components. Participants from the July 2007 Primary PM NAAQS workshop identified elemental carbon, organics, nickel, vanadium, sulfates, and products of photochemically oxidized organics as PM components that should be given greater attention in this review.
- The ISA will assess new evidence on the characterization of particles from various sources, including primary and secondary particles, and the methods used to characterize particle sources. The ISA will discuss the utility of source apportionment modeling techniques in determining exposure surrogates for epidemiology. Consideration will be given to where samples are collected, the frequency of sampling, and the analyses performed on the samples.

Human Exposure: The ISA will evaluate the factors that influence exposure to PM and the uncertainties associated with extrapolation from ambient concentrations to personal exposures to PM of ambient origin, particularly in the context of interpreting results from epidemiologic studies. The issues of uncertainty differ by the exposure period of interest. Short-term exposure studies (e.g., population-level studies using time-series analyses, field/panel studies) primarily

[16] "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, NOx, and SOx) in the U.S., Canada, and Mexico.

rely on temporal variation in exposure while long-term exposure studies (e.g., longitudinal cohort studies) rely on spatial variability of exposure. The ISA will consider the available information on differential exposures to ultrafine, fine, and thoracic coarse particles and particle characteristics such as chemical composition, size, surface area, number, and source.

- Are new data available that classify PM exposure according to PM characteristics such as chemical constituents, size fraction, surface area, and source/environment?
- What new data are available on the relationship between exposures to PM components, size fractions, and sources/environments? What data exist on relationships between exposure to specific PM size fractions and/or components and corresponding exposure to gaseous co-pollutants? What are the uncertainties when extrapolating between stationary PM monitoring instruments and personal exposure to PM of ambient origin, especially for susceptible subpopulations and how do these uncertainties vary for particles of different size or composition? Issues include measurement error in outdoor ambient monitors, the use of centralized monitors for estimating community concentrations, and the use of centralized monitors as a surrogate for personal exposure to PM of ambient origin.
- What do measurements of ambient concentrations of PM represent? To what extent do they provide an estimate of ambient exposures for health studies, an indicator of personal exposure to PM, and/or an indicator of exposure to other pollutants or pollutant mixtures?
- What data are available to interpret peak, short-term, and long-term PM exposures? This includes such information as air exchange rates, indoor sources, distance to highways, and methods for measuring personal exposures to ambient PM. Is this information available classified by PM characteristic (e.g., size, chemical composition, sources/environments)?
- How do modeled predictions of PM concentrations compare with monitoring results? Do quality assurance (QA) checks suggest that modeling is accurate? How do the models perform at the tails of the distribution, such as in high concentration areas and near roadways?

Health Effects

The ISA will evaluate the literature related to cardiovascular, respiratory, and other health effects associated with short and/or long term exposures to PM. This will include evaluation of mortality and morbidity effects. Other health effects that will be evaluated include reproductive, developmental, inflammatory, autonomic, carcinogenic/mutagenic, and cellular outcomes. Health effects that occur following short- (including sub-daily) and/or long-term exposures to PM will be evaluated in epidemiologic, human clinical, and toxicologic studies. Causality, uncertainty, biological mechanism of action, susceptible and vulnerable populations, and public health impact will all be considered. The data will be reviewed with the understanding that PM mass may not be the only indicator to understand and characterize health effects. Evidence will be sought that may implicate a specific chemical composition and/or source(s)/environment(s) to more fully explain PM health effects.

For a given type of health outcome, the ISA will evaluate the strength, robustness and consistency of the findings from the different disciplines. The health findings will be further integrated, using the toxicologic and human clinical studies to assess biologic plausibility and mechanistic evidence for the epidemiology findings. A key focus of the integration of health evidence will be on the attribution of health effects to exposure to different size fractions, components or characteristics of PM. Efforts will be directed at identifying the lower levels at which effects are observed and at determining concentration-response relationships for various PM size fractions and components. Concentration-response relationships among these studies will be evaluated for coherence. The ISA will evaluate the scientific evidence on the occurrence of health effects from long-term or short-term exposure to PM at ambient levels. The ISA will also assess the evidence for uncertainties related to these associations and information on the public health implications related to ambient PM exposure. The evaluation will also focus on which exposure durations and developmental time periods of exposure are most strongly associated with effects, for both short-term and long-term exposures.

<u>Short-Term Exposure</u>:

- What new evidence is available on associations between PM and mortality (total, respiratory or cardiovascular)?

- What new evidence is available on effects occurring from exposures at sub-daily averaging times?
- How do results of recent studies expand our understanding of the relationship between acute exposure to PM and respiratory effects, such as lung function changes, lung inflammation, and host defense against infectious disease? What new evidence is available on the potential clinical relevance of these effects?
- To what extent does new evidence from studies of hospital admissions or emergency department visits support previous findings regarding respiratory effects of PM? Is there evidence of coherence and plausibility for effects of different PM size fractions or other particle characteristics on the respiratory system?
- The ISA will evaluate evidence from studies of hospitalization or emergency department visits for cardiovascular diseases, and the extent to which there is evidence of coherence or plausibility for effects of different PM size fractions or other particle characteristics on the cardiovascular system.
- What new evidence is available on PM-related effects on the cardiovascular system? Which electrocardiogram changes may be indicative of an adverse response to PM and which populations may be particularly susceptible to these effects? What do studies of heart rate variability tell us? Do these effects appear to be reversible and to what extent? How does PM affect vascular and endothelial function and through which pathways?
- PM exposure is associated with acute coronary syndrome, myocardial infarction, and stroke (all conditions related to rupture of a vulnerable plaque and subsequent thrombosis). What is the effect of PM on homeostasis, rupture-prone plaque, and thrombosis? Do PM-induced oxidant stress and /or acute inflammation contribute to these adverse effects?
- To what extent does exposure to PM contribute to health effects in other organ systems?
- What is the nature of health effects in persons exposed to multipollutant mixtures that contain PM in comparison to exposure to PM alone?

- What biomarkers of early effect may be used in the assessments?

Long-Term Exposure:

- How do results of recent studies expand current understanding of the relationships between acute, repeated exposure to PM and lung function or lung function development?
- Can long-term exposures to PM result in chronic effects manifested as permanent lung tissue damage, reduction in baseline lung function, or impaired lung function development? To what extent does long-term PM exposure promote development of asthma or chronic lung or cardiovascular disease? What is the relationship between long-term PM exposure and shortening of human life span via promotion of such diseases?
- To what extent does the evidence indicate that long-term exposure to PM can increase the incidence of cancer, or have mutagenic or genotoxic effects?
- How does PM affect the developing fetus or infant?
- What new studies are investigating measures of cardiovascular disease development with chronic PM exposure? What evidence exists that demonstrates a link between long-term PM exposure and atherosclerosis development or progression? Can long-term exposure to PM result in chronic effects manifested as permanent cardiovascular tissue damage, altered blood pressure, or reductions in baseline cardiac function? How does long-term exposure to PM affect serum lipids, insulin-sensitivity, and vascular oxidant stress and what are the possible mechanisms for these effects? What is the role of systemic inflammation in initiating or exacerbating these effects?
- The ISA will also assess the evidence from studies linking long-term exposure to PM with mortality from cardiovascular and respiratory diseases or cancer.

Causality: The ISA will evaluate the evidence for a causal relationship between observed health outcomes and PM exposures, focusing on different size classes, components and/or characteristics of PM, to the extent possible. Biologic plausibility and coherence of the evidence will be key considerations in drawing conclusions about causality. The ISA will place emphasis on epidemiologic studies conducted at or near typical ambient levels, except regarding evidence

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

Uncertainties: The ISA will evaluate uncertainty in the scientific data, particularly in relation to observed epidemiologic findings and their consistency with toxicologic studies in terms of observed effects and biological pathways.

- How does confounding by coexposure to other pollutants (e.g., O_3, NO_2, SO_2, CO, and biological aerosols) and meteorological factors influence the uncertainty of the evidence base for both short- and long-term PM exposures?
- To what extent are the observed health effects associations attributable to PM versus the pollutant mixtures that PM may be representing? For example, what is the possibility that PM ambient concentrations may serve as a surrogate for personal exposure to mixtures or sources, such as motor vehicle exhaust?
- What are the uncertainties due to other confounding or other factors in epidemiologic studies (e.g., demographic and lifestyle attributes, socioeconomic status, genetic susceptibility factors, occupational exposure, and medical care)?
- What is the nature and shape of the concentration-response models (e.g., linear, non-linear, threshold models) based on PM studies?
- What uncertainties surround the evidence for long-term effects such as life shortening and development/progression of disease?
- How do the findings of the available studies improve our understanding of exposure error? What evidence is newly available on the uncertainties related to statistical model specification and how can it be used to assess the influence of these uncertainties on the outcome of epidemiologic studies?

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

- Is there new information related to the pathways and biological mechanism(s) of action for PM of different size classes or characteristics?
- What are the potential mechanisms of response to PM, with a focus on physical-chemical particle characteristics, response pathway(s), oxidative stress, and exposure-dose-response relationships?
- What are the inherent interspecies differences in sensitivity to PM and in PM dosimetry in different regions of the respiratory tract? Are there site-specific responses to PM in the respiratory tract that would better explain local and systemic effects of PM exposure? How does dosimetry differ based upon particle size?
- What are the interspecies differences in basic mechanisms of lung injury and repair and cardiovascular responses? What are the implications of interspecies difference for extrapolation of results to humans?
- Are there interactions between PM components that increase bioavailability, such as sulfate increasing the bioavailability or activity of iron or other transition metals?
- What are the mechanisms and time-courses of PM-induced cellular and tissue injury, repair, and remodeling?
- Which PM-induced health effects are sufficiently characterized to be quantitatively compared across species?

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

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

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

- The ISA will assess new evidence on the extent to which children and older adults are more sensitive than the general population to effects from PM exposure. The ISA will examine the implications of sensitive subpopulations on interpretation of epidemiological results and exposure-response characteristics of populations that may be more driven by the sensitive subpopulations.
- The ISA will evaluate the extent to which susceptibility to the effects of short-term PM exposure is associated with long-term PM susceptibility.
- What evidence is available regarding susceptibility of other subgroups, such as those based on gender or on genetic makeup, on PM-induced responses?
- What host and environmental factors (e.g., demographic, socioeconomic, and genetic) are associated with susceptibility and/or vulnerability to short- and long-term exposure to PM?
- New evidence will be evaluated regarding population groups with potentially greater vulnerability to effects of PM, such as those populations living near roads or in other areas with increased exposures.
- What information is available on exposure of sensitive and vulnerable populations to PM and its components?

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

Ecological and Welfare Effects

Visibility: The ISA will summarize long-known information needed for placing current information in context. Previous evaluations have indicated that anthropogenic sulfate and nitrate

particles are responsible for most of the regional haze in the eastern U.S. In the West, sulfates may be generally of less importance since less sulfur dioxide is emitted there, but important sub-regional and seasonal differences still exist. Nitrates are a leading factor in haze generation in specific areas such as southern California in winter, for example, while in many of the less-populous areas of the West, soil particles can be the largest contributor to visibility extinction during the spring.

In addition, anthropogenic nitrates and organic species, either emitted directly or formed secondarily from other emissions, can be significant factors in haze formation. Other sources of visibility extinction (e.g., dust, smoke, sea salt) have anthropo-, bio-, and geogenic sources that vary in strength and significance sub-regionally as well. Smoke from wildfires and prescribed burnings contribute to visibility extinction both directly and indirectly, though much less is known of these indirect effects through secondary organic aerosol generation. The ISA will evaluate newly available evidence summarizing the recent important policy-relevant findings and will include sections for aerosol optical characteristics, spatial and temporal trends, and causes of haze.

- The ISA will present the relationship between visibility impacts and PM and will include definitions and metrics and algorithms to estimate haze from PM species levels and from unspeciated fine particle mass measurements.
- The ISA will include a section on aerosol/optical characteristics that presents details of the size-resolved chemistry, transformation relationships and effects, and the algorithms used to estimate haze from monitoring data for particles taken in the regulatory measurement networks.
- Other findings to be included in the ISA will be spatial patterns (e.g., the Midwest nitrate bulge in the U.S. and enhancement of sulfate concentrations in the eastern U.S.), urban excess above remote-area background, seasonal patterns, and multi-year trends, including descriptions of the roles of emissions changes and annual meteorology in helping determine those trends.
- The ISA will discuss results of valuation studies concerned with describing the extent to which air pollution-related visibility impairment may be considered adverse. This will include discussion and evaluation of effects on nighttime or celestial landscapes to the extent that these are available in the open literature.

Non-nutrient Ecosystem and Environmental Effects. Discussions will include issues of non-nutrient (N and S) particle chemistry/composition (e.g., cations, trace metals, semi-volatile organics); associated size fraction, and magnitude and rates of wet and dry deposition across the landscape. Both direct and indirect secondary welfare effects will be discussed in the ISA, including effects on vegetation, soils, waters and wildlife (e.g., bioaccumulation) as described in the phytotoxicology and ecotoxicology literature. Soiling and materials damage will also be discussed. Nutrient N and S ecosystem effects will be addressed in the concurrent review of NO_2 and SO_2 secondary NAAQS.[17]

Effects of PM on Climate: The ISA will present information on temperature effects related to the various components of PM. Also addressed will be aerosol size/effect dependencies (e.g., cloud formation and precipitation) and aerosol constituent/effect dependencies (e.g., black carbon vs. SO_4).

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

Outline and Annexes

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

The ISA will be supplemented by a series of annexes, which will be focused on accomplishing two goals. The first goal will be to identify scientific research that is relevant to informing key policy-relevant issues. The second goal will be to produce a base of evidence containing all of the publications relevant to the PM review. The annexes will provide information on (1) the chemistry, physics, sources, emissions, and measurement of PM; (2) environmental concentrations and human exposure to PM; (3) dosimetry; (4) toxicologic studies of PM health effects in laboratory animals and *in vitro* systems; (5) human clinical studies

[17] See http://www.epa.gov/ttn/naaqs/standards/no2so2sec/index.html for more information on the NO_2/SO_2 Secondary NAAQS review.

examining health effects following controlled exposure to PM; (6) epidemiologic studies of health effects from short- and long-term exposure to PM; (7) environmental studies on visibility, material damage, and ecosystem stress; and (8) climate change related to PM. More detailed information on various methods and results for the health and environmental studies will be summarized in tabular form in the annexes. These tables will generally be organized to include information about (1) concentrations, size fractions and components of PM and related averaging times; (2) description of study methods used; (3) results and comments; and (4) quantitative outcomes for PM measures. Additionally, annexes will contain background material on legislative requirements, the NAAQS review process, and the history of earlier PM reviews.

4.3 SCIENTIFIC AND PUBLIC REVIEW

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

5 HUMAN HEALTH RISK AND EXPOSURE ASSESSMENTS

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. EPA is planning to focus the quantitative exposure/risk assessments primarily on fine particles ($PM_{2.5}$), but will consider, to the extent relevant information is available, exposures/risks associated with $PM_{10-2.5}$ in the ambient air, as well as exposures/risks associated with specific PM components, sources and/or environments. 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 more detail in a draft Scope and Methods Plan. Preparation of this draft 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 or variable of interest that is inherent and cannot be reduced through further research.

5.2 OVERVIEW OF HEALTH RISK ASSESSMENT FROM LAST 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 decisions on the standards. The limitations of such an assessment were clearly articulated.[18] EPA did not conduct an exposure assessment for that review. The approach used to develop quantitative risk estimates associated with exposures to $PM_{2.5}$ was built upon the more limited risk assessment conducted during the review completed in 1997. The expanded and updated assessment conducted in the review completed in 2006 included estimates of risks of mortality (total non-accidental, cardiovascular, and respiratory), morbidity (hospital admissions for cardiovascular and respiratory causes), and respiratory symptoms (not requiring hospitalization) associated with recent short-term (daily) ambient $PM_{2.5}$ levels and risks of total, cardiopulmonary, and lung cancer mortality associated with long-term exposure to $PM_{2.5}$ in a number of example urban areas.[19]

The EPA recognized that there were many sources of uncertainty and variability inherent in the inputs to this assessment and that there was a high degree of uncertainty in the resulting $PM_{2.5}$ risk estimates. Such uncertainties generally related to a lack of clear understanding of a number of important factors, including, for example, the shape of concentration-response functions, particularly when effect thresholds could neither be discerned nor determined not to exist; issues related to selection of appropriate statistical models for the analysis of the epidemiologic data; the role of potentially confounding and modifying factors in the concentration-response relationships; issues related to simulating how daily $PM_{2.5}$ ambient concentrations would likely change in any given area upon meeting a particular standard, since strategies to reduce emissions had not yet been defined; and whether there would be differential reductions in the many components within $PM_{2.5}$ and, if so, whether this would result in differential reductions in risk. While some of these uncertainties were addressed quantitatively in the form of estimated confidence ranges around central risk estimates, other uncertainties and

[18] 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.

[19] The risk assessment was discussed in the Staff Paper (EPA, 2005a, 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).

the variability in key inputs were not reflected in these confidence ranges, but rather were addressed through separate sensitivity analyses or characterized qualitatively (U.S. EPA, 2005a, Section 4; Abt Associates, 2005).

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

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

The general overview and discussion of key components of the risk assessment used to develop risk estimates for $PM_{2.5}$ presented above is also applicable to the risk assessment done for $PM_{10-2.5}$ as part of the last review. However, the scope of the risk assessment for $PM_{10-2.5}$ was much more limited than that for $PM_{2.5}$, reflecting the much more limited body of epidemiologic evidence and air quality information available for $PM_{10-2.5}$. As discussed in Section 4 of the Staff Paper (U.S. EPA, 2005a), the $PM_{10-2.5}$ risk assessment included risk estimates for just three urban

areas for two categories of health endpoints related to short-term exposure to $PM_{10-2.5}$: hospital admissions for cardiovascular and respiratory causes and respiratory symptoms.

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

5.3 AIR QUALITY CHARACTERIZATION

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

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

this review, EPA also will examine current techniques that may be used to assess the variability and uncertainty of the simulated change in concentrations likely to result from just meeting the current or alternative standards.

5.4 POPULATION EXPOSURE ASSESSMENT APPROACH

As part of the last PM NAAQS review, EPA did not conduct an exposure assessment. For this review, EPA is considering conducting a quantitative exposure assessment. This assessment would build upon the information presented in the ISA and include discussions of factors that affect exposure to ambient PM and the use of fixed site measurements of ambient PM concentrations as a surrogate for population exposure in epidemiologic studies. There are two specific purposes that such an assessment would serve: (1) providing insight on population exposures with respect to informing the interpretation of available epidemiologic studies and (2) assessing population exposures above benchmark levels of concern, and possibly providing input to quantitative risk assessments based on exposure-response information derived from clinical or controlled-human studies.[20]

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

An exposure assessment addressing the second purpose would be designed to estimate population exposures to ambient $PM_{2.5}$ and $PM_{10-2.5}$ in a number of generally representative urban areas across the U.S. These areas would be selected to represent a variety of populations, geographic areas, climates, and patterns of PM air quality levels. In addition, selection criteria

[20] 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.

might include consideration of locations of critical PM field and epidemiologic studies used to support the planned quantitative risk assessment. The exposure periods to be modeled would, at a minimum, encompass the most recent 3-year period for which air quality data are available. EPA is considering developing exposure estimates for the general population as well as for selected sensitive subpopulations (e.g., children, children with asthma or diabetes, adults over 70 years of age, individuals with pre-existing heart or respiratory conditions). The areas, time periods, and populations modeled will depend on the availability of data and time and resource constraints.

A quantitative exposure assessment would take into account factors including the magnitude and duration of PM exposures and the extent to which individuals experience repeated exposures at high levels. Estimates could be developed for several measures of exposure to various levels of $PM_{2.5}$ and/or $PM_{10\text{-}2.5}$ air quality, including estimates of the number of people exposed one or more times at or above a given PM concentration, and estimates of person-occurrences which accumulate occurrences of specific exposure conditions over all people in the population of interest.

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

Planning for conducting an exposure assessment will include building upon the information presented in the ISA and its annexes. This includes information on atmospheric chemistry and components of PM, air quality data, factors that influence exposures, human exposures, and information on sensitive subpopulations. EPA is planning on conducting an exposure assessment that will focus primarily on ambient $PM_{2.5}$, but will consider, to the extent relevant information is available, exposures associated with ambient $PM_{10\text{-}2.5}$, as well. In addition, to the extent possible, implications for variations in PM composition may be considered. EPA currently believes that exposure modeling for $PM_{10\text{-}2.5}$ would likely be significantly more uncertain than for $PM_{2.5}$, primarily due to the limitations of the spatial coverage of available ambient $PM_{10\text{-}2.5}$ data.

Modeling Population Exposures

EPA is considering using the Air Pollutants Exposure (APEX) model (Richmond et al., 2002; U.S. EPA, 2006b, c) and/or the Stochastic Human Exposure and Dose Simulation model for PM (SHEDS-PM) (U.S. EPA, 2005b). APEX has its origins in the NAAQS Exposure Model (NEM) which was developed in the early 1980's (McCurdy, 1994), has been continually improved since then, and was recently used during EPA's ozone NAAQS review. APEX is also referred to as the Total Risk Integrated Methodology/Exposure (TRIM.Expo) model. SHEDS-PM was developed by EPA/ORD's National Exposure Research Laboratory (Burke et al., 2001). APEX and SHEDS-PM are Monte Carlo simulation models that simulate a large number of randomly sampled individuals within a metropolitan area to represent area-wide population exposures. Both these models simulate the movements of individuals through time and space and their exposure to a given pollutant in indoor, outdoor, and in-vehicle microenvironments. They stochastically generate simulated individuals using census-derived probability distributions for demographic characteristics. A large number of simulated individuals are modeled, and collectively they represent a random sample of the study area population.

Drawing on information from the ISA, EPA will consider specific microenvironments included in past SHEDS-PM analyses that could be evaluated in a quantitative exposure assessment for PM (Burke et al. 2001). The development of appropriate distributions representing variability and uncertainty in various model inputs (e.g., air exchange rates, decay rates, indoor source emissions, and physiological parameters) will be a key aspect of this modeling effort. APEX and SHEDS-PM both employ flexible approaches for simulating microenvironmental concentrations, where the user can define the microenvironments to be modeled and their characteristics. Using input from the ISA, EPA will consider specific microenvironments that could be evaluated in a quantitative exposure assessment.

In considering conducting an exposure assessment, EPA plans to review the methodologies, inputs and results of other inhalation exposure modeling assessments[21] to help inform the development of model inputs and to understand the most significant uncertainties involved in estimating $PM_{2.5}$ exposures. EPA will also analyze available near roadway and in-

[21] PM exposure modeling studies to be reviewed would include the recent studies by Meng et al., 2007; Hering et al. 2007; Chan et al., 2005; McBride et al., 2007; Cressie et al., 2007; Issarayangyun and Greaves, 2007; Klepeis and Nazaroff, 2006; Fryer et al., 2006; Wilson and Zawar-Reza, 2006; Georgopoulos et al., 2005; Wu et al., 2005; Gulliver and Briggs, 2005; Marshall et al., 2005, as well as additional studies identified in the ISA.

vehicle PM measurements and consider the use of GIS-based transit route data to better characterize on-road and near-road exposures to PM.

Uncertainty and Variability

The primary difficulty in performing an exposure modeling uncertainty analysis is the quantitative characterization of the uncertainties of the model inputs and model formulation. Information about the variability of model inputs or the variability and uncertainty combined is often available, but it is usually difficult to estimate the uncertainty separately from the variability. In developing an analysis of the uncertainties in the PM exposure assessment, EPA will consider the availability of information to provide reasonable distributions or ranges for the uncertainties of key model inputs. EPA will build upon the APEX exposure modeling uncertainty analysis conducted in support of the review of the ozone NAAQS (Langstaff, 2007), as well as the uncertainty analysis previously conducted for $PM_{2.5}$ using the SHEDS model (Burke et al., 2001). In particular, EPA plans to refine the available distributions of variability and uncertainty, where data are available to do so and also extend the analysis to address model formulation uncertainty.

Once estimates of the uncertainty of the model inputs have been developed, one can propagate these uncertainties through the model to quantify the resultant uncertainty of the model predictions. The uncertainty methodology for both APEX and SHEDS-PM incorporates a 2-stage Monte Carlo modeling approach that explicitly characterizes and models the variability and uncertainty in model inputs and outputs. This 2-dimensional Monte Carlo method allows for the separate characterization of the variability and uncertainty in the model results (Morgan and Henrion, 1990). EPA plans to conduct this combined variability-uncertainty analysis for a limited number of cities which represent the range of exposure characteristics covered within the study set.

Uncertainties are inherent in modeled representations of physical reality due to simplifying assumptions and other aspects of model formulation. The methods for assessing input parameter uncertainty and model formulation or structure uncertainty are different. However, it is difficult to incorporate the uncertainties due to the model formulation into a quantitative assessment of uncertainty in a straightforward manner. A commonly preferred way is to assess model formulation uncertainty by comparing model predictions with measured

values, while having fairly complete knowledge of the uncertainty due to input parameters. EPA will evaluate whether it is feasible to perform such an analysis with existing information. In the absence of measurements that can be used to estimate model uncertainty, one must rely on informed judgment. Our approach to assessing model formulation uncertainty will be to partition this uncertainty into that of the components, or sub-models, of the exposure model. For each of the sub-models, EPA will discuss the simplifying assumptions and those uncertainties associated with the sub-models which are distinct from the input data uncertainties. Where possible, EPA will evaluate these sub-models by comparing their predictions with measured data. Otherwise, EPA will formulate an informed judgment as to a range of plausible uncertainties for the sub-models. EPA will quantitatively assemble the different types of uncertainties and variability to present an integrated analysis of uncertainty and variability.

5.5 HEALTH RISK ASSESSMENT APPROACH

The goals of a PM health risk assessment are: (1) to provide estimates of the potential magnitude of mortality and/or selected morbidity health effects in the population associated with recent ambient $PM_{2.5}$ and $PM_{10-2.5}$ levels and with meeting the current suite of PM standards and any alternative standards that might be considered in specific urban areas, (2) to develop a better understanding of the influence of various inputs and assumptions on the risk estimates; and (3) to gain insights into the distribution of risks and patterns of risk reduction and uncertainties in those risk estimates. The approach to the current health risk assessment will build upon the methods developed and insights gained from the risk assessment completed for the last review. Several key considerations in planning for the health risk assessment are discussed below.

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

The risk and exposure assessments will draw upon the information presented in the ISA and its annexes. This includes information on atmospheric chemistry and components of PM, air quality, human exposure, the impact of local source emissions, and health effects of concern. In

particular, the availability of air quality, concentration-response, and baseline incidence rate data will impact the type of risk assessments that will be performed.

Air Quality Considerations

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

Concentration-Response Functions

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

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

EPA plans to develop concentration-response relationships for health effects associated with short- and long-term exposures to $PM_{2.5}$ and to a lesser extent, associated with short-term exposures to $PM_{10-2.5}$ exposures based on recently conducted and previous epidemiologic studies presented in the ISA. The scientific evidence presented in the ISA will also be carefully considered to determine if sufficient exposure-response data from controlled clinical studies are available to characterize health risks based on these studies.

Uncertainty and Variability

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

A persistent issue raised in CASAC and public review of the quantitative risk assessment was the desire to provide a more comprehensive characterization of the most significant uncertainties impacting the health risk estimates. For the current health risk assessment, EPA is considering the use of, at a minimum, a similar approach to that used in the previous assessment to characterize uncertainties in the risk estimates. In addition, EPA is considering the feasibility

of conducting additional analyses to better characterize uncertainties in its PM health risk assessment. One approach under consideration is the use of expert elicitation to characterize and quantify the most important sources of uncertainty (for more information on expert elicitation, see Morgan and Henrion, 1990). As part of EPA's final regulatory impact analysis for the PM NAAQS review completed in 2006, EPA conducted a study of the concentration-response relationship between changes in $PM_{2.5}$ exposures and mortality using formally elicited expert judgments (IEC, 2006; Roman et al., 2008). The goal of the study was to elicit, from a group of PM health experts probabilistic distributions describing uncertainty in estimates of the reduction in mortality among the adult U.S. population resulting from reductions in ambient annual average $PM_{2.5}$ levels. These distributions were obtained through a formal interview protocol using methods designed to elicit expert judgments.

The full-scale expert elicitation study involved personal interviews with twelve health experts who have conducted research on the relationship between $PM_{2.5}$ exposures and mortality (IEC, 2006; Roman et al., 2008). These experts were selected through a peer-nomination process and included experts in epidemiology, toxicology, and medicine. The elicitation interview consisted of a protocol of carefully structured questions, both qualitative and quantitative, about the nature of the $PM_{2.5}$-mortality relationship. The questions requiring qualitative responses probed experts' beliefs concerning key evidence and critical sources of uncertainty and enabled them to establish a conceptual basis supporting their quantitative judgments. Questions covered topics such as potential biological mechanisms linking $PM_{2.5}$ exposures with mortality; the role of study design in capturing PM/mortality effects; key scientific evidence on the magnitude of the PM/mortality relationship; sources of potential error or bias in epidemiological results; the likelihood of a causal relationship between $PM_{2.5}$ and mortality, and the shape of the concentration-response function.

As noted above, EPA is considering the feasibility and value of conducting additional uncertainty analysis as part of the current PM health risk assessment to improve the quantitative characterization of the most significant uncertainties associated with the risk assessment. EPA staff will be exploring alternative approaches, including expert elicitation, that have potential for providing an improved characterization of uncertainties in the assessment. Factors that will be weighed in making a decision on whether or not to proceed with such an assessment include the perceived value of the project in informing the Administrator's decision in view of the

considerable resources and effort required to carry out such an assessment and the time constraints for developing the risk assessment.

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

5.6 BROADER RISK CHARACTERIZATION

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

- Additional health endpoints not considered in the quantitative risk assessment;
- Additional locations not evaluated in the quantitative risk/exposure assessment to inform a broader understanding of public health impacts including non-urban environments;
- Regional differences in PM risks taking into consideration the following factors:
  - variations in individual and/or population susceptibility;
  - population demographics;
  - variations in exposures;
  - variations in particle size, composition, and levels; and
  - impacts of potential effect modifiers (e.g., weather, co-pollutants).

5.7 SCIENTIFIC AND PUBLIC REVIEW

A draft of the Scope and Methods Plan for the risk/exposure assessment will be submitted to CASAC for consultation and will be provided to the public for comment. The CASAC PM Review Panel will discuss their comments on the draft Scope and Methods Plan in a public meeting that will be announced in the Federal Register. In conducting the risk/exposure assessment, EPA will take into account comments received from CASAC or from the public at the meeting itself and in any written comments. EPA will prepare two drafts of the risk/exposure assessment for CASAC review and public comment. The CASAC PM Review Panel will review each draft risk/exposure assessment and discuss their comments in two public meetings to be announced in the Federal Register. Based on CASAC's past practice, EPA anticipates that key CASAC advice and recommendations for revision of the draft risk/exposure assessment will be presented in letters to the EPA Administrator. EPA will also consider comments received from CASAC or from the public at the meetings themselves and any written public comments. In finalizing the risk/exposure assessment, EPA will take into account any such comments and recommendations. After appropriate revision, the final risk/exposure assessment document will be made publicly available on an EPA website and in hard copy. A notice announcing the availability of the final document will be published in the Federal Register. In addition, the final 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 reducing materials damage associated with PM soiling of outdoor surfaces. 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 more detail in a draft Scope and Methods Plan. Preparation of this draft 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 LAST 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[22] (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 conditions are determined by the scattering and absorption of light by particles and gases, from both natural and anthropogenic sources. The result of the scattering and

[22] 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.

absorption processes is a reduction of the amount of light from a scene that is returned to the observer, and scattering of other light into the sight path, creating a hazy condition. Visibility is often described in terms of visual range, light extinction, or deciviews.[23] The classes of fine particles principally responsible for visibility impairment are sulfates, nitrates, organic matter, elemental carbon, and soil dust. Fine particles are more efficient per unit mass at scattering light than coarse particles. The effective scattering efficiency of certain classes of fine particles, such as sulfates, nitrates, and some organics, increases as relative humidity rises because these particles absorb water causing them to grow larger, and scatter more light. In addition to limiting the distance that one can see, the scattering and absorption of light caused by air pollution also degrades the perceived color, clarity, textural detail, and contrast of scenes.

Air Quality Analyses

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

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

2005) would result in improvements to visual air quality, particularly in eastern Class I and non-urban areas. Therefore, the visibility-related assessments conducted in the last review focused primarily on evaluating visibility impairment in urban areas.

In evaluating correlations between urban visibility and $PM_{2.5}$ mass, EPA considered that direct relationships existed between measured ambient pollutant concentrations and their contributions to light extinction and thus to visibility impairment. The contribution of each PM constituent to total light extinction was derived by multiplying the constituent concentration by its extinction efficiency to calculate a "reconstructed" light extinction.[24] For certain fine particle constituents, extinction efficiencies increased significantly with increases in relative humidity. As a consequence, while higher $PM_{2.5}$ mass concentrations generally indicated higher levels of visibility impairment, it was not as precise a metric as the light extinction coefficient. Nonetheless, by using historic averages, regional estimates, and actual day-specific, component-specific ambient measurements of $PM_{2.5}$ total mass, reasonable estimates of light extinction from PM mass concentrations were developed.

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

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[24] 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, 2005a, Section 2.8.1). "Reconstructed" light extinction simply refers to the calculation of PM-related light extinction by the use of that formula.

Both 24-hour and shorter-term daylight hour averaging periods were considered in evaluations of correlations between $PM_{2.5}$ concentrations in urban areas and visibility in eastern and western areas, as well as nationwide. Clear and similarly strong correlations were found between visibility and 24-hour average $PM_{2.5}$ in eastern, western, and all urban areas (U.S. EPA, 2005a, Figure 6-3). Somewhat stronger correlations were observed between visibility and $PM_{2.5}$ concentrations averaged over certain sub-daily (e.g., a 4-hour) time periods (U.S. EPA, 2005a, Figure 6-5), principally because the relative humidity, which effects the extinction efficiency of much of the PM, varies less during any of the sub-daily time periods than over entire days. The correlations between visibility and $PM_{2.5}$ concentrations during daylight hours, which tend to have the lowest relative humidity levels, were relatively more reflective of $PM_{2.5}$ mass rather than relative humidity effects and aerosol composition, in comparison to correlations based on a 24-hour averaging time. Another rationale for considering the use of daylight sub-daily time periods is the expected greater importance of visibility during hours when most people are awake and most scenes are better illuminated.

Surveys of Public Perception

In the last review, EPA considered survey research on public awareness of visual air quality. The importance of visual air quality to public welfare across the country had been demonstrated by a number of studies designed to quantify the benefits (or willingness to pay) associated with potential improvements in visibility (Chestnut and Dennis, 1997; Chestnut and Rowe, 1991). These economic benefits may include the value of improved aesthetics during daily activities (e.g., driving or walking, daily recreations), for special activities (e.g., visiting parks and scenic vistas, hiking, hunting), and for viewing scenic photography. They may also include the value associated with improved road and air safety, and/or preservation of resources by those who may never personally experience them.

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

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

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

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

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

6.3 VISIBLITY AND OTHER WELFARE-RELATED ASSESSMENT APPROACH

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

Urban Visibility

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

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

In addition to the above issues, both the Administrator and the CASAC panel observed in the last review that one of the key limitations to selecting an appropriate level of $PM_{2.5}$ that would afford the requisite protection against visibility impairment in urban areas was the limited number of cities for which information of this nature (e.g., public perceptions of adverse impacts

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

- Identifying new literature that addresses methods for characterizing the value of visibility and assessing which approach (es) are potentially appropriate for use in the NAAQS review process. This effort could potentially be expanded to incorporate literature that includes information on how the psychological value of visual air quality, stress and human behavior are related and how those qualitative aspects are or could be included.
- Expanding the characterization of perceptions of visibility impairment to include urban areas having sight paths to fixed scenic elements that are too short to be sensitive to changes in haze by exploring alternative ways to communicate change (e.g., based on changes in sky color and the appearance of clouds in the sky). Several methods are available to represent different levels of visual air quality (see discussion of the EPA pilot study above, Abt Associates, 2001).
- Expanding the characterization of perceptions of adversity for urban areas with non-traditional views[25] as described above by developing new or modifying existing survey techniques to elicit information about what constitutes an acceptable versus unacceptable degradation of the scene (e.g., clouds against a blue sky).

Other Welfare Effects

There are several new or expanded sources of speciated PM data that might lend themselves to further analysis with respect to the welfare effects associated with deposition of heavy metals to vegetation and ecosystems, deposition of fine and coarse particles onto man-made structures, and the potential localized impacts of aerosol pollution on downwind precipitation patterns and trends. These new data sources include the urban PM speciation network and data from assessments being conducted by state-run regional planning organizations

[25] 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.

(RPOs) in conjunction with fulfilling the requirements of the Regional Haze Rule. EPA will therefore investigate these and any other additional sources of information identified in the ISA and associated annexes and consider whether additional welfare effects assessments are appropriate.

6.4 SCIENTIFIC AND PUBLIC REVIEW

A draft of the Scope and Methods Plan for the visibility and other welfare-related assessments will be submitted to CASAC for consultation and will be provided to the public for comment. The CASAC PM Review Panel will discuss their comments on the draft Scope and Methods Plan in a public meeting that will be announced in the Federal Register. In conducting the visibility and other welfare-related assessments, EPA will take into account comments received from CASAC and from the public at the meeting itself and in any written comments. EPA will prepare two drafts of the visibility and other welfare-related assessments for CASAC review and public comment. The CASAC PM Review Panel will review each draft visibility and other welfare-related assessment and discuss their comments in two public meetings to be announced in the Federal Register. Based on CASAC's past practice, EPA anticipates that key CASAC advice and recommendations for revision of the draft risk/exposure assessment will be presented in letters to the EPA Administrator. EPA will also consider comments received from CASAC or from the public at the meetings themselves and any written public comments. In finalizing the visibility and other welfare-related assessments, EPA will take into account any such comments and recommendations. After appropriate revision, the final visibility and other welfare-related assessment document will be made publicly available on an EPA website and in hard copy. A notice announcing the availability of the final document will be published in the Federal Register. In addition, the final visibility and welfare-related assessment document will 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 this review of 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_{10}, EPA and its state/local partners implemented the first size-selective PM monitoring network in 1990 with the establishment of a PM_{10} network consisting of mainly high-volume samplers. Approximately 1,000 PM_{10} 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 $PM_{10-2.5}$ sampling. After setting the first $PM_{2.5}$ NAAQS in 1997, EPA implemented a $PM_{2.5}$ network consisting of ambient air monitoring sites with mass and/or chemical speciation measurements. Within the $PM_{2.5}$ network, there are approximately 900 FRM filter-based samplers that provide 24-hour $PM_{2.5}$ mass concentration data and about 600 continuous $PM_{2.5}$ 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

fine particle mass at selected locations. Chemical speciation measurements are made at 54 ''Speciation Trends Network (STN)'' sites that are intended to remain in operation indefinitely and about 150 other, potentially less permanent sites used to support State Implementation Plan (SIP) development and other monitoring objectives.[26] Specific components of fine particles are also measured through the Interagency Monitoring of Protected Visual Environments (IMPROVE) monitoring program[27] which supports regional haze characterization and tracks changes in visibility in Class I areas as well as many other rural and some urban areas. Together, the CSN and IMPROVE data provide chemical species information for fine particles that are critical for use in health and epidemiologic studies to help inform reviews of the PM NAAQS.

EPA recently made changes to the NAAQS-related monitoring regulations. Specifically, the general monitoring network design requirements for the minimum number of ambient air monitors were modified to focus more on populated areas with air quality problems and to significantly reduce the requirements for criteria pollutant monitors that have measured ambient air concentrations well below the applicable NAAQS. A number of the changes related to the monitoring of $PM_{2.5}$ include revisions to the requirements for reference and equivalent method determinations (including specifications and test procedures). These regulations also add a requirement for a new multi-pollutant monitoring network called National Core (NCore) and revise certain provisions regarding monitoring network descriptions and periodic assessments, quality assurance, and data certifications (71 FR 61236, October 17, 2006).

In the last review, EPA promulgated a new FRM for the measurement of $PM_{10-2.5}$ in ambient air. Although the standard for thoracic coarse particles does not use a $PM_{10-2.5}$ indicator, a new FRM for $PM_{10-2.5}$ was developed to provide a basis for approving FEMs and to promote the gathering of scientific data to support future reviews of the PM NAAQS. The new $PM_{10-2.5}$ FRM – or an approved FEM, if available - is to be implemented at required NCore stations by January 1, 2011. Despite this long period of implementation, there are already a number of collocated PM_{10} and $PM_{2.5}$ low-volume FRMs operating across the country that are essentially

[26] See http://www.epa.gov/ttn/amtic/speciepg.html for more information on the $PM_{2.5}$ speciation monitoring program.

[27] 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.

providing the $PM_{10-2.5}$ FRM measurement now by the difference method. There is currently no chemical speciation network for characterizing the specific components of thoracic coarse particles. EPA is developing an implementation plan for a thoracic coarse particle speciation network as $PM_{10-2.5}$ at about 75 locations that will be part of the NCore monitoring stations.

7.3 MONITORING ISSUES RELATED TO THE PM NAAQS

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

Network Design

Monitoring sites must represent ambient air (e.g., that portion of the atmosphere, external to buildings, to which the general public has access). The minimum number of required monitors for PM is stated in 40 CFR part 58, Appendix D, Network Design Criteria for Ambient Air Quality Monitoring. EPA negotiates with States to determine the total number of monitors needed to represent an area's air quality. The total number is typically greater than the basic rule requirements. It should be noted that although monitors are often sited with the intention to represent an area of a certain geographic scale, in general, a monitor need not be representative of the ambient air quality across an area of any specific size to be eligible for comparison to most NAAQS. The current monitoring requirements for the $PM_{2.5}$ NAAQS are an exception. Data from a $PM_{2.5}$ monitor can be compared to the NAAQS only if its location is "population-oriented."[28] Consequently, the existing $PM_{2.5}$ monitoring network is primarily designed to be "population-oriented." PM_{10} monitoring requirements have an urban focus and are based on both population and concentration.

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

[28] 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.

- Is there a need to define more quantitative criteria for population-oriented exposure (e.g., minimum population density requirements, proximity to closest residences or work areas) than is currently provided in the 40 CFR part 58?
- Is there evidence to support expanding the network from being mainly based on monitors representing community-wide air quality to also consider "hot-spot" monitoring where ambient concentrations are potentially higher? As an example, sites that represent populations that reside near roadways (e.g., an environmental justice community with a middle-scale[29] or micro-scale[30] location for protection against acute exposures to fine particles).
- Acknowledging that $PM_{10-2.5}$ monitoring will be done at NCore stations (including rural sites), is there new evidence to support a network expansion to improve the characterization of ambient $PM_{2.5}$ and PM_{10} concentrations (eligible for comparison to the NAAQS) in additional areas such as remote or rural areas that are not considered "population-oriented?" In what ways could this information be used to assess potential health and/or welfare effects in these areas?
- One of the monitoring data uses is to support measurement of overall progress for air pollution control. Is there a need to consider other monitoring siting strategies in support of accountability (e.g., in areas representative of varying PM emissions)?

The requirements for $PM_{10-2.5}$ mass and speciation monitoring at NCore include a provision for both urban and rural monitoring sites. Additional $PM_{10-2.5}$ network design issues that will be considered in this review are reflected in the following questions:

- What factors should be considered in identifying the size (number of monitors, geographic distribution) of a $PM_{10-2.5}$ mass and speciation monitoring network (including consideration of the NCore network requirements) that would be sufficient to characterize levels across urban and rural areas?

[29] 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.
[30] 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.

- What additional sampling and statistical techniques (e.g., saturation sampling) are available to help determine the minimum number of $PM_{10-2.5}$ monitors needed across an urban area to adequately assess issues of spatial and temporal variability?
- What are the appropriate monitor placement criteria for thoracic coarse particle characterization of $PM_{10-2.5}$, including the distance relative to sources, measurement scale, and inlet height? Should data from $PM_{10-2.5}$ monitors located nearly adjacent to sources (micro-scale) be excluded from comparison with a potential NAAQS?

Sampling Methods

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

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

- To what extent do the variations in PM_{10} sampling architecture used in FRM and FEM sampling heads lead to significant changes in measured PM_{10} in areas affected by high concentrations of particles greater than 10 microns in size relative to each other and to the required performance specifications in 40 CFR part 53?
- In 2006, EPA considered, but did not adopt, a sub-daily $PM_{2.5}$ secondary NAAQS to protect against visibility-related impairment in urban areas. Have new data altered previous conclusions about using continuous $PM_{2.5}$ monitoring methods capable of providing hourly time resolution to support a potential sub-daily standard and/or other metrics (e.g., light scattering) that may be considered? What method(s) should be considered as the reference method?
- What new information is available to inform options and technologies for sampling and analysis of components of thoracic coarse particles? Speciation monitoring of $PM_{10-2.5}$ is

required in some areas as part of the NCore monitoring network that must be implemented by 2011.

  - What operational experiences learned in the $PM_{2.5}$ speciation network and during the multi-site evaluation of $PM_{10-2.5}$ monitors are useful in the evaluation of sampler design and laboratory analysis methods being considered for $PM_{10-2.5}$ filters? What are the $PM_{10-2.5}$ speciation sampling artifacts that may be encountered?
  - Currently the difference and dichot methods are the basis for developing a thoracic coarse particle speciation network. What other sampling methods or technologies are available and appropriate for collection of particles for $PM_{10-2.5}$ speciation?
  - To what extent can we address the collection of biological materials (e.g., pollen, etc.) and fly ash? If biological particles and fly ash need to be characterized, what specific types of biological materials and fly ashes need to be measured and how should they be collected and analyzed?
  - The current $PM_{2.5}$ speciation sampler flow rate is significantly lower (6.7 versus 16.7 LPM) than the FRM and different than the dichot flow rates. If this sampler is used to collect filters for $PM_{10-2.5}$ speciation filters by difference, would the low flow rate be problematic, especially with the concern about low-flow cutpoints and particle intrusion, and the need to compare to what is collected by the FRM?

- In addition to $PM_{10-2.5}$ monitoring being implemented as part of NCore, what other PM and PM precursor-related measurements or reactive species (e.g., ammonia, true NO_2, nitric acid) should be considered for incorporation into these multi-pollutant monitoring stations?
- In addition to 24-hour ambient measurements of $PM_{10-2.5}$, are there other time-resolved measurements needed to evaluate the evidence for a causal relationship between observed health outcomes and thoracic coarse particle exposures?
- Is new technology available to advance ambient monitoring methods for ultra-fine particles (particles less than 100 nanometers in diameter) from being research-only instruments to being field-ready techniques that can be operated within conventional monitoring networks?

- To what extent should sample volume measurement[31] be consistent across the various PM methods? Is there evidence to support modifying the PM_{10} FRM to operate at local rather than standard conditions?
- What are the current $PM_{2.5}$ mass and speciation sampling artifacts and can they be addressed through modifications to the sampling methodology?

Data Reporting and Assessments

In the 2006 revisions to the $PM_{2.5}$ FRM reporting requirements, EPA reduced the data reporting requirements associated with the $PM_{2.5}$ FRM to decrease the data management burden for monitoring agencies. EPA also added a requirement for submission of data on $PM_{2.5}$ field blank mass in addition to $PM_{2.5}$ filter-based measurements. Reporting requirements will be the same for $PM_{10\text{-}2.5}$ monitoring data. Quality assurance (QA) and network assessments are also an important part of evaluating and confirming that the data from the monitoring networks continue to meet the data needs. States conduct in-depth network assessments intended to ensure that future gaps between data needs and monitoring operations are identified and filled in a timely manner. Network assessments are required every 5 years, with the next one due by July 1, 2010. As part of the QA framework, EPA establishes data quality objectives (DQOs) so that data can be used effectively in making decisions regarding attainment of the NAAQS. DQOs for $PM_{2.5}$ and $PM_{10\text{-}2.5}$ monitoring data have been developed. Regular data quality assessments are performed to determine if the data are continually meeting the specified DQOs.

Data reporting and assessment issues that will be considered in this review are reflected in the following questions:

- What has been learned from the analysis of $PM_{2.5}$ filter blank mass data that was newly required to be reported to the Air Quality System (AQS) in the 2006 revisions to monitoring regulations? To what extent should the blank data be considered in this review of the $PM_{2.5}$ NAAQS?
- An increase in the number of low volume PM_{10} samplers is expected with the transition to $PM_{10\text{-}2.5}$ measurement and the desire of monitoring agencies to deploy more automated

[31] The current PM_{10} FRM requires operation and data reporting on a standard temperature and pressure basis, (measurements adjusted to 25 degrees C and 1 atmosphere). The current $PM_{2.5}$ and $PM_{10\text{-}2.5}$ 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).

(sequential) filter-based samplers into the networks. Does an analysis of precision and bias data sets from high-volume and low-volume PM_{10} samplers demonstrate a significant advantage for low-volume samplers to the extent that the phase-out of high-volume samplers PM_{10} should be considered?

- What new assessments of $PM_{2.5}$ data should be considered to evaluate the performance of newer, continuous FEMs and Approved Regional Methods (ARMs) in comparison to the FRM? What should be the consequences of identifying a poor comparison between an approved FEM or ARM versus a collocated FRM?
- In anticipation of the use of hourly continuous $PM_{2.5}$ data to help inform consideration of a potential sub-daily secondary or primary NAAQS, should FEM approval regulations (40 CFR part 53) and/or ambient monitoring quality assurance regulations (40 CFR part 58, Appendix A) be modified to specifically require quantitative assessment of sub-daily data (e.g., precision assessment of hourly data)?

8 POLICY ASSESSMENT/ RULEMAKING

Based on the information in the ISA, the human health risk and exposure assessments, and the visibility and other welfare-related assessments, the Agency will develop an ANPR that reflects EPA's initial views regarding the need to retain or revise the NAAQS for $PM_{2.5}$ and PM_{10}. 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 for 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 review of the PM standards as outlined in Section 7 will be developed, if necessary, in conjunction with this NAAQS rulemaking.

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APPENDIX A

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, exposure effect estimates, confounding, cause-specific mortality

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, socio-economic status (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 –WELFARE EFFECTS

CONCLUSIONS

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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