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

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

U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
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Research Triangle Park, NC

DISCLAIMER

This integrated review plan for the national ambient air quality standards for particulate matter serves as a public information document and a management tool for the U.S. Environmental Protection Agency's (EPA) Office of Air Quality Planning and Standards (OAQPS) and National Center for Environmental Assessment (NCEA). The approach described in this plan may be modified to reflect information developed during this review and in consideration of advice and comments received from the Clean Air Scientific Advisory Committee and the public during the course of the review. Mention of trade names or commercial products does not constitute endorsement or recommendation for use. For more information contact 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 Mr. 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 AND ABBREVIATIONS

AAMS	Ambient Air Monitoring Subcommittee
ACS	American Cancer Society
AMTIC	Ambient Monitoring Technology Information Center
APEX	Air Pollutants Exposure model
AQCD	Air Quality Criteria Document
AQI	Air Quality Index
AQS	Air Quality System
ATUS	American Time Use Survey
BC	Black carbon
BenMAP-CE	Environmental Benefits Mapping and Analysis Program – Community Edition
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CBSA	Core-based statistical area
CHAD	Consolidated Human Activity Database
CPL	Candidate protection level
C-R	Concentration-response
CSN	Chemical Speciation Network
dv	Deciview
EC	Elemental carbon
U.S. EPA	United States Environmental Protection Agency
FEM	Federal Equivalent Method
FR	Federal Register
FRM	Federal Reference Method
HERO	Health and Environmental Research Online
HREA	Health Risk and Exposure Assessment
IARC	International Agency for Research on Cancer
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
Mm^{-1}	Megameters
N	Nitrogen
NAAQS	National Ambient Air Quality Standards

NATTS	National Air Toxics Trends Stations
NCEA	National Center for Environmental Assessment
NCore	National Core
NO_2	Nitrogen dioxide
NO_X	Oxides of nitrogen
O_3	Ozone
OAR	Office of Air and Radiation
OAQPS	Office of Air Quality Planning and Standards
OC	Organic carbon
OMB	Office of Management and Budget
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
QA	Quality assurance
QMP	Quality Management Plan
REA	Risk and Exposure Assessment
RIA	Regulatory impact assessment
S	Sulfur
SES	Socioeconomic status
SIP	State Implementation Plan
SLAMS	State and Local Air Monitoring Stations
SO_2	Sulfur dioxide
SO_X	Sulfur oxides
SOPM	Secondary Organic Particulate Matter
STN	Speciation Trends Network
TAD	Technical Assistance Document
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 Integrated Review Plan (IRP) is to communicate the plan for reviewing the air quality criteria and the primary and secondary NAAQS for PM.[2]

The Clean Air Scientific Advisory Committee (CASAC), an independent scientific advisory committee established under the Clean Air Act (CAA), reviewed a draft of the IRP at public teleconference meetings held on May 23, 2016 and August 9, 2016. The CASAC provided its advice on the draft IRP to the Administrator in a letter dated August 31, 2016 (Diez Roux, 2016).[3] This final IRP reflects the EPA staff's consideration of the CASAC's advice and of comments received from members of the public. As this review progresses, the plan described in this IRP may be modified to reflect information received during the review process, to address additional advice received from the CASAC, and/or to address comments received from the public.

This 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

[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] With regard to welfare effects in particular, this review of the PM NAAQS will address visibility, climate, and materials effects. As discussed in more detail below (section 1.4), the ecological effects associated with the deposition of oxides of nitrogen, oxides of sulfur, and PM are addressed in the ongoing review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM.

[3] 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.

6 discuss the key assessment documents for this review (i.e., Integrated Science Assessment (ISA), Risk and Exposure Assessments (REAs), Policy Assessment (PA)), the 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 certain "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).[4] 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."[5] 42 U.S.C. § 7409(b)(2).

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

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

[5] Welfare effects as defined in 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."

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 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 the CASAC.

Section 109(d)(2)(C) further states that "[s]uch committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards." The CAA does not specify the timing for advice under section 109(d)(2)(C), and this requirement is not tied to the five-year review cycle established for the air quality criteria and the NAAQS.

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 degree of protection against hazards that research has not yet identified.[6] 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. 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),[7] and the kind and degree of uncertainties. The selection of any

[6] 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).

[7] In recent reviews, the term "at-risk" has been used to define populations and lifestages potentially at increased risk of an air pollutant-related health effect (e.g., see recent ISAs for O_3 and NO_2; U.S. EPA, 2013; U.S. EPA, 2016a). At-risk populations can include those with intrinsic factors that make them more susceptible to pollutant-related effects (e.g., pre-existing disease, genetic characteristics) or that increase pollutant dose (e.g., breathing patterns),

particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment.[8] 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.[9]

In establishing 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, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. It is recognized that this final decision will be largely a public welfare policy judgment and will 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. The CAA 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.

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. Although, as noted above, section 109(d)(2)(C)(iv) provides that CASAC shall advise the Administrator of any adverse social, economic, or energy effects which may result from strategies for attainment and maintenance of the NAAQs, for EPA to consider advice on the costs of attaining and maintaining the NAAQS as part of the review of the NAAQS would be grounds for judicial vacatur of EPA's final decision. *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472 & n.4 (2001).[10]

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and extrinsic factors that could increase pollutant exposures (e.g., activity patterns; proximity to sources) (U.S. EPA, 2016a, pp. 1xiii to 1xiv).

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

[9] 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).

[10] In its review of the draft IRP for PM, the CASAC noted that any advice on possible adverse effects associated with implementation of the NAAQS pursuant to section 109(d)(2)(C)(iv) would be provided "separate from the standard-setting process" by an ad-hoc CASAC panel with the necessary expertise (Diez Roux, 2016).

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.[11] The phases of the NAAQS review process, and the documents developed, are described in more detail below.

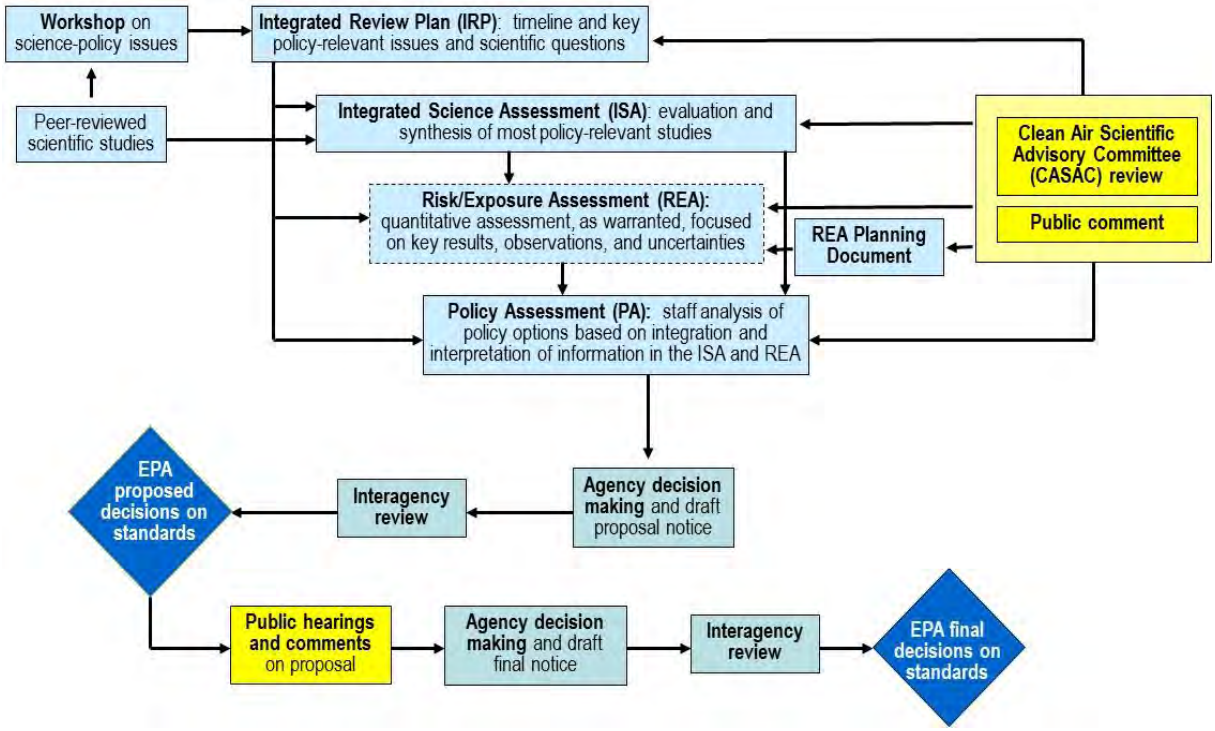

Figure 1-1. Overview of the EPA's process for reviewing NAAQS.

[11] The EPA maintains a website on which key documents developed for NAAQS reviews are made available (https://www.epa.gov/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 the CASAC's 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 the CASAC's 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 the CASAC's 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 the CASAC's 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 the 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 the CASAC's 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 the CASAC. Followed by 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 the 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 the 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.[12] The final ISA reflects staff's consideration of the 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 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

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

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 the 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 the 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 informed by 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; the 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.[13] Materials upon which proposed decisions are based, including the documents described above, are made available to the public in the regulatory docket for review.[14]

A public comment period, during which one or more public hearings may be held, follows publication of the notice of proposed rulemaking. Taking into account comments received on the proposed rule,[15] 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 dioxide (SO_2), nitrogen oxide (NO_X), ammonia (NH_3) and volatile organic compounds (VOC). Examples of secondary particle formation include: (1) the conversion of SO_2 to sulfuric acid (H_2SO_4) vapor that nucleates new particles or condenses on existing particles and further reacts with 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) (U.S. EPA, 2004, Chapter 3). The chemical and physical properties of PM vary greatly with time, region, meteorology, and source category, complicating the assessment of health and welfare effects.

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[13] 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.

[14] 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. A separate docket has also been established for the ISA (docket ID number EPA-HQ-ORD-2014-0859).

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

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 NAAQS promulgated for particulate matter 1971-2012.[16]

Review Completed	Indicator	Averaging 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[17]
	PM_{10}	24-hour	150 μg/m^3	99th percentile, averaged over 3 years[18]
		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
		Annual	15.0 μg/m^3	Annual arithmetic mean, averaged over 3 years[19]
	PM_{10}	24-hour[20]	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

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

[17] 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.

[18] 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).

[19] 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.

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

		Annual	12.0 μg/m^3 (primary) 15.0 μg/m^3 (secondary)	Annual mean, averaged over 3 years[21]
	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).[22] 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.[23] The level of the 24-hour standards (primary and secondary) was set at 150 μg/m^3, and the form was one expected exceedance per year, on average over three years. The level of the annual standards (primary and secondary) was set at 50 μg/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

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

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

[23] 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.

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;[24] 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 setting them equal 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 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

[24] 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).

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.[25]

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 the 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).[26] 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

[25] 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).

[26] 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.

the form of the annual $PM_{2.5}$ standards by narrowing the constraints on the optional use of spatial averaging.[27] 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.[28] 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 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

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

[28] In the 2006 proposal, the EPA proposed to revise the 24-hour PM_{10} standard in part by establishing a new $PM_{10-2.5}$ indicator for thoracic coarse particles (i.e., particles generally between 2.5 and 10 μm in diameter). The EPA proposed to include any ambient mix of $PM_{10-2.5}$ that was dominated by resuspended dust from high density traffic on paved roads and by PM from industrial sources and construction sources. The EPA proposed to exclude any ambient mix of $PM_{10-2.5}$ that was dominated by rural windblown dust and soils and by PM generated from agricultural and mining sources. In the final decision, the existing PM_{10} standard was retained, in part due to an "inability…to effectively and precisely identify which ambient mixes are included in the [$PM_{10-2.5}$] indicator and which are not" (71 FR 61197, October 17, 2006).

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,[29] 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)[30] and an urban-focused visibility assessment (U.S. EPA, 2010b),[31] 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).

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).[32] With regard to primary standards for $PM_{2.5}$, the EPA revised the level of the annual $PM_{2.5}$ standard[33] 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[34] 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).

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

[30] 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.

[31] 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.

[32] The bases for these decisions are discussed further in sections 2.1 and 2.2, below.

[33] The EPA also eliminated the option for spatial averaging (section 2.1.1, below).

[34] Consistent with the primary standard, the EPA eliminated the option for spatial averaging with the annual standard (section 2.1.1, below).

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 short-term (i.e., hours up to one month) or long-term (i.e., one month to years) 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 short- or long-term exposures to PM based on 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 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, the ecological effects associated with the deposition of oxides of nitrogen, oxides of sulfur, and PM are being addressed in a separate review (i.e., the review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM).[35] These PM-related ecological effects include eutrophication, acidification, and sulfur enrichment associated with particle deposition, and the direct and indirect effects of PM on vegetation, soils, and biota. In this review of the PM NAAQS, welfare effects to be considered include PM-related visibility impairment, climate effects, and materials damage and soiling (i.e., materials effects). 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.

[35] In recognition of the linkages between oxides of nitrogen, oxides of sulfur, and PM with respect to atmospheric chemistry and deposition, and with respect to ecological effects, the reviews of the ecological effects evidence and the secondary standards for these pollutants are being conducted together. For more information on the current review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM, see https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-air-quality-standards.

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 workshop was organized around a series of panel discussions focused on the following topics:

- Characterizing PM Emissions, Air Quality and Exposure
- Planning for the Review of the Health Effects Evidence
- Planning for the Quantitative Health Risk and/or Exposure Assessments
- Planning for the Review of the Welfare Effects Evidence
- Integrating Evidence and Quantitative Assessments.

The input received at the workshop guided the EPA staff in developing this IRP.[36] The workshop agenda, including the questions that served to guide panel discussions, is attached as an appendix to this IRP. The EPA's anticipated schedule for the remainder of this review is summarized in Table 1-3, below.

[36] Input to the EPA from workshop participants reflected the views of those individuals. Panelists were not charged with providing a consensus viewpoint or consensus advice to the Agency, and a summary report of the workshop was not prepared.

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	December 2016
Science Assessment	Release First Draft ISA for CASAC/public review	Fall 2017
	CASAC Review Meeting for First Draft ISA	Winter 2018
	Release Second Draft ISA for CASC/public review	Fall 2018
	CASAC Review Meeting for Second Draft ISA	Winter 2019
	Release Final ISA	Fall 2019
Risk/Exposure Assessments	Release REA Planning Document(s) for CASAC/public review	Fall 2017
	CASAC Review Meeting for REA Planning Document(s)	Winter 2018
	Release First Draft REA(s) for CASAC/Public Review	Fall 2018
	CASAC Review Meeting for First Draft REA(s)	Winter 2019
	Release Second Draft REA(s) for CASAC/Public Review	Fall 2019
	CASAC Review Meeting for Second Draft REA(s)	Winter 2020
	Release Final REA(s)	Fall 2020
Policy Assessment/ Rulemaking	Release First Draft PA for CASAC/public review	Fall 2018
	CASAC Review Meeting on First Draft PA	Winter 2019
	Release Second Draft PA	Fall 2019
	CASAC Review/Public Comment on Second Draft PA	Winter 2020
	Release Final PA	Fall 2020
	Proposed Rulemaking	2021
	Final Rulemaking	2022

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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[37] 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 key policy-relevant questions for the current review. 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.

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 $\mu g/m^3$,[38] 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

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

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

of 150 μg/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);[39] the advice and recommendations of the 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 μg/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" (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 the 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

[39] 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.

Administrator's conclusions, are summarized in sections 2.1.1.1 to 2.1.1.4 below. Section 2.1.1.5 summarizes the key areas for additional research and data collection identified in the last review.

2.1.1.1 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).[40] 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 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, the CASAC advised that it was appropriate to consider retaining $PM_{2.5}$ as the indicator for fine particles. The 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 the

[40] 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, 2009, pp. 3-2 to 3-3).

CASAC's recommendations, and concluded that it was "appropriate to retain $PM_{2.5}$ as the indicator for fine particles" (78 FR 3123, January 15, 2013).

2.1.1.2 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).[41] With regard to potential support for a seasonal averaging time, few studies were available 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). The CASAC agreed that these conclusions were reasonable (Samet, 2010a, p. 13). The Administrator concurred with the PA conclusions and with the CASAC's advice. Specifically, she judged that it was "appropriate to retain the current annual and 24-hour averaging times for the primary $PM_{2.5}$

[41] 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).

standards to protect against health effects associated with long- and short-term exposure periods" (78 FR 3124, January 15, 2013).

2.1.1.3 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.[42] 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)[43] (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 98th 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).[44]

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

[42] 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 core-based statistical area (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.

[43] 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).

[44] 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).

persons with lower SES levels are a susceptible group for PM-related health risks, [the] 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.[45] 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 that it was appropriate to retain the 98th percentile form for the 24-hour $PM_{2.5}$ standard (78 FR 3127, January 15, 2013).

2.1.1.4 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

[45] 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.

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).[46] 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

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

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.[47] 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 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 25^{th} 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).[48]

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[47] 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).

[48] 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).

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.[49]

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 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 the 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.

[49] 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).

2.1.1.5 Areas for Additional Research and Data Collection

In the last review, the PA identified key areas for additional research and data collection for fine particles, based on the uncertainties and limitations that remained in the evidence and technical information, and on CASAC advice (U.S. EPA, 2011, section 2.5; Samet, 2010b, pp. 5-6). An important focus was on improving our understanding of the range of ambient $PM_{2.5}$ concentrations over which the evidence indicates confidence in the PM-associated health effects observed in epidemiologic studies. This included the need to better understand PM concentration-response relationships at low ambient concentrations. The PA also emphasized the need for additional health research on PM components and sources, ultrafine particles, the impacts of co-occurring pollutants and susceptible populations. The PA further recognized the importance of research into the factors that influence PM exposures and the most relevant exposure durations, as well as the importance of monitoring and modeling efforts to enhance our understanding of the temporal and spatial variability of $PM_{2.5}$, $PM_{2.5}$ components, and PM size fractions other than $PM_{2.5}$ (e.g., UFPs). As discussed below (section 2.1.3), an important consideration in the current review will be the extent to which recent research and technical advances have reduced key uncertainties and limitations from the last review.

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.[50]

(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;[51] 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} standard, with its one-expected exceedance form and a level of 150 $\mu g/m^3$, is requisite to protect

[50] 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.

[51] 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).

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.

As for fine particles, in the last review the PA and CASAC identified key areas for additional research and data collection for thoracic coarse particles. Beyond the areas that were also identified for fine particles (section 2.1.1.5, above), the PA identified the need for additional well-conducted $PM_{10-2.5}$ experimental studies to inform causality determinations in the ISA, studies with well-characterized personal exposures to $PM_{10-2.5}$, an understanding of the relationships between the $PM_{10-2.5}$ exposure surrogates used across epidemiologic studies (given the various monitoring approaches employed) and additional studies of long-term $PM_{10-2.5}$ exposures (U.S. EPA, 2011, section 3.5). In its review of the second draft PA, the CASAC concluded that the areas identified were reasonable, and emphasized the need for national monitoring of $PM_{10-2.5}$ in order to provide a basis for future epidemiologic studies (Samet, 2010b). As discussed below (section 2.1.3), an important consideration in the current review will be the extent to which recent research and technical advances have reduced key uncertainties and limitations from the last review.

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.[52]

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 warranted), 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

[52] 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.

evaluating the health protection afforded by the current standards, and by any alternatives considered.

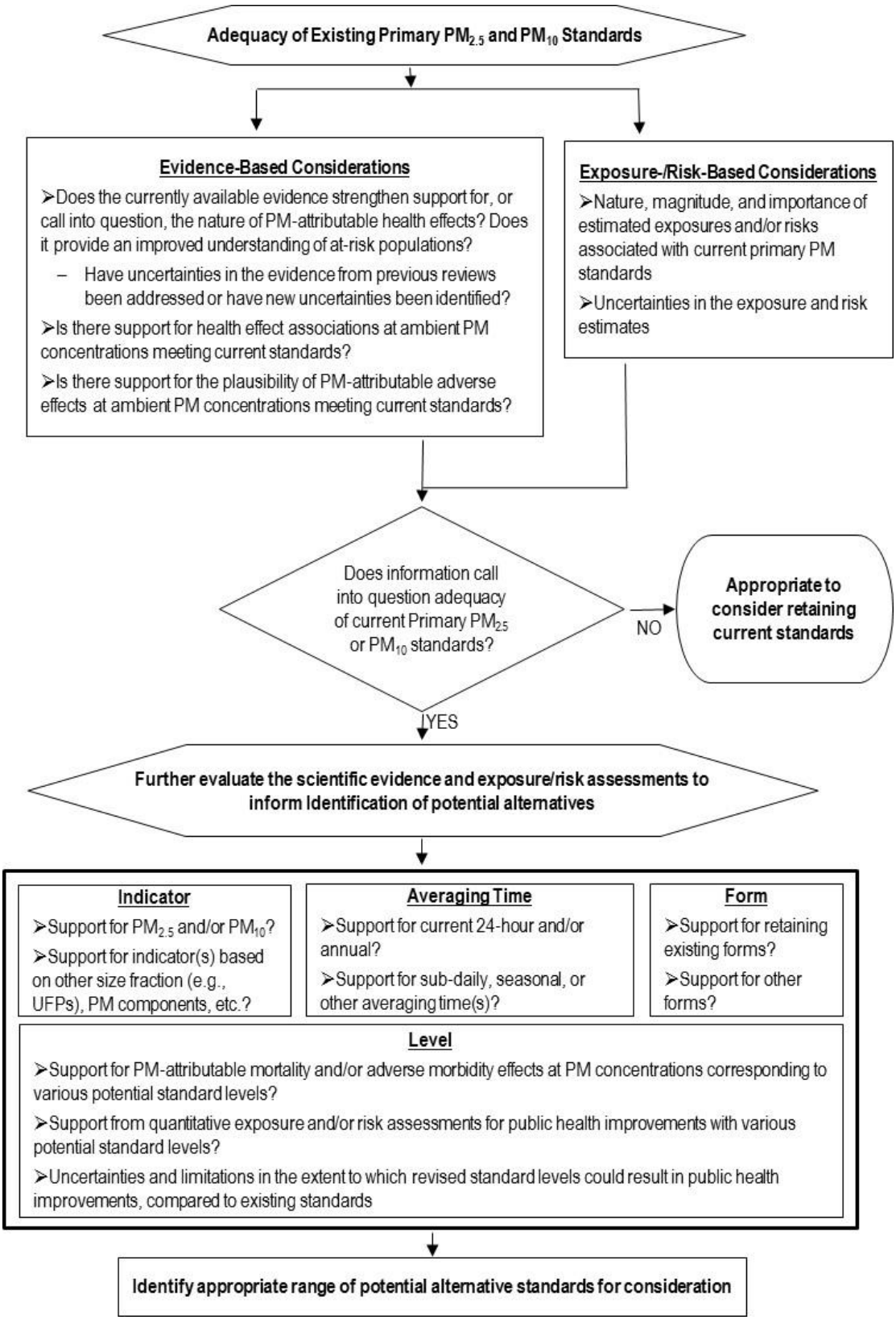

Figure 2-1. Overview of general approach for review of primary PM standards.

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). Policy-relevant questions 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?
- 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 modified (e.g., larger and/or more serious) by 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, air quality information, and exposure/risk 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). As described below, the EPA retained the 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 2.2.1.1 and 2.2.2.1, respectively. Sections 2.2.1.2 and 2.2.2.2 summarize the key areas for additional research and data collection identified in the previous review. Key policy-relevant issues for the current review are discussed in section 2.2.3.

[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.

2.2.1 Non-Visibility Welfare Effects

2.2.1.1 Decisions in the Previous Review

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 in the last review included climate effects, ecological effects (e.g., effects on plants, soil and nutrient cycling, wildlife and water),[54] 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[55] 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, 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

[54] As described above, the on-going review of the secondary NAAQS for Oxides of Nitrogen and Oxides of Sulfur includes consideration of the ecological effects of oxides of nitrogen, oxides of sulfur, and PM. Thus, these endpoints are not discussed in this review.

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

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 the CASAC advice related to non-visibility effects. Specifically, the 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).

2.2.1.2 Areas for Additional Research and Data Collection

In the last review, the EPA and the CASAC identified key areas for additional research and data collection for non-visibility welfare effects, based on the uncertainties and limitations that remained in the evidence and technical information (U.S. EPA, 2011, sections 5.2.4, 5.3.4, and 5.4.4). These key areas were identified for climate effects, ecological effects, and materials effects of fine and coarse particles.

One of the primary areas for additional research and data collection related to climate effects was a lack of accurate measurement of aerosol contributions, specifically the quantification of aerosol absorption, and the inability to separate the anthropogenic component from total aerosol forcing. The spatial and temporal heterogeneity of aerosols were uncertainties in the last review, including the contributions of regional differences in aerosol concentrations, policy-relevant and natural concentrations, and individual components to aerosol forcing. The improved representation of aerosols in climate models and the interaction of PM with clouds were identified as areas for additional research in climate modeling. The CASAC also highlighted that an improved understanding of size-dependent PM composition would also help address questions related to the role and scattering and absorbing aerosols (Samet, 2010b, p. 13).

Areas for additional research and data collection related to ecological effects included the presence of multiple ecological stressors confounding attempts to link specific ecosystem responses to PM deposition and predicting the amount of PM deposited to sensitive receptors

from measured concentrations of PM in the ambient air. Additionally, because of the variety and lack of sufficient baseline data on unique features of ecosystems and the variability in ecosystem responses, it was not possible to extrapolate from one ecosystem to another.

One area for additional research and data collection related to materials effects included the improvement of quantitative relationships between particle size, concentration, chemical concentrations, and frequency of repainting and repair. Deposition rates of airborne PM to surfaces and the interaction of co-pollutants were also identified as areas for additional research and data collection.

As discussed below (section 2.2.3), an important consideration in the current review will be the extent to which these key uncertainties and limitations from the last review have been reduced by recent efforts.

2.2.2 Visibility Effects

2.2.2.1 Decisions in the Previous Review

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.[56] 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

[56] 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.

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).[57] 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.

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,[58] 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

[57] 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).

[58] The IMPROVE algorithm (Pitchford et al., 2007) uses major PM chemical composition 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.

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 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 to 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 90th 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)[59] as being a reasonable range of "candidate protection levels" (CPLs).[60] 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 90th 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

[59] 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.

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

$\mu g/m^3$ 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 "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).

2.2.2.2 Areas for Additional Research and Data Collection

In the last review, the EPA and the CASAC identified key areas for additional research and data collection for visibility welfare effects, based on the uncertainties and limitations that remained in the evidence and technical information (U.S. EPA, 2011, section 4.5). The EPA identified two major overarching areas for future research and data collection: refining the understanding of visibility preferences and characterization of urban visibility conditions.

Future research areas identified by EPA to address deficiencies in understanding how the public reacts to and values visibility conditions included designing and conducting additional preference, valuation and exposure studies to:

- Expand the number and geographic coverage of urban area preference results;
- Evaluate the sensitivity of results to the differences in survey study methodology;
- Apply consistent methodology at multiple urban areas to better understand reasons for preference difference among results in different urban areas;
- Develop information on the strength of preference and relative importance of intensity versus frequency of visibility impairment;

[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).

- Identify the types of scenic elements that are most influential for informing public visibility impact awareness; and
- Provide insights concerning visibility impact exposure duration, intensity, and timing and their relationship to the degree and longevity of public welfare effects.

The CASAC also identified a strong need for additional urban visibility preference studies conducted using consistent methodology and using a range of urban scenes (Samet, 2010b, p. 12).

The PA also noted that a pilot $PM_{2.5}$ light extinction monitoring program could help with determining ambient visibility conditions and the relationships between PM component concentrations and light extinction. The information from such a pilot monitoring program could be used to:

- Evaluate the performance of $PM_{2.5}$ light extinction monitoring methods that could ultimately be use as an FRM;
- Evaluate and refine approaches for apportioning 24-hour $PM_{2.5}$ species to hourly values (needed for sites without continuous $PM_{2.5}$ speciation monitoring);
- Evaluate and refine light extinction calculation algorithms for use in urban settings; and
- Conduct the visibility effects assessment for the next PM secondary NAAQS.

The CASAC supported the proposal to conduct studies in several cities, pairing direct monitoring of light extinction with enhanced monitoring of PM size and composition distributions (Samet, 2010b, p. 12).

As discussed below (section 2.2.3), an important consideration in the current review will be the extent to which these key uncertainties and limitations from the last review have been reduced by recent efforts.

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.

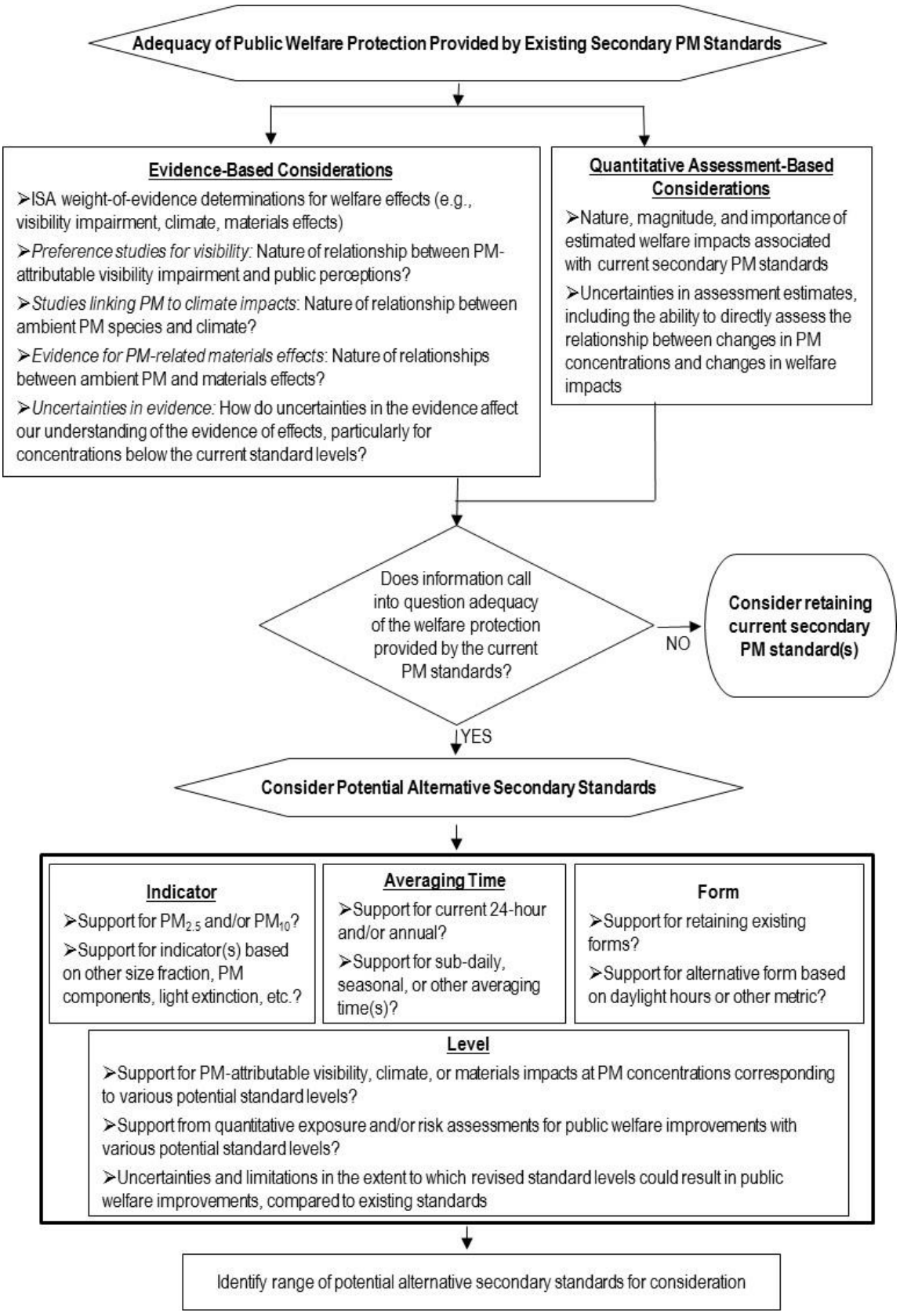

Figure 2-2. Overview of general approach for review of secondary PM standards.

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. Policy-relevant questions include the following:

- To what extent has new scientific evidence improved our understanding of the nature and magnitude of visibility, climate, 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?
- 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 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)[62] 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.

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.

[62] 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).

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 $PM_{10-2.5}$ 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.[63] All sampler and monitor counts provided below are based on data submitted to the EPA for calendar year 2015, unless otherwise noted.

2.3.1.1 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 are 184 TSP samplers still in operation as part of the lead monitoring program; of these, 58 also report TSP mass.

2.3.1.2 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 730 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 385 of the stations operate continuous mass monitors

[63] More information on ambient monitoring networks can be found at https://www.epa.gov/amtic/.

approved as FEMs and 435 operate FRMs. About 60 of the PM_{10} stations have collocation with both continuous FEMs and FRMs. Over two thirds of the PM_{10} stations with FRMs operate on a sample frequency of one in every sixth day, with about 100 operating every third day and 25 operating every day.

2.3.1.3 $PM_{2.5}$ 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 761 FRM filter-based samplers that provide 24-hour $PM_{2.5}$ mass concentration data. Of these operating FRMs, 114 are providing daily $PM_{2.5}$ data, 519 every third day, and 128 every sixth day. Approximately 900 continuous $PM_{2.5}$ mass monitors provide hourly data on a near real-time basis. 414 of the $PM_{2.5}$ continuous monitors are FEMs and therefore used for comparison with the NAAQS and AQI, and another 489 monitors use 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, the 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 76 largely urban locations comprised of either the STN or the National Core (NCore) network.[64] 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 $PM_{10-2.5}$ mass utilizing an FRM, FEM or IMPROVE for some of the 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 11 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 72 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.[65] Supplemental CSN stations typically operate every sixth day. In January 2015, 38 supplemental CSN stations that are largely located in the eastern half of the country stopped operations to ensure a sustainable CSN network moving forward.

[64] 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.

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

Specific components of fine particles are also measured through the IMPROVE monitoring program[66] 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 IMPROVE network includes 110 monitoring locations that are part of the base network supporting regional haze and another 46 locations 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 funded are available on an interactive website[67]. 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.[68]

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

[66]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.

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

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

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).[69]

2.3.1.4 $PM_{10-2.5}$ 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} 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 are 264 stations where $PM_{10-2.5}$ data are being reported to the EPA.

[69] 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).

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.[70] The coarse particle speciation pilot study should provide useful information for any organization wishing to pursue coarse particle speciation.

2.3.1.5 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 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)[71].

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 23 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.

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[70] 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

[71] 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

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 data is measured at just two locations: one station each in North Carolina and Indiana. The continuous sulfate analyzer provides hourly data and these 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 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.[72]

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 a public meeting with the Ambient Air Monitoring Subcommittee (AAMS) of the Clean Air Scientific Advisory Committee.[73] 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.[74] 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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[72] For more information, see https://www.epa.gov/sciencematters/epas-next-generation-air-measuring-research and https://www.epa.gov/air-sensor-toolbox/air-sensor-toolbox-what-epa-doing#pane-1

[73] For example, the EPA is planning to request a consultation with the AAMS on development of a Fourier transform-infrared (FT-IR) spectroscopy that may be an alternative method for carbon characterization in the CSN and IMPROVE programs.

[74] 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 non-ecological welfare evidence necessary to support the PM NAAQS review process. The ecological effects of PM are being addressed in a separate assessment along with ecological effects of oxides of nitrogen and oxides of sulfur (i.e., the Integrated Science Assessment for Oxides of Nitrogen, Oxides of Sulfur and Particulate Matter – Ecological Criteria).

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,[75] as well as on any new interpretations of 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, and materials 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 non-ecological 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 non-ecological 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 non-ecological 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 visibility, climate, and materials), the PM ISA will focus more specifically on policy-relevant considerations, such as the level at which effects are observed, and 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. 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? For both epidemiologic and toxiciological studies,

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

key study-specific details that are relevant to informing the adequacy of the current PM NAAQS 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.[76] For example, CASAC provided specific advice about the evaluation of PM_{10}. Although the indicator for coarse particles is PM_{10},[77] 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 non-ecologcial welfare effects evidence or evaluate a new health or non-ecological 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 non-ecological 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, transport, and transformation of PM in the environment; (3) measurement of PM and recent ambient concentrations of PM; (4) the validity of inferences that can be drawn about PM

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

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

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 non-ecological 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 extensively detailed in the Preamble to the Integrated Science Assessments (U.S. EPA, 2015). An overall summary of the process will be described throughout this chapter. Collectively, the approach outlined for the health and non-ecological 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 non-ecological 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 new information (since the last PM NAAQS review) further inform the relationship between exposure to PM and specific health and non-ecological welfare effects?
- 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 of the PM NAAQS 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 of short-term (i.e., hours up to one month) and long-term (i.e., one month to years) exposures 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 supported by CASAC during the development of the 2009 PM ISA (Samet, 2009)) and (1) include a composite measure of PM[78] or (2) apply some approach to assess the direct effect of PM when the exposure of interest is a source-based mixture (e.g., diesel exhaust, gasoline exhaust, wood smoke). Additionally, consistent with previous CASAC recommendations 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 (Samet, 2009). 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 $PM_{2.5}$ and/or $PM_{10\text{-}2.5}$, or in the case of ultrafine particles [UFP] mass, particle number, etc.) 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 for individual components or alternative metrics to the current mass-based PM indicators. Additionally, these criteria ensures that a systematic approach is used in both identifying and evaluating those studies that examine PM components. Case (2) primarily applies to experimental studies that attempt to disentangle the effect of PM on health from a complex air pollution mixture of particles, gases, and species distributed between the gas and particle phases. 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.

For non-ecological welfare effects (i.e., visibility, climate, and materials effects), this ISA will build on information available during the last review describing the role of PM on visibility impairment, radiative forcing resulting in global and regional climate change, and materials damage and soiling. For visibility effects, 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 effects, 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

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

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) as well as other recent and more focused reports relevant to PM climate forcing (e.g., the 2012 Report to Congress on Black Carbon). 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. For effects on materials, studies will be included that examine the role of PM and relevant precursor gases on materials damage and soiling. Specifically, studies will be considered that examine both particulate and gaseous contributions from oxides of nitrogen and oxides of sulfur along with other PM components due to the difficulty associated with isolating the effects of gaseous and particulate N and S wet deposition and because the ISA for Oxides of Nitrogen, Oxides of Sulfur and Particulate Matter – Ecological Criteria will focus only on ecological effects.

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 non-ecological welfare effects, information describing the extent to which health and non-ecological 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). 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] The next chapter will examine studies that provide evidence of differential exposure to PM within a population as well as evidence of differential risk for PM-related health effects to draw conclusions about potential at-risk lifestages and populations. The last chapter of the ISA will be devoted to non-ecological welfare effects evidence with causal determinations for visibility, climate, and materials effects.

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.

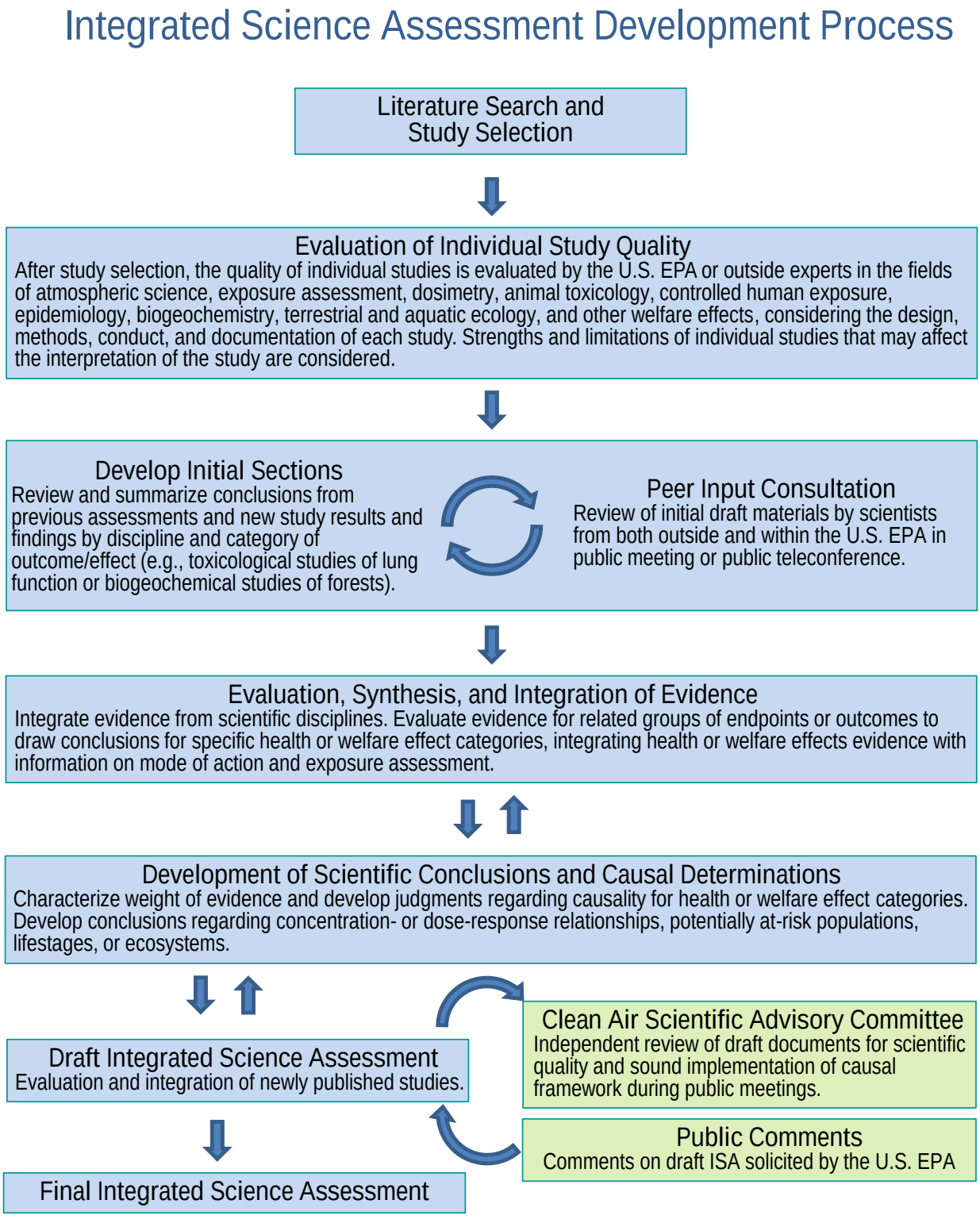
3.3 ASSESSMENT APPROACH

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 research studies in the identified subject areas. The subsequent key components of the ISA development process that follow the "Call for Information" 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.

[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/.



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, aerosol, PM, PM10, PM2.5, PM10-2.5, 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 non-ecological 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 visibility, climate and materials effects. 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, the individual study quality is evaluated by considering the design, methods, conduct, and documentation of each study, but not the study results. In the PM ISA, conclusions about the strength of inference from study results will be made by independently evaluating each study and their overall quality (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 individual studies and the

strength of inference from the results of the study. Particular study quality aspects, relevance, or limitations of some of these features do not necessarily define a less informative study or exclude a study from consideration in an ISA. As stated initially, the intent of the ISA is to provide a concise review, synthesis, and evaluation of the most policy-relevant science to serve as a scientific foundation for the review of the NAAQS, not extensive summaries of all human health and welfare effects studies for a pollutant. Of most importance for inclusion of a study is whether it provides useful qualitative or quantitative information on exposure-response relationships for effects associated with pollutant exposures at doses or concentrations relevant to ambient conditions that can inform decisions on whether to retain or revise the NAAQS.

In general, in assessing the scientific quality of studies on health and welfare effects, the following considerations are taken into account.

- Were study design, study groups, methods, data, and results clearly presented in relation to the study objectives to allow for study evaluation? Were limitations and any underlying assumptions of the design and other aspects of the study stated?
- Were the study site(s), study populations, subjects, or models adequately selected, and are they sufficiently well defined to allow for meaningful comparisons between study or exposure groups?
- Are the air quality, exposure, or dose metrics of adequate quality and are they sufficiently representative of or pertinent to ambient conditions?
- Are the health or welfare effect measurements meaningful, valid, and reliable?
- Were likely covariates or modifying factors adequately controlled or taken into account in the study design and statistical analysis?
- Do the analytical methods provide adequate sensitivity and precision to support conclusions?
- Were the statistical analyses appropriate, properly performed, and properly interpreted?

Additional considerations in evaluating individual study quality specific to particular scientific disciplines (e.g., epidemiology, toxicology) 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. 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 $PM_{10-2.5}$, and concentrations of PM associated with health effects; and (2) with respect to non-ecological 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 non-ecological 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 non-ecological welfare effects, the evidence indicated a "causal

relationship" for PM exposures and effects on visibility, climate, and materials (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 non-ecological 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, sources or precursors; 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 non-ecological 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. For visibility, there were uncertainties associated with the visibility preference studies and insufficient urban monitoring data. For climate, the 2009 PM ISA identified uncertainties in quantification and modeling of aerosols, effects of aerosol mixing and coating on optical properties, and relating observed

effects to measured concentrations of ambient PM. 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 PM ISA will evaluate the status of these uncertainties and limitations in each of the non-ecological 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), 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 (Table 3-1).

Table 3-1. Weight of evidence for causal determinations.

	Health Effects	Welfare Effects
Causal relationship	Evidence is sufficient to conclude that there is a causal relationship with relevant pollutant exposures (e.g., doses or exposures generally within one to two orders of magnitude of recent concentrations). That is, the pollutant has been shown to result in health effects in studies in which chance, confounding, and other biases could be ruled out with reasonable confidence. For example: (1) controlled human exposure studies that demonstrate consistent effects, or (2) observational studies that cannot be explained by plausible alternatives or that are supported by other lines of evidence (e.g., animal studies or mode of action information). Generally, the determination is based on multiple high-quality studies conducted by multiple research groups.	Evidence is sufficient to conclude that there is a causal relationship with relevant pollutant exposures. That is, the pollutant has been shown to result in effects in studies in which chance, confounding, and other biases could be ruled out with reasonable confidence. Controlled exposure studies (laboratory or small- to medium-scale field studies) provide the strongest evidence for causality, but the scope of inference may be limited. Generally, the determination is based on multiple studies conducted by multiple research groups, and evidence that is considered sufficient to infer a causal relationship is usually obtained from the joint consideration of many lines of evidence that reinforce each other.

	Health Effects	Welfare Effects
Likely to be a causal relationship	Evidence is sufficient to conclude that a causal relationship is likely to exist with relevant pollutant exposures. That is, the pollutant has been shown to result in health effects in studies where results are not explained by chance, confounding, and other biases, but uncertainties remain in the evidence overall. For example: (1) observational studies show an association, but copollutant exposures are difficult to address and/or other lines of evidence (controlled human exposure, animal, or mode of action information) are limited or inconsistent, or (2) animal toxicological evidence from multiple studies from different laboratories demonstrate effects, but limited or no human data are available. Generally, the determination is based on multiple high-quality studies.	Evidence is sufficient to conclude that there is a likely causal association with relevant pollutant exposures. That is, an association has been observed between the pollutant and the outcome in studies in which chance, confounding, and other biases are minimized but uncertainties remain. For example, field studies show a relationship, but suspected interacting factors cannot be controlled, and other lines of evidence are limited or inconsistent. Generally, the determination is based on multiple studies by multiple research groups.
Suggestive of, but not sufficient to infer, a causal relationship	Evidence is suggestive of a causal relationship with relevant pollutant exposures but is limited, and chance, confounding, and other biases cannot be ruled out. For example: (1) when the body of evidence is relatively small, at least one high-quality epidemiologic study shows an association with a given health outcome and/or at least one high-quality toxicological study shows effects relevant to humans in animal species, or (2) when the body of evidence is relatively large, evidence from studies of varying quality is generally supportive but not entirely consistent, and there may be coherence across lines of evidence (e.g., animal studies or mode of action information) to support the determination.	Evidence is suggestive of a causal relationship with relevant pollutant exposures, but chance, confounding, and other biases cannot be ruled out. For example, at least one high-quality study shows an effect, but the results of other studies are inconsistent.
Inadequate to infer a causal relationship	Evidence is inadequate to determine that a causal relationship exists with relevant pollutant exposures. The available studies are of insufficient quantity, quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect.	Evidence is inadequate to determine that a causal relationship exists with relevant pollutant exposures. The available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect.
Not likely to be a causal relationship	Evidence indicates there is no causal relationship with relevant pollutant exposures. Several adequate studies, covering the full range of levels of exposure that human beings are known to encounter and considering at-risk populations and lifestages, are mutually consistent in not showing an effect at any level of exposure.	Evidence indicates there is no causal relationship with relevant pollutant exposures. Several adequate studies examining relationships with relevant exposures are consistent in failing to show an effect at any level of exposure.

Source: U.S. EPA (2015)

Determination of causality involves evaluating and integrating evidence for different types of health or welfare effects associated with short- and long-term exposure periods. 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 or groups of related endpoints (e.g., respiratory effects) 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, NCEA 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. 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? Specifically, what new evidence is there for assessing consistency of retention of volatile $PM_{2.5}$ during and after sampling, similarity between $PM_{2.5}$ FEM and FRM data, and consistency between measured mass and mass reconstructed from component concentrations? What are other 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 are the uncertainties associated with emission inventory estimates, including the extent of agreement between current emission profiles and real-world emissions? Are there greater uncertainties in the current emission profiles for some sources (e.g., diesel exhaust contribution to ambient PM)? 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, and improved industrial and motor vehicle emission controls 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, formation of particulate organosulfates and organonitrates, the role of semi-volatile species, the role of volatile water soluble species, and anthropogenic-biogenic interactions? 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? Is there new information available regarding the role of seasonal variations in atmospheric chemistry and photochemistry on the toxicity of ambient PM? 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 non-ecological 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 simulate 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 central site monitors for estimating community concentrations across different spatial scales (e.g., neighborhood scale, urban scale), the use of central site monitors as a surrogate for personal exposure to PM of ambient origin, and uncertainty in the time-activity patterns of exposed individuals whose exposure is represented by central site monitors.
- 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 high and low concentration areas and times (e.g., near roadways, rural 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. As detailed in

Section 3.1, evaluation of PM component and source studies will be limited to those that also include a composite metric of PM. 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. Consistent with previous ISAs, animal toxicological and controlled human exposure studies that examine cancer-related endpoints will be discussed in combination with the epidemiologic evidence in the health chapters. Mutagenesis studies involving in vitro systems will also be discussed because they are pertinent to the biological pathways underlying cancer. 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. While some components of PM are known carcinogens (e.g., benzene), the focus of the PM NAAQS review is on specific size fractions of PM and whether there are alternative indicators (e.g., specific PM components) that are more representative of PM exposure. As such, the relationship between PM exposure and cancer is evaluated similarly to that of other health effects, resulting in the exclusion of studies that examine individual PM components without a composite PM measure. The evaluation of cancer will include studies that use PM filter extracts with the understanding that bioavailability of particulate matter components in vivo is a complex issue not easily mimicked by extraction of PM collected on filters. For these reasons, the evaluation of cancer in the ISA will primarily focus on studies of inhaled particles since these studies are more relevant to ambient exposure conditions. EPA recognizes there is extensive historical evaluations on the mutagenicity, genotoxicity, and carcinogenicity of PM as a whole, which includes studies of PM collected on filters and subsequently extracted. This information will be summarized at the beginning of the section to provide the proper context for the evaluation of PM and cancer that will ensue within the PM ISA.

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)? Are there exposures during critical windows of development that contribute to increased risk of PM-related health effects later in life?

- 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? Is there evidence that specific components or sources modify the association between PM exposure and health effects?
- How do recent studies support the attribution of health effects to one or more PM component(s) or source(s) (e.g., ., industrial facilities, roads, atmospheric formation), 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?
- What is the relationship between short- and long-term exposures and PM-related health effects? More specifically, 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 Non-Ecological Welfare Effects

In the 2009 PM ISA, the non-ecological welfare effects evidence for PM focused on the effects of airborne PM, including oxides of nitrogen and sulfur, on visibility and climate, and on the effects of deposition of PM constituents (primarily metals and carbonaceous compounds) on materials. The evidence indicated that a "causal relationship exists" for PM exposures and effects on visibility, climate, and materials. The EPA will build on the 2009 PM ISA by evaluating the newly available literature related to PM exposures and non-ecological welfare effects, specifically visibility, climate, and materials.

3.4.10.1 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 sulfate, nitrate, particulate organic matter, elemental carbon, and airborne soil particles are all important contributors to regional haze. Their relative impacts on visibility impairment vary regionally, with sulfates, nitrates, and particulate organic matter usually the greatest contributors in the Eastern U.S., and nitrates, particulate organic matter in airborne soil in areas of the Western U.S. Haze forming particles can be either emitted directly from anthropogenic, biogenic or geogenic sources, or formed secondarily from anthropogenic or biogenic precursors.

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 visibility preference studies or other metrics are available to describe the extent to which PM-related visibility impairment may be considered adverse to public welfare?

3.4.10.2 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., on 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 where information is available.

- 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.?

3.4.10.3 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 because the ISA for Oxides of Nitrogen, Oxides of Sulfur and Particulate Matter – Ecological Criteria will focus only on ecological 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 exposures and health risks associated with the existing primary standards and with potential alternative primary standard(s), if any are 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 the 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 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, if warranted.

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 such an assessment would have as part of a PM NAAQS review from both staff and CASAC (Samet, 2009a).

The health endpoints evaluated in the 2010 HREA were selected based on 1) the overall weight of evidence and subsequent causal determinations in the 2009 PM ISA for general health

[82] The 2010 HREA estimated risk for the urban areas where $PM_{2.5}$ concentrations were higher than 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 $\mu g/m^3$.

effect categories that are 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 (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

[84] The baseline incidence rate is the number of new cases of a health effect in a given period (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.

[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.

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 to simulate the distribution of $PM_{2.5}$ ambient concentrations that would "just meet" the then-existing and alternative suites of standards. A proportional "rollback" approach, [90] was used to generate the primary or "core" set of risk estimates presented in the HREA. In addition, two alternative approaches (locally focused and a hybrid of local and proportional rollback approaches) were applied as sensitivity analyses 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

[88] These risks 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 various standards. Design values are the ambient concentration metrics (i.e., statistics) that are compared to the NAAQS levels. A proportional rollback, 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).

[91] A local 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 the 24-hour standard was exceeded (typically requiring reductions in peak levels) and where no adjustment was needed to meet the annual standard (which would typically necessitate a more generalized reduction in ambient levels). The hybrid approach reflected a

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 policy-relevant background (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-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 just meeting alternative annual standard levels of between 10.0 to 14.0 $\mu g/m^3$. 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

combination of a localized pattern of rollback focused on source-oriented monitors with relatively elevated ambient $PM_{2.5}$ concentrations, 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: https://www.epa.gov/fera/total-risk-integrated-methodology-trim-trimrisk

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.

4.2.1.1 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):

- *Long-term PM 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.

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[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 (24-hour 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 adjusted upwards to meet 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).

4.2.1.2 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 PM 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 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 PM 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]

[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 10.0 $\mu g/m^3$ 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 have 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 have risk reductions associated with lower alternative 24-hour standards.

[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).

4.2.2 Key Uncertainties in the 2010 HREA

The EPA recognized that uncertainties were associated with both the inputs to the risk assessment and the risk model used that could affect the magnitude and distribution of the risk estimations. The 2010 HREA used an approach similar to that described by the World Health Organization (WHO, 2008) 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 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"

[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.

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.
- *Applicability 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.
- *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 PM exposure-related mortality*: (a) different C-R function model choices (e.g., fixed versus random effects, log-linear versus log-log, single- versus copollutant), (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 PM 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 copollutant model forms.

[102] The 2010 HREA classified factors as "moderate to large impact" if they had a 50 percent to greater than a 100 percent difference on risk results.

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

Potential support for conducting updated health-based quantitative assessments in the current review will be considered in the HREA Planning Document. Conclusions regarding such support will be based on our consideration of the available scientific evidence; the available technical information, tools, and methods; and judgments as to the likelihood that particular quantitative assessments will add substantially to our understanding of PM exposures or health risks, beyond the insights gained from the assessments conducted in the last review. Our anticipated approach to considering these factors, and for reaching conclusions on the support for particular health-based quantitative assessments, is summarized in Figure 4-1, below.

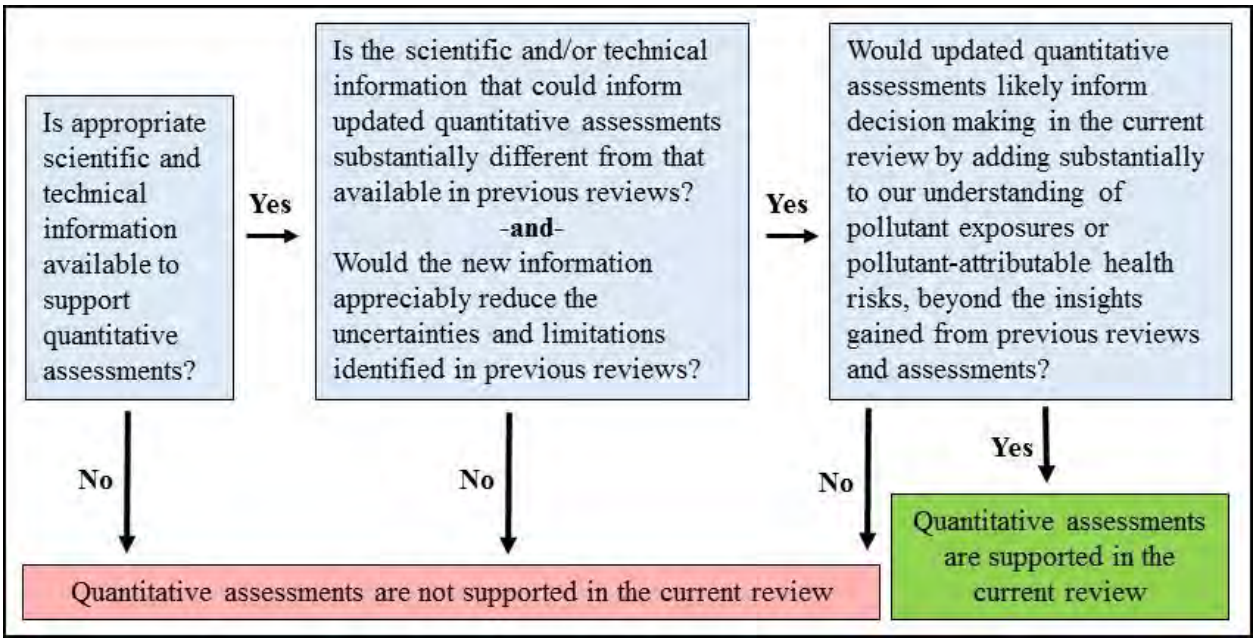

Figure 4-1. Planned approach to considering support for quantitative assessments.

Quantitative assessments will be presented in either an HREA or as part of the PA. The goal of such assessments will be 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. Key policy-relevant

questions to inform the HREA Planning Document are presented in greater detail in section 2.1.3. As we develop the HREA Planning Document, we expect to further refine and expand the set of policy questions which will play a central role in defining both the purpose and scope of quantitative assessments. As warranted, these assessments will build on the approaches used and lessons learned in the 2010 HREA and would focus on improving the characterization of PM exposure and 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. In addition, we will consider potential support for modeling risk at a broader regional and/or national-level to provide a more comprehensive picture of the public health impact associated with ambient PM.

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 the current review 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 concentrations, 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 consideration of alternative indicators (e.g., $PM_{2.5}$ components, $PM_{10-2.5}$, or ultrafine particles), additional quantitative analyses could be considered which focus on 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. In addition, if the evidence supports evaluating potential alternative standards, we will consider whether alternative averaging times (seasonal or sub-daily), forms, and/or levels are appropriate in modeling risk and exposure.

If warranted, 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 would intend to evaluate the distribution of risks and patterns of risk reduction across urban study areas and/or more broadly at the regional level depending on the scope of the risk assessment. If we model risk at the national-level, besides providing a broader and more complete picture of risk, we may be able to use the national analysis to evaluate the degree to which the set of urban study areas included in the HREA are representative of risk across the

nation, or capture risk associated with a portion of the broader risk distribution (e.g., higher-end). In presenting the results of any new assessments, we plan to also evaluate the influence of various inputs and assumptions on the exposure and risk estimates as part of characterizing overall confidence in those estimates. This may help us to more clearly differentiate between potential alternative standard(s) being considered. In addition to capturing the broader public health impacts associated with PM, to the extent supported by data and methods, we will also include characterization of risk experienced by various at-risk populations and lifestages across the range of standards being considered.

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 C-R 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. We may be able to further explore variability by expanding the scope of the HREA to include a larger number of urban study areas and/or model risk at a larger spatial scale (e.g., the regional level).

Consistent with the 2010 HREA, we are considering following the WHO framework (WHO, 2008) to characterize uncertainty, which describes a multi-tiered approach 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 perform in this risk assessment will depend on the availability of information for characterizing the various sources of uncertainty. Similar to the 2010 HREA, we anticipate that the uncertainty characterization in any HREA for the current review would likely have sufficient data to perform qualitative assessments of the direction and magnitude of influence the source of uncertainty has on the estimated risks and a quantitative evaluation using targeted sensitivity analyses.

In sections 4.3.1 and 4.3.2 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 considered and described in greater detail in the HREA Planning Document. Preparation of the HREA 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, C-R, 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.

Figure 4-2 presents an overview of the analytical approach used in conducting an epidemiological risk assessment including data inputs, calculation steps and outputs. Key inputs to the model include PM concentrations, population and demographic data, baseline incidence data and C-R function(s) for the health endpoint(s) being modeled. 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 risks associated with changes in air pollution (see section 4.3.1.2 for additional details regarding BenMAP-CE).

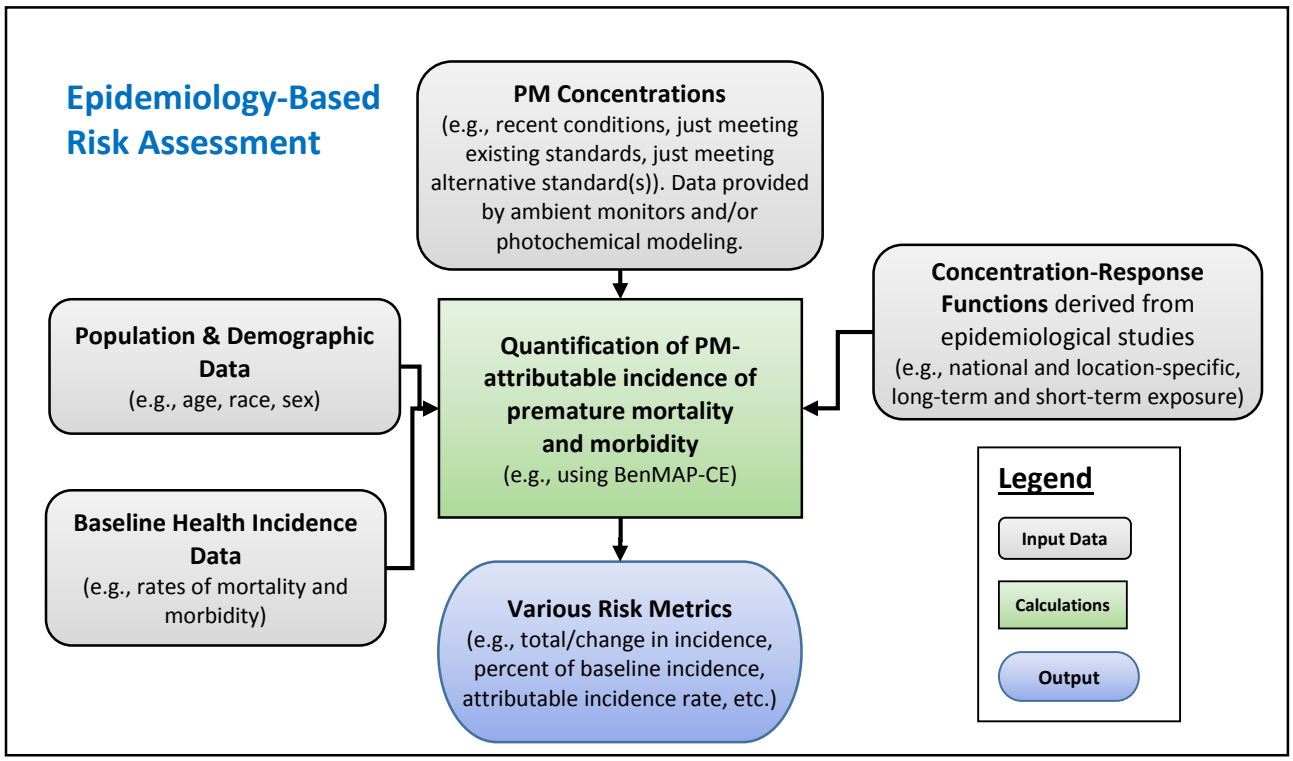

Figure 4-2. Analytical approach for the epidemiological-based risk assessment.

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 consideration of 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 substantially influenced 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

Regarding the use of ambient monitored data in the context of modeling risk at the urban study area-level, 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 from 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 selecting urban study areas will be identified in the HREA Planning Document.

We anticipate the availability in this review of epidemiology studies based on more sophisticated exposure characterizations. For example, there are epidemiology studies available since the last review that are based on fused $PM_{2.5}$ data (i.e., characterizations of ambient levels using a combination of monitored and modeled data). If risk assessments based on fused $PM_{2.5}$ data are performed, then characterization of recent ambient conditions (as part of risk estimation) would likely also require a combination of modeled and monitored data. Options for conducting air quality modeling in support of fused $PM_{2.5}$-based risk modeling will be discussed in greater detail in the HREA Planning Document should those types of studies be employed. In addition, we may identify epidemiological studies based on other more sophisticated exposure characterization (e.g., interpolating ambient $PM_{2.5}$ levels at individual census tracts, or even individual residences). If such studies are identified and our review and evaluation concludes that they should be utilized in the HREA, then our method for characterizing population exposure may have to be expanded to incorporate these more sophisticated methods (at least for those health endpoints involved).

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,[104] 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 appropriate C-R functions for specific $PM_{2.5}$ components and sources had not been identified at that time.[105] 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 support 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)

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 adjust recent ambient concentrations to reflect the distribution of $PM_{2.5}$ concentrations in an urban area (or regional or larger area if appropriate) that could correspond to these air quality scenarios. Because there are multiple combinations of emissions profiles that could result in $PM_{2.5}$ concentrations just meeting the current standards or any potential alternative standards, there are many possible scenarios of various spatially and temporally distributed $PM_{2.5}$ concentrations that would correspond to the target air quality scenarios. Given this, 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

[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] The availability of ultrafine particle data has improved since the last review of the PM NAAQS and currently include areas such as, Baltimore, MD, Boise ID, Buffalo NY, Los Angeles CA, and Tampa FL, among a few others.

[105] 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 $PM_{2.5}$.

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 the same, 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 we anticipate would be 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 standards and potential alternative standard(s), if appropriate. If warranted, 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.

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 the health endpoints for which the available evidence and technical information supports conducting quantitative risk assessments, with a focus on those 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. We recognize that both demographics and baseline incidence rates can vary over time and as such, risk estimates may only be representative of a given urban study area or region for a fixed time period. Similarly, if there is a temporal disconnect between when the demographic and/or baseline incidence data was collected and the modeling period reflected in the HREA, this can introduce uncertainty into the risk estimates generated.

- *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. As noted earlier in section 4.3, the availability of epidemiology studies based on fused $PM_{2.5}$ data means that we may utilize gridded modeled air quality surfaces as the basis for modeling some health endpoints in the HREA.
- *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. In addition, we will consider potential support for a regional/national-scale risk assessment as part of the HREA. We would also anticipate adjusting recent $PM_{2.5}$ concentrations to just meet the existing and, if appropriate, potential alternative standard(s), in each area we generate estimates, including consideration of various adjustment approaches (e.g., proportional rollback). In addition, if we do include a national-scale risk assessment, in addition to providing a more complete picture of risk, such an analysis could be useful for evaluating the representativeness of the study areas included in the analysis (e.g., are the urban areas modeled for the HREA generally representative of risk across the nation, or are they biased in some way). In considering whether to include a regional- or national-level analysis of risk, we recognize that adjusting air quality can be even more challenging at these broader scales than at the smaller urban study area-level.
- *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. We note again however, that if there is a temporal disconnect between the demographic and/or baseline incidence data for these special subgroups and the modeling period of the HREA, this can introduce uncertainty into the analysis.
- *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 risks associated with changes in air pollution.[106] BenMAP-CE draws upon a database of population, baseline incidence and prevalence, and effect estimates to automate the calculation of health risk. [107] 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 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. A limited probabilistic analysis (i.e., Monte Carlo) was used to incorporate confidence intervals associated with effect estimates from epidemiologic studies into the risk analysis, producing 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, constituting a more comprehensive quantitative analysis of uncertainty, 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

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

[107] 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.

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).

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
Selection of, shape, and statistical fit of the C-R functions[108]	The initial selection of the C-R function to be used in modeling a specific endpoint can introduce significant uncertainty into an analysis. This is of particular note when there are multiple functions available within a given study or across candidate studies addressing a specific endpoint. Once selected, there is also 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.
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 depending on the degree to which	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

[108] 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
	unmeasured attributes associated with response differ between locations.[109]	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. In addition, fused $PM_{2.5}$-based epidemiology studies may be used as the basis for modeling specific health endpoints in the HREA.
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 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).	New epidemiologic studies in the PM ISA might provide information regarding which factors drive spatial heterogeneity in effect estimates. This information could help us to differentiate between effect estimates (and hence the risk estimates) in terms of overall confidence.
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	New epidemiologic studies in the PM ISA could provide additional information regarding the lag structure most strongly associated with specific health endpoints.

[109] Should the HREA use epidemiology studies that use fused $PM_{2.5}$ data to characterize exposure levels (and health endpoint response) at the broader regional/national, then this issue of transferability would be largely ameliorated at least for those risk estimates using effect estimates drawn from these studies.

Category of Uncertainty/ Limitation	Description of Uncertainty/ Limitation in the Last Review	Consideration of Information Newly Available in this Review
	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.	
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.[110]
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.

[110] Population mobility is only one of a number of possible factors linked to exposure measurement error in long-term epidemiology studies of $PM_{2.5}$ (e.g., characterization of the spatial and temporal profile of ambient $PM_{2.5}$ levels using monitor and/or modeled data, characterization of housing attributes including air conditioning use).

4.3.2 Exposure Assessment

In addition to a risk assessment based on information from epidemiologic studies, in this review we will consider potential support for conducting a PM exposure assessment. Such an assessment may be able to provide insights into the potential public health implications of particular PM exposures and could potentially provide information on the population attributes or other factors that contribute to the highest PM exposures. However, as indicated in Figure 4-1 above, the decision to conduct, or not conduct, an exposure assessment will be informed by our consideration of the available scientific evidence and technical information, and by judgments as to the likelihood that the assessment will add substantially to our understanding of PM exposures, in light of associated uncertainties of the analyses. 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 and interpretation of such an assessment, and the limited insight it could provide in better understanding ambient PM-related health risks beyond the insights gained from 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 both purposeful and informative when interpreted in light of important uncertainties.

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), the important elements of exposure (i.e., magnitude, frequency, duration, and pattern) could be better characterized by accounting for variability in human time location activity patterns and the PM concentrations that occur within microenvironments that people visit throughout their day (e.g., those occurring on-roads while commuting). Such quantitative exposure assessments could range from a screening level analysis, perhaps based on a combination of ambient concentration data, key exposure factors, and time expenditure information to a complex air quality and exposure modeled population-based, microenvironmental exposure assessment. Historically, a variety of approaches have been proposed and used to reasonably estimate variability in exposures and associated potential health risks for several NAAQS pollutants other than PM (Nitrogen Dioxide: U.S. EPA, 2008; Sulfur Dioxide: U.S. EPA, 2009b; Carbon Monoxide: U.S. EPA, 2010c) and most recently, having an important role in supporting revisions to the ozone NAAQS (U.S. EPA, 2014).

Figure 4-3 presents an overview of the analytical approach used in conducting a microenvironmental exposure analysis including data inputs, calculation steps, and outputs. The figure is intended to highlight the conceptual elements associated with this type of analysis in general rather than presenting the details associated with a specific modeling approach. Key

inputs in conducting a microenvironmental exposure analysis include PM concentrations, population and demographic data, physiologic/anthropometric data, time-location activity pattern data, meteorological data, and microenvironmental data. In evaluating the potential public health importance of the modeled PM exposures we will consider the importance of various exposure metrics, including whether we can incorporate exposure-response data for specific health endpoints to translate simulated population-level exposure profiles into population incidence or probabilities of specific adverse health effects.

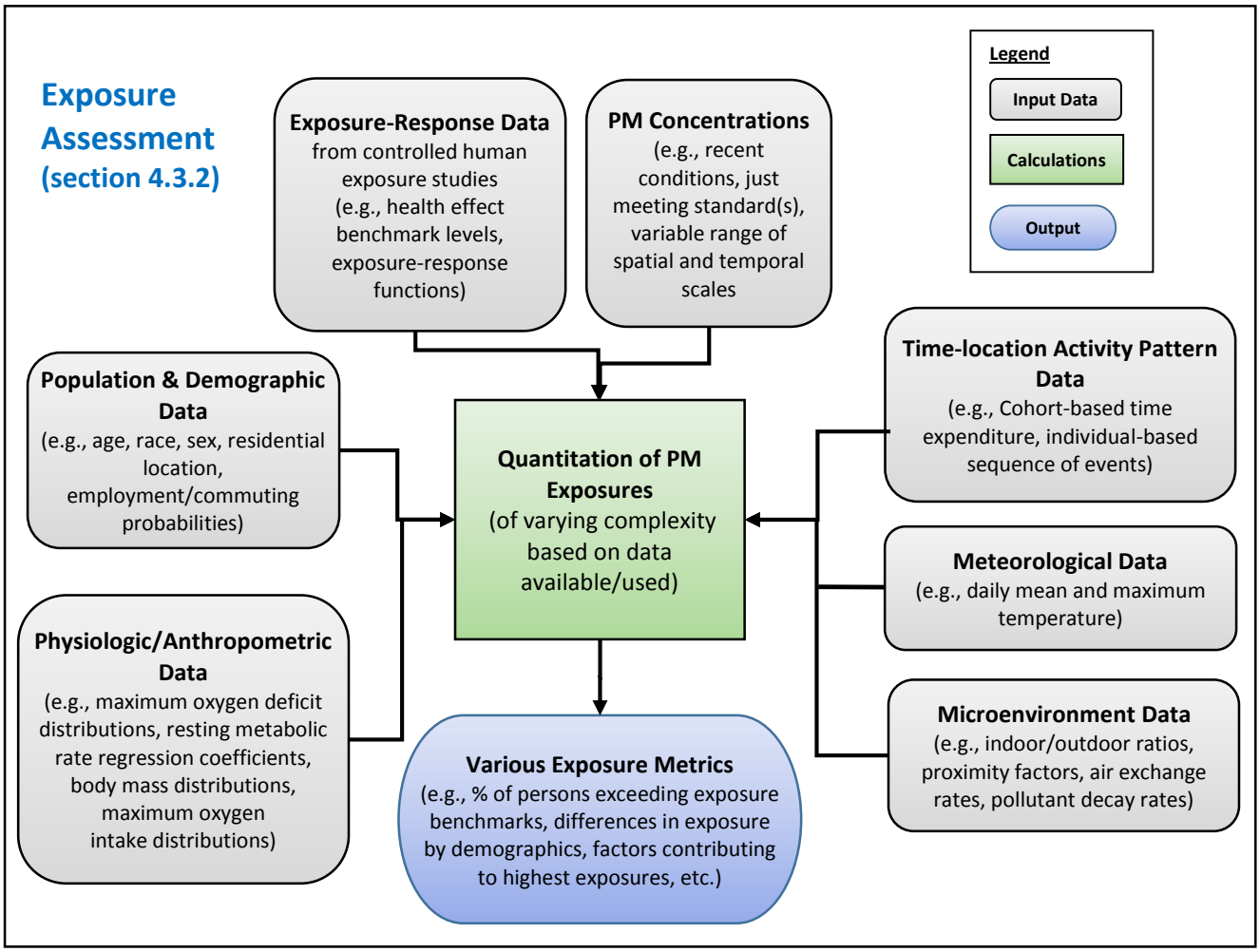

Figure 4-3. Analytical approach for the microenvironmental exposure analysis.

In addition to data availability and approach limitations, ultimately the degree of complexity in an exposure assessment, if conducted, would be guided by how well the expected results could help achieve the overall goals of the assessment and, in particular, whether the assessment provides relevant and unique estimates of exposure that can reasonably inform policy decisions. For instance, a simplified approach employing conservative assumptions may be appropriate when assessment results indicate estimated exposures of concern are limited. Further, having spatial variability in ambient concentrations linked to demographics in a study area could improve our understanding of differential exposures potentially experienced by particular population study groups of interest (e.g., older adults). A more complex exposure assessment could provide insight into some of the detailed features of exposure that may be important such as identifying: 1) individuals/populations experiencing the highest exposures; 2) exposure location, timing, and duration; and 3) population factors or attributes contributing to the highest exposures. While generally informative, understanding physical and personal attributes

of those experiencing the highest exposures alone and/or generating the complete time series of exposure profiles for a population may not translate to an improved understanding of those at greatest health risk from exposure to ambient pollutants. However, if available human exposure studies provide a basis for identifying ambient-relevant exposure concentrations that result in effects of potential public health concern, a health-based exposure assessment of greater policy-relevance would include a comparison of exposure estimates to the exposure concentrations shown to cause such effects (i.e., an exposure benchmark analysis).[111]

If conducting an exposure assessment is determined to be warranted for this review, at a minimum, exposure calculations would rely largely on measurements of ambient PM concentrations potentially supplemented with information from air quality models, and could include databases of activity patterns, personal attributes, and population demographics. An approach with increasing complexity may also include information on important physical factors that may influence microenvironmental concentrations, account for time spent in particular microenvironments and participation in activities at varying exertion levels, and approximate internal doses. Additionally, other important exposure factors could include information on atmospheric chemistry and components of PM, fine-scale temporal and spatial distributions of air quality data, 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, exposures associated with other PM size fractions and/or particular PM components. If warranted, such an exposure assessment could employ the 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 important factors to be considered in designing an ambient PM exposure assessment. Section 4.3.2.2 identifies several challenges in conducting such an assessment and potential sources of uncertainty, and where possible, basic strategies to minimize these uncertainties. These design factors and strategies for minimizing uncertainties

[111] It has been suggested that estimating population-based exposures across differing study areas could help inform the interpretation of epidemiologic study effects estimates by improving the representation of within- and between-study area variability in ambient-related exposures and dose. However, the availability and ability of exposure data needed to uncover such differences in exposure would be an important consideration in determining whether to perform such a complex assessment. More specifically, additional exposure model input data (e.g., housing stock and residential air exchange rates) may need to be on a similarly fine spatial and temporal scale to extend the variability in estimated exposures beyond that offered by considering the fine-scale spatial and temporal variability in ambient concentrations alone. It should also be noted that if population-based exposure modeling were performed for this review, the estimated exposures in a study area would likely not be used as an alternative metric to be input to epidemiology-based C-R functions (i.e., ambient concentration derived) to estimate health risks in any study area.

would be evaluated in the HREA Planning Document. We will consider whether these factors and strategies, including having a well-defined purpose, would support moving forward with an exposure assessment in the current review.

4.3.2.1 Factors to Consider in Designing an Exposure Assessment

- *Characterizing ambient PM concentrations*. The most appropriate air quality data used in exposure assessments would generally correspond to fine spatial and temporal scales in ambient concentrations, the level of which is largely a function of the magnitude of heterogeneity in concentrations and human activity patterns, factors that can substantially influence important exposure metrics and microenvironments of interest.[112] Developing highly resolved $PM_{2.5}$ concentrations from existing monitoring and air quality modeling data 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*: Depending on the exposure objectives and data availability, the exposure model selected can vary from simple to complex. If a population-based, microenvironmental exposure modeling approach is determined as useful for the current review, we anticipate using the APEX model[113] 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) and time period (e.g., minute, hourly) to represent ambient concentrations for calculating exposures.
- *Population exposures*: An exposure assessment could be designed to estimate exposures to ambient PM in study areas that represent particular 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., regional climatic conditions across the U.S.). In addition, depending on the short-term and long-term exposure metrics developed, we could evaluate the relative importance of short-term PM exposure variability with respect to long-term cumulative exposure.

[112] For example, the temporal and spatial scales used in recent exposure model-based 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.

[113] Additional information on APEX can be found at: http://www2.epa.gov/fera/human-exposure-modeling-air-pollutants-exposure-model.

- *Human activity patterns*: The best human activity data available for use in estimating exposures are 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. EPA continues to incorporate new human activity pattern data into CHAD, currently containing nearly 180,000 diary days, the majority of which are from recent studies such as the 2003-2013 American Time Use Survey (ATUS) (BLS, 2014). In addition, while CHAD still contains data from older studies, some conducted as far back as four decades ago and for varying U.S. study locations, when controlling for the most important variables that could affect time expenditure (e.g., age, sex, mean daily temperature), data analysis results showed little to no influence by study date and US region (U.S. EPA, 2014).
- *Microenvironmental concentrations*: An exposure assessment can estimate exposures that people experience while in indoor, outdoor, and inside-vehicle microenvironments using the ambient concentrations and microenvironmental factors. If using a complex, probabilistic exposure model based approach to estimating exposure and dose, we could use statistical distributions representing variability for various inputs (e.g., air exchange rates, decay rates, and physiological parameters) and consider developing those to represent uncertainty.
- *Spatial and temporal scale of exposure assessment*: The overall scope of an exposure assessment, if determined useful for the current review, could focus on a subset of urban study areas selected for the epidemiology-based assessment (we would not expect to conduct a microenvironmental exposure analysis at a broader regional scale). 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 $PM_{2.5}$ presents a number of challenges in regards to obtaining the most appropriate inputs for the selected approach. Having incomplete or uncertain model input data or approaches lead to uncertainties in the estimated exposures. The primary limitations associated with generalized exposure data are listed in Table 4-2. Identification of available model inputs and data limitations is one of the first steps in determining whether an 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 data used to estimate exposures.

Category of Uncertainty/ Limitation	Description of Uncertainty/ Limitation
Spatial variability of ambient $PM_{2.5}$ concentrations	To capture the spatial variation of exposure across the study area, ambient concentrations that appropriately represent the spatial variability are needed. If performing population-based exposure modeling, the spatial resolution of other model inputs would likely be at a census tract level (e.g., the existing population demographic data), which are compatible with tract-to-tract spatial variation of ambient $PM_{2.5}$. However, the spatial scale should be based on expected degree of heterogeneity in concentrations across the selected study areas.
PM aerodynamic properties	If the selected exposure assessment approach uses PM size fractions and estimates PM dose, the aerodynamic properties of particles that affect indoor infiltration rates and deposited PM in different lung regions would also be considered. The appropriate apportioning into size fractions and density of the ambient $PM_{2.5}$ are likely to be fairly uncertain.
Near-road and inside-vehicle exposures	For some PM size fractions (e.g., $PM_{10-2.5}$, 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.
CHAD activity pattern data 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. When considering a population-based exposure model approach, activity sequences can be constructed to account for the effects of population demographics and local climate, though this adjustment procedure may 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. The extent to which a particular at-risk population (e.g., individuals having ischemic heart disease) or life stage group is fully represented by the range of CHAD diaries may be uncertain. In addition, other potentially important influential exposure attributes (e.g., occupation, household income) may not be available for the surveyed individuals.
Approach for developing longitudinal diary profile	One limitation of the CHAD activity pattern is that, on average, study participants provided less than two days of diary data. Thus, when estimating long-term exposures (e.g., across a year), the activity sequence of days for each simulated individual would be a combination of diary 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). Past performance evaluations of these longitudinal algorithms have been limited by the small number of CHAD individuals having multiday diaries. Recently collected multi-day diaries would be considered for new evaluations of the longitudinal diary profile approach, where appropriate data are available.
Indoor air exchange rates (AER)	Because people generally spend a significant amount of time indoors, AER are important in estimating exposures. Currently available are statistical distributions of AER that account for regional variability, are stratified by several temperature ranges, and consider separately the presence of mechanical and non-mechanical building

Category of Uncertainty/ Limitation	Description of Uncertainty/ Limitation
	ventilation, to the extent possible. One limitation is that these distributions do 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[114] associated with the existing secondary standards and with potential alternative secondary standard(s), if any are 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 welfare 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).

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 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 the draft IRP will

[114] 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."

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, 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.[115] 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.

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.

[115] 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.

5.2.1 Quantitative Assessments of Urban Visibility Impairment in the Last Review

5.2.1.1 Reanalysis of Public Preference Survey Studies

The 2010 UFVA included a detailed, quantitative reanalysis of the available urban visibility preference studies, which are briefly described below for context. 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)[116] 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 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[117] 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

[116] 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).

[117] 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.

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)[118] 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.[119] 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 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.[120]

The 2010 UFVA focused on calculated PM_{10} light extinction as the indicator for the quantitative assessments based on the data collected from the CSN network in urban areas (as described in section 2.3 above) and consideration of the requirements of the EPA's Regional Haze Program in Class I areas (U.S. EPA, 2009a, sections 9.2.3.2 and 9.2.3.4). These

[118] 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.

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

[120] 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.

assessments used a combination of several datasets[121] as inputs into the IMPROVE algorithm[122] 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 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

[121] 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).

[122] The IMPROVE algorithm (Pitchford et al., 2007) uses major PM composition measurements and relative humidity estimates to calculate light extinction. 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.

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 policy-relevant background (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).[123] 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).[124] 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 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).

5.2.2 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, geographic differences in preference across different urban study areas, and alternative measures of acceptable visibility impairments

[123] 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).

[124] 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.

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 light extinction 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.

5.2.3 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, climate, and materials effects) 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.[125] 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, $PM_{10-2.5}$, or ultrafine particles.

[125] As noted above (section 1.4), in recognition of the linkages between oxides of nitrogen, oxides of sulfur, and PM with respect to atmospheric chemistry and deposition, and with respect to ecological effects, PM-related ecological effects are being considered in the review of the secondary NAAQS for Oxides of Nitrogen and Oxides of Sulfur. For more information on the current review of the secondary NAAQS for oxides of nitrogen and oxides of sulfur, see https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-air-quality-standards.

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 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[126] 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 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; U.S. Global Change Research Program, 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

[126] 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.

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[127]) 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 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.

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

5.3.3 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,[128] 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,c). 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 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[129] 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

[128] 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.

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

NAAQS, sufficient evidence was not available to conduct a quantitative assessment of PM-attributable soiling effects (U.S. EPA, 2004, 2009a,c). 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.

5.3.4 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 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 major PM chemical composition measurements and relative humidity estimates to calculate light extinction, but the algorithm 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 preference studies did not provide insights on frequency or duration.	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.
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.

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

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 the CASAC's recommendations and public comments in the design and when conducting the quantitative assessments, if warranted, 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 the CASAC's review and public comment. The 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 the 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 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 the 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.[130]

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 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

[130] 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.

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. The CASAC will review the draft PA at a public meeting that will be announced in the *Federal Register*. Based on past practice by the CASAC, the EPA expects that the 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 the 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.[131] 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.[132] Publication of the final rule in the *Federal Register* completes the rulemaking process.

[131] 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.

[132] 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).

REFERENCES

U.S. EPA (2012). Responses to Significant Comments on the 2012 Proposed Rule on the National Ambient Air Quality Standards for Particulate Matter. U.S. Environmental Protection Agency, Research Triangle Park, NC. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/data/20121214rtc.pdf

Appendix:

Agenda for the Workshop to Inform EPA's Review of the PM NAAQS (February 9–11, 2015)

AGENDA

U.S. EPA Building Auditorium C 111
109 T.W. Alexander Drive
Research Triangle Park, North Carolina 27711
February 9–11, 2015

Agenda in Brief

Monday, February 9	
11:30 am	Registration Begins
12:00 pm	Workshop Begins
5:00 pm	Day 1 Adjourns

Tuesday, February 10	
7:30 am	Registration Begins
8:00 am	Workshop Begins
12:00 – 1:00 pm	Lunch
5:00 pm	Day 2 Adjourns

Wednesday, February 11	
7:30 am	Registration Begins
8:00 am	Workshop Begins
12:00 pm	Workshop Adjourns

Background

Scope and Objectives

This purpose of this workshop is to inform the planning for EPA's next review of the primary (health-based) and secondary (welfare-based) national ambient air quality standards (NAAQS) for particulate matter (PM). This workshop will provide 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 will be 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. They will also be encouraged to think broadly about the body of new scientific evidence and how it can be best used to build upon the scientific evidence that supported the last review of the PM NAAQS (completed in December 2012).

Workshop discussions will provide important input to inform the development of the planning and assessment documents that will be developed as part of this review of the PM NAAQS. These include the Integrated Review Plan (IRP), which will highlight the key science and policy issues that will guide this review; the Integrated Science Assessment (ISA), which will summarize and assess the most policy-relevant scientific evidence for PM, and will make key science judgments that will inform the development of quantitative and qualitative analyses; and the Risk and Exposure Assessments (REAs), which will assess PM-associated exposures and health and welfare risks, to the extent such quantitative analyses of exposures and risks are judged appropriate. These documents, in turn, will inform the Policy Assessment (PA), which will present the EPA staff's conclusions regarding the range of policy options that could be supported by the available scientific evidence and exposure/risk information.[1]

Participants invited to the workshop, which is open to the public, include external scientists, including members of the Clean Air Scientific Advisory Committee (CASAC), and internal EPA scientists and policy experts with a wide range of expertise (e.g., epidemiology, human and animal toxicology, statistics, risk/exposure analysis, atmospheric science, policy analysis). The workshop discussions will build upon three publications from the last review:[2]

[1] Additional information regarding the NAAQS review process is available at: http://www.epa.gov/ttn/naaqs/review.html.
[2] Documents related to the PM NAAQS review completed in 2012, as well as reviews completed in 2006 and 1997, are available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_index.html.

1. *National Ambient Air Quality Standards for Particulate Matter: Final Rule* (78 FR 2086, January 15, 2013). The preamble to the final rule included detailed discussions of science and policy issues central to the last review and to the rationale for the Agency's final decisions.
2. *Integrated Science Assessment for PM – Final Report. (EPA/600/R-08/139F, December 2009).* The ISA is developed by EPA's National Center for Environmental Assessment (NCEA). It is a comprehensive review, synthesis, and evaluation of the most policy-relevant science, including key science judgments that inform the development of the quantitative analyses in the REAs and staff conclusions in the PA. The 2009 PM ISA included consideration of published peer-reviewed scientific literature through mid-2009.
3. *Provisional Assessment of Recent Studies on Health Effects of Particulate Matter Exposure. (EPA/600/R-12/056F, December 2012).* The provisional science assessment, which was also completed by NCEA, evaluated studies published too late for inclusion in the final 2009 PM ISA. This assessment evaluated studies published through August 2012, with a focus on U.S. and Canadian epidemiologic studies that used $PM_{2.5}$ (i.e., fine PM) or $PM_{10-2.5}$ (i.e., thoracic coarse PM), and on toxicological or epidemiologic studies that compared effects of PM from different sources, with different components, or different size fractions. The provisional science assessment was not intended to critically review individual studies or integrate the scientific findings to draw causal conclusions as is done for an ISA, but rather to ensure that the Administrator was fully aware of the "new" science that had developed since 2009 before making final decisions on whether to retain or revise the then-current PM standards.

Workshop participants are encouraged to review these documents before the meeting, as they provide important background information on the scientific findings and analytical approaches considered in the previous review, as well as insights into the key policy-relevant questions from that review. In addition, participants may also want to review related documents, including the *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards* (Final Report, April 2011), *Quantitative Health Risk Assessment for Particulate Matter* (Final Report, June 2010), and *Particulate Matter Urban-Focused Visibility Assessment* (Final Document, July 2010).[2]

Workshop Structure

The workshop will begin with an introductory session in which EPA will highlight the significant features of the NAAQS review process including opportunities for CASAC and public participation throughout this multi-year review. Building on the experiences gained in previous reviews, this session will also include a brief history of the PM NAAQS, with emphasis on the final decisions made in the last review and the scientific basis for these final decisions. The panel sessions, each facilitated by two co-chairs, will then address the following topic areas:

- Session I: Characterizing PM Emissions, Air Quality and Exposure
- Session II: Planning for the Review of the Health Effects Evidence
- Session III: Planning for the Quantitative Health Risk and/or Exposure Assessments
- Session IV: Planning for the Review of the Welfare Effects Evidence
- Session V: Integrating Evidence and Quantitative Assessments: Characterizing the Broader Public Health Impacts of PM

Each session will begin with EPA staff highlighting appropriate background information and policy issues that were most critical for the 2012 PM NAAQS decisions. Lead discussants will provide opening comments on specific topics. Other panel members and interested participants will then be invited to join a structured discussion of the issues, with a focus on the extent to which recent research has addressed key uncertainties and limitations in the science from the last review, and on the extent to which that research indicates new science policy issues for consideration in the current review. The co-chairs will moderate each session to ensure the discussion remains focused on providing guidance to help EPA plan for the current review of the PM NAAQS.

The potential session questions are detailed within the agenda with the supplement at the end of this agenda providing more detailed discussion points that fall within each question. These questions and potential discussion points are viewed as a starting point for the discussions in each session, and are not intended to be prescriptive or to limit discussion of other relevant issues. Rather, it is understood that some questions will warrant more discussion time than others, and that new topics could be identified as panel members and other participants offer input and respond to issues that are raised.

Monday, February 9, 2015

12:00 – 12:15 Welcome/Overview
Kimber Scavo | *U.S. EPA*
John Vandenberg | *U.S. EPA*

12:15 – 12:45 Building on the Last PM NAAQS Review: Focus on Key Policy-Relevant Issues
Scott Jenkins | *U.S. EPA*

12:45 – 5:00 **Session I: Characterizing PM Emissions, Air Quality, and Exposures**

Session I will be divided into two parts. The first part of this session will focus on the broad scientific issues surrounding recent research on approaches to measuring or estimating PM emissions, the atmospheric chemistry of PM, and the monitoring and modeling approaches that are available to characterize ambient PM concentrations. The second part of this session will focus on the integration of information across scientific disciplines (i.e., atmospheric science, exposure science, and health sciences) to identify the strengths and limitations of the various metrics used as exposure surrogates in epidemiologic studies, and of the various approaches to generating exposures in experimental studies.

12:45 – 3:00 **Session Ia: Broad Scientific Issues of Atmospheric Science, Modeling, and Monitoring of PM**

12:45 – 1:00 Background/Introductory Remarks
Steve Dutton | *U.S. EPA*

1:00 – 3:00 Panel Discussion

Co-Chairs: Steve Dutton | *U.S. EPA*
Mike Kleeman | *University of California, Davis*

Panel Members: Peter Babich | *Connecticut Department of Energy & Environmental Protection (CT DEEP)*
Gayle Hagler | *U.S. EPA*
Tim Hanley | *U.S. EPA*
Havala Pye | *U.S. EPA*
Nicole Riemer | *University of Illinois – Urbana*
Jamie Schauer | *University of Wisconsin*
Jason Surratt | *University of North Carolina, Chapel Hill*

Session Questions

- Emissions, Atmospheric Chemistry, Fate and Transport
  Lead Discussants: Gayle Hagler | *U.S. EPA*
  Jason Surratt | *University of North Carolina, Chapel Hill*
  1. To what extent has recent research addressed the quantification and characterization of PM emissions, and does this research provide increased confidence in such characterization compared to previous reviews?
  2. What new information is available regarding the relationship between PM size distribution and particle composition?
  3. What new science is available to improve our understanding of PM chemistry?

- Characterization of PM Ambient Monitoring Data and Air Quality
  Lead Discussants: Peter Babich | *CT DEEP*
  Tim Hanley | *U.S. EPA*
  4. To what extent have new or improved ambient monitoring techniques or instrumentation been developed since the last review?
  5. To what extent have new or improved modeling methods, tools, protocols, or data analysis techniques (e.g., satellite measurements) been developed since the last review?

3:00 – 3:15 Break

3:15 – 5:00 **Session Ib: Linkages Among Atmospheric Science, Exposure Characterization, and the Interpretation of Results from Health Studies**

3:15 – 3:30 Background/Introductory Remarks
Tom Long | *U.S. EPA*

3:30 – 5:00 Panel Discussion

Co-Chairs: Jeff Brook | *Environment Canada*
Tom Long | *U.S. EPA*

Panel Members: Lisa Baxter | *U.S. EPA*
Rick Burnett | *Health Canada*
David Diaz-Sanchez | *U.S. EPA*
Pat Kinney | *Columbia University*
Nino Künzli | *Swiss Tropical and Public Health Institute*
Jason Surratt | *University of North Carolina, Chapel Hill*

Session Questions

- Characterization of PM Exposures
  Lead Discussants: Lisa Baxter | *U.S. EPA*
  Rick Burnett | *Health Canada*

  6. What new or emerging measurement methodologies (e.g., satellite data, cell phone monitoring) or modeling approaches are available to characterize PM exposures?

- Exposure Assignment – Epidemiologic Studies
  Lead Discussants: Pat Kinney | *Columbia University*
  Lisa Baxter | *U.S. EPA*

  7. What new information is available to evaluate the potential impacts of differences across epidemiologic studies in exposure assessment methodologies, exposure measurement error, exposures to specific PM components, or co-exposures to pollutants other than PM?

- PM Exposures in Experimental Studies
  Lead Discussants: David Diaz-Sanchez | *U.S. EPA*
  Jason Surratt | *University of North Carolina, Chapel Hill*

  8. What new information is available regarding the use of experimentally controlled atmospheres for *in vitro*, animal toxicology, and controlled human exposure studies?

5:00 Day 1 Adjourns

Tuesday, February 10, 2015

8:00 – 12:00 **Session II: Planning for the Review of the Health Effects Evidence**

This session will be broken up into two parts. The first part of the discussion will focus on the key lines of evidence that can provide the basis for the modes of action of PM-related health effects. In the last review, such evidence provided the foundation for conclusions regarding the biological plausibility of PM-related health effects. The second part of the discussion will focus more broadly on the current state of the science for PM-related health effects, including how the available experimental and epidemiologic evidence for various health endpoints and at-risk populations has evolved since the 2009 PM ISA.

8:00 – 8:30 Review of Health Effects Evidence from 2009 PM ISA

Jason Sacks | *U.S. EPA*

8:30 – 9:45 **Session IIa: Modes of Action Associated with PM-related Health Effects**

8:30 – 9:45 Panel Discussion

Co-Chairs: Barbara Buckley | *U.S. EPA*
Matt Campen | *University of New Mexico*

Panel Members: Sara Adar | *University of Michigan*
Aimen Farraj | *U.S. EPA*
Ian Gilmour | *U.S. EPA*
David Peden | *University of North Carolina, Chapel Hill*

Session Questions

- Mechanistic Evidence and Biological Plausibility

  Lead Discussant: Aimen Farraj | *U.S. EPA*
  Ian Gilmour | *U.S. EPA*

  9. What new information is available to inform our understanding of the potential biological mechanisms and modes of action underlying responses to PM?

  10. Do specific methodological issues warrant the exclusion of studies from the evaluation of mechanistic evidence and biological plausibility (e.g., unrealistically high PM exposure concentrations, use of intratracheal instillation, *in vitro* studies, occupational studies, studies of engineered particles)?

  11. When organizing the mechanistic evidence does it make more sense to discuss in the context of modes of action or an adverse outcome pathway framework?

9:45 – 10:00 Break

10:00 – 12:00 **Session IIb: Evaluation and Integration of PM Health Effects Evidence**

10:00 – 12:00 Panel Discussion

Co-Chairs: Doug Dockery | *Harvard University*
Wayne Cascio | *U.S. EPA*

Panel Members: Sara Adar | *University of Michigan*
Jeff Brook | *Environment Canada*
Matt Campen | *University of New Mexico*
Aaron Cohen | *HEI*
David DeMarini | *U.S. EPA*
Bob Devlin | *U.S. EPA*
David Peden | *University of North Carolina, Chapel Hill*
Annette Peters | *German Research Center for Environmental Health*
Ana Rappold | *U.S. EPA*
Matt Strickland | *Emory University*
Antonella Zanobetti | *Harvard University*

Session Questions

- Interpretation of the Health Evidence Across Disciplines
  Lead Discussants: Matt Campen | *University of New Mexico*
  Bob Devlin | *U.S. EPA*
  David Peden | *University of North Carolina, Chapel Hill*
  12. What new research is available that has more fully characterized the role of $PM_{2.5}$ or $PM_{10-2.5}$ in the complex ambient mixture (e.g., understanding the role of PM vs. copollutants)?
  13. To what extent is new evidence available to enhance our understanding of the relative toxicity of different particle size fractions (e.g., $PM_{2.5}$ or $PM_{10-2.5}$) or components of PM?
  14. What new information is available to assess whether there is a relationship between UFP exposure and health effects?

- Exposure Metrics and Timing of Health Effects
  Lead Discussants: Jeff Brook | *Environment Canada*
  Matt Strickland | *Emory University*
  15. To what extent is key scientific evidence becoming available to improve the understanding of the health effects associated with various time periods of PM exposures?

- Questions Specific to Interpreting the Epidemiologic Evidence
  Lead Discussants: Sara Adar | *University of Michigan*
  Ana Rappold | *U.S. EPA*
  16. What new information is available to further assess the factors contributing to heterogeneity in PM risk estimates?
  17. What new information is available to characterize the PM-health effect C-R relationship along the full range of PM concentrations?

- Evaluation of Populations and Lifestages at Increased Risk of a PM-related Health Effect
  Lead Discussants: Annette Peters | *German Research Center for Environmental Health*
  Antonella Zanobetti | *Harvard University*
  18. What new information is available to inform the characterization of populations potentially at increased risk of PM-related health effects?

12:00 – 1:00	Lunch
1:00 – 2:00	**Session IIb: Evaluation and Integration of PM Health Effects Evidence (continuation)**

Session Questions (continued)

- Evaluation of Cancer, Genotoxicity, and Mutagenicity
  Lead Discussants: Aaron Cohen | *Health Effects Institute*
  David DeMarini | *U.S. EPA*

19. When evaluating the independent effect of PM at relevant ambient concentrations, how should EPA consider the evidence from studies that focus on PM mass at ambient concentrations with evidence from studies of sources (e.g., diesel exhaust) and individual components (e.g., benzene, PAHs) at exposures that are much higher than ambient concentrations, to assess the relationship between PM and cancer, mutagenicity, and/or genotoxicity?

2:00 – 2:15 Break

2:15 – 5:00 **Session III: Planning for Quantitative Health Risk and/or Exposure Assessments**

The discussions in this session will focus on the extent to which new research and/or improved methodologies may be available to inform how EPA designs a quantitative health risk assessment, whether it is appropriate to conduct a quantitative exposure assessment, and, if an exposure assessment is conducted, how such an assessment might be structured. These discussions will include consideration of key uncertainties identified in the last review and the extent to which new scientific evidence may be available to substantially inform our ability to characterize and/or reduce these uncertainties.

2:15 – 2:45 Background/Introductory Remarks
Zach Pekar | *U.S. EPA*

2:45 – 5:00 Panel Discussion

Co-Chairs: Rick Burnett | *Health Canada*
Stephen Graham | *U.S. EPA*

Panel Members: Janet Burke | *U.S. EPA*
Aaron Cohen | *HEI*
Jim Crooks | *U.S. EPA*
Ted Johnson | *TRJ Environmental*
Pat Kinney | *Columbia University*

Session Questions

- Characterizing Air Quality/Rollback Approaches
  Lead Discussants: Jim Crooks | *U.S. EPA*
  Ted Johnson | *TRJ Environmental*

  20. To what extent does newly available data, analyses, or models inform potential approaches to adjusting PM concentrations to just meet existing and alternative PM standards?

- Quantitative Risk Assessment
  Lead Discussants: Aaron Cohen | *Health Effects Institute*
  Pat Kinney | *Columbia University*

  21. To what extent is there new and emerging scientific evidence available that could potentially support the development of PM risk estimates beyond those generated in the last review?

  22. To what extent does new information inform our confidence in applying concentration-response functions generated at a specific spatial scale (e.g., for a metropolitan statistical areas) to different spatial scales (e.g., individual counties, individual grid cells)?

- Quantitative Exposure Assessment
  Lead Discussants: Janet Burke | *U.S. EPA*
  Ted Johnson | *TRJ Environmental*

  23. What critical factors should be considered by EPA in determining whether a quantitative exposure assessment should be conducted for this review?

  24. If an exposure assessment were conducted for this review, how might EPA define the scope and purpose of such an analysis?

5:00 Day 2 Adjourns

Wednesday, February 11, 2015

8:00 – 9:30 **Session IV: Planning for the Review of the Welfare Effects Evidence**

In the last review, to provide protection for PM-related visibility impairment, the EPA identified a target level of protection defined in terms of a $PM_{2.5}$ visibility index (based on speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction). The EPA concluded that, based on this target level of protection, the existing mass-based 24-hour $PM_{2.5}$ standard would provide sufficient protection and that a distinct secondary standard was not warranted. This session will include consideration of key uncertainties identified in the last review and discussion of the extent to which new scientific evidence may be available to substantially inform our ability to characterize and/or reduce these uncertainties. Additionally, this session will discuss evidence related to other PM welfare effects, including effects on climate.

8:00 – 8:30 Background/Introductory Remarks
Vicki Sandiford | *U.S. EPA*

8:30 – 9:30 Panel Discussion

Co-Chairs: Neil Frank | *U.S. EPA*
Jason West | *University of North Carolina, Chapel Hill*

Panel Members: Kevin Boyle | *Virginia Tech*
Mike Kleeman | *University of California, Davis*
Meredith Lassiter | *U.S. EPA*
Rohit Mathur | *U.S. EPA*
Drew Shindell | *Duke University*

Session Questions

- Visibility

Lead Discussants: Kevin Boyle | *Virginia Tech*
Mike Kleeman | *University of California, Davis*

25. 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)?

26. To what extent are new studies available regarding visibility preferences?

- Climate

Lead Discussants: Rohit Mathur | *U.S. EPA*
Drew Shindell | *Duke University*

27. To what extent is new information available that changes or enhances our understanding of climate impacts from PM-related aerosols, particularly regarding the quantification of anthropogenic aerosol effects on radiative forcing?

- Other Effects

Lead Discussant: Meredith Lassiter | *U.S. EPA*

28. To what extent is new information available to link PM (excluding nitrates and sulfates) to ecological effects, including information regarding interactions with other ecosystem stressors and co-occurring pollutants?

9:30 – 9:45 Break

9:45 – 11:45

Session V: Integrating Evidence and Quantitative Assessments: Characterizing the Broader Public Health Impacts of PM

This session will build on the previous panel discussions to provide a broader consideration of the new information that is available to inform our understanding of PM-related health impacts. The focus will be on the ways in which this review of the PM NAAQS can comprehensively characterize the national-scale public health impacts of PM exposures. Panelists will be asked to provide an integrated perspective on the nature and magnitude of PM health effects, the populations at greatest risk, variability in effects across the U.S., and the key uncertainties in the health evidence.

9:45 – 10:35 Key Messages from Sessions I-III

Co-Chairs: Dan Costa | *U.S. EPA*
Dan Greenbaum | *Health Effects Institute*

9:45 – 9:55 Session Ia Recap: Steve Dutton and Mike Kleeman
9:55 – 10:05 Session Ib Recap: Tom Long and Jeff Brook
10:05 – 10:15 Session IIa Recap: Barbara Buckley and Matt Campen
10:15 – 10:25 Session IIb Recap: Wayne Cascio and Doug Dockery
10:25 – 10:35 Session III Recap: Stephen Graham and Rick Burnett

10:35 – 11:45 Panel Discussion

Co-Chairs: Dan Costa | *U.S. EPA*
Dan Greenbaum | *Health Effects Institute*

Panel Members: Jeff Brook | *Environment Canada*
Barbara Buckley | *U.S. EPA*
Rick Burnett | *Health Canada*
Matt Campen | *University of New Mexico*
Wayne Cascio | *U.S. EPA*
Doug Dockery | *Harvard University*
Steve Dutton | *U.S. EPA*
Stephen Graham | *U.S. EPA*
Mike Kleeman | *University of California, Davis*
Tom Long | *U.S. EPA*

Session Questions

29. How can we use the new and emerging information in this review to address key uncertainties identified in the last review?

30. What are the most important uncertainties that are likely to remain in this review of the PM NAAQS?

11:45 – 12:00 Closing Remarks
John Vandenberg | *U.S. EPA*

12:00 Workshop Adjourns

SUPPLEMENT

Session Ia: Characterizing PM Emissions, Air Quality, and Exposures

Emissions, Atmospheric Chemistry, Fate and Transport

1. To what extent has recent research addressed the quantification and characterization of PM emissions, and does this research provide increased confidence in such characterization compared to previous reviews?
   - For specific source types, specific PM components.
2. What new information is available regarding the relationship between PM size distribution and particle composition?
   - For $PM_{2.5}$, $PM_{10\text{-}2.5}$, and ultrafine particles.
   - Near important sources such as roads, industrial sources, etc.
   - Variability in size distribution and composition over different spatial scales (e.g., intra-urban, inter-regional), temporal scales, and land-use types (e.g., urban, rural, near-road).
3. What new science is available to improve our understanding of PM chemistry?
   - Formation of secondary organic aerosols.
   - Variability in chemistry across the U.S., in urban versus non-urban environments, and near important emissions sources (roads, industrial facilities).

Characterization of PM Ambient Monitoring Data and Air Quality

4. To what extent have new or improved ambient monitoring techniques or instrumentation been developed since the last review?
   - For different size fractions, different components, etc.
   - Strengths and limitations of the various approaches.
5. To what extent have new or improved modeling methods, tools, protocols, or data analysis techniques (e.g., satellite measurements) been developed since the last review?
   - For different size fractions, different components, etc.
   - Strengths and limitations of the various approaches.

Session Ib: Linkages Among Atmospheric Chemistry, Exposure Characterization, and the Interpretation of Results from Health Studies

Characterization of PM Exposures

6. What new or emerging measurement methodologies (e.g., satellite data, cell phone monitoring) or modeling approaches are available to characterize PM exposures?
   - Special challenges for characterizing $PM_{10\text{-}2.5}$ and UFP exposures.
   - Linking PM sources or ambient PM concentrations with exposures.
   - Characterization of high-exposure microenvironments (e.g., near-source).
   - Strengths and limitations of the various approaches.

Exposure Assignment – Epidemiologic Studies

7. What new information is available to evaluate the potential impacts of differences across epidemiologic studies in exposure assessment methodologies, exposure measurement error, exposures to specific PM components, or co-exposures to pollutants other than PM?
   - Strengths and limitations of different methods used in epidemiologic studies for translating ambient concentrations into exposure estimates (e.g., averaging across central site monitors, land use regression models, fusion of modeled and monitored data, satellite data, modeling).
   - Relationships between central-site, outdoor, and personal exposure measurements.
   - Factors that affect exposure measurement error (e.g., placement of central site monitors, activity patterns, building characteristics), specifically for different size fractions and chemical/physical compositions.

- Confounding or effect modification by co-occurring pollutants.
- Impact of PM exposure error on results for different epidemiologic study designs (e.g., time-series, longitudinal) and exposure characterization methodologies.
- Informing characterization of concentration-response (C-R) relationships from studies using various approaches to characterize exposures.
- For $PM_{10-2.5}$, implications of various measurement/estimation approaches for interpreting epidemiologic results (e.g., direct measurements, difference method, etc.).
- Urban and regional differences in PM components, source contributions, and personal- and building related factors that may influence interpretation of the epidemiologic evidence.

PM Exposures in Experimental Studies

8. What new information is available regarding the use of experimentally controlled atmospheres for *in vitro*, animal toxicology, and controlled human exposure studies?
- Strengths and limitations of using studies based on various types of experimental exposures (e.g., concentrated ambient particles, generated atmospheres, instillation) to draw conclusions about health effects of exposures to ambient PM.
- Use of exposure-response relationships in experimental studies to inform evaluation of concentration-response relationships reported in epidemiologic studies.

Session IIa: Planning for the Review of the Health Effects Evidence

Mechanistic Evidence and Biological Plausibility

9. What new information is available to inform our understanding of the potential biological mechanisms and modes of action underlying responses to PM?
- Cardiovascular, respiratory, developmental/reproductive endpoints, as well as emerging endpoints such as central nervous system effects and cardiometabolic syndrome.
- Extent to which dosimetry or modes of action are completely characterized.
- Potential mechanisms for effect modification resulting from co-exposures to other ambient pollutants.

10. Do specific methodological issues warrant the exclusion of studies from the evaluation of mechanistic evidence and biological plausibility (e.g., unrealistically high PM exposure concentrations, use of intratracheal instillation, *in vitro* studies, occupational studies, studies of engineered particles)?

11. When organizing the mechanistic evidence does it make more sense to discuss in the context of modes of action or an adverse outcome pathway framework?

12. To what extent is new dosimetric information becoming available to inform our understanding of the linkages between health effects observed in humans with health effects observed in various animal species?
- Exposure concentrations in animal studies that are relevant for our understanding of effects linked to ambient exposures in humans.

Session IIb: Evaluation and Integration of PM Health Effects Evidence

Interpretation of the Health Evidence Across Disciplines

13. What new research is available that has more fully characterized the role of $PM_{2.5}$ or $PM_{10-2.5}$ in the complex ambient mixture (e.g., understanding the role of PM vs. copollutants)?
- Epidemiologic or toxicological studies that further our understanding of the independent relationship between particles and specific health effects.
- Studies that further our understanding of potential confounding or effect modification by copollutants within the ambient mixture.

14. To what extent is new evidence available to enhance our understanding of the relative toxicity of different particle size fractions (e.g., $PM_{2.5}$ or $PM_{10-2.5}$) or components of PM?
- Types of studies that are most informative in assessing the relative toxicity of PM components.

- Evidence that specific PM compositions may have greater or lesser toxicity due to a variety of factors such as emissions sources, geographical differences, intra- or inter-city differences, urban/combustion-based mixture versus windblown dust.
- Appropriate interpretation of PM_{10} health studies in the context of the larger body of PM literature focusing on $PM_{2.5}$, $PM_{10-2.5}$, or other size fractions as well as PM components.

15. What new information is available to assess whether there is a relationship between UFP exposure and health effects?

- Appropriate approach to considering the total body of evidence for health effects of UFPs, given the inconsistency in exposure metrics and siting of monitors used in epidemiologic studies.
- Types of studies most informative for assessing the potential health effects of UFP exposure.

Exposure Metrics and Timing of Health Effects

16. To what extent is key scientific evidence becoming available to improve the understanding of the health effects associated with various time periods of PM exposures?

- Daily and chronic exposures, as well as peak exposures (i.e., less than 24-hour) and seasonal exposures.
- Relevant latency period for long-term exposure to PM and mortality.
- Relationship between various health endpoints and different lag periods (e.g., single day, multi-day average, distributed lag).
- Cessation lag between reductions in PM and reductions in risk of health effects.

Questions Specific to Interpreting the Epidemiologic Evidence

17. Multi-city epidemiologic studies provide evidence of heterogeneity in PM risk estimates. What new information is available to further assess the factors contributing to this heterogeneity?

- Heterogeneity in PM composition, exposure differences or demographic differences between cities, differences in the multipollutant mixtures in different locations.

18. At the completion of the last review, the available evidence indicated a linear, no-threshold relationship. What new information is available to characterize the PM-health effect C-R relationship along the full range of PM concentrations?

- New and innovative statistical approaches to characterize the PM-health effect concentration-response relationship (i.e., both short- and long-term exposures).
- Approaches to quantify uncertainty in the shape of the curve across entire air quality distribution, including at the lower end.

Evaluation of Populations and Lifestages at Increased Risk of a PM-related Health Effect

19. The 2009 PM ISA developed a new approach to integrate evidence across scientific disciplines to assess consistency, coherence and biological plausibility when evaluating populations and lifestages potentially at increased risk of a PM-related health effects. What new information is available to inform the characterization of populations potentially at increased risk of PM-related health effects?

Evaluation of Cancer, Genotoxicity, and Mutagenicity

20. In assessing the health evidence, a central component of the ISA is to evaluate whether there is an independent effect of PM at exposures that are relevant to ambient concentrations. A number of studies have evaluated the carcinogenicity, mutagenicity, or genotoxicity of individual PM components (e.g., benzene, PAHs) or of PM from specific sources (e.g., diesel exhaust) using in vitro assays that are not clearly linked to real-world exposures. In addition, some of these studies have evaluated pollutant concentrations far in excess of what would generally be considered an exposure that is relevant to ambient PM concentrations. How should EPA consider these studies within the context of reaching weight of evidence conclusions for exposures that are relevant to ambient concentrations of PM?

Session III: Planning for Quantitative Health Risk and/or Exposure Assessments

Characterizing Air Quality/Rollback Approaches

21. Ambient concentrations are typically adjusted to simulate air quality scenarios used in estimating exposure and risk, in particular, scenarios for just meeting the existing or alternative standard(s). Three approaches were used in the previous $PM_{2.5}$ risk assessment: (1) proportional rollback (main approach), (2) hybrid rollback (sensitivity analysis), and (3) locally focused rollback (sensitivity analyses): To what extent does newly available data, analyses, or models inform potential approaches to adjusting PM concentrations to just meet existing and alternative PM standards?

- Mathematical/statistical versus physical/chemical model-based approaches to adjusting air quality.

Quantitative Risk Assessment

22. To what extent is there new and emerging scientific evidence available that could potentially support the development of PM risk estimates beyond those generated in the last review?

- For endpoints beyond mortality (total, cardiovascular), hospital admissions (respiratory, cardiovascular), emergency department visits (respiratory, cardiovascular).
- For size fractions beyond $PM_{2.5}$.
- For specific components, mixtures, environments (near-road, urban vs. rural), sources.

23. To what extent does new information allows us to more effectively characterize overall confidence in modeling risks across the range of ambient PM concentrations? Does this new information inform our confidence in applying C-R functions generated at a specific spatial scale (e.g., for a metropolitan statistical areas) to different spatial scales (e.g., individual counties, or individual grid cells)?

Quantitative Exposure Assessment

24. In the last review, EPA did not conduct a quantitative exposure assessment. What critical factors should be considered by EPA in determining whether a quantitative exposure assessment should be conducted for this review?

- New data or approaches that can appropriately represent temporal and spatial variability in ambient PM concentrations.
- Evidence from controlled human exposure studies on exposure-response relationships.

25. If an exposure assessment were conducted for this review, how might EPA define the scope and purpose of such an analysis?

- Appropriate interpretation and contribution of a PM exposure assessment (e.g., input for quantitative risk assessment, characterize exposures of concern, understand personal attributes and other factors that lead to elevated exposures).
- Quantify relationship between short-term and long-term exposures.
- Determine relative contributions of ambient and non-ambient exposures.
- Characterize whether there are regional/study area differences in exposures.
- Estimate exposures in study groups having potentially increased risk of PM-related health effects relative to other study groups.
- Relate PM exposures to correlated gaseous co-pollutants.

Session IV: Planning for the Review of the Welfare Effects Evidence

Visibility

26. 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)?

27. To what extent are new studies available regarding visibility preferences?

- Studies in additional urban and non-urban areas.
- Distinguish visibility preferences from health preferences.
- Sensitivity of visibility preferences to survey methods .
- Potential relationship between intensity versus frequency of visibility impairment in stated public preferences.

Climate

28. To what extent is new information available that changes or enhances our understanding of climate impacts from PM-related aerosols, particularly regarding the quantification of anthropogenic aerosol effects on radiative forcing?

Other Effects?

29. To what extent is new information available to link PM (excluding nitrates and sulfates) to ecological effects, including information regarding interactions with other ecosystem stressors and co-occurring pollutants?

Session V: Integrating Evidence and Quantitative Assessments: Characterizing the Broader Public Health Impacts of PM

30. How can we use the new and emerging information in this review to address key uncertainties identified in the last review?

- Causality at low PM concentrations.
- Linking experimental and mechanistic work with epidemiologic endpoints (e.g., mortality, hospital admissions).
- Critical particle characteristics, beyond $PM_{2.5}$ and $PM_{10\text{-}2.5}$ size fractions, linked to health effects.
- Support for a national assessment of PM health risks.
- Support for a quantitative analysis of PM exposures.

31. What are the most important uncertainties that are likely to remain in this review of the PM NAAQS?

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