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

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Draft 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
Office of Air Quality Planning and Standards
Office of Air and Radiation

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DISCLAIMER

This draft integrated review plan has been prepared by staff in the U.S. Environmental Protection Agency's (EPA) Office of Air Quality Planning and Standards (OAQPS) and National Center for Environmental Assessment (NCEA). Any findings and conclusions are those of the authors and do not necessarily reflect the views of the EPA. This draft document is being circulated to facilitate discussion with the Clean Air Scientific Advisory Committee and for public comment to inform the EPA's review of the PM National Ambient Air Quality Standards. This information is distributed for the purposes of pre-dissemination peer review under applicable information quality guidelines. It does not represent, and should not be construed to represent, any Agency determination or policy. Questions or comments related to this draft document should be addressed to Dr. Scott Jenkins, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, C539-06, Research Triangle Park, North Carolina 27711 (email: jenkins.scott@epa.gov) and Dr. Jason Sacks, U.S. Environmental Protection Agency, National Center for Environmental Assessment, MDB243-01, Research Triangle Park, North Carolina 27711 (email: sacks.jason@epa.gov).

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List of acronyms/abbreviations

AER	Indoor air exchange rates
APEX	Air Pollutants Exposure model
BenMAP-CE	Environmental Benefits Mapping and Analysis Program – Community Edition
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CHAD	Consolidated Human Activity Database
CMAQ	Community Multi-scale Air Quality modeling system
CPL	Candidate Protection Levels
C-R	Concentration-response
CSN	Chemical Speciation Network
DEARS	Detroit Exposure Aerosol Research Study
EC	Elemental carbon
U.S. EPA	United States Environmental Protection Agency
FEM	Federal Equivalent Method
FRM	Federal Reference Method
HREA	Health Risk and Exposure Assessment
IHD	Ischemic heart disease
IMPROVE	Interagency Monitoring of Protected Visual Environments
IPCC	Intergovernmental Panel on Climate Change
IRP	Integrated Review Plan
ISA	Integrated Science Assessment
LML	Lowest measured level
METS	Metabolic equivalents of work
NCEA	National Center for Environmental Assessment
NAAQS	National Ambient Air Quality Standards
NO_2	Nitrogen dioxide
NO_X	Oxides of nitrogen
OAR	Office of Air and Radiation
OAQPS	Office of Air Quality Planning and Standards
OC	Organic carbon
ORD	Office of Research and Development
PA	Policy Assessment
PM	Particulate matter
$PM_{2.5}$	In general terms, particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 μm; a measurement of fine particles In regulatory terms, particles with an upper 50% cut-point of 2.5 μm aerodynamic diameter (the 50% cut point diameter is the diameter at which the sampler collects 50% of the particles and rejects 50% of the particles) and a penetration curve as measured by a reference method based on Appendix L of 40 CFR Part 50 and designated in accordance with 40 CFR Part 53, by an equivalent method designated in accordance

	with 40 CFR Part 53, or by an approved regional method designated in accordance with Appendix C of 40 CFR Part 58
PM_{10}	In general terms, particulate matter with an aerodynamic diameter less than or equal to a nominal 10 μm; a measurement of thoracic particles (i.e., that subset of inhalable particles thought small enough to penetrate beyond the larynx into the thoracic region of the respiratory tract) In regulatory terms, particles with an upper 50% cut-point of 10± 0.5 μm aerodynamic diameter (the 50% cut point diameter is the diameter at which the sampler collects 50% of the particles and rejects 50% of the particles) and a penetration curve as measured by a reference method based on Appendix J of 40 CFR Part 50 and designated in accordance with 40 CFR Part 53 or by an equivalent method designated in accordance with 40 CFR Part 53
$PM_{10-2.5}$	In general terms, particulate matter with an aerodynamic diameter less than or equal to a nominal 10 μm and greater than a nominal 2.5 μm; a measurement of thoracic coarse particulate matter or the coarse fraction of PM_{10} In regulatory terms, particles with an upper 50% cut-point of 10 μm aerodynamic diameter and a lower 50% cut-point of 2.5 μm aerodynamic diameter (the 50% cut point diameter is the diameter at which the sampler collects 50% of the particles and rejects 50% of the particles) as measured by a reference method based on Appendix O of 40 CFR Part 50 and designated in accordance with 40 CFR Part 53 or by an equivalent method designated in accordance with 40 CFR Part 53
PRB	Policy relevant background
SES	Socioeconomic status
SHEDS-PM	Stochastic Human Exposure and Dose Simulation for Particulate Matter
SO_2	Sulfur dioxide
SO_X	Sulfur oxides
SOPM	Secondary Organic Particulate Matter
TRIM	Total Risk Integrated Methodology
TSP	Total Suspended Particles
UFP	Ultrafine Particles
UFVA	Urban-Focused Visibility Assessment
VAQ	Visual air quality
VOC	Volatile organic compound
WHO	World Health Organization
WREA	Welfare Risk and Exposure Assessment

1 INTRODUCTION

The U.S. Environmental Protection Agency (EPA) is conducting a review of the existing air quality criteria for particulate matter (PM) and of the primary (health-based) and secondary (welfare-based) national ambient air quality standards (NAAQS) for PM. This review will provide an integrative assessment of relevant scientific information on PM and will focus on the basic elements of the PM NAAQS: the indicator, averaging time, form,[1] and level. These elements, which together serve to define each NAAQS, are considered collectively in evaluating the protection to public health and public welfare afforded by the standards. The purpose of this draft Integrated Review Plan (IRP) is to communicate the plan for reviewing the air quality criteria and the primary and secondary NAAQS for PM.

The Clean Air Scientific Advisory Committee (CASAC), an independent scientific advisory committee established under the Clean Air Act, will review this draft IRP at a public meeting and will provide advice to the EPA based on that review.[2] The final IRP will reflect the EPA staff's consideration of CASAC advice and of comments received from members of the public as part of the review process. As this review progresses, the plan described in the IRP may be modified to reflect information received during the review process, to address additional advice received from CASAC, and/or to address comments received from the public.

This draft IRP is organized into six chapters. Chapter 1 presents the legislative requirements for the review of the NAAQS (section 1.1), background information on the NAAQS review process (section 1.2), an overview of the decisions made in past reviews of the PM NAAQS (section 1.3), the general scope of the current review (section 1.4), and the anticipated schedule for the current review (section 1.5). Chapter 2 summarizes the supporting rationales for the Administrator's decisions in the last review of the PM NAAQS, including the important uncertainties and limitations in the scientific evidence and quantitative assessments in the last review, and the key policy-relevant issues that will frame the current review. Chapters 3 through 6 discuss the key assessment documents for this review (i.e., Integrated Science Assessment (ISA), Risk and Exposure Assessments (REAs), Policy Assessment (PA)), the

[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%20(2015-2018) for a list of the CASAC PM Panel members.

planned approaches for preparing these documents, and plans for their scientific and public review. Chapter 6 also includes an overview of the rulemaking process.

1.1 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 or her judgment, "cause or contribute to air pollution which 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 air pollutants 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 for which air quality criteria are issued 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." 42 U.S.C. § 7409(b)(1).[3] A secondary standard, as defined in section 109(b)(2), "shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air."[4] 42 U.S.C. § 7409(b)(2).

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable

[3] 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)].

[4] Welfare effects as defined in CAA 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."

degree of protection against hazards that research has not yet identified.[5] Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.[6]

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive group(s), and the kind and degree of uncertainties. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment.[7]

In setting standards that are "requisite" to protect public health and welfare, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary. In so doing, the EPA may not consider the costs of implementing the standards. See generally *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001). Likewise, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards." American Petroleum Institute v. Costle, 665 F. 2d at 1185.

Section 109(d)(1) requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate . . . ." 42 U.S.C. § 7409(d)(1). Sections 109(d)(2)(A) and 109(d)(2)(B) require 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

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[5] See *Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981); *American Farm Bureau Federation v. EPA*, 559 F. 3d 512, 533 (D.C. Cir. 2009); and *Association of Battery Recyclers v. EPA*, 604 F. 3d 613, 617-18 (D.C. Cir. 2010).

[6] See *Lead Industries v. EPA*, 647 F.2d at 1156 n.51, *Mississippi v. EPA*, 723 F. 3d 246, 255, 262-63 (D.C. Cir. 2013).

[7] See Lead Industries Association v. EPA, 647 F.2d at 1161-62; Mississippi v. EPA, 723 F. 3d at 265.

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 1980s, this independent review function has been performed by CASAC.

1.2 OVERVIEW OF THE NAAQS REVIEW PROCESS

The current process for reviewing the NAAQS includes five major phases: (1) the planning phase, (2) the science assessment phase, (3) the risk/exposure assessment phase, (4) the policy assessment phase, and (5) the rulemaking phase. Figure 1-1 provides an overview of the NAAQS review process and Table 1-1 provides an overview of each of the documents that are developed as part of this process.[8] The phases of the NAAQS review process, and the documents developed, are described in more detail below.

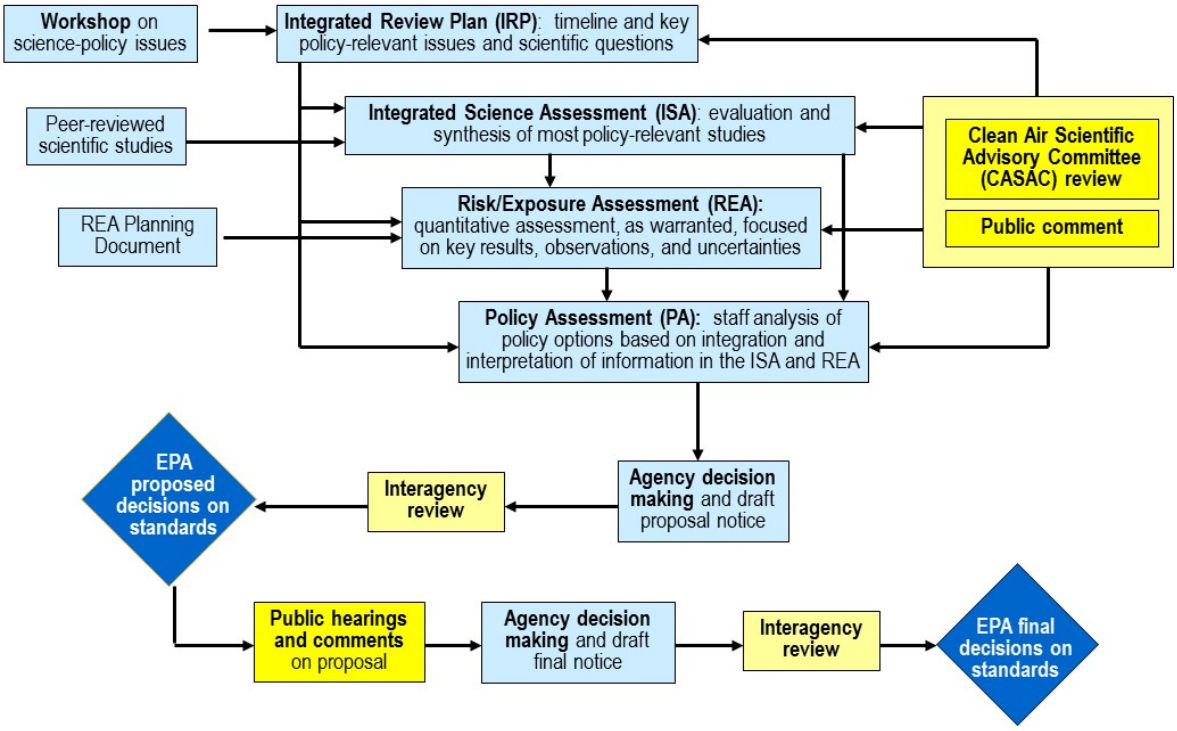

Figure 1-1. Overview of the EPA's Process for Reviewing NAAQS

[8] The EPA maintains a website on which key documents developed for NAAQS reviews are made available (http://www3.epa.gov/ttn/naaqs/).

Table 1-1. Overview of Documents Developed in NAAQS Reviews

Document	Purpose	CASAC Review
Integrated Review Plan (IRP)	Presents the anticipated schedule and process for the review, and the key policy-relevant science issues. Not intended to provide detailed scientific or technical information, plans for quantitative assessments, or conclusions on existing or alternative standard(s).	One draft; consideration of CASAC advice and public comments on the draft IRP is reflected in the final IRP.
Integrated Science Assessment (ISA)	Comprehensive review, synthesis and evaluation of the most policy-relevant science, including key science judgments. Does not present quantitative assessments or conclusions on existing or alternative standard(s).	Consideration of CASAC advice and public comments on drafts of the ISA (multiple drafts, as warranted) is reflected in the final ISA.
Risk and Exposure Assessment (REA) Planning Document(s)	Drawing upon the information in the ISA, presents the planned approaches and scopes of the quantitative risk and exposure analyses that are warranted. Does not present conclusions on existing or alternative standard(s).	Consideration of CASAC advice and public comments on the REA Planning document is reflected in the REA(s).
Health and Welfare REAs (HREA, WREA)	Drawing upon the information in the ISA, presents quantitative assessments of risks and exposures, as warranted, under various air quality scenarios, including just meeting the existing and potential alternative standard(s). Does not present conclusions on existing or alternative standard(s).	Consideration of CASAC advice and public comments on drafts of the REA(s) (multiple drafts, as warranted) is reflected in the final REA(s).
Policy Assessment (PA)	Drawing upon the information in the ISA and REA(s), provides a transparent staff analysis of the scientific basis for policy options for consideration; facilitates CASAC advice to the Agency and recommendations to the Administrator on the adequacy of the existing standards and, as warranted, on the revisions that may be appropriate to consider.	Consideration of CASAC advice and public comments on drafts of the PA (multiple drafts, as warranted) is reflected in the final PA.
Proposed Rule	Communicates the Administrator's proposed decision(s); informed by the ISA, REA(s), PA and the advice of CASAC – Public comment period, including public hearings as warranted.	
Final Rule	Communicates the Administrator's final decision(s); informed by the ISA, REA(s), PA, advice of CASAC and public comments on the proposed rule.	

The planning phase of the NAAQS review process begins with a public workshop intended to provide the EPA an opportunity to receive input and advice on the key science and policy issues around which the review will be structured. Workshop participants are asked to highlight significant new and emerging research related to these key science and policy issues, and to make recommendations to Agency staff regarding the design and scope of the review. Drawing from workshop discussions, a draft IRP is prepared jointly by the EPA's National Center for Environmental Assessment (NCEA), within the Office of Research and Development (ORD), and the EPA's Office of Air Quality Planning and Standards (OAQPS), within the Office of Air and Radiation (OAR). The IRP presents the plan for the review, including the anticipated schedule, the key policy-relevant science issues that will guide the review, and the approach to developing the assessment documents that will inform the review. A draft of the IRP is made available for CASAC review and for public comment, and the final IRP reflects the EPA staff's consideration of CASAC advice and public input.

Following the IRP, the EPA's NCEA develops the Integrated Science Assessment (ISA). The ISA provides a concise review, synthesis, and evaluation of the most policy-relevant science and includes key science judgments. The ISA provides the scientific foundation for the NAAQS review, and it is intended to provide information useful in forming judgments about air quality indicator(s), averaging time(s), form(s), and level(s) for the NAAQS. The schedule typically includes production of a first and, if needed, second draft ISA, both of which undergo CASAC review at public meetings.[9] The final ISA reflects staff's consideration of CASAC advice and of the public input provided on drafts of the ISA. Chapter 3 below provides a more detailed description of the planned scope, organization, and assessment approach for the ISA in the current review of the PM NAAQS.

Building on the assessment of the evidence in the ISA, staff in the EPA's OAQPS considers the extent to which there is support for the development of Health and/or Welfare Risk and Exposure Assessments (HREA, WREA). As an initial step in these considerations, staff prepares Risk and Exposure Assessment planning document(s) (REA Planning Document(s)) that consider the extent to which the available scientific evidence and tools/methodologies warrant the conduct of quantitative assessments. As discussed in Chapters 4 and 5 below, the REA Planning Document(s) will focus on the degree to which important uncertainties from previous reviews could be addressed by updated quantitative analyses, and on the degree to

[9] The availability of draft documents (ISA, REA, PA), and a request for public input on those documents, is also announced in the Federal Register.

which updated or additional analyses could improve the understanding of pollutant exposures and/or risks. To the extent warranted, the REA Planning Document(s) will also outline a general plan, including scope and methods, for conducting quantitative assessments. REA Planning Documents are typically prepared in conjunction with the first or second draft ISA and are reviewed by CASAC at a public meeting.

When developed, REAs provide concise presentations of exposure and/or risk assessments, including presentations of methods, key results, and uncertainties. One or more drafts of the REA(s) undergo CASAC review at public meetings. Staff considers the CASAC advice and public input received in preparing final REAs. Chapters 4 and 5 below provide more detailed descriptions of the approaches in this review of the PM NAAQS to considering the potential support for an HREA and WREA, respectively.

Staff in the EPA's OAQPS also prepares a Policy Assessment (PA), presenting staff's considerations and conclusions regarding the adequacy of the current standards and, if warranted, the range of revised standards that could be supported by the available scientific evidence and exposure/risk information. The PA integrates and interprets the information from the ISA and REA(s) to frame policy options for consideration by the Administrator. Such an evaluation of policy options is intended to help bridge the gap between the Agency's scientific assessments, presented in the ISA and REA(s) (when available), and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS. The PA is also intended to facilitate CASAC's advice to the Agency and recommendations to the Administrator on the adequacy of the existing standards and on revisions that may be appropriate to consider. Staff's considerations and conclusions in the PA are based on the available scientific evidence and quantitative exposure and risk information, including the uncertainties and limitations in that evidence and information. The PA focuses on the evidence and information that is most pertinent to evaluating the basic elements of NAAQS: indicator, averaging time, form, and level. The schedule typically includes production of a first and, if needed, second draft PA, both of which undergo CASAC review at public meetings. Staff considers the CASAC advice and public input received in preparing the final PA.

Following issuance of the final PA, the EPA develops and publishes a notice of proposed rulemaking that communicates the Administrator's proposed decisions on the NAAQS. These proposed decisions are based on the Administrator's consideration of the scientific evidence assessed in the ISA; quantitative exposure and risk information presented and assessed in the REAs, as available; staff's considerations and conclusions based on the evidence and information, as presented in the PA; CASAC advice received during the development of the ISA, REA(s), and PA; and public input received on drafts of those assessment documents. Prior to

publication in the *Federal Register*, a draft proposal notice undergoes interagency review involving other federal agencies.[10] Materials upon which proposed decisions are based, including the documents described above, are made available to the public in the regulatory docket for review.[11]

A public comment period, during which one or more public hearings are generally held, follows publication of the notice of proposed rulemaking. Taking into account comments received on the proposed rule,[12] the Agency develops a final rule, a draft version of which undergoes interagency review prior to publication in the *Federal Register*. Chapter 6 of this IRP discusses the development of the PA and the rulemaking steps for this review of the PM NAAQS.

1.3 HISTORY OF REVIEWS OF THE PM NAAQS

Particulate matter is the generic term for a broad class of chemically and physically diverse substances that exist as discrete liquid and/or solid particles 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), oxides of nitrogen (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) vapor that nucleates new particles or condenses on existing particles and further reacts with gaseous ammonia (NH_3) to form various inorganic salts (e.g., ammonium sulfate, $(NH_4)_2SO_4$, or ammonium bisulfate, NH_4HSO_4); (2) the conversion of nitrogen dioxide (NO_2) to nitric acid (HNO_3) vapor that condenses onto existing particles and reacts further with ammonia to form ammonium nitrate (NH_4NO_3); and (3) reactions involving gaseous VOC yielding organic compounds with low vapor pressures that nucleate or condense on existing particles to form secondary organic particulate matter (SOPM)

[10] Where implementation of the proposed decision would have an annual effect on the economy of $100 million of more, (e.g., by necessitating the implementation of emissions controls) the EPA also develops and releases a draft regulatory impact analysis (RIA) concurrent with the notice of proposed rulemaking. This activity is conducted under Executive Order 12866. The RIA is conducted independently of the rulemaking process and, by law, is not considered in decisions regarding the NAAQS.

[11] All documents in the docket are listed in the www.regulations.gov index. Publicly available docket materials are available either electronically at www.regulations.gov or in hard copy at the Air and Radiation Docket and Information Center. The docket ID number for this review of the PM NAAQS is EPA-HQ-OAR-2015-0072.

[12] When issuing the final rulemaking, the Agency responds to all significant comments on the proposed rule.

(U.S. EPA, 2004, Chapter 3).[13] The chemical and physical properties of PM vary greatly with time, region, meteorology, and source category, complicating the assessment of health and welfare effects.

This section summarizes the PM NAAQS that have been promulgated in past reviews (Table 1-2). Each of these reviews is discussed briefly below.

Table 1-2. Summary of National Ambient Air Quality Standards Promulgated for Particulate Matter 1971-2012[14]

Review Completed	Indicator	Avg. Time	Level	Form
1971	**Total Suspended Particles (TSP)**	**24-hour**	**260 µg/m^3** (primary) **150 µg/m^3** (secondary)	Not to be exceeded more than once per year
		Annual	**75 µg/m^3** (primary) **60 µg/m^3** (secondary)	Annual geometric mean
1987	**PM_{10}**	**24-hour**	**150 µg/m^3**	Not to be exceeded more than once per year on average over a 3-year period
		Annual	**50 µg/m^3**	Annual arithmetic mean, averaged over 3 years
1997	**$PM_{2.5}$**	**24-hour**	**65 µg/m^3**	98th percentile, averaged over 3 years
		Annual	**15.0 µg/m^3**	Annual arithmetic mean, averaged over 3 years[15]
	PM_{10}	**24-hour**	**150 µg/m^3**	99th percentile, averaged over 3 years[16]
		Annual	**50 µg/m^3**	Annual arithmetic mean, averaged over 3 years
2006	**$PM_{2.5}$**	**24-hour**	**35 µg/m^3**	98th percentile, averaged over 3 years

[13] As discussed below (section 1.4), the ecological effects associated with deposited particulate NO_X and SO_X and their transformation products are addressed in the review of the secondary NO_X and SO_X NAAQS.

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

[15] 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 concentration or, if specific constraints were met, measurements from multiple community-oriented monitoring sites could be averaged (i.e., "spatial averaging"). Spatial averaging is discussed further in section 2.1.1, below.

[16] When the 1997 standards were vacated (see below), the form of the 1987 standards remained in place (i.e., not to be exceeded more than once per year on average over a 3-year period).

		Annual	**15.0 µg/m^3**	Annual arithmetic mean, averaged over 3 years[17]
	PM_{10}	**24-hour[18]**	**150 µg/m^3**	Not to be exceed more than once per year on average over a 3-year period
2012	**$PM_{2.5}$**	**24-hour**	**35 µg/m^3**	98th percentile, averaged over 3 years
		Annual	**12.0 µg/m^3** (primary) **15.0 µg/m^3** (secondary)	Annual mean, averaged over 3 years[19]
	PM_{10}	**24-hour**	**150 µg/m^3**	Not to be exceeded more than once per year on average over 3 years

The EPA first established NAAQS for PM in 1971 (36 FR 8186, April 30, 1971), based on the original Air Quality Criteria Document (AQCD) (DHEW, 1969).[20] The federal reference method (FRM) 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 were set at 260 µg/m^3, 24-hour average, not to be exceeded more than once per year, and 75 µg/m^3, annual geometric mean. The secondary standards were set at 150 µg/m^3, 24-hour average, not to be exceeded more than once per year, and 60 µg/m^3, annual geometric mean.

In October 1979 (44 FR 56730, October 2, 1979), the EPA announced the first periodic review of the air quality criteria and NAAQS for PM. Revised primary and secondary standards were promulgated in 1987 (52 FR 24634, July 1, 1987). In the 1987 decision, the EPA changed the indicator for particles from TSP to PM_{10}, in order to focus on the subset of inhalable particles small enough to penetrate to the thoracic region of the respiratory tract (including the tracheobronchial and alveolar regions), referred to as thoracic particles.[21] The level of the 24-hour standards (primary and secondary) was set at 150 µg/m^3, and the form was one expected

[17] The EPA tightened the constraints on the spatial averaging criteria by further limiting the conditions under which some areas may average measurements from multiple community-oriented monitors to determine compliance. Spatial averaging is discussed further in section 2.1.1, below.

[18] The EPA revoked the annual PM_{10} NAAQS in 2006.

[19] In the 2012 decision, the EPA eliminated the option for spatial averaging.

[20] Prior to the review initiated in 2007 (see below), the AQCD provided the scientific basis for the NAAQS.

[21] PM_{10} refers to particles with a nominal mean aerodynamic diameter less than or equal to 10 µm. More specifically, 10 µm is the aerodynamic diameter for which the efficiency of particle collection is 50 percent. Larger particles are not excluded altogether, but are collected with substantially decreasing efficiency while smaller particles are collected with increasing efficiency.

exceedance per year, on average over three years. The level of the annual standards (primary and secondary) was set at 50 $\mu g/m^3$, and the form was annual arithmetic mean, averaged over three years.

In April 1994, the EPA announced its plans for the second periodic review of the air quality criteria and NAAQS for PM, and in 1997 the EPA promulgated revisions to the NAAQS (62 FR 38652, July 18, 1997). In the 1997 decision, the EPA determined that the fine and coarse fractions of PM_{10} should be considered separately. This determination was based on evidence that serious health effects were associated with short- and long-term exposures 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). These new standards were as follows: (1) an annual standard with a level of 15.0 $\mu g/m^3$, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors;[22] and (2) a 24-hour standard with a level of 65 $\mu g/m^3$, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each monitor within an area. Also, the 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 the coarse fraction of PM_{10} (referred to as thoracic coarse particles or $PM_{10-2.5}$; generally including particles with a nominal mean aerodynamic diameter greater than 2.5 μm and less than or equal to 10 μm), the EPA retained the annual PM_{10} standard and revised the form of the 24-hour PM_{10} standard to be based on the 99th percentile of 24-hour PM_{10} concentrations at each monitor in an area. The EPA revised the secondary standards by making them identical in all respects to the primary standards.

Following promulgation of the 1997 PM NAAQS, petitions for review were filed by a large number of parties, addressing a broad range of issues. In May 1999, the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) upheld the 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

[22] 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 concentration or, if specific constraints were met, measurements from multiple community-oriented monitoring sites could be averaged (i.e., "spatial averaging" as discussed in section 2.1.1, below). In the last review (completed in 2012) the EPA replaced the term "community-oriented" monitor with the term "area-wide" monitor. *Area-wide* monitors are those sited at the neighborhood scale or larger, as well as those monitors sited at micro-or middle scales that are representative of many such locations in the same CBSA (78 FR 3236, January 15, 2013).

1027, 1055-56 (D.C. Cir. 1999). The D.C. Circuit also found "ample support" for the EPA's decision to regulate coarse particle pollution, but vacated the 1997 PM_{10} standards, concluding that the 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 D.C. Circuit's decision, the EPA removed the vacated 1997 PM_{10} standards, and the pre-existing 1987 PM_{10} standards remained in place (65 FR 80776, December 22, 2000). The D.C. Circuit also upheld the EPA's determination not to establish more stringent secondary standards for fine particles to address effects on visibility. 175 F. 3d at 1027.

The D.C. Circuit also addressed more general issues related to the NAAQS, including issues related to the consideration of costs in setting NAAQS and the EPA's approach to establishing the levels of NAAQS. Regarding the cost issue, the court reaffirmed prior rulings holding that in setting NAAQS the EPA is "not permitted to consider the cost of implementing those standards." Id. at 1040-41. Regarding the levels of NAAQS, the court held that the EPA's approach to establishing the level of the standards in 1997 (i.e., both for PM and for the ozone NAAQS promulgated on the same day) effected "an unconstitutional delegation of legislative authority." Id. at 1034-40. Although the court stated that "the factors EPA uses in determining the degree of public health concern associated with different levels of ozone and PM are reasonable," it remanded the rule to the EPA, stating that when the EPA considers these factors for potential non-threshold pollutants "what EPA lacks is any determinate criterion for drawing lines" to determine where the standards should be set.

The D.C. Circuit's holding on the cost and constitutional issues were appealed to the United States Supreme Court. In February 2001, the Supreme Court issued a unanimous decision upholding the EPA's position on both the cost and constitutional 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 the EPA's discretion, affirming the EPA's approach of setting standards that are neither more nor less stringent than necessary.[23]

[23] 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 a March 2002 decision, the Court of Appeals rejected all remaining challenges to the standards, holding that the EPA's $PM_{2.5}$ standards were reasonably supported by the administrative record and were not "arbitrary and capricious" *American Trucking Associations v. EPA*, 283 F. 3d 355, 369-72 (D.C. Cir. 2002).

In October 1997, the EPA published its plans for the third periodic review of the air quality criteria and NAAQS for PM (62 FR 55201, October 23, 1997). After CASAC and public review of several drafts, the EPA's NCEA finalized the AQCD in October 2004 (U.S. EPA, 2004). The EPA's OAQPS finalized a Risk Assessment and Staff Paper in December of 2005 (Abt, 2005; U.S. EPA, 2005).[24] On December 20, 2005, the EPA announced its proposed decision to revise the NAAQS for PM, and solicited comment on a broad range of options (71 FR 2620, January 17, 2006).

On September 21, 2006, the 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, the EPA revised the level of the 24-hour $PM_{2.5}$ standards to 35 $\mu g/m^3$, retained the level of the annual $PM_{2.5}$ standards at 15.0 $\mu g/m^3$, and revised the form of the annual $PM_{2.5}$ standards by narrowing the constraints on the optional use of spatial averaging.[25] With regard to the primary and secondary standards for PM_{10}, the EPA retained the 24-hour standards, with levels at 150 $\mu g/m^3$, and revoked the annual standards. The Administrator judged that the available evidence generally did not suggest a link between long-term exposure to existing ambient levels of coarse particles and health or welfare effects. In addition, a new reference method was added for the measurement of $PM_{10-2.5}$ in the ambient air, in order to provide a basis for approving federal equivalent methods (FEMs) and to promote the gathering of scientific data to support future reviews of the PM NAAQS.

Several parties filed petitions for review following promulgation of the revised PM NAAQS in 2006. These petitions addressed the following issues: (1) selecting the level of the primary annual $PM_{2.5}$ standard; (2) retaining PM_{10} as the indicator of a standard for thoracic coarse particles, retaining the level and form of the 24-hour PM_{10} standard, and revoking the PM_{10} annual standard; and (3) setting the secondary $PM_{2.5}$ standards identical to the primary standards. On February 24, 2009, the U.S. Court of Appeals for the District of Columbia Circuit issued its opinion in the case *American Farm Bureau Federation v. EPA*, 559 F. 3d 512 (D.C. Cir. 2009). The court remanded the primary annual $PM_{2.5}$ NAAQS to EPA because EPA failed to adequately explain why the standards provided the requisite protection from both short- and

[24] Prior to the review initiated in 2007, the Staff Paper, rather than the PA, presented the EPA staff's considerations and conclusions regarding the adequacy of existing NAAQS and, when appropriate, the potential alternative standards that could be supported by the evidence and information.

[25] Spatial averaging is discussed in more detail in section 2.1.1, below.

long-term exposures to fine particles, including protection for at-risk populations. *American Farm Bureau Federation v. EPA*, 559 F. 3d 512, 520-27 (D.C. Cir. 2009). With regard to the standards for PM_{10}, the court upheld EPA's decisions to retain the 24-hour PM_{10} standard to provide protection from thoracic coarse particle exposures and to revoke the annual PM_{10} standard. *American Farm Bureau Federation,* 559 F. 2d at 533-38. With regard to the secondary $PM_{2.5}$ standards, the court remanded the standards to EPA because the Agency failed to adequately explain why setting the secondary PM standards identical to the primary standards provided the required protection for public welfare, including protection from visibility impairment. *American Farm Bureau Federation*, 559 F. 2d at 528-32. The EPA responded to the court's remands as part of the next review of the PM NAAQS, which was initiated in 2007 (discussed below).

In June 2007, the EPA initiated the fourth periodic review of the air quality criteria and the PM NAAQS by issuing a call for information in the *Federal Register* (72 FR 35462, June 28, 2007). Based on the NAAQS review process, as revised in 2008 and again in 2009,[26] the EPA held science/policy issue workshops on the primary and secondary PM NAAQS (72 FR 34003, June 20, 2007; 72 FR 34005, June 20, 2007), and prepared and released the planning and assessment documents that comprise the review process (i.e., IRP (U.S. EPA, 2008), ISA (U.S. EPA, 2009a), REA planning documents for health and welfare (U.S. EPA, 2009b, c), a quantitative health risk assessment (U.S. EPA, 2010a)[27] and an urban-focused visibility assessment (U.S. EPA, 2010b),[28] and PA (U.S. EPA, 2011)). In June 2012, the EPA announced its proposed decision to revise the NAAQS for PM (77 FR 38890, June 29, 2012).

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[26] The history of the NAAQS review process, including revisions to the process, is discussed at http://www3.epa.gov/ttn/naaqs/review2.html.

[27] The quantitative assessment of health risks conducted in the last review was presented in the *Quantitative Health Risk Assessment for Particulate Matter* (U.S. EPA, 2010a). In the current review, quantitative assessments for health-related exposures and risks, if warranted, would be presented in the Health Risk and Exposure Assessment (HREA). For consistency with the documents developed under the current NAAQS process, the *Quantitative Health Risk Assessment for Particulate Matter* (U.S. EPA, 2010a) from the last review will be referenced in this document as the 2010 HREA.

[28] The quantitative assessment of welfare effects conducted in the last review was presented, in part, in the *Urban-Focused Visibility Assessment* (U.S. EPA, 2010b). In the current review, quantitative assessments for welfare effects, if warranted, would be presented in the Welfare Risk and Exposure Assessment (WREA). The *Urban-Focused Visibility Assessment* (U.S. EPA, 2010b) from the last review will be referenced in this document as the 2010 UFVA.

In December 2012, the EPA announced its final decisions to revise the primary NAAQS for PM to provide increased protection of public health (78 FR 3086, January 15, 2013).[29] With regard to primary standards for $PM_{2.5}$, the EPA revised the level of the annual $PM_{2.5}$ standard[30] to 12.0 $\mu g/m^3$ and retained the 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$. For the primary PM_{10} standard, the EPA retained the 24-hour standard to continue to provide protection against effects associated with short-term exposure to thoracic coarse particles (i.e., $PM_{10-2.5}$). With regard to the secondary PM standards, the EPA generally retained the 24-hour and annual $PM_{2.5}$ standards[31] and the 24-hour PM_{10} standard to address visibility and non-visibility welfare effects. On judicial review, the revised standards were upheld in all respects. *NAM v EPA*, 750 F.3d 921 (D.C. Cir. 2014).

1.4 GENERAL SCOPE OF THE CURRENT REVIEW

With regard to scope, this review is focused on the air quality criteria for PM and on the primary and secondary NAAQS for $PM_{2.5}$ and PM_{10}. As discussed above, the current primary and secondary $PM_{2.5}$ standards are meant to protect against the health and welfare effects, respectively, that have been associated with exposures to fine particles. The primary and secondary PM_{10} standards are meant to protect against the effects associated with exposures to thoracic coarse particles (i.e., $PM_{10-2.5}$). Therefore, an important aspect of the current review will be the EPA's assessment of the health and welfare effects that have been associated with size fractionated PM mass, with a particular focus on the $PM_{2.5}$ and $PM_{10-2.5}$ size fractions. In addition, as in the last review, the EPA will also assess the available scientific evidence for health or welfare effects associated with additional size fractions (e.g., ultrafine particles) and with particular PM components or groups of components, sources, or environments (e.g., urban and non-urban environments).

Based on the available scientific information, the EPA will consider the extent to which the current $PM_{2.5}$ and PM_{10} standards are requisite to protect public health and welfare, within the meaning of section 109(b) of the CAA (section 1.1, above). To the extent the available information calls into question the adequacy of the protection afforded by one or more of the existing PM standards, the EPA will consider potential alternatives that could be supported by

[29] The bases for these decisions are discussed further in sections 2.1 and 2.2, below.
[30] The EPA also eliminated the option for spatial averaging (section 2.1.1, below).
[31] Consistent with the primary standard, the EPA eliminated the option for spatial averaging with the annual standard (section 2.1.1, below).

the available scientific evidence and, as available, exposure-/risk-based information, in terms of the basic elements of the NAAQS (indicator, averaging time, form, level).

With regard to the secondary standards in particular, as in the last review (77 FR 38991, June 29, 2012), this review of the PM NAAQS will consider the PM-related welfare effects that are not being addressed in the ongoing review of the secondary NO_X and SO_X NAAQS. Specifically, the review of the secondary NO_X and SO_X NAAQS is addressing the ecological effects of ecosystem loading of oxides of nitrogen and oxides of sulfur, which includes particulate nitrogen and sulfur compounds.[32] In this review of the PM NAAQS, welfare effects to be considered include PM-related visibility impairment, climate effects, ecological effects (other than those attributable to deposition of NO_X, SO_X and their transformation products) and materials damage and soiling (i.e., materials effects). While N and/or S may contribute to these welfare effects, other components of PM play a role as well. Therefore, it is appropriate to consider these welfare effects in this review of the PM NAAQS to the extent that they are not being covered in the ongoing review of the secondary NO_X and SO_X NAAQS. In the case of materials effects, the impacts of gaseous and particulate N and S wet deposition cannot be clearly distinguished, so both will be considered in this review of the PM NAAQS, along with other materials effects of PM-related deposition.

In contrast, as noted above, the ongoing review of the secondary NAAQS for ecological effects of NO_X and SO_X is considering the ecological effects that result specifically from the deposition of NO_X and SO_X and their transformation products.[33] This approach is consistent with the previous review of the secondary NO_2 and SO_2 standards,[34] in which the EPA conducted a joint review focused on the protection provided against the effects of deposition of NO_X and SO_X to sensitive aquatic and terrestrial ecosystems. The approach in the last review recognized that NO_X and SO_X, and their associated transformation products, are linked from the perspectives of both atmospheric chemistry and ecological effects, providing "a strong basis for considering these pollutants together" (77 FR 20222, April 3, 2012).

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[32] See http://www3.epa.gov/ttn/naaqs/standards/no2so2sec/index.html for more information on the current review of the secondary NO_X and SO_X NAAQS.

[33] More broadly, the review of the secondary NAAQS for ecological effects of NO_X and SO_X includes consideration of the ecological effects of ecosystem loading of particulate nitrogen and sulfur compounds.

[34] When discussing specific standards, we refer to those standards by their indicator species (i.e., in this case NO_2 and SO_2). As described in the draft NO_X/SO_X IRP (U.S. EPA, 2015, p. 1-1) the terms NO_2 and SO_2 are not interchangeable with the terms NO_X and SO_X. NO_X and SO_X include many more chemical species than just NO_2 and SO_2.

1.5 ANTICIPATED SCHEDULE FOR CURRENT REVIEW

In December 2014, the EPA announced the initiation of the current periodic review of the air quality criteria for PM and of the $PM_{2.5}$ and PM_{10} NAAQS and issued a call for information in the *Federal Register* (79 FR 71764, December 3, 2014). On February 9 to 11, 2015, the EPA's NCEA and OAQPS held a public workshop to inform the planning for the current review of the PM NAAQS (announced in 79 FR 71764, December 3, 2014). This workshop was meant to provide the EPA an opportunity to receive input and advice on the key science and policy issues around which the PM NAAQS review will be structured. Workshop participants were asked to highlight significant new and emerging PM research related to these key science and policy issues, and to make recommendations to the Agency regarding the design and scope of this review. The input received at this workshop was considered by the EPA staff in developing this draft IRP. The EPA's anticipated schedule for the remainder of this review is summarized in Table 1-3, below.

Table 1-3. Anticipated Schedule for the Review of the PM NAAQS

Stage of Review	Major Milestone	Actual or Target Date
Planning	Literature Search	Ongoing
	Federal Register Call for Information	December 3, 2014
	Workshop on Science/Policy Issues	February 9-11, 2015
	Release Draft IRP for CASAC/public review	April 2016
	CASAC Review Meeting for Draft IRP	May 23, 2016
	Release Final IRP	September 2016
Science Assessment	Release First Draft ISA for CASAC/public review	Spring 2017
	CASAC Review Meeting for First Draft ISA	Summer 2017
	Release Second Draft ISA for CASC/public review	Winter 2018
	CASAC Review Meeting for Second Draft ISA	Spring 2018
	Release Final ISA	Spring 2019
Risk/Exposure Assessments	Release REA Planning Document(s) for CASAC/public review	Spring/Summer 2017
	CASAC Review Meeting for REA Planning Document(s)	Summer 2017
	Release First Draft REA(s) for CASAC/Public Review	Winter/Spring 2018
	CASAC Review Meeting for First Draft REA(s)	Spring 2018
	Release Second Draft REA(s) for CASAC/Public Review	Fall 2018
	CASAC Review Meeting for Second Draft REA(s)	Fall/Winter 2018
	Release Final REA(s)	Winter 2019
Policy Assessment/ Rulemaking	Release First Draft PA for CASAC/public review	Fall 2018
	CASAC Review Meeting on First Draft PA	Fall/Winter 2018
	Release Second Draft PA	Fall 2019
	CASAC Review/Public Comment on Second Draft PA	Fall/Winter 2019
	Release Final PA	Winter 2020
	Proposed Rulemaking	2020
	Final Rulemaking	2021

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2 KEY POLICY-RELEVANT ISSUES IN THE CURRENT REVIEW

In order to inform the Administrator's decisions on the adequacy of the existing primary and secondary PM NAAQS, in the current review we[35] will address the following overarching question:

- **Does the currently available scientific evidence and exposure-/risk-based information support or call into question the adequacy of the protection afforded by the current primary and/or secondary PM standards?**

If warranted, we will also address a second overarching question:

- **What alternative standards are supported by the currently available scientific evidence and exposure-/risk-based information, and are appropriate for consideration?**

To inform our evaluation of these overarching questions, we will identify a number of more specific policy-relevant questions for consideration (see below). These policy-relevant questions will focus on key issues reflecting aspects of the health and welfare effects evidence, air quality information, and information from quantitative exposure and risk assessments that can inform the Administrator's decisions in the current review. Questions will build upon the conclusions from the last review on the evidence and information, including conclusions on the uncertainties and limitations in that evidence and information.

Sections 2.1 and 2.2 below summarize the decisions made in the last review of the PM NAAQS, the interpretations of the underlying scientific evidence and information supporting those decisions, the important uncertainties and limitations in the evidence and information in the last review, and potential key policy-relevant questions for the current review.[36] Section 2.1 focuses on the primary PM standards, and section 2.2 focuses on the secondary PM standards. Section 2.3 provides an overview of the PM ambient monitoring networks and the key monitoring-related issues to be considered as part of the current standards review.

[35] In this document, the terms "we" or "our" refer to staff in the EPA's OAQPS and/or NCEA.

[36] Based on CASAC advice and public input on this draft IRP, we will modify these potential questions as appropriate for the final IRP. The key policy-relevant questions identified in the final PM IRP will provide an overall framework for the development of the PM ISA, REAs (if warranted), and the PA.

2.1 PRIMARY STANDARDS

The last review of the primary PM NAAQS was completed in 2012 (78 FR 3086, January 15, 2013). As noted above (section 1.3), in the last review the EPA lowered the level of the primary annual $PM_{2.5}$ standard from 15.0 to 12.0 $\mu g/m^3$,[37] retained the existing 24-hour $PM_{2.5}$ standard with its level of 35 $\mu g/m^3$, and retained the existing 24-hour PM_{10} standard with its level of 150 $\mu g/m^3$. Sections 2.1.1 and 2.1.2 below discuss the primary $PM_{2.5}$ and PM_{10} standards, respectively. These sections summarize the rationales for the decisions made in the last review, including the Agency's consideration of important uncertainties and limitations in the scientific evidence and in the air quality and risk information. Section 2.1.3 provides an overview of the general approach and the potential key policy-relevant questions in the current review of the primary $PM_{2.5}$ and PM_{10} standards.

2.1.1 $PM_{2.5}$ Standards

The 2012 decision to strengthen the suite of primary $PM_{2.5}$ standards was based on the Administrator's consideration of the extensive body of scientific evidence assessed in the 2009 PM ISA (U.S. EPA, 2009); the quantitative risk analyses presented in the 2010 HREA (U.S. EPA, 2010a);[38] the advice and recommendations of CASAC (e.g., Samet, 2009; 2010a, b); and public comments on the proposed rule (78 FR 3086, January 15, 2013; U.S. EPA, 2012). In particular, the Administrator noted the "strong and generally robust body of evidence of serious health effects associated with both long- and short-term exposures to $PM_{2.5}$" (78 FR 3120, January 15, 2013). This included epidemiologic studies reporting health effect associations based on long-term average $PM_{2.5}$ concentrations ranging from about 15.0 $\mu g/m^3$ or above (i.e., at or above the level of the then-existing annual standard) to concentrations "significantly below the level of the annual standard" (78 FR 3120, January 15, 2013). The Administrator further observed that such studies were part of an overall pattern across a broad range of studies reporting positive associations, which were frequently statistically significant. Based on her "confidence in the association between exposure to $PM_{2.5}$ and serious public health effects, combined with evidence of such an association in areas that would meet the current standards"

[37] The Agency also eliminated spatial averaging provisions as part of the form of the annual standard.

[38] In the last review, the EPA generated a quantitative health risk assessment for PM, and did not conduct an exposure assessment (U.S. EPA, 2010a). To be consistent with our general process for reviewing the NAAQS (section 1.2, above), and with our discussion of potential quantitative analyses in the current review (Chapter 4, below), we refer to the 2010 health risk assessment as the 2010 HREA.

(78 FR 3120, January 15, 2013), the Administrator concluded that revision of the suite of primary $PM_{2.5}$ standards was necessary in order to provide increased public health protection. Specifically, she concluded that the then-existing suite of primary $PM_{2.5}$ standards was not sufficient, and thus not requisite, to protect public health with an adequate margin of safety. This decision was consistent with advice received from CASAC (Samet, 2010b).

The Administrator next considered what specific revisions to the existing primary $PM_{2.5}$ standards were appropriate, given the available evidence and quantitative risk information. She considered both the annual and 24-hour $PM_{2.5}$ standards, focusing on the basic elements of those standards (i.e., indicator, averaging time, form, and level). These considerations, and the Administrator's conclusions, are summarized below.

Indicator

In initially setting standards for fine particles in 1997, the EPA concluded it was appropriate to control fine particles as a group, based on $PM_{2.5}$ mass, rather than singling out any particular component or class of fine particles (62 FR 38667, July 18, 1997). In the review completed in 2006, based on similar considerations, the EPA concluded that the available information supported retaining the $PM_{2.5}$ indicator and remained too limited to support a distinct standard for any specific $PM_{2.5}$ component or group of components associated with particular source categories of fine particles (71 FR 61162 to 61164, October 17, 2006).

In the last review, the EPA again considered issues related to the appropriate indicator for fine particles, with a focus on evaluating support for the existing $PM_{2.5}$ mass-based indicator and for potential alternative indicators based on the ultrafine particle fraction or on fine particle composition (78 FR 3121, January 15, 2013).[39] With regard to $PM_{2.5}$ mass, as in the 1997 and 2006 reviews, the health studies available during the last review continued to link adverse health outcomes (e.g., premature mortality, hospital admissions, emergency department visits) with long- and short-term exposures to fine particles indexed largely by $PM_{2.5}$ mass (78 FR 3121, January 15, 2013). With regard to the ultrafine fraction of ambient PM, the PA noted the limited body of health evidence assessed in the ISA (summarized in U.S. EPA, 2009, section 2.3.5 and Table 2–6) and the limited monitoring information available to characterize ambient concentrations of ultrafine particles (U.S. EPA, 2011, section 1.3.2 and Appendix B, section B.1.3). With regard to PM composition, the ISA concluded that "the evidence is not yet

[39] In the last review, the ISA defined ultrafine particles as generally including particles with a mobility diameter less than or equal to 0.1 μm. Mobility diameter is defined as the diameter of a particle having the same diffusivity or electrical mobility in air as the particle of interest, and is often used to characterize particles of 0.5 μm or smaller (U.S. EPA, 2009a, pp. 3-2 to 3-3).

sufficient to allow differentiation of those constituents or sources that are more closely related to specific health outcomes" (U.S. EPA, 2009, pp. 2-26 and 6-212; 78 FR 3123, January 15, 2013). The PA further noted that "many different constituents of the fine particle mixture as well as groups of components associated with specific source categories of fine particles are linked to adverse health effects" (U.S. EPA, 2011, p. 2–55; 78 FR 3123, January 15, 2013). Consistent with the conclusions of the PA, CASAC advised that it was appropriate to consider retaining $PM_{2.5}$ as the indicator for fine particles. CASAC specifically stated that "[t]here [is] insufficient peer-reviewed literature to support any other indicator at this time" (Samet, 2010a, p. 12). The Administrator concurred with the conclusions of the Policy Assessment and with CASAC recommendations, and concluded that it was "appropriate to retain $PM_{2.5}$ as the indicator for fine particles" (78 FR 3123, January 15, 2013).

Averaging time

In 1997, the EPA set an annual $PM_{2.5}$ standard to provide protection from health effects associated with long- and short-term exposures to $PM_{2.5}$, and a 24-hour standard to supplement the protection afforded by the annual standard (62 FR 38667 to 38668, July, 18, 1997). In the 2006 review, the EPA retained both annual and 24-hour averaging times (71 FR 61164, October 17, 2006).

In the last review, the EPA again considered issues related to the appropriate averaging times for $PM_{2.5}$ standards, with a focus on evaluating support for the existing annual and 24-hour averaging times and for potential alternative averaging times based on sub-daily or seasonal metrics. Based on the evidence assessed in the ISA, the PA noted that the overwhelming majority of studies that had been conducted since the 2006 review continued to utilize annual (or multi-year) or 24-hour PM averaging periods (U.S. EPA, 2011, section 2.3.2). With regard to potential support for an averaging time shorter than 24-hours, the PA noted that studies of cardiovascular effects associated with sub-daily PM concentrations had evaluated a variety of PM metrics (e.g., $PM_{2.5}$, PM_{10}, $PM_{10-2.5}$, ultrafine particles), averaging periods (e.g., 1, 2, and 4 hours), and health outcomes (U.S. EPA, 2011, section 2.3.2). The PA concluded that this information, when viewed as a whole, was too uncertain to serve as a basis for establishing a primary $PM_{2.5}$ standard with an averaging time shorter than 24-hours (U.S. EPA, 2011, p. 2-57).[40] With regard to potential support for a seasonal averaging time, few studies were available

[40] For respiratory effects specifically, the Administrator further noted the ISA conclusion that the strongest associations were observed with 24-hour average or longer exposures, not with exposures less than 24-hours (U.S. EPA, 2009, section 6.3).

to deduce a general pattern in $PM_{2.5}$-related risk across seasons, and these studies did not provide information on health effects associated with season-long exposures to $PM_{2.5}$ (U. S. EPA, 2011, p. 2-58; 78 FR 3124, January 15, 2013).

The PA reached the overall conclusions that the available information provided strong support for considering retaining the current annual and 24-hour averaging times and did not provide support for considering alternative averaging times (U.S. EPA, 2011, p. 2-58). CASAC agreed that these conclusions were reasonable (Samet, 2010a, p. 13). The Administrator concurred with the PA conclusions and with CASAC's advice. Specifically, she judged that it was "appropriate to retain the current annual and 24-hour averaging times for the primary $PM_{2.5}$ standards to protect against health effects associated with long- and short-term exposure periods" (78 FR 3124, January 15, 2013).

Form

In 1997, the EPA established the form of the annual $PM_{2.5}$ standard as an annual arithmetic mean, averaged over 3 years, from single or multiple community-oriented monitors.[41] That is, the level of the annual standard was to be compared to measurements made at each community-oriented monitoring site or, if specific criteria were met, measurements from multiple community-oriented monitoring sites could be averaged together (i.e., spatial averaging)[42] (62 FR 38671 to 38672, July 18, 1997). In the 1997 review, the EPA also established the form of the 24-hour $PM_{2.5}$ standard as the 98^{th} percentile of 24-hour concentrations at each monitor within an area (i.e., no spatial averaging), averaged over three years (62 FR at 38671 to 38674, July 18, 1997). In the 2006 review, the EPA retained these standard forms but tightened the criteria for using spatial averaging with the annual standard (78 FR 3124, January 15, 2013).[43]

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[41] As noted above (section 1.3), in the last review the EPA replaced the term "community-oriented" monitor with the term "area-wide" monitor. *Area-wide* monitors are those sited at the neighborhood scale or larger, as well as those monitors sited at micro-or middle scales that are representative of many such locations in the same CBSA (78 FR 3236, January 15, 2013). CBSAs are required to have at least one area-wide monitor sited in the area of expected maximum $PM_{2.5}$ concentration.

[42] The original criteria for spatial averaging included: (1) the annual mean concentration at each site shall be within 20% of the spatially averaged annual mean, and (2) the daily values for each monitoring site pair shall yield a correlation coefficient of at least 0.6 for each calendar quarter (62 FR 38671 to 38672, July 18, 1997).

[43] Specifically, the Administrator revised spatial averaging criteria such that "(1) [t]he annual mean concentration at each site shall be within 10 percent of the spatially averaged annual mean, and (2) the daily values for each monitoring site pair shall yield a correlation coefficient of at least 0.9 for each calendar quarter (71 FR 61167, October 17, 2006).

In the last review, the EPA's consideration of the form of the annual $PM_{2.5}$ standard again included a focus on the issue of spatial averaging. An analysis of air quality and population demographic information indicated that the highest $PM_{2.5}$ concentrations in a given area tended to be measured at monitors in locations where the surrounding populations were more likely to live below the poverty line and to include larger percentages of racial and ethnic minorities (U.S. EPA, 2011, p. 2-60). Based on this analysis, the PA concluded that spatial averaging could result in disproportionate impacts in at-risk populations, including minority populations and populations with lower socioeconomic status (SES). Therefore, the PA concluded that it was appropriate to consider revising the form of the annual $PM_{2.5}$ standard such that it did not allow for the use of spatial averaging across monitors (U.S. EPA, 2011, p. 2-60). The CASAC agreed with staff conclusions that it was "reasonable" for the EPA to eliminate the spatial averaging provisions (Samet, 2010b, p. 2), stating the following: "Given mounting evidence showing that persons with lower SES levels are a susceptible group for PM-related health risks, CASAC recommends that the provisions that allow for spatial averaging across monitors be eliminated" (Samet, 2010a, p. 13).

The Administrator concluded that public health would not be protected with an adequate margin of safety in all locations, as required by law, if disproportionately higher $PM_{2.5}$ concentrations in low income and minority communities were averaged together with lower concentrations measured at other sites in a large urban area. Therefore, she concluded that the form of the annual $PM_{2.5}$ standard should be revised to eliminate spatial averaging provisions. Thus, the level of the annual $PM_{2.5}$ standard established in the last review is to be compared with measurements from each appropriate monitor in an area, with no allowance for spatial averaging.

In the last review, the EPA also considered the form of the 24-hour $PM_{2.5}$ standard. The Agency recognized that the existing 98th percentile form for the 24-hour standard was originally selected to provide a balance between limiting the occurrence of peak 24-hour $PM_{2.5}$ concentrations and identifying a stable target for risk management programs.[44] Updated air quality analyses in the last review provided additional support for the increased stability of the 98th percentile $PM_{2.5}$ concentration, compared to the 99th percentile (U.S. EPA, 2011, Figure 2-2, p. 2-62). Consistent with the PA conclusions based on this analysis, the Administrator concluded

[44] See *ATA III,* 283 F.3d at 374–376 which concludes that it is legitimate for the EPA to consider overall stability of the standard and its resulting promotion of overall effectiveness of NAAQS control programs in setting a standard that is requisite to protect the public health.

that it was appropriate to retain the 98th percentile form for the 24-hour $PM_{2.5}$ standard (78 FR 3127, January 15, 2013).

Level

The EPA's approach to considering alternative levels of the $PM_{2.5}$ standards in the last review was based on evaluating the public health protection afforded by the annual and 24-hour standards, taken together, against mortality and morbidity effects associated with long-term or short-term $PM_{2.5}$ exposures. This approach recognized that there is no bright line clearly directing the choice of level. Rather, the choice of what is appropriate is a public health policy judgment entrusted to the Administrator. In the last review, this judgment included consideration of the strengths and limitations of the evidence and the appropriate inferences to be drawn from the evidence and the exposure and risk assessments.

In evaluating alternative standards, the Agency considered the extent to which specific alternative $PM_{2.5}$ standard levels were likely to reduce the magnitudes of both long-term exposure-related mortality risk and short-term exposure-related mortality and morbidity risk. Results of the 2010 Health Risk and Exposure Assessment (HREA) indicated that, compared to revising the 24-hour standard, lowering the level of the annual standard would result in more consistent risk reductions across urban study areas, thereby potentially providing a more consistent degree of public health protection (U.S. EPA, 2010a, pp. 5-15 to 5-17; 78 FR 3128, January 15, 2013). Based on risk results, together with the available evidence, the Administrator concluded that it was appropriate to lower the level of the annual standard in order to increase protection against both long- and short-term $PM_{2.5}$ exposures. She further concluded that it was appropriate to set the 24-hour standard in order to provide supplemental protection, particularly for areas with high peak-to-mean ratios of 24-hour $PM_{2.5}$ concentrations (e.g., areas with important local or seasonal sources) and for $PM_{2.5}$-related effects that may be associated with shorter-than daily exposure periods. The Administrator judged that this approach was the "most effective and efficient way to reduce total $PM_{2.5}$-related population risk and to protect public health with an adequate margin of safety" (78 FR 3158, January 15, 2013).

In selecting the level of the annual $PM_{2.5}$ standard, the Administrator recognized the substantial increase in the number and diversity of studies available in the last review, including extended analyses of seminal studies of long-term $PM_{2.5}$ exposures (i.e., American Cancer Society (ACS) and Harvard Six Cities studies), important new long-term exposure studies, and new U.S. multi-city studies that greatly expanded and reinforced our understanding of mortality and morbidity effects associated with short-term $PM_{2.5}$ exposures. She placed the greatest emphasis on health endpoints for which the evidence was strongest, based on the assessment of the evidence in the ISA and on the ISA's causality determinations (U.S. EPA, 2009, section

2.3.1).[45] In particular, she noted that the evidence was sufficient to conclude a causal relationship exists between $PM_{2.5}$ exposures and mortality and cardiovascular effects (i.e., for both long- and short-term exposures) and that the evidence was sufficient to conclude a causal relationship is "likely" to exist between $PM_{2.5}$ exposures and respiratory effects (i.e., for both long- and short-term exposures). The Administrator also noted additional, but more limited, evidence for a broader range of health endpoints including evidence "suggestive of a causal relationship" between long-term exposures and developmental and reproductive effects as well as carcinogenic effects (78 FR 3158, January 15, 2013).

Based on information discussed and presented in the ISA, the Administrator recognized that health effects may occur over the full range of ambient $PM_{2.5}$ concentrations observed in epidemiologic studies, since no discernible population-level threshold could be identified based on the evidence available in the last review (78 FR 3158, January 15, 2013; U.S. EPA, 2009, section 2.4.3). To inform her decisions on an appropriate level for the annual standard in the absence of a discernible population-level threshold, the Administrator considered the degree to which epidemiologic studies indicate confidence in the magnitude and significance of health effect associations over distributions of ambient $PM_{2.5}$ concentrations. In doing so, she recognized that epidemiologic studies provide greater confidence in the magnitude and significance of observed associations for the part of the air quality distribution corresponding to the bulk of the health events evaluated, generally at and around the long-term mean $PM_{2.5}$ concentrations. Accordingly, the Administrator weighed most heavily the long-term mean concentrations reported in key multi-city epidemiologic studies. She also took into account additional population-level information from a subset of studies, beyond the long-term mean concentrations, to identify a broader range of $PM_{2.5}$ concentrations to consider in judging the need for public health protection.[46] In doing so, the Administrator recognized that studies indicate diminished confidence in the magnitude and significance of observed associations in the lower part of the air quality distribution, corresponding to where a relatively small proportion of the health events are observed.

In revising the level of the annual standard to 12.0 $\mu g/m^3$, the Administrator noted that such a level was below the long-term mean $PM_{2.5}$ concentrations reported in key epidemiologic

[45] The ISA framework for reaching causality determinations is discussed in Chapter 3, below.

[46] This information characterized the distribution of health events in the studies, and the corresponding long-term mean $PM_{2.5}$ concentrations (78 FR 3130 to3134, January 15, 2013). The additional population-level data helped inform the Administrator's judgment of how far below the long-term mean concentrations to set the level of the annual standard (78 FR 3160).

studies that provided evidence of an array of serious health effects, including premature mortality and increased hospitalizations for cardiovascular and respiratory effects (78 FR 3161, January 15, 2013). The Administrator further noted that 12.0 $\mu g/m^3$ generally corresponded to the lower portions (i.e., about the 25th percentile) of distributions of health events in the limited number of epidemiologic studies for which population-level information was available. The Administrator viewed this population information as helpful in guiding her determination as to where her confidence in the magnitude and significance of the $PM_{2.5}$ associations were reduced to such a degree that a standard set at a lower level was not warranted. The Administrator also recognized that a level of 12.0 $\mu g/m^3$ reflected placing some weight on studies of reproductive and developmental effects, for which the evidence was less strong (78 FR 3161-3162, January 15, 2013).[47]

In conjunction with a revised annual standard with a level of 12.0 $\mu g/m^3$, the Administrator concluded that the evidence supported retaining the 35 $\mu g/m^3$ level of the 24-hour $PM_{2.5}$ standard to provide supplemental protection (78 FR 3163, January 15, 2013). Specifically, she judged that by lowering the level of the annual standard, the distribution of 24-hour $PM_{2.5}$ concentrations would be lowered as well, affording additional protection against effects associated with short-term $PM_{2.5}$ exposures.[48]

The Administrator recognized that uncertainties remained in the scientific information. She specifically noted uncertainties related to understanding the relative toxicity of the different components in the fine particle mixture, the role of $PM_{2.5}$ in the complex ambient mixture, exposure measurement errors in epidemiologic studies, and the nature and magnitude of estimated risks related to relatively low ambient $PM_{2.5}$ concentrations. Furthermore, the Administrator noted that epidemiologic studies had reported heterogeneity in responses both within and between cities and in geographic regions across the U.S. She recognized that this heterogeneity may be attributed, in part, to differences in fine particle composition in different regions and cities. With regard to evidence for reproductive and developmental effects, the Administrator recognized that there were a number of limitations associated with this body of

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[47] With respect to cancer, mutagenic, and genotoxic effects, the Administrator observed that the $PM_{2.5}$ concentrations reported in studies evaluating these effects generally included ambient concentrations that are equal to or greater than ambient concentrations observed in studies that reported mortality and cardiovascular and respiratory effects (U.S. EPA, 2009, section 7.5). Therefore, the Administrator concluded that, in selecting a standard level that provides protection from mortality and cardiovascular and respiratory effects, it is reasonable to anticipate that protection will also be provided for carcinogenic effects (78 FR 3161-3162, January 15, 2013).

[48] This judgment is supported by risk results presented in the 2010 HREA. For example, see section 4.2.2, and Figures 4-4 and 4-6 (U.S. EPA, 2010a).

evidence, including the following: the limited number of studies evaluating such effects; uncertainties related to identifying the relevant exposure time periods of concern; and limited toxicological evidence providing little information on the mode of action(s) or biological plausibility for an association between long-term $PM_{2.5}$ exposures and adverse birth outcomes.

On balance, the Administrator found that the available evidence, interpreted in light of the remaining uncertainties (noted above), did not justify an annual standard level set below 12.0 $\mu g/m^3$ as being "requisite" (i.e., neither more nor less stringent than necessary) to protect public health with an adequate margin of safety. Thus, the Administrator concluded that the available evidence and information supported an annual standard with a level of 12.0 $\mu g/m^3$, combined with a 24-hour standard with a level of 35 $\mu g/m^3$. She noted that this combination of standard levels was consistent with CASAC's advice to consider an annual standard level within the range of 13 to 11 $\mu g/m^3$ and a 24-hour standard level from 35 to 30 $\mu g/m^3$ (Samet, 2010b). Taken together, the Administrator concluded that the revised annual $PM_{2.5}$ standard, with its level of 12.0 $\mu g/m^3$ and a form that does not allow for spatial averaging, combined with the existing 24-hour standard, would be requisite to protect the public health with an adequate margin of safety from effects associated with long- and short-term $PM_{2.5}$ exposures.

2.1.2 PM_{10} Standard

In the last review the EPA retained the existing 24-hour primary PM_{10} standard, with its level of 150 $\mu g/m^3$ and its one-expected-exceedance form, in order to continue to provide public health protection against exposures to $PM_{10-2.5}$. In support of this decision, the Administrator considered the extent to which a standard with a PM_{10} indicator can provide protection against exposures to $PM_{10-2.5}$ and the degree of public health protection provided by the existing PM_{10} standard. Her consideration of each of these issues is summarized below.

In reaching the conclusion that a standard with a PM_{10} indicator can provide appropriate protection against exposures to $PM_{10-2.5}$, the Administrator noted that PM_{10} mass includes both coarse PM ($PM_{10-2.5}$) and fine PM ($PM_{2.5}$). As a result, the concentration of $PM_{10-2.5}$ allowed by a PM_{10} standard set at a single level declines as the concentration of $PM_{2.5}$ increases. Because $PM_{2.5}$ concentrations tend to be higher in urban areas than rural areas (U.S. EPA, 2005, p. 2–54, and Figures 2–23 and 2–24), the Administrator observed that a PM_{10} standard will generally allow lower $PM_{10-2.5}$ concentrations in urban areas than in rural areas. She judged it appropriate to maintain such a standard given that the large majority of the evidence for $PM_{10-2.5}$ toxicity, particularly at relatively low particle concentrations, came from study locations where thoracic coarse particles were of urban origin, and given the possibility that $PM_{10-2.5}$ contaminants in urban areas could increase particle toxicity. Thus, in the last review the Administrator concluded

that it remained appropriate to maintain a standard that allows lower ambient concentrations of $PM_{10-2.5}$ in urban areas, where the evidence was strongest that thoracic coarse particles are linked to mortality and morbidity, and higher concentrations in non-urban areas, where the public health concerns were less certain.

In specifically evaluating the degree of public health protection provided by the primary PM_{10} standard, with its level of 150 $\mu g/m^3$ and its one-expected-exceedance form, the Administrator recognized that the available health evidence and air quality information was much more limited for $PM_{10-2.5}$ than for $PM_{2.5}$. In particular, the strongest evidence for health effects attributable to $PM_{10-2.5}$ exposures was for cardiovascular effects, respiratory effects, and/or premature mortality following short-term exposures. For each of these categories of effects, the ISA determined that the evidence was "suggestive of a causal relationship" (U.S. EPA, 2009, section 2.3.3). These determinations contrast with those for $PM_{2.5}$, as described in section 2.1.1 above, which were judged in the ISA to be either "causal" or "likely to be causal" for mortality, cardiovascular effects, and respiratory effects (U.S. EPA, 2009, Tables 2-1 and 2-2).

The Administrator judged that the important uncertainties and limitations associated with the $PM_{10-2.5}$ evidence and information raised questions as to whether additional public health improvements would be achieved by revising the existing PM_{10} standard. She specifically noted the following:

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

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

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

(4) Limitations in $PM_{10-2.5}$ monitoring data and the different approaches used to estimate $PM_{10-2.5}$ concentrations across epidemiologic studies resulted in uncertainty in the ambient $PM_{10-2.5}$ concentrations at which the reported effects occur, increasing

uncertainty in estimates of the extent to which changes in ambient $PM_{10-2.5}$ concentrations would likely impact public health.[49]

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

With regard to these uncertainties and limitations, the Administrator noted in particular the considerable degree of uncertainty in the extent to which health effects reported in epidemiologic studies are due to $PM_{10-2.5}$ itself, as opposed to one or more co-occurring pollutants. This uncertainty reflected the relatively small number of $PM_{10-2.5}$ studies that had evaluated co-pollutant models, particularly co-pollutant models that included $PM_{2.5}$, and the very limited body of controlled human exposure evidence supporting the plausibility of $PM_{10-2.5}$-attributable adverse effects at ambient concentrations. The Administrator noted that these important limitations in the overall body of health evidence introduce uncertainty into the interpretation of individual epidemiologic studies, particularly those studies reporting associations with $PM_{10-2.5}$ that are not statistically significant.

When she viewed the evidence as a whole, the Administrator concluded that the degree of public health protection provided against short-term exposures to $PM_{10-2.5}$ should be maintained but did not need to be increased beyond that provided by the current PM_{10} standard. This conclusion emphasized (1) the important uncertainties and limitations associated with the overall body of health evidence and air quality information for $PM_{10-2.5}$, as reflected in the ISA causal determinations; (2) information indicating that $PM_{10-2.5}$ effect estimates for the most serious health effect, mortality, were not statistically significant in U.S. locations that met the current PM_{10} standard and where coarse particle concentrations were either directly measured or estimated based on co-located samplers;[50] and (3) that $PM_{10-2.5}$ effect estimates for morbidity endpoints were both positive and negative in locations that met the current standard, with most not statistically significant. Thus, the Administrator concluded that the existing 24-hour PM_{10}

[49] Such limitations also contributed to the decision not to conduct a quantitative risk assessment for $PM_{10-2.5}$. The lack of a quantitative $PM_{10-2.5}$ risk assessment further contributed to uncertainty regarding the extent to which any revisions to the current PM_{10} standard would be expected to improve the protection of public health, beyond the protection provided by the current standard.

[50] The Administrator noted that the study by Zanobetti and Schwartz (2009) was the only study to estimate ambient $PM_{10-2.5}$ concentrations as the difference between county-wide PM_{10} mass and county-wide $PM_{2.5}$ mass (78 FR 3178, January 15, 2013). As discussed in the PA, it is not clear how such computed $PM_{10-2.5}$ measurements compare with the $PM_{10-2.5}$ concentrations obtained in other studies either by direct measurement or by calculating the difference using co-located samplers (U.S. EPA, 2009, section 6.5.2.3).

standard, with its one-expected exceedance form and a level of 150 $\mu g/m^3$, is requisite to protect public health with an adequate margin of safety against effects that have been associated with $PM_{10-2.5}$. In light of this conclusion, the EPA retained the existing PM_{10} standard.

2.1.3 General Approach in the Current Review of the Primary Standards

The approach for this review will build on the substantial body of work done during the course of the last review, taking into account the more recent scientific information and air quality data now available to inform our understanding of the key policy-relevant issues. The approach summarized below is most fundamentally based on using the EPA's assessment of the current scientific evidence, quantitative assessments of exposures and/or risks, and other associated analyses (e.g., air quality analyses) to inform the Administrator's judgments regarding primary standards for PM that are requisite to protect public health with an adequate margin of safety. This approach will involve translating scientific and technical information into the basis for addressing a series of key policy-relevant questions using both evidence- and exposure-/risk-based considerations.[51]

Figure 2-1 summarizes the general approach in the current review to reaching conclusions on the current primary standards and on potential alternative standards, if appropriate. The ISA, HREA (if developed), and PA developed in this review will provide the basis for addressing the key policy-relevant questions and will inform the Administrator's decisions as to whether to retain or revise the primary PM NAAQS. The four basic elements of the NAAQS (i.e., indicator, averaging time, form, and level) will be considered collectively in evaluating the health protection afforded by the current standards, and by any alternatives considered.

[51] Evidence-based considerations include those related to the health effects evidence assessed and characterized in the ISA. Exposure-/risk-based considerations draw from the results of the quantitative assessments.

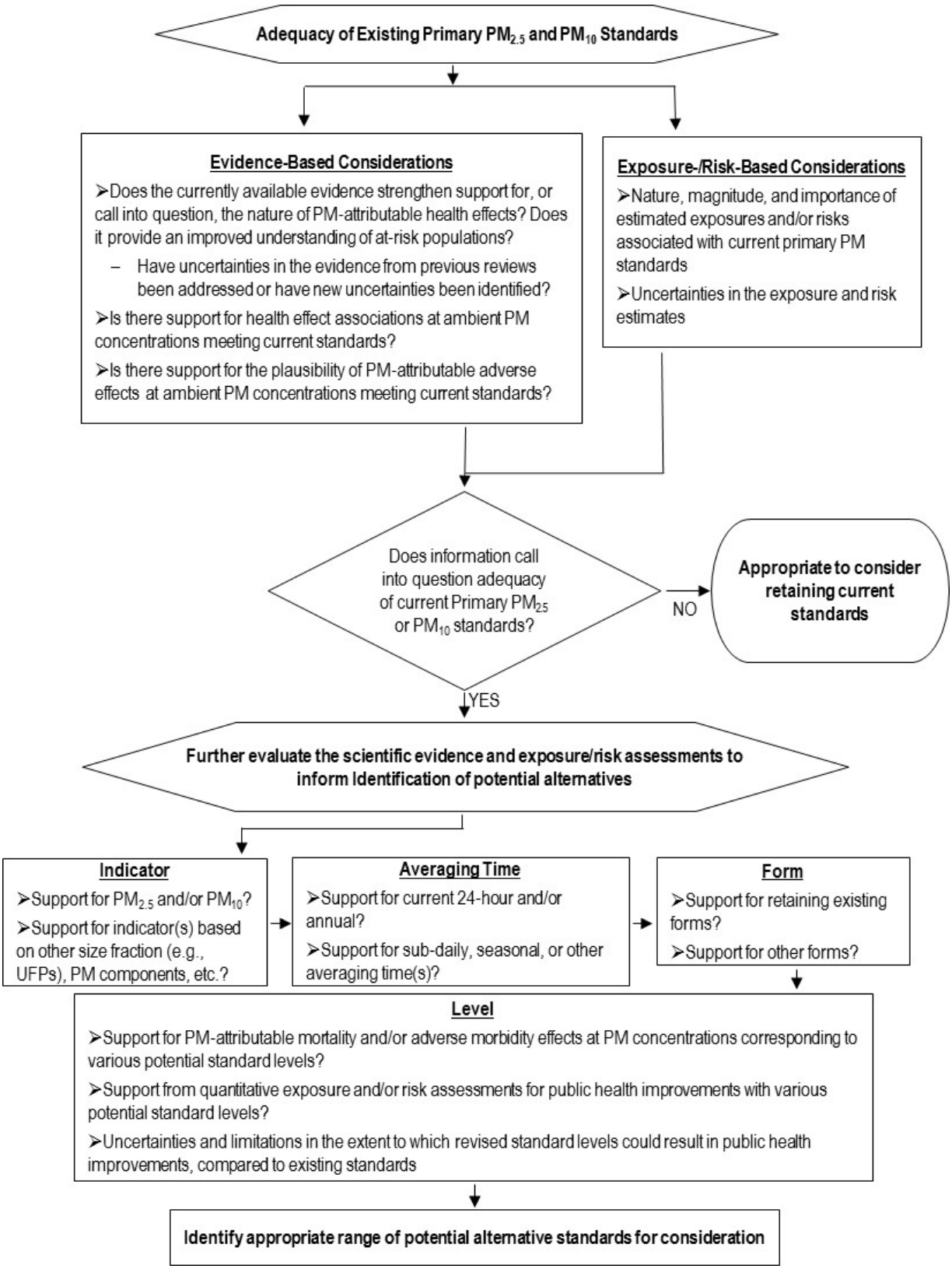

Figure 2-1. Overview of General Approach for Review of Primary PM Standards

The final decisions on the adequacy of the current standards and, if appropriate, potential alternative standards, are largely public health policy judgments to be made by the Administrator. The Administrator's final decisions will draw upon the scientific evidence for PM-related health effects, quantitative analyses of population exposures and/or health risks, and judgments about how to consider the uncertainties and limitations that are inherent in the scientific evidence and quantitative analyses. To inform the Administrator's public health policy judgments and decisions, we will consider the support for, and the potential implications of, placing more or less emphasis on various aspects of the scientific evidence, the exposure-/risk-based information, and the associated uncertainties and limitations.

The current review of the primary $PM_{2.5}$ and PM_{10} standards will build upon the conclusions from the last review, taking into account the updated evidence and information that has become available since that review. Our consideration of the evidence and information will inform the answer to the following overarching question:

- **Does the currently available scientific evidence and exposure-/risk-based information support or call into question the adequacy of the public health protection afforded by the current primary $PM_{2.5}$ or PM_{10} standards?**

In order to answer this overarching question, we will consider a series of more specific policy-relevant questions related to the health effects and health risks of short- and long-term PM exposures. These questions will focus on PM exposures indexed by $PM_{2.5}$ and $PM_{10-2.5}$ mass, as well as PM exposures indexed by other metrics such as other size fractions (e.g., ultrafine fraction), PM characteristics other than size (e.g., chemical composition), PM from particular sources, or PM present in particular types of environments (e.g., urban versus non-urban, various geographic areas). Potential policy-relevant questions[52] include the following:

- To what extent has new evidence strengthened or otherwise altered the scientific support for the occurrence of adverse health effects or premature mortality as a result of exposures to particles in the ambient air? To what extent have important uncertainties in the evidence from the last review been addressed, and have new uncertainties emerged?
- To what extent has new evidence improved our understanding of human lifestages and populations that are at increased risk of experiencing health effects associated with exposures to ambient PM?

[52] As noted above, based on CASAC advice and public input on this draft IRP, we will modify these potential questions as appropriate for the final IRP. The key policy-relevant questions identified in the final PM IRP will provide an overall framework for the development of the PM ISA, REAs (if warranted), and the PA.

- What does the evidence indicate with regard to confidence in the occurrence of adverse health effects attributable to exposures to ambient PM concentrations that would likely have met the current primary standards?
    - What do available epidemiologic studies indicate with regard to the shapes of PM concentration-response functions and confidence in PM health effect associations at ambient particle concentrations that would meet the existing standards? Do studies indicate departures from linearity at such low concentrations?
    - When taken together, what do available epidemiologic and experimental studies indicate with regard to confidence in PM-attributable adverse effects at ambient PM concentrations that would meet existing standards?
- To what extent does the evidence indicate that health effects are associated with exposures to $PM_{2.5}$ or $PM_{10-2.5}$ themselves (or other indicator of PM), as opposed to one or more co-occurring pollutants, particularly at relatively low ambient PM concentrations that would meet the existing standards?
- To what extent are PM-attributable health effects larger and/or more serious with co-exposures to other pollutants or other stressors?
- Is new information available to better inform our understanding of factors other than pollutant exposures that might influence the associations between ambient PM concentrations and health effects (e.g., weather-related factors, behavioral factors, heating/air conditioning use, driving patterns, time-activity patterns)?
- Do studies examining the potential for effect modification, either by co-occurring pollutants or by factors other than pollutant exposures, improve our understanding of the geographic heterogeneity in epidemiologic associations with PM?
- Is new information available to improve our understanding of PM exposures, and how those exposures relate to the ambient concentrations often used as exposure surrogates in epidemiologic studies? Does our understanding of geographic variability in exposure measurement error inform our understanding of geographic heterogeneity in epidemiologic associations?
- Is new information available to improve our understanding of the PM exposure periods (e.g., exposure durations and/or windows of exposure) that are most relevant for PM-associated mortality and/or morbidity?
- To what extent do quantitative estimates indicate that PM-attributable health risks of public health importance could occur at ambient PM concentrations meeting the current primary standards? To what extent do uncertainties and limitations in the underlying health evidence or in the assessment approaches affect our interpretation of these quantitative estimates?

If the available evidence and exposure/risk information call into question the adequacy of the public health protection afforded by the current primary $PM_{2.5}$ or PM_{10} standards, we will also consider the following overarching question:

- **What alternative standards are supported by the currently available scientific evidence and exposure-/risk-based information, and are appropriate for consideration?**

The answer to this second overarching question will also be informed by our consideration of a series of more specific questions focused on the basic elements of the NAAQS (indicator, averaging time, form, level). In addressing these more specific questions, we will draw from our consideration of the scientific evidence and from the results of any additional air quality, exposure, and/or risk analyses that focus on potential alternative standards.[53] We will consider the elements of the NAAQS collectively in evaluating the health protection afforded by potential alternative standards. Specific policy-relevant questions on potential alternative standards will include the following:

- Do the available health effects evidence and air quality information provide support for consideration of *indicators* for fine and thoracic coarse particles in addition to, or in place of, $PM_{2.5}$ and PM_{10}, respectively? Does the evidence support an alternative approach for defining particle pollution, including in terms of other size fractions, specific components, source-related mixtures, or specific environments?
- Do the available health effects evidence, air quality information, and exposure/risk information provide support for considering *averaging times* in addition to, or in place of, the current 24-hour and annual averaging times?
- To what extent do the available health effects evidence, air quality information, and exposure/risk information provide support for consideration of alternative standard *forms*?
- What range of alternative standard *levels* could be supported based on the scientific evidence, air quality analyses, and exposure/risk assessments?
- What are the important uncertainties and limitations in the available evidence and in the available quantitative analyses, and how might these uncertainties and limitations be taken into consideration in identifying alternative standard *indicators, averaging times, forms and/or levels*?

2.2 SECONDARY STANDARDS

In the last review, the EPA generally retained the existing suite of secondary PM standards (78 FR 3228, January 15, 2013).[54] As described below, the EPA retained the

[53] Such additional quantitative analyses can inform conclusions on the magnitude of the public health improvement that would be expected upon just meeting various potential alternative standards, and on the exposures and/or risks expected to remain.

[54] The previous review of the secondary PM NAAQS focused on the welfare effects associated with particles present in the ambient air, including the effects of ambient particulate species of NO_X and SO_X. The review did not focus on the deposition related effects of particulate species of NO_X and SO_X. The EPA reviewed the secondary NO_2 and SO_2

secondary 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$, and the 24-hour PM_{10} standard, with its level of 150 $\mu g/m^3$. The EPA also retained the secondary annual $PM_{2.5}$ standard, with its level of 15.0 $\mu g/m^3$, except for a change to the form of the annual standard. Consistent with the change to the form of the primary annual $PM_{2.5}$ standard (section 2.1.1 above), the EPA removed the option for spatial averaging from the form of the secondary annual $PM_{2.5}$ standard (78 FR 3228, January 15, 2013). Key aspects of the Administrator's decisions on the secondary PM standards for non-visibility welfare effects and visibility effects are described below in sections 2.2.1 and 2.2.2, respectively. Key policy-relevant issues for the current review are discussed in section 2.2.3.

2.2.1 Non-Visibility Welfare Effects

In the last review of the PM NAAQS, the Administrator concluded that it was important to maintain an appropriate degree of control of both fine and coarse particles to address non-visibility welfare effects. Lacking information that would support revised standards, she further concluded that it was appropriate to retain the existing suite of secondary standards to protect against such effects. Non-visibility welfare effects considered include climate effects, ecological effects (e.g., effects on plants, soil and nutrient cycling, wildlife and water),[55] and materials effects. The Administrator's consideration of each of these types of effects is discussed below.

With regard to the role of PM in climate, the Administrator considered whether it was appropriate to establish any distinct secondary PM standards to address welfare effects associated with climate impacts. In considering the scientific evidence, she noted the ISA conclusion "that a causal relationship exists between PM and effects on climate" and that aerosols[56] alter climate processes directly through radiative forcing and by indirect effects on cloud brightness, changes in precipitation, and possible changes in cloud lifetimes (U.S. EPA, 2009, section 9.3.10). Additionally, the ISA noted that the major aerosol components contributing to climate processes (i.e., black carbon (BC), organic carbon (OC), sulfates, nitrates and mineral dusts) vary in their reflectivity, forcing efficiencies, and direction of climate forcing,

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NAAQS separately and evaluated the ecosystem-related welfare effects that result from the deposition of particulate species of NO_X, SO_X, and their transformation products.

[55] As described above, the on-going NO_X/SO_X review includes consideration of the ecological effects of ecosystem loading of particulate nitrogen and sulfur compounds. Thus, these endpoints are not discussed in this review.

[56] The term *aerosol* is used in this document when discussing suspended ambient particles in the context of climate impacts.

though there is an overall net climate cooling associated with aerosols in the global atmosphere (U.S. EPA, 2009, section 9.3.10).

Noting the strong evidence indicating that aerosols affect climate, the Administrator further considered whether there was sufficient information to revise the secondary PM standards. She noted that a number of uncertainties in the scientific information were identified in the ISA and PA. For example, the ISA and PA noted the spatial and temporal heterogeneity of PM components that contribute to climate forcing, uncertainties in the measurement of aerosol components, inadequate consideration of aerosol impacts in climate modeling, insufficient data on local and regional microclimate variations and heterogeneity of cloud formations. In light of these uncertainties and the lack of sufficient data, the PA concluded that it was not feasible in the last review "to conduct a quantitative analysis for the purpose of informing revisions [to the secondary PM NAAQS] based on climate" (U.S. EPA, 2011, pp. 5-11 to 5-12) and that there was insufficient information available to base a national ambient standard on climate impacts associated with ambient concentrations of PM or its constituents (U.S. EPA, 2011, section 5.2.3). The Administrator agreed with this conclusion (78 FR 3225-3226, January 15, 2013).

The Administrator also considered ecological effects in the last review, including direct effects on metabolic processes of plants; contribution to total metal loading resulting in alteration of soil biogeochemistry and microbiology, plant and animal growth and reproduction; and contribution to total organics loading resulting in bioaccumulation and biomagnification across trophic levels. The ISA determined that the evidence was sufficient to conclude that "a causal relationship is likely to exist between deposition of PM and a variety of effects on individual organisms and ecosystems" (U.S. EPA, 2009, p. 2-30; sections 2.5.3 and 9.4.7). However, the ISA also noted that it is generally difficult to characterize the nature and magnitude of effects and to quantify relationships between ambient concentrations of PM and ecosystem responses. Such difficulty is due to significant data gaps and uncertainties, as well as to the considerable variability that exists in the components of PM and their various ecological effects (U.S. EPA, 2009, p. 9-193). Given uncertainties and limitations in the available evidence, the PA concluded that the information available at the time of the last review was insufficient for the purposes of assessing the adequacy of the protection for ecosystems afforded by the existing suite of secondary PM standards or for establishing a distinct national PM standard based on ecosystem effects of particulates (U.S. EPA, 2011, p. 5-24). The Administrator agreed with this conclusion (78 FR 3225-3226, January 15, 2013).

With regard to materials effects, the Administrator also considered effects associated with the deposition of PM (i.e., dry and wet deposition), including both physical damage (materials effects) and impaired aesthetic qualities (soiling effects). The deposition of PM can physically

affect materials, adding to the effects of natural weathering processes, by promoting or accelerating the corrosion of metals; by degrading paints; and by deteriorating building materials such as stone, concrete, and marble (U.S. EPA, 2009, section 9.5). Additionally, the deposition of ambient PM can reduce the aesthetic appeal of buildings and objects through soiling. The ISA concluded that evidence was sufficient to support a causal relationship between PM and effects on materials (U.S. EPA, 2009, sections 2.5.4 and 9.5.4). However, the PA noted that quantitative relationships are lacking between particle size, concentrations, and frequency of repainting and repair of surfaces and that considerable uncertainty exists in the contributions of co-occurring pollutants to materials damage and soiling processes (U.S. EPA, 2011, p. 5-29). The PA concluded that none of the evidence available in the last review called into question the adequacy of the existing secondary PM standards to protect against material effects and that such effects could play no quantitative role in determining whether revisions to the secondary PM NAAQS were appropriate (U.S. EPA, 2011, p. 5-29). The Administrator agreed with this conclusion (78 FR 3225-3226, January 15, 2013).

In considering non-visibility welfare effects in the last review, as discussed above, the Administrator concluded that, while it is important to maintain an appropriate degree of control of fine and coarse particles to address non-visibility welfare effects, "[i]n the absence of information that would support any different standards…it is appropriate to retain the existing suite of secondary standards" (FR 78 3225 to 3226, January 15, 2013). Her decision was consistent with CASAC advice related to non-visibility effects. Specifically, CASAC agreed with the PA conclusions that, while these effects are important, "there is not currently a strong technical basis to support revisions of the current standards to protect against these other welfare effects" (Samet, 2010a, p. 5). Thus, the Administrator concluded that it was appropriate to retain all aspects of the existing 24-hour $PM_{2.5}$ and PM_{10} secondary standards. With regard to the secondary annual $PM_{2.5}$ standard, the Administrator concluded that it was appropriate to retain a level of 15.0 $\mu g/m^3$ while revising only the form of the standard to remove the option for spatial averaging, consistent with this change to the primary annual $PM_{2.5}$ standard (78 FR 3225-3226, January 15, 2013).

2.2.2 Visibility Effects

The Administrator also considered the level of protection that would be requisite to protect public welfare with regard to visual air quality and whether to adopt a distinct secondary standard to achieve this level of protection. In reaching her final decision that the existing 24-hour $PM_{2.5}$ standard provides sufficient protection against PM-related visibility impairment (78 FR 3228, January 15, 2013), the Administrator considered the evidence assessed in the ISA (U.S.

EPA, 2009) and the analyses included in the Urban Focused Visibility Assessment (UFVA) (U.S. EPA, 2010b) and the PA (U.S. EPA, 2011). She also considered the degree of protection for visibility that would be provided by the existing secondary standard, focusing specifically on the secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$. These considerations, and the Administrator's conclusions regarding visibility, are discussed in more detail below.

In the last review, the ISA concluded that, "collectively, the evidence is sufficient to conclude that a causal relationship exists between PM and visibility impairment" (U.S. EPA, 2009, p. 2-28). Visibility impairment is caused by light scattering and absorption by suspended particles and gases, including water content of aerosols.[57] The available evidence in the last review indicated that various components of PM have been shown to contribute to visibility impairment. For example, at sufficiently high relative humidity values, sulfate and nitrate are the particulate species that contribute most efficiently to visibility impairment. Elemental carbon (EC) and organic carbon (OC) also are important contributors, especially in the northwestern U.S. Crustal material can be significant contributors to visibility impairment, particularly for remote areas in the arid southwestern U.S. (U.S. EPA, 2009, section 2.5.1).

Visibility impairment can have implications for people's enjoyment of daily activities and for their overall sense of well-being (U.S. EPA, 2009, section 9.2). In consideration of the potential public welfare implications of various degrees of visibility impairment, the Administrator considered the available visibility preference studies which were reviewed by EPA in the 2010 UFVA (U.S. EPA, 2010b, chapter 2).[58] These preference studies provided information about the potential public welfare implications of visibility impairment from survey studies in which participants were asked questions about their preferences or the values they placed on various visibility conditions, as displayed to them in scenic photographs or in images with a range of known light extinction levels.

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[57] All particles scatter light and, although a larger particle scatters more light than a similarly shaped smaller particle of the same composition, the light scattered per unit of mass is greatest for particles with diameters from ~0.3-1.0 μm (U.S. EPA, 2009, section 2.5.1). Particles with hygroscopic components (e.g., particulate sulfate and nitrate) contribute more light extinction at higher relative humidity than at lower relative humidity because they change size in the atmosphere in response to ambient relative humidity conditions.

[58] Preference studies were available in four urban areas in the last review. Three western preference studies were available, including one in Denver, Colorado (Ely et al., 1991), one in the lower Fraser River valley near Vancouver, British Columbia, Canada (Pryor, 1996), and one in Phoenix, Arizona (BBC Research & Consulting, 2003). A pilot focus group study was also conducted for Washington, DC (Abt Associates Inc., 2001), and a replicate study with 26 participants was also conducted for Washington, DC (Smith and Howell, 2009).

In noting the relationship between ambient PM and PM-related light extinction, the Administrator focused on identifying an adequate level of protection against visibility-related welfare effects. She first concluded that a standard based on a $PM_{2.5}$ visibility index would provide a measure of protection against PM-related light extinction that directly takes into account the factors (i.e., species composition and relative humidity) that influence the relationship between $PM_{2.5}$ in ambient air and PM-related visibility impairment. A $PM_{2.5}$ visibility index standard would afford a relatively high degree of uniformity of visual air quality protection in areas across the country by directly incorporating the effects of differences of $PM_{2.5}$ composition and relative humidity. In defining a target level of protection based on a $PM_{2.5}$ visibility index, as discussed below, the Administrator considered specific elements of the index, including the appropriate indicator, averaging time, level, and form.

With regard to the indicator of a visibility index, the Administrator concluded that a calculated $PM_{2.5}$ light extinction indicator that utilized an adjusted version of the original IMPROVE algorithm,[59] in conjunction with monthly average relative humidity data based on long-term climatological means, would be the most appropriate indicator for a $PM_{2.5}$ visibility index standard (78 FR 3226, January 15, 2013). In reaching her final decision, the Administrator further noted the CASAC conclusion that it was reasonable to rely on a calculated $PM_{2.5}$ light extinction indicator based on $PM_{2.5}$ chemical composition and relative humidity. The Administrator also considered the $PM_{2.5}$ mass indicator and directly measured $PM_{2.5}$ light extinction. She concluded that a $PM_{2.5}$ mass-based indicator would not be appropriate because the available mass monitoring methods did not include measurement of the full water content of ambient $PM_{2.5}$, nor did they provide information on the composition of $PM_{2.5}$, both of which contribute to visibility impacts (77 FR 38980, June 29, 2012). In addition, at the time of the proposal, the Administrator provisionally concluded that directly measured $PM_{2.5}$ light extinction was not an appropriate option because a suitable specification of available equipment or performance-based verification procedures for direct measurement of light extinction could not be developed in the time frame of the review (77 FR 38980-38981, June 29, 2012).

With regard to averaging time of the index, the Administrator concluded that a 24-hour averaging time would be appropriate for a visibility index (78 FR 3226, January 15, 2013). She concluded that hourly or sub-daily (4- to 6-hour) averaging times, within daylight hours and

[59] The IMPROVE algorithm uses PM mass concentration measurements and relative humidity estimates to calculate light extinction. For more information about the derivation of and input data required for the original and revised IMPROVE algorithms, see 78 FR 3186-3177, January 15, 2013.

excluding hours with high relative humidity, are more directly related to the short-term nature of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public than a 24-hour averaging time. However, she also noted the data quality uncertainties associated with the instruments used to provide the hourly $PM_{2.5}$ mass measurements required for an averaging time shorter than 24 hours. The Administrator also considered comparative analyses of 24-hour and 4-hour averaging times in conjunction with a calculated $PM_{2.5}$ indicator in the PA (U.S. EPA, 2011, pp. 4-55 - 4-56, Appendix G, section G.4). These analyses showed good correlation between 24-hour and 4-hour average $PM_{2.5}$ light extinction, as evidenced by reasonably high city-specific and pooled R-squared values, generally in the range of over 0.6 to over 0.8. The Administrator considered and agreed with the PA conclusion that at a 24-hour averaging time would be a reasonable and appropriate surrogate for a sub-daily averaging time.

With regard to form of the index, the Administrator concluded that a multi-year percentile-based form offered greater stability to the air quality management process by reducing the possibility that statistically unusual indicator values would lead to transient violations in the standard. She noted that a three-year average form provided stability from the occasional effects of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year (U.S. EPA, 2011, p. 4-58). In the UFVA, 90^{th}, 95^{th}, and 98^{th} percentile forms were assessed for alternative PM light extinction standards (U.S. EPA, 2010b, chapter 4). In considering these alternative percentiles, the PA noted that the Regional Haze Program targets the 20 percent most impaired days for improvements in visual air quality in Federal Class I areas. A focus on improving the 20 percent most impaired days suggests that the 90^{th} percentile, which represents the median of the distribution of the 20 percent worst days, would be an appropriate form to consider. Strategies that are implemented so that 90 percent of days would have visual air quality that is at or below the level of the standard would reasonably be expected to lead to improvements in visual air quality for the 20 percent most impaired days. Given that the preference studies did not provide information with regard to the frequency of time that visibility levels should be below these values, the PA found no basis to conclude that it would be appropriate to consider limiting the occurrence of days with peak PM-related light extinction in urban areas to a greater degree (U.S. EPA, 2011, p. 4-59). Based on the above considerations, the Administrator concluded that a 90^{th} percentile form was the most appropriate form (78 FR 3226, January 15, 2013).

With regard to level of the index, the Administrator considered the visibility preference studies conducted in four urban areas (U.S. EPA, 2011, p. 4-61) and further quantitative analyses of visibility conditions for 15 urban study areas (U.S. EPA, 2011, Appendix G, Tables G-7 and

G-8). Based on these studies the PA identified a range of levels from 20 to 30 deciviews (dv)[60] as being a reasonable range of "candidate protection levels" (CPLs). In considering this range of CPLs, the Administrator noted the uncertainties and limitations in public preference studies, including the small number of stated preference studies available; the relatively small number of study participants and the extent to which the study participants may not be representative of the broader study area population in some of the studies; and the variations in the specific materials and methods used in each study. She concluded that the substantial degrees of variability and uncertainty in the public preference studies should be reflected in a target protection level at the upper end of the range of CPLs than if the information were more consistent and certain. Therefore, the Administrator concluded that it was appropriate to set a target level of protection in terms of a 24-hour $PM_{2.5}$ visibility index at 30 dv (78 FR 3226-3227, January 15, 2013).

Based on her considerations and conclusions summarized above, the Administrator concluded that the protection provided by a secondary standard defined in terms of a $PM_{2.5}$ visibility index with a 24-hour averaging time, a 90^{th} percentile form averaged over 3 years, and a level of 30 dv, would be requisite to protect public welfare with regard to visual air quality (78 FR 3227, January 15, 2013). Having reached this conclusion, she next determined whether to adopt such a visibility index as a distinct secondary standard, particularly in the context of the full suite of existing secondary standards.

In determining whether a distinct secondary standard was needed, the Administrator considered the degree of protection from visibility impairment afforded by the existing secondary standards. She considered both whether the existing 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ is sufficient (i.e., not under-protective) and whether it is not more stringent than necessary (i.e., not over-protective). In doing so, she noted that the air quality analyses showed that all areas meeting the existing 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$, had visual air quality at least as good as 30 dv (based on the visibility index defined above) (Kelly et al., 2012a, 2012b). Thus, the secondary 24-hour $PM_{2.5}$ standard would likely be controlling relative to a 24-hour visibility index set at a level of 30 dv. Additionally, areas would be unlikely to exceed the target level of protection for visibility of 30 dv without also exceeding the existing secondary 24-hour standard.[61] Thus, the Administrator judged that the 24-hour $PM_{2.5}$ standard

[60] Deciview refers to a scale for characterizing visibility that is defined directly in terms of light extinction. The deciview scale is frequently used in the scientific and regulatory literature on visibility.

[61] The Administrator also recognized that air quality analyses indicated that "the 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ also would likely achieve *more than* the target level of protection of visual air quality (30 dv) in some areas" (78 FR 3227, January 15, 2013).

"provides sufficient protection in all areas against the effects of visibility impairment—i.e., that the existing 24-hour $PM_{2.5}$ standard would provide *at least* the target level of protection for visual air quality of 30 dv which the Administrator judges appropriate" (78 FR 3227, January 15, 2013). She further judged that "[s]ince sufficient protection from visibility impairment would be provided for all areas of the country without adoption of a distinct secondary standard, and adoption of a distinct secondary standard will not change the degree of over-protection provided for some areas of the country…adoption of such a distinct secondary standard is not needed to provide requisite protection for both visibility and nonvisibility related welfare effects" (78 FR 3228, January 15, 2013).

2.2.3 General Approach in the Current Review of the Secondary Standards

The approach for this review builds on the substantial body of work completed during the course of the last review, taking into account the more recent scientific information and air quality data now available to inform our understanding of the key-policy relevant issues. The approach described below is most fundamentally based on using the EPA's assessment of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgments regarding secondary standards for PM that are requisite to protect the public welfare from any known or anticipated adverse effects.

Figure 2-2 summarizes the general approach, including consideration of the policy-relevant questions which will frame the current review. The ISA, WREA (if warranted), and PA developed in this review will provide the basis for addressing the key policy-relevant questions and will inform the Administrator's judgments as to the adequacy of the current secondary $PM_{2.5}$ and PM_{10} standards, as well as his/her decisions as to whether to retain or revise these standards.

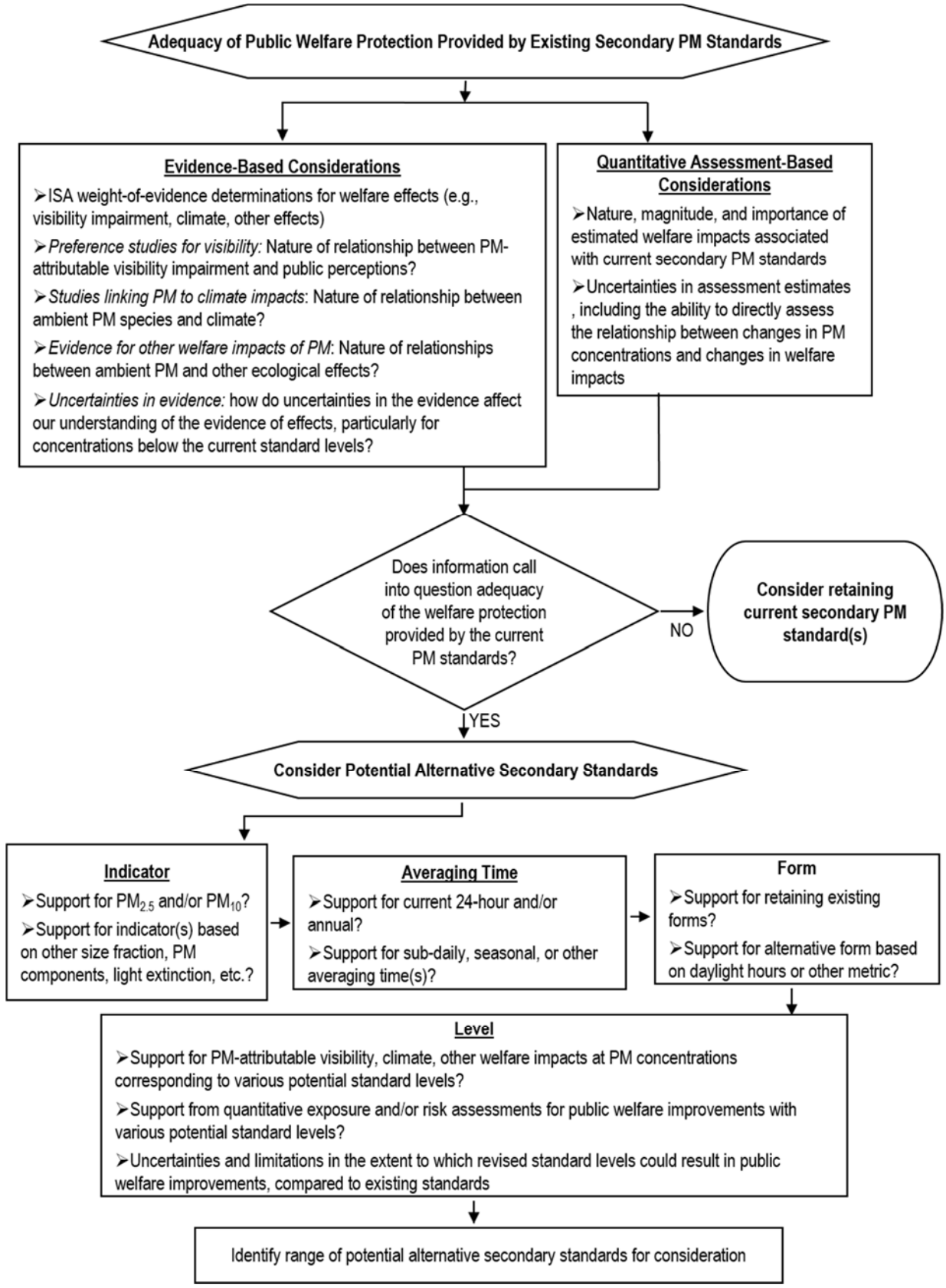
Adequacy of Public Welfare Protection Provided by Existing Secondary PM Standards
Evidence-Based Considerations
➢ISA weight-of-evidence determinations for welfare effects (e.g., visibility impairment, climate, other effects)
➢Preference studies for visibility: Nature of relationship between PM-attributable visibility impairment and public perceptions?
➢Studies linking PM to climate impacts: Nature of relationship between ambient PM species and climate?
➢Evidence for other welfare impacts of PM: Nature of relationships between ambient PM and other ecological effects?
➢Uncertainties in evidence: how do uncertainties in the evidence affect our understanding of the evidence of effects, particularly for concentrations below the current standard levels?
Quantitative Assessment-Based Considerations
➢Nature, magnitude, and importance of estimated welfare impacts associated with current secondary PM standards
➢Uncertainties in assessment estimates , including the ability to directly assess the relationship between changes in PM concentrations and changes in welfare impacts
Does information call into question adequacy of the welfare protection provided by the current PM standards?
NO
Consider retaining current secondary PM standard(s)
YES
Consider Potential Alternative Secondary Standards
Indicator
➢Support for PM2.5 and/or PM10?
➢Support for indicator(s) based on other size fraction, PM components, light extinction, etc.?
Averaging Time
➢Support for current 24-hour and/or annual?
➢Support for sub-daily, seasonal, or other averaging time(s)?
Form
➢Support for retaining existing forms?
➢Support for alternative form based on daylight hours or other metric?
Level
➢Support for PM-attributable visibility, climate, other welfare impacts at PM concentrations corresponding to various potential standard levels?
➢Support from quantitative exposure and/or risk assessments for public welfare improvements with various potential standard levels?
➢Uncertainties and limitations in the extent to which revised standard levels could result in public welfare improvements, compared to existing standards
Identify range of potential alternative secondary standards for consideration

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Figure 2-2. Overview of General Approach for Review of Secondary PM Standards

The current review of the secondary $PM_{2.5}$ and PM_{10} standards will build upon the conclusions from the last review, taking into account the updated evidence and information that has become available since that review. Our consideration of the evidence and information will inform the answer to the following overarching question:

- **Does the currently available scientific evidence and quantitative information support or call into question the adequacy of the welfare protection afford by the current secondary $PM_{2.5}$ or PM_{10} standards?**

In order to answer this overarching question, we will consider a series of more specific policy-relevant questions related to the available scientific evidence and information from quantitative assessments. Potential policy-relevant questions[62] include the following:

- To what extent has new scientific evidence improved our understanding of the nature and magnitude of visibility, climate, ecosystem responses, and materials effects to ambient PM, including the variability associated with such responses? To what extent have important uncertainties in the evidence from the last review been addressed, and have new uncertainties emerged?
- To what extent is new information available that changes or enhances our understanding of the physics of light extinction and/or its quantification in urban and non-urban areas (e.g., through light extinction or other monitoring methods or through algorithms such as IMPROVE)?
- To what extent are new studies available on the nature of the relationship between PM-attributable visibility impairment and public perceptions of such impairment? What information is available to inform judgments about the potential adversity to public welfare of PM-attributable visibility impairment?
    - Is evidence available from recent studies in additional urban and non-urban areas, beyond the studies in the previous review?
    - To what extent is evidence available that distinguishes visibility preferences from health preferences?
    - To what extent is evidence available that evaluates the sensitivity of visibility preferences to survey methods?
    - To what extent is evidence available that examines the potential relationship between intensity versus frequency of visibility impairment in stated public preferences?

[62] As noted above (section 2.1), based on CASAC advice and public input on this draft IRP, we will modify these potential questions as appropriate for the final IRP. The key policy-relevant questions identified in the final PM IRP will provide an overall framework for the development of the PM ISA, REAs (if warranted), and the PA.

- To what extent is new information available that changes or enhances our understanding of the climate impacts of PM-related aerosols, particularly regarding the quantification of anthropogenic aerosol effects on radiative forcing?
- To what extent is new information available to link PM (excluding nitrates and sulfates) to ecological effects?
- To what extent is new information available to link PM to materials effects, including degradation of surfaces, and deterioration of materials such as metal, stone, concrete and marble? Are there studies linking perceptions of reduced aesthetic appeal of buildings and other objects to PM or wet deposition of N and S species?
- Does the available evidence and/or quantitative analyses suggest that PM-induced visibility impairment or other PM-related welfare effects could occur with ambient concentrations of PM that meet the current standards? If so, could these effects be of sufficient magnitude and/or frequency such that they might reasonably be judged to be adverse to public welfare? To what degree would updated or additional analyses improve our understanding of the welfare effects that could be allowed by the current standards?
- To what extent have important uncertainties identified in the last review been reduced and/or have new uncertainties emerged?

If the available evidence and information from quantitative analyses call into question the adequacy of the welfare protection afforded by the current secondary $PM_{2.5}$ or PM_{10} standards, we will also consider the following overarching question:

- **What alternative standards are supported by the currently available scientific evidence and quantitative information and are appropriate for consideration?**

To answer this second overarching question, we will also consider a series of more specific questions focused on the basic elements of the NAAQS (indicator, averaging time, form, level). We will consider these elements collectively in evaluating the public welfare protection afforded by potential alternative standards. With regard to consideration of alternative standards, the specific policy-relevant questions will include the following:

- Do the available welfare effects evidence and air quality information provide support for consideration of *indicators* in addition to, or in place of, the current mass-based indicators? Do the evidence and information from the quantitative analyses, if warranted, support alternative indicators based on light extinction, chemical composition, or other factors?
- Do the available welfare effects evidence, air quality information, and information from quantitative assessments, provide support for considering *averaging times* in addition to, or in place of, the current 24-hour and annual averaging times? Do the evidence and information support a sub-daily or other alternative averaging time?
- To what extent do air quality analyses or information from quantitative assessments provide support for considering alternative standard *forms*? To what extent do assessments support an alternative form based on daylight hours or other metric?

- What range of *levels* should be considered, based on the scientific evidence, air quality analyses, and quantitative assessments? At what concentrations of ambient PM do adverse visibility impairment and/or other environmental effects of concern for public welfare occur?
- What are the important uncertainties and limitations in the available evidence, analyses, and assessments and how might those uncertainties and limitations be taken into consideration in identifying alternative standard *indicators, averaging times, forms, and/or levels*?

2.3 PM AMBIENT MONITORING

Achieving the degree of public health and welfare protection intended for the NAAQS depends, in large part, on appropriate ambient monitoring networks. In the case of PM, existing monitoring networks provide data for a variety of objectives as part of an iterative process in managing air quality. These objectives include: (1) determining compliance with the NAAQS; (2) characterizing air quality status, including providing the public with timely reports and forecasts of the Air Quality Index (AQI); (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 trends and 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. The EPA amended these regulations in the 2006 and 2012 reviews of the PM NAAQS, in part to support changes necessary for implementation of the revised PM standards. The EPA expects to follow a similar process for monitoring rule changes during this review, if appropriate. Potential monitoring rule changes include the Federal Reference Methods (FRMs)[63] 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.

Section 2.3.1 below provides an overview of the PM monitoring networks and their history. Section 2.3.2 summarizes the key potential monitoring-related issues in the current review.

[63] 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. The EPA keeps a complete list of designated reference and equivalent methods available on its Ambient Monitoring Technology Information Center (AMTIC) website (http://www3.epa.gov/ttn/amtic/files/ambient/criteria/reference-equivalent-methods-list.pdf).

2.3.1 PM Monitoring Networks

The EPA and its partners at state, local, and tribal monitoring agencies manage and operate the nations' ambient air monitoring networks. The EPA provides minimum monitoring requirements for criteria pollutants and related monitoring (e.g., the Chemical Speciation Network (CSN)) including identification of an FRM for criteria pollutants and guidance documents to support implementation and operation of the networks. Monitoring agencies carry out and perform ambient air monitoring in accordance with the EPA's requirements and guidance as well as often meeting their own state monitoring needs that may go beyond the minimum federal requirements. This partnership results in a nationally consistent ambient air monitoring program that supports the objectives listed above. Data from the ambient air monitoring networks are available from two national databases. The AirNow database provides data used in public reporting and forecasting of the AQI, while the Air Quality System (AQS) database is the EPA's long-term repository of ambient air monitoring data.

The EPA and states currently operate robust national networks for both PM_{10} and $PM_{2.5}$, as these are the two measurement programs directly supporting NAAQS. PM_{10} measurements are based on gravimetric mass, while $PM_{2.5}$ measurements include gravimetric mass and chemical speciation. A smaller network of stations is operating and reporting data for $PM_{10\text{-}2.5}$ gravimetric mass and a small number of monitors are operated to support special projects, including pilot studies, for continuous speciation and particle count data. Monitoring networks and additional monitoring efforts for each of the various PM size fractions and for PM composition are discussed below.[64] All sampler and monitor counts provided below are based on data submitted to the EPA for calendar year 2014, unless otherwise noted.

Total Suspended Particulates (TSP) Sampling

The EPA first established NAAQS for PM in 1971, based on the original air quality 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 particles or TSP). TSP was replaced by PM_{10} as the indicator for particles in a 1987 final notice (52 FR 24854, July 1, 1987). However, TSP sampling remains in operation to provide the aerosol needed for TSP lead sampling as well as for cases where a state may continue to have state standards for TSP. The size of the TSP network peaked in the mid-1970s when over 4,300 TSP samplers were in operation. Today, there

[64] More information on ambient monitoring networks can be found at http://www3.epa.gov/ttn/amtic/.

are about 200 TSP samplers still in operation as part of the lead monitoring program; of these, about 50 also report TSP mass.

PM_{10} Monitoring

As a result of the 1987 standard for PM_{10}, the EPA and its state and 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. The PM_{10} monitoring network peaked in size in 1995 with 1,665 stations reporting data.

Approximately 750 PM_{10} stations with samplers and monitors are currently in operation to support comparison of the PM_{10} data to the NAAQS, trends, and reporting and forecasting of the AQI. Though the current PM_{10} network is relatively stable, monitoring agencies may continue divesting of some of the PM_{10} monitoring stations where concentration levels are low relative to the NAAQS.

While the PM_{10} network is national in scope, there are areas of the west such as California and Arizona with substantially higher PM_{10} station density than the rest of the country. In the PM_{10} mass network, about 320 of the stations operate continuous mass monitors approved as FEMs and 480 operate FRMs. Thus, about 50 of the PM_{10} stations have collocation with both continuous FEMs and FRMs. Almost half of the PM_{10} stations with FRMs operate on a sample frequency of one in every sixth day, with about 140 operating every third day and just over 100 operating every day.

$PM_{2.5}$ Monitoring

After setting the first $PM_{2.5}$ NAAQS in 1997, the EPA and states implemented a $PM_{2.5}$ network consisting of ambient air monitoring sites with mass and/or chemical speciation measurements. Network operation began in 1999 with nearly 1000 monitoring stations operating FRMs to provide fine particle mass. The $PM_{2.5}$ monitoring program remains one of the major ambient air monitoring programs operated across the country.

There are three main components of the current $PM_{2.5}$ monitoring program including FRMs, $PM_{2.5}$ continuous mass monitors, and Chemical Speciation Network (CSN) samplers. The FRMs are primarily used for comparison to the NAAQS, but also serve other important purposes such as developing trends and evaluating the performance of $PM_{2.5}$ continuous mass monitors. $PM_{2.5}$ continuous mass monitors are primarily used to support forecasting and reporting of the AQI, but are also used for comparison to the NAAQS, where approved as FEMs. The CSN and related Interagency Monitoring of Protected Visual Environments (IMPROVE) network are used to provide chemical composition of the aerosol which serve a variety of objectives. This section provides an overview of each of these components of the $PM_{2.5}$ monitoring program.

As noted above, the $PM_{2.5}$ monitoring network began operation in 1999 with nearly 1,000 monitoring stations operating FRMs. The $PM_{2.5}$ FRM network peaked in operation in 2001 with over 1,150 monitoring stations. In the current $PM_{2.5}$ network, there are approximately 773 FRM filter-based samplers that provide 24-hour $PM_{2.5}$ mass concentration data. Of these operating FRMs, 111 are providing daily $PM_{2.5}$ data, 535 every third day, and 125 every sixth day. Close to 800 continuous $PM_{2.5}$ mass monitors provide hourly data on a near real-time basis. About 363 of the $PM_{2.5}$ continuous monitors are FEMs and therefore used for comparison with the NAAQS and AQI, and another 424 are methods not approved as FEMs and therefore used just for the AQI.

Due to the complex nature of fine particles, in 2000 the EPA and states implemented the CSN to better understand the components of fine particle mass at selected locations across the country. The CSN was first piloted at 13 sites. After the pilot phase, the program continued with deployment of the Speciation Trends Network (STN) in the fall of 2000. The CSN ultimately grew to 54 trends sites and peaked in operation in 2005 with 252 stations; the 54 trends stations and nearly 200 supplemental stations. The original CSN program had multiple sampler configurations including the Thermo Andersen RAAS, Met One SASS/SuperSASS, and URG MASS. During the 2000s, the EPA and states worked to align the network to one common sampler for elements and ions, which was the Met One SASS/SuperSASS. In 2005, CASAC provided recommendations to the EPA for making changes to the CSN. These changes were intended to improve data comparability with the rural IMPROVE carbon concentration data. To accomplish this, the EPA replaced the existing carbon channel sampling and analysis methods with a new modified IMPROVE version III module C sampler, the URG 3000N. Implementation of the new carbon sampler and analysis was broken into three phases starting in May of 2007 through October of 2009.

In the current $PM_{2.5}$ CSN, long-term measurements are made at about 90 largely urban locations comprised of either the STN or the National Core (NCore) network.[65] NCore is a multipollutant network measuring particles, gases, and basic meteorology that has been in formal operation since January 1, 2011. Particle measurements made at NCore include $PM_{2.5}$ filter-based mass, which is largely the FRM, except in some rural locations which utilize the IMPROVE program $PM_{2.5}$ mass filter-based measurement; $PM_{2.5}$ speciation using either the CSN program or IMPROVE program; and $PM_{10\text{-}2.5}$ mass utilizing an FRM, FEM or IMPROVE for some of the

[65] In most cases where a city has an STN station, it is located at the same site as the NCore station. In a few cases, a city may have an STN station located at a different location than the NCore station.

rural locations. The NCore network includes a total of 78 stations of which 63 are in urban or suburban stations designed to provide representative population exposure and another 15 rural stations designed to provide background and transport information. The NCore network is deployed in all 50 States, DC, and Puerto Rico with at least one station in each state and two or more stations in larger population states. Since 2008, the EPA's Office of Research and Development has approved ten models of $PM_{2.5}$ continuous monitors as FEMs; about 75% of the reporting $PM_{2.5}$ continuous FEMs in the country are the Met One BAM 1020.

Both the STN and NCore networks are intended to remain in operation indefinitely. The CSN measurements at NCore and STN stations operate every third day. Another approximately 70 CSN stations are known as supplemental sites are intended to be potentially less permanent locations used to support State Implementation Plan (SIP) development and other monitoring objectives.[66] Supplemental CSN stations typically operate every sixth day. In 2014, about 40 supplemental CSN stations that are largely located in the eastern half of the country stopped operations to ensure a sustainable CSN network moving forward. Specific components of fine particles are also measured through the IMPROVE monitoring program[67] which supports regional haze characterization and tracks changes in visibility in Class I areas as well as many other rural and some urban areas. The base IMPROVE network includes 110 monitoring locations and. another approximately 20 locations are operated as IMPROVE protocol sites where a monitoring agency has requested participation in the program. These IMPROVE protocol sites are operated the same way as the IMPROVE program, but they may serve a number of monitoring objectives (i.e., the same objectives as the CSN) and are not explicitly tied to the Regional Haze Program. Samplers at IMPROVE stations operate every third day. In January of 2016, 8 IMPROVE protocol stations stopped operating to ensure a sustainable IMPROVE program moving forward. Details on the process and outcomes of the CSN supplemental and IMPROVE protocol assessments used to identify sites that would no longer be

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

[67]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.

funded are available on an interactive website[68]. 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.[69]

Key changes made to the EPA's monitoring requirements as a result of the 2012 PM NAAQS review included the addition of $PM_{2.5}$ monitoring at near road locations in CBSAs over 1 million in population; the clarification of terms used in siting of $PM_{2.5}$ monitors and their applicability to the NAAQS; and providing flexibility on data uses to monitoring agencies where their $PM_{2.5}$ continuous monitors are not providing data that meets the performance criteria used to approve the continuous method as an FEM. The addition of $PM_{2.5}$ monitoring at near road locations is being phased in 2015 and 2017. By January 1, 2015, 22 CBSAs with a population of 2.5 million or more were to have a $PM_{2.5}$ FRM or FEM operating at a near-road monitoring station. By January 1, 2017, 30 CBSAs with a population between 1 million and 2.5 million are to have a $PM_{2.5}$ FRM or FEM operating are a near-road monitoring station. The terms clarified in the 2012 rule ensure consistency with other NAAQS and long standing definitions used by the EPA (78 FR 3234, January 15, 2013). The flexibility provided to monitoring agencies such that data from certain $PM_{2.5}$ continuous FEM monitors are not applicable to the NAAQS, where appropriate, ensures that the incentives of utilizing $PM_{2.5}$ continuous monitors (e.g., efficiencies in operation and availability of hourly data in near-real time) are realized without having potentially poor performing data be misused in a NAAQS decision (78 FR 3241, January 15, 2013).[70]

$PM_{10-2.5}$ Monitoring

In the 2006 PM NAAQS review, the EPA promulgated a new FRM for the measurement of $PM_{10-2.5}$ mass in ambient air. Although the standard for thoracic coarse particles uses a PM_{10}

[68] See the Chemical Speciation Network Assessment Interactive Website at: https://www.sdas.battelle.org/CSNAssessment/html/Default.html

[69] These data could also be used to better understand visibility through calculation of light extinction using the IMPROVE algorithm.

[70] Although not explicitly required under any existing monitoring regulations, the EPA and state and local agencies have also been working together to pilot additional PM methods at near-road monitoring stations that may be of interest to data users. These methods include such techniques as particle counters, particle size distribution, and black carbon by aethalometer. These methods and their rationale for use at near-road monitoring stations are described in a Technical Assistance Document (TAD) on NO_2 near road monitoring (Near-road NO_2 Monitoring Technical Assistance Document, EPA-454/B-12-002, June 2012).

indicator, a new FRM for $PM_{10-2.5}$ mass 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 $PM_{10-2.5}$ FRM (or approved FEMs, where available) was implemented at required NCore stations by January 1, 2011. In addition to NCore, there are other collocated PM_{10} and $PM_{2.5}$ low-volume FRMs operating across the country that are essentially providing the $PM_{10-2.5}$ FRM measurement by the difference method.

$PM_{10-2.5}$ measurements are currently performed across the country at NCore stations, IMPROVE monitoring stations, and at a few additional locations where state or local agencies choose to operate the method. For urban NCore stations and other State and Local Air Monitoring Stations (SLAMS) the method employed is either a $PM_{10-2.5}$ FRM, which is performed using a low-volume PM_{10} FRM collocated with a low volume $PM_{2.5}$ FRM of the same make and model, or FEMs for $PM_{10-2.5}$, including filter-based dichotomous methods and continuous methods of which several makes and models are approved. Filter-based $PM_{10-2.5}$ measurements at NCore (i.e., the FRM or dichotomous filter-based FEM) operate every third day, while continuous methods have data available every hour of every day. $PM_{10-2.5}$ filter-based methods at other SLAMS typically operate every third or sixth day. For IMPROVE, which is largely a rural network, $PM_{10-2.5}$ measurements are made with two sample channels; one each for PM_{10} and the other $PM_{2.5}$. All IMPROVE program samplers operate every third day. All together there approximately 250 stations where $PM_{10-2.5}$ data are being reported to the EPA.

There is no operating chemical speciation network for characterizing the specific components of thoracic coarse particles. Washington University at St. Louis recently reported on a coarse particle speciation pilot study with several objectives aimed at addressing this issue, such as evaluating a coarse particle species analyte list and evaluating sampling and analytical methods.[71] The coarse particle speciation pilot study should provide useful information for any organization wishing to pursue coarse particle speciation.

Additional PM Metrics

There are additional PM measurement metrics made at a much smaller number of stations. These measurements may be associated with special projects or are complementary measurements to other networks where the monitoring agency has prioritized having the

[71] Pilot Study on Coarse PM Monitoring, EPA-454/R-15-001, February 2015. http://www3.epa.gov/ttn/amtic/files/pm10pilot/PMc_ReportEPA454R-15-001.pdf

measurements. None of these measurements are required by regulation. They include PM measurements such as particle counts, continuous carbon, and continuous sulfate.

Particle count measurements are being implemented at several near-road monitoring stations as part of the recent deployment of the near-road monitoring program, but may be used at other locations. Particle counts are one of several measurements identified as being a secondary priority for multipollutant monitoring at near-road monitoring stations. Details on priorities for multipollutant monitoring at near-road monitoring stations can be found in Section 16 of the Near-road NO_2 Monitoring Technical Assistance Document (TAD)[72].

Aethalometer data has been measured and submitted to AQS for many years. Data uses include characterizing black carbon and wood smoke. Ambient air monitoring stations that may have aethalometers include some of the near-road monitoring stations and National Air Toxics Trends Stations (NATTS). About 40 monitoring sites across the county are reporting data from aethalometers. While aethalometer data is available at high time resolutions, it is typically reported to the AQS data base in one hour periods.

Continuous elemental and organic carbon data are monitored at select locations participating in a pilot of the Sunset EC/OC analyzer as well as a few additional sites that were already operating before the EPA initiated the pilot study. The Sunset EC/OC analyzer provides high time resolution carbon data, typically every hour, but in some remote locations the instrument is programmed to run every 2 hours to ensure collection of enough aerosol. The data from the Sunset is being compared to filter-based carbon methods from the carbon channel of the CSN program. The six sites participating in the study are Washington DC, Chicago IL, St. Louis MO, Houston TX, Las Vegas NV, and Los Angeles CA. Each of the six sites participating in the pilot study are operating for at least three years.

Continuous sulfate continues to be measured at four locations. One station each in North Carolina, Tennessee, Indiana, and Maine are reporting data. The continuous sulfate analyzer provides hourly data and data can be readily compared to 24-hour sulfate data collected from the ion channel in the CSN program.

In addition, over the last few years, the EPA has investigated the use of a number of PM sensor technologies as one of several areas of research intended to address the next generation of air measurements. The investigation into air sensors is envisioned to work towards near real-time or continuous measurement options that are smaller, cheaper, and more portable than traditional

[72] Near-road NO_2 Monitoring Technical Assistance Document, Publication No. EPA-454/B-12-002, June 2012. Available on EPA's Web site at: http://www3.epa.gov/ttn/amtic/files/nearroad/NearRoadTAD.pdf

FRM or FEM methods. These sensor devices have the potential to be used in a number of applications such as identifying hot spots, informing network design, providing personal exposure monitoring, supporting risk assessments, and providing background concentration data for permitting. The EPA has hosted workshops and published a number of documents and peer-reviewed articles on this work (See the EPA's web site at: http://www2.epa.gov/air-research/next-generation-air-measuring-research).

2.3.2 Consideration Of PM Monitoring Issues In The Current Review

This review of the PM NAAQS will include the consideration of policy-relevant issues associated with measuring and characterizing PM in ambient air. These issues include the design of the PM network, the performance of existing FRMs and FEMs, the performance of continuous monitors, PM chemical speciation, PM monitoring near major roadways, the availability and performance of low-cost PM sensors, and data reporting requirements. The EPA will draw upon the information presented in the ISA to inform the evaluation of appropriate ambient monitoring methods and network design for PM. If there is a need for formal scientific input on important changes to ambient air monitoring, the EPA may request convening the Ambient Air Monitoring Subcommittee of the Clean Air Scientific Advisory Committee. This subcommittee has worked closely with the EPA during past reviews, where appropriate, to provide the scientific review of monitoring options under consideration as part of the PM NAAQS review process.[73] Input and development of options to improve ambient air monitoring are also based on input from monitoring agencies and other interested stakeholders.

[73] The EPA will draw upon the information presented in the ISA to inform the evaluation of appropriate ambient monitoring methods and network design for PM. Input and development of options to improve ambient air monitoring are also based on input from monitoring agencies and other interested stakeholders.

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3 SCIENCE ASSESSMENT

Integrated Science Assessments (ISAs) serve as the scientific foundation of the NAAQS review process and are developed by the EPA's National Center for Environmental Assessment in Research Triangle Park (NCEA-RTP). As outlined in sections 1.2 and 1.4 above, the particulate matter (PM) ISA will inform the review of both the primary (health-based) and secondary (welfare-based) PM standards.

3.1 SCOPE OF THE PM ISA

3.1.1 General Description

The ISA provides a comprehensive synthesis and evaluation of the most policy-relevant science, including key science judgments that are important to inform the development of the risk and exposure assessments, as well as other aspects of the NAAQS review (U.S. EPA, 2016). The shift to the ISA away from the Air Quality Criteria Documents, which originally provided the scientific basis of the NAAQS review process, was initiated in 2006. This change was rooted in the "broad recognition that the Criteria Document is typically 'encyclopedic' in nature, which is seen by many as contributing to an unnecessarily lengthy process for preparing document drafts and for reviews by CASAC [(Clean Air Scientific Advisory Committee)] and the public, and obscuring a focus on the most policy-relevant scientific information" (U.S. EPA, 2006). CASAC provided positive feedback on this transition to the ISA, encouraging "the development of a more timely and more concise integrated assessment of the policy-relevant science that would replace the voluminous air quality criteria document"(Peacock, 2008). The purpose of the PM ISA is to provide a critical evaluation and synthesis of the current scientific literature on health and welfare evidence necessary to support the PM NAAQS review process.

The PM ISA is not intended to provide a detailed review of all studies of the aforementioned topics but rather, will draw from the available evidence to synthesize the current state of knowledge of the most policy-relevant issues for the review of the primary and secondary PM NAAQS. The PM ISA will update the scientific assessment upon which the last PM NAAQS review was based. Thus, the PM ISA will build on the conclusions of the last review of the air quality criteria for PM as presented in the 2009 PM ISA and focus on peer-reviewed literature published since that document,[74] as well as on any new interpretations of

[74] The 2009 PM ISA included studies through May 2009.

previously available literature. Key findings, conclusions, and uncertainties from the 2009 PM ISA will be briefly summarized at the beginning of the PM ISA and at the beginning of individual sections. Important older studies may be discussed in detail to reinforce key concepts and conclusions and/or if they are open to reinterpretation in light of newer data. Older studies also may be the primary focus in some subject areas or scientific disciplines (e.g., epidemiology, controlled human exposure, animal toxicology, atmospheric science, exposure science, visibility impairment, climate, materials effects, and ecological effects) where research efforts have subsided, and these older studies remain the definitive works available in the literature.

In order to provide a more focused evaluation of the scientific evidence for health- and welfare-related effects, the PM ISA will discuss the most important topics that address policy-relevant questions. Therefore, the PM ISA will more fully evaluate those health and welfare effects for which the evidence in the 2009 PM ISA was less certain (i.e., effects where the causal determination was "likely to be causal", "suggestive", or "inadequate" as detailed below in section 3.4.3) and where there is now a larger body of evidence (e.g., diabetes, nervous system effects, etc.). For those health and welfare effects where the 2009 PM ISA concluded that the evidence was sufficient to infer a causal relationship (i.e., health: short- and long-term $PM_{2.5}$ exposures and cardiovascular effects; short- and long-term $PM_{2.5}$ exposures and mortality; and welfare: PM exposures and effects on materials, visibility, and climate), the PM ISA will focus the evaluation on characterizing the extent to which new studies address key uncertainties and limitations identified in the previous review or provide insight on new issues. For the epidemiologic studies the focus of the evaluation will include, but not be limited to, addressing the impact of exposure assessment techniques on associations observed; evaluating potential copollutant confounding; assessing the impact of PM components and sources on associations observed; and examining heterogeneity in PM associations. Those epidemiologic studies that do not directly address uncertainties and limitations as identified in the 2009 PM ISA, but still meet our inclusion criteria will be detailed in tables presenting information for consideration in evaluating the adequacy of the current PM NAAQS (e.g., averaging time of exposure, distribution of PM concentrations, etc.). For experimental studies, specifically toxicological studies, the evaluation will focus on those studies that also address key uncertainties and limitations in the evidence identified in the previous review. For example, does the new evidence further our understanding of the biological mechanisms by which PM elicits a health effect or provide coherence for the effects observed in epidemiologic studies? Similar to the epidemiologic studies, a more detailed description of key pieces of information from the toxicological studies will be detailed in tables.

Consistent with the goal of making the PM ISA a focused assessment of the current state of the science with respect to PM, this ISA incorporates CASAC advice received during the review of External Review Drafts of the 2009 PM ISA.[75] For example, CASAC provided specific advice about the evaluation of PM_{10}. Although the indicator for coarse particles is PM_{10},[76] studies that examine the health or welfare effects of exposures to only PM_{10} are limited in their ability to inform the health and welfare effects of $PM_{10-2.5}$ or $PM_{2.5}$. As a result, CASAC suggested revisions to the PM ISA to "remove the impression that PM_{10} is a separate pollutant from $PM_{2.5}$ and $PM_{10-2.5}$", specifically the removal of causal determinations for short- and long-term exposures to PM_{10} (Samet, 2009) Additionally, CASAC suggested detailing "when possible, the particle size distribution of the PM_{10} mixture" (Samet, 2009). As such, the final 2009 PM ISA had minimal discussion of PM_{10} health effect studies, and these studies were used as supporting evidence of $PM_{2.5}$-related health effects primarily due to the majority of PM_{10} studies being conducted in large urban areas where, in many locations, ambient monitoring typically indicates that $PM_{2.5}$ comprises a large percent of PM_{10} mass. Therefore, consistent with the previous CASAC panel's recommendation, the current PM ISA will focus on the evaluation of health studies of $PM_{2.5}$ and $PM_{10-2.5}$ as the most pertinent to addressing the key policy-relevant questions of the PM NAAQS review. This is also consistent with the 2012 PM Final Rule, which stated that "… the extent to which PM_{10} effect estimates reflect associations with $PM_{10-2.5}$ versus $PM_{2.5}$ can be highly uncertain [and, as a result]… it is preferable to consider $PM_{10-2.5}$ studies when such studies are available" (78 FR 3086). Therefore, the evaluation of PM_{10} studies will be limited to those that specifically address remaining uncertainties or limitations in the $PM_{2.5}$ or $PM_{10-2.5}$ health or welfare effects evidence or evaluate a new health or welfare effect not previously examined.

The general scope presented above will allow the PM ISA to primarily focus on scientific evaluations that are pertinent to the key policy-relevant questions described in Chapter 2 (sections 2.1 and 2.2) above. Within the discussion of the health and welfare effects information, other scientific information will also be presented and evaluated in order to provide a better understanding of the following issues: (1) the sources of PM in the ambient air; (2) fate and transport of PM in the environment; (3) measurement of PM and recent ambient concentrations

[75] External Review Drafts of the PM ISA are available at: http://www3.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_isa.html

[76] As discussed above (sections 1.3 and 2.1.2), the purpose of the PM_{10} standard is to protect against exposures to $PM_{10-2.5}$.

of PM; (4) the validity of inferences that can be drawn about PM health and welfare effects based on exposure assessment methodology; (5) the potential influence of other factors (e.g., other pollutants in the ambient mixture, ambient temperature) shown to be correlated with PM and health or welfare effects; (6) the shape of the concentration-response (C-R) relationship at PM concentrations at the low end of the distribution; and (7) populations and lifestages at greatest risk of PM-related health effects. The process for evaluating and synthesizing scientific literature and addressing key policy questions is detailed in the Preamble to the Integrated Science Assessments (U.S. EPA, 2015). Collectively, the approach outlined for the health and welfare effects will allow for the EPA to provide a focused assessment of the scientific evidence that more directly informs policy-relevant considerations detailed in the Policy Assessment (PA) and Risk and Exposure Assessment(s) (REA) as detailed in Chapter 2.

3.1.2 Defining Policy-Relevant Literature

PM is unique among the criteria pollutants in that it is composed of multiple components and size fractions. PM is often examined using mass-based metrics for overall mass and the mass of individual components within the following size fractions: PM_{10} (thoracic PM; particulate matter with a nominal mean aerodynamic diameter less than or equal to 10 μm), $PM_{2.5}$ (fine PM; particulate matter with a nominal mean aerodynamic diameter less than or equal to 2.5 μm), and $PM_{10-2.5}$ (thoracic coarse or coarse PM; particulate matter with a nominal mean aerodynamic diameter greater than 2.5 μm and less than or equal to 10 μm). Ultrafine particles (UFP, generally considered as particulates with a diameter less than or equal to 0.1 μm [typically based on physical size, thermal diffusivity or electrical mobility] (U.S. EPA, 2009)) are examined using multiple indices such as mass, number concentration, and surface area. As discussed in Chapter 1, the current indicators of the PM NAAQS are mass-based for both fine particles, represented by $PM_{2.5}$, and for thoracic coarse particles, represented by PM_{10}.

Given the array of PM size fractions and components examined in studies of atmospheric chemistry, exposure, health effects, and welfare effects, it is important to clearly define the types of studies that will be evaluated within the PM ISA to ensure its conclusions are pertinent to the key questions of the PM NAAQS review, specifically:

- Does exposure to PM cause a direct health or welfare effect (i.e., an independent effect)?
- Are the current indicators (i.e., $PM_{2.5}$ for fine particles and PM_{10} for thoracic coarse particles), averaging times (e.g., 24-hour average, annual average), and levels appropriate?

When evaluating the broad body of literature across scientific disciplines, the EPA considers whether the studies fall within the scope of the PM ISA (i.e., provide information

which can address the above questions). As a result, the focus of the PM ISA with respect to the health evidence is on studies conducted at concentrations of PM that are relevant to the range of human exposures across ambient microenvironments (up to 2 mg/m^3 PM, which is one to two orders of magnitude above ambient concentrations) and (1) include a composite measure of PM[77] or (2) apply some approach to assess the independent effect of PM when the exposure of interest is a source-based mixture (e.g., diesel exhaust, gasoline exhaust, wood smoke). However, the scope of experimental studies included in the PM ISA may be broader when examining modes of action for PM, and may include in vitro studies, studies examining relative toxicity, and studies conducted at concentrations > 2 mg/m^3. In the case of (1), if a study focuses on a single component, group of components, or source, the study must also examine a composite measure of PM (e.g., mass of $PM_{2.5}$, $PM_{10-2.5}$, ultrafine particles [UFP]) to be included in this review. This requirement ensures that the study is relevant to the scope of the PM ISA and evaluated in the proper context; specifically, this approach will facilitate a comparison of effects or associations observed to the current mass-based PM indicator. Case (2) primarily applies to experimental studies that attempt to disentangle the independent effects of PM from a complex air pollution mixture of particles, gases, and semi-volatile components. This may be accomplished by using filtration (e.g., a particle trap) or other approaches to distinguish between effects due to the mixture and effects due to the particles alone.

With respect to identifying policy-relevant studies for welfare effects (ecological effects, visibility, materials effects, and climate) PM composition and/or size fraction are important to consider. For ecological effects, studies that focus on deposited components of PM (including metals and organics, but not nitrogen (N) and sulfur (S)-containing compounds or their transformation products)[78] at ambient or near-ambient concentrations of PM will be emphasized, leading to the evaluation of the direct and indirect effects of PM on vegetation, soils, and biota. Generally, components of PM drive ecosystem responses, although size fraction may play a role in the direct effects of PM such as deposition to vegetation. As a result, the emphasis will be on studies of ecological effects detailing 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.

[77] Composite measures of PM may include mass, volume, surface area, or number concentration.

[78] The PM ISA will not evaluate nutrient N and S ecosystem effects, which will be addressed in the concurrent review of the secondary NO_x and SO_x NAAQS for ecological effects, see: http://www3.epa.gov/ttn/naaqs/standards/no2so2sec/index.html.

For materials effects, visibility, and climate effects, this ISA will build on information available during the last review describing the role of PM on materials damage and soiling, visibility impairment, and in radiative forcing resulting in global and regional climate change. For effects on materials, studies will be included that examine the role of PM, or related N and S species as discussed in Section 1.4, on materials damage and soiling. Specifically, studies will be considered that examine gaseous and particle contributions from nitrogen and sulfur along with other PM components due to the difficulty in determining whether an effect on materials is due to the particle or gaseous component of NOx and SOx and because the NO_x/SO_x secondary ISA focuses only on ecological effects, not other welfare effects. For visibility, studies will be included which advance our understanding of visual impairment of airborne PM, including studies of atmospheric chemistry, visibility preference, or other measures of adversity to public welfare, in urban and rural settings. For climate, the ISA will focus on climate as the welfare effect as listed in the 1977 Amendment to the Clean Air Act and will not focus on downstream ecosystem effects, human health effects, or future air quality projections resulting from changes in climate (Clean Air Act Amendments of 1977). The primary literature base for the evaluation of the effects of airborne and deposited PM on climate will come from recent national and international climate assessments such as the National Climate Assessment (Melillo et al., 2014) and International Panel on Climate Change (IPCC, 2014). Focus will be on studies that inform the independent role of PM in climate forcing as well as effects on U.S. national and regional climate.

3.2 ORGANIZATION OF THE PM ISA

The broad organization of the PM ISA will be consistent with that used in the recent assessments for other criteria pollutants (e.g., ISA for Ozone and Related Photochemical Oxidants, U.S. EPA, 2013c). The detailed description of the procedures for the assessment of scientific information within the ISA for each of the criteria air pollutants can be found in the Preamble to the Integrated Science Assessments (U.S. EPA, 2015). The PM ISA will begin with a Preface discussing major legal and historical aspects of prior PM NAAQS reviews. An executive summary will succinctly summarize the conclusions of the ISA. An integrative synthesis chapter will provide a more detailed summary of the key information for each topic area, including the causal determinations for relationships between exposure to PM and health and welfare effects, information describing the extent to which health and welfare effects can be attributable specifically to PM, evaluation of at-risk lifestages and populations, and other uncertainties related to the interpretation of scientific information. The integrative synthesis chapter also will discuss policy-relevant issues such as the exposure averaging times and the lag

structure of associations for health effects; the C-R relationships including the overall shape and whether or not the evidence supports identification of a discernible threshold below which effects are not likely to occur; and the public health and welfare impact of effects associated with exposure to PM. Subsequent chapters will be organized by subject area with the health evidence presented in separate chapters by PM size fraction (i.e., $PM_{2.5}$, $PM_{10-2.5}$, and UFPs) and all of the welfare (i.e., ecological, visibility, materials, and climate) effects evidence discussed in a separate chapter(s). Each of the chapters will contain an evaluation of results from recent policy-relevant studies integrated with previous findings (see section 3.4 below for specific issues to be addressed). Sections for each broad health effect category (e.g., respiratory effects) will conclude with a causal determination about the relationship with relevant exposures to PM for health outcomes that are specific to the size fraction being evaluated (e.g., $PM_{2.5}$, $PM_{10-2.5}$, UFPs).[79] Sections on welfare will conclude with causal determinations for ecological effects, visibility, materials effects, and climate. The PM ISA will conclude with a chapter that examines studies for evidence of differential exposure and risk for PM-related health effects to draw conclusions about potential at-risk lifestages and populations.

The PM ISA may be supplemented with other materials (e.g., tables, figures) if additional documentation is required to support information contained within the PM ISA. These supplementary materials may include more detailed and comprehensive coverage of relevant publications and may accompany the PM ISA or be available in electronic form as output from the Health and Environmental Research Online (HERO) database developed by the EPA (http://hero.epa.gov).[80] Supplementary information that is available in the HERO database will be presented as electronic links in the PM ISA.

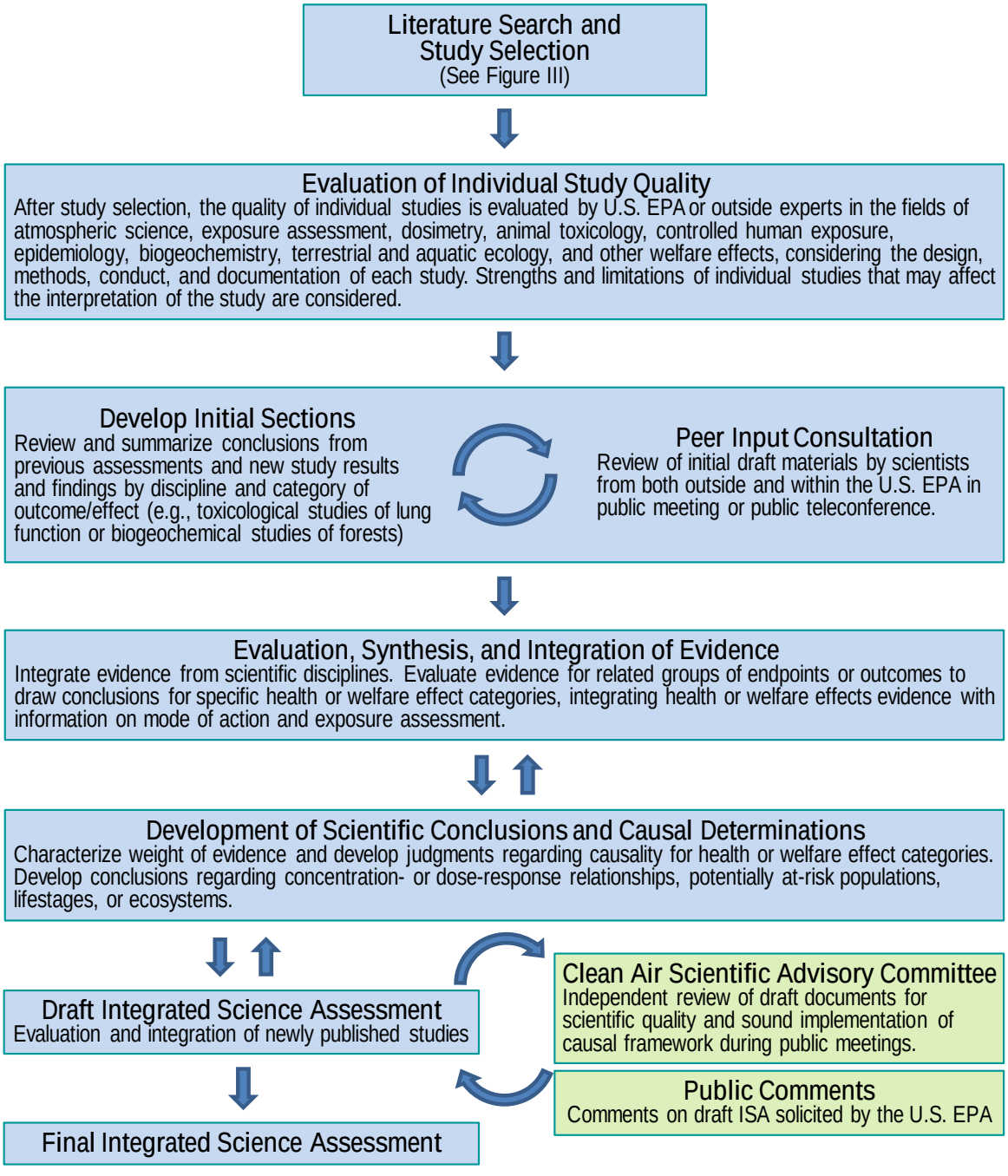
3.3 ASSESSMENT APPROACH

3.3.1 Introduction

In each NAAQS review, development of the ISA begins with a "Call for Information" published in the *Federal Register*. This notice, which for PM was published December 3, 2014 (79 FR 71764), announces the EPA's initiation of activities in the preparation of an ISA for the specific NAAQS review and invites the public to assist in this process through the submission of

[79] Within the evaluation of the evidence for specific size fractions, the ISA will also evaluate the strength of evidence for PM components and sources.
[80] For more information on the HERO database, see http://hero.epa.gov/.

research studies in the identified subject areas. This and subsequent key components of the process currently followed for the development of an ISA are presented in Figure 3-1 and are described in greater detail in the Preamble to the Integrated Science Assessments (U.S. EPA, 2015). Section 1.2 (above) briefly describes how the PM ISA fits into the larger PM NAAQS review. Important aspects of the development of the PM ISA are described in the sections below, including the approach for searching the literature, identifying relevant publications, and informing specific policy-relevant questions that are intended to guide the assessment. These responsibilities are undertaken by expert authors of the PM ISA chapters, which include the EPA staff in NCEA-RTP with extensive knowledge in their respective fields and extramural scientists solicited by the EPA for their expertise in specific fields. The process for scientific and public review of drafts of the PM ISA is described in section 3.5 below.



Source: Modified from Figure II of the Preamble to the Integrated Science Assessments (U.S. EPA, 2015).

Figure 3-1. General process for development of Integrated Science Assessments.

3.3.2 Literature Search and Selection of Relevant Studies

The EPA uses a structured approach to identify relevant studies for consideration and inclusion in the ISAs. To be deemed relevant, studies must fall within the scope of the PM ISA, as detailed in Section 3.1. A *Federal Register* notice is published that announces the initiation of a review and requests information, including relevant literature, from the public (79 FR 71764). In addition, the EPA identifies publications by conducting a recursive multi-tiered literature search process that includes extensive manual and computer-aided citation mining of computer databases (e.g., PubMed, Web of Science) on specific topics in a variety of disciplines. The search strategies are designed *a priori* and iteratively modified to optimize identification of pertinent published papers.

For this PM ISA, a broad search string will be developed with keywords including, but not limited to, particulate, PM, PM_{10}, $PM_{2.5}$, $PM_{10-2.5}$, and ultrafine particles with the specific syntax tailored for each database (e.g., PubMed, Web of Science). The broad search string will then be used in combination with additional search strings to identify references relevant to health and welfare topic areas. In addition to the use of the broad PM search strings, papers will be identified for inclusion in several additional ways: specialized searches on specific topics; relational searches that identify recent publications that have cited references from previous assessments; identification of relevant literature by expert scientists; recommendations from the public and CASAC during the call for information and external review process; and review of citations in previous assessments. These search methods will be used to identify recent research published or accepted for publication since the 2009 PM ISA, i.e., starting in January 2009, through approximately two months before the release of the second external review draft of the PM ISA (see Table 1-3 for target dates). Studies published after the PM ISA cut-off date may also be considered in subsequent phases of the NAAQS review, after assessing whether they provide new information that impacts key scientific issues.

Once studies are identified through the multipronged search strategy, PM ISA authors (EPA staff and extramural scientists) will review the studies for relevance. Relevant to the review of the primary PM NAAQS are epidemiologic, toxicological, and controlled human exposure studies or reports that examine health effects in relation to exposure to PM as well as studies or reports that examine sources, emissions, atmospheric chemistry, human exposure, dosimetry, and modes of action. For the review of the secondary PM NAAQS relevant studies are those that examine ecological effects, visibility, effects on materials and climate. Specific information detailing the scope of the PM ISA, and subsequently those studies that will be evaluated within it are detailed above in section 3.1.2.

To be included in the PM ISA, relevant studies and reports must have undergone scientific peer review and have been published or accepted for publication. Some publications retrieved from the literature search will be excluded as not being relevant (e.g., do not meet aforementioned criteria) based on screening of the title or citation (e.g., not about air pollution, conference abstract, review articles, commentaries) and will not documented further. For other publications, decisions about relevance require reading beyond the title. These publications will be labeled as "considered" for inclusion in the PM ISA and are listed in the HERO database (http://hero.epa.gov).

From the group of "considered" references, studies and reports will be selected for inclusion in the PM ISA based on review of the abstract and full text. The selection process will be based on the extent to which the study is potentially policy-relevant and informative. Potentially policy-relevant and informative studies will include those that provide a basis for or describe the relationship between PM and effects, in particular, those studies that reduce uncertainty or address limitations of critical issues. Also pertinent are studies that offer innovation in method or design or present novel information on effects or issues previously not identified. Uncertainty can be addressed, for example, by analyses of potential confounding or effect modification by copollutants or other factors, analyses of C-R or dose-response relationships, or analyses related to time between exposure and response. In keeping with the purpose to accurately reflect the latest scientific knowledge, a majority of the discussion in the PM ISA will describe studies published since the 2009 PM ISA. However, evidence from previous studies will be included and integrated with results from recent studies. In some cases, evidence from previous studies may be the key policy-relevant information in a particular subject area or scientific discipline. Analyses conducted by the EPA using publicly available data, for example, air quality and emissions data, will also be considered for inclusion in the PM ISA. Informative studies will not be limited to specific study designs, model systems, or outcomes. While study quality is important, it is not the sole criteria for study inclusion. The combination of approaches described above are intended to produce a comprehensive collection of pertinent studies needed to address the key scientific issues that form the basis of the PM ISA. References will be cited in the PM ISA by a hyperlink to the HERO database and also are compiled into reference lists.

3.3.3 Evaluation of Individual Study Quality

After selecting studies for inclusion, individual study quality is evaluated by considering the design, methods, conduct, and documentation of each study, but not by considering whether the study results are positive, negative, or null. In the PM ISA, conclusions about the strength of

inference from study results will be made by weighing the authors' conclusions and independently evaluating study quality as detailed in the Preamble to the Integrated Science Assessments (U.S. EPA, 2015). This uniform approach aims to consider the strengths, limitations, and possible roles of chance, confounding, and other biases that may affect the interpretation of the results from individual studies for both health and welfare. In assessing the scientific quality of studies, the following broad parameters will be considered:

- How clearly were the study design, study groups, methods, data, and results presented to allow for study evaluation?
- To what extent are the air quality data, exposure, or dose metrics of adequate quality to serve as credible exposure indicators?
- Were the study populations, species, subjects, or animal models adequately selected, and are they sufficiently well-defined to allow for meaningful comparisons between study or exposure groups?
- Are the statistical analyses appropriate, properly performed, and properly interpreted? Do the analytical methods provide adequate sensitivity and precision to support study conclusions?
- Are likely covariates (i.e., potential confounding factors, modifying factors) adequately controlled for or taken into account in the study design or statistical analyses?
- Are the endpoint measurements meaningful, valid, and reliable?

Additional considerations in evaluating individual study quality specific to particular scientific disciplines (e.g. epidemiology, toxicology, ecology) are discussed in detail in the Preamble to the Integrated Science Assessments (U.S. EPA, 2015).

3.4 SPECIFIC ISSUES TO BE ADDRESSED IN THE PM ISA

The PM ISA will contain information relevant to considering whether it is appropriate to retain or revise the current primary and secondary PM NAAQS. Decisions on the specific content of the PM ISA will be guided by policy-relevant questions that frame the entire review of the primary and secondary PM NAAQS as outlined in Chapter 2 above. These policy-relevant questions are related to two overarching issues. The first overarching issue is whether new evidence reinforces or calls into question the evidence presented and evaluated in the last PM NAAQS review: (1) with respect to factors such as the plausibility of health effects caused by exposure to PM, specifically $PM_{2.5}$ and $PM_{10\text{-}2.5}$, and concentrations of PM associated with health effects; and (2) with respect to welfare-related effects of PM. The second overarching issue is whether uncertainties from the last review have been reduced and/or whether new uncertainties have emerged, such as whether other measures of PM (e.g., different size fractions or

components) are better at capturing the health and welfare effects attributed to PM exposures than those used as the indicators for the current NAAQS. The PM ISA also will address a set of more specific policy-relevant questions related to the available scientific evidence that stem from these issues. These questions were derived from the last PM NAAQS review, as well as from discussions of the scientific evidence that occurred at the February 2015 science policy workshop which initiated this PM NAAQS review (79 FR 71764, December 3, 2014). The PM ISA may include supplementary material if additional documentation is required to support information contained in the PM ISA. As in recently completed ISAs, such supplementary material will be available in the online HERO database and referenced in the PM ISA as electronic links to HERO.

3.4.1 Causal Determinations from 2009 PM ISA

In the 2009 PM ISA, the EPA concluded that the findings of epidemiologic, controlled human exposure, and animal toxicological studies collectively provided evidence of a "causal relationship" for short- and long-term $PM_{2.5}$ exposures and cardiovascular effects as well as mortality (U.S. EPA, 2009, as summarized in Chapter 2). In evaluating a broader range of health effects for $PM_{2.5}$, the 2009 PM ISA concluded there was evidence of a "likely to be causal relationship" for short- and long-term $PM_{2.5}$ exposures and respiratory effects (U.S. EPA, 2009, as summarized in Chapter 2). Additionally, there was evidence "suggestive of a causal relationship" for long-term $PM_{2.5}$ exposures and other health effects, including developmental and reproductive effects (e.g., low birth weight, infant mortality) and carcinogenic, mutagenic, and genotoxic effects (e.g., lung cancer mortality) (U.S. EPA, 2009, as summarized in Chapter 2). The 2009 PM ISA also formed causal determinations for exposures to $PM_{10-2.5}$ and ultrafine particles. With respect to $PM_{10-2.5}$, the 2009 PM ISA concluded that the evidence was "suggestive of a causal relationship" for short-term exposures and cardiovascular effects, respiratory effects, and mortality, with the evidence "inadequate to infer a causal relationship" for long-term $PM_{10-2.5}$ exposures and all health effects (U.S. EPA, 2009, as summarized in Chapter 2). For ultrafine particles, the 2009 PM ISA concluded the evidence was "suggestive of a causal relationship" for short-term exposure and cardiovascular and respiratory effects, but "inadequate to infer a causal relationship" for short-term exposures and central nervous system effects and mortality, and for long-term exposure and all health effects (U.S. EPA, 2009, as summarized in Chapter 2). For welfare effects, the evidence indicated a "causal relationship" for PM exposures and effects on visibility, climate, and materials; and a "likely to be causal relationship" for PM exposures and ecological effects (U.S. EPA, 2009, as summarized in Chapter 2).

The causal determinations in the 2009 PM ISA, based on the causal framework and integration of available evidence from previous and recent studies, were presented with a summary of the available evidence at the end of the sections for each broad health and welfare effect category and in the integrative synthesis chapter at the beginning of the PM ISA. In the current review, specific policy-relevant questions related to the causal determinations that will be addressed include:

- Does the evidence base from recent studies contain new information to support or re-evaluate the causal determinations made for relationships between PM exposure and various health and welfare effects in the 2009 PM ISA?
- Does new evidence confirm or extend biological plausibility of PM-related health effects?
- What is the strength of inference from epidemiologic studies based on the extent to which they have:
  - Examined exposure metrics that capture the spatial and/or temporal pattern of PM in the study area?
  - Assessed potential confounding by other pollutants and factors?
- What information is available to support a rationale for forming causal determinations for PM size fractions other than $PM_{2.5}$, specific PM components, or PM from specific sources?
- What information is available regarding the health impacts of a decrease in ambient PM concentrations to inform causal determinations?

3.4.2 Uncertainties/Limitations Identified in 2009 PM ISA

The causal determinations described above for the relationships between $PM_{2.5}$, $PM_{10-2.5}$, and UFPs exposure and health and welfare effects were informed by uncertainties and limitations in the evidence. For example, the 2009 PM ISA noted a number of uncertainties and limitations in the health evidence, such as the heterogeneity often observed in multi-city epidemiologic studies and whether this can be attributed to exposure differences or regional differences in PM components or sources; and uncertainty related to the use of ambient PM concentrations from central-site monitors and their ability to represent personal ambient PM exposure (U.S. EPA, 2009, Chapter 2). In each of the health and welfare effects sections, and the integrative synthesis chapter, the PM ISA will evaluate uncertainties and limitations in the scientific data. These uncertainties also will inform causal determinations. The PM ISA will evaluate potential confounding by other ambient pollutants. To assess the independent effects of PM, the PM ISA will examine whether epidemiologic associations with PM are observed in copollutant models. Copollutant models are the predominant method used in air pollution epidemiology to estimate

the effect of one pollutant for a given concentration of a copollutant. The PM ISA also will evaluate whether PM has interactions with copollutants or joint effects in associations with health outcomes. The assessment of potential confounding, interactions, or joint effects will draw upon results from health effects studies, available information on copollutant interactions in the atmosphere that influence the spatial distributions of PM and copollutants, as well as information from experimental studies that examine the health effects of PM exposures alone and PM in combination with other pollutants. In the absence of these aforementioned methods, the PM ISA will examine whether single-pollutant epidemiologic associations with health effects in a given study differ between PM and copollutants, and if insights regarding potential copollutant confounding can be gained by examining the magnitude of correlation between pollutants.

Drawing from discussion about the strengths and limitations of various exposure assessment methods, the PM ISA will evaluate the strength of inference in epidemiologic studies by considering information such as the exposure duration being examined, the extent of spatial and/or temporal variability in PM in the study area, the distribution of monitoring sites in the study area, the performance of exposure models used, and time-activity patterns of the study population. Additionally, monitoring data will be used to characterize the spatial distributions in ambient PM concentrations and human exposures, and in turn, the potential exposure measurement error in particular study areas based on the particular method of exposure assessment used. The adequacy of exposure assessment in epidemiologic studies will be considered in weighing the quality of evidence, and in turn, forming causal determinations.

Epidemiologic evidence is unlikely to completely address the uncertainties mentioned above. Any individual study is unlikely to evaluate all potentially correlated copollutants, and the limitations of epidemiologic methods in separating effects of highly correlated pollutants or separating the effects of more than two pollutants in the same model are well recognized. With respect to exposure measurement error, few studies with personal ambient exposure measurements are likely to be available. Thus, coherence with other lines of evidence may strengthen inferences when there are uncertainties in epidemiologic evidence due to copollutant confounding or exposure measurement error. Controlled human exposure and toxicological studies that demonstrate similar effects at relevant PM exposures may provide coherence with epidemiologic evidence. Further, experimental results that identify key events in the mode of action may provide biological plausibility.

In the 2009 PM ISA, a number of uncertainties were identified with respect to quantitative relationships between PM and effects on welfare. Although ecological effects due to PM deposition were described in the previous ISA, there was a lack of information linking specific ambient concentrations of PM to impairment of ecological receptors. For materials effects, the

rate of deposition of PM onto surfaces was identified as an uncertainty as was the role of co-pollutants in soiling effects. The 2009 PM ISA identified uncertainties in assessment of climate effects including quantification and modeling of aerosols and relating observed effects to measured concentrations of ambient PM. For visibility in the 2009 PM ISA, there were uncertainties associated with the visibility preference studies and insufficient urban monitoring data. The PM ISA will evaluate the status of these uncertainties and limitations in each of the welfare effects sections and this information will be used in the development of causal determinations.

3.4.3 Integration of Evidence and Causal Determinations

As described in the Preamble to the Integrated Science Assessments {U.S. EPA, 2015, 3037426}, the EPA uses a structured framework to provide a consistent and transparent basis for classifying the weight of available evidence for health and welfare effects according to a five-level hierarchy: (1) causal relationship; (2) likely to be a causal relationship; (3) suggestive, but not sufficient, to infer a causal relationship; (4) inadequate to infer a causal relationship; and (5) not likely to be a causal relationship. In the framework, key considerations in drawing conclusions about causality include consistency of findings for an endpoint across studies, coherence of the evidence across disciplines and across related endpoints, and biological plausibility. As judged by these parameters, evidence that rules out chance, confounding, and other biases with reasonable confidence is sufficient to infer a causal relationship. Increasing uncertainty due to limited available information, inconsistency, and/or limited coherence and biological plausibility leads to conclusions lower in the hierarchy. Causality determinations are based on the confidence in the integrated body of evidence, considering study design and quality and strengths and weaknesses in the overall collection of previous and recent studies across disciplines. In discussing each determination of causality, the EPA characterizes the evidence upon which the judgment is based, including the weight of evidence for individual endpoints within the health or welfare effect category or group of related endpoints.

For evaluation of human health effects, determinations of causality are made for major health effect categories (e.g., respiratory effects) or more specific groups of related outcomes and for the range of exposure concentrations of PM defined to be relevant to ambient concentrations (e.g., up to 2 mg/m^3). Findings based on higher exposure concentrations may be considered if they add to the understanding of biological plausibility, provided that they do not reflect different biological mechanisms operating at higher concentrations. The main lines of evidence for use in causal determinations for human health are controlled human exposure, epidemiologic, and toxicological studies. Evidence is integrated from previous and recent studies. Other information

including mechanistic evidence, toxicokinetics, and exposure assessment may be drawn upon if relevant to the evaluation of health effects and if of sufficient importance to affect the overall evaluation. The relative importance of different sources of evidence to the conclusions varies by pollutant or assessment, as does the availability of different sources of evidence when making a determination regarding causality. In judgments of causality, scientists will also evaluate uncertainty in the scientific evidence, considering issues such as generalizing results from a small number of controlled human exposure subjects to the larger population; extrapolations of observed pollutant-induced pathophysiological alterations from laboratory animals to humans; confounding by co-exposure to other ambient pollutants, meteorological factors, or other factors; the potential for effects to be due to exposure to air pollution mixtures; and the influence of exposure measurement error on epidemiologic study findings. Judgments of causality also are informed by the extent to which uncertainty in one line of evidence (e.g., potential copollutant confounding in epidemiologic results) is addressed by another line of evidence (e.g., coherence of effects observed in epidemiologic studies with experimental findings, mode of action information). Thus, evidence integration is not a unidirectional process but occurs iteratively within and across scientific disciplines and related outcomes.

A similar process is used for the integration of evidence and determination of causality for welfare-related effects. For ecological effects, several types of experimental approaches (e.g. field studies, mesocosm, controlled laboratory exposures, gradient) may be relevant for assessing PM effects to ecosystems. Field studies measure biological changes in uncontrolled situations and describe an association between a disturbance and an ecological effect. They are most useful for linking stressors with effects when stressor and effect levels are measured concurrently. The presence of confounding factors can make it difficult to attribute observed effects to specific stressors. Mesocosm studies are performed in the natural environment while controlling for some, but not all, of the environmental conditions and can be considered a hybrid between a field and a laboratory study. Controlled exposure studies provide the strongest evidence for causality, however the scope of inference to conditions in natural systems may be limited. Studies where effects are observed at relevant ambient concentrations are weighted more heavily, however, studies conducted at higher concentrations can inform the understanding of mode of action in aquatic and terrestrial organisms. The EPA evaluates evidence relevant to understanding the quantitative relationships between pollutant exposures and ecological effects. Integration of evidence for visibility and climate draws upon modeling and monitoring data as well as experimental approaches designed to characterize the role of PM in atmospheric processes. In the case of visibility, new preference studies designed to quantitatively assess the impact of PM on visibility will also be incorporated if available. This includes evaluating the C-R or deposition-

response relationships and, to the extent possible, drawing conclusions on the levels at which effects are observed. For materials effects, evidence of corrosive and soiling effects on stone, metals, paint and other surfaces at relevant concentrations of PM will be considered. Generally, a causal determination is made based on many lines of evidence that reinforce each other and are based on integrating evidence from both previous and recent studies.

3.4.4 Atmospheric Chemistry and Ambient Concentrations of PM

The PM 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; the deposition of PM; and chemical reactions that determine the formation, transformation, and lifetime of PM in the atmosphere. Specific policy-relevant questions related to atmospheric chemistry and ambient concentrations that will be addressed in the PM ISA include:

- What are the strengths and limitations of existing and new measurement methods and approaches (including low cost sensors and remote sensing) for both advancing science and providing routine measurements of particulate matter? What are the important biases and uncertainties associated with existing and new monitoring methods? How do new methods and approaches compare with or complement routine measurement tools (e.g., FRMs)?
- What changes have occurred in primary PM and PM precursor emissions rates over time? Can the impacts of biomass burning (including occurrence of more fires due to climate change and potentially identification of more fires with more sensitive sensors on satellites), new transportation and industrial technologies, improved industrial and motor vehicle emission controls, and strategies for accounting for semi-volatile organic emissions be observed in current atmospheric PM concentrations? What are the uncertainties associated with source apportionment approaches, whereby individual PM sources can be distinguished as a function of the chemical composition of the emitted PM?
- What changes have occurred in the quantities of sulfate (SO_4^{2-}), nitrate (NO_3^-), and secondary organic PM (SOPM) formed in the atmosphere over time? What new information is available regarding mechanisms of their production, including aqueous phase SOPM formation, the role of sulfur and nitrogen in SOPM formation, and the role of semi-volatile species? Have the relative contributions of primary and secondary PM components changed as a result of decreases in precursor emissions?
- What are the current ambient concentrations of different size fractions of PM (i.e., $PM_{2.5}$, $PM_{10-2.5}$, UFP), and how have they changed over time? What are the uncertainties in the spatial and temporal distributions of PM? How do those patterns vary with particle size fraction?
- What uncertainties exist concerning the sources and atmospheric chemistry of PM components (both primary and secondary particles)? How does PM composition change over various spatial and temporal scales? What new information is available

regarding the composition of the PM size fractions that could not be well characterized during the last review (e.g., coarse PM, ultrafine PM)?

- How does intercontinental or trans-boundary transport of pollutants contribute to background PM concentrations? What information is available to quantify the emissions from natural PM sources that contribute to background PM concentrations? Is there enough information to estimate background concentrations of PM species?

The information provided in the Atmospheric Chemistry and Ambient Concentrations chapter will provide context for understanding ambient concentration data used as surrogates for human exposure and for interpretation of the health and welfare effects evidence in subsequent chapters.

3.4.5 Human Exposure

The PM ISA will evaluate methods for estimating exposure to ambient PM, the factors that influence exposure to PM, as well as the ability to make inferences about personal exposure to ambient PM when extrapolating from ambient concentration data, particularly in the context of interpreting results from epidemiologic studies, and from controlled human exposure, animal toxicology, and *in vitro* chamber studies of near-atmospheric conditions. The issues surrounding the ability to make inferences about personal exposure differ by the exposure period of interest. Short-term exposure studies (i.e., exposures ranging from hours to days to weeks) primarily rely on temporal variation in exposure while long-term exposure studies (i.e., exposures ranging from months to years) rely on spatial variability of exposure. The PM ISA will consider the available information on differential exposures to UFPs, $PM_{2.5}$, and $PM_{10-2.5}$ and on particle characteristics such as chemical composition, size, surface area, number, and source. Specific policy-relevant questions related to human exposure that will be addressed in the PM ISA include:

- Are new models or other techniques available to estimate human exposure to ambient PM? What are the strengths and limitations of existing and new techniques? Do any of these techniques characterize PM by size fraction or composition?
- What techniques are available to replicate human exposure to ambient PM in controlled human exposure, animal toxicology, and *in vitro* experiments? What factors lead to uncertainty in the exposure conditions established within these experiments? What factors affect inference about human exposure from such experiments?
- What are the limitations in our understanding of exposures to PM components, size fractions, sources/environments, and relationships between exposure to specific PM size fractions and/or components and corresponding exposure to gaseous co-pollutants? What uncertainties exist regarding the spatial and temporal patterns of PM

concentrations, size fractions, and components as they relate to patterns of human exposure?

- What are the uncertainties when extrapolating from stationary PM monitoring instruments to personal exposure to PM of ambient origin, especially in populations at increased risk of PM-related health effects? 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 are the uncertainties associated with using measurements of ambient concentrations of PM to 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?
- Higher sampler density is more likely for saturation samplers or low-costs sensors than for other measurement tools with greater sensitivity and precision. How does sampler density affect data quality objectives needed for individual samplers, particularly for saturation samplers or low-cost sensors?
- What limitations exist for interpretation of sub-daily, daily, and longer-term PM concentration data used to estimate exposures? How do factors such as air exchange rates, indoor sources, ambient sources, and methods for measuring personal exposures to ambient PM influence interpretation of PM concentration data over different sampling periods? Does this information differ by PM characteristics (e.g., size, chemical composition, sources/environments)?
- What new developments have occurred with respect to chemical transport modeling of short-term and long-term PM concentrations for use in exposure assessment? How might modeling and satellite data supplement monitoring data for understanding human exposures? What are the limitations of using modeling or satellite data in lieu of monitoring data? What advancements have been made with respect to techniques for fusing modeling, monitoring, and/or satellite data for assessing long-term exposures to ambient PM? What are the uncertainties in data from chemical transport models and satellites at the extremes of the concentration distribution, such as in low concentration areas?
- What new developments have been made in use of source apportionment techniques for assessing human exposure to ambient PM?
- What new developments have been made in assessing and/or correcting the influence of exposure measurement error on health effect estimates for epidemiologic studies of short-term and long-term exposure? How do these methods reduce the uncertainty and/or bias in the health effect estimates for PM exposure?

3.4.6 Dosimetry

The PM ISA will evaluate literature focusing on dosimetry that may underlie the health outcomes associated with exposure to PM. In Chapter 4 of the 2009 PM ISA, in relation to

particle deposition in the body, it was concluded that the first line of defense for protecting the lower respiratory tract from inhaled particles is the nose and mouth; that the lower respiratory tract of children receive a higher surface dose of ambient PM compared to adults; and that people with COPD generally have greater total deposition and more heterogeneous deposition patterns compared to healthy individuals. In relation to particle clearance, it was concluded that particles depositing on the olfactory mucosa may translocate to the brain; and that a small, but statistically significant fraction (<1% of deposited material) of poorly soluble particles deposited in the alveolar region may translocate into circulation. A number of factors such as age and respiratory disease were recognized as affecting both rates of deposition and clearance. Interspecies differences in deposition and clearance were also discussed. In the current review, specific policy-relevant questions related to dosimetry that will be addressed in the PM ISA include:

- Are there new data that better quantify extrathoracic and thoracic deposition of particles in children, adults, and among species?
- Are new data available evaluating the effects of respiratory disease on deposition and clearance?
- What new data or models are available that help facilitate interspecies comparisons?
- Is there new information related to the translocation of particles into circulation or the olfactory bulb?

3.4.7 Modes of Action

The PM ISA will evaluate literature focusing on modes of action that may underlie the health outcomes associated with exposure to PM. These topic areas will be developed using both human and animal data. In the current review, specific policy-relevant questions related to modes of action that will be addressed include:

- How do physical-chemical particle characteristics influence biological responses to inhaled PM?
- What new evidence is available to characterize biologic responses of various PM size fractions or PM from different sources?
- What are the time-courses of biological responses to inhaled PM? What are the implications of these time-courses for health effects associated with short-and long-term exposure to PM?
- What are the interspecies differences in biological responses to inhaled PM? What are the implications of interspecies differences for extrapolation of results to humans?
- Is there a common underlying biological response (e.g., inflammation) that supports an effect of PM exposure on an array of health outcomes (e.g., cardiovascular, respiratory, or nervous system)?

- What new evidence is available to elucidate mechanisms by which pulmonary deposition of PM leads to extrapulmonary effects?

3.4.8 Health Effects

In the 2009 PM ISA, the health effects evidence for PM largely focused on $PM_{2.5}$; fewer studies were available for $PM_{10-2.5}$, UFPs, and sources/components of PM. The evidence indicated that a "causal relationship exists" for short- and long-term exposures to $PM_{2.5}$ and cardiovascular effects and mortality, and a "likely to be causal relationship exists" for short- and long-term $PM_{2.5}$ exposures and respiratory effects. More limited evidence with a larger degree of uncertainty formed the basis for the determinations for other health effects and other PM size fractions (i.e., $PM_{10-2.5}$ and UFPs). Additionally, with respect to sources and PM components, the EPA concluded "that many PM [components] can be linked with differing health effects and the evidence is not yet sufficient to allow differentiation of those [components] or sources that are more closely related to specific health outcomes (U.S. EPA, 2009, p. 2-26)" The EPA will build on the 2009 PM ISA by evaluating the newly available literature related to PM exposures and health effects, including, but not limited to respiratory, cardiovascular, neurologic, reproductive and developmental effects, mortality, and cancer. Depending on data availability, other health effects may be evaluated.

The PM ISA will evaluate health effects that occur following both short- and long-term exposures as examined in epidemiologic, controlled human exposure, and animal toxicological studies. Efforts will be directed towards identifying the concentrations at which effects are observed, particularly in potential at-risk lifestages and populations, and assessing the role of PM within the broader mixture of ambient air pollutants. The data will be reviewed for relevance to the current elements of the PM NAAQS (i.e., indicator, averaging time, form, and level) in order to support decisions regarding the adequacy of the current primary standard. Additionally, the evidence will be evaluated to determine whether specific chemical components and/or source(s)/environment(s) (e.g., near-road) more fully explain PM health effects. The discussion of health effects will be integrated with relevant information on dosimetry and modes of action, as well as with information from the exposure chapter.

In light of recent International Agency for Research on Cancer (IARC) conclusions on the carcinogenicity of outdoor air pollution, and specifically of PM, it is important for the EPA to clearly outline its approach for evaluating the relationship between long-term PM exposures and cancer in the PM ISA (Loomis et al., 2013). While IARC focuses on whether a chemical is a carcinogen at any concentration and through any route of exposure, the PM ISA focuses on whether PM can directly cause cancer through inhalation exposures at ambient and near-ambient

concentrations. When evaluating the epidemiologic evidence for cancer, the EPA will focus on those studies with composite measures of PM and with exposures consistent with the overall scope of the PM ISA detailed in Section 3.1, i.e., concentrations of PM that represent the range of human exposures across ambient microenvironments (up to 2 mg/m^3 PM, which is one to two orders of magnitude above ambient concentrations). For the toxicological evidence, the EPA will describe in vitro studies and other mechanistic studies related to cancer in the Mode of Action chapter because these types of studies are pertinent to the biological pathways underlying cancer. Consistent with previous ISAs, in vivo studies that examine cancer-related endpoints will be discussed in combination with the epidemiologic evidence in the health chapters. The evaluation of toxicological studies related to mutagenicity, genotoxicity, epigenetic changes, and carcinogenicity will focus on inhalation exposures primarily at ambient relevant concentrations (i.e., up to 2 mg/m^3) with the potential inclusion of exposures above this concentration. Lastly, the evaluation of cancer will not focus on studies that use PM filter extracts because they may not mimic what is bioavailable in vivo, or on studies of individual PM components due to the inability to compare effects to the current mass-based PM indicator.

In the current review, specific policy-relevant questions that will be addressed in consideration of health effects associated with short- and long-term exposure to PM, include the following:

Short-Term Exposure:

- What new evidence is available to inform policy-relevant considerations of the PM NAAQS (e.g., considerations related to indicator, averaging time, form, level) for those health categories where the 2009 PM ISA concluded that a "causal relationship" exists (i.e., short-term $PM_{2.5}$ exposures and mortality and cardiovascular effects)? Do new controlled human exposure and toxicological studies continue to provide support for biologically plausible relationships between short-term PM exposures and cardiovascular health effects? Do new studies report PM-attributable effects at lower PM concentrations than indicated by studies available in the last review?
- How do results of recent studies expand understanding of the relationship between short-term exposure to PM and respiratory effects, such as exacerbation of asthma or chronic obstructive pulmonary disease and respiratory infection? Does recent evidence improve coherence across disciplines for lung function changes, pulmonary inflammation, host defense mechanisms, and outcomes such as symptoms, hospital admissions, or emergency department visits?
- To what extent is short-term exposure to PM related to or associated with the progression of diabetes, other metabolic diseases, and/or to other endocrine system effects? To what extent are new health outcomes related to or associated with PM exposures?

- Across the evaluated health effects, what new evidence is available on effects occurring from exposures at averaging times different (e.g., 1-hour) than the current 24-hour average PM NAAQS?

Long-Term Exposure:

- What new evidence is available to inform policy-relevant considerations of the PM NAAQS (e.g., considerations related to indicator, averaging time, form, level) for those health categories where the 2009 PM ISA concluded that a "causal relationship" exists (i.e., long-term $PM_{2.5}$ exposures and mortality and cardiovascular effects)? Do new controlled human exposure and toxicological studies continue to provide support for biologically plausible relationships between long-term PM exposures and cardiovascular health effects? Do new studies report PM-attributable effects at lower PM concentrations than indicated by studies available in the last review?
- To what extent do recent studies improve understanding of the relationships between long-term PM exposure and the development of asthma or to the impairment of lung development? Do recent studies improve coherence across disciplines for respiratory disease incidence, pulmonary inflammation and oxidative stress, and development of allergic responses?
- To what extent do recent studies improve understanding of the relationship between long-term PM exposure and reproductive and developmental health outcomes, such as adverse birth outcomes, fertility and pregnancy outcomes (e.g., infertility, sperm quality, preeclampsia, gestational hypertension), or developmental outcomes (e.g., neurocognitive ability)?
- To what extent does new literature support a biologically plausible relationship between long-term PM exposures and a number of nervous system effects (e.g., cognitive decline and autism)?
- How do results of recent studies expand our understanding of the relationship between long-term PM exposure and cancer, mutagenic, genotoxic, and epigenetic effects? To what extent does the evidence indicate that long-term exposure to PM can increase the incidence of cancer?
- To what extent is long-term exposure to PM related to or associated with the development of diabetes and other metabolic diseases, as well as to health effects in the endocrine system or other organ systems? To what extent are new health outcomes related to or associated with PM exposures?

Additional Policy-Relevant Considerations:

- Across the evaluated health effects, to what extent does new evidence inform the understanding of differential effects from exposures to various PM size fractions (i.e., $PM_{2.5}$, $PM_{10-2.5}$, UFPs)?
- Do studies of mortality, hospital admissions, or emergency department visits provide new information to improve our understanding of the potential heterogeneity in effects observed across the U.S. in multi-city studies?

- How do recent studies support the attribution of health effects to one or more PM component(s) or source(s), in addition to PM mass, for health effects for which there is sufficient evidence of a strong relationship (e.g., cardiovascular effects, mortality) with PM exposure?
- How do the results of recent studies inform the shape of the concentration-response relationship for PM and various health outcomes (e.g., mortality, hospital admissions, etc.), especially for concentrations near or below the levels of the current PM NAAQS?
- What new evidence adds to the understanding of which lifestages and populations are at risk of PM-related health effects?
- What new evidence supports evaluation of inter-individual variability in response to PM exposures?
- Across health effects, what new information is available to delineate the effects of chronic exposure to lower concentrations versus acute, repeated exposures to higher concentrations of PM?
- What is the nature of health effects in persons exposed to multipollutant mixtures that contain PM in comparison to exposure to PM alone?

3.4.9 At-Risk Lifestages and Populations and Public Health Impact

The PM ISA will evaluate an array of factors that may contribute to increased risk of PM-related health effects for various lifestages or populations. These factors reflect the multiple avenues through which a lifestage or population may be at increased risk of an air pollutant-related health effect, specifically: intrinsic factors (e.g., biological factors such as age or genetic variants), extrinsic factors (nonbiological factors such as diet, low SES), and/or factors affecting dose or exposure (e.g., sex, age, outdoor activity or work, low SES, physical activity). It is also important to recognize the interconnectedness among these factors that may also confer increased risk, an example being pre-existing diseases or conditions and socioeconomic status. The 2009 PM ISA evaluated studies that provided evidence that children, older adults, people with pre-existing cardiopulmonary diseases, and people with lower SES are at increased risk of PM-related health effects (U.S. EPA, 2009, Chapter 8). Since completion of the 2009 PM ISA, the EPA has developed a more detailed framework to provide a consistent and transparent basis for communicating the overall confidence in the evidence that a particular factor may increase the risk of an air pollutant-related health effect for a lifestage or population according to one of four levels: adequate evidence, suggestive evidence, inadequate evidence, and evidence of no effect (U.S. EPA, 2013c, Table 8-1). Key considerations in characterizing the evidence include consistency of findings for a factor within a discipline and, where available, coherence of the evidence across disciplines as well as biological plausibility. Several lines of evidence inform

conclusions about at-risk lifestages and populations, but primarily include observational or experimental studies that compare exposure to PM or relationships with health effects among groups that vary by some characteristic, such as pre-existing disease or age (i.e., exposure or effect modification). Also relevant are comparisons of results among observational or experimental studies that examine different lifestage or population characteristics or time windows of exposure and experimental studies that examine health effects of PM in a group with a particular characteristic (e.g., genetic background, pre-existing disease). Where possible, the discussion will also include evaluation of the adversity of the health effects potentially associated with exposure to PM. The assessment of public health impact also may include, as appropriate, an estimation of the sizes of potential at-risk lifestages and populations. Further, to the extent that evidence is available, the at-risk chapter of the PM ISA will discuss what evidence is available regarding interrelationships among risk factors in a particular lifestage or population as described in the preceding section that may add to the understanding of the public health impact of exposure to PM. Specific questions include:

- Is there new information that identifies a combination of factors (i.e., co-occurring) that can lead to one lifestage or population being at greater risk compared to another?
- Have recent studies characterized whether certain lifestages or populations experience differential exposures to PM mass, PM components or PM sources, which may contribute to them being at increased risk?
- What new evidence is available regarding additional lifestages or populations (e.g., pre-existing diseases such as diabetes, pregnant women) potentially at increased risk of a PM-related health effect?
- Have recent studies been able to delineate whether those lifestages or populations at increased risk of a PM-related health effect differ depending on exposures to different PM size fractions, PM components, or PM sources?

3.4.10 Welfare Effects

In the 2009 PM ISA, the welfare effects evidence for PM focused on the effects of airborne PM, including NO_x and SO_x, on visibility and climate, and on the effects of deposition of PM constituents other than NO_x and SO_x, primarily metals and carbonaceous compounds on materials and ecology. The evidence indicated that a "causal relationship exists" for PM exposures and effects on visibility, climate, and materials; and a "likely to be causal relationship exists" for PM exposures and ecological effects. The EPA will build on the 2009 PM ISA by evaluating the newly available literature related to PM exposures and welfare effects, specifically ecological effects, visibility, climate, and materials.

Ecological Effects

The PM ISA will summarize studies of impacts of PM deposition with the secondary NO_x/SO_x ISA covering the depositional effects of N and S on ecological receptors. As indicated in the previous ISA, chemical components of PM determine ecological response to a greater degree than PM size class. However, size fraction may play a role in direct effects such as deposition on vegetative surfaces near PM sources. In regards to effects of PM on ecosystem components (e.g. plants, soils, wildlife, nutrient cycling), both direct and indirect effects of PM deposition will be considered. PM deposited directly on vegetative surfaces may impair photosynthesis and gas exchange between the plant and the atmosphere. Indirect effects of trace metals and organics associated with PM deposition on ecosystem receptors including aquatic and terrestrial organisms, as well as effects on ecosystem structure and function, will be evaluated. If studies are available that link PM deposition to ecosystem services these findings will be discussed. Specific questions include:

- Is there new information on PM that can be correlated to a specific physiological response in aquatic and terrestrial biota?
- Do new studies show effects on ecosystem structure, function and biodiversity or PM impacts to ecosystem services?

Visibility Effects

The PM ISA will summarize long-known information needed for placing current information in context with respect to visibility. 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, airborne 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 anthropogenic, biogenic, 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 SOPM generation. The PM 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. Specific questions include:

- What relationships exist between ambient PM and visibility impairment? How do these relationships vary between urban and rural settings?
- What metrics and algorithms are available to estimate visibility impairment as a function of PM mass, optical characteristics, and composition?
- What role do spatial patterns (e.g., elevated particulate nitrate in the midwestern U.S. and enhancement of sulfate concentrations in the eastern U.S.), seasonal patterns, multi-year trends, emissions changes, and meteorology play with respect to PM effects on visibility?
- What new preference studies or other metrics are available to describe the extent to which PM-related visibility impairment may be considered adverse to public welfare?

Climate Effects

The PM ISA will present information on radiative forcing and climate change impacts of PM and PM components. Background information on the physics of climate and radiative forcing and observed trends in anthropogenic and natural PM will be presented as well as climate impacts of changes in anthropogenic PM since preindustrial times. Focus will be on information necessary for interpretation of effects described in the chapter and on newly available information since the last ISA. PM size/effect dependencies (e.g., cloud formation and precipitation) and PM composition/effect dependencies (e.g., black carbon and sulfate aerosol) will be addressed as they pertain to climate effects.

- What are the important and relevant climate metrics used to quantify PM-related climate effects and what are their strengths and limitations in assessing climate effects at different temporal and spatial scales?
- What is the current understanding of the magnitude and direction (warming vs. cooling) of PM climate impacts and what important uncertainties remain?
- To what extent do we understand the independent effect of PM on climate in the broader context of other climate forcers?
- What is the current state of knowledge of PM size and composition in relation to climate forcing and what is the relationship between PM metrics (e.g., size, composition) and important and relevant climate metrics used to quantify PM-related climate effects?
- What recent advancements have been made in understanding PM effects on regional climate in the U.S.?

Materials Effects:

The PM ISA will summarize soiling and deterioration of materials attributable to PM and related N and S components because of the difficulty associated with isolating the effects of gaseous and particulate N and S wet deposition and the NOx/SOx secondary ISA only focuses

on ecological effects, not other welfare effects (See Section 1.4). Previous PM assessments indicated that stone, paint, metal and other materials can become discolored and/or undergo corrosion processes from particle pollution. Culturally important items such as buildings, statues or works of art can be physically damaged and/or lose aesthetic appeal. The focus of the PM ISA will be on whether there is new information on soiling and corrosion, dose-response relationships between PM or related N and S species and damage to surfaces. Any new areas of research focus on PM-related materials effects will also be emphasized in the PM ISA.

- Is there new information on soiling of stone, metal and paint surfaces due to PM or related N and S species? Corrosive effects?
- Do new studies show effects on additional types of materials?

3.5 QUALITY MANAGEMENT

Within the EPA, Quality Management Plans (QMP) are developed to ensure that all Agency materials meet a high standard for quality. NCEA-RTP participates in the Agency-wide Quality Management System, which requires the development of a QMP. Implementation of the NCEA QMP ensures that all data generated or used by NCEA scientists are "of the type and quality needed and expected for their intended use" and that all information disseminated by NCEA adheres to a high standard for quality including objectivity, utility, and integrity. Quality assurance (QA) measures detailed in the QMP will be employed for the development of the PM ISA. NCEA QA staff will be responsible for the review and approval of quality-related documentation. NCEA scientists will be responsible for the evaluation of all inputs to the PM ISA, including primary (new) and secondary (existing) data, to ensure their quality is appropriate for their intended purpose. NCEA adheres to Data Quality Objectives, which identify the most appropriate inputs to the science assessment and provide QA instruction for researchers citing secondary information. The approaches utilized to search the literature and criteria applied to select and evaluate studies were detailed in the two preceding subsections. Generally, NCEA scientists rely on scientific information found in peer-reviewed journal articles, books, and government reports. The PM ISA also can include information that is integrated or summarized from multiple sources to create new figures, tables, or summation, which is subject to rigorous quality assurance measures to ensure their accuracy.

3.6 SCIENTIFIC AND PUBLIC REVIEW

Drafts of the PM ISA will be made available for review by the CASAC and the public as indicated in Figure 1-1 and Tables 1-1 and 1-3 above. Availability of draft documents will be announced in the *Federal Register*. The CASAC will review the draft PM ISA documents and

discuss its comments in public meetings that will be announced in the *Federal Register*. The EPA will take into account comments, advice, and recommendations received from the CASAC and from the public in revising the draft PM ISA documents. The EPA has established a public docket for the development of the PM ISA.[81] After appropriate revision based on comments received from the CASAC and the public, the final document will be made available on the EPA website. A notice announcing the availability of the final PM ISA will be published in the *Federal Register*.

[81] The ISA docket can be accessed at www.regulations.gov using Docket ID number EPA-HQ-ORD-2014-0859.

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4 HUMAN HEALTH RISK AND EXPOSURE ASSESSMENT

4.1 INTRODUCTION

Within the context of NAAQS reviews, a quantitative health risk and exposure assessment (HREA) is designed to estimate human exposure and health risks associated with the existing primary standards and with potential alternative primary standard(s), if any, that might be appropriate to consider. This assessment can inform conclusions on the adequacy of the public health protection provided by just meeting these standards. The purpose of this chapter is to highlight key findings from the quantitative risk assessments conducted in the last review of the PM NAAQS and to identify key issues to be addressed in planning for any additional quantitative assessments that might be warranted for the current review. The scope of any HREA would be informed by the scientific evidence in the upcoming PM ISA; existing and historical air quality patterns and trends; the availability of improved data, methods, tools, and models that may better characterize important uncertainties or provide additional insights beyond those provided by prior HREAs; and available resources.

In the upcoming HREA Planning Document (discussed in sections 1.2 and 1.5, above), the EPA will evaluate newly available information within the context of the 2010 HREA from the last review of the PM NAAQS to determine 1) the extent to which important uncertainties may be better characterized by information newly available for the current review and 2) the extent to which this new information may affect the health risks estimated in the 2010 HREA in important ways or suggest new quantitative analyses that can increase our understanding of the health risks associated with ambient PM exposures. The HREA Planning Document will also describe the scope and methods for any new or updated quantitative assessments warranted for this review. CASAC advice and public comments on this draft IRP will be considered in developing the HREA Planning Document, which will also be subject to CASAC review and will be made available for public comment. If warranted, one or more drafts of an HREA would then be prepared and released for CASAC review and public comment prior to completion of a final HREA.

Section 4.2 describes the key analyses, findings and uncertainties from the 2010 HREA. Section 4.3 describes the two major components of potential new quantitative health risk assessments (i.e., epidemiology-based risk assessment and exposure assessment) that the EPA will further evaluate in the HREA Planning Document. Section 4.4 describes the process for obtaining scientific and public review of the HREA Planning Document and the HREA itself.

4.2 OVERVIEW OF HEALTH RISK AND EXPOSURE ASSESSMENT FROM THE LAST REVIEW

In the last review of the PM NAAQS, the EPA conducted a quantitative, epidemiology-based risk assessment for selected health endpoints to provide information and insights that could help inform decisions on the primary standards, namely, the degree of protection provided by the then-existing suite of primary standards, as summarized below (in sections 4.2.1 and 4.2.2). The 2010 HREA (U.S. EPA, 2010a) characterized risk associated with ambient fine particle ($PM_{2.5}$) concentrations because at that time it was decided that any risks estimated using the limited data available for thoracic coarse (i.e., $PM_{10-2.5}$) and ultrafine particles would have uncertainties too large to provide reasonable and informative results for the review. The 2010 HREA quantified endpoints from health effect categories classified as having a "causal" or "likely to be causal" relationship with exposure to $PM_{2.5}$ in the 2009 PM ISA (U.S. EPA, 2009a). Endpoints included total, cardiopulmonary, and lung cancer mortality associated with long-term ($\geq$ 1 year) exposure to $PM_{2.5}$, and mortality (total non-accidental, cardiovascular, and respiratory) and morbidity (hospital admissions for cardiovascular and respiratory causes and respiratory symptoms not requiring hospitalizations) associated with short-term (24-hour) $PM_{2.5}$ exposures. The 2010 HREA quantified health risks associated with ambient $PM_{2.5}$ concentrations (as a surrogate for population exposure) in fifteen urban study areas (U.S. EPA, 2010a, section 3.1).[82] In addition, the 2010 HREA included a representativeness analysis that contrasted these urban study areas against national-level patterns and trends for key PM related attributes (e.g., $PM_{2.5}$ composition, demographics, and weather) and the total number of deaths that could be attributed to $PM_{2.5}$ (U.S. EPA 2010a, sections 4.4.1 and 4.4.2). The 2010 HREA focused on estimating risk remaining with $PM_{2.5}$ concentrations adjusted to just meet the then-existing primary $PM_{2.5}$ standards (15.0 $\mu g/m^3$ annual and 35 $\mu g/m^3$ 24-hour, which are abbreviated here as 15/35[83]), as well as risk reductions from just meeting alternative suites of standard levels (relative to 15/35). The EPA did not conduct a quantitative population-based, microenvironmental exposure assessment (such as described below in section 4.3.2) due to concerns related to the utility of such an assessment from both staff and CASAC (Samet, 2009a).

[82] The 2010 HREA only estimated remaining risk and risk reductions for the urban areas where $PM_{2.5}$ improvements were needed to just meet the then-existing standards and alternative suites of standards. As described below, two of the 15 urban study areas did not exceed existing standards.

[83] In discussing the then-existing standards and alternative suites of $PM_{2.5}$ standards, the notation used throughout this document is "annual standard/24-hour standard" in units of $\mu g/m^3$.

The health endpoints evaluated in the 2010 HREA were selected based on: 1) the overall weight of evidence and subsequently causal determinations in the 2009 PM ISA for general health effect categories that is based on the collective body of evidence from epidemiologic, controlled human exposure, and toxicological studies; 2) the extent to which particular health endpoints within these broader health effect categories are considered important from a public health perspective; 3) the availability of epidemiologic studies providing effect estimates for specific health endpoints; 4) the availability of air quality monitoring data in urban areas that were evaluated in the epidemiologic studies; 5) the availability of baseline incidence and prevalence data[84] to support population risk (incidence) modeling; and 6) the anticipated usefulness of developing quantitative risk estimates[85] for the health endpoint(s) to inform decision-making in the context of the PM NAAQS review. The 2010 HREA also considered information in the 2009 PM ISA on at-risk populations, which identified the life stages of children and older adults, people with pre-existing cardiovascular and respiratory diseases, and people with lower socioeconomic status as populations at increased risk for PM-related health effects.

Criteria used in selecting the urban study areas included 1) the availability of air quality monitoring data; 2) inclusion in an epidemiologic study providing effect estimates; 3) the availability of study area-specific baseline incidence and prevalence data; 4) the potential for risk reductions by adjusting $PM_{2.5}$ concentrations to just meet alternative annual and 24-hour standard levels being considered, using the lowest of the alternative suite of standards as the cutoff

[84] The baseline incidence rate is the number of new cases of a health effect at a given time (often per 10,000 or 100,000 of the general population in a year) in a given location due to all causes, including air pollution. These data are an integral part of the C-R functions used to determine the number of new cases that can be attributed to changes in $PM_{2.5}$ concentrations. For some health endpoints (e.g., asthma exacerbation), we also use prevalence rates to define the applicable population with a given health condition (e.g., asthmatics). Prevalence refers to the rate of all cases in the population (both new and pre-existing).

[85] The term "risk estimate" as used here refers to a quantitative, model-derived estimate of the likelihood for adverse health effects within a defined population following exposure to a specific chemical agent or agents. In the context of NAAQS reviews, risk estimates typically take the form of incidence (count) estimates for specific morbidity or mortality endpoints for a defined population.

(12/25); and 5) regional representation.[86] After selecting the 15 urban study areas,[87] the 2010 HREA identified the "spatial template" to use in defining the geographical area associated with each urban study area, including which counties and $PM_{2.5}$ monitors were associated with a particular urban study area. A national-scale assessment evaluated the representativeness of the risk estimates for the urban study areas compared to national-level results. First, the national-scale assessment considered key $PM_{2.5}$ risk-related attributes to determine whether the selected urban study areas are nationally representative or more focused on a particular portion of the population distribution for a given attribute (e.g., demographics) (U.S. EPA, 2010a, section 4.4.1). Second, the national-scale assessment analyzed estimates of mortality associated with recent long-term $PM_{2.5}$ concentrations,[88] to assess the extent to which the 15 urban study areas reflected locations within the U.S. likely to experience the highest $PM_{2.5}$-related risk (U.S. EPA, 2010a, section 4.4.2).

The 2010 HREA quantified risks using concentration-response (C-R) functions derived from effect estimates reported in epidemiologic studies identified in the 2009 PM ISA. These studies generally used ambient air quality data from fixed-site, population-oriented monitors;[89] thus, the appropriate application of these estimates in C-R functions for a PM risk assessment similarly required the use of ambient air quality data at fixed-site, population-oriented monitors. The 2010 HREA adjusted ambient air quality concentrations using several different methods, including a proportional "rollback" approach,[90] to simulate the distribution of $PM_{2.5}$ ambient

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[86] The goal of the 2010 HREA was to select at least one urban study area from each of the seven geographic regions identified in the 1996 PM Criteria Document (U.S. EPA, 1996, section 6.4) (i.e., PM regions). The selected urban study areas represented six of these seven regions, with the Upper Midwest not represented.

[87] The 15 urban study areas were Tacoma, Fresno, Los Angeles, Phoenix, Salt Lake City, Dallas, Houston, St. Louis, Birmingham, Atlanta, Detroit, Pittsburgh, Baltimore, Philadelphia, and New York. Collectively, these 15 urban study areas comprised 31 counties.

[88] These impacts were estimated down to policy relevant background (PRB) for short-term exposure and the lowest measured level (LML) observed in the epidemiologic study for long-term exposure. PRB concentrations have historically been defined by the EPA as those concentrations that would occur in the U.S. in the absence of anthropogenic emissions in continental North America, defined as the U.S., Canada, and Mexico. The 2010 HREA used regional PRB estimates generated using a combination of chemical transport modeling tools, as discussed in the 2009 PM ISA (section 3.2.2). LML refers to the lowest measured $PM_{2.5}$ concentration within an epidemiologic study.

[89] Most studies applied the composite monitor approach, where $PM_{2.5}$ levels were averaged across monitors within an urban study area in order to produce a single, generalizable $PM_{2.5}$ distribution for that urban area.

[90] "Rollback" is a mathematical approach to lower recent concentrations at ambient monitors in order to simulate just meeting the "design value" for various standards. "Design values" are the metrics (i.e., statistics) that are compared to the NAAQS levels to determine compliance. The proportional rollback method, which had been used in previous risk assessments, reflected a uniform percentage of reduction in ambient $PM_{2.5}$ concentrations across all monitors in an urban study area (U.S EPA, 2010a, section 3.2.3).

concentrations that would "just meet" the then-existing and alternative suites of standards. In addition, two alternative approaches (locally focused and a hybrid of local and proportional rollback approaches) were applied to improve our understanding of the uncertainty associated with the air quality adjustment (U.S. EPA, 2010a, section 3.2.3).[91] The general PM health risk model combined $PM_{2.5}$ concentrations in specific urban areas, C-R functions derived from epidemiologic studies, baseline incidence data for specific health endpoints, and urban area population estimates to derive estimates of the annual incidence of specified health effects attributable to ambient PM concentrations under different air quality scenarios. The human health risks were estimated using the risk assessment component of the EPA's Total Risk Integrated Methodology model (TRIM.Risk).[92] The analyses conducted in the 2010 HREA focused on estimating changes in risks associated with air quality adjusted to just meet the then-existing primary standards, as well as any additional risk reductions estimated to occur upon just meeting alternative suites of standards. In the short-term exposure analysis, the 2010 HREA modeled risk down to PRB, while the long-term exposure analysis modeled down to the LML observed in the epidemiologic study.

4.2.1 Key Observations in the 2010 HREA

Section 5.2 of the 2010 HREA discussed the key observations from the quantitative analyses (U.S. EPA, 2010a, pp. 5-9 to 5-10). In summary, the 2010 HREA emphasized cardiovascular-related health effects due to the greater degree of confidence in these endpoints stemming from information provided in the 2009 PM ISA relative to other health effect outcomes, including respiratory effects (U.S. EPA 2010a, p. 5-9). Thus, for long-term exposure-

[91] The locally focused rollback approach reflected a local pattern of reduction in ambient $PM_{2.5}$ concentrations focused exclusively on those monitors within an urban study area that exceeded the 24-hour standard under consideration. As such, this approach was only applied to the subset of urban study areas where no adjustment was needed to meet the annual standard. The hybrid approach reflected a combination of a more localized pattern of rollback focused on source-oriented monitors with relatively elevated ambient $PM_{2.5}$ levels, followed by a more generalized regional pattern of rollback across all monitors in the study area to just meet the standards. For one urban study area (Pittsburgh), the 2010 HREA also applied a refined rollback approach that used a dual-zone approach to take into account monitor locations and the related topography in that area (U.S. EPA, 2010a, section 3.2.3)

[92] Additional information on the risk characterization module in TRIM can be found at: http://www2.epa.gov/fera/total-risk-integrated-methodology-trim-trimrisk

related risk, the focus of the key observations was on ischemic heart disease (IHD)-related mortality, and for short-term exposures the focus was on cardiovascular-related mortality and morbidity. The 2010 HREA assessed risks associated with $PM_{2.5}$ concentrations adjusted to just meet the then-existing standards and for $PM_{2.5}$ levels meeting an alternative suite of annual and 24-hour standards. The 2010 HREA also estimated the risks that remained after attaining alternative annual standard levels of between 10 to 14 $\mu g/m^3$. This choice accounts both for epidemiologic evidence in the ISA and advice from CASAC. The 2010 HREA recognized that the risks reported at the lower end of the standard levels were subject to greater uncertainty. The 2010 HREA evaluated five suites of annual and 24-hour standard levels to provide a range of combinations across the urban study areas. These air quality analyses found that the annual standard was controlling in some urban study areas, and the 24-hour standard was controlling in others.[93] The analysis reported separate risk estimates for years 2005, 2006 and 2007. However, the 2010 HREA focused on the 2007-based estimates, as these estimates for 2007 fell in the middle of the risk estimates, in terms of the magnitude of risk (U.S. EPA, 2010a, p. 4-5). Consequently, 2007-based risk estimates are reflected in the key observations below.

Magnitude of risk associated with air quality adjusted to just meet the then-existing $PM_{2.5}$ standards (15/35)

In considering $PM_{2.5}$-related risks associated with air quality just meeting the then-existing $PM_{2.5}$ standards in the 15 urban study areas, the 2010 HREA focused on the 13 urban study areas that would not meet 15/35 based on air quality from 2005 to 2007.[94] These 13 urban study areas had annual and/or 24-hour design values that were above the levels of the then-existing standards. Based on the risk estimates for these areas, the 2010 HREA made the following key observations regarding the magnitude of risk remaining[95] upon just meeting 15/35 (using proportional rollback):

[93] The controlling standard in a particular area is the one that, if met, ensures that the other standard would also be met in that area. Because the NAAQS for $PM_{2.5}$ includes standards using both 24-hour and annual averages, the controlling standard in an area was determined by the annual or 24-hour average requiring the largest adjustment or "rollback" to meet the existing or potential alternative standard(s), if any. In general, only one of the two standards (daily or annual) would be the controlling standard in a particular area and 3-year period.

[94] The two urban study areas that did not exceed either the then-existing annual and/or 24-hour design values were Dallas and Phoenix. Thus, the 2010 HREA did not estimate risk reductions in this analysis for these urban study areas. $PM_{2.5}$ concentrations in these two areas were not "rolled up" to the then-existing standards.

[95] Risk remaining refers to the estimation of total risk from the then-existing standard down to the lowest bound for the analysis (either PRB or LML).

- *Long-term exposure-related mortality risk remaining*: The analysis estimated that across the urban study areas, the IHD-related mortality attributable to long-term $PM_{2.5}$ exposure ranged from less than 100 to approximately 2,000 cases per year, with this variability reflecting, to a great extent, differences in the population size of each urban study area. These estimates represented from 4 to 17 percent of all IHD-related mortality in a given year across the urban study areas, which is a measure of risk that takes into account differences in population size and baseline mortality rates.

- S*hort-term exposure-related mortality and morbidity risk remaining*: The analysis estimated that across the urban study areas, the cardiovascular-related mortality attributable to short-term $PM_{2.5}$ exposure ranged from <10 to 500 cases per year. These estimates represented from approximately 1 to 2 percent of total cardiovascular-related mortality in a given year across the urban study areas. In terms of morbidity risk, cardiovascular-related hospital admissions ranged from approximately 10 to 800 cases per year across the study areas, representing less than one percent of total cardiovascular-related hospital admissions in each study area.

Magnitude of risk reductions associated with air quality adjusted to just meet alternative $PM_{2.5}$ standards

In characterizing $PM_{2.5}$-related risks associated with air quality adjusted to just meet the alternative annual standards (14/35, 13/35 and 12/35), the 2010 HREA estimated both the magnitude of risk reductions (relative to risk remaining upon just meeting 15/35)[96] and the magnitude of risk associated with air quality adjusted to just meet the alternative standards.[97] More uniform risk reductions were estimated to result from just meeting the alternative annual standard levels than just meeting alternative 24-hour standard levels.[98] Thus, in discussing these risks, the 2010 HREA focused on the set of urban study areas that would have risk reductions by just meeting each alternative annual standard.

- *Reductions in long-term exposure-related mortality risk:* Upon just meeting the alternative annual standard levels considered in conjunction with the existing 24-hour standard (denoted as 14/35, 13/35 and 12/35), the analysis estimated reductions in long-term exposure-related mortality for 12[99] of the 15 urban study areas, with the degree of risk reduction increasing

[96] Risk reductions refers to the difference in risk between the then-existing standard (in this case 15/35) and the alternative standard being analyzed.

[97] The 2010 HREA also estimated risks at 10 $\mu g/m^3$ for the annual standard; however, the HREA noted the larger degree of uncertainty in these estimates and therefore, these results are not presented here (U.S. EPA, 2010a, section 5.2.2).

[98] The degree of estimated risk reduction in long-term exposure-related IHD mortality risk provided by the alternative 24-hour standards was highly variable across the study areas, in part due to different rollback approaches (U.S. EPA, 2010a, section 4.2.2 and section 5.2.3).

[99] For 12/35, three of the urban study areas (i.e., Tacoma, Fresno and Salt Lake City) did not experience any decreases in risk when the annual standard was rolled back, as the design values in these urban study areas met the annual standard but exceeded the 24-hour standard, and thus would only experience risk reductions under alternative 24-hour standards.

incrementally across the alternative standard levels (both in terms of the number of study areas experiencing risk reduction and the magnitude of those reductions). For the alternative annual standard level of 12.0 $\mu g/m^3$ (in conjunction with the existing 24-hour standard), the analysis estimated that these urban study areas have reductions in mortality risk (relative to risk remaining upon just meeting then-existing suite of standards) ranging from about 11 to 35 percent.

- *Reductions in short-term exposure-related mortality and morbidity risk*: For the alternative annual standard level of 12.0 $\mu g/m^3$ (in conjunction with the existing 24-hour standard), the analysis estimated that reductions in both short-term exposure-related cardiovascular mortality and morbidity risk ranged from 5 to 23 percent across the urban study areas. [100]

4.2.2 Key Uncertainties in the 2010 HREA

The EPA recognized that both the inputs to the risk assessment and the risk model used were each subject to uncertainties that affected the magnitude and distribution of the results. The 2010 HREA followed the World Health Organization (WHO, 2008) framework for characterizing uncertainty in the analyses and incorporated elements intended to increase the EPA's overall confidence in the risks estimated in the fifteen urban study areas (U.S. EPA, 2010a, section 3.5.1 and 4.3), including:

- The use of a rigorous, transparent, and fully documented process subject to peer and public review in developing all key elements of the 2010 HREA (U.S. EPA, 2010a, section 5.1.1);
- Integration of key sources of variability into the design and interpretation of results;
- Assessment of the degree to which the urban study areas included in the 2010 HREA are representative of areas in the U.S. experiencing higher $PM_{2.5}$-related risk; and
- Identification and assessment of the impact (i.e., magnitude and direction) of important sources of uncertainty on risk estimates.

The 2010 HREA included both qualitative (U.S. EPA, 2010a, section 3.5.3) and quantitative sensitivity analyses (U.S. EPA, 2010a, section 3.5.4 and 4.3) designed to identify sources of uncertainty most influencing the estimated risk. These analyses characterized the sources of uncertainty likely to substantially impact the estimated risk. Since quantitative information was not available to characterize overall levels of confidence in alternative model

[100] The patterns of risk reduction (as a percentage) were similar for both sets of endpoints because the rollback was the same for both and the C-R functions were assumed to be linear (U.S. EPA 2010a, section 4.2.2).

inputs, the uncertainty characterization in the 2010 HREA did not include a full probabilistic assessment of uncertainty and its impact on risk estimates.

Key observations from analyses of uncertainty

The qualitative analysis of uncertainty identified the following sources of uncertainty as potentially having a medium to high impact[101] on risk estimates (see Table 3-6, p. 3-72 of the 2010 HREA for additional detail, U.S. EPA, 2010a):

- *Intra-urban variability in $PM_{2.5}$ exposure in epidemiologic studies*: Use of composite monitors as exposure surrogates in epidemiologic studies may not fully capture spatial variability in PM concentrations within an urban area, and introduces exposure measurement error and uncertainty into the effect estimates obtained from the epidemiologic studies.
- *Shape and statistical fit of the C-R functions*: There is uncertainty in the shape of the C-R function, particularly at lower ranges of concentrations due to a lack of observations. In addition, we consider the statistical fit of the of the C-R function. The term "statistical fit" as used here indicates the precision of a statistical model for capturing the observations. It can be influenced by a variety of factors, including exposure measurement error, sample size, and control for confounders.
- *Lag structure (short-term exposure studies)*: Different lags may have varying degrees of association with a particular health endpoint, and it may be difficult to clearly identify the specific lag that produces the majority of a PM-related effect. A lack of information regarding the specific lag(s) most associated with a particular health endpoint adds uncertainty into risk estimates for that endpoint.
- *Transferability of C-R functions from epidemiologic study areas to HREA urban study areas (long-term exposure health endpoints)*: The use of effects estimates based on data collected in a particular location(s) as part of the underlying epidemiologic study in different locations (the focus of the risk assessment) introduces uncertainty into the analysis.
- *Single-city versus multi-city epidemiologic studies*: Often both single-city and multi-city epidemiologic studies are available (for a given health endpoint) for the derivation of C-R functions. Each of these study types has advantages and disadvantages, and both study types can introduce uncertainty into the analysis.
- *Historical $PM_{2.5}$ exposures:* Long-term exposure studies of mortality suggest that different time periods of PM exposure can produce substantially different effects estimates, introducing uncertainty in identifying the exposure window that is most strongly associated with mortality.

[101] The 2010 HREA classified sources as "medium impact" if they have the *potential to change* the interpretation of the risk estimates in the context of the PM NAAQS review, and classified sources as "high impact" if they are *likely to influence* the interpretation of risk.

- *PM compositional differences*: The composition of PM can differ across urban study areas. If these compositional differences contribute to different effect estimates (i.e., heterogeneity), then substantial uncertainty may be introduced into risk estimates if these compositional differences are not explicitly addressed.

The 2010 HREA included two types of quantitative sensitivity analyses: single-factor and multi-factor. The single-factor sensitivity analysis varied one source of uncertainty at a time and identified the following sources of uncertainty as having a moderate to large impact[102] on risk estimates (U.S. EPA, 2010a, section 4.3.1):

- *Long-term exposure-related mortality*: (a) different C-R function model choices (e.g., fixed versus random effects, log-linear versus log-log, single- versus co-pollutant), (b) modeling risk down to PRB rather than LML, (c) use of C-R functions from different epidemiologic studies, and (d) nature of the spatial pattern of ambient $PM_{2.5}$ reductions (i.e., rollback method).
- *Short-term exposure-related mortality and morbidity*: (a) use of seasonally differentiated versus annual-based C-R functions and (b) different models, lag structures and single-versus co-pollutant model forms.

The multi-factor sensitivity analysis varied multiple sources of uncertainty simultaneously and covered both long-term exposure-related mortality and short-term exposure-related mortality and morbidity. This multi-factor analysis found that a number of sources of uncertainty, identified above, could work in concert to affect risk estimates, and that these combined effects would be more than additive in certain circumstances (U.S. EPA, 2010a, section 4.3.1.2).

4.3 CONSIDERATION OF POTENTIAL QUANTITATIVE ASSESSMENTS FOR THIS REVIEW

The goal of an HREA is to provide information relevant to answering questions regarding the adequacy of the existing PM primary standards and, if appropriate, the potential improvements in public health from meeting potential alternative standards. A quantitative HREA for this review, if warranted, would build on the approaches used and lessons learned in the 2010 HREA and would focus on improving the characterization of PM exposure and

[102] The 2010 HREA classified factors as "moderate to large impact" if they had a 20 percent to greater than a 100 percent difference on risk results.

associated health risks, including related uncertainties, by incorporating a number of enhancements, in terms of newly available models, methods, tools, and data.

Characterizing health risks for the current review of the primary PM NAAQS could include conducting air quality analyses to support quantitative assessments of risk and exposure in specific urban study areas as well as putting the results into a national public health perspective. We anticipate that, consistent with the large body of available scientific and air quality evidence available to support quantitative assessments, the most likely focus of quantitative analyses in an HREA would be $PM_{2.5}$. These assessments would be designed to estimate human exposures and/or to characterize the potential health risks that are associated with recent ambient levels, with ambient $PM_{2.5}$ concentrations adjusted to just meet the now-existing standards (12/35) and, if appropriate, with ambient concentrations adjusted to just meet alternative standard(s) that may be considered. To the extent that information becomes available in the PM ISA for the current review that could support quantitative analyses of $PM_{2.5}$ components, $PM_{10-2.5}$, or ultrafine particles, additional quantitative analyses could be considered which focus on these other size fractions or components. Similar to considerations for $PM_{2.5}$ risk analyses, we would evaluate whether sufficient information is available for other size fractions and/or components, including air quality information, endpoints with causal or likely to be causal determinations in the ISA, availability of concentration-response functions, and baseline incidence data. The considerations for all potential quantitative epidemiology-based risk analyses are described in greater detail in section 4.3.1 below.

As described further in this section, an HREA for the current review would consider a variety of health endpoints for which, in staff's judgment, there would be adequate information to develop quantitative risk estimates that can meaningfully inform the review of the primary PM NAAQS. We also intend to evaluate the distribution of risks and patterns of risk reduction (e.g., among urban case study areas and across ambient $PM_{2.5}$ concentrations) and uncertainties in those risk estimates. In presenting the results of any new assessments, we plan to evaluate the influence of various inputs and assumptions on the exposure and risk estimates to more clearly differentiate potential alternative standard(s) that might be considered, including potential impacts on various at-risk populations and lifestages. In addition, we will consider characterizing risk on a national scale. This assessment could also evaluate the distribution of PM-related health risk across the U.S. (and the factors that influence the distribution of risk) to assess the degree to which risks estimated in each urban study area are representative of national-level risks.

An important issue associated with conducting exposure and human health risk assessments is the treatment of variability and the characterization of uncertainty. Variability refers to the inherent differences in a population or variable of interest (e.g., residential air

exchange rates); it cannot be reduced through further research, but it may be better characterized with additional measurement. However, models can account for variability. Uncertainty refers to the lack of knowledge regarding both the actual values of model input variables (i.e., parameter uncertainty) and the physical systems or relationships (i.e., model uncertainty – e.g., the shapes of concentration-response relationships). Uncharacterized spatial and temporal variability in $PM_{2.5}$ mass or species concentrations is often an important source of uncertainty in PM risk assessments. As part of such analyses, variability and uncertainty will be explicitly addressed, where feasible, in any new air quality, exposure, and health risk assessments.

Consistent with the 2010 HREA, we are considering following the WHO framework (WHO, 2008) to characterize uncertainty and variability, which presents a multi-tiered approach for characterizing uncertainty (and to a lesser extent variability) in the context of a risk assessment. This framework provides a method for systematically linking the characterization of uncertainty to the level of complexity of the underlying risk assessment. Ultimately, the decision as to which tier of uncertainty characterization to include in this risk assessment will depend on the availability of information for characterizing the various sources of uncertainty. The four WHO tiers range from application of default uncertainty factors up to probabilistic assessments. Similar to the 2010 HREA, we anticipate that the uncertainty characterization in any HREA for the current review would likely have sufficient data to conduct uncertainty assessments in the middle tiers (e.g., qualitative assessments of direction/magnitude of the effect on results and sensitivity analyses).

Below, we outline the two major components of the quantitative health risk characterization (i.e., epidemiology-based risk assessments and exposure assessment) that will be described in more detail in the HREA Planning Document. Preparation of this planning document will draw from the assessments of the scientific evidence in the first draft PM ISA to facilitate the integration of policy-relevant science into the planning document. In particular, the availability of air quality, exposure-response, concentration-response, and baseline incidence and prevalence data as well as consideration of available resources will influence the type of risk and exposure assessments that would be developed.

4.3.1 Epidemiology-Based Risk Assessment

The goals of an updated epidemiology-based risk assessment for PM would be to: (1) estimate the potential magnitude of mortality and morbidity risks in urban study areas for recent ambient concentrations as well as for PM concentrations adjusted to meet the existing standards and, if appropriate, potential alternative standard(s); (2) develop a better understanding of how various inputs and assumptions influence the risk estimates, including a characterization of the

confidence in the risk estimates ; and (3) gain insights into the distribution of risks and patterns of risk reduction across modeled populations (including at-risk populations and lifestages) as well as the spatial distribution of risk within and across modeled study areas.

The approach for an epidemiology-based risk assessment for the current review would build upon the methods developed for and insights gained from the 2010 HREA (section 4.2 above). Section 4.3.1.1 below describes the ambient PM concentrations for recent conditions and adjustments to just meet the existing and potential alternative standard(s). Section 4.3.1.2 discusses factors to be considered in designing any new epidemiology-based risk assessment. Section 4.3.1.3 identifies the sources of uncertainty that had a substantial impact on risk estimates in the 2010 HREA and discusses potential strategies for reducing and characterizing those sources of uncertainty in the current review. Each of these design factors and strategies for reducing uncertainties, including data availability, would be further evaluated in the HREA Planning Document.

4.3.1.1 Ambient PM Concentrations

Recent Ambient Conditions

For an HREA for the current review, we anticipate relying on data from the national air quality monitoring networks described above (in section 2.3) to characterize ambient PM concentrations for the time period and metric of interest (e.g., size fraction, form). As described above (in section 4.2), the 2010 HREA used data from these monitoring networks to characterize $PM_{2.5}$ concentrations and associated health risks during 2005 to 2007 for 15 urban study areas. A similar degree of $PM_{2.5}$ monitoring is now available for more recent years that could be considered in the current review. We would select specific urban study areas to assess in this HREA by considering the available monitoring data in conjunction with the new epidemiologic studies in the upcoming PM ISA, and this new information may suggest we consider the same study areas in the upcoming HREA that were assessed in the 2010 HREA. Criteria for identifying urban study areas will be identified in the HREA Planning Document.

In the 2010 HREA, the air quality analyses focused on $PM_{2.5}$. Due to the substantial uncertainties and data gaps that were identified, the 2010 HREA did not include quantitative analyses for additional PM size fractions (e.g., $PM_{10-2.5}$ or ultrafine particles). For $PM_{10-2.5}$, these uncertainties were related to (1) concerns that the monitoring data for 2005 to 2007 would not be similar to the data used in the epidemiologic studies that provided the effect estimates for the C-R functions; (2) uncertainty in the prediction of ambient concentrations under the then-existing and alternative standards; (3) concerns that the 15 urban study areas in the 2010 HREA may not be representative of areas experiencing the highest $PM_{10-2.5}$ concentrations; and (4) concerns

about the much smaller number of relevant epidemiologic studies for $PM_{10-2.5}$ compared to the larger number of studies for $PM_{2.5}$. The 2010 HREA also concluded that the available information was too limited to support quantitative assessments for ultrafine particles. A lack of information on the appropriate metric[103] for characterizing ultrafine particles in risk assessments, as well as the lack of a national monitoring network for ultrafine particles, are likely to continue to challenge our ability to conduct a quantitative assessment for ultrafine particles in the current review. In the current review, we will consider whether new information on these areas of uncertainty has become available since the last review of the PM NAAQS that would be sufficient to support quantitative air quality assessments of recent ambient conditions for $PM_{10-2.5}$ or ultrafine particles. If so, we will consider in the HREA Planning Document the degree to which these ambient concentrations could be adequately characterized using available data from the national monitoring networks (or other datasets in the case of ultrafine particles) to support the HREA.

The 2010 HREA did not evaluate $PM_{2.5}$ composition differences quantitatively because C-R functions for specific $PM_{2.5}$ components and sources had not been identified at that time.[104] In the HREA Planning Document, we will consider whether new information on C-R functions for components and/or sources has become available in the PM ISA for the current review and could necessitate the characterization of ambient $PM_{2.5}$ components and/or sources. If warranted for the HREA for the current review, we would consider the degree to which measurements from the CSN and IMPROVE networks described in Chapter 2 could be used to adequately characterize $PM_{2.5}$ components or sources.

Approach for Adjusting PM Concentrations to Just Meet the Existing and Potential Alternative Standard(s)

In order to estimate changes in health risks from just meeting the existing $PM_{2.5}$ standards, and potential alternative standard(s) if appropriate, we would first need to adjust recent ambient concentrations to reflect the distribution of $PM_{2.5}$ concentrations in an urban area that could correspond to these air quality scenarios. Since there are multiple combinations of emissions profiles that could result in just meeting the current standards or any potential alternative standards, there are many possible scenarios of various spatially and temporally distributed $PM_{2.5}$

[103] For example, total particle number, solid particle number, active particle surface area, Brunauer–Emmett–Teller surface area, or mass of particles in a certain size range.

[104] However, the 2010 HREA indirectly considered PM composition differences by applying region- or city-specific effect estimates in modeling health risks for short-term exposure to ambient $PM_{2.5}$.

concentrations that would correspond to the target air quality scenarios. Given this fact, the 2010 HREA used multiple air quality adjustment approaches (i.e., proportional, local, and hybrid rollback) to estimate the effects on the distribution of $PM_{2.5}$ concentrations at monitors in an urban study area of just meeting the then-existing and alternative standards. Use of multiple adjustment approaches enabled exploration of the sensitivity of risk results to different spatial patterns of $PM_{2.5}$ reduction, with the goal of largely bounding potential risks.

In the HREA Planning Document, we will consider whether it would be appropriate to use additional or different approaches to adjusting air quality concentrations including methods based on results from chemical transport modeling of national emission reduction scenarios. These additional or different adjustment approaches would aim to improve the representation of $PM_{2.5}$ reduction patterns over an area. If estimates of PRB concentrations are needed for the air quality adjustments in the HREA, we would consider information provided in the PM ISA for the current review. In selecting methods for air quality adjustment, we would consider the ability of the approaches to represent the relationship between the annual and 24-hour NAAQS.

There is relatively limited information on $PM_{10-2.5}$, specific PM components and sources, or ultrafine particles compared with $PM_{2.5}$ to develop approaches for adjusting their concentrations to meet the existing $PM_{2.5}$ standards and potential alternative standard(s), if appropriate. We will consider in the HREA Planning Document the ability of various adjustment approaches, including those based on statistical and air quality modeling relationships, to provide reasonable estimates of adjusted concentrations for $PM_{10-2.5}$, specific PM components and sources, and ultrafine particles, if warranted.

4.3.1.2 Factors to Consider in Designing any New Epidemiology-based Risk Assessment

- *PM size fractions, components, and sources*: We anticipate focusing any new quantitative risk assessments primarily on $PM_{2.5}$ but will consider, to the extent sufficient air quality and epidemiologic data become available in the PM ISA for the current review, characterizing risks associated with $PM_{10-2.5}$ and ultrafine particles as well as risks associated with specific PM components and/or sources.
- *Health endpoints and health input data*: For any quantitative risk assessment, we would follow a multi-step process for each health endpoint considered. First, we would identify those health endpoints that the PM ISA for the current review determines have either a "causal" or "likely to be causal" relationship with PM exposure. Next, we would use information from the PM ISA and the epidemiologic studies to specify C-R functions for those health endpoints, including details on model form and associated effect estimates. Last, we would obtain the necessary baseline incidence and/or prevalence rate data for each endpoint. These rates originate from a variety of sources and often reflect varying spatial scales.

- *Exposure metrics:* Similar to previous PM HREAs, we anticipate modeling health endpoints associated with both short-term (24-hour average) and long-term (annual average) exposure depending on the epidemiologic study data available in the PM ISA for this review. Furthermore, for short-term exposure-related endpoints, we could consider whether to differentiate risk estimates through application of seasonally differentiated effect estimates paired with seasonal mortality rates, if available.

- *Spatial scale of the analysis*: Based on the epidemiologic studies available in the PM ISA for the current review and the available air quality monitoring data, we would anticipate analyzing a set of study areas in detail and applying effect estimates specific to each study area. We would also anticipate adjusting recent $PM_{2.5}$ concentrations to just meet the existing and, if appropriate, potential alternative standard(s), in each urban area, including consideration of various adjustment approaches (e.g., proportional rollback). In addition, we will consider whether a national-scale analysis of risk for recent ambient concentrations (such as completed in the 2010 HREA) is useful for evaluating the representativeness of the study areas. We will also consider whether to estimate risk reductions at the national-level from just meeting potential alternative standard level(s), if any. However, adjusting air quality can be more challenging at broader regional or national scales than at the urban study area scale. We anticipate that any national-level estimates, if generated, would supplement the higher confidence risks estimated for the study areas.

- *At-risk populations and lifestages*: Based on information from the PM ISA, we would consider whether data would be sufficient to generate more refined risk estimates for these populations groups, including whether effect estimates and baseline incidence rates for these at-risk populations and lifestages are available.

- *Risk metrics*: The 2010 HREA quantified risks using several risk metrics, including (a) $PM_{2.5}$-related incidence (for both morbidity and mortality endpoints), (b) $PM_{2.5}$-related incidence per 100,000 exposed individuals, representing a standardized risk metric that can be readily compared across urban study areas, (c) percent of baseline incidence attributable to $PM_{2.5}$ exposure, and (d) percent reduction in PM-related risk from just meeting the then-existing and alternative standard levels. We anticipate including similar risk metrics in any new risk assessment, and we will consider including some additional risk metrics based on information from the PM ISA to more fully characterize PM-related mortality risk. For example, we may consider metrics that characterize person-level risk, such as life years gained (from just meeting the existing and potential alternative standard(s), if any), life years lost (from exposure to recent PM concentrations), and/or estimation of population-level changes in life expectancy.

- *Differentiating risk estimates by PM concentration*: Based on information from the PM ISA, we would consider whether it would be appropriate and informative to differentiate the magnitude of risks or overall confidence in risk estimates for different concentration ranges. Such an analysis could reflect, among other factors, reduced confidence in specifying C-R functions at lower PM concentrations where less data exist. For such an analysis, we would explore methods such as (a) binning risk estimates into categories of confidence based on data available for C-R functions including differences in the size of standard errors at various

PM concentrations, and (b) using other types of evidence (clinical and/or toxicological) to differentiate risk estimates semi-quantitatively within specified $PM_{2.5}$ concentration ranges.

- *BenMAP-CE*: Consistent with the HREA conducted for the last ozone NAAQS review (U.S. EPA, 2014), we anticipate using the environmental Benefits Mapping and Analysis Program – Community Edition (BenMAP-CE) (U.S. EPA, 2015), the EPA's GIS-based computer program for the estimation of health impacts associated with changes in air pollution.[105] BenMAP-CE draws upon a database of population, baseline incidence and prevalence, and effect estimates to automate the calculation of health impacts. [106] In addition, BenMAP-CE can utilize standard errors from the effect estimates to generate 95th percentile confidence intervals around point estimates. These confidence intervals reflect the statistical fit (precision) of the underlying epidemiologic models, assuming that the form of the model is correct.

4.3.1.3 Characterization of Sources of Uncertainty and Consideration of Information Newly Available in this Review

As described above, the 2010 HREA primarily used sensitivity analyses (including both single and multi-factor) to evaluate the impact of uncertainty in specific input factors on the risk estimates, while a probabilistic analysis (i.e., Monte Carlo) was used to cascade the impact of standard errors in the effect estimates from epidemiologic studies into 95th percentile confidence intervals around the risk estimates. Although Monte Carlo analyses could be used to reflect the combined impact of multiple sources of uncertainty affecting the risk estimates, this type of analysis would require information not previously available, including the specification of defensible distributions of values for key inputs and any potential correlations between those inputs. For an HREA in the current review, we anticipate relying on single and multi-factor sensitivity analysis as the primary method for characterizing the combined impact of uncertainty from multiple key inputs on the risk estimates, although we will consider additional tools should they become available. Based on information from the PM ISA for the current review, we would anticipate conducting additional sensitivity analyses to better characterize uncertainties related to the specification of C-R functions (e.g., model specification, treatment of copollutants, and treatment of lag for short-term exposure endpoints).

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[105] The BenMAP software and associated documentation are available for download at http://www2.epa.gov/benmap.

[106] As noted in section 4.2, the 2010 HREA used the TRIM model to estimate human health risks (U.S. EPA, 2010a). For subsequent NAAQS epidemiology-based risk assessments (U.S. EPA, 2014), we utilize BenMAP-CE, which provides a more efficient and flexible platform for modeling PM-related health risk. For example, BenMAP-CE allows users to readily conduct sensitivity analyses exploring the impact of alternative modeling choices (e.g., effect estimates, thresholds, age ranges for target populations, units of spatial aggregation) on risk estimates.

In designing an HREA for the current review, our goal will be to reduce and/or better characterize the impact of the sources of uncertainty identified in the 2010 HREA to the extent possible given available information. In addition, we would address any newly identified sources of uncertainty. In Table 4-1 below, we identify several important sources of uncertainty and discuss our considerations for potentially addressing these sources of uncertainty. These strategies would be further described in the HREA Planning Document.

Table 4-1. Areas of Uncertainty Associated with Epidemiology-Based Risk Estimates and Potential Strategies for Addressing these Sources of Uncertainty

Category of Uncertainty/ Limitation	Description of Uncertainty/ Limitation in the Last Review	Consideration of Information Newly Available in this Review
Transferability of C-R functions from epidemiologic study areas to HREA urban study areas	At times, the EPA applies effect estimates to urban study areas that were not included in the original epidemiologic study providing those effect estimates. This geographic extrapolation can introduce uncertainty into the risk estimates for those urban study areas.	New epidemiologic studies in the PM ISA and other available data may provide additional perspective on which urban areas or regions are likely to have similar population-level responses to PM pollution and which are likely to have different responses. This information may guide decision-making regarding the transferability of effect estimates to broader geographic areas.
Transferability of C-R functions from an earlier time period (in the epidemiologic study) to a more recent time period in the HREA	Depending on the degree to which conditions associated with PM exposure and risk (e.g., population behavior and mobility, baseline health effects incidence rates, ambient urban PM profiles) changed over time, uncertainty may be associated with the temporal extrapolation of effect estimates.	New epidemiologic studies in the PM ISA may provide additional perspective on the degree to which effect estimates vary (for the same geographic location) over time and hence the degree to which uncertainty associated with this type of temporal extrapolation of effect estimates may introduce uncertainty into the risk results.
Use of composite monitors as exposure surrogates in the epidemiologic studies	The 2010 HREA asserted that the exposure surrogate used in epidemiologic studies (i.e.., a single composite monitor representing an entire urban study area) could impact the magnitude of the effect estimates.	New epidemiologic studies in the PM ISA may characterize the degree to which different spatial scales (used in defining exposure surrogates) introduce exposure measurement error, depending on the endpoint, location and pollutant being evaluated.
Spatial heterogeneity in effect estimates in the epidemiologic studies	In the 2010 HREA, effect estimates for short-term mortality and morbidity endpoints demonstrated considerable spatial heterogeneity. At that time, the EPA noted that this	New epidemiologic studies in the PM ISA might provide information regarding which factors drive spatial heterogeneity in effect

Category of Uncertainty/ Limitation	Description of Uncertainty/ Limitation in the Last Review	Consideration of Information Newly Available in this Review
	heterogeneity could reflect a number of factors (e.g., differences in behavior across/within cities, PM compositional/source differences, different degrees of exposure measurement error).	estimates. This information could help us to differentiate between effect estimates (and hence the risk estimates) in terms of overall confidence.
Shape and statistical fit of the C-R functions[107]	There is uncertainty in the shape and statistical fit of the C-R functions, particularly at lower ranges of concentrations. Although the 2010 HREA applied linear C-R functions, these functions could have non-linearities, thresholds or concentrations with reduced confidence in the effect estimate.	New epidemiologic studies in the PM ISA could provide additional information regarding risk across the range of PM concentrations or possible non-linearities in the C-R function, particularly in lower PM concentrations where there tends to be less data. Greater data density at lower concentrations could also result in increased precision (and hence statistical fit) within that range.
Lag structure in short-term exposure epidemiologic studies	Different lags have varying degrees of association with a particular health endpoint, and it may be difficult to clearly identify the specific lag that produces the majority of a PM-related effect. A lack of information regarding the specific lag(s) most associated with a particular health endpoint adds uncertainty into risk estimates for that endpoint. For short-term mortality, the 2010 HREA used an average of 0 and 1-day lags, and other lags, where available, were considered in sensitivity analyses.	New epidemiologic studies in the PM ISA could provide additional information regarding the lag structure most strongly associated with specific health endpoints.

[107] The term "statistical fit" as used here indicates the precision of a statistical model for capturing the observations. It can be influenced by a variety of factors, including exposure measurement error, sample size, and control for confounders.

Category of Uncertainty/ Limitation	Description of Uncertainty/ Limitation in the Last Review	Consideration of Information Newly Available in this Review
Single pollutant models versus copollutant models	Ozone and other ambient copollutants may confound effect estimates associated with PM.	New epidemiologic studies in the PM ISA could provide additional information regarding potential confounding by copollutants.
Single-city versus multi-city epidemiologic studies	For long-term exposure mortality, the 2010 HREA employed effect estimates from multi-city epidemiologic studies. For short-term exposure mortality, the 2010 HREA used a combination of single and multi-city epidemiologic studies, acknowledging advantages and disadvantages with both types of studies.	New epidemiologic studies in the PM ISA could provide additional information regarding whether either type of study (or a combination of both) would be preferred in modeling specific endpoints. New single-city epidemiologic studies in the PM ISA could add confidence to the individual city risk results estimated using multi-city effect estimates.
Historical PM exposure in long-term exposure studies	Long-term epidemiologic studies suggest that different time periods of PM exposure can produce substantially different effects estimates. This can introduce uncertainty in identifying the exposure window is most strongly associated with an endpoint.	New epidemiologic studies in the PM ISA could provide additional information regarding which exposure windows are most strongly associated with long-term exposure endpoints, recognizing potential measurement error linked to population mobility (within and between cities) over time.
Differences in PM composition or sources	The composition of PM and overall pollution mixture can differ across urban study areas. If these compositional differences contribute to different effect estimates (i.e., heterogeneity), then substantial uncertainty may be introduced into the risk estimates if these compositional differences are not explicitly addressed.	New epidemiologic, toxicological and clinical studies in the PM ISA could provide additional information regarding differences in PM composition, including whether there is sufficient evidence to model risk by applying differential effect estimates.

4.3.2 Exposure Assessment

As noted above, neither the 2010 HREA nor any prior review of the PM NAAQS included a quantitative population-based, microenvironmental exposure assessment, largely because of the uncertainties surrounding the purpose of such an assessment and the insights it could provide in better understanding PM-related health risks beyond those provided using the epidemiology-based approach. In the current review, we will again consider whether to perform an exposure assessment. In doing so, we will consider the extent to which the results of such an assessment could be informative when interpreted in light of important uncertainties. Key factors that we will consider when determining whether to perform an exposure assessment include our technical ability to generate estimates of PM exposure on temporal and spatial scales that would be informative for the review, quantitative and qualitative characterizations of uncertainties in exposure estimates, and the availability in this review of PM human exposure studies that provide insight into the potential public health importance of particular PM exposures.

Unlike an epidemiology-based risk assessment that often uses composite ambient monitor concentrations to represent generalized exposure over an urban area (as described in section 4.3.1), an exposure assessment could estimate the magnitude, frequency, duration, and pattern of exposures to PM concentrations, considering activity patterns and microenvironments. Such quantitative assessments could range from a data simplified analysis up to a modeled population-based, microenvironmental exposure assessment. A detailed exposure assessment could provide insight into the populations with the highest PM exposures. In addition, if available human exposure studies provide a basis for identifying ambient-relevant PM exposure concentrations that result in effects of potential public health concern, an exposure assessment could also include a comparison of PM exposure estimates to the exposure concentrations shown to cause such effects (i.e., an exposure benchmark analysis).

If a quantitative population-based, microenvironmental exposure assessment is warranted, exposure calculations would rely largely on measurements of ambient PM concentrations potentially supplemented with information from air quality models and databases of daily time/location/activity patterns and personal attributes, as well as information on physical factors that influence microenvironmental concentrations, exposures, and internal doses. Important exposure factors include information on atmospheric chemistry and components of PM, temporal and spatial distributions of air quality data, time spent in particular microenvironments and at varying exertion levels, and information on at-risk populations and lifestages. Such an assessment, if warranted, would likely focus primarily on ambient-related exposures to $PM_{2.5}$ but could consider, to the extent sufficient information becomes available in the PM ISA, exposures associated with other PM size fractions and/or particular PM components. If warranted, such an

exposure assessment would build upon the information presented in the PM ISA, could employ a modeling approach recently used for other NAAQS reviews (Nitrogen Dioxide: U.S. EPA, 2008; Sulfur Dioxide: U.S. EPA, 2009b; Carbon Monoxide: U.S. EPA, 2010c; Ozone: U.S. EPA, 2014), and would depend upon available data and resources.

Section 4.3.2.1 below discusses factors to be considered in designing an exposure assessment. Section 4.3.2.2 presents challenges in conducting such an assessment and sources of uncertainty. These design factors and strategies for reducing uncertainties would be further evaluated in the HREA Planning Document. In the HREA Planning Document, we will consider whether these strategies, including information from the PM ISA for the current review and available air quality monitoring data, would provide sufficient confidence to move forward with an exposure assessment and the associated air quality analyses in the current review.

4.3.2.1 Factors to Consider in Designing an Exposure Assessment

- *Characterizing ambient PM concentrations*. The air quality data used in exposure assessments generally correspond to the finest spatial and temporal scales in ambient concentrations that substantially influence important exposure metrics and microenvironments of interest.[108] Developing highly resolved $PM_{2.5}$ concentrations from existing monitoring and modeling data to support a population-based, microenvironmental exposure would present a number of challenges, including adequately representing temporal and spatial variability in concentrations at fine scales over urban areas with a variety of microenvironments. The challenges would be greater for $PM_{2.5}$ components and/or different PM size fractions, because less monitoring is available, gradients may be sharper, and modeling may be less reliable for $PM_{2.5}$ components and different size fractions compared with $PM_{2.5}$.

- *Exposure model*: If a population-based, microenvironmental exposure is warranted for the current review, we would likely use the APEX model[109] to estimate exposures. APEX is a probabilistic human exposure model that simulates the movement of individuals through time and space within a study area. Exposures are calculated in APEX by accounting for the complete time series of exposure concentrations and doses as they occur in the simulated individual (minute by minute), and then typically, they are aggregated to a metric of interest at the individual level and summarized for the population simulated in the study area. APEX can use any geographic frame of reference (e.g., census tract centroids, 1x1 km grid blocks)

[108] For example, the temporal and spatial scales used in recent APEX simulations for ozone (U.S. EPA, 2014) were hourly concentrations at the census tract level, due to observed health effects resulting from 6-8 hour ozone exposures in controlled human exposure studies and the availability of comprehensive population demographics.
[109] Additional information on APEX can be found at: http://www2.epa.gov/fera/human-exposure-modeling-air-pollutants-exposure-model.

and time period (e.g., minute, hourly) to represent ambient concentrations for calculating exposures.

- *Population exposures*: An APEX-based exposure assessment could be designed to estimate population exposures to ambient PM in urban study areas that represent a variety of study groups of interest (e.g., at-risk populations). Such an assessment could evaluate the influence of factors that contribute to temporal/spatial patterns of PM concentrations (e.g., climatic conditions) and variability in activity patterns and microenvironmental concentrations. Further, because APEX estimates both short-term and long-term exposures for each simulated individual, we could determine the importance of short-term exposure variability with respect to long-term cumulative exposure, which could improve the understanding of the relationship between short-term and long-term exposure health effects via their linked exposure profiles.

- *Ambient concentrations and human activity patterns*: An APEX-based exposure assessment can use ambient concentrations with a range of time or spatial scales, and we could design an exposure assessment to focus on the scale of other APEX model input data (e.g., population demographics at the census tract level) and the exposure output of interest. The human activity data used by APEX are drawn from the EPA's Consolidated Human Activity Database (CHAD; McCurdy et al., 2000; U.S. EPA, 2002). The CHAD includes data from several surveys sampling at city, state, and national levels, including diaries of their daily activities, locations visited, activities performed, time-of-day and their durations. We could consider whether it would be informative to conduct a child-specific analysis that calculates exposure for various lifestages utilizing activity patterns and exposure parameters specific to these lifestages. However, we note that we are currently unaware of exposure parameters for early lifestages (age < 5), and therefore such an analysis may not be feasible for this review.

- *Microenvironmental exposure*: An APEX-based exposure assessment estimates exposures that individuals experience while in indoor, outdoor, and inside-vehicle microenvironments using the ambient concentrations and other input variables specific to microenvironments. In addition to drawing on information from the PM ISA for the current review to parameterize these and other input variables, we could consider including specific microenvironments and variables in other exposure model analyses (e.g., SHEDS-PM; Burke et al., 2001). Because APEX has a flexible, probabilistic approach to estimating exposure and dose, we could consider developing appropriate distributions representing variability and uncertainty for various inputs (e.g., air exchange rates, decay rates, and physiological parameters).

- *Spatial and temporal scope of exposure assessment*: The overall scope of an exposure assessment, if warranted, could focus on a subset of urban study areas selected for the epidemiology-based assessment. We could evaluate exposures associated with the recent air quality conditions and, if feasible and informative, evaluate exposures associated with just meeting the existing and potential alternative standard(s), if any. We note that there are likely to be additional challenges and uncertainties associated with characterizing ambient PM concentrations at high spatial and temporal resolution for just meeting the existing and any potential alternative standard(s).

4.3.2.2 Characterization of Sources of Uncertainty and Consideration of Information Newly Available in this Review

Conducting an exposure assessment for $PM_{2.5}$ using APEX presents a number of challenges in obtaining the inputs for the model. Incomplete or uncertain model inputs result in uncertainties in the estimated exposures. The primary limitations in input data for APEX are listed in Table 4-2. Identification of available model inputs and data limitations is one of the first steps in determining whether an APEX-based exposure assessment is warranted for this review. These considerations will be discussed, along with possible strategies for addressing the uncertainties and limitations, in the HREA Planning Document.

Table 4-2. Uncertainties and Limitations to Input Data used by APEX to Estimate Exposures

Category of Uncertainty/ Limitation	Description of Uncertainty/ Limitation
Spatial variability of ambient $PM_{2.5}$ concentrations	APEX requires spatially variable ambient concentrations in order to capture the spatial variation of exposure across the study area, and home/work differential exposures. The spatial resolution of other APEX inputs would be at a census tract level, so ideally tract-to-tract spatial variation of ambient $PM_{2.5}$ would be available for input to APEX.
PM aerodynamic properties	The aerodynamic properties of particles affect indoor infiltration rates and deposited PM in different lung regions. The breakdown into size fractions and density of the ambient $PM_{2.5}$ (which are input to APEX) are likely to be fairly uncertain.
Near-road and inside-vehicle exposures	For some PM size fractions (e.g., $PM_{10\text{-}2.5}$, ultrafine particles), the near-road and in-vehicle microenvironments may be important contributors to high ambient-related exposures. How these concentrations might be characterized could have varying degrees of uncertainty depending on the data available or the approach taken.
Activity pattern representativeness	The extent to which the human activity database (CHAD) provides a balanced representation of the population being modeled will vary across simulated study areas. APEX constructs activity sequences to account for the effects of population demographics and local climate, though this adjustment procedure does not fully capture all of the variability within an urban study area that exists in the people's activities that actually reside in the study area. Also, the extent to which a particular at-risk population or lifestage group is represented by the complete range of CHAD diaries may be uncertain.
Approach for developing longitudinal diary profile	One limitation of the CHAD activity pattern data used in our exposure model is that, on average, study participants provided less than two days of diary data. Thus, annual activity sequences of days for each simulated individual in APEX are a combination of diary

Category of Uncertainty/ Limitation	Description of Uncertainty/ Limitation
	days from a single or multiple similarly related subjects (e.g., age, sex), generated using a statistical algorithm and appropriate linking variables (e.g., daily time spent outdoors). Performance evaluations of the APEX algorithms have been limited by the small number of CHAD individuals having multiday diaries.
Indoor air exchange rates (AER)	Because people generally spend a significant amount of time indoors, AER are important in estimating exposures. APEX uses statistical distributions of AER that account for regional variability and several temperature ranges and considers separately the presence of mechanical and non-mechanical building ventilation, to the extent possible. One limitation is that it does not account for spatial differences that may exist in AER within an urban study area (e.g., based on differences in age of residence or building). In addition, while the set of existing AER distributions were developed from measurement studies conducted in specific geographic areas in the U.S., they may not include all specific study areas that could be selected for a population-based exposure assessment.

4.4 SCIENTIFIC AND PUBLIC REVIEW

The HREA Planning Document will be distributed to the CASAC for review and provided to the public for review and comment. The document will be the subject of a review with the CASAC at a public meeting or teleconference that will be announced in the *Federal Register*. The EPA does not produce a final HREA Planning Document, but instead considers CASAC recommendations and public comments in the design and when conducting the quantitative assessments either in a new HREA or in updating or expanding the last assessment as part of the PA. In either case, staff would prepare at least one draft of the assessment for CASAC review and public comment. CASAC would review the document and discuss it at a public meeting that would be announced in the *Federal Register*. Based on past practice, the EPA expects that CASAC would summarize key advice and recommendations for revision of the assessment in a letter to the EPA Administrator. In revising any draft HREA, the EPA would take into account any such recommendations and also consider comments received from the public, both at the meeting itself and directly in writing. A final assessment would then be made available on an EPA website, with its public availability announced in the *Federal Register*.

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5 WELFARE-RELATED RISK AND EXPOSURE ASSESSMENTS

5.1 INTRODUCTION

Within the context of NAAQS reviews, a quantitative welfare risk and exposure assessment (WREA) is designed to estimate exposure and risks to public welfare[110] associated with the existing secondary standards and with potential alternative secondary standard(s), if any, that might be appropriate to consider. This assessment can inform conclusions on the adequacy of the public welfare protection provided by these standards. The purpose of this chapter is to highlight key findings from the quantitative risk assessments conducted in the last review of the PM NAAQS and to identify key issues to be addressed in planning for any additional quantitative assessments that might be warranted for the current review. The scope of any WREA would be informed by the scientific evidence in the upcoming PM ISA; existing and historical air quality patterns and trends; the availability of improved data, methods, tools, and models that may better characterize important uncertainties or provide additional insights beyond those provided by previous assessments; and available resources.

In the last review of the PM NAAQS, the quantitative welfare assessments focused primarily on urban visibility and were presented in the Urban-Focused Visibility Assessment (2010 UFVA, U.S. EPA, 2010b) and the Policy Assessment (2011 PA, U.S. EPA, 2011). The EPA did not conduct quantitative assessments for other welfare-related effects from PM (e.g., ecological effects, climate effects, and materials effects).[111]

In the upcoming WREA Planning Document (discussed in sections 1.2 and 1.5, above), the EPA will evaluate the newly available information within the context of the 2010 UFVA and 2011 PA analyses from the last review of the PM NAAQS to determine 1) the extent to which important uncertainties may be better characterized by information newly available for the current review and 2) the extent to which new information may affect the results of the quantitative analyses from the last review in important ways or may suggest additional

[110] Welfare effects as defined in CAA 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."

[111] The on-going NO_X/SO_X review includes consideration of the ecological effects of ecosystem loading of particulate nitrogen and sulfur compounds. Thus, these endpoints are not discussed in this review.

quantitative analyses that can improve our understanding of the welfare exposures and risks associated with PM, including consideration of welfare effects beyond visibility impairment. The WREA Planning Document will also include a preliminary determination of whether a distinct WREA document would be needed. CASAC advice and public comments on this draft IRP will be considered in developing the WREA Planning Document, which will also be subject to CASAC review and will be made available for public comment. If warranted, one or more drafts of the WREA would then be prepared and released for CASAC review and public comment prior to completion of a final WREA.

Section 5.2 below describes the key analyses, findings and uncertainties from the last review of the PM NAAQS. Section 5.3 describes the effect categories to be considered for potential welfare assessments (i.e., visibility impairment, ecological effects, climate effects, and materials effects) that the EPA will further evaluate in the WREA Planning Document. Section 5.4 describes the process for obtaining scientific and public review of the WREA Planning Document and the WREA itself, if warranted.

5.2 SUMMARY OF WELFARE RISK AND EXPOSURE ASSESSMENT FROM THE LAST REVIEW

In the last review of the PM NAAQS, as summarized below, the EPA conducted quantitative assessments of PM-related visibility impairment in urban areas, recognizing that a secondary PM NAAQS developed with an urban focus would complement the EPA's Regional Haze Program, which focuses on Class I areas.[112] The purpose of these assessments was to provide information and insights to help inform decisions on the secondary standards. As noted above, these quantitative analyses were provided in two documents for the last review of the PM NAAQS: the 2010 UFVA and the 2011 PA. The 2010 UFVA combined information from urban-focused public preference studies, urban air quality data, and urban visibility protection programs. The 2011 PA incorporated some additional air quality analyses and used more recent air quality data. These assessments (described in section 5.2.1) included evaluations of different indicators, levels, averaging times, and forms for their appropriateness in the context of measuring urban visibility impairment and its impacts on public welfare.

[112] In 1977, Congress established as a national goal ''the prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Federal Class I areas which impairment results from manmade air pollution'', CAA section 169(a)(1). Currently, 156 national parks and wilderness areas are designated as Class I areas. For more information regarding the EPA's Regional Haze Program, please see http://www3.epa.gov/visibility/program.html.

As noted above (in section 5.1), in the last review of the PM NAAQS the EPA did not quantify welfare risks for effects other than visibility impairment. At the time of the last review, the Agency determined that any risks estimated using the limited data available for other PM-related welfare effects would have uncertainties too large to provide reasonable and informative results for the review. We discuss below (in section 5.2.2) the uncertainties identified in the last review of the PM NAAQS regarding additional PM-related welfare effects.

5.2.1 Quantitative Assessments of Urban Visibility Impairment in the Last Review

5.2.1.1 Reanalyses of Public Preference Survey Studies

The 2010 UFVA included a detailed reanalysis of the available urban visibility preference studies. These studies are surveys designed to elicit information about the public's preferences regarding visibility impairment by asking participants to rate the acceptability or unacceptability of a haze-obscured scene from each urban area. Each of these studies investigated the same question, "What level of visibility degradation is acceptable?" The studies available for the last review of the PM NAAQS were composed of three completed western urban visibility preference survey studies plus a pair of smaller focus studies designed to explore and further develop urban visibility survey methods. The three western studies included one in Denver, Colorado (Ely et al., 1991), one in the lower Fraser River valley near Vancouver, British Columbia, Canada (Pryor, 1996), and one in Phoenix, Arizona (BBC Research & Consulting, 2003). A pilot focus group with 9 participants was conducted in Washington, DC (Abt Associates, Inc., 2001), and a replicate study with 26 participants was also conducted for Washington, DC (Smith and Howell, 2009). When taken together, these studies included acceptability ratings regarding visual air quality (VAQ)[113] from a total of 852 individuals.

The approaches in the four studies were all derived from the method first developed for the Denver urban visibility study. Although the approaches used in the four preference studies were similar, the specific materials and methods used in each study introduced uncertainties to be considered when interpreting the results of the comparison of the studies. Key differences

[113] VAQ is defined as the visibility effect caused solely by air quality conditions and excluding those associated with meteorological conditions like fog and precipitation. It is commonly measured as either light extinction (in terms of inverse megameters, Mm^{-1}) or the haziness index (in terms of deciview, dv) (Pitchford and Malm, 1993). The deciview scale was developed for use in visibility perception studies because it has a more linear relationship to perceived changes in haze compared with light extinction. A dv is defined as ten times the natural logarithmic of one tenth of the light extinction in Mm^{-1} (Pitchford and Malm, 1993).

between the studies include the following: 1) scene characteristics; 2) image presentation methods (e.g., projected slides of actual photos, projected images generated using WinHaze[114] or use of a computer monitoring screen); 3) number of participants in each study; 4) participant representativeness of the general populations of the relevant metropolitan area; and 5) specific wording used to frame the questions used in the group interview process.

Given the similarities in the approaches used in the preference studies, the EPA used regression analysis to reanalyze the results of the preferences studies individually and in combination. Specifically, the 2010 UFVA used a logit model to develop response curves that depicted the percentage of participants in each study that rated the VAQ (measured in dv) as either "acceptable" or "unacceptable", for each of the visual images presented for a given area. The 2010 UFVA adopted the "50% acceptability" criterion from the Denver preference study (Ely et al., 1991), which identifies the inflection point along the response curve above which the visibility impairment of the scenes was found unacceptable by at least 50% of the participants and below which the level of VAQ in the images was found acceptable by at least 50% of participants, as a useful index for comparing the results across studies.

These results were used to identify similarities in public preferences regarding VAQ and to inform the range of candidate protection levels (CPLs)[115] in the 2010 UFVA and the 2011 PA. Specifically, the 2010 UFVA used the 50 percent acceptance criteria from each of the four urban preference studies to identify the range of CPLs from 20 dv to 30 dv, with a midpoint of 25 dv.[116] These values bracketed the daytime urban light extinction conditions that were judged unacceptable by 50 percent of the participants in the preference studies for those urban scenes, and provided low, medium, and high cut-points for use in the remaining assessments (U.S. EPA, 2010b, pp. 2-28 to 2-29).

5.2.1.2 Analyses of Visibility Conditions

Building on prior reviews of the PM NAAQS, in the last review the EPA conducted quantitative analyses to further characterize ambient PM conditions in terms of PM

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[114] The WinHaze model (Molenar et al., 1994) uses image processing technology to apply user-specified changes in light extinction values to the same base photograph with set scene and lighting characteristics.

[115] The term CPL refers to the target levels of visibility within a range that the EPA staff deemed appropriate for consideration that could, in conjunction with other elements of the standard, including indicator, averaging time, and form, potentially provide an appropriate degree of visibility protection.

[116] For comparison, 20 dv, 25 dv, and 30 dv are equivalent to 64, 112, and 191 Mm^{-1}, respectively.

concentrations and light extinction in 15 urban study areas. Analyses of visibility conditions were conducted as a part of the 2010 UFVA and the 2011 PA. Analyses in the 2010 UFVA evaluated calculated PM_{10} light extinction and were expanded in the 2011 PA to evaluate calculated $PM_{2.5}$ light extinction.[117]

The 2010 UFVA focused on calculated PM_{10} light extinction as the indicator for the quantitative assessments based on the data collected from the IMPROVE network (as described in section 2.3 above) and the requirements of the EPA's Regional Haze Program (U.S. EPA, 2009a, sections 9.2.3.2 and 9.2.3.4). These assessments used a combination of several datasets[118] as inputs into the IMPROVE algorithm[119] to estimate the daily maximum 1-hour PM_{10} light extinction using data from 2005 to 2007. The goals of these air quality assessments were to: 1) improve understanding of the extent, patterns, and causes of PM-related impairment of urban visibility during daylight hours; 2) create the basis for projections of $PM_{2.5}$ mass and PM_{10} light extinction under potential alternative standard scenarios; and 3) examine the correlation between PM_{10} light extinction and potential alternative indicator(s) based on $PM_{2.5}$ mass concentration (U.S. EPA, 2010b, chapters 3, 4, and Appendix D; U.S. EPA, 2011, Appendix F).

The 2011 PA contained additional air quality analyses in order to estimate $PM_{2.5}$ light extinction. $PM_{2.5}$ is the size fraction of PM responsible for the visibility impairment in most urban areas, and the methods for estimating $PM_{2.5}$ light extinction were simpler than the methods used in the 2010 UFVA for estimating PM_{10} light extinction. Benefits of moving to a simpler approach included: 1) more transparency in the required calculations; 2) less intensive data processing; 3) an increase in the number of monitoring sites that could meet the data requirements of the approach without adding sampling equipment or additional laboratory

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[117] Analyses in the 2010 UFVA and 2011 PA used the same 15 urban study areas as the 2010 HREA: Tacoma, Fresno, Los Angeles, Phoenix, Salt Lake City, Dallas, Houston, St. Louis, Birmingham, Atlanta, Detroit, Pittsburgh, Baltimore, Philadelphia, and New York. Collectively, these 15 study areas comprised 31 counties.

[118] Several datasets were combined for the 2010 UFVA analysis: 1) continuous hourly averaged $PM_{2.5}$ mass concentrations and relative humidity; 2) 24-hour average filter measurements for $PM_{2.5}$ composition; 3) hourly daylight $PM_{2.5}$ components generated using the Community Multi-scale Air Quality modeling system (CMAQ); and, 4) estimated/measured hourly $PM_{10-2.5}$ concentrations (U.S. EPA, 2010b, section 3). The resulting estimates of hourly averaged $PM_{2.5}$ component concentrations, $PM_{10-2.5}$ mass concentration, and the measured relative humidity were used in the IMPROVE algorithm to estimate hourly PM_{10} light extinction to be calculated for daylight hours with relative humidity no greater than 90 percent (U.S. EPA, 2010b, section 3.2, 3.3).

[119] The IMPROVE algorithm is based on data generated at monitoring sites in the IMPROVE network to estimate light extinction as a function of PM concentrations and relative humidity levels. For more detailed information on the IMPROVE algorithm, see section 9.2.2.2 of the 2009 PM ISA (U.S. EPA, 2009a). As noted above (in section 2.2.2), there is both an original and revised version of the IMPROVE algorithm (Pitchford et al. 2007). The revised version was developed to address observed biases in rural areas under certain light extinction conditions.

analysis; and 4) an increase in the number of days per year for which the calculation of PM light extinction could be conducted (U.S. EPA, 2011, Appendix F).

The quantitative analyses of visibility conditions can be considered as two distinct analyses, covering recent conditions and adjustments to just meet the existing standards. The first analysis presented in both the 2010 UFVA and the 2011 PA characterized the recent visibility conditions in the 15 urban study areas. However, the 2010 UFVA focused on PM_{10} light extinction using monitoring data from 2005 to 2007, whereas the 2011 PA focused on $PM_{2.5}$ light extinction using monitoring data from 2007 to 2009. The estimates of the percentage of daily maximum hourly $PM_{2.5}$ light extinction values exceeding the CPLs from the 2011 PA were somewhat lower than for the PM_{10} light extinction values from the 2010 UFVA. However, the patterns of the estimates across the 15 urban study areas were similar. Specifically, 13 of the 15 urban study areas in the 2011 PA (with the exception of two Texas and non-California western urban study areas) were estimated to have exceeded the high CPL (30 dv) from about 10 to 50 percent of the days based on the $PM_{2.5}$ light extinction analysis, while all 15 urban study areas were estimated to exceed the low CPL (20 dv) from 10 to 90 percent of the days (U.S. EPA, 2011, pp. 4-29 to 4-30).

The second analysis characterized visibility conditions adjusted to just meet the existing secondary standards. This adjustment applied a proportional rollback approach that uniformly reduced all $PM_{2.5}$ components to just meet the target levels (with a lower bound on potential air quality adjustments at PRB). For $PM_{2.5}$ light extinction in the 2011 PA, the analysis was designed to assess the likelihood that PM-related visibility impairment would exceed CPLs upon just meeting the suite of secondary $PM_{2.5}$ NAAQS (15.0 $\mu g/m^3$ annual and 35 $\mu g/m^3$ 24-hour (98^{th} percentile form)) (U.S. EPA, 2011, p. 4-33).[120] The $PM_{2.5}$ light extinction was estimated in terms of both daily maximum 1-hour average values and multi-hour (i.e., 4-hour) average values for daylight hours (U.S. EPA, 2011, p. 4-33).[121] When adjusted to just meet the existing standards, the daily maximum 1-hour average $PM_{2.5}$ light extinction values in a majority of the urban study areas were estimated to show improvement across the CPLs (U.S. EPA, 2011, Figures 4-4 and 4-7, Tables 4-3 and 4-6). Similar patterns of visibility improvement were also

[120] The 2010 UFVA included additional analyses characterizing visibility conditions on PM_{10} light extinction after adjustments to just meet an alternative suite of secondary $PM_{2.5}$ standards (i.e., 12.0 $\mu g/m^3$ annual and 25 $\mu g/m^3$ 24-hour) (U.S. EPA, 2010b).

[121] As mentioned in section 2.2.2, the EPA focused on sub-daily averaging times as the relevant exposure periods for segments of the viewing public due to the short-term nature of the perception of PM-related visibility impairment.

shown with daily maximum 4-hour average $PM_{2.5}$ light extinction values (U.S. EPA, 2011, Figure 4-8, Appendix G, Figure G-3).

5.2.1.3 Key Uncertainties in the 2010 UFVA and 2011 PA

- *Visibility Preferences*: In the last review of the PM NAAQS, a number of uncertainties were identified with respect to the public preference studies. There was substantial variability between studies in the range of visibility conditions that were judged by study participants to be "unacceptable" (U.S. EPA, 2010, Chapter 2). The relative importance of the degree of visibility impairment (e.g., light extinction level) versus the frequency and duration of visibility impairment in preference studies was unclear. Additionally, differences in the strength of preference for visibility conditions across the study areas (e.g., why visibility impairment that is acceptable in one area is not acceptable in another area) were not well understood. Moreover, the value of visibility in the preference studies is not distinctly defined beyond acceptable or unacceptable, and consideration of other metrics of valuing visibility may be needed. A better understanding of the reasons for differences in preferences across studies, differences in preference in different urban study areas, and alternative measures of acceptable visibility impairments could influence the interpretation of the results in defining additional or alternative range of CPLs for visibility impairment.
- *Calculation of Visibility Conditions*: In the last review of the PM NAAQS, a number of uncertainties were identified regarding the estimation of recent visibility conditions and adjustments to just meet alternative scenarios. Calculated light extinction estimates have uncertainties compared to directly measured PM light extinction. A number of uncertainties were identified with the inputs for the IMPROVE algorithm, including the use of measured or estimated PM concentrations and components and the influence of relative humidity in the IMPROVE calculations. The methods used to temporally apportion 24-hour $PM_{2.5}$ components to calculate hourly-averaged values relied on monthly-averaged $PM_{2.5}$ component variations from chemical transport modeling. The mass balance method used in this modeling to estimate organic carbon concentrations and the loss of nitrate was considered to be a reasonable approach but is not likely to be precise. Moreover, the IMPROVE algorithm was designed for use under the Regional Haze Program, which applies in rural areas, and the algorithm has not been validated for urban areas. Uncertainties remain with respect to the timeframe (e.g., 1-hour, 4-hour, 24-hour) for evaluating visibility conditions, particularly given that the public preference studies did not provide insight on the frequency or duration of visibility impairment that would be acceptable. In addition, the rollback approach uniformly reduced all non-PRB $PM_{2.5}$ components, but emission control programs in practice would not likely operate in this manner.

5.2.2 Consideration of Quantitative Assessments for Additional PM-related Welfare Effects in the Last Review

Based on the determination in the 2009 PM ISA (U.S. EPA, 2009a) that there was a "causal" relationship between PM and effects on visibility, climate, and materials, as well as a "likely to be causal" determination with ecological effects, the 2009 Scope and Methods Plan (U.S. EPA, 2009c) considered whether adequate evidence was available to conduct quantitative

assessments for each of these categories of effects. This Plan also noted that the chemical components of PM (to a greater extent than PM mass or size fraction) largely determine the nature, degree, and direction of the non-visibility welfare effects. After a careful evaluation of these categories of effects, the EPA determined in the 2009 *PM Scope and Methods Plan* that data were not available to conduct quantitative assessments for non-visibility welfare effects in the last review, including the following:

- *Ecological effects from deposition of particulate organics and metals*: Data to link PM toxicity to ecosystem function effects were available for only one tree species, and limited data on other species hindered additional analyses. Toxic effects of some PM components on plant leaves and soil were not well-characterized and it was difficult to isolate these endpoints from other environmental stressors. A lack of data on the site-specific composition of PM and soil-associated biota prevented quantitative analysis of population shifts from deposited PM. A lack of data on bioavailability of PM components and uncertainties in cumulative exposure effects prevented quantitative analysis of PM metal toxicity to biota. Data on PM components were only available for a few urban areas. Data were unavailable regarding seasonal composition of near roadway PM and trophic transfer to animals that forage on roadsides.
- *Climate effects*: Representation of aerosols in climate models was needed to more accurately predict changes in climate. Complex interactions of aerosols and linkages between clouds and the overall climate system limited the feasibility of conducting a quantitative analysis. Insufficient data on local and regional microclimate variations for many regions of the U.S. and heterogeneity of cloud formations limited the feasibility of conducting a quantitative analysis.
- *Materials effects*: New evidence was not sufficient to conduct a quantitative assessment of materials damage or soiling from PM deposition onto surfaces.

5.3 CONSIDERATION OF POTENTIAL QUANTITATIVE ASSESSMENTS FOR THIS REVIEW

The goals of a WREA in the current review would be to provide information relevant to answering questions regarding the adequacy of the existing PM secondary standards and, if appropriate, the potential improvements in public welfare that could be achieved from meeting potential alternative standard(s). Any quantitative WREA for the current review would build on the approaches used and lessons learned in the last review and would focus on whether newly available models, methods, tools, and data would substantially reduce the previously identified uncertainties.

As described further in this section, any WREA for the current review would consider the main categories of PM-related welfare effects (e.g., visibility effects, ecological effects, climate

effects, and materials) for which, in staff's judgment, there would be adequate information to develop quantitative risk estimates that can meaningfully inform the review of the secondary PM NAAQS. These considerations will be described in more detail in the WREA Planning Document. Preparation of the WREA Planning Document will draw from the assessments of the scientific evidence in the first draft PM ISA to facilitate the integration of policy-relevant science into the planning document. In particular, consideration of the availability of new data regarding each of these effects as well as consideration of available resources to conduct such assessments will influence whether we develop additional quantitative assessments in a new WREA. We anticipate that any quantitative analyses, if warranted, could focus on $PM_{2.5}$, but we would also consider the extent to which information becomes available in the PM ISA for the current review that could support quantitative analyses of PM components, $PM_{10\text{-}2.5}$, or ultrafine particles.

5.3.1 Visibility Effects

As described above (in section 5.2), the EPA conducted extensive quantitative assessments of the impact of visibility impairment on public welfare based on public preferences for VAQ and visibility conditions in 15 urban study areas in the 2010 UFVA and 2011 PA. The goals of any new or additional quantitative assessment for visibility would be to utilize newly available information to address the key uncertainties identified in the last review regarding the two key aspects of those analyses: visibility preference studies and air quality analyses. We discuss both of these below.

In the last review, the EPA heavily relied on surveys of public preferences regarding the acceptability of various levels of urban VAQ. Quantitative reanalysis of those survey results in the 2010 UFVA informed the development of the range of visibility CPLs (i.e., 20 to 30 dv). Based on information discussed during the 2015 PM NAAQS kick-off workshop (79 FR 71764), limited new evidence related to visibility preferences in urban areas has been identified in the available literature. The WREA Planning Document will evaluate any new visibility preference studies identified in the PM ISA for the current review to determine whether additional quantitative assessments would be warranted. To the extent that additional urban preference studies are identified in the PM ISA, we would consider whether an updated quantitative analysis that considered any new information provided by the new studies would substantially change the range of CPLs identified in the last review. If no additional visibility preference studies in urban areas become available in this review, we anticipate that the upcoming PA would continue to rely upon the quantitative analyses of the preference studies available in the last review. In addition, the PA would consider any additional information beyond preference studies that may

become available in the PM ISA relevant to assessing adversity to public welfare from urban visibility impairment.

In addition, we would consider in the WREA Planning Document whether providing updated air quality assessments to include more recent PM monitoring data would substantially reduce the uncertainties identified in the last review of the PM NAAQS regarding the characterization of recent visibility conditions and adjustment approaches to just meet the existing standards. The determination whether to conduct additional quantitative assessments of visibility conditions in the current review could depend on (1) whether updated information is available in the PM ISA to warrant new air quality assessments, such as significantly updated understanding of the variables that affect light extinction including relative humidity, PM species composition, $PM_{10-2.5}$ data, or the IMPROVE algorithm (Pitchford et al, 2007), and (2) whether we determine that an updated reanalysis of the preference studies would be warranted and would substantially change the range of the CPLs identified in the last review (20 to 30 dv). New quantitative air quality assessments, if warranted, could also use more recent air quality monitoring data, including data for PM concentrations and components to determine the extent to which the existing secondary standards are adequate given recent ambient concentrations. For example, such assessments could determine whether exceedances of the range of CPLs would be estimated to occur under more recent ambient conditions and under the existing secondary standards, if warranted.

In the WREA Planning Document, we will consider any new data that have become available in the PM ISA for the current review on preference studies and estimating visibility conditions in order to determine whether conducting additional quantitative analyses on visibility effects would meaningfully inform the current review of the secondary PM NAAQS. The EPA may determine that certain quantitative assessments are more appropriate in a PA rather than in a WREA.

5.3.2 Ecological Effects

As noted above, the EPA did not include a quantitative ecological risk assessment for any prior reviews of the PM NAAQS. For the current review, we are considering whether information would now be sufficient to conduct a quantitative ecological risk assessment associated with deposition of PM, primarily particulate organics and metals, including whether information and data are now available to address the uncertainties identified in the last review of the PM NAAQS that prohibited a quantitative ecological risk assessment. As noted above (in section 5.2.2), these uncertainties included limited data to link deposition of PM organics and metals to ecosystem functions and specific ecological receptors (e.g., soils, vegetation, and

fauna) effects, and other site-specific data. In the WREA Planning Document, we would consider whether any new information in the PM ISA for the current review substantially reduces the uncertainties identified in the last review of the PM NAAQS. In particular, we would consider any new information that 1) quantitatively elucidates pathways of exposure, 2) quantitatively characterizes ecological effects[122] from deposition of PM mass or PM components (e.g., specific organic and metal PM) on ecological receptors, and 3) provides information sufficient to quantify relationships between ambient PM, deposited PM, specific ecological effects, and, to the extent feasible, associated ecosystem services.

The first step in potentially assessing ecological effects associated with deposition of organic and metal PM would require the identification and quantification of the pathways of exposure. Pathways of PM exposure for ecological receptors can include direct deposition to the receptor surface via wet, dry or occult (e.g., fog) deposition, or transfer from one environmental compartment (e.g., aquatic, terrestrial) or organism to another. The last review of the PM NAAQS noted that the chemical constituents that make up PM (rather than PM mass) largely determine the nature, degree, and direction of the ecological effects (U.S. EPA, 2009c, Appendix A). The components that make up a given mass concentration of PM can vary substantially both temporally and spatially, which would affect the nature and magnitude of resulting ecological effects. Uncertainty associated with heterogeneity in deposition of PM components, along with significant data gaps, confounded efforts to evaluate PM-related ecological effects on ecosystem function at the ecosystem, regional, watershed, or national scale in the last review of the PM NAAQS (U.S. EPA, 2009c, Appendix A). In the WREA Planning Document, we would evaluate whether sufficient data have become available to estimate the spatial heterogeneity in site-specific PM deposition (across and within ecosystems), particularly of organic and metal components, and then to quantitatively link this deposition to ecological effects in various types of ecosystems.

In the last review of the PM NAAQS, vegetation was shown to be sensitive to heavy metal deposition (U.S. EPA, 2009c, Appendix A). For example, PM dry deposition to leaf surfaces and the inner canopy is well documented (U.S. EPA, 2009a, section 3.3.4.3). Impacts on vegetation from PM metal deposition include growth suppression, toxicity to root colonizing microorganisms, impairment of root development and induction of phytochelatins (U.S. EPA,

[122] As described above, the on-going NO_X/SO_X review includes consideration of the ecological effects of ecosystem loading of particulate nitrogen and sulfur compounds. Thus, these endpoints are not discussed in this review.

2009a, section 9.4.5.3).[123] However, the last review of the PM NAAQS also noted that toxic effects of some components of PM on plants are not well characterized, and it was difficult to isolate these endpoints from other environmental stressors (U.S. EPA, 2009c, Appendix A). Similarly, based on information discussed during the 2015 PM NAAQS kick-off workshop, limited new evidence has been identified related to PM effects on vegetation, but most of those plants were not native to the U.S. In addition, workshop participants also noted that new studies and models are available to quantify the removal of ambient PM by plants (e.g., air filtration by dry deposition on leaves), but this is a distinct issue from quantifying how PM deposition affects those plants (e.g., PM deposition on leaf surfaces that inhibits photosynthesis). In the WREA Planning document, we would evaluate whether sufficient data and tools are available to apply environmental modeling techniques to PM concentration and deposition data to quantify the responses in U.S. vegetation and the extent to which such information would provide additional insight regarding how PM toxicity affects ecosystem functioning considering the inherent uncertainties in such approaches.

Information from the last review of the PM NAAQS indicated a variety of potential adverse effects from PM deposition on soils (U.S. EPA, 2009a, section 9.4.5.2). For example, PM effects on soil and soil-associated microfauna from heavy metals (such as zinc, copper, and cadmium) have been shown to be toxic to soil fungi and bacteria, which could have broader implications at the ecosystem level because many plant species are dependent upon fungal and bacterial associations to obtain nutrients from the rhizosphere (U.S. EPA, 2009a). Shifts in soil microflora populations can also affect nutrient and organic matter cycling and carbon utilization. In addition, vegetation can take up heavy metals from the soil, which could lead to effects on wildlife and humans who consume those plants. These effects were not quantified in the last review of the PM NAAQS because of a lack of sufficient data. In the WREA Planning Document, we could evaluate whether sufficient data now exist to quantify the site-specific composition of PM deposition and the resulting population shifts in soil-associated biota in response to ecological stressors such as PM deposition.

The last review of the PM NAAQS indicated that fauna may also be an ecological receptor for deposition of PM organics and metals through ingestion, absorption, trophic transfer, transfer between aquatic to terrestrial compartments, and bioaccumulation and biomagnification of heavy metals across trophic levels (U.S. EPA, 2009a, section 9.4.5.6). However the last

[123] Phytochelatins are intracellular metal-binding peptides that act as specific indicators of metal stress (U.S. EPA, 2009a).

review of the PM NAAQS noted that quantitative assessment of particulate metal toxicity to biota was limited due to the heterogeneous composition of PM, lack of data on the bioavailability of PM components, and uncertainties in cumulative exposure effects (U.S. EPA, 2009c, Appendix A). In the WREA Planning Document, we could consider whether new data and information from the PM ISA in the current review would provide sufficient information on the effects of PM on aquatic and terrestrial invertebrates, amphibians, birds and mammals to conduct quantitative analyses of these ecological effects and associated ecosystem services.

In the WREA Planning Document, we could consider whether sufficient data have become available in the PM ISA for the current review to conduct quantitative analyses on the PM-related ecological risks to vegetation, soils, and fauna associated with PM deposition in light of inherent uncertainties. Although we do not anticipate that sufficient information would become available to reduce these uncertainties, if it did, we would give consideration to whether conducting such quantitative analyses of PM-related ecological risks and associated ecosystem services would be practicable and would meaningfully inform this review. If uncertainties and data gaps prevent the EPA from conducting a quantitative ecological risk assessment for this review, we anticipate that the upcoming PA would rely on information from the PM ISA regarding PM-related ecological effects.

5.3.3 Climate Effects

As noted above, the EPA did not include a quantitative climate risk assessment for any prior reviews of the PM NAAQS. The last review of the PM NAAQS noted that the addition of anthropogenic aerosols[124] to the atmosphere perturbs the Earth's energy balance and constitutes an aerosol climate forcing (U.S. EPA, 2009c, Appendix A). The influence of this forcing on various climate metrics across a wide range of scales is an active area of research, and studies have identified both direct and indirect aerosol forcing pathways that can lead to effects on climate (U.S. EPA, 2009a, section 9.3.1). Aerosol direct effects on climate can occur when changes in ambient aerosol properties (e.g., concentration, composition, and size distribution) alter atmospheric radiative budgets by modifying the scattering and absorption of radiation by particles. Aerosol indirect effects on climate can occur when changes in aerosol properties alter radiative budgets by modifying cloud amount, lifetime, and microphysical and radiative properties. Aerosol indirect effects include the effects on clouds resulting from the role of

[124] As noted above (in section 2.2.1), the term *aerosol* is used in this document when discussing suspended ambient particles in the context of climate impacts.

particles in the formation of cloud droplets and ice. An aerosol semi-direct effect can occur when clouds are affected by changes in atmospheric properties (e.g., relative humidity and vertical temperature structure) resulting from the absorption of radiation by particles.

Recent climate assessments characterize the current scientific understanding of aerosol effects on climate (Bond et al., 2013; IPCC, 2014; National Climate Assessment, 2014), and we anticipate that the evaluation of climate evidence in the PM ISA for the current review would be informed largely by findings of these major assessments. Improvements in measurements and modeling of atmospheric aerosol properties are continually occurring and will contribute to the understanding of aerosol effects on climate in this review. For example, remote sensing measurements from satellite systems and surface-based networks (e.g., AERONET[125]) can facilitate more advanced analysis of variables relevant to aerosol-climate interactions. We anticipate that atmospheric models with improved algorithms will be available in this review to better represent the interactions of atmospheric particles with radiation and clouds and improve the understanding of the role of aerosols in global climate change.

However, our current understanding is that considerable uncertainty in the effects of aerosols on climate still exists (Bond et al., 2013; IPCC, 2014). Large spatial and temporal heterogeneities in direct and indirect aerosol climate forcings occur due to the variety of aerosol sources, the intermittency of these sources, the short atmospheric lifetime of aerosols relative to the major greenhouse gases, and the chemical and microphysical processing that occurs in the atmosphere. These features lead to greater uncertainty in quantitative estimates of the effect of aerosols on climate relative to that of the major greenhouse gases. This uncertainty is especially large at the local and regional scales in the U.S. that would likely be most relevant to a quantitative assessment of the potential effects of a national PM standard on climate in this review. In the WREA Planning Document, we will consider the extent to which information in the PM ISA for the current review substantially reduces this uncertainty and whether information and tools would be sufficient to quantify the local and regional effects from aerosols in this review. Specifically, the WREA Planning Document will consider the extent to which conducting a quantitative climate assessment would provide meaningful information for this review beyond the information available in the PM ISA and the other major scientific assessments and considering the inherent uncertainties in such an assessment. For example, we would consider whether a quantitative assessment in the current review (1) could quantify how the PM NAAQS alone would affect climate and (2) how changes in PM (via changes in the

[125] See http://aeronet.gsfc.nasa.gov/

standards) would result in changes to climate. If uncertainties suggest that it would not be of value to the current review for the EPA to conduct a quantitative climate risk assessment for this review, we anticipate that the upcoming PA would rely on information from the PM ISA regarding PM-related climate effects.

5.3.4 Materials Effects

As noted above, the EPA did not include a quantitative risk assessment on materials for any prior reviews of the PM NAAQS due to a lack of data. PM-related materials effects are generally classified into two categories: materials damage and soiling.

Materials damage associated with deposited PM, particularly sulfates and nitrates,[126] include the corrosion of metals, degradation of painted surfaces, deterioration of building materials, and weakening of material components. Because of their electrolytic, hygroscopic, and acidic properties and their ability to sorb corrosive gases, particles contribute to materials damage by adding to the effects of natural weathering processes. Deposited pollutants often undergo chemical transformations and are commonly oxidized to acids, leading to materials damage particularly from reactions between materials and NOx and SO_2. Wet and dry deposition contribute to PM accumulation and surface damage, although the presence of moisture can accelerate some materials damage (e.g., corrosion of metals). Generally, SO_2 is more corrosive than NOx, but mixtures of SO_2, NOx, and other PM components and species can corrode certain metals at a faster rate than individual pollutants alone. In the last review of the PM NAAQS, sufficient evidence was not available to conduct a quantitative assessment of PM-attributable materials damage (U.S. EPA, 2004, 2009a, b). While ambient particles play a role in the corrosion of metals and in the weathering of materials, no quantitative relationships between ambient particle concentrations and rates of damages had been established (U.S. EPA, 2009a). If this information becomes available in the PM ISA, we would consider whether this information would be sufficient to support a quantitative assessment for PM-attributable materials damage.

Deposition of PM onto surfaces, such as metal, paint, and stone, can lead to soiling. Soiling is the result of PM accumulation on an object that alters the optical characteristics (appearance). The presence of PM may alter light transmission or change the reflectivity of a surface. These soiling effects can impact the aesthetic value of a structure or result in reversible

[126] In the case of materials effects, it is difficult to isolate the effects of gaseous and particulate N and S wet deposition so both will be considered along with other PM-related deposition effects on materials in this review of the PM NAAQS.

or irreversible damage to the surface. The presence of air pollution can increase the frequency and duration of cleaning and can enhance biodeterioration processes on the surface of materials. For example, deposition of carbonaceous components of PM can lead to the formation of black crusts on surfaces, and the buildup of microbial biofilms[127] can discolor surfaces by trapping PM more efficiently (U.S. EPA, 2009a, p. 9-195). Additionally, the organic or nutrient content of deposited PM may enhance microbial growth on surfaces. However, in the last review of the PM NAAQS, sufficient evidence was not available to conduct a quantitative assessment of PM-attributable soiling effects (U.S. EPA, 2004, 2009a,b). While soiling associated with fine and coarse particles can result in increased cleaning frequency and repainting of surfaces, no quantitative relationships between particle characteristics and the frequency of cleaning or repainting had been established (U.S. EPA, 2011). Additionally, despite the limited new data in the last review of the PM NAAQS on the role of microbial colonizers in biodeterioration processes and contributions of black crust to soiling, these data were not sufficient for quantitative analyses (U.S. EPA, 2011). Should new information about cleaning frequency and repainting of surfaces and the role of microbial colonizers in soiling effects become available in this review, we would consider whether this information would support a quantitative assessment.

In the WREA Planning Document, we will consider whether sufficient data have become available in the PM ISA for the current review to conduct quantitative analyses on either category of PM-related materials effects. If data gaps and uncertainties prevent the EPA from conducting a quantitative materials effects assessment for this review, we anticipate that the upcoming PA would rely on information from the PM ISA regarding PM-related materials effects.

5.3.5 Characterization of Sources of Uncertainty and Consideration of Information Newly Available in this Review

Table 5-1 summarizes the potentially important uncertainties related to the quantification of PM-related welfare effects where additional information, if available, could improve our understanding of PM-related welfare risks and/or reduce uncertainties identified in the last review of the PM NAAQS. To the extent that we would not be able to reduce these uncertainties in the current review, the utility of conducting additional quantitative welfare assessments would

[127] Microbial biofilms, primarily composed of fungi, can stain exposed rock surfaces with yellow, orange, brown, gray, or black colors.

be limited. We will further discuss these issues, including whether additional information has come available in the PM ISA for this review, in the WREA Planning Document.

Table 5-1 Areas of Uncertainty in the Welfare Assessments and Potential Strategies to Address Them

Major Uncertainty or Limitation	Uncertainty/Limitation Remaining from Last Review	Consideration of Information Newly Available in this Review
Variability in "acceptable" VAQ levels across preference studies and urban areas	There was substantial variability in the range of VAQ judged to be "acceptable" by the preference study participants across the urban areas studied. Limited studies and data were available to better inform our understanding of the factors leading to this variability. In addition, differences in the strength of preferences across urban areas were not well understood.	If new preference studies are available in the PM ISA and include additional explanatory variables regarding this issue, we would consider whether incorporating these studies into another quantitative assessment of the preference studies would be warranted for this review.
Degree of visibility impairment versus frequency and duration	The relative importance of the degree of visibility impairment (e.g., light extinction level) compared to the frequency and duration of visibility impairment in the preference studies was unclear.	If new preference studies are available in the PM ISA and include additional explanatory variables regarding this issue, we would consider whether incorporating these studies into another quantitative assessment of the preference studies would be warranted for this review.
Recent visibility conditions	Calculated estimates of PM light extinction have inherent uncertainties. For example, the IMPROVE algorithm uses measured or estimated PM concentrations and components, is influenced by relative humidity, and had not been validated for urban areas at the time of the last review. Limited hourly $PM_{10-2.5}$ monitoring, continuous $PM_{2.5}$ speciation monitoring, and direct measurement of PM_{10} light extinction contributed to uncertainties in estimating the light extinction. In addition, the time frame for assessing visibility conditions was uncertain because the	If a new quantitative analysis of visibility conditions is warranted for this review (i.e., based on the availability of new preference studies), we would evaluate whether new or different methods are available to reduce this uncertainty in characterizing $PM_{2.5}$ light extinction for recent conditions.

Major Uncertainty or Limitation	Uncertainty/Limitation Remaining from Last Review	Consideration of Information Newly Available in this Review
	preference studies did not provide insights on frequency or duration.	
Visibility conditions under existing and alternative standards	The proportional rollback approach used to just meet the existing (and alternative) standards uniformly reduced all $PM_{2.5}$ components, but emission control programs in practice would not likely operate in this manner.	If a new quantitative analysis of visibility conditions under alternative scenarios is warranted for this review, we would evaluate whether new or different methods are available to reduce this uncertainty in estimating $PM_{2.5}$ light extinction upon just meeting the existing standards and, if appropriate, potential alternative standards under evaluation.
Heterogeneity and data gaps in quantifying ecological effects	Ecological effects from PM deposition on soils, flora, and fauna vary greatly depending on the specific PM component, the ecosystem affected, and other site-specific information. However, data were limited on PM components outside of urban areas (other than near specific point sources) and the associated ecosystem responses from deposition of metals and organics.	If studies and data become available in the PM ISA to sufficiently reduce the uncertainties associated with quantifying the ecological effects, we would consider whether this new information would be sufficient to warrant a quantitative ecological assessment for this review.
Aerosols in climate models and local/regional variability	Improved representation of aerosols in climate models is essential to more accurate predictions of the role of PM in climate forcing. Most climate model simulations available did not consider local variations in climate forcing due to emissions sources and local meteorological patterns.	If the PM ISA provides an improved understanding of the local and regional effects of aerosols on climate, we would evaluate whether this new information would be sufficient to warrant a quantitative climate assessment for this review.
Materials damage and soiling effects	No quantitative relationships were available between ambient particle concentrations and rates of corrosion of metals and in the weathering of materials. In addition, no quantitative relationships were available between particles and the frequency of cleaning or repainting of surfaces. Data on the role of	If additional studies become available in the PM ISA to substantially reduce the uncertainty in quantifying materials damage and soiling effects, we would consider whether this new information would be sufficient to warrant a quantitative materials assessment for this review.

Major Uncertainty or Limitation	Uncertainty/Limitation Remaining from Last Review	Consideration of Information Newly Available in this Review
	microbial colonizers in biodeterioration processes and contributions of black crust to soiling were not sufficient for quantitative analyses.	

5.4 SCIENTIFIC AND PUBLIC REVIEW

The WREA Planning Document will be distributed to the CASAC for review and provided to the public for review and comment. The document will be the subject of a review with the CASAC at a public meeting or teleconference that will be announced in the *Federal Register*. The EPA does not produce a final WREA Planning Document but instead considers CASAC recommendations and public comments in the design and when conducting the quantitative assessments either in a new WREA or in updating or expanding the last assessment as part of the PA. In either case, staff would prepare at least one draft of the assessment for CASAC review and public comment. CASAC would review the document and discuss it at a public meeting that would be announced in the *Federal Register*. Based on past practice, the EPA expects that CASAC would summarize key advice and recommendations for revision of the assessment in a letter to the EPA Administrator. In revising any draft WREA, the EPA would take into account any such recommendations and also consider comments received from the public, both at the meeting itself and directly in writing. A final assessment would then be made available on an EPA website, with its public availability announced in the *Federal Register*.

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6 POLICY ASSESSMENT AND RULEMAKING

As outlined in section 1.2 above, the PA and rulemaking comprise the final phases of the review. These phases are described briefly in sections 6.1 (PA) and 6.2 (rulemaking) below.

6.1 POLICY ASSESSMENT

The PA will provide a transparent analysis and presentation of staff conclusions regarding the adequacy of the existing PM standards and the potential alternatives, if any, that are appropriate to consider in the current review. The PA will integrate and interpret the information from the ISA and, if available, REA(s) to frame policy options for consideration by the Administrator. The PA is also intended to facilitate CASAC's advice to the Agency, and recommendations to the Administrator, on the adequacy of the existing standards and on revisions that may be appropriate to consider, as provided for in the CAA. Staff conclusions will be based on the assessment of the scientific evidence in the PM ISA; the results of exposure and risk assessments in the REA(s), as available; and any additional staff evaluations and analyses that are included in the PA.

The discussion in the PA will be framed by consideration of a series of policy-relevant questions drawn from those presented in sections 2.1.3 and 2.2.3 above. These will include questions on the adequacy of the current PM standards and, as appropriate, on the elements of potential alternative standards (i.e., indicator, averaging time, form, level). The PA will identify evidence-based and exposure-/risk-based approaches for addressing these policy-relevant questions and for reaching public health and welfare policy judgments.

The PA will identify the range of policy options that the staff concludes could be supported by the available scientific evidence and the information from available quantitative assessments. In so doing, the PA will describe the interpretations of this evidence and information that could support various policy options, as appropriate, and that could be considered by the Administrator in making decisions on the PM NAAQS. This will include the identification of key uncertainties and limitations in the underlying scientific evidence and in the information available from quantitative assessments.[128]

In identifying ranges of primary and secondary standard options for consideration, the PA will recognize that the Administrator's final decisions will reflect public health and public

[128] In addition to presenting staff conclusions on the NAAQS, the PA will also highlight areas for future health- and welfare-related research, model development, and data collection.

welfare policy judgments. It will further recognize that the Administrator's final decisions will draw upon scientific information and analyses of health or welfare effects and risks, as well as judgments about how to deal with the range of uncertainties that are inherent in the scientific evidence and analyses.

Our approach in the PA to informing the Administrator's judgments on the primary PM standards will recognize that the available health effects evidence reflects a continuum consisting of PM exposure concentrations at which scientists generally agree that health effects are likely to occur, through lower exposure concentrations at which the likelihood and magnitude of the response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the CAA and with how the EPA and the courts have historically interpreted the CAA. These provisions require the Administrator to establish primary standards that are requisite to protect public health and that are neither more nor less stringent than necessary for this purpose. As discussed in section 1.1 above, the provisions do not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health, including the health of at-risk populations.

Similarly, our approach in the PA to informing the Administrator's judgments on the secondary PM standards will recognize that a final decision must draw upon scientific evidence and analyses about effects on public welfare, as well as judgments about how to deal with the range of uncertainties that are inherent in the relevant information. As is the case for the primary standards discussed above, this approach is consistent with the requirements of the NAAQS provisions of the CAA and with how the EPA and the courts have historically interpreted the CAA. These provisions require the Administrator to establish secondary standards that are requisite to protect public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The provisions do not require that secondary standards be set to eliminate all welfare effects, but rather at a level that protects public welfare from those effects that are judged to be adverse.

Staff will prepare at least one draft of the PA for CASAC review and public comment. CASAC will review the draft PA at a public meeting that will be announced in the *Federal Register*. Based on past practice by CASAC, the EPA expects that CASAC will summarize key advice and recommendations for revision of the document in a letter to the EPA Administrator. In revising the draft PA, we will take into account such recommendations, comments received from CASAC and from the public at the meeting itself, and any written comments received. The final document will be made available on the EPA website, with its public availability announced in the *Federal Register*.

6.2 RULEMAKING

Following the issuance of the final PA and the EPA management consideration of staff analyses and conclusions presented therein, and taking into consideration CASAC advice and recommendations, the Agency will develop a notice of proposed rulemaking. The notice of proposed rulemaking will convey the Administrator's proposed conclusions regarding the adequacy of the current standard(s) and any revision that may be appropriate. A draft notice of proposed rulemaking will be submitted to the Office of Management and Budget (OMB) for interagency review, in which OMB and other federal agencies are provided the opportunity for review and comment. After the completion of interagency review, the EPA will publish the notice in the *Federal Register* seeking comment on the proposed agency action – namely whether or not to revise the current standard, and if so, how. Monitoring rule changes associated with review of the PM standards will be developed and proposed, as appropriate, in conjunction with the NAAQS rulemaking.

At the time of publication of the notice of proposed rulemaking, all materials on which the proposal is based will be made available in the public docket of the rulemaking.[129] Publication of the proposal notice is followed by a public comment period, generally lasting 60 to 90 days, during which the public is invited to submit comments on the proposal to the rulemaking docket.

Taking into account comments received on the proposed rule, the Agency will then develop a notice of final rulemaking, which again undergoes OMB-coordinated interagency review prior to issuance by the EPA of the final rule. At the time of the final rulemaking, the Agency responds to all significant comments on the proposed rule.[130] Publication of the final rule in the *Federal Register* completes the rulemaking process.

[129] The rulemaking docket for the current PM NAAQS review is identified as the EPA-HQ-OAR-2015-0072. This docket has incorporated the ISA docket (EPA-HQ-ORD-2014-0859) by reference. Both dockets are publicly accessible at www.regulations.gov.

[130] For example, Agency responses to all significant comments on the 2009 notice of proposed rulemaking in the last review were provided in the preamble to the final rule and in a document titled *Responses to Significant Comments on the 2012 Proposed Rule on the National Ambient Air Quality Standards for Particulate Matter (June 29, 2012; 77 FR 28890)* (U.S. EPA, 2012).

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