Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards

First External Review Draft

March 2010

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LIST OF ACRONYMS/ABBREVIATIONS

ACS	American Cancer Society
AHR	Airway Hyperesponsiveness
AHSMOG	California Seventh Day Adventist Study
ANS	Autonomic nervous system
AQCD	Air Quality Criteria Document
AQS	EPA's Air Quality System
AR4	Fourth Assessment Report of the Intergovernmental Panel on Climate Change
BC	Black carbon
BenMAP	Benefits Mapping Analysis Program
BP	Blood pressure
C	Carbon
Ca	Calcium
CAA	Clean Air Act
CAPs	Concentrated Ambient Particles
CARB	California Air Resources Board
CASAC	Clean Air Scientific Advisory Committee
CBSA	Consolidated Business Statistical Area
CBVD	Cerebrovascular disease
CCN	Cloud Condensation Nuclei
CCSP	US Climate Change Science Program
Cd	Cadmium
CHD	Coronary Heart disease
CHF	Congestive heart failure
CHS	Childrens Health Study
CO	Carbon Monoxide
COPD	Chronic obstructive pulmonary disease
C-R	Concentration-response relationship
CRP	C-reactive protein
CSN	Chemical Speciation Network
CTM	Chemical transport models
Cu	Copper

1	CV	Cardiovascular
2	CVD	Cardiovascular disease
3	DE	Diesel Exhaust
4	DEP	Diesel Exhaust Particles
5	dv	deciview
6	DVT	Deep Vein Thrombosis
7	EC	Elemental Carbon
8	ECG	Electrocardiogram
9	ED	Emergency department
10	EPA	Environmental Protection Agency
11	FEM	Federal Equivalent Method
12	FEV_1	Change in forced expiratory volume in one second
13	FRM	Federal Reference Method
14	GAMs	Generalized additive models
15	GEOS	Global Scale Air Circulation Model
16	GHG	Greenhouse Gas
17	GI	Group Interviews
18	GLMs	Generalized linear models
19	GSH	Glutathione
20	GST	Glutathione-S-transferase
21	HA	Hospital admissions
22	HEI	Health Effects Institute
23	Hg	Mercury
24	HR	Heart rate
25	HRV	Heart rate variability
26	ICD	International Classification of Disease
27	ICR	Information Collection Request
28	IFG	Investigative Focus Groups
29	IHD	Ischemic heart disease
30	IMPROVE	Interagency Monitoring of Protected Visual Environment
31	IPCC	Intergovernmental Panel on Climate Change
32	IRP	Integrated Review Plan
33	ISA	Integrated Science Assessment
34	IT	Intratracheal

1	Km	Kilometer
2	Lag	Time between one event and another
3	Lag 0	Same day as the death, test, hospital, ED, clinic, physician visit; that occurs on the same day as the exposure to the pollutant(s)
5	Lag 0-x	All the deaths test, hospital, ED, clinic, physician visit; that occurs on the same day as the exposure to the pollutant(s) and the x days following the day of exposure
8	MCAPS	Medicare Air Pollution Study
9	MEA	Millennium Ecosystem Assessment
10	MENTOR	Modeling ENvironment for TOtal Risk
11	MI	Myocardial infarction
12	Mm	Megameter
13	MOA	Mode(s) or mechanism(s) of action
14	MSA	Metropolitan Statistical Area
15	N	Nitrogen
16	NAAQS	National Ambient Air Quality Standards
17	NCEA	National Center for Environmental Assessment
18	NCore	National Core Monitoring Network
19	Ni	Nickel
20	NMMAPS	National Morbidity, Mortality, and Air Pollution Study
21	NO	Nitric Oxide
22	NO_2	Nitrogen dioxide
23	NO_3^-	Nitrate
24	NOx	Nitrogen oxides
25	NPS	National Park Service
26	NRC	National Research Council
27	NWS	National Weather Service
28	O_3	Ozone
29	OAQPS	Office of Air Quality Planning and Standards
30	OAR	Office of Air and Radiation
31	OC	Organic Carbon
32	OR	Odds Ratio
33	ORD	Office of Research and Development
34	OS	Observational Study
35	PA	Policy Assessment

PA	Pulmonary arterial
PAH	Polyaromatic Hydrocarbon
Pb	Lead
PEF	Peak Expiratory Flow L/min
PM	Particulate matter
PM_{10}	Particles with an upper 50% cut-point of 10± 0.5 μm aerodynamic diameter and a penetration curve as specified in the Code of Federal Regulations.
$PM_{10-2.5}$	Particles with an upper 50% cut-point of 10 μm aerodynamic diameter and a lower 50% cut-point of 2.5 μm aerodynamic diameter.
$PM_{2.5}$	Particles with an upper 50% cut-point of 2.5 μm aerodynamic diameter and a penetration curve as specified in the Code of Federal Regulations.
PM_X	The legal definition for PM_X, as defined in the Code of Federal Regulations, includes both a 50% cut-point and a penetration curve. A 50% cut-point of X μm diameter means that 50% of particles with aerodynamic diameter of X are removed by the inlet and 50% pass through the inlet and are collected on the filter. Depending on the specific penetration curve specified, particles larger than X μm aerodynamic diameter are collected with an efficiently than decreases rapidly for particles larger than X while the collection efficiency for particles smaller than X increases rapidly with decreasing size until 100 % efficiency is reached.
PRB	Policy-Relevant Background
PSAS	The French National Program on Air Pollution Health Effects
PT	Prothrombin Time
PTT	Partial Thomboplastin Time
QA	Quality assurance
QT	Time for depolarization and repolarization of the ventricles
RA	Risk Assessment
REA	Risk and Exposure Assessment
RF	Radiative forcing
RH	Relative humidity
RNS	Reactive Nitrogen Species
ROS	Reactive Oxygen Species
RR	Relative risk

SAB	Science Advisory Board
SANDWICH	Sulfate, Adjusted Nitrate, Derived Water, Inferred Carbonaceous mass approach
SAP	Synthesis and Assessment Product
SBP	Systolic Blood Pressure
SD	Standard deviation
SEARCH	Southeastern Aerosol Research and Characterization Study
SEDD	State Emergency Department Databases
SES	Socioeconomic Status
Si	Silicon
SID	State Inpatient Database
SMOKE	Sparse Matrix Operator Kernal Emissions
S	Sulfur
SO_2	Sulfur Dioxide
SO_4^{2-}	Sulfate
SO_x	Sulfur Oxides
SOPHIA	Study of Particulates and Health in Atlanta
STP	Standard Temperature and Pressure
TB	Tracheobronchial
TSP	Total suspended particulate
UFPs	Ultrafine particles
UFVA	Urban-Focused Visibility Assessment
V	Vanadium
VAQ	Visual Air Quality
VOC	Volatile organic compounds
WACAP	Western Airborne Contaminants Assessment Project
WHI	Women's Health Initiative
Zn	Zinc

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1. INTRODUCTION

1.1 PURPOSE

The U.S. Environmental Protection Agency (EPA) is presently conducting a review of the national ambient air quality standards (NAAQS) for particulate matter (PM). The overall plan and schedule for this review were presented in the *Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter* (IRP; US EPA, 2008a). The IRP identified key policy-relevant issues to be addressed in this review as a series of questions that frame our consideration of whether the current NAAQS for PM should be retained or revised.

This Policy Assessment (PA), prepared by staff in the EPA's Office of Air Quality Planning and Standards (OAQPS), is intended to help "bridge the gap" between the relevant scientific information and assessments and the judgments required of the EPA Administrator in determining whether, and if so, how, it is appropriate to revise the NAAQS for PM.[1] This first draft PA presents factors relevant to EPA's review of the primary (health-based) and secondary (welfare-based) PM NAAQS. It focuses on both evidence- and risk-based information in evaluating the adequacy of the current PM NAAQS and in identifying potential alternative standards for consideration. In this first draft PA, we consider the scientific and technical information available in this review as assessed in the *Integrated Science Assessment for Particulate Matter (Final Report)* (ISA, US EPA, 2009a), the *Quantitative Health Risk Assessment for Particulate Matter – Second External Review Draft* (US EPA, 2010a) and the *Particulate Matter Urban-Focused Visibility Assessment – Second External Review Draft* (US EPA, 2010b). In so doing, we focus on information that is most pertinent to evaluating the basic elements of NAAQS: indicator[2], averaging time, form,[3] and level. These elements, which together serve to define each standard, must be considered collectively in evaluating the health and welfare protection afforded by the PM standards.

We also recognize that part of the definition of the NAAQS includes specifying allowable monitoring methods by which the indicator is to be measured as well as minimum requirements for monitoring, such as monitor siting criteria. Such monitoring issues were identified in the IRP (US EPA, 2008a, chapter 7) and we plan to include a discussion of them in the second draft PA.

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[1] Preparation of a PA by OAQPS staff reflects Administrator Jackson's decision to modify the NAAQS review process that was presented in the IRP. See http://www.epa.gov/ttn/naaqs/review.html for more information on the current NAAQS review process.

[2] The "indicator" of a standard defines the chemical species or mixture that is to be measured in determining whether an area attains the standard.

[3] 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.

Although this first draft PA should be of use to all parties interested in this PM NAAQS review, it is written with an expectation that the reader has familiarity with the technical discussions contained in the ISA (US EPA, 2009a) and in the draft quantitative risk and visibility assessment documents (US EPA, 2010a,b).

1.2 BACKGROUND

1.2.1 Legislative Requirements

Two sections of the Clean Air Act (Act) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. section 7408) directs the Administrator to identify and list air pollutants that meet three specified criteria, including air pollutants "emissions of which, in his 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 those that are listed. Air quality criteria are to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air . . ." 42 U.S.C. § 7408(b).

Section 109 (42 U.S.C. section 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants for which air quality criteria are issued. Section 109(b)(1) defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on [air quality] criteria and allowing an adequate margin of safety, are requisite to protect the public health."[4] A secondary standard, as defined in Section 109(b)(2), must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such [air quality] 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]

The requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries*

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

[5] Welfare effects as defined in section 302(h) (42 U.S.C. section 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."

Association v. EPA, 647 F.2d 1130, 1154 (D.C. Cir 1980), cert. denied, 449 U.S. 1042 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981), cert. denied, 455 U.S. 1034 (1982); *American Farm Bureau Federation v. EPA,* 559 F. 3d 512, 533 (D.C. Cir. 2009). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

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

In setting standards that are "requisite" to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, EPA may not consider the costs of implementing the standards. See generally *Whitman v. American Trucking Associations*, 531 U.S. 457, 471, 475-76 (2001).

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

1.2.2 Overview of the NAAQS Review Process

Since completion of the last PM NAAQS review, the Agency has made a number of changes to the process for reviewing the NAAQS. In making these changes, the Agency consulted with CASAC and the public. This revised process contains four major components: planning, science assessment, risk/exposure assessment, and policy assessment/rulemaking.

The planning phase begins with a "kick-off" workshop to get input from external and internal experts and the public regarding policy-relevant issues from the last review and others that have more recently emerged. The workshop discussions help inform the preparation of an IRP jointly by OAQPS and Office of Research and Development/National Center for Environmental Assessment (ORD/NCEA) staff. A draft IRP is presented for consultation with CASAC and for public comment. A final IRP reflects consideration of CASAC and public comments together with early guidance from Agency management. The IRP presents the policy-relevant questions that will frame the review, the review process and schedule, and descriptions of the purpose, contents, and approach for developing each of the key documents.

The science assessment phase involves the preparation of an ISA by NCEA staff. The ISA provides a concise evaluation and integration of the policy-relevant science, including key science judgments that are important to inform the design and scope of the risk and exposure assessments. The ISA and its supporting annexes provide a comprehensive assessment of the current scientific literature pertaining to known and anticipated effects on public health and welfare associated with the presence of the pollutant in the ambient air, emphasizing information that has become available since the last review. The process generally includes production of a first and second draft ISA, which undergo CASAC and public review prior to completion of the final ISA.

In the risk/exposure assessment phase, OAQPS staff draws upon information and conclusions presented in the ISA to develop quantitative estimates of the risks/exposures for health and/or welfare effects associated with current ambient levels of PM, with levels that just meet the current standards, and with levels that just meet potential alternative standards. The REAs present methods, key results, observations, and related uncertainties. These assessments begin with preparation of a planning document that discusses the scope and methods planned for use in conducting the quantitative assessments. Scope and Methods Plans are generally prepared in conjunction with the first draft ISA and presented for consultation with CASAC and for public comment. Comments received on the Scope and Methods Plans are considered by EPA staff in conducting the analyses and preparing draft REAs. The process generally includes production of first and second draft REAs, which undergo CASAC and public review prior to completion of final REAs.

The review process ends with a policy assessment/rulemaking phase. Recent revisions to process have reinstated the preparation of a Policy Assessment (PA). The PA, like the previous Staff Paper, integrates and interprets the information from the ISA and REAs to provide a transparent staff analysis of the scientific basis for alternative policy options for consideration by the Administrator prior to the issuance of proposed and final rules (Jackson, 2009). One or more drafts of the PA undergo CASAC and public review prior to completion of the final PA. The PA

is intended to facilitate CASAC's advice and recommendations to the Administrator on any new standards or revisions to existing standards as may be appropriate, as provided for in the CAA. Following issuance of the final PA, the Agency publishes a proposed rule, followed by a public comment period. Taking into account comments received on the proposed rule, the Agency issues a final rule to complete the rulemaking process.

1.2.3 History of PM NAAQS Reviews

The NAAQS for PM that have been promulgated to date are summarized in Table 1-1 and briefly discussed below. Particulate matter is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes, such that the indicator for a PM NAAQS has historically been defined in terms of particle size ranges.

The EPA first established NAAQS for PM in 1971 (36 FR 8186), 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). The primary standards (measured by the indicator TSP) were 260 $\mu g/m^3$, 24-hour average, not to be exceeded more than once per year, and 75 $\mu g/m^3$, annual geometric mean. The secondary standard was 150 $\mu g/m^3$, 24-hour average, not to be exceeded more than once per year.

In October 1979, EPA announced the first periodic review of the criteria and NAAQS for PM, and significant revisions to the original standards were promulgated in 1987 (52 FR 24634, July 1, 1987). In that decision, EPA changed the indicator for PM from TSP to PM_{10}, the latter including particles with a median aerodynamic diameter[6] less than or equal to 10 μm, which delineates thoracic particles (i.e., that subset of inhalable particles small enough to penetrate beyond the larynx to the thoracic region of the respiratory tract). The EPA also revised the primary standards by: (1) replacing the 24-hour TSP standard with a 24-hour PM_{10} standard of 150 $\mu g/m^3$ with no more than one expected exceedance per year; and (2) replacing the annual TSP standard with a PM_{10} standard of 50 $\mu g/m^3$, annual arithmetic mean. The secondary standard was revised by replacing it with 24-hour and annual standards identical in all respects to the primary standards. The revisions also included a new reference method for the measurement of PM_{10} in the ambient air and rules for determining attainment of the new standards. On

[6] The more precise term is 50 percent cutpoint or 50 percent diameter (D_{50}). This is the aerodynamic particle diameter for which the efficiency of particle collection is 50 percent. Larger particles are not excluded altogether, but are collected with substantially decreasing efficiency and smaller particles are collected with increasing (up to 100 percent) efficiency.

Table 1-1. Summary of National Ambient Air Quality Standards Promulgated for Particulate Matter 1971-2006[7]

Final Rule	Indicator	Ave. Time	Level	Form
1971 (36 FR 8186 April 30, 1971)	**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)	Annual average
1987 (52 FR 24634; July 1, 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 (62 FR 38652 July 18, 1997)	**$PM_{2.5}$**	**24-hour**	**65 µg/m^3**	98th percentile, averaged over 3 years
		Annual	**15 µg/m^3**	Annual arithmetic mean, averaged over 3 years[8]
	PM_{10}	**24-hour**	**150 µg/m^3**	Initially promulgated 99th percentile, averaged over 3 years; when 1997 standards were vacated, the form of 1987 standards remained in place (not to be exceeded more than once per year on average over a 3-year period)
		Annual	**50 µg/m^3**	Annual arithmetic mean, averaged over 3 years
2006 (71 FR 61144 October 17, 2006)	**$PM_{2.5}$**	**24-hour**	**35 µg/m^3**	98th percentile, averaged over 3 years
		Annual	**15 µg/m^3**	Annual arithmetic mean, averaged over 3 years[9]
	PM_{10}	**24-hour**	**150 µg/m^3**	Not to be exceeded more than once per year on average over a 3-year period

[7] When not specified, primary and secondary standards are identical.
[8] The level of the standard was to be compared to measurements made at sites that represent "community-wide air quality" recording the highest level, or, if specific constraints were met, measurements from multiple community-wide air quality monitoring sites could be averaged ("spatial averaging").
[9] The constraints on the spatial averaging criteria were tightened by further limiting the conditions under which some areas may average measurements from multiple community-oriented monitors to determine compliance (see 71 FR 61165-61167).

In April 1994, EPA announced its plans for the second periodic review of the criteria and NAAQS for PM, and promulgated significant revisions to the NAAQS in 1997 (62 FR 38652, judicial review, the revised standards were upheld in all respects. *Natural Resources Defense Council v. EPA,* 902 F. 2d 962 (D.C. Cir. 1990), cert. denied, 498 U.S. 1082 (1991). July 18, 1997). Most significantly, EPA determined that although the PM NAAQS should continue to focus on particles less than or equal to 10 μm in diameter, the fine and coarse fractions of PM_{10} should be considered separately. New standards were added, using $PM_{2.5}$, referring to particles with a nominal median aerodynamic diameter less than or equal to 2.5 μm, as the indicator for fine particles. The PM_{10} standards were retained for the purpose of regulating the coarse fraction of PM_{10} (referred to as thoracic coarse particles or coarse-fraction particles; generally including particles with a nominal median aerodynamic diameter greater than 2.5 μm and less than or equal to 10 μm, or $PM_{10-2.5}$). The EPA established two new $PM_{2.5}$ standards: an annual standard of 15 $\mu g/m^3$, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple monitors sited to represent community-wide air quality; and a 24-hour standard 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 population-oriented monitor within an area. Also, EPA established a new reference method for the measurement of $PM_{2.5}$ in the ambient air and rules for determining attainment of the new standards. To continue to address thoracic coarse particles, the annual PM_{10} standard was retained, while the form, but not the level, of the 24-hour PM_{10} standard was revised to be based on the 99^{th} percentile of 24-hour PM_{10} concentrations at each monitor in an area. The EPA revised the secondary standards by making them identical in all respects to the primary standards.

Following promulgation of the revised PM NAAQS in 1997, petitions for review were filed by a large number of parties, addressing a broad range of issues. In May 1998, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit issued an initial decision that upheld EPA's decision to establish fine particle standards, holding that "the growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects amply justifies establishment of new fine particle standards." *American Trucking Associations v. EPA* , 175 F. 3d 1027, 1055-56 (D.C. Cir. 1999) (rehearing granted in part and denied in part, 195 F. 3d 4 (D.C. Cir. 1999), affirmed in part and reversed in part, *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001). The panel also found "ample support" for EPA's decision to regulate coarse particle pollution, but vacated the 1997 PM_{10} standards, concluding in part that PM_{10} is a "poorly matched indicator for coarse particulate pollution" because it includes fine particles. Id. at 1053-55. Pursuant to the court's decision, EPA removed the vacated 1997 PM_{10} standards from the Code of Federal Regulations (CFR) (69 FR 45592, July 30, 2004) and deleted the regulatory provision [at 40 CFR section 50.6(d)] that

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

More generally, the panel held (over a strong dissent) that EPA's approach to establishing the level of the standards in 1997, both for the PM and for the ozone (O_3) NAAQS promulgated on the same day, effected "an unconstitutional delegation of legislative authority." Id. at 1034-40. Although the panel stated that "the factors EPA uses in determining the degree of public health concern associated with different levels of ozone and PM are reasonable," it remanded the rule to EPA, stating that when EPA considers these factors for potential non-threshold pollutants "what EPA lacks is any determinate criterion for drawing lines" to determine where the standards should be set. Consistent with EPA's long-standing interpretation and D.C. Circuit precedent, the panel also reaffirmed its prior holdings that in setting NAAQS EPA is "not permitted to consider the cost of implementing those standards" Id. at 1040-41.

On EPA's petition for rehearing, the panel adhered to its position on these points. *American Trucking Associations v. EPA*, 195 F. 3d 4 (D.C. Cir. 1999). The full Court of Appeals denied EPA's request for rehearing en banc, with five judges dissenting. Id. at 13. Both sides filed cross appeals on these issues to the United States Supreme Court, which granted certiorari. In February 2001, the Supreme Court issued a unanimous decision upholding EPA's position on both the constitutional and cost issues. *Whitman v. American Trucking Associations*, 531 U.S. 457, 464, 475-76. On the constitutional issue, the Court held that the statutory requirement that NAAQS be "requisite" to protect public health with an adequate margin of safety sufficiently cabined EPA's discretion, affirming EPA's approach of setting standards that are neither more nor less stringent than necessary. The Supreme Court remanded the case to the Court of Appeals for resolution of any remaining issues that had not been addressed in that court's earlier rulings. Id. at 475-76. In March 2002, the Court of Appeals rejected all remaining challenges to the standards, holding under the traditional standard of review that EPA's $PM_{2.5}$ standards were reasonably supported by the administrative record and were not "arbitrary and capricious." *American Trucking Associations v. EPA,* 283 F. 3d 355, 369-72 (D.C. Cir. 2002).

In October 1997, EPA published its plans for the next periodic review of the air quality criteria and NAAQS for PM (62 FR 55201, October 23, 1997), including the 1997 $PM_{2.5}$ standards and the 1987 PM_{10} standards. After CASAC and public review of several drafts, NCEA finalized the *Air Quality Criteria Document for Particulate Matter* (henceforth, AQCD or the "Criteria Document") in October 2004 (U.S. EPA, 2004) and OAQPS finalized an assessment document, *Particulate Matter Health Risk Assessment for Selected Urban Areas*

(Abt, 2005), and a "Staff Paper," *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information,* in December 2005 (U.S. EPA, 2005). In conjunction with their review of the Staff Paper, CASAC provided advice to the Adminstrator on revisions to the PM NAAQS (Henderson, 2005a). In particular, most CASAC PM Panel members favored revising the level of the 24-hour $PM_{2.5}$ primary standard in the range of 35 to 30 $\mu g/m^3$ with a 98th percentile form, in concert with revising the level of the annual $PM_{2.5}$ standard in the range of 14 to 13 $\mu g/m^3$ (Henderson, 2005a, p.7). For thoracic coarse particles, the Panel had reservations in recommending a 24-hour $PM_{10-2.5}$ primary standard, and agreed that there was a need for more research on the health effects of thoracic coarse particles (Henderson, 2005b). With regard to secondary standards, most Panel members strongly supported establishing a new, distinct secondary $PM_{2.5}$ standard to protect urban visibility (Henderson, 2005a, p. 9).

On January 17, 2006, EPA proposed to revise the primary and secondary NAAQS for PM (71 FR 2620) and solicited comment on a broad range of options. Proposed revisions included: revising the level of the 24-hour $PM_{2.5}$ primary standard to 35 $\mu g/m^3$; revising the form, but not the level, of the annual $PM_{2.5}$ primary standard by tightening the constraints on the use of spatial averaging; replacing the 24-hour PM_{10} primary standard with a 24-hour standard defined in terms of a new indicator, $PM_{10-2.5}$ [10] set at a level of 70 $\mu g/m^3$; revoking the annual PM_{10} primary standard; and revising the secondary standards by making them identical in all respects to the proposed suite of primary standards for fine and coarse particles.[11] Subsequent to the proposal, CASAC provided additional advice to EPA in a letter to the Administrator requesting reconsideration of CASAC's recommendations for both the primary and secondary $PM_{2.5}$ standards as well as the standards for thoracic coarse particles (Henderson, 2006a).

On October 17, 2006, EPA promulgated revisions to the PM NAAQS to provide increased protection of public health and welfare (71 FR 61144). With regard to the primary and secondary standards for fine particles, EPA revised the level of the 24-hour $PM_{2.5}$ standard to 35 $\mu g/m^3$, retained the level of the annual $PM_{2.5}$ standard at 15 $\mu g/m^3$, and revised the form of the annual $PM_{2.5}$ standard by adding further constraints on the optional use of spatial averaging. The EPA revised the secondary standards for fine particles by making them identical in all respects to the primary standards. With regard to the primary and secondary standards for thoracic coarse

[10] This proposed indicator was qualified so as to include any ambient mix of $PM_{10-2.5}$ dominated by particles generated by high-density traffic on paved roads, industrial sources, and construction sources, and to exclude any ambient mix of particles dominated by rural windblown dust and soils and agricultural and mining sources.

[11] In recognition of an alternative view expressed by most members of the CASAC PM Panel, the Agency also solicited comments on a subdaily (4 to 8 hour averaging time) secondary $PM_{2.5}$ standard to address visibility impairment, within the range of 20 to 30 $\mu g/m^3$ and with a form within the range of the 92nd to 98th percentile (71 FR 2685).

particles, EPA retained the level and form of the 24-hour PM_{10} standard (such that the standard remained at a level of 150 $\mu g/m^3$ with a one expected exceedance form), and revoked the annual PM_{10} standard. The EPA also established a new Federal Reference Method (FRM) for the measurement of $PM_{10-2.5}$ in the ambient air (71 FR 61212-13). Although the standards for thoracic coarse particles were not defined in terms of a $PM_{10-2.5}$ indicator, the new FRM for $PM_{10-2.5}$ was established to provide a basis for approving Federal Equivalent Methods (FEMs) and to promote gathering scientific data to support future reviews of the PM NAAQS.

Following issuance of the final rule, CASAC articulated its concern that "EPA's final rule on the NAAQS for PM does not reflect several important aspects of the CASAC's advice" (Henderson et al, 2006b). With regard to the $PM_{2.5}$ annual primary standard, CASAC expressed serious concerns regarding the decision to retain the level of the standard at 15 $\mu g/m^3$. With regard to EPA's final decision to retain the 24-hour PM_{10} standard for thoracic coarse particles, CASAC acknowledged concerns associated with retaining this standard while recognizing the need to have a standard in place to protect against effects associated with short-term exposures to thoracic coarse particles. With regard to EPA's final decision to revise the secondary $PM_{2.5}$ standards to be identical in all respects to the revised primary $PM_{2.5}$ standards, CASAC expressed concerns that CASAC's advice to establish a distinct secondary standard for fine particles to address visibility impairment was not followed.

1.2.4 Litigation Related to the 2006 PM Standards

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 standard 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, (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* 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.

The decisions of the court with regard to these three issues are discussed in chapters 2, 3 and 4, respectively. The EPA is responding to the court's remands as part of the current review of the PM NAAQS.

1.2.5 Current PM NAAQS Review

The EPA initiated the current review of the air quality criteria for PM in June 2007 with a general call for information (72 FR 35462, June 28, 2007). In July 2007, EPA held two "kick-off" workshops on the primary and secondary PM NAAQS, respectively (72 FR 34003 and 34005, June 20, 2007).[12] These workshops provided an opportunity for the participants to discuss the key policy-relevant issues around which EPA would structure this PM NAAQS review and the most meaningful new science that would be available to inform our understanding of these issues.

Based in part on the workshop discussions, EPA developed a draft IRP outlining the schedule, process, and key policy-relevant questions that would guide the evaluation of the air quality criteria for PM and the review of the primary and secondary PM NAAQS. On November 30, 2007, EPA held a consultation with CASAC[13] on the draft IRP (72 FR 63177, November 8, 2007), which included the opportunity for public comment. The final IRP (US EPA, 2008a) incorporated comments from CASAC and the public on the draft plan as well as input from senior Agency managers.

As part of the process of preparing the PM ISA, NCEA hosted a peer review workshop in June 2008 on preliminary drafts of key ISA chapters (73 FR 30391, May 27, 2008). The first external review draft ISA (US EPA, 2008b) was reviewed by CASAC and the public at a meeting held in April 2009 (74 FR 2688, February 19, 2009). Based on CASAC and public comments, NCEA prepared a second draft ISA (US EPA, 2009b), which was reviewed by CASAC and the public at a meeting held on October 5-6, 2009 (74 FR 46586, September 10, 2009). Based on CASAC and public comments, NCEA prepared the final ISA (US EPA, 2009a; 74 FR 66353, December 15, 2009).

In preparing the REA documents that build on the scientific evidence presented in the ISA, OAQPS released two planning documents: *Particulate Matter National Ambient Air*

[12] See workshop materials http://www.regulations.gov/search/Regs/home.html#home Docket ID numbers EPA-HQ-OAR-2007-0492-008; EPA-HQ-OAR-2007-0492-009; EPA-HQ-OAR-2007-0492-010; and EPA-HQ-OAR-2007-0492-012.

[13] The CASAC PM NAAQS Review Panel was consitituted to perform the statutorily required review of the criteria and standards for this review of the PM NAAQS. For more information on the CASAC PM Panel, see http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommitteesSubcommittees/CASAC%20Particulate%20Matter%20Review%20Panel.

Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment and *Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Urban Visibility Impact Assessment* (henceforth, Scope and Methods Plans, US EPA, 2009c,d). These planning documents outlined the scope and approaches that staff planned to use in conducting quantitative assessments as well as key issues that would be addressed as part of the assessments. In designing and conducting the initial health risk and visibility impact assessments, we considered CASAC comments (Samet 2009a,b) on the Scope and Methods Plans made during an April 2009 consultation (74 FR 11580, March 18, 2009) as well as public comments.. Two draft assessment documents, *Risk Assessment to Support the Review of the $PM_{2.5}$ Primary National Ambient Air Quality Standards: External Review Draft* - September 2009 (US EPA 2009e) and *Particulate Matter Urban-Focused Visibility Assessment - External Review Draft* - September 2009 (US EPA, 2009f) were reviewed by CASAC and the public at a meeting held on October 5-6, 2009. Based on CASAC (Samet 2009c,d) and public comments, OAQPS staff revised these draft documents and released second draft assessment documents (US EPA, 2010a,b) in January and February 2010 (75 FR 4067, January 26, 2010) for CASAC and public review at an upcoming meeting to be held on March 10-11, 2010.

A preliminary draft PA (US EPA, 2009g) was released in September 2009 for informational purposes and to facilitate discussion with CASAC at the October 5-6, 2009 meeting on the overall structure, areas of focus, and level of detail to be included in the PA. This first draft PA reflects consideration of CASAC's comments on the preliminary draft that encouraged the development of a document focused on the key policy-relevant issues that draws from and is not repetitive of information in the ISA and REAs. This first draft PA draws from the information presented in the final ISA and the two second draft assessment documents. We plan to present an overview of this document at the upcoming CASAC meeting on March 10-11, 2010, and CASAC and public review of this document will occur during an upcoming teleconference to be held on April 8-9, 2010 (75 FR 8062, February 23, 2010). We will consider CASAC and public comments on this first draft PA and on the two draft REAs in preparing a second draft PA, which will be released for CASAC and public review.

1.3 GENERAL APPROACH AND ORGANIZATION OF THIS DOCUMENT

This first draft PA includes staff's preliminary evaluation of the policy implications of the scientific assessment of the evidence presented in the ISA and the results of quantitative assessments based on that evidence presented in the second draft REAs. Taken together, this information informs preliminary staff conclusions and the identification of policy options for consideration in addressing public health and welfare effects associated with exposure to ambient PM.

Since the last review, much new information is now available on PM air quality and human health effects directly in terms of $PM_{2.5}$ and, to a much more limited degree, $PM_{10-2.5}$ and ultrafine particles (UFPs). Since the purpose of this review is to evaluate the adequacy of the current standards, which separately address fine and thoracic coarse particles, staff is focusing this policy assessment and associated quantitative analyses primarily on the evidence related directly to $PM_{2.5}$ and $PM_{10-2.5}$. In so doing, we are considering PM_{10}-related evidence primarily to help inform our understanding of key issues and to help interpret and provide context for understanding the public health and welfare impacts of ambient fine and coarse particles. We are also considering the currently available evidence related to UFPs as well as $PM_{2.5}$ components to aid in considering whether or not there is support to consider standards with a different size fraction and/or distinct standards focused on regulating specific $PM_{2.5}$ components or categories of fine particle sources.

Following this introductory chapter, this document is organized into two main parts: review of the primary PM NAAQS (chapters 2 and 3) and review of the secondary PM NAAQS (chapters 4 and 5). Chapters 2 and 3 present staff observations and preliminary conclusions related to review of the primary standards for fine and thoracic coarse particles, respectively. Each chapter begins with a discussion of policy assessment approaches and focuses on both evidence-based and quantitative risk-based considerations. Preliminary staff conclusions are presented with regard to the adequacy of the current primary standards and potential alternative primary standards for consideration, in terms of indicators, averaging times, forms, and levels. Chapter 4 focuses on PM-related visibility impairment, and presents staff observations and preliminary conclusions with regard to the adequacy of the current standards and potential distinct secondary standards for consideration, in terms of alternative indicators, averaging times, forms, and levels. Chapter 5 focuses on other PM-related welfare effects, including effects on climate, ecological effects, and effects on materials, and presents staff observations and preliminary conclusions with regard to the adequacy of the current standards and the extent to which information is available to support consideration of alternative standards.

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2 REVIEW OF THE PRIMARY STANDARDS FOR FINE PARTICLES

This chapter presents preliminary staff conclusions with regard to the adequacy of the current suite of primary $PM_{2.5}$ standards and the alternative primary standards for fine particles that are appropriate for consideration in this review. Our assessment of these issues is framed by a series of key policy-relevant questions, which expand upon those presented in the Integrated Review Plan (IRP) (US EPA, 2008a) at the outset of this review. The answers to these questions will inform decisions on whether, and if so how, to revise the current suite of primary fine particle standards.

Staff notes that final decisions regarding the primary standards must draw upon scientific information and analyses about health effects and risks, as well as judgments about how to deal with the range of uncertainties that are inherent in the scientific evidence and analyses. Ultimately, the final decisions are largely public health policy judgments. Our approach to informing these judgments, discussed more fully below, recognizes that the available health effects evidence generally reflects a continuum consisting of ambient levels at which scientists generally agree that health effects are likely to occur through lower levels at which the likelihood and magnitude of the response become increasingly uncertain

Our current approach for reviewing the primary standards for fine particles is presented in section 2.1. Our preliminary conclusions regarding the adequacy of the current suite of primary $PM_{2.5}$ standards are presented in section 2.2, focusing on both evidence-based and quantitative risk-based considerations. Section 2.3 presents our initial conclusions with respect to alternative fine particle standards, focusing on each of the basic elements of the standards: pollutant indicator (section 2.3.1), averaging time (section 2.3.2), form (section 2.3.3), and level. We have evaluated separately the protection that a suite of $PM_{2.5}$ standards with alternative levels would likely provide against effects associated with long-term exposures (section 2.3.4) and short-term exposures (section 2.3.5). These separate evaluations provide the basis for preliminary integrated conclusions on alternative suites of standards that would appropriately protect against effects associated with both long- and short-term exposures to fine particles (section 2.3.6) Section 2.4 summarizes all preliminary staff conclusions on the primary fine particle standards. The next draft of this chapter will conclude with an initial overview of key uncertainties and suggested future research areas and data collection efforts (section 2.5).

2.1 APPROACH

Staff's approach for reviewing the current primary $PM_{2.5}$ standards builds upon and broadens the approaches used in previous PM NAAQS reviews. Our current approach is based on the updated scientific and technical information presented in the Integrated Science

Assessment (ISA) and second draft quantitative risk assessment (RA). These assessments take into consideration the currently available scientific information as well as enhanced tools and methods for informing the current review.

The past and current approaches described below are all based most fundamentally on using information from epidemiological studies to inform the selection of PM standards that, in the Administrator's judgment, protect public health with an adequate margin of safety. Such information can be in the form of air quality distributions over which health effect associations have been observed, or in the form of concentration-response functions that support quantitative risk assessment. However, evidence- and risk-based approaches using information from epidemiological studies to inform decisions on PM standards are complicated by the recognition that no population threshold, below which it can be concluded with confidence that PM-related effects do not occur, can be discerned from the available evidence. As a result, any approach to reaching decisions on what standards are appropriate necessarily requires judgments about how to translate the information available from the epidemiological studies into a basis for appropriate standards, which includes consideration of how to weigh the uncertainties in reported associations across the distributions of PM concentrations in the studies or in quantitative estimates of risk. Such approaches are consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

2.1.1 Approaches Used in Previous Reviews

Staff has considered policy assessment approaches used in past reviews to inform the approach we are using in this review to reach preliminary conclusions regarding the adequacy of the current standard and alternative standards that are appropriate to consider in this review. We begin this section with a review of the approach used to set the original fine particle standards in 1997 (section 2.1.1.1). The approach used to review and ultimately support revisions to these standards in 2006 is discussed in section 2.1.1.2. Litigation related to the standards finalized in 2006, including the remand of the primary $PM_{2.5}$ annual standard are then discussed in section 2.1.1.3.

2.1.1.1 Review Completed in 1997

In setting the 1997 primary $PM_{2.5}$ annual and 24-hour standards, the Agency relied primarily on an evidence-based approach that focused on epidemiological evidence, especially from short-term exposure studies of fine particles judged to be the strongest evidence at that time. The EPA did not place much weight on quantitative risk estimates from the very limited risk assessment conducted, but did conclude that the assessment results confirmed the general conclusions drawn from the epidemiological evidence that a serious public health problem was

associated with ambient PM levels allowed under the then current PM_{10} standards (62 FR 38665/1, July 18, 1997).

The EPA considered the epidemiological evidence and data on air quality relationships to set an annual $PM_{2.5}$ standard that was intended to be the "generally controlling" standard; i.e., the primary means of lowering both long- and short-term ambient concentrations of $PM_{2.5}$.[1] In conjunction with the annual standard, EPA also established a 24-hour $PM_{2.5}$ standard to provide supplemental protection against days with high peak concentrations, localized "hotspots," and risks arising from seasonal emissions that might not be well controlled by a national annual standard. (62 FR 38669/3). Recognizing that there are various ways to combine two standards to achieve an appropriate degree of public health protection, such as an approach that only considered short- and long-term exposure evidence, analyses, and standards independently, EPA concluded that the selected approach based on a generally controlling annual standard was the most effective and efficient approach. This conclusion was based in part on one of the key observations from the quantitative risk assessment, that much if not most of the aggregate annual risk associated with short-term exposures results from the large number of days during which the 24-hour average concentrations are in the low- to mid-range, below the peak 24-hour concentrations. As a result, lowering a wide range of ambient 24-hour $PM_{2.5}$ concentrations by means of a generally controlling annual standard, as opposed to focusing on control of peak 24-hour concentrations, was determined to be the most effective and efficient way to reduce total population risk (62 FR 38670 to 38671).

In setting the level of the annual standard in 1997, EPA first determined a level for the annual standard based on the short-term exposure studies, and then considered whether the key long-term exposure studies suggested the need for a lower level. While recognizing that health effects may occur over the full range of concentrations observed in the studies, EPA concluded that the strongest evidence for short-term $PM_{2.5}$-related effects occurs at concentrations near the long-term (e.g., annual) average in the short-term exposure studies. Given the serious nature of the potential effects, EPA selected a level for the annual standard at or below the long-term mean concentrations in studies providing evidence of associations with short-term exposures, placing greatest weight on those short-term exposure studies that reported clearly statistically significant associations with mortality and morbidity effects (62 FR 38676/1). Further consideration of the

[1] In so doing, EPA noted that an annual standard would focus control programs on annual average $PM_{2.5}$ concentrations, which would generally control the overall distribution of 24-hour exposure levels, as well as long-term exposure levels, and would also result in fewer and lower 24-hour peak concentrations. Alternatively, a 24-hour standard that focused controls on peak concentrations could also result in lower annual average concentrations. Thus, EPA recognized that either standard could provide some degree of protection from both short- and long-term exposures, with the other standard serving to address situations where the daily peaks and annual averages are not consistently correlated (62 FR 38669).

average $PM_{2.5}$ concentrations across the cities in the key long-term exposure studies of mortality and respiratory effects in children did not provide a basis for establishing a lower annual standard level. Because the annual standard level selected was below the range of annual concentrations most strongly associated with both short- and long-term exposure effects, and because even small changes in annual means in this concentration range could make significant difference in overall risk reduction and total population exposures, EPA concluded that this standard would provide an adequate margin of safety against effects observed in these epidemiological studies (62 FR 68676/3).

The selection of the level of the annual standard was done in conjunction with having first selected the form of the annual standard to be based on the concentration measured at a single monitor sited to represent community-wide air quality, or a value resulting from an average of measurements from multiple community-wide air quality monitoring sites that met specific criteria and constraints ("spatial averaging"). This decision emphasized consistency with the types of air quality measurements that were used in the relevant epidemiological studies. In reaching this decision, EPA recognized the importance of ensuring that spatial averaging would not result in inequities in the level of protection provided by the $PM_{2.5}$ standards in some areas. Because the annual standard, defined in terms of single or averaged community-wide air quality monitoring sites, could not be expected to offer an adequate margin of safety against the effects of all potential short-term exposures in areas with strong local or seasonal sources that could not be directly evaluated in the epidemiological studies, EPA set the level of the 24-hour standard to supplement the control afforded by the annual standard based on air quality relationships between annual and 24-hour concentrations. This approach was intended to provide an adequate margin of safety against infrequent or isolated peak concentrations that could occur in areas that attain the annual standard (62 FR 38677).

2.1.1.2 Review Completed in 2006

In 2006, EPA used a different evidence-based approach to assess the appropriateness of the levels of the 24-hour and annual $PM_{2.5}$ standards. Based on an expanded body of epidemiological evidence that was stronger and more robust, including both short- and long-term exposure studies, the Administrator decided that using evidence of effects associated with periods of exposure that were most closely matched to the averaging time of each standard was the most appropriate public health policy approach for evaluating the scientific evidence to inform selecting the level of each standard. Thus, the Administrator relied upon evidence from the short-term exposure studies as the principal basis for selecting the level of the 24-hour $PM_{2.5}$ standard, with the 24-hour standard designed to protect against effects associated with short-term exposures. The Administrator relied upon evidence from long-term exposure studies as the

principal basis for selecting the level of the annual $PM_{2.5}$ standard, with the annual standard designed to protect against effects associated with long-term exposures.

With respect to quantitative risk-based considerations, the Administrator recognized that the analyses conducted for this review were based on "a more extensive body of data and [was] more comprehensive in scope than the assessment conducted in the last review, but was mindful that significant uncertainties continue[d] to underlie the resulting risk estimates" (71 FR 61168/2, October 17, 2006).[2] The Administrator determined that the estimates of risks likely to remain upon attainment of the 1997 suite of $PM_{2.5}$ standards were indicative of risks that could be reasonably judged important from a public health perspective, and, thus, supported revision of the standards. However, the Administrator judged that the quantitative risk assessment had important limitations and did not provide an appropriate basis for selecting either the level of the 24-hour or annual $PM_{2.5}$ standard (71 FR 61174/1-2). The Administrator more heavily weighed the implications of the uncertainties associated with the quantitative risk assessment than the Clean Air Scientific Advisory Committee (CASAC) apparently did in their comments on the proposed rulemaking, where CASAC stated, "[w]hile the risk assessment is subject to uncertainties, most of the PM Panel found EPA's risk assessment to be of sufficient quality to inform its recommendations…The risk analyses indicated that the uncertainties would increase rapidly below an annual level of 13 $\mu g/m^3$ – and that was the basis for the PM Panel's recommendation of 13 $\mu g/m^3$ as the lower bound for the annual $PM_{2.5}$ standard level" (Henderson, 2006a, p.3).

With regard to final decisions on the primary annual $PM_{2.5}$ standard, the Administrator placed the greatest weight for determining the level of the annual standard on the long-term means of the concentrations associated with mortality effects in the two key long-term exposure studies in the record, the American Cancer Society (ACS) and Harvard Six Cities studies (71 FR at 61172 to 61177). Important validation and reanalyses of the original ACS and Harvard Six Cities studies provided "evidence of generally robust associations and provide[d] a basis for greater confidence in the reported associations than in the last review, for example, in the extent to which they have made progress in understanding the importance of issues related to co-pollutant confounding and the specification of statistical models." Furthermore, the extended ACS study provided "new evidence of mortality related to lung cancer and further

[2] Uncertainties identified in the quantitative risk assessment were generally related to a lack of clear understanding of a number of important factors, including, for example, the shape of concentration-response functions, particularly when, as here, effect thresholds could neither be discerned nor determined not to exist; issues related to selection of appropriate statistical models for the analysis of the epidemiologic data; the role of potentially confounding and modifying factors in the concentration-response relationships; issues related to simulating how $PM_{2.5}$ air quality distributions would likely change in any given area upon attaining a particular standard, since strategies to reduce emissions were not yet defined; and whether there would be differential reductions in the many components within $PM_{2.5}$ and, if so, whether this would result in differential reductions in risk (71 FR 61168/2).

substantiate[d] the statistically significant associations with cardiorespiratory-related mortality observed in the original studies" (71 FR 61172/1-2). The Administrator also recognized the availability of long-term exposure studies that provided evidence of respiratory morbidity, including changes in lung function measurements and decreased growth in lung function as reported in the 24-Cities study and the Southern California Children's Health Study, respectively. In retaining the level of the annual standard at 15 $\mu g/m^3$, the Administrator selected a level that was "appreciably below" the long-term average concentrations reported in the key long-term mortality studies and "basically at the same level" as the long-term average concentrations in the key long-term respiratory morbidity studies. In the judgment of the Administrator, the two long-term respiratory morbidity studies provided an uncertain basis for setting the level of a national standard, and therefore, did "not warrant setting a lower level for the annual standard than the level warranted based on the key mortality studies" (71 FR 61176/3).

In considering the form of the primary annual $PM_{2.5}$ standard, the Administrator retained the form of the standard as an annual arithmetic mean, averaged over 3 years with modifications that strengthen the standard by tightening the criteria for use of spatial averaging. Specifically, the Administrator narrowed the circumstances under which spatial averaging may be utilized. Analyses conducted in the review completed in 2006, based on a much larger set of $PM_{2.5}$ air quality data than was available for the review completed in 1997, provided evidence concerning the potential for disproportionate impacts on potentially vulnerable subpopulations. Specifically, the results of the analyses suggested that "the highest concentrations in an area tend to be measured at monitors located in areas where the surrounding population [was] more likely to have lower education and income levels, and higher percentages of minority populations" (71 FR 61166/2, see also US EPA, 2005, section 5.3.6.1; Schmidt et al., 2005, Attachment A/Analysis 7).[3]

In deciding to revise the level of the 24-hour $PM_{2.5}$ standard from 65 $\mu g/m^3$ to 35 $\mu g/m^3$, the Administrator placed the greatest weight on the much expanded body of evidence from short-term exposure studies, with a focus on U.S. and Canadian studies that had been reanalyzed, as appropriate, to address statistical modeling issues and that used relatively reliable air quality data. A comprehensive evaluation considered and weighed a variety of evidence, including

[3] As summarized in footnote 29 at 71 FR 61166/2, the 2004 AQCD noted that some epidemiologic studies, most notably the ACS study of associations between long-term $PM_{2.5}$ exposure and mortality, reported larger effect estimates in the cohort subgroup with lower education levels (US EPA, 2004, p 8-103). The 2004 AQCD also noted that lower education level may be a marker for lower socioeconomic status (SES) that may be related to increased vulnerability to the effects of fine particle exposures, for example, as a result of greater exposure from proximity to sources such as roadways and industry, as well as other factors such as poorer health status and access to health care (US EPA, 2004, section 9.2.4.5).

biological plausibility of associations between various pollutants and health outcomes, and focused on the stability of the size of the effect estimates in time-series studies using both single- and multi-pollutant models, rather than just looking at statistical significance in a large number of alternative models to simplistically delineate between real and suspect associations (71 FR 61170/2). Emphasis was placed on those studies that provided evidence of statistically significant associations in areas that would have met the then current annual and 24-hour $PM_{2.5}$ standards during the time of the study. The Administrator recognized that these studies provided no evidence of clear effect thresholds or lowest-observed effect levels. Nonetheless, in focusing on the 98th percentile air quality values in these studies, the Administrator sought to establish a standard level that would require improvements in air quality generally in areas in which the distribution of daily short-term exposure to $PM_{2.5}$ could reasonably be expected to be associated with serious health effects. The Administrator recognized that although future air quality improvement strategies in any particular area were not yet defined, most such strategies were likely to move a broad distribution of $PM_{2.5}$ air quality values in an area lower, resulting in reductions in risk associated with exposures to $PM_{2.5}$ levels across a wide range of concentrations and not just at the 98th percentile concentrations (71 FR 61168/3).

2.1.2 Remand of Primary Annual $PM_{2.5}$ Standard

As noted above in section1.2.4, several parties filed petitions for review following promulgation of the revised PM NAAQS in 2006. These petitions challenged several aspects of the final rule including the selection of the level of the primary $PM_{2.5}$ annual standard. More specifically, petitioners representing environmental groups (American Lung Association, Environmental Defense, and the National Parks Conservation Association) and several states and state agencies argued that the decision to retain the level of the annual $PM_{2.5}$ standard at 15 $\mu g/m^3$ was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. 7607(d)(9). The primary 24-hour $PM_{2.5}$ standard was not challenged by any of the litigants and, thus, not considered in the court's review and final decision.

On judicial review, the D.C. Circuit remanded the primary annual $PM_{2.5}$ NAAQS to EPA because the Agency failed to adequately explain why the annual standard provided the requisite protection from both short- and long-term exposures to fine particles including protection for susceptible populations. American Farm Bureau Federation v. EPA, 559 F. 3d 512 (D.C. Cir. 2009). With respect to human health protection from short-term $PM_{2.5}$ exposures, the court considered the different approaches used by EPA in the 1997 and 2006 PM NAAQS decisions as summarized above. The court found that EPA failed to adequately explain why a 24-hour $PM_{2.5}$ standard by itself would provide the protection needed from short-term exposures and remanded the annual $PM_{2.5}$ standard to EPA "for further consideration of whether it is set at a level

requisite to protect the public health while providing an adequate margin of safety from the risk of short-term exposures to $PM_{2.5}$." American Farm Bureau Federation, 559 F. 3d at 520-24.

With respect to protection from long-term exposure to fine particles, the court found that EPA failed to adequately explain how the current primary annual $PM_{2.5}$ standard provided an adequate margin of safety for children and other susceptible populations. The court found that EPA did not provide a reasonable explanation of why certain morbidity studies, including a study of children in Southern California showing lung damage associated with long-term $PM_{2.5}$ exposure (Gauderman et.al, 2000) and a multi-city study (24-Cities Study) evaluating decreased lung function in children associated with long-term $PM_{2.5}$ exposures (Raizenne et al., 1996), did not call for a more stringent annual $PM_{2.5}$ standard. Id. at 522-23. Specifically, the court found that:

> EPA was unreasonably confident that, even though it relied solely upon long-term mortality studies, the revised standard would provide an adequate margin of safety with respect to morbidity among children. Notably absent from the final rule, moreover, is any indication of how the standard will adequately reduce risk to the elderly or to those with certain heart or lung diseases despite (a) the EPA's determination in its proposed rule that those subpopulations are at greater risk from exposure to fine particles and (b) the evidence in the record supporting that determination. Id. at 525.

Petitioners also objected to the EPA analysis of the long-term exposure studies arguing that the EPA "unreasonably focused" upon the long-term mean ambient concentrations of $PM_{2.5}$ in the ACS (17.7 $\mu g/m^3$) and the Harvard Six Cities Study (18 $\mu g/m^3$) and then set a level below those concentrations for the annual $PM_{2.5}$ standard. Specifically, these petitioners claimed that "this approach violates the requirement of the Clean Air Act (CAA) that the NAAQS provide 'an adequate margin of safety' which requires that EPA 'err on the side of caution'" and argued that the level of the annual standard should be revised lower because the most recent data from these studies "showed adverse health effects in years when the mean ambient concentration of $PM_{2.5}$ was below 15 $\mu g/m^3$." Id. at 526. The court rejected these arguments stating: "The EPA, mindful of its obligation to set a standard 'not lower or higher than is necessary…to protect public health,' *Whitman,* 531 U.S. at 475-76, reasonably decided to address long-term mean concentrations in the ACS and Six Cities studies…We approved a similar approach to assuring an adequate margin of safety in *ATAIII* and we do so again here." Id. at 527.

Petitioners also challenged the Agency's decision not to rely upon the quantitative risk assessment in making final decisions on the level of the primary annual $PM_{2.5}$ standard. More specifically, these petitioners argued that "[b]oth CASAC and EPA staff concluded that the Agency's risk assessment … was of sufficient quality to deserve consideration in determining the level of the annual standard necessary to provide an adequate margin of safety" and that, in

retaining the level of the annual standard at 15 $\mu g/m^3$ significant public health impacts remained (State brief, pp. 22 to 23). The court rejected arguments that EPA was compelled to use a risk-based approach to determine the level of the standards, or otherwise compelled to use the risk assessment quantitatively in the standard-setting process, concluding that EPA "reasonably analyzed the risk assessment," and deferred to the EPA's assessment of "scientific data within its technical expertise." Id at 529-530.

In remanding the primary annual standard for reconsideration, the court did not vacate the annual standard. Id. at 530.

2.1.3 Current Approach

Staff's approach in this review is founded on a much expanded body of epidemiological evidence, more extensive air quality data and analyses, and a more comprehensive risk assessment relative to the information available in past reviews. As a result, our approach to reaching conclusions about the adequacy of the current suite of $PM_{2.5}$ standards and potential alternative standards that are appropriate for consideration is broader and more integrative than in past reviews. Our approach takes into account both evidence-based and risk-based considerations, and the uncertainties related to both types of information, to inform the preliminary conclusions presented in this first draft Policy Assessment (PA). In so doing, we are seeking to provide as broad an array of options as is supportable by the available information, recognizing that the selection of a specific approach to reaching final decisions on the primary $PM_{2.5}$ standards will reflect the judgments of the Administrator as to what weight to place on the various approaches and types of information presented in the final PA.

As an initial matter, we believe it is most appropriate to consider the protection against $PM_{2.5}$-related mortality and morbidity effects, associated with both long- and short-term exposures, afforded by the annual and 24-hour standards taken together, rather than to consider each standard separately. In so doing, we look at the types of evidence that can inform each standard, then integrate the results of those considerations to reach preliminary conclusions about the current and alternative suites of standards. This approach reflects the recognition that changes in $PM_{2.5}$ air quality designed to meet an annual standard would likely result not only in lower annual average concentrations but also in fewer and lower peak 24-hour concentrations. Conversely, we recognize that changes designed to meet a 24-hour standard would result not only in fewer and lower peak 24-hour concentrations but also in lower annual average concentrations, especially to the extent that changes of a more regional, rather than local, nature occur. The extent to which these two standards are interrelated in any given area depends in large part on the relative levels of the standards, the peak-to-mean ratios that characterize air

quality patterns in an area, and whether changes in air quality designed to meet a given suite of standards is of a more regional or more localized nature.

Our consideration of the protection afforded by the current and alternative suites of standards focuses first on $PM_{2.5}$-related health effects associated with long-term exposures, for which quantitative estimates of risks to public health are appreciably larger; we then also focus on effects associated with short-term exposures. In both cases, we place greatest weight on associations that have been judged in the ISA to be causal and likely causal, while also considering associations judged to be suggestive of a causal relationship or that focus on specific susceptible populations. We focus on studies conducted in the U.S. and Canada and place relatively greater weight on statistically significant associations that yield relatively more precise effect estimates and that are judged to be robust to confounding by other air pollutants. In the case of short-term exposure studies, we place greatest weight on large multi-city studies, while also considering associations in single-city studies.

As part of our evidence-based approach, we first evaluate the evidence from long-term exposure studies, as well as the uncertainties and limitations in that evidence, to assess the degree to which the current and alternative suites of standards can be expected to protect against effects related to long-term exposures. As in past reviews, we believe this evidence can most directly help inform consideration of the protection afforded by an annual $PM_{2.5}$ standard. In evaluating the long-term exposure evidence, we look at the aggregate long-term mean $PM_{2.5}$ concentration in each study, the range of long-term mean $PM_{2.5}$ concentrations across cities, and the distribution of city-specific means in terms of the standard deviation or interquartile range, to the extent such data are available. In considering the adequacy of the current suite of $PM_{2.5}$ standards in protecting against long-term exposure-related effects, we consider whether associations from long-term exposure studies have been reported across areas in which the aggregate long-term study mean concentrations are at or below the level of the current annual standard. We conclude that such long-term exposure studies can reasonably be viewed as calling into question the adequacy of the current annual standard.

In considering what alternative standards would be protective against effects observed in such long-term exposure studies, we first note the absence of any discernable threshold within the range of long-term mean concentrations reported in the long-term exposure studies. While recognizing that health effects may occur over the full range of concentrations observed in the studies, we believe that it is reasonable to conclude that the evidence of association is strongest down to somewhat below the aggregate mean concentration, such as down to one standard deviation below the mean or to the lower end of the interquartile range, which includes the range in which the data in the study are most concentrated. We also believe it is appropriate to consider the long-term mean concentration at the point where the confidence interval becomes

notably wider, suggestive of a concentration below which the association becomes appreciably more uncertain and the possibility that an effects threshold may exist becomes more likely. Based on these considerations, we identify a range of alternative annual standard levels that we judge to be appropriate to consider for protecting against $PM_{2.5}$-related long-term exposure effects based on the evidence available in this review.

We next evaluate the evidence from short-term exposure studies, as well as the uncertainties and limitations in that evidence, to assess the degree to which the current and alternative suites of standards can be expected to protect against effects related to short-term exposures. As in past reviews, it is staff's view that this evidence can help inform consideration of the protection afforded by both an annual and 24-hour standard.[4] In evaluating the short-term exposure evidence, we look both at the aggregate long-term mean $PM_{2.5}$ concentrations in key studies as well as the distributions of 24-hour $PM_{2.5}$ concentrations, with a focus on the 98th percentile concentrations to match the form of the current 24-hour standard, to the extent such data are available. In evaluating the short-term exposure studies to help inform consideration of the protection afforded by an annual $PM_{2.5}$ standard, we observe, based on quantitative risk assessments conducted in past reviews, that much of the risk related to daily exposures, when aggregated on an annual basis, results from the large number of days during which the 24-hour average concentrations are in the low- to mid-range of the entire distribution. Thus, to reduce the aggregate short-term exposure-related risk, it is necessary to shift the bulk of the air quality distribution to lower levels, not just to limit the concentrations on days when the $PM_{2.5}$ concentrations are relatively high.

While shifting the distribution can be accomplished through control strategies aimed at meeting either an annual or 24-hour standard, we have seen in quantitative risk assessments conducted in this and past reviews that more consistent aggregated risk reductions across study areas are likely to be accomplished through strategies aimed at meeting an annual standard. Thus, in considering the adequacy of the current suite of standards in protecting against effects associated with short-term exposures, we consider whether associations in short-term exposure studies have been reported in areas in which the aggregate long-term study mean concentrations are at or below the level of the current annual standard, as well as by considering whether the 98th percentile $PM_{2.5}$ concentrations in such studies are at or below the level of the current 24-hour standard. We conclude that such short-term exposure studies can reasonably be viewed as calling into question the adequacy of the current annual and/or 24-hour standards.

[4] While this view is consistent with that presented in the 2005 Staff Paper, in the review completed in 2006, as noted above, the Administrator chose to focus more narrowly and considered the short-term exposure evidence as a basis for the 24-hour standard alone.

In considering what alternative standards would be protective against effects observed in such short-term exposure studies, we first note the absence of any discernable threshold within the distribution of 24-hour average concentrations in the short-term exposure studies. While recognizing that health effects may occur over the full range of 24-hour concentrations observed in the studies, as with the long-term exposure studies, we believe that it is reasonable to conclude that the evidence of association is strongest down to somewhat below the mean 24-hour average concentration, such as down to one standard deviation below the mean or to the lower end of the interquartile range, where the data in the study are most concentrated. We also believe it is appropriate to consider whether, and if so, where in the distribution of 24-hour average concentrations the confidence interval becomes notably wider, suggestive of a concentration below which the association becomes appreciably more uncertain and the possibility that an effects threshold may exist becomes more likely. Based on these considerations, we identify a range of alternative annual standard levels that we conclude are appropriate to consider for protecting against $PM_{2.5}$-related short-term exposure effects based on the evidence available in this review. We also recognize that it is unlikely that an annual standard could effectively protect against short-term exposure-related effects in all areas across the country, especially in areas with relatively high peak-to-mean ratios in $PM_{2.5}$ concentrations or in areas that are strongly affected by localized "hotspots" or by seasonal exposures that may not be well controlled by an annual standard. Thus, we also identify a range of alternative 24-hour standard levels that we judge to be appropriate to consider for protecting against $PM_{2.5}$-related short-term exposure effects, in conjunction with a range of alternative annual standards, based on the evidence available in this review.

Based on the evidence-based considerations outlined above, we then develop integrated preliminary conclusions with regard to alternative suites of standards, including both annual and 24-hour standards, that we believe are appropriate for consideration in this review based on the currently available evidence. In so doing, we discuss the roles that each standard might be expected to play in the protection afforded by alternative suites of standards.

Beyond these evidence-based considerations, we also consider the quantitative risk estimates and the key observations presented in the second draft quantitative risk assessment (RA). This assessment included an evaluation of 15 urban case study areas and estimated risk associated with a number of health endpoints associated with long-term and short-term $PM_{2.5}$ exposures (US EPA, 2010a). As part of our risk-based considerations, we have considered estimates of the magnitude of $PM_{2.5}$-related risks associated with recent air quality levels and air quality simulated to just meet the current and alternative suites of standards using alternative simulation approaches. We have also characterized the risk reductions, relative to the risks remaining upon just meeting the current standards, associated with just meeting alternative suites

of standards. In so doing, we recognize the uncertainties inherent in such risk estimates, and have taken such uncertainties into account by considering the sensitivity of the "core" risk estimates to alternative assumptions and methods likely to have substantial impact on the estimates. In addition, we have conducted additional analyses to characterize the representativeness of the urban study areas within a broader national context. We have considered this risk-based information to help inform our preliminary conclusions on the adequacy of the current suite of standards, potential alternative suites of standards that are appropriate for consideration in this review, and on the roles that the annual and 24-hour standards may play in affording protection against effects related to both long- and short-term $PM_{2.5}$ exposures.

Our preliminary conclusions reflect our understanding of both evidence-based and risk-based considerations to inform two overarching questions related to: (1) the adequacy of the current suite of $PM_{2.5}$ standards and (2) what potential alternative standards, if any, should be considered in this review to provide appropriate protection from the effects associated with both long- and short-term exposures to fine particles. In addressing these broad questions, we have organized the discussions below around a series of more specific questions reflecting different aspects of each overarching question. When evaluating the health protection afforded by the current or any alternative suites of standards considered, we have taken into account the four basic elements of the NAAQS (e.g., indicator, averaging time, form, and level).

We believe that the approach outlined above, when presented in the final PA, will provide a comprehensive basis to help inform the judgments required of the Administrator in reaching decisions about the current and potential alternative primary $PM_{2.5}$ standards and in responding to the remand of the 2006 annual $PM_{2.5}$ standard.

2.2 ADEQUACY OF CURRENT STANDARDS

In considering the adequacy of the current suite of $PM_{2.5}$ standards, staff addresses the following overarching question:

Does the currently available scientific evidence and risk-based information, as reflected in the ISA and RA, support or call into question the adequacy of the protection afforded by the current suite of fine particle standards?

To inform the answer to this broad question, we have posed a series of more specific questions to aid in considering the currently available scientific evidence and the results of recent quantitative risk analyses in a policy-relevant context, as discussed below. In considering the scientific and technical information, we reflect upon both the information available in the last review and information that is newly available since the last review as assessed and presented in the ISA and second draft RA (US EPA, 2009a; US EPA, 2010a).

2.2.1 Evidence-based Considerations

In reviewing the adequacy of the current suite of $PM_{2.5}$ standards, we have taken into account evidence-based considerations primarily by assessing the currently available evidence as presented in the ISA. Our review of the adequacy of the current standards begins by considering causal inference, impacts on susceptible populations, and whether health effects have been observed in areas where the air quality concentrations extend to levels lower than previously reported.

- **To what extent does the newly available scientific evidence and related uncertainties strengthen or call into question evidence of associations between ambient fine particle exposures and health effects?**

In considering the strength of the associations between short- and long-term exposures to $PM_{2.5}$ and health effects, we first recognize that, in the last review, EPA concluded that there was "strong epidemiological evidence" for $PM_{2.5}$ linking short-term exposures with cardiovascular and respiratory mortality and morbidity, and long-term exposures with cardiovascular and lung cancer mortality and respiratory morbidity (US EPA, 2004, p. 9-46; US EPA, 2005, p. 5-4). Overall, the epidemiological evidence supported "likely causal associations" between $PM_{2.5}$ and both mortality and morbidity from cardiovascular and respiratory diseases, based on "an assessment of strength, robustness, and consistency in results" (US EPA, 2004, p. 9-48).

In looking across the extensive new scientific evidence available in this review, our overall understanding of health effects associated with fine particle exposures has been greatly expanded. The currently available evidence is stronger in comparison to evidence available in the last review because of its breadth and the substantiation of previously observed health effects (US EPA, 2009a, section 2.3.1). A number of large multi-city epidemiological studies have been conducted throughout the U.S. including extended analyses of studies that were important to inform decisionmaking in the last review. These studies have reported consistent increases in morbidity and/or mortality related to ambient $PM_{2.5}$ concentrations, with the strongest evidence reported for cardiovascular-related effects. In addition, the findings of new toxicological and controlled human exposure studies provide stronger support for a number of potential biologic mechanisms or pathways for PM-related cardiovascular and respiratory effects (US EPA, 2009a, chapter 5; Figures 5-4 and 5-5). In summary, the ISA concludes, "[t]he new evidence … greatly expands upon the evidence available in the 2004 PM AQCD particularly in providing greater understanding of the underlying mechanisms for $PM_{2.5}$ induced cardiovascular and respiratory effects for both short- and long-term exposures" (US EPA, 2009a, p. 2-17).

As an initial matter, we note that since the conclusion of the last PM NAAQS review, the Agency has developed a more formal framework for reaching causal inferences from the body of scientific evidence drawing upon the evaluation and synthesis of evidence from across

epidemiological, controlled human exposure, and toxicological studies. This framework uses a five-level hierarchy that classifies the overall weight of evidence and causality using the following categorizations: causal relationship, likely to be a causal relationship, suggestive of a causal relationship, inadequate to infer a causal relationship, and not likely to be a causal relationship (US EPA, 2009a, Table 1-3).

In reaching causal inferences, EPA has considered uncertainties that bear on our understanding of the body of currently available scientific evidence (US EPA, 2009a, section 1.5). For example, in epidemiological studies the potential for confounding bias remains an important source of uncertainty in evaluating the health effects associated with one pollutant that is part of a larger, complex mixture of pollutants. Epidemiological studies attempt to disentangle the effects of the air pollution mixture and identify the health effects associated with a specific pollutant, such as $PM_{2.5}$, using multivariate regression models to control for the potential confounding effects by other pollutants (e.g., gaseous co-pollutants[5]) for which measurements are available. However, there are several statistical issues influencing results generated using co-pollutant models that lead to uncertainty in the quantitative interpretation of these results. In this review, the uncertainties associated with the evaluation of the body of scientific evidence for $PM_{2.5}$-associated health effects remain largely the same as in previous reviews (e.g., co-pollutant confounding, exposure misclassification) and have been considered in reaching causality determinations as discussed in the ISA.

Looking broadly to integrate epidemiological evidence with that from controlled human exposure studies and toxicologic studies and using this causal framework, the ISA concludes that the collective evidence is largely consistent with past studies and substantially strengthens what was known in the last review to reach the conclusion that a *causal* relationship exists between both short- and long-term exposures to $PM_{2.5}$ and mortality and cardiovascular effects. Furthermore, the ISA concludes that the collective evidence continues to support *likely causal* associations between short- and long-term $PM_{2.5}$ exposures and respiratory effects. Additional evidence is *suggestive* of a causal relationship between long-term $PM_{2.5}$ exposures and other health effects, including developmental and reproductive effects (e.g., low birth weight) and carcinogenic, mutagenic, and genotoxic (e.g., lung cancer mortality) effects. Table 2-1 summarizes the causal determinations for health outcomes associated with short- and long-term exposures to $PM_{2.5}$ (US EPA, 2009a, sections 2.3.1 and 2.6).

[5] A gaseous co-pollutant (e.g., O_3, CO, SO_2, NO_2) meets the criteria for potential confounding in $PM_{2.5}$-related effects if: (1) it is a potential risk factor for the health effect under study; (2) it is correlated with $PM_{2.5}$ and (3) it does not act as an intermediate step in the pathway between $PM_{2.5}$ exposure and the health effect under study (US EPA, 2004, p. 8-10).

Table 2-1. Summary of Causality Determinations for $PM_{2.5}$

Exposure Duration	Outcome	Causality Determination
Long-term	Mortality	Causal
	Cardiovascular Effects	Causal
	Respiratory Effects	Likely to be Causal
	Reproductive and Developmental Effects	Suggestive
	Cancer, Mutagenicity, Genotoxicity Effects	Suggestive
Short-term	Mortality	Causal
	Cardiovascular Effects	Causal
	Respiratory Effects	Likely to be Causal
	Central Nervous System Effects	Inadequate

Source: adapted from US EPA, 2009, Table 2-6.

Health Effects Associated with Long-term $PM_{2.5}$ Exposure

With regard to mortality associated with long-term $PM_{2.5}$ exposures, the ISA concludes that newly available evidence significantly strengthens the evidence linking long-term exposure to $PM_{2.5}$ and mortality, while providing indications that the magnitude of the $PM_{2.5}$-mortality association may be larger than previously estimated (US EPA, 2009a, sections 7.2.10, 7.2.11, 7.6.1; Figures 7-6 and 7-7). A number of large U.S. cohort studies have been published since the last review. This evidence includes new analyses and insights from extended analyses of the American Cancer Society (ACS) and Harvard Six Cities studies (US EPA, 2009a, pp 7-84 to 7-85; Figure 7-6; Krewski et al., 2009; Pope et al., 2004; Jerrett et al., 2005; Laden et al., 2006). In addition, new long-term $PM_{2.5}$ exposure studies evaluating mortality impacts in additional cohorts are now available. The Women's Health Initiative has investigated the effects of $PM_{2.5}$ on cardiovascular-related mortality in post-menopausal women with no previous history of cardiac disease (US EPA, 2009a, p. 7-87; Miller et al., 2007). Mortality impacts in older adults using Medicare data have been reported by a number of investigators (US EPA, 2009a, pp. 7-87 to 7-89; Eftim et al., 2008; Zeger et al., 2007, 2008). We note that other long-term $PM_{2.5}$ exposure studies provide additional evidence of mortality associated with long-term $PM_{2.5}$ exposures as discussed more fully in section 7.6 of the ISA. Collectively, these long-term $PM_{2.5}$ exposure studies, along with the evidence available in the last review, provide us with consistent and stronger evidence of associations between long-term exposure to $PM_{2.5}$ and mortality (U.S. EPA, 2009a, sections 2.3.1 and 7.6).

When integrating the mortality evidence, EPA considered impacts on all-cause or non-accidental mortality as well as cause-specific mortality (e.g., cardiovascular-related mortality, respiratory-related mortality, lung cancer mortality) and reached the conclusion that there is a causal association between mortality and long-term $PM_{2.5}$ exposure (US EPA, 2009a, pp. 2-12 and 7-96). The strongest evidence indicates an association between long-term $PM_{2.5}$ exposures and mortality due to cardiovascular disease, with additional evidence supporting an association between $PM_{2.5}$ and mortality related to lung cancer (US EPA, 2009a, pp. 2-12, 7-81, and 7-95 to 7-96; Figure 7-7). We note that fewer long-term $PM_{2.5}$ exposure studies have evaluated the respiratory component of cardiopulmonary mortality, and the evidence to support an association with long-term exposure to $PM_{2.5}$ and respiratory mortality is, therefore, much more limited (US EPA 2009a, p. 2-12; Figure 7-7). The strength of associations for cause-specific mortality is coherent with cardiovascular-related morbidity endpoints as discussed below. The most recent evidence for cardiovascular-related mortality in post-menopausal women indicates that the evidence of association with long-term exposure to $PM_{2.5}$ in this population is "particularly strong" (US EPA, 2009a, p. 7-96).

In addition, the strength of the causal association between long-term $PM_{2.5}$ exposure and mortality builds upon new studies providing evidence of improvement in community health following reduction in ambient fine particle concentrations. Pope et al. (2009) have documented the population health benefits of reducing ambient air pollution by correlating past reductions in ambient $PM_{2.5}$ concentrations with increased life expectancy. These investigators report that reductions in fine particle ambient concentrations that occurred during the 1980s and 1990s account for as much as 15 percent of the overall improvement in life expectancy in 51 U.S. metropolitan areas also analyzed in the ACS study. The decrease in fine particle exposure was reported to be associated with an estimated increase in mean life expectancy of approximately 5 to 9 months (US EPA, 2009a, p. 7-95; Pope et al., 2009). An extended analysis of the Harvard Six Cities study found that as cities cleaned up their air, locations with the largest reductions in $PM_{2.5}$ saw the largest improvements in reduced mortality rates, while those with the smallest decreases in $PM_{2.5}$ concentrations saw the smallest improvements in reduced mortality rates (Laden et al., 2006). Reduced mortality risk observed in this extended follow-up study was related to deaths due to cardiovascular and respiratory-related disease, but not from lung cancer (US EPA, 2009a, p. 7-84). An additional extended follow-up to the Harvard Six Cities study investigated the delay between changes in exposure and changes in mortality. Schwartz et al. (2008) reported that the effects of changes in $PM_{2.5}$ exposures were seen within the 2 years prior to death (US EPA, 2009a, p. 7-92; Figure 7-9).

With regard to cardiovascular effects associated with fine particle exposures, the ISA includes consideration of both cardiovascular-related mortality as well as morbidity effects and

concludes that a causal association exists between long-term $PM_{2.5}$ exposure and cardiovascular effects (US EPA, 2009a, pp. 2-12 and 7-19). Recent studies have provided new evidence linking long-term exposure to $PM_{2.5}$ with cardiovascular outcomes that has "expanded upon the continuum of effects ranging from the more subtle subclinical measures to cardiopulmonary mortality" (US EPA, 2009a, p. 2-17). Several new epidemiologic studies have examined the association between cardiovascular effects and long-term $PM_{2.5}$ exposures in multi-city studies conducted in the U.S. and Europe. The ISA concludes that the strongest evidence of cardiovascular effects related to long-term exposure to $PM_{2.5}$ has been reported in recent studies investigating cardiovascular-related mortality. This includes evidence from a number of large, multi-city U.S. long-term cohort studies including extended follow-up analyses of the ACS and Harvard Six Cities studies as well as the WHI as outlined above (US EPA, 2009a, sections 7.2.10 and 7.6.1; Krewski et al., 2009; Pope et al., 2004; Laden et al., 2006; Miller et al., 2007). Pope et al. (2004) report a positive association between mortality and long-term $PM_{2.5}$ exposure for a number of specific cardiovascular diseases, including ischemic heart disease (IHD), dysrhythmia, heart failure, and cardiac arrest (US EPA, 2009a, p. 7-84; Figure 7-7). Krewski et al. (2009) provides further evidence and precision for IHD-related mortality associated with long-term $PM_{2.5}$ exposure (US EPA, 2009a, p. 7-84, Figure 7-7).

Epidemiologic studies examining cardiovascular morbidity associated with long-term $PM_{2.5}$ exposures were not available in the previous PM reviews. In the current review, studies are now available that evaluated a number of endpoints ranging from subtle indicators of cardiovascular health to serious clinical events associated with coronary heart disease (CHD) and cerebrovascular disease (CVD) including myocardial infarction (MI), coronary artery revascularization (e.g., bypass graft, angioplasty, stent, atherectomy), congestive heart failure (CHF), and stroke. The most significant new evidence comes from the WHI study which provides evidence of nonfatal cardiovascular events including both coronary and cerebrovascular events in a cohort of post-menopausal women with no previous history of cardiac disease (Miller et al., 2007; US EPA, 2009a, sections 7.2.9 and 7.6.1).

As noted in the ISA, there may be multiple mechanisms related to the observed associations between $PM_{2.5}$ and cardiovascular effects, and these processes may be interlinked (US EPA, 2009a, sections 5.2, 5.3, 5.5, 5.6, 5.7). For example, myocardial ischemia and MI may occur as a result the proposed effects of PM on atherosclerosis, plaque instability, plaque rupture, thrombosis, and/or altered vasoreactivity of coronary vessels. Myocardial ischemia and MI may alter the conduction and depolarization properties of the heart and lead to arrhythmic events. In addition, thrombosis may lead to stroke and/or thromboembolic disease. The ISA notes that "it is not clear at this time whether PM initiates cardiovascular disease or whether it perturbs existing disease" (US EPA, 2009a, p. 5-18).

Toxicological studies provide evidence that the cardiovascular morbidity effects observed in epidemiological studies are biologically plausible and coherent with studies of cardiovascular-related mortality observed in long-term exposures as well as with studies of cardiovascular-related morbidity and mortality associated with short-term exposures to $PM_{2.5}$ as described below (US EPA, 2009a, p 7-19). For example, it has been hypothesized that that exposure to $PM_{2.5}$ can lead to myocardial ischemia through an effect on the autonomic nervous system or by altering vasomotor function. Furthermore, PM-induced systemic inflammation and oxidative stress may contribute to altered vasomotor function which has been demonstrated as altered microvascular reactivity, altered vessel tone, and reduced blood flow during ischemia.[6] Toxicological studies demonstrating increased right ventricular pressure and diminished cardiac contractility also provide biological plausibility for the associations observed between $PM_{2.5}$ and CHF in epidemiological studies (US EPA, 2009a, p. 2-15). Additional evidence of cardiovascular-related morbidity and mortality associated with long-term $PM_{2.5}$ exposures is discussed more fully in section 7.2 of the ISA. Additional evidence discussing potential mechanisms underlying cardiovascular effects are discussed more fully in sections 5.2 through 5.6 of the ISA.

The ISA notes extended analyses of studies available in the last review as well as new epidemiologic studies conducted in the U.S. and abroad provide stronger evidence of respiratory-related morbidity associated with long-term $PM_{2.5}$ exposure. As mentioned above, more limited data are available for respiratory-related mortality effects. Considering morbidity and mortality effect collectively, the ISA has concluded that there is continued support for a likely causal association between long-term $PM_{2.5}$ exposures and respiratory effects. The strongest evidence for respiratory-related effects available in this review is from studies that have evaluated decrements in lung function growth, increased respiratory symptoms, and asthma development (U.S. EPA, 2009a, sections 2.3.1.2, 7.3.1.1, and 7.3.2.1).[7] Specifically, extended analyses of the Southern California Children's Health Study (CHS) provide evidence that clinically important deficits in lung function[8] associated with long-term exposure to $PM_{2.5}$ persisted into early

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[6]The vasculature of all tissues is lined with endothelial cells that will naturally encounter any systemically absorbed toxin. The endothelium (1) maintains barrier integrity to ensure fluid compartmentalization, (2) communicates dilatory and constrictive stimuli to vascular smooth muscle cells, and (3) recruits inflammatory cells to injured regions. Smooth muscle cells lie within the layer of endothelium and are crucial to the regulation of blood flow and pressure. In states of injury and disease, both cell types can exhibit dysfunction and even pathological responses. Endothelial dysfunction is a factor in many diseases and may contribute to the origin and/or exacerbation of perfusion-limited diseases, such as MI or IHD, as well as hypertension. Endothelial dysfunction is also a characteristic feature of early and advanced atherosclerosis (US EPA, 2009a, p. 6-24).

[7] Supporting evidence comes from studies "that observed associations between long-term exposure to PM_{10} and an increase in respiratory symptoms and reductions in lung function grown in areas where PM_{10} is dominated by $PM_{2.5}$" (US EPA, 2009a, p. 2-12).

[8] Clinical significance was defined as a FEV_1 below 80% of the predicted value, a criterion commonly used in clinical settings to identify persons at increased risk for adverse respiratory conditions (US EPA, 2009a, p. 7-29-7-30).

adulthood (U.S., EPA, 2009a, p. 7-27; Gauderman et al., 2004). Additional analyses of the CHS cohort report an association between long-term $PM_{2.5}$ exposure and bronchitic symptoms (US EPA, 2009a, p. 7-24; McConnell et al., 2003) and a strong modifying effect on the association between lung function with asthma incidence (US EPA, 2009, 7-25; Islam et al., 2007). The strength and robustness of the outcomes observed in these more recent reports from the Southern California CHS, including evaluation of a broader range of endpoints than previous CHS studies with shorter follow-up periods, were larger in magnitude and more precise. Supporting these results are new longitudinal cohort studies conducted by other researchers in varying locations using different methods (U.S. EPA, 2009a, section 7.3.9.1). New evidence from a U.S. cohort of cystic fibrosis (CF) patients provides evidence of association between long-term $PM_{2.5}$ exposures and exacerbations of respiratory symptoms resulting in hospital admissions or use of home intravenous antibiotics (US EPA, 2009a, p. 7-25; Goss et al., 2004).

Toxicological studies provide coherence and biological plausibility for the respiratory effects observed in epidemiological studies (US EPA, 2009a, p. 7-42). For example, pre- and postnatal exposure to ambient levels of urban particles has been found to affect lung development in an animal model (US EPA, 2009a, section 7.3.2.2; p. 7-43). This finding is important because impaired lung development is one mechanism by which PM exposure may decrease lung function growth in children (US EPA, 2009a, p. 2-12; section 7.3). Subchronic and chronic toxicological studies of concentrated ambient particles (CAPs) as well as evaluations of specific sources of fine particles including, diesel exhaust (DE), roadway air, and woodsmoke provide some evidence for altered pulmonary function, mild inflammation, oxidative responses, immune suppression, and histopathologic changes. In addition, exacerbated allergic responses have been observed in animals exposed to DE and wood smoke (US EPA, 2009a, p. 2-12, section 7.3).

With respect to respiratory-related mortality associated with long-term $PM_{2.5}$ exposure, evidence is "limited and inconclusive" (US EPA, 2009a, p. 7-41). The extended follow-up of the Harvard Six Cities study reports a positive but non-statistically significant association between long-term $PM_{2.5}$ exposure and respiratory-related mortality (Laden et al., 2006). Pope et al. (2004) found no association with long-term $PM_{2.5}$ exposure and respiratory-related mortality (US EPA, 2009a, p. 7-84). There is emerging but limited evidence for an association between long-term $PM_{2.5}$ exposure and respiratory mortality in post-neonatal infants where long-term exposure was considered as approximately one month to one year (US EPA, 2009a, pp. 7-54 to 7-55). Emerging evidence of short- and long-term exposure to $PM_{2.5}$ and respiratory morbidity effects and infant mortality are coherent with the weak respiratory mortality effects observed.

Beyond effects considered to have causal or likely causal associations with long-term $PM_{2.5}$ exposure as discussed above, the ISA also notes health outcomes classified as having

evidence suggestive of a causal association with long-term $PM_{2.5}$ exposure. This includes two broad categories of health outcomes: (1) reproductive and developmental effects and (2) cancer, mutagenicity, and genotoxicity effects (US EPA, 2009a, Table 2-6). With respect to reproductive and developmental effects, the ISA notes, "[e]vidence is accumulating for $PM_{2.5}$ effects on low birth weight and infant mortality, especially due to respiratory causes during the post-neonatal period" (US EPA, 2009a, section 2.3.1.2). New evidence available in this review reports a significant association between exposure to $PM_{2.5}$ during pregnancy and lower birth weight, pre-term birth, and intrauterine growth restriction, respectively, and post-natal exposure to $PM_{2.5}$ associated with an increased risk of infant mortality (US EPA, 2009a, section 7.4). The ISA further notes that "[i]nfants and fetal development processes may be particularly vulnerable to PM exposure, and although the physical mechanisms are not fully understood, several hypotheses have been proposed involving direct effects on fetal health, altered placenta function, or indirect effects on the mother's health" (US EPA, 2009a, section 7.4.1). However, toxicological studies provide some evidence which is coherent with an association between long-term $PM_{2.5}$ exposure and adverse reproductive and developmental outcomes, but provide "little mechanistic information or biological plausibility for an association between long-term PM exposure and adverse birth outcomes (e.g., low birth weight or infant mortality)" (US EPA, 2009a, p. 2-13).

With respect to cancer, mutagenic and genotoxic effects, "[m]ultiple epidemiologic studies have shown a consistent positive association between $PM_{2.5}$ and lung cancer mortality, but studies have generally not reported associations between $PM_{2.5}$ and lung cancer incidence" (US EPA, 2009a, sections 2.3.1.2 and 7.5; Table 7-7; Figures 7-6 and 7-7). The extended follow-up to the ACS study reported an association between long-term $PM_{2.5}$ exposure and lung cancer mortality (US EPA, 2009a, p. 7-71; Krewski et al., 2009). The extended follow-up of the Harvard Six Cities study also evaluated lung cancer mortality and reported a positive association when considering the entire 25-year follow-up period. However, estimated decreases in average $PM_{2.5}$ concentrations between the first and second follow-up periods were not associated with reduced lung cancer mortality (US EPA, 2009a, p. 7-71; Laden et al, 2006). Epidemiological evidence is not currently available to evaluate cancer in organs or systems other than the lung related to long-term exposure to $PM_{2.5}$ (US EPA, 2009a, p. 7-81). There is some evidence, primarily from *in vitro* studies, providing biological plausibility for the PM-lung cancer relationships observed in epidemiological studies (US EPA, 2009a, p. 7-80). Toxicological studies providing evidence of carcinogenicity, mutagenicity, and genotoxicity reported mixed results as discussed in section 7.5 of the ISA.

Health Effects Associated with Short-term $PM_{2.5}$ Exposure

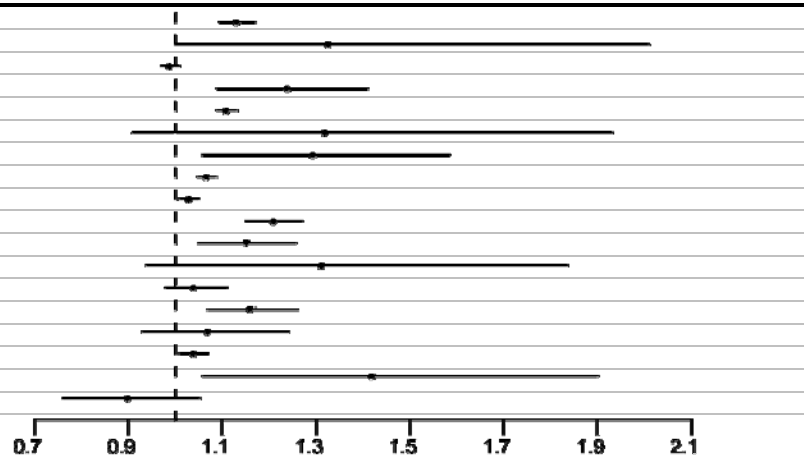
In considering effects associated with short-term $PM_{2.5}$ exposure, the body of currently available scientific evidence has been expanded greatly by the publication of a number of new multi-city time-series studies that have used uniform methodologies to investigate the effects of short-term fine particle exposures on public health. This body of evidence provides a more expansive data base and considers multiple locations representing varying regions and seasons that provide evidence on the influence of climate and air pollution mixes on $PM_{2.5}$-associated health effects. These studies provide more precise estimates of the magnitude of effects associated with short-term $PM_{2.5}$ exposure than most smaller-scale single-city studies that were more commonly available in the last review (U.S. EPA 2009a, chapter 6).

With regard to mortality effects, looking broadly across all of the available scientific evidence, the ISA concludes that a causal association exists between short-term $PM_{2.5}$ exposure and premature death. Extended and expanded analyses of multi-city studies available in the last review as well as a large number of new U.S. multi-city and single-city short-term $PM_{2.5}$ exposure studies have found generally consistent positive associations between short-term $PM_{2.5}$ exposures and cardiovascular- and respiratory-related mortality as well as all-cause (non-accidental) mortality (US EPA, 2009a, sections 2.3.1.1, 6.2.11 and 6.5.2.2; Figures 6-26, 6-27, and 6-28). These newly published U.S. multi-city short-term $PM_{2.5}$ exposure studies provide a much larger body of evidence since the last review. In an analysis of National Morbidity, Mortality, and Air Pollution Study (NMMAPS) data, Dominici et al. (2007) reported associations between fine particle exposures and all-cause and cardio-respiratory mortality (US EPA, 2009a, p. 6-175, Figure 6-26). A Canadian multi-city study available in the last review was expanded from 8 to 12 cities (Burnett and Goldberg, 2003; Burnett et al., 2004). The results of this expanded analysis were consistent with the earlier findings of a positive and statistically significant association between short-term $PM_{2.5}$ exposure and mortality (US EPA, 2009a, p 6-182, Figure 2-1). However, the influence of NO_2 and limited $PM_{2.5}$ data for several years during the study period somewhat diminish these findings and underscore the need for additional data on the co-pollutants in relation to the $PM_{2.5}$-mortality association. Zanobetti and Schwartz (2009) reported positive (99%) and frequently statistically significant (55%) associations across most of the 112 cities between short-term $PM_{2.5}$ exposure and total, cardiovascular-related, and respiratory-related mortality (US EPA, 2009a, pp 6-176 to 6-179; Figures 6-23 and 6-24). Collectively, these studies provide generally consistent and much stronger evidence than the evidence available in the last review.

With respect to cardiovascular effects, the ISA considers both cardiovascular-related mortality as well as cardiovascular morbidity effects in reaching the conclusion that there is a causal association between short-term $PM_{2.5}$ exposure and cardiovascular effects. New multi-city as well as single-city short-term $PM_{2.5}$ exposure studies conducted since the prior review

Figure 2-1. Summary of Effect Estimates (per 10 µg/m^3) and Air Quality Distributions for Long-term Exposure Studies

Study	Outcome	Mean (SD)	Mean – 1SD	Lower IQR	Range
Zeger et al. (2008)	All-Cause Mortality, Central U.S.	10.7*		9.8	9.8-12.2*
Kim et al. (2004)	Bronchitis (Children)	12.0			11-15***
Zeger et al. (2008)	All-Cause Mortality, Western U.S.	13.1*		10.4	10.4-18.5*
Miller et al. (2007)	CVD Morbidity or Mortality	13.5 (3.3)	10.2	11.6	3.4 – 28.3
Eftim et al. (2008)	All-Cause Mortality, ACS Sites	13.6 (2.8)	10.8		6.0-25.1
Goss et al. (2004)	All-Cause Mortality	13.7 (4.2)	9.5	11.8	11.8-15.9
McConnell et al. (2003)	Bronchitis (Children)	13.8 (7.7)	6.1		6-29
Zeger et al. (2008)	All-Cause Mortality, Eastern U.S.	14.0*		12.3	12.3-15.3*
Krewski et al. (2009)	All-Cause Mortality	14.0 (3.0)	11.0	11.8	5.8-22
Eftim et al. (2008)	All-Cause Mortality, Harv 6-Cities	14.1 (3.1)	11.0		9.6-19.1
Lipfert et al. (2006)	All-Cause Mortality	14.3 (3.0)	11.3		5.0 - ?
Dockery et al. (1996)	Bronchitis (Children)	14.5 (4.2)	10.3		5.8-20.7
Woodruff et al. (2008)	Infant Mortality (Respiratory)	14.9****		12.0	
Laden et al. (2006)	All-Cause Mortality	16.4 (5.6)*	10.8		10-22
Woodruff et al. (2006)	Infant Mortality (Respiratory)	19.2			
Enstrom (2005)	All-Cause Mortality	23.4			
Chen et al. (2005)	CHD Mortality, Females	29.0			
	CHD Mortality, Males	29.0			



* Zeger et al. (2008) reported median with IQR; overall study reported median of 13.2 µg/m^3 (lower IQR - 11.1)
**Estimated from data provided by study author
***range of averages at 10 schools
**** median for all cause mortality; median for survivors; = 14.8, lower end of IQR (11.7)

Modified from Figure 2-2, US EPA, 2009a.

support a largely positive and frequently statistically significant relationship between short-term exposure to $PM_{2.5}$ and cardiovascular-related disease, substantiating prior findings of a positive relation between exposure to fine particles and cardiovascular morbidity. For example, short-term exposure to $PM_{2.5}$ in association with cardiovascular and respiratory effects was evaluated among a multi-city cohort of older adults participating in the Medicare Air Pollution Study (MCAPS) (US EPA, 2009a, pp. 6-57 to 58; Dominici et al, 2006a; Bell et al, 2008). Overall, short-term $PM_{2.5}$ exposure studies available in the current review provide consistent evidence of a positive association between short-term $PM_{2.5}$ exposures and hospital admissions (HA) or emergency department (ED) visits as well as premature mortality related to cardiovascular outcomes. The strongest evidence has been observed for cardiovascular morbidity effects predominately associated with HA and ED visits reported for ischemic heart disease (IHD) and congestive heart failure (CHF) and cardiovascular-related mortality (US EPA, 2009a, Figure 2-1, p. 6-79, sections 6.2.10.3, 6.2.10.5, and 6.2.11; Bell et al., 2008; Dominici et al., 2006a; Tolbert et al., 2007; Zanobetti and Schwartz, 2009). Furthermore, these findings are supported by a recent study of a multi-city cohort of women participating in the Women's Health Initiative that reported a non-significantly association between short-term exposure to $PM_{2.5}$ and myocardial ischemia (Zhang et al., 2009).

In focusing on respiratory effects, the ISA integrates evidence of respiratory-related mortality with respiratory morbidity effects to reach the conclusion that there is a likely causal association between short-$PM_{2.5}$ exposure and respiratory effects. The strongest evidence from short-term $PM_{2.5}$ exposure studies has been observed for respiratory-related ED visits and HAs for chronic obstructive pulmonary disease (COPD) and respiratory infections (U.S. EPA, 2009a, sections 2.3.1.1 and 6.3.8.3; Figures 2-1 and 6-13; Dominici et al., 2006a;). Evidence for $PM_{2.5}$-related respiratory effects has also been observed in panel studies, which indicate associations with respiratory symptoms, pulmonary function, and pulmonary inflammation among asthmatic children. Although not consistently observed, some controlled human exposure studies have reported small decrements in various measures of pulmonary function following controlled exposures to $PM_{2.5}$ (US EPA, 20009a, p. 2-10). Furthermore, the comparatively larger body of toxicological evidence since the last review is coherent with short-term exposures to $PM_{2.5}$ and respiratory effects (US EPA 2009a, section 6.3.10.1).

Summary

In considering the extent to which newly available scientific evidence strengthens or calls into question evidence of associations identified in the last review between ambient fine particle exposures and health effects, we recognize that much progress has been made in assessing some key uncertainties related to our understanding of health effects associated with short- and long-

term exposure to $PM_{2.5}$. As briefly discussed above as well as in the more complete discussion of the evidence as assessed in the ISA, we note that the newly available information combined with information available in the last review provides substantially stronger confidence in a causal association between short- and long-term exposures to $PM_{2.5}$ and mortality and cardiovascular effects. In addition, the newly available evidence reinforces and expands the evidence supporting the likely causal nature of the associations between short- and long-term exposure to $PM_{2.5}$ and respiratory effects. Causal inferences, as discussed in the ISA, are based not only on the more expansive epidemiological evidence available in this review but also reflects consideration of important progress that has been made to advance our understanding of a number of potential biologic modes of actions or pathways for PM-related cardiovascular and respiratory effects (US EPA 2009a, chapter 5). With respect to suggestive evidence for a broader range of effects, the body of scientific evidence is somewhat expanded but is still limited with respect to associations between long-term $PM_{2.5}$ exposures and developmental and reproductive effects as well as cancer, mutagenic, and genotoxic effects. Thus, we reach the preliminary conclusion that there is stronger and more consistent and coherent support for associations between short- and long-term $PM_{2.5}$ exposure and a broader range of health outcomes than was available in the last review, providing the basis for fine particles at least as protective as the current $PM_{2.5}$ standards.

Having reached this initial conclusion, we then consider how the new evidence informs our understanding of susceptible populations by asking the following question:

- **To what extent does the newly available scientific evidence expand our understanding of susceptible populations, including identification of new susceptible populations?**

As an initial matter, interindividual variation in human responses to air pollutants indicates that some population groups are at increased risk for the detrimental effects of ambient exposure to PM.[9] To facilitate the identification of populations at greatest risk for PM-related health effects, studies have evaluated factors that contribute to the susceptibility or vulnerability of an individual to PM. The definition for both of these terms has been found to vary across studies, but in most instances susceptibility refers to biological or intrinsic factors (e.g., lifestage, gender) while vulnerability refers to non-biological or extrinsic factors (e.g., socioeconomic status [SES]) (see US EPA, 2009a, Table 8-1). However, in many cases a factor identified that increases an individual's risk for morbidity or mortality effects from exposure to an air pollutant (e.g., PM) cannot be easily categorized as a susceptibility or vulnerability factor. At times, the terms susceptibility and vulnerability cannot be distinguished from one another. As it has been

[9] Although studies have primarily used exposures to PM_{10} or $PM_{2.5}$, the available evidence suggests that the identified factors also increase risk from $PM_{10-2.5}$ (US EPA, 2009a, section 8.1.8).

defined in the ISA (US EPA, 2009a, p. 8-1), the term "susceptible" encompasses both these concepts. This document maintains that definition.

The 2004 AQCD noted that the existence of heart and lung disease was clearly linked with increased susceptibility to effects from PM exposure, based on epidemiological and toxicological studies along with dosimetric evidence. The epidemiological evidence for increased susceptibility to PM in this population was primarily derived from studies of short-term exposure. Long-term exposure studies suggested that PM may result in chronic respiratory disease or decreased lung function growth, thereby increasing susceptibility to short-term changes in PM. It was also noted that studies available at that time supported considering older adults and children, including possibly infants, as susceptible groups, recognizing that there is likely overlap between age categories and the preexistence of cardiopulmonary diseases. Emerging evidence indicated that people of lower (SES) or people who have particularly elevated exposures, due to factors such as residential location, may be at greater risk of PM-related effects. The evidence available at that time did not generally allow distinctions to be drawn between the PM indicators, in terms of which groups might be more susceptible to $PM_{2.5}$ and/or $PM_{10-2.5}$.

As discussed below, the ISA concludes that the epidemiological, controlled human exposure and toxicological studies continue to provide evidence of increased risk for various populations, including people at certain life stages, in this case children and older adults, people with pre-existing cardiovascular and respiratory diseases (e.g., asthma), and people with lower SES (US EPA, 2009a, section 2.4.1, chapter 8). This section expands on the discussion in the ISA of susceptible populations in that it also considers supporting evidence for increased risk in these populations from studies that examined only one susceptible population. However it does not contain information from the ISA for potentially susceptible populations for which there was not sufficient evidence to it to draw conclusions about increased susceptibility (e.g., people with diseases that involve chronic inflammation, such as diabetes, or with genetic susceptibility).

Children and Older Adults

Childhood represents a life stage that has generally been considered susceptible to exposure to PM due to the following factors: children spend more time outdoors; children have greater activity levels than adults; children have exposures resulting in higher doses per body weight and lung surface area; and also because of the potential for irreversible effects on the developing lung (US EPA, 2009a, section 8.1.1.2). Recent studies of long-term exposure to $PM_{2.5}$ have greatly expanded the evidence for effects on lung development in children. The extended follow-up for the Southern California CHS includes several new studies that report positive associations between long-term exposure to $PM_{2.5}$ and respiratory morbidity, particularly for such endpoints as lung function growth, respiratory symptoms (i.e., bronchitic

symptoms), and respiratory disease incidence (US EPA, 2009a, section 7.3; Gauderman et al., 2004). New analyses have been conducted that include longer follow-up periods of the CHS cohort through 18 years of age, provide evidence that effects from exposure to $PM_{2.5}$ persist into early adulthood and are more robust and larger in magnitude than reported for shorter follow-up periods available in 2004. Supporting these results are new cohort studies conducted by other researchers in other locations with different methods that provide enhanced evidence for respiratory effects related to long-term exposures to PM_{10} that is dominated by $PM_{2.5}$ (US EPA, 2009a, section 7.3). New studies provide positive associations from Mexico City, Sweden, and a national cystic fibrosis cohort in the U.S. A natural experiment in Switzerland reported that improving PM air quality may slow the annual rate of decline in lung function in adulthood, indicating benefits to public health. In addition, investigators of the CHS suggest $PM_{2.5}$ may also act as a modifier of the association between lung function and asthma, inducing declines in lung function and a concomitant increase in new onset asthma (Islam et al 2007). Thus, the ISA (US EPA, 2009a, section 7.3.9.1) concludes that the data for respiratory morbidity in children are consistent and coherent across several study designs, locations, and researchers. Preliminary evidence from toxicological studies provides some coherence and biological plausibility for the observed associations with lung function decrements (US EPA, 2009a, section 7.3.2.2).

With respect to short-term exposures to PM, the 2004 AQCD found that studies which stratified results by age typically reported associations between short-term exposures to PM and respiratory-related health effects in children with asthma (US EPA, 2004, section 8.4.9). This body of evidence has been strengthened by newly available epidemiological studies that provide evidence of reductions in lung function (FEV_1) and an increase in respiratory symptoms and medication use associated with PM exposure among asthmatic children (US EPA, 2009a, sections 6.3.1 and 6.3.2.1). These include two large, longitudinal studies in urban areas of the US, as well as a number of smaller panel studies conducted in the U.S. (US EPA, 2009a, section 6.3.1).

No epidemiologic studies of pulmonary inflammation were described in the 2004 AQCD. Several new panel studies of children, using exhaled NO (eNO) as a biomarker of airway inflammation, found generally positive associations between PM exposure and eNO levels in asthmatic children who did not use inhaled corticosteroids (US EPA, 2009a, section 6.3.3.1).

With respect to short-term increases in PM concentrations associated with respiratory-related hospitalizations and ED visits, the epidemiologic evidence presented in the 2004 AQCD was consistent across studies (US EPA, 2004, section 8.3.2.5). Newly available evidence provides further support for this relationship, with larger effect estimates observed among children and older adults. However, effect estimates are clearly heterogeneous and sensitive to

choice of lag, with evidence of both regional and seasonal differences (US EPA, 2009a, sections 6.3.8 and 6.3.10).

Two recent toxicological studies, presented in the ISA (US EPA, 2009a, section 8.1.1.2), provide biological plausibility for the increase in PM-related respiratory effects in children observed in the epidemiological studies. These studies include effects on lung function, pulmonary injury and evidence suggesting that the developing lung is more susceptible to PM. The ISA (US EPA, 2009a, p. 8-5) concludes that the evidence from epidemiological studies that have examined the health effects associated with all size fractions of PM and toxicological studies that have examined individual PM components provide support for the hypothesis that children are at greater risk of respiratory effects from exposure to PM.

With respect to older adults, the 2004 AQCD (US EPA, 2004, section 9.2.4.2) concluded that people aged 65+ years appear to be at somewhat higher risk for PM exacerbation of cardiovascular-related disease effects and, perhaps, tend to experience higher PM-related total (nonaccidental) mortality risk, as well. The higher prevalence of pre-existing cardiovascular and respiratory diseases found in this age range compared to younger age groups increases risk, primarily due to the gradual decline in physiological processes as part of the aging process (US EPA, 2009a, section 8.1.1.1). Therefore, some overlap exists between this life stage and the group of people with pre-existing diseases.

Newly available evidence for PM-related health effects in the older adult life stage spans epidemiologic, controlled human exposure, and toxicological studies (US EPA, 2009a, section 8.1.1.1). One new large epidemiologic study (US EPA, 2009a, section 7.2.9; Miller et al., 2007) of post-menopausal female residents of 36 U.S. metropolitan areas (age range = 50-79 yr) found increases in $PM_{2.5}$-related risk of MI, coronary revascularization,[10] and their combination with CHD-related death for participants free of CVD at baseline. While recent epidemiological evidence for cardiovascular morbidity effects in older adults in response to short-term exposure to $PM_{2.5}$ and $PM_{10-2.5}$ is limited, when taken together with evidence from studies of PM_{10}, support is found for increased risk of cardiovascular morbidity in older adults. With regard to respiratory morbidity, while some epidemiologic studies have reported an increase in respiratory hospital admissions in individuals 65 years of age and older, consistent associations have not been observed across all such studies.

With respect to mortality, recent epidemiologic studies have also found that individuals greater than 65 years old are at greater risk of all-cause (non-accidental) mortality upon short-term exposure to both $PM_{2.5}$ and PM_{10}, consistent with the findings of the 2004 AQCD. Epidemiological studies that examined the association between mortality and long-term exposure

[10] Coronary revascularization includes percutaneous coronary interventions, such as angioplasty.

to $PM_{2.5}$ and stratified the results by age (i.e., less than 65 year of age compared to aged 65 and older) reported results that are consistent with the short-term exposure studies. However, in sensitivity analyses studies have found evidence that risk declines with age starting at age 60 until there is no evidence of an association among people age 85 and older.

Controlled human exposure and dosimetry studies provide additional evidence for an increase in cardiovascular and respiratory effects among older adults. Healthy older subjects exposed to $PM_{2.5}$ concentrated ambient particles (CAPs) experienced significant decreases in HRV (both in time and frequency) immediately following exposure, when compared to healthy young subjects and to older adults with COPD (US EPA, 2009a, section 8.1.1.1). Dosimetry studies have shown a depression of fine and coarse PM clearance in all regions of the respiratory tract with increasing age beyond young adulthood. These results suggest that older adults are at greater risk of PM-related respiratory health effects (US EPA, 2009a, section 8.1.1).

Animal toxicological studies have attempted to characterize the relationship between age and PM-related health effects through the development of models that mimic the physiologic conditions associated with older people. For example, arrhythmias have been observed in older, but not younger, rats exposed to $PM_{2.5}$ CAPs. In addition, studies that used a mouse model of terminal senescence observed various cardiovascular-related responses. Overall, these studies provide biological plausibility for the increase in cardiovascular effects in older adults observed in the controlled human exposure and epidemiologic studies (US EPA, 2009a, section 8.1.1).

In summary, the ISA concludes that evidence from epidemiological, controlled human exposure, and toxicological studies provide coherence and biological plausibility for the association between short-term exposure to PM and cardiovascular morbidity in older adults (US EPA, 2009a, section 8.1.1.1). Additional evidence from epidemiological studies that focus on mortality and respiratory morbidity in response to short-term exposure to PM also indicate that older adults represent a susceptible life stage.

Pre-existing Cardiovascular or Respiratory Diseases

With regard to the risk from PM exposure to people with pre-existing cardiovascular or respiratory diseases, the 2004 AQCD (US EPA, 2004, section 9.2.4.1) noted that a number of time-series epidemiological studies reported increased risk in study subsets of individuals with preexisting heart or lung diseases. Toxicological studies using animal models of cardiopulmonary disease provided evidence suggestive of enhanced susceptibility to inhaled PM in "compromised" hosts. Human dosimetry studies of subjects with COPD and asthma indicated that airways disease leads to very heterogeneous distributions of PM deposited within the lung. These studies have shown up to 10-fold higher than normal deposition at airway bifurcations, thus creating "hot-spots" that may have biological implications.

The ISA notes that more recent epidemiological and controlled human exposure studies have directly examined the effect of PM on individuals with pre-existing diseases and toxicological studies have employed disease models to identify whether exposure to PM disproportionately effects certain populations (US EPA, 2009a, section 8.1.6).

The potential effect of underlying cardiovascular diseases on PM-related health responses has been examined using epidemiological studies that stratify effect estimates by underlying conditions or secondary diagnoses, and toxicological studies that use animal models to mimic the pathophysiological conditions associated with various cardiovascular diseases (e.g., MI, ischemia, and atherosclerosis). A limited number of controlled human exposure studies have also examined the potential relationship between cardiovascular diseases and exposure to PM in individuals with underlying cardiovascular conditions, but these studies have provided somewhat inconsistent evidence for these associations.

One epidemiological study (US EPA, 2009a, section 7.2.9; Zanobetti and Schwartz, 2007) investigated associations between long-term exposure to PM_{10} and the progression of disease or reduced survival in a 21-city study of people discharged following an acute myocardial infarction (MI). The study found significant associations for mortality, CHF and new hospitalization for MI. This is the first long-term study showing a significant association between particle exposure and adverse post-MI outcomes in people who survived an MI. A few toxicological studies examined potential effect modification of pre-existing cardiovascular conditions on effects of long-term exposure to PM. In studies that focused on the cardiovascular effects following subchronic exposure to PM in $ApoE^{-/-}$ mice, pathophysiological effects were observed that included a decreasing trend in heart rate, physical activity, and temperature along with responses in HRV; enhanced size of early atherosclerotic lesions was observed consistently across studies.

The majority of the epidemiological literature that examined associations between short-term exposure to PM and cardiovascular outcomes focuses on cardiovascular-related hospital admissions (HA) and emergency department (ED) visits. Hypertension is the pre-existing condition that has been considered to the greatest extent when examining the association between short-term exposure to PM and cardiovascular-related HAs and ED visits. The results of these studies have been mixed. There is also some new evidence from epidemiological studies that individuals with pre-existing IHD are at greater risk from PM exposure, with evidence from a toxicological study implicating impaired myocardial blood flow in the response. Additional studies have examined the effects of PM on cardiac function in individuals with dysrhythmia with mixed results. Limited and inconclusive evidence is available from epidemiological studies that examined other pre-existing cardiovascular conditions, such as CHF and MI. Toxicological studies have provided some additional evidence for the cardiovascular

health effects associated with exposure to PM in rodent models of underlying MI, but the evidence is also inconclusive. Controlled human exposure studies that examined the effect of pre-existing diseases on cardiovascular outcomes with exposure to PM are less consistent and difficult to interpret in the context of the results from the epidemiological and toxicological studies.

A few new studies have also examined effect modification in mortality associations. These studies have found evidence of an increase in risk estimates for associations between PM_{10} and mortality in individuals with underlying stroke, and effect modification of the PM-mortality association in individuals with CHF.

In summary, the newly available evidence from epidemiological and toxicological, and to a lesser extent, controlled human exposure studies indicates increased susceptibility of individuals with underlying cardiovascular diseases to PM exposure. Although the evidence for some outcomes was inconsistent across epidemiological and toxicological studies, this could be due to a variety of issues including the PM size fraction used in the study, along with the study location.

With regard to pre-existing respiratory illnesses, studies evaluated in the ISA have examined the effect of these illnesses on multiple health outcomes (e.g., mortality, asthma symptoms) in response to exposure to ambient concentrations of PM (US EPA, 2009a, section 8.1.6.2). Epidemiological studies have examined the effect of short-term exposure to PM on the respiratory health of asthmatic individuals finding an increase in medication use and respiratory symptoms (i.e., asthma symptoms, cough, shortness of breath, and chest tightness) with short-term exposure to $PM_{2.5}$, and morning symptoms and asthma attacks with short-term exposure to PM_{10}. Toxicological studies provide evidence that PM exposure results in allergic sensitization, and that individuals with allergic airways conditions are at greater risk of allergic airways responses upon exposure to $PM_{2.5}$. Further, there is much more limited evidence which suggests that non-allergic respiratory morbidities may also increase the susceptibility of an individual to PM-related respiratory effects.

The results from the epidemiological and toxicological studies that focused on underlying allergic airways disease are supported by a series of controlled human exposure studies which have shown that exposure to diesel exhaust particles (DEPs) increases the allergic inflammatory response in atopic individuals. However, other studies reported that healthy and asthmatic subjects exposed to coarse, fine and ultrafine CAPs, exhibited similar respiratory responses, although these studies excluded moderate and severe asthmatics that would be expected to show increased susceptibility to PM exposure.

With respect of pre-existing COPD, the results of epidemiological studies have been mixed. A few controlled human exposure studies examined the effects of exposure to $PM_{2.5}$

CAPs on healthy and COPD subjects and found no significant difference in respiratory effects. However, the results from dosimetric studies have shown that COPD patients have increased dose rates and impaired mucociliary clearance relative to age-matched healthy subjects, suggesting that individuals with COPD are potentially at a greater risk of PM-related health effects (US EPA, 2009a, section 3.2.1).

A few epidemiological studies examined the effect of underlying respiratory illnesses on the association between short- and long-term exposure to PM and mortality. Using different pre-existing respiratory illnesses, two studies found that short-term exposure to PM_{10} increased the risk of non-accidental mortality in individuals with a secondary diagnosis of pneumonia and circulatory mortality in individuals with a secondary diagnosis of a respiratory illnesses. Another study observed an association between long-term exposure to PM_{10} and mortality in individuals that had previously been hospitalized for COPD. Together, these studies show the potential effect of underlying respiratory illnesses on the PM-mortality relationship (US EPA, 2009a, p. 8-13).

In summary, with respect to the potential for increased risk from PM exposure to people with respiratory disease, overall, the controlled human exposure and toxicological studies evaluated in the ISA provide biological plausibility for the increased risk of health effects observed in epidemiological studies among asthmatic individuals in response to PM exposure (US EPA, 2009a, section 8.1.6.2). The evidence from studies that examined associations between PM and health effects in individuals with COPD is inconsistent.

Socioeconomic Status

Socioeconomic status is a composite measure that usually consists of economic status, measured by income; social status measured by education; and work status measured by occupation. Based on data from the U.S. Census Bureau in 2006, from among commonly-used indicators of SES, about 12% of individuals and 11% of families are below the poverty line (US EPA, 2009a, section 8.1.7). Within the U.S. approximately 16% of the population does not have a high school degree and only 27% have a bachelor's degree or higher level of education (US Census, 2009). Educational attainment generally coincides with an individual's income level, which is correlated to other surrogates of SES, such as residential environment. Additionally, low SES individuals have been found to have a higher prevalence of pre-existing diseases; limited access to medical treatment; and limited access to fresh foods leading to a reduced intake of antioxidants, polyunsaturated fatty acids and vitamins, which can increase this population group's risk from PM. Low SES and surrogates of SES such as educational attainment, residential location and nutritional status have been shown in some studies to modify health outcomes of PM exposure for a population.

The 2004 AQCD concluded there is effect modification of long-term PM exposures-mortality associations due to socioeconomic factors. In the ACS and Harvard Six Cities cohort analyses on mortality risk with long-term exposure to $PM_{2.5}$, there was clear evidence of greater effects being reported in the cohort subgroups with lower education levels (US EPA 2004, section 9.2.4.5). The ISA concludes that this is further supported by a reanalysis of the ACS cohort (Krewski et al., 2009), which found moderate evidence for increased lung cancer mortality in individuals with a high school education or less in response to long-term exposure to $PM_{2.5}$ (US EPA, 2009a, section 8.1.7). Another study examined whether long-term exposure to traffic-related pollutants varied by SES at the block group level. The authors found higher concentrations of NO_2 associated with lower SES areas, which suggests that lower SES individuals are disproportionately exposed to traffic-related pollutants, including PM.

Among the studies of short-term PM exposure, the 2004 CD concluded that the evidence was mixed regarding SES and PM-related health risks. New studies evaluated in the ISA indicate that evidence of the influence of SES on health outcomes related to short-term exposures is stronger (US EPA, 2009a, section 8.1.7). These include an increased risk in mortality associated with short-term exposure to $PM_{2.5}$ and its components. Jerrett et al. (2004) examined the modification of short-term mortality effects due to particulate air pollution exposure by residential location in Hamilton, Canada. The authors found that the area of the city with the highest SES characteristics (measured using the surrogate educational attainment) displayed no evidence of effect modification while the area with the lowest SES characteristics had the largest health effects. Another study noted an increased risk in mortality associated with short-term exposure to $PM_{2.5}$ and its components for individuals with low SES, while additional analyses stratified by education level have also observed consistent trends of increased mortality for $PM_{2.5}$ and $PM_{2.5}$ species for individuals with low educational attainment (US EPA 2009a, section 8.1.7).

Nutritional deficiencies have been associated with increased susceptibility to a variety of infectious diseases and chronic health effects. Low SES may decrease access to fresh food, thereby nutritional deficiencies could increase susceptibility to PM-related health effects. One study that examined the association between exposure to $PM_{2.5}$ and HRV in individuals with genetic polymorphisms associated with increased risk of CVD, found that when individuals with these genetic polymorphisms increased their intake of B6, B12, or methionine, no $PM_{2.5}$ effect on HRV was observed.

The ISA concludes that there is evidence that SES, measured using surrogates such as educational attainment or residential location, modifies the association between PM and morbidity and mortality outcomes (US EPA, 2009a, section 8.1.8). In addition, nutritional

status, another surrogate of SES, has been shown to have protective effects against PM exposure in individuals that have a higher intake of some vitamins and nutrients.

Summary

In summary, we reach the preliminary conclusion that there are several population groups that are likely to be susceptible to PM-related effects. These groups include the life stages of children and older adults, those with preexisting heart and lung diseases, and those of lower SES. We also preliminarily conclude that the available evidence does not generally allow distinctions to be drawn between the PM indicators, in terms of which groups might have greater susceptibility to $PM_{2.5}$ and $PM_{10-2.5}$.

- **To what extent does the newly available scientific evidence report associations that extend to air quality concentrations that are lower than had previously been observed or that are observed in areas that would likely meet the current suite of $PM_{2.5}$ standards?**

We now focus our attention on addressing the question of whether the available evidence supports consideration of standards that are more protective than the current suite of $PM_{2.5}$ standards. In addressing this question, we first recognize that the ISA concludes there is no evidence to support the existence of a discernable threshold below which effects would not occur (US EPA, 2009a, section 2.4.3). We consider whether new evidence provides information for health effects associated with air quality levels that are lower than had previously been observed, in particular to levels at or below the level of the current annual standard (15 $\mu g/m^3$) and/or to levels at or below the level of the current 24-hour standard (35 $\mu g/m^3$). As an initial matter, we first focus on levels at which effects classified as having a causal or likely causal association with $PM_{2.5}$ exposure have been observed. We consider effects classified as having suggestive associations with $PM_{2.5}$ exposure in section 2.3 when considering the margin of safety provided by alternative suites of standards. We have evaluated the air quality data using the forms of the current $PM_{2.5}$ standards.[11]

Associations with Long-term $PM_{2.5}$ Exposure

With regard to mortality associated with long-term $PM_{2.5}$ exposure, in the last review, the 2004 AQCD placed greatest weight on the reanalyses and extensions of two prospective cohort studies, the ACS and the Harvard Six Cities studies, finding that these studies provided "strong evidence" for associations with fine particles and confirmed and strengthened the evidence available in the review completed in 1997 (US EPA, 2004, p. 9-33; Krewski et al., 2000). In the

[11] The current form of the annual $PM_{2.5}$ standard is the annual arithmetic mean, averaged over 3 years with limited conditions allowing spatial averaging. The current form of the 24-hour $PM_{2.5}$ standard is the 98th percentile, averaged over 3 years.

current review, as stated above, staff notes that newly available extended follow-up analyses of the ACS and Harvard Six Cities studies provide consistent and stronger evidence of a causal association with mortality at lower air quality distributions of $PM_{2.5}$.

In considering studies of the ACS cohort, in the last review, the original and reanalysis studies reported significant associations between fine particles and mortality (US EPA, 2004, 8.2.3.2.1; Pope et al., 1995; Krewski et al., 2000). In addition, an extended analysis using the ACS cohort also available in the last review doubled the original follow-up period to more than 16 years. This study continued to report statistically significant associations with long-term $PM_{2.5}$ exposure with the inclusion of more recent $PM_{2.5}$ air quality data and triple the number of deaths (US EPA, 2004, 8.2.3.2.2; Pope et al., 2002). As with the original ACS cohort study, no evidence of a threshold was observed in the relationships with total, cardiovascular-related, and lung cancer mortality reported in this extended study. A recent extended analysis of the ACS cohort available in this review lengthens the follow-up of this important study to 18 years (1982 to 2000) (US EPA, 2009a, pp. 7-84 to 7-85; Figure 7-6; Krewski et al., 2009). This extended analysis has "confirmed with remarkable consistency the association of mortality and exposure to $PM_{2.5}$ reported in previous studies of the ACS data starting 15 years ago… and added precision, especially for the evidence that ischemic heart disease is a cause of death particularly affected by exposure" to $PM_{2.5}$ (HEI, 2009, p. 135). We note the decline in ambient $PM_{2.5}$ concentrations over 18 years, from an aggregate long-term mean in 58 metropolitan statistical areas (MSAs) of 21.2 (4.6)[12] $\mu g/m^3$ (ranging from approximately 9 to 34 $\mu g/m^3$ across cities) in the original monitoring period (1979 to 1983) declining to air quality distributions reported for the most recent years evaluated (1999-2000) for 116 MSAs with an aggregate long-term mean $PM_{2.5}$ concentration of 14.0 (3.0) $\mu g/m^3$ (ranging from approximately 6 to 22 $\mu g/m^3$ across cities) to an overall average across all year of 17.1 (3.7) $\mu g/m^3$ (ranging from about 7.5 to 30 $\mu g/m^3$)(US EPA, 2009a, Figure 7-6; Krewski et al, 2009; Pope et. al, 2004). In addition, Eftim et al., (2008) assessed the ACS sites using an ecological cross-sectional study design of a Medicare cohort, incorporating more recent air quality (2000-2002) with an aggregate long-term mean $PM_{2.5}$ concentration of 13.6 (2.8) $\mu g/m^3$ (ranging from approximately 6 to 25 $\mu g/m^3$). This study reported somewhat higher effect estimates than those reported by the original investigators. The ISA concludes there may be several possible explanations for this apparent increase, especially that this is an older population or more likely because of the lack of personal confounder information (e.g., past personal smoking information) that "led to an insufficient control for the effects of these other variables' effects on mortality, inflating the pollution effect estimates

[12] Throughout this discussion concentrations reported are mean (standard deviation, SD) or median (interquartile range, IQR, 25 to 75%).

somewhat, similar to what has been found in the ACS analyses when only ecological-level control variables were included" (US EPA, 2009a, pp. 7-87 to 7-88; Figures 7-6 and 7-7).

With respect to a the Harvard Six Cities study, Laden et al (2006) have extended mortality follow-up for an additional eight years during a period of "reduced air pollution concentrations" lengthening the follow-up period to 25 years. These investigators reported statistically significant associations between long-term exposure to $PM_{2.5}$ and mortality for air quality data for the original study period (1974 to 1989) as well as the extended follow-up period (1990-1998). As noted in the ISA, this study provides evidence of a statistically significant reduction in mortality risk with decreasing long-term $PM_{2.5}$ concentrations (US EPA, 2009a, p. 7-84). Evidence from the original and reanalysis of the Harvard Six Cities study available in the last review reported an aggregate long-term mean $PM_{2.5}$ concentration of 18 $\mu g/m^3$ (ranging from approximately 11 to 30 $\mu g/m^3$ across cities) (US EPA, 2004, p. x.x; Dockery et al., 1993; Krewski et al., 2000). In the extended follow-up period, an aggregate long-term mean $PM_{2.5}$ concentration of 14.8 (4.2) $\mu g/m^3$ (ranging from approximately 10 to 22 $\mu g/m^3$ across cities) with an overall aggregate mean across both study periods of 16.4 (5.6) $\mu g/m^3$ (ranging from approximately 11 to 25 $\mu g/m^3$) (US EPA, 2009a, Figure 7-6; Laden et al., 2006; Laden, 2009). This reduction was observed for total mortality as well as cardiovascular-related and respiratory-related mortality but not deaths related to lung cancer, "a disease with a longer latency period and less reversibility" (Laden et al, 2006). The ISA notes that "a statistically significant reduction in mortality risk [was] reported with reduced long-term $PM_{2.5}$ concentrations" (US EPA, 2009a, p. 7-84). These findings suggest that the mortality effects of long-term air pollution may be at least partially reversible over periods of a decade" (Laden et al., 2006; Table 3). In an additional analysis of the extended follow-up of the Harvard Six Cities cohort study, investigators reported the concentration-response relationship was linear and "clearly continuing below the level" of the current annual standard (US EPA, 2009a, p. 7-92; Schwartz et al., 2008). Eftim et al. (2008) also analyzed the Harvard Six Cities study sites using a Medicare cohort with more recent air quality data (2000-2002) and reported consistent but somewhat higher effect estimates with relation to the extended follow-up of this study conducted by Laden et al. (2006) (US EPA, 2009a, pp. 77-87-7-88, Figures 7-6 and 7-7). The aggregate long-term mean reported in this study was 14.1(3.1) $\mu g/m^3$ (ranging from about 10 to 19 $\mu g/m^3$) (Eftim et al., 2008).

In addition to extended follow-up analyses of the ACS and Harvard Six Cities studies, new evidence is available in this review from two new U.S. long-term cohort studies. The Women's Health Initiative (WHI) provides evidence of association between long-term $PM_{2.5}$ exposure and cardiovascular morbidity and mortality effects. This study reported results consistent with the ACS and Harvard Six Cities studies while identifying much larger relative risk estimates per $\mu g/m^3$. This study represents an important new cohort of postmenopausal

women with no previous history of pre-existing cardiac disease, potentially a "healthier cohort population" than that considered by the ACS and Harvard Six Cities studies (US EPA, 2009a, p. 7-87). The ISA notes, that the "$PM_{2.5}$ impacts may yield higher relative risk estimates in the WHI population because the $PM_{2.5}$ risk is being compared to a much lower prevailing risk of cardiovascular death in this select study population" (US EPA, 2009a, p. 7-87). The overall $PM_{2.5}$ concentration averaged across cities reported in this study was 13.5(3.3) $\mu g/m^3$ (ranging from about 3.4 to 28 $\mu g/m^3$) (Miller et al., 2007).

A new retrospective cohort study, the Medicare Cohort Air Pollution Study (MCAPS) has evaluated long-term $PM_{2.5}$ exposure and mortality risk in older adults (65 years of age and older) within 3 geographic regions. Zeger et al. (2007) reported that long-term exposure to $PM_{2.5}$ was significantly associated with an increase in mortality among Medicare participants, and stronger associations were observed in eastern counties compared to a national estimate, and no association was observed among Western counties. However, effect estimates decreased by 50% with adjustment for spatial confounding. In a subsequent retrospective cohort study (MCAPS), Zeger et al. (2008), reported that average 6-year exposure to $PM_{2.5}$ was significantly associated with increased risk of mortality in the eastern and central regions.[13] In addition, the results indicated that risk declined with increasing age, and similar to their earlier study, no association was observed between $PM_{2.5}$ and mortality in the western region. Moreover, risk estimates were similar to effect estimates reported in the ACS and Harvard Six Cities study, providing coherence across prospective studies for an association between long-term exposure to $PM_{2.5}$ and mortality. This study reported associations between long-term $PM_{2.5}$ exposure and mortality for the eastern and central regions that were qualitatively similar to those reported in the ACS and Harvard Six Cities studies. The long-term aggregate $PM_{2.5}$ median concentration reported across all cities was 13.2 $\mu g/m^3$ (with an interquartile range from about 11 to 15 $\mu g/m^3$) (US EPA, 2009a, p. 7-88; Zeger et al., 2008).[14]

With respect to respiratory morbidity effects associated with long-term $PM_{2.5}$ exposure, the 2004 AQCD concluded that new studies of a cohort of children in Southern California had built upon earlier limited evidence to provide evidence that long-term exposure to fine particles was associated with development of chronic respiratory disease and reduced lung function growth (US EPA, 2004, p. 9-33). The across-city mean of 2-week average $PM_{2.5}$ concentrations reported in the initial Southern California Children's Health Study was approximately 15.1

[13] The Zeger et al. (2008) analysis included COPD as a proxy for smoking status. The investigators reported the risk estimate for the eastern region declined and the central region increased using this adjustment. This result may possibly be related to bias introduced in using COPD as a proxy for smoking.

[14] Zeger et al. (2008) assessed the relative risk of death associated with long-term $PM_{2.5}$ exposure for three U.S. regions. Median (IQR) $PM_{2.5}$ concentrations reported by region were: Eastern region - 14.0 $\mu g/m^3$ (12.3-15.3); Central region – 10.7 $\mu g/m^3$ (9.8-12.2); Western region – 13.1 $\mu g/m^3$ (10.4-18.5).

$\mu g/m^3$ (ranging from approximately 7 to 32 $\mu g/m^3$) (Peters et al., 1999). These results were found to be consistent with results of cross-sectional analyses of the 24-City study by Dockery et al. (1996) and Raizenne et al. (1996) which reported a long-term cross-city mean $PM_{2.5}$ concentration of 14.5(4.2) $\mu g/m^3$ (ranging from approximately 6 to 21 $\mu g/m^3$). Gauderman et al. (2004) have now extended the analysis of the Southern California Children's Health Study to 8 years, following the children between the ages of 10 and 18, "a period of rapid lung development" and reported that the "pollution-related deficits in the average growth in lung function over the 8-year period resulted in clinically important deficits in attained lung function at the age of 18" (US EPA, 2009a, p. 7-27). The four year cross-city mean was 13.8 (7.7) $\mu g/m^3$ (ranging from approximately 6 to 29 $\mu g/m^3$) across the 12 study communities (McConnell et al., 2003).

In summary, newly available scientific evidence provides support for associations between long-term $PM_{2.5}$ exposure and mortality and morbidity effects that extend to air quality levels that are lower than had previously been observed. These studies evaluate a broader range of health outcomes than were considered in the last review and include extended follow-up for prospective epidemiological studies that were important in the last review as well as additional evidence in important new cohorts. In looking across the body of scientific evidence and focusing on the most recent years of air quality data considered in these studies, we observe effects occurring below the level of the current annual $PM_{2.5}$ standard (US EPA, 2009a, chapter 7; Figures 2-2 and 7-7).

Associations with Short-term $PM_{2.5}$ Exposure

In the last review, in selecting the level of the 24-hour $PM_{2.5}$ standard, emphasis was placed on short-term exposure studies and their 98th percentile air quality values that provided evidence of associated health effects in areas that would have met the then current annual and 24-hour $PM_{2.5}$ standards during the time of the study. In focusing on the 98th percentile value in these studies the Administrator recognized that these studies did not provide evidence of clear effect thresholds or lowest-observed levels. Therefore, the Administrator sought to establish a standard level that would require improvements in air quality generally in areas in which the distribution of daily short-term exposure to $PM_{2.5}$ can reasonably be expected to be associated with serious health outcomes (i.e., mortality, respiratory and cardiovascular morbidity). In the prior review, we noted an overall pattern of statistically significant associations observed in studies of short-term exposure to $PM_{2.5}$ across a wide range of 24-hour average 98th percentile values in predominately single-city studies as well as a limited number of multi-city studies. A predominance of studies with 98th percentile values down to approximately 39 $\mu g/m^3$ (Burnett and Goldberg, 2003) reported statistically significant associations with mortality, hospital

admissions, and respiratory symptoms. Within the range of 24-hour average 98th percentile $PM_{2.5}$ concentrations of about 35 to 30 $\mu g/m^3$, we did not observe a preponderance of statistically significant results. Furthermore, the limited number of studies in which the 98th percentile values were below this range did not provide a basis for reaching conclusions about associations at such levels (71 FR 61168/3 – 61169/2, October 17, 2006).

As discussed in section 2.1.3, our current approach to reaching preliminary conclusions about the adequacy of the current suite of $PM_{2.5}$ standards is more integrative than the approach used in the last review. In this review, in considering the adequacy of the current suite of standards, in evaluating the currently available evidence from short-term $PM_{2.5}$ exposure studies, we look both at the aggregate long-term mean $PM_{2.5}$ concentration in key studies as well as the distributions of 24-hour $PM_{2.5}$ concentrations, with a focus on the 98th percentile concentrations to match the form of the current 24-hour standard, to the extent such data are available.

A number of new multi-city and single-city short-term $PM_{2.5}$ exposure studies and additional analysis of a previously existing cohort study available in this review examine the association between short-term exposure to $PM_{2.5}$ and mortality and a broader range of cardiovascular and respiratory morbidity endpoints. Multi-city studies support a largely positive and frequently statistically significant relationship between short-term exposure to $PM_{2.5}$ and increased risk of mortality. In a multi-city time-series analysis of 112 U.S. cities, Zanobetti and Schwartz (2009) reported that an overall 24-hour average[15] $PM_{2.5}$ level across all years of 34.3 (8.8) $\mu g/m^3$ (ranging from 17.9 to 80.3 $\mu g/m^3$) (US EPA, 2009a, Figure 6-24) from lag 0-1 days were positively and significantly associated with all-cause, cardiovascular-related (e.g., myocardial infarction, stroke), and respiratory-related mortality. Furthermore, city-specific effect estimates included in Figure 6-24 of the ISA indicate the association between short-term exposure to $PM_{2.5}$ and total mortality and cardiovascular mortality and respiratory mortality endpoints is consistently positive for an overwhelming majority (99%) of the 112 cities across a wide range of air quality concentrations (US EPA, 2009a, p. 6-178 to 179). In addition, the authors report that for all-cause mortality city-specific effect estimates were statistically significant for 55% of the 112 cities, with 24-hour $PM_{2.5}$ levels ranging from 18.4 to 64.9 $\mu g/m^3$.

In the current review of evidence on mortality associated with short-term exposure to $PM_{2.5}$, we note that an expansion of the multi-city Canadian study from 8 (Burnett and Goldberg, 2003) to 12 Cities (Burnett et al 2004) yielded results consistent with prior findings of a positive and statistically significant association between an average 1-day lag 24-hour $PM_{2.5}$ exposure across all years of 38.1 $\mu g/m^3$(extending from 25 to 50 $\mu g/m^3$) and daily mortality (US EPA, 2009a, Figure 2-1). However, the influence of NO_2 and limited $PM_{2.5}$ data for several years

[15] Concentrations reported for short-term studies are mean 98th percentile (standard deviation, SD)

during the study period somewhat diminish these findings and underscore the need for more frequent $PM_{2.5}$ measurements and additional data on co-pollutants to inform our understanding of the $PM_{2.5}$-mortality association. In general, as can be seen in Figure 6-27 of the ISA, effect estimates for associations between mortality and short-term exposure to $PM_{2.5}$ are positive and a number are statistically significant (ISA, US EPA, 2009a, p. 6-184). Larger effect estimates were reported in some studies for associations with respiratory mortality in comparison to cardiovascular and all-cause mortality, but these effect estimate include larger confidence intervals (i.e. less precision) since respiratory deaths comprise only a small proportion of total deaths.

With regard to cardiovascular and respiratory morbidity effects, in the first analysis of the MCAPS cohort conducted by Dominici et al (2006a) across 204 US counties, investigators reported a statistically significant association between an average 24-hour $PM_{2.5}$ concentration across all years of 34.8 $\mu g/m^3$ (extending from 10.4 to 85.6 $\mu g/m^3$) and hospitalizations for cardiovascular and respiratory diseases. Furthermore, a sub-analysis restricted to days with 24-hour average concentrations of $PM_{2.5}$ at or below 35 $\mu g/m^3$ indicated that, in spite of a reduced statistical power from a smaller number of study days, statistically significant associations were still observed between short-term exposure to $PM_{2.5}$ and hospital admissions for cardiovascular and respiratory diseases (Dominici, 2006b[16])). These results along with the observation that approximately 50% of $PM_{2.5}$ levels across the 204 counties across all years were below the 24-hour standard suggests that the overall health effects observed across the U.S. are not primarily driven by the higher end of the $PM_{2.5}$ air quality distribution (Cite Docket # for AQ provided by authors). In an extended analysis of the MCAPS study, Bell et al (2008) reported a positive and statistically significant increase in cardiovascular hospitalizations associated with and average0-day lag $PM_{2.5}$ concentration across all years of 34.2 (8.5) $\mu g/m^3$ (extending from 9.4 to 77.0 $\mu g/m^3$). In addition, significant increases in respiratory disease hospitalizations were associated with mean $PM_{2.5}$ at lag 2. Furthermore, several single-city short-term $PM_{2.5}$ exposure studies with average 98^{th} percentile $PM_{2.5}$ exposures below 35 $\mu g/m^3$substantiate findings from the aforementioned multi-city studies generally reporting positive statistically significant and non-significant associations for $PM_{2.5}$ exposures in relation to mortality, cardiovascular and respiratory hospitalizations and ED visits (Figure 2-4). Consequently, these short-term studies provide evidence of $PM_{2.5}$ associated mortality and morbidity effects occurring at and below the level of the current 24-hour standard.

[16] This sub-analysis was not included in the original publication (Dominici et al., 2006a). Authors provided sub-analysis results for the Administrator's consideration as a letter to the docket following publication of the proposed rule in January 2006.

In considering long-term average ambient concentrations from short-term $PM_{2.5}$ exposure studies, we recognize that in the last review, several U.S. and Canadian studies provided evidence of associations between short-term exposure to $PM_{2.5}$ and serious health effects in areas with $PM_{2.5}$ levels at and above the level of the current annual $PM_{2.5}$ standard (15 $\mu g/m^3$). Moreover, a few short-term $PM_{2.5}$ exposure studies (Figure 2-4) available in that review provided evidence of statistically significant associations with $PM_{2.5}$ in relation to cardiovascular and respiratory effects for areas in which long-term average $PM_{2.5}$ concentrations ranged between 12 and 14 $\mu g/m^3$ and 98th percentile 24-hour concentrations ranged between 31 and 59 $\mu g/m^3$ (US EPA, 2005, p. 5-7).

Similarly, in this review, many short-term $PM_{2.5}$ exposure studies, and in particular those conducted across multiple cities, report statistically significant effects with mean concentrations below the level of the current annual standard. Dominici et al. (2006a) and Bell et al. (2008) report 24-hour average $PM_{2.5}$ levels across all years of 13.4 (2.9) $\mu g/m^3$ (extending from 4.4 to 22.7 $\mu g/m^3$) and 12.9 (2.7) $\mu g/m^3$(extending from 4.3 to 20.4 $\mu g/m^3$), respectively (US EPA, 2009a, Figure 2-1). Likewise, Zanobetti and Schwartz (2009) report city annual averages across all years of 13.2 () $\mu g/m^3$ (extending from 6.6 $\mu g/m^3$ to 24.7 $\mu g/m^3$) (Figures 2-1 and 6-24, US EPA, 2009a). In addition, Burnett et al. 2004, reports city annual averages across all years of 12.8 $\mu g/m^3$ (extending 8.1 to 16.7 $\mu g/m^3$) (Figure 2-1, ISA – US EPA, 2009a). Based on the findings from these multi-city short-term $PM_{2.5}$ exposure studies, the ISA concludes that overall, consistent positive associations have been reported for a range of mortality and cardiovascular and respiratory morbidity effects for mean 24-hour $PM_{2.5}$ concentrations at and above 12.8 $\mu g/m^3$ (US EPA, section 2.3.1.1).

Taken together, these findings from single- and multi-city epidemiological studies of short-term $PM_{2.5}$ exposure in relation to mortality and cardiovascular and respiratory morbidity provide evidence of short-term $PM_{2.5}$ associated health effects occurring at or below the current levels of the 24-hour standard (Figure 2-1, US EPA, 2009a, p. 2-14). These findings are bolstered by evidence of statistically significant $PM_{2.5}$ associated health effects occurring in analyses restricted to days in which 24-hour average $PM_{2.5}$ levels were below 35 $\mu g/m^3$ (Dominici, 2006b). Multi-city short-term studies conducted since the prior review (Burnett et al. 2004; Dominici et al. 2006a; Bell et al. 2008; Zanobetti and Schwartz, 2009) also provide supportive evidence for short-term $PM_{2.5}$ exposure associated health effects occurring at levels at and below the annual standard.

Summary

In evaluating the currently available scientific evidence, we reach the preliminary conclusion that the evidence from long and short-term $PM_{2.5}$ exposure studies, and in particular those studies conducted across multiple U.S. cities calls into question whether the current suite of

$PM_{2.5}$ primary standards protects public health with an adequate margin of safety from effects associated with long- and short-term exposures to $PM_{2.5}$. We also reach the preliminary conclusion that this evidence provides strong support for considering fine particle standards that would impart increased protection beyond that afforded by the current annual and 24-hour $PM_{2.5}$ standards. More protective standards would reflect the substantially stronger and broader body of evidence for mortality and cardiovascular and respiratory morbidity effects now available in this review both at lower levels of air quality than had previously been observed and at levels below the current annual (15 $\mu g/m^3$) and 24-hr (35 $\mu g/m^3$) $PM_{2.5}$ standards.

2.2.2 Risk-based Considerations

Looking beyond evidence-based considerations, staff also has considered the extent to which health risks estimated to occur upon just meeting the current suite of $PM_{2.5}$ standards may be judged to be important from a public health perspective, taking into account key uncertainties associated with the estimated risks.

The quantitative risk assessment conducted in this review (US EPA, 2010a) builds upon and expands upon the analyses conducted for the previous review (US EPA, 2005, chapter 4; Abt, 2005). As an initial matter, we recognize that the previous quantitative risk assessment incorporated alternative assumed cutpoints as surrogates for potential population thresholds. In the current review, the ISA examined the available epidemiologic evidence to characterize the shape of the concentration-response (C-R) relationship and assess possible PM "thresholds" (i.e., levels which $PM_{2.5}$ concentrations must exceed in order to elicit a health response). Overall, based on limited evidence primarily focusing on cardiovascular-related hospital admissions and emergency department visits associated with short-term exposures to PM_{10} and mortality associated with long-term exposure to $PM_{2.5}$, using a variety of methods and models, the ISA concludes the currently available evidence supports the use of a no-threshold, log-linear model (US EPA, 2009a, p. 2-25). Therefore, the quantitative risk assessment conducted for this review did not include assumed cutpoints as surrogates for potential population thresholds. We concluded that is was more appropriate to focus on alternative rollback strategies.[17]

The assessment of uncertainty and variability completed for this analysis is more comprehensive than had been done for previous risk assessments. This reflects, in part, the development of methods by EPA staff to address potentially important sources of variability and

[17] While we have not included cutpoints in the risk assessment for the reasons cited, in the case of long-term exposure-related mortality, we have limited estimation of risk to ambient $PM_{2.5}$ levels above the lowest measured level (LML) of the epidemiological study from which the concentration-response function was obtained (Krewski et al., 2009; US EPA, 2010a, section 3.2.3). In the case of short-term exposure-related mortality and morbidity, we modeled risk down to PRB. In both cases, this reflects consideration for the range of ambient $PM_{2.5}$ where we believe we have confidence in characterizing the nature of the CR function shape (and not an assumption that risk is negligible below these levels).

uncertainty. For example, to more fully explore potential variability in the patterns of reductions in ambient $PM_{2.5}$ that may occur upon just meeting the current and alternative standards, we incorporated as part of the sensitivity analysis, two additional rollback approaches (hybrid and peak shaving) in addition to the proportional rollback used in the core analysis. In addition, recently published literature has allowed us to more rigorously examine the impact of uncertainty related to specifying C-R functions for long-term exposure-related mortality through a series of sensitivity analyses (i.e., Krewski et al. (2009) provided extensive analysis of alternative model specifications for mortality which could be readily incorporated into our sensitivity analysis).

For this review, we have estimated risk for a set of health effects endpoints that reflected consideration of the degree of support in the literature for a causal relationship between $PM_{2.5}$ exposure and the health effect of interest as assessed in the ISA, together with consideration of the health significance of the endpoint.[18] Specifically, we have estimated risks for (a) all-cause, IHD, cardiopulmonary and lung cancer mortality related to long-term $PM_{2.5}$ exposure, (b) non-accidental, cardiovascular (CV) and respiratory mortality related to short-term $PM_{2.5}$ exposure, and (c) cardiovascular-related and respiratory-related hospital admissions (HA) and asthma-related emergency department visits associated with short-term $PM_{2.5}$ exposure. While we have modeled risk for a selection of long-term and short-term exposure-related endpoints, in the discussion of risk estimates presented below, we focus on cardiovascular-related endpoints, since the causal association for these endpoints based on available literature is assessed in the ISA to be the strongest of the endpoints considered.

In considering the health risks estimated in selected urban study areas to occur upon just meeting the current suite of $PM_{2.5}$ standards, we focused on a core (primary) set of risk results based on the application of modeling element choices (e.g., concentration-response functions, lag periods) that have the greatest overall support in the literature (hereafter referred to as the "core" results). In addition, to gain insights into which sources of uncertainty may have the greatest impact on risk estimates when acting alone, or in combination with other sources of uncertainty, as noted above, we conducted a series of single-element and multi-element sensitivity analyses to generate a broader set of reasonable alternative risk estimates that allowed us to place the results of the core analysis in context with regard to uncertainty. We also conducted additional analyses to place the results of the urban study area analysis into a broader context for characterizing potential national risks. While the core risk estimates receive primary focus in the discussion of risk estimates presented below, we do references the results of these additional supplemental

[18] In addition, we considered whether sufficient information existed in the literature to develop C-R functions and whether we could obtain baseline incidence data necessary to generate risk estimates with a reasonable degree of confidence.

analyses in addressing overall confidence associated with the core risk estimates and in placing the core risk estimates in a broader national-context.

An important factor to consider in interpreting risk results is that the magnitude of both long- and short-term exposure-related risk depends primarily on annual-average $PM_{2.5}$ concentrations. Furthermore, reductions in both categories of risk, as we consider simulating just meeting current and alternative suites of standards, also depend primarily on changes in annual-average $PM_{2.5}$ concentrations.

The role of annual-average ambient $PM_{2.5}$ concentrations in driving long-term exposure-related risk is intuitive given that this risk category is modeled using the annual-average air quality metric.[19] The fact that short-term exposure-related risk is also driven by changes in long-term average $PM_{2.5}$ concentrations is less intuitive, since changes in average daily $PM_{2.5}$ concentrations are used to estimate changes in risk for this category.[20] Analyses in previous PM NAAQS risk assessments have shown that short-term exposure-related risks are not primarily driven by the small number of days with $PM_{2.5}$ concentrations in the upper tail of the air quality distribution, but rather by the large number of days with $PM_{2.5}$ concentrations at and around the mean of the distribution. Consequently, consideration for changes in annual-average $PM_{2.5}$ concentrations will explain to a large extent changes in short-term exposure-related risk. Therefore, in interpreting patterns of long-term exposure-related risk, and the similar patterns we observe in short-term exposure-related risk, we consider how simulating just meeting specific suites of $PM_{2.5}$ standards impacts the annual-average $PM_{2.5}$ concentration for the study areas.

We have considered a series of questions to inform our understanding of the adequacy of the current suite of fine particle standards based on the insights obtained from the quantitative risk assessment. The remainder of the discussion is organized around these questions.

- **What is the nature and magnitude of the <u>long-term</u> exposure-related risks remaining upon just meeting the current suite of $PM_{2.5}$ standards? What level of confidence is associated with these risk estimates?**

Of the fifteen study areas included in the risk assessment, thirteen are simulated to experience risk reductions upon meeting the current suite of standards. Of these thirteen study

[19] As noted in section 3.2.1 of the second draft RA, estimates of long-term exposure-related mortality are actually based on an average annual $PM_{2.5}$ level across monitors in a study area (i.e., the composite monitor annual-average). Therefore, in considering changes in long-term exposure-related mortality, it is most appropriate to compare composite monitor estimates generated for a study area under each suite of standards. The maximum monitor annual-average for a study area (i.e., the annual design value) determines the percent reduction in $PM_{2.5}$ levels required to attain a particular standard. Both types of air quality estimates are provided in Tables F-49 and F-50 in Appendix F of the second draft RA and both are referenced in this discussion of core risk estimates, as appropriate.

[20] Estimates of short-term exposure-related mortality and morbidity are based on composite monitor daily $PM_{2.5}$. concentrations. However, similar to the case with long-term exposure-related mortality, it is the maximum monitor 98th percentile 24-hour concentration (the 24-hour design value) that will determine the degree of reduction required to meet a given 24-hour standard.

areas, three areas (Atlanta, Birmingham and Houston) have design values which resulted in the current annual standard controlling. Therefore, in assessing the level of long-term exposure-related mortality risk remaining upon just meeting the current annual standard, we focus on risk estimates for these three study areas. Total incidence of $PM_{2.5}$-related mortality ranges from 131-165 (Birmingham) to 344-434 (Houston) (Table 2-2). The percent of total incidence of IHD mortality attributable to $PM_{2.5}$ ranges from 10.7-13.6% (Houston) to 13.2-16.7% (Atlanta) (Table 2-2). Total incidence estimates for all-cause and cardiopulmonary mortality related to $PM_{2.5}$ exposure for these study areas are larger than for IHD, while total $PM_{2.5}$-attributable incidence estimates for lung-cancer are lower. However, the percent of total incidence attributable to $PM_{2.5}$ exposure is larger for IHD than for the other mortality categories assessed.

The remaining ten study areas that would experience reductions in risk under the current suite of standards (relative to risk under recent conditions) have design values which result in the current 24-hour standard controlling. These study areas include: Baltimore, Detroit, Fresno, Los Angeles, New York, Philadelphia, Pittsburgh, Salt Lake City, St. Louis, and Tacoma. Therefore, we consider risk estimates for these study areas in assessing the degree of risk associated with just meeting the current 24-hour standard. Total incidence of $PM_{2.5}$-related mortality ranges from 15-19 (Salt Lake City) to 1,755-2,222 (New York City) (Table 2-2). The percent of total incidence of IHD mortality attributable to $PM_{2.5}$ ranges from 2.9-3.7 (Salt Lake City) to 11.2-14.2% (St. Louis) (Table 2-2). Total incidence estimates for all-cause and cardiopulmonary mortality related to $PM_{2.5}$ exposure for these study areas are larger than for IHD, while total $PM_{2.5}$-attributable incidence estimates for lung-cancer are lower. However, the percent of total incidence attributable to $PM_{2.5}$exposure is larger for IHD than for the other mortality categories assessed.

Estimates of risk under the current suite of standards is significantly more variable for the ten study areas where the 24-hour standard is controlling compared with the three study areas where the current annual standard is controlling. This notable difference in variability reflects the fact that simulation of just meeting the current 24-hour standard (for those study areas where it is controlling) produces varying impacts on annual-average $PM_{2.5}$ concentrations. By contrast, simulation of just meeting the annual standard results in similar annual-average $PM_{2.5}$ concentrations for those study areas where the annual standard is controlling. Because annual-average $PM_{2.5}$ concentrations are one of the primary determinants of the level of long-term exposure-related mortality risk, variation in this statistic translates into greater variation in risk remaining upon simulation of the current suite of standards for the ten study areas where the 24-hour level is controlling.

A related point, which has bearing on the level of confidence associated with our risk estimates, is the observation that several of the study areas where the 24-hour standard was

Table 2-2. Estimated Incidence and Percent of Total Annual Incidence Associated with Long-term $PM_{2.5}$ Exposure Based on Simulation of the Current Suite of Standards (for IHD mortality based on 2007 $PM_{2.5}$ Concentrations)[1,2]

Risk Assessment Location	Design Values (ug/m^3)		Incidence of Ischemic Heart Disease Mortality Associated with Long-term Exposure to $PM_{2.5}$[3]		Percent of Incidence of Ischemic Heart Disease Mortality Associated with Long-term Exposure to $PM_{2.5}$[3]	
	Annual	24-hour	Exposure Period: 1979-1983	Exposure Period: 1999-2000	Exposure Period: 1979-1983	Exposure Period: 1999-2000
Atlanta, GA	16.2	35	220 (180 - 258)	277 (227 - 324)	10.4% (8.5% - 12.3%)	13.2% (10.8% - 15.5%)
Baltimore, MD	15.6	37	297 (243 - 349)	374 (307 - 440)	8.9% (7.3% - 10.5%)	11.3% (9.2% - 13.3%)
Birmingham, AL	18.7	44	131 (107 - 154)	165 (135 - 194)	8.4% (6.9% - 9.9%)	10.7% (8.7% - 12.6%)
Dallas, TX	12.8	26	195 (159 - 230)	247 (202 - 291)	9% (7.3% - 10.6%)	11.4% (9.3% - 13.4%)
Detroit, MI	17.2	43	377 (308 - 445)	478 (390 - 563)	6.7% (5.4% - 7.9%)	8.5% (6.9% - 10%)
Fresno, CA	17.4	63	77 (63 - 92)	98 (80 - 116)	4.6% (3.7% - 5.5%)	5.9% (4.8% - 7%)
Houston, TX	15.8	31	344 (281 - 405)	434 (355 - 511)	8.2% (6.7% - 9.7%)	10.5% (8.5% - 12.3%)
Los Angeles, CA	19.6	55	860 (701 - 1018)	1094 (890 - 1296)	4% (3.3% - 4.8%)	5.2% (4.2% - 6.1%)
New York, NY	15.9	42	1755 (1435 - 2070)	2222 (1814 - 2620)	6.8% (5.6% - 8.1%)	8.7% (7.1% - 10.3%)
Philadelphia, PA	15	38	261 (214 - 308)	330 (270 - 389)	7.9% (6.4% - 9.3%)	10% (8.1% - 11.8%)
Phoenix, AZ	12.6	32	317 (258 - 374)	402 (327 - 476)	5.8% (4.7% - 6.8%)	7.3% (6% - 8.7%)
Pittsburgh, PA	19.8	60	256 (209 - 302)	324 (264 - 382)	6.9% (5.6% - 8.1%)	8.7% (7.1% - 10.3%)
Salt Lake City, UT	11.6	55	15 (12 - 18)	19 (16 - 23)	1.3% (1.1% - 1.6%)	1.7% (1.4% - 2%)
St. Louis, MO	16.5	39	446 (365 - 525)	563 (461 - 662)	8.6% (7% - 10.1%)	10.9% (8.9% - 12.8%)
Tacoma, WA	10.2	43	38 (31 - 46)	49 (40 - 58)	2% (1.6% - 2.4%)	2.5% (2.1% - 3%)

[1]The current primary $PM_{2.5}$ standards include an annual standard set at 15 ug/m^3 and a daily standard set at 35 ug/m^3.
[2]Numbers rounded to the nearest whole number. Numbers in parentheses are 95% confidence or credible intervals based on statistical uncertainty surrounding the PM coefficient.
[3]Estimates Based on Krewski et al. (2009), Using Ambient $PM_{2.5}$ from 1979 - 1983 and from 1999-2000 respectively.

controlling have annual-average $PM_{2.5}$ concentrations that are well below the level of the current annual standard and in some instances, approaching the lowest measured level (LML) of 5.8 $\mu g/m^3$ used as the lower bound for risk estimation. Although we are not able to quantify the degree of increased uncertainty, we do have reduced confidence in risk estimates involving annual-average $PM_{2.5}$ concentrations that are substantially below the mean annual $PM_{2.5}$ concentrations reported by Krewski et al. (2009) (14-21 $\mu g/m^3$ – see Table 1 in the study) and approaching the LML of 5.8 $\mu g/m^3$ identified for that study. This reflects the fact that, while available literature does not support a $PM_{2.5}$-related threshold for health effects, we do have increased uncertainty in characterizing the nature of the C-R function as we move away from the central mass of observations in the epidemiological study from which the C-R functions was obtained and towards the LML. Study areas with relatively low annual-average $PM_{2.5}$ concentrations less than the level of the current standard include: Tacoma (8.4 $\mu g/m^3$), Salt Lake City (7.7 $\mu g/m^3$), and Fresno (9.9 $\mu g/m^3$) (note, that the current 24-hour standard is controlling for all of these study areas – see US EPA, 2010a, Appendix F, Table F-49). Conversely, we note that we would have greater confidence in applying C-R functions in the risk assessment for those study areas with annual-average $PM_{2.5}$ levels under the current suite of standards near the range of 14-21 $\mu g/m^3$. Study areas in this category include: Atlanta, Birmingham and Houston (where the annual standard is controlling) and Baltimore, Detroit, Philadelphia, St. Louis, New York (where the 24-hour standard is controlling).

Consideration of variability in the spatial pattern of $PM_{2.5}$ reductions associated with simulation of the current suite of standards suggests that this factor can impact risk estimates, particularly in those instances where the 24-hour standard is controlling. For example, consideration of a more localized pattern of reduction in $PM_{2.5}$ concentrations (as reflected in the peak shaving rollback method), resulted in risk estimates for the 10 study areas where the 24-hour standard is controlling that are from ~0 to 53% higher than those estimated assuming a more regionalized pattern of $PM_{2.5}$ reductions (as reflected in the proportional rollback method used in the core analysis).

Additional sensitivity analyses considering sources of uncertainty impacting the core risk estimates focused on specification of the C-R function for long-term $PM_{2.5}$ exposure-related mortality. This analysis suggested that most of the alternative model specifications supported by available literature would produce risk estimates that were higher (by up to a factor of 2 to 3) than the core risk estimates. These findings would apply both to estimates of $PM_{2.5}$-attributable IHD mortality incidence, as well as to estimates of the percent of total IHD mortality incidence attributable to $PM_{2.5}$ exposure.

Taken together, the sensitivity analyses completed for this risk assessment, including those considering variability in rollback methods as well as uncertainty in the form of C-R

functions, suggest that the set of alternative risk model specifications that we identified generally produced risk estimates that are higher than the core risk estimates. Furthermore, our decision to model risk down to the LML (rather than to lower policy-relevant background (PRB) concentrations) for long-term $PM_{2.5}$ exposure-related mortality, despite the lack of evidence for a threshold, results in lower estimates of risk that would have resulted from modeling risk down to PRB. These considerations increase our overall confidence that we did not over-state risks with the core risk estimates. However, as noted above, there are different levels of confidence associated with risk estimates reflecting the annual-average $PM_{2.5}$ concentrations associated with the risk estimates (with lower confidence associated with annual-average $PM_{2.5}$ concentrations closer to the LML of 5.8 $\mu g/m^3$).

- **What is the nature and magnitude of the <u>short-term</u> exposure-related risks remaining upon just meeting the current suite of $PM_{2.5}$ standards? What level of confidence is associated with these risk estimates?**

As noted earlier, changes in annual-average $PM_{2.5}$ levels drive reductions in both long-term and short-term exposure-related risk. Consequently, patterns of risk reduction for long-term exposure-related mortality associated with the suite of annual standard levels generally hold for short-term exposure-related mortality and morbidity (although absolute levels of risk will differ). As was done above for long-term exposure-related mortality, we have divided the discussion of risk for short-term exposure-related mortality and morbidity, between (a) the three study areas where the current annual standard was driving and (b) the ten study areas where the 24-hour standard was controlling. Again, this reflects the fact that these two groups of study areas had different patterns of risk reduction under the current suite of standards, reflecting differences in the way the two standard levels effected annual-average $PM_{2.5}$ levels (i.e., fairly similar annual-average $PM_{2.5}$ levels for study areas where the annual standard controls and more variable annual-average $PM_{2.5}$ levels for study areas where the 24-hour standard controls).

Total incidence of short-term exposure-related CV mortality attributable for $PM_{2.5}$ for the three study areas where the current annual standard controls (Atlanta, Birmingham and Houston) ranges from 32 (Atlanta) to 46 (Houston) (Table 2-3). The percent of total CV mortality incidence attributable to $PM_{2.5}$ for this subset of study areas ranges from 0.8% (Atlanta) to 0.9% (Houston) (Table 2-3). Total incidence of CV hospital admissions (HA) attributable to $PM_{2.5}$ for this group of study areas ranges from 16 (Birmingham) to 56 (Houston) (Table 2-3), while percent of total incidence attributable to $PM_{2.5}$ ranges from 0.3% (Birmingham) to 0.4% (Atlanta) (Table 2-3).

Total incidence of short-term exposure-related CV mortality attributable for $PM_{2.5}$ for the ten study areas where the 24-hour standard is controlling (Baltimore, Detroit, Fresno, Los Angeles, New York, Philadelphia, Pittsburgh, Salt Lake City, St. Louis, and Tacoma), range

from 9 (Salt Lake City) to 106 (St. Louis) (Table 2-3). The percent of total incidence of CV mortality attributable to $PM_{2.5}$ ranges from 0.7% (Tacoma) to 2.1% (New York and Philadelphia) (Table 2-3). Total incidence of CV hospital admissions (HA) attributable to $PM_{2.5}$ for this group of study areas ranges from 9 (Salt Lake City) to 752 (Los Angeles) (Table 2-3), while percent of total incidence attributable to $PM_{2.5}$ ranges from 0.4% (Salt Lake City) to 1.3% (St. Louis and Philadelphia) (Table 2-3).

As observed with the long-term exposure-related mortality, estimates of short-term exposure-related mortality and morbidity risk under the current suite of standards are significantly more variable for the ten study areas where the 24-hour standard is controlling compared with the three study areas where the current annual standard is controlling. Again, this notable different in variability reflects the fact that simulation of just meeting the current 24-hour standard (for those study areas where it is controlling) produces varying impacts on annual-average $PM_{2.5}$ concentrations and hence on risk. By contrast, those study areas where the annual standard is controlling have similar annual-average $PM_{2.5}$ levels and consequently similar levels of risk remaining upon simulation of the current suite of standards (recall that short-term exposure-related risk is driven more by changes in annual-average $PM_{2.5}$ then by changes in peak daily $PM_{2.5}$ levels).

Given increased emphasis placed in this analysis on long-term exposure-related mortality, the uncertainty analyses completed for this health endpoint category are more comprehensive than those conducted for short-term exposure-related mortality and morbidity, which to some extent reflects limitations in study data available for addressing uncertainty in the later category.

- **What roles do the current 24 hour and annual standards have in simulating the risks remaining upon just meeting the current suite of standards?**

As note above, of the thirteen urban study areas that do not meet the current suite of standards based on 2005-2007 air quality data, ten areas have the 24-hour standard controlling, while only 3 areas have the annual standard controlling. This pattern is generally characteristic of the larger set of urban areas across the U.S. that do not meet the current suite of standards (US EPA, 2010a, section 4.5).[21]

Estimated risks remaining upon just meeting the current suite of standards vary across study areas, even when considering risks normalized for differences in population size and baseline incidence rates. This variability in estimated risks is a consequence of the variability in the annual-average $PM_{2.5}$ concentrations across study areas that result from simulating just

[21] Of the 256 urban areas in the U.S. (including a combination of CSA and CBSAs), 67 have ambient $PM_{2.5}$ levels exceeding either the 24-hour or annual standard (or both) based on $PM_{2.5}$ monitoring data from 2005-2007. Of these, 51 have the 24-hour standard controlling, while 16 have the annual standard controlling.

Table 2-3. Estimated Incidence and Percent of Total Annual Incidence Associated with Short-Term $PM_{2.5}$ Exposure Based on Simulation of the Current Suite of Standards (CV mortality and hospital admissions based on 2007 $PM_{2.5}$ concentrations)[1,2]

Risk Assessment Location	Design Values (ug/m^3)		$PM_{2.5}$-Attributable Incidence		Percent of Total Incidence Attributable to $PM_{2.5}$	
	Annual	24-hour	Cardiovascular Mortality[3]	Cardiovascular Hospital Admissions[4]	Cardiovascular Mortality[3]	Cardiovascular Hospital Admissions[4]
Atlanta, GA	16.2	35	27 (-28 - 81)	35 (-23 - 92)	0.7% (-0.7% - 2.1%)	0.31% (-0.2% - 0.83%)
Baltimore, MD	15.6	37	54 (-4 - 111)	189 (139 - 239)	1.4% (-0.1% - 2.8%)	1.16% (0.85% - 1.47%)
Birmingham, AL	18.7	44	-1 (-36 - 34)	14 (-9 - 36)	0% (-1.3% - 1.2%)	0.27% (-0.18% - 0.72%)
Dallas, TX	12.8	26	29 (-19 - 76)	28 (-18 - 73)	0.8% (-0.5% - 2.2%)	0.28% (-0.18% - 0.74%)
Detroit, MI	17.2	43	55 (-7 - 116)	214 (157 - 271)	0.9% (-0.1% - 2%)	1.04% (0.76% - 1.32%)
Fresno, CA	17.4	63	12 (-9 - 33)	23 (0 - 46)	0.7% (-0.5% - 2%)	0.48% (0.01% - 0.94%)
Houston, TX	15.8	31	39 (-27 - 104)	48 (-31 - 127)	0.8% (-0.5% - 2%)	0.27% (-0.17% - 0.71%)
Los Angeles, CA	19.6	55	-30 (-132 - 72)	258 (3 - 511)	-0.2% (-0.7% - 0.4%)	0.46% (0.01% - 0.91%)
New York, NY	15.9	42	461 (269 - 651)	733 (538 - 927)	2% (1.2% - 2.9%)	1.12% (0.83% - 1.42%)
Philadelphia, PA	15	38	79 (20 - 136)	190 (140 - 240)	2% (0.5% - 3.4%)	1.18% (0.87% - 1.5%)
Phoenix, AZ	12.6	32	84 (-4 - 170)	108 (1 - 215)	1.3% (-0.1% - 2.7%)	0.5% (0.01% - 0.99%)
Pittsburgh, PA	19.8	60	42 (-8 - 91)	136 (100 - 172)	1% (-0.2% - 2.3%)	1.08% (0.8% - 1.37%)
Salt Lake City, UT	11.6	55	9 (-2 - 20)	9 (0 - 18)	0.8% (-0.2% - 1.7%)	0.36% (0% - 0.7%)
St. Louis, MO	16.5	39	92 (20 - 162)	155 (114 - 196)	1.6% (0.4% - 2.9%)	1.1% (0.81% - 1.4%)
Tacoma, WA	10.2	43	11 (-6 - 27)	19 (-46 - 82)	0.7% (-0.4% - 1.8%)	0.52% (-1.28% - 2.26%)

[1]The current primary

[2]Percents rounded to the nearest tenth. Numbers in parentheses are 95% confidence or credible intervals based on statistical uncertainty surrounding the PM coefficient.

[3]Based on location-specific single pollutant concentration-response function estimates from Zanobetti and Schwartz (2009) that have been "shrunken" towards the appropriate regional means. "Shrunken" coefficient estimates and their standard errors were sen

[4]Incidence estimates were calculated using the appropriate regional concentration-response function estimates reported in Table 2 of Bell et al. (2008). Location-specific C-R function estimates were not available from this study.

meeting the current standards.[22] Variability in annual-average $PM_{2.5}$ concentrations is substantially greater in those study areas in which the 24-hour standard is controlling. In such areas, the variability across study areas in estimated risks is largest when regional patterns of reductions in $PM_{2.5}$ concentrations are simulated (using proportional rollback, as was done in the core analyses), with less variability when more localized patterns of $PM_{2.5}$ reductions are simulated (using peak shaving rollback, as was done in a sensitivity analysis).

In simulating just meeting the current suite of standards for the urban study areas, the resulting annual-average $PM_{2.5}$ concentrations range from about 15 $\mu g/m^3$ (for the study areas in which the annual standard was controlling) down to as low as about 8 $\mu g/m^3$ (for the study areas in which the 24-hour standard was controlling). We note that, for long-term exposure-related mortality, estimates of risk based on annual-average $PM_{2.5}$ concentrations approaching the LML of 5.8 $\mu g/m^3$ have greater uncertainty than estimates based on annual-average concentrations closer to the mean of the epidemiological study from which the C-R functions are obtained (14 to 21 $\mu g/m^3$).[23] Therefore, we generally have less confidence in risk estimates generated for study areas where the 24-hour standard is controlling since these tend to have lower annual-average $PM_{2.5}$ levels (which can approach the LML) compared with study areas where the annual-average is controlling.

These observations when considered together suggest that, when we simulate $PM_{2.5}$ concentrations meeting the current suite of standards, we find that in study areas where the current 24-hour standard is controlling, the degree of public health protection afforded by the current suite of standards is much more variable than in study areas where the annual standard is controlling. Furthermore, we generally have less confidence in the risk estimates generated for urban areas where the current 24-hour standard is controlling due simulated lower annual-average $PM_{2.5}$ concentrations that are in some cases much lower, approaching the LML.

- **How representative are the risk estimates generated for the urban study areas from a national perspective?**

As part of the risk assessment, we completed several additional analyses intended to place the core risk estimates in the broader national-context by considering the degree to which the 15 urban study areas are representative of larger urban areas within the U.S., particularly areas likely to experience elevated risk related to PM exposure. Below we provide brief descriptions of each analysis, along with observations results from each analysis regarding the

[22] As noted earlier, changes in both short-term and long-term exposure-related risk reflect primarily changes in long-term average (annual) $PM_{2.5}$ levels.

[23] This observation also holds for estimates of risk associated with short-term $PM_{2.5}$ although we note that the LML for these studies is below PRB, which allows us to make estimates of risk for lower $PM_{2.5}$ levels with greater confidence relative to modeling long-term exposure-related mortality with its higher LML.

representativeness of the urban study areas:

- The representativeness analysis (US EPA, 2010a, section 4.4) compared attributes of the 15 urban study eras (assessed at the county-level) against national distributions for the same attributes. The analysis suggests that the 15 urban study areas represent areas in the U.S. that are among the most densely populated, have relatively higher levels of annual and 24-hour 98th percentile $PM_{2.5}$ concentrations, and capture well the range of effect estimates represented by the Zanobetti and Schwartz (2009) study. Together, these factors suggest that the urban study areas should capture well the overall distribution of risk for the nation, with the potential for better characterization of the high end of that distribution.[24]
- Consideration of the mix of design values across the 15 urban study areas as contrasted with design values for the broader set of urban study areas in the U.S. suggests that the 15 urban study areas do a good job of capturing the key groupings of urban areas in the U.S. likely to experience elevated risk due to PM (i.e., we have coverage for each of the zones containing urban study areas likely to experience risk reductions under the suites of alternative standard levels considered – see US EPA,2010a, section 4.5.1). Furthermore, this analysis suggested that we have also included study areas likely to experience relatively greater degrees of $PM_{2.5}$-related risk, considering the pattern of design values across urban areas in the U.S.
- Consideration of where the 15 urban study areas fell along the distribution of U.S. counties included in the national-scale mortality analysis further suggests that we have captured counties likely to experience elevated $PM_{2.5}$-related risk**.** As part of the national-scale mortality analysis (see US EPA, 2010a, chapter 5), we created a cumulative distribution of the *percentage of mortality attributable to $PM_{2.5}$* based on the county-level estimates for the U.S.[25] We then identified where along this cumulative distribution the 31 counties comprising our 15 urban study areas fell. This analysis suggests that our urban study areas capture the upper end of the tail with regard to $PM_{2.5}$-attributable risk, with 23 of these counties falling within the upper 5th percentile of the distribution. These findings support the assertion based on the other analyses described above that the urban study areas are likely to capture risk at urban areas experiencing relatively elevated levels of $PM_{2.5}$-attributable mortality.

Our overall assessment of the representativeness of the 15 urban study areas in the national context, based on the three analyses summarized above, is that our study areas do a good job of representing urban areas in the U.S. experiencing elevated levels of risk related to ambient $PM_{2.5}$ exposure. The results of the national-scale mortality analysis also suggest that, while our 15 urban study areas do provide coverage for urban areas in the U.S. experiencing elevated levels of $PM_{2.5}$-related risk, there are many additional areas (counties) not modeled in the risk

[24] This analysis also showed that the urban study areas do not capture areas with the highest baseline morality risks or the oldest populations (both of which can result in higher $PM_{2.5}$-related mortality estimates). However, some of the areas with the highest values for these attributes have relatively lower $PM_{2.5}$ levels (e.g., urban areas in Florida) and consequently failure to include these areas in the set of urban study areas is unlikely to bias the risk estimates in terms of excluding high $PM_{2.5}$-risk locations.

[25] Note that by using this risk metric, we avoid influence by difference in overall population size (as would be the case with raw incidence) and focus on a unitized estimate of $PM_{2.5}$-related mortality which reflects differences in (a) baseline mortality incidence, and (b) the annual average $PM_{2.5}$ concentrations for each county.

assessment that experience elevated $PM_{2.5}$-related risk. In other words, it should not be construed that significant $PM_{2.5}$-related risk is limited only to the urban study areas included in the risk assessment.

- **To what extent are the risks remaining upon simulation of the current suite of standards important from a public health perspective?**

With respect to considering the results of the quantitative risk assessment to inform our understanding of risks associated with long-term $PM_{2.5}$ exposures, we reach the preliminary conclusion that the long-term exposure-related mortality risks remaining upon simulation of just meeting the current suite of $PM_{2.5}$ standards can reasonably be judged to be important from a public health perspective. This preliminary conclusion is based, in part, on both the nature of the risks (total and cause-specific mortality) as well as the magnitude of these risks (the total incidence and percentage of incidence associated with $PM_{2.5}$ exposure as presented in Table 2-2). In addition, based on consideration of both our qualitative and quantitative assessments of uncertainty, as well as additional factors considered in the risk model (e.g., modeling risk down to LML rather than PRB), we are reasonably confident that we have not overstated the magnitude of risk associated with simulating the current suite of standards. However, we do note that we have greater overall confidence in estimates of risk associated with long-term $PM_{2.5}$ exposure in the subset of urban study areas for which the current annual standard is controlling, since these locations tend to have higher annual-average $PM_{2.5}$ concentrations. In contrast, the urban study areas where the current 24-hour standard is controlling tend to have substantially lower annual-average $PM_{2.5}$ concentrations, which reduces our overall confidence in these estimates of risks related to long-term exposures.

With regard to considering the results of the quantitative risk assessment to inform our understanding of risks associated with short-term $PM_{2.5}$ exposures, we reach the preliminary conclusion that short-term exposure-related mortality and morbidity risks upon simulation of the current suite of $PM_{2.5}$ standards can reasonably be judged to be important from a public health perspective. Similar to the discussion of risks associated with long-term $PM_{2.5}$ exposure, this preliminary conclusion is based, in part, on both the nature of the risks (total and cause-specific mortality as well as cause-specific hospital admissions) as well as the magnitude of those risks (total incidence and percentage of incidence associated with $PM_{2.5}$ exposure as presented in Table 2-3). We note however, that in the case of mortality associated with short-term $PM_{2.5}$ exposure, the magnitude of these risks is substantially lower than that associated with long-term exposure to $PM_{2.5}$. With regard to our overall confidence in the estimates of risks related to short-term $PM_{2.5}$ exposures, while we believe that the core simulation of risk is based on C-R functions that are well-supported in the literature, we acknowledge that we have not completed as comprehensive an assessment of uncertainty and variability as was done for estimates of

mortality risks related to long-term $PM_{2.5}$ exposure. Therefore, our overall confidence that we have not over-stated risk associated with short-term exposure-related mortality and morbidity is not as high as for long-term exposure-related mortality, although we have no reason to believe that we have over-stated risk.

2.2.3 Preliminary Staff Conclusions on Adequacy of Current Standards

Collectively, taking into consideration the responses to specific questions focusing on different ways to address the adequacy of the current suite of $PM_{2.5}$ standards, we revisit the overarching policy question: does the currently available scientific evidence and risk-based information support or call into question the adequacy of the protection afforded by the current suite of fine particle standards?

With respect to evidence-based considerations, the currently available evidence provides stronger evidence beyond what was available in the last review, that associations between short- and long-term $PM_{2.5}$ exposures and a broad range of adverse health effects exist. The newly available information strengthens the associations between $PM_{2.5}$ and mortality and cardiovascular and respiratory morbidity effects observed in the last review and expands our understanding of a broader range of health outcomes as well as our understanding of effects in susceptible populations. The newly available evidence provides support for associations that extend to lower concentrations than what had been observed in the last review, including at ambient concentrations below the levels of the current standards.

In relation to risk-based considerations for informing our understanding of the adequacy of the current fine particle standards, we focus on the estimates of $PM_{2.5}$-related mortality and morbidity effects likely to remain upon meeting the current standards in a number of example urban areas. In considering the core risk estimates together with our understanding of the uncertainties in these estimates based upon extensive sensitivity analyses, we reach the preliminary conclusion that the risks estimated to be associated with just meeting the current standards can reasonably be judged to be important from a public health perspective and these estimated risks provide support for consideration of standards that would provide increased protection beyond that afforded by the current $PM_{2.5}$ standards.

We recognize that important uncertainties and research questions remain when considering both evidence- and risk-based approaches. Nonetheless, we note that much progress has been made in reducing some key uncertainties since the last review, including important progress in advancing our understanding of potential mechanisms by which ambient $PM_{2.5}$ is causally linked with mortality, cardiovascular, and respiratory effects observed in epidemiologic studies. Additional information continues to emerge for a broader range of health effects including reproductive and development effects and more information is available to understand

susceptible populations including children, older adults, and individuals with pre-existing cardiovascular and respiratory disease. As was true in the last review, we recognize that as the body of available evidence has expanded, it has added greatly both to our knowledge of health effects associated with fine particle exposures, as well as to the complexity inherent in interpreting the evidence in a policy-relevant context as a basis for setting appropriate standards. In evaluating both evidence-based and risk-based considerations, along with associated limitations and uncertainties, we reach the preliminary conclusion that the available information clearly calls into question the adequacy of the current suite of $PM_{2.5}$ standards and provides strong support for giving consideration to revising the current standards to provide increased public health protection.

2.3 CONSIDERATION OF ALTERNATIVE STANDARDS

Having reached the conclusion that the currently available scientific evidence calls into question the adequacy of the current suite of $PM_{2.5}$ standards, staff considers a second overarching question:

What alternative suite(s) of fine particle standards is (are) supported by the currently available scientific evidence and risk-based information, as reflected in the ISA and second draft RA?

To inform the answer to this overarching question, we have posed a series of more specific questions to aid in considering how the current suite of primary $PM_{2.5}$ standards might be revised to provide requisite public health protection. Specifically, we consider how the currently available scientific evidence informs decisions regarding the basic elements of the NAAQS: indicator (section 2.3.1), averaging time (section 2.3.2), form (section 2.3.3), and level (sections 2.3.4 and 2.3.5). These elements will be considered collectively in evaluating the health protection afforded by alternative suites of standards under consideration. In considering the currently available scientific and technical information, we consider both the information available in the last review and information that is newly available since the last review as assessed and presented in the ISA and second draft RA prepared for this review (US EPA, 2009a; US EPA, 2010a).

2.3.1 Indicator

In 1997, EPA decided that particles from the fine and coarse fractions of thoracic particles (PM_{10}) should be defined as separate pollutants. At that time, the Agency established $PM_{2.5}$ as the indicator for fine particle, while retaining PM_{10} as the indicator for thoracic coarse particles. In determining the indicator for fine particles, the Agency first considered whether the indicator should be based on the mass of a size-differentiated sample of fine particles or one or

more components within the mix of fine particles. In that review, EPA first concluded it was more appropriate to control fine particles as a group, as opposed to singling out any particular component or class of fine particles. Second, in establishing a size-based indicator, a size cut was selected that would appropriately distinguish fine particles from particles in the coarse mode. In focusing on a size cut within the size range of 1 to 3 μm (i.e., the intermodal range between fine and coarse mode particles), EPA recognized that the choice of any specific sampling size cut within this range was largely a policy judgment. In making this judgment, the Agency noted that the available epidemiologic studies of fine particles were based largely on $PM_{2.5}$ and also considered monitoring technology that was generally available. In the Administrator's final decision, the selection of a 2.5 μm size cut reflected the regulatory importance that was placed on defining an indicator that would more completely capture fine particles under all conditions likely to be encountered across the U.S., especially when fine particle concentrations are likely to be high, while recognizing that some small coarse particles would also be captured by current methods to monitor $PM_{2.5}$ (62 FR 38667 to 38668, July, 18, 1997).

In reaching the decision to retain $PM_{2.5}$ as the indicator for fine particles in the last review, the same considerations continued to apply for selection of an appropriate indicator for fine particles (71 FR 61162 to 61164, October, 17, 2006). The available epidemiologic studies linking mortality and/or morbidity effects with short- and long-term exposures to fine particles continued to be largely indexed by $PM_{2.5.}$ While emerging evidence focused on various $PM_{2.5}$ constituents and provided some evidence related to various components within the mix of fine particles (e.g., sulfates (SO_2^{-4}), nitrates, elemental carbon (EC), organic compounds, and metals) as well as associations between mortality and particles from different sources of fine particles, this evidence was deemed too limited to support a distinct standard for a specific $PM_{2.5}$ component or fine particle source. More specifically, the Agency concluded, there was "not sufficient evidence that would lead toward the selection of one or more PM components as being primarily responsible for effects associated with fine particles, nor is there sufficient evidence to suggest that any component should be eliminated from the indicator for fine particles" (71 FR 61163/1).

In this review, in considering alternative fine particle standards, we first address the issue of indicator by asking the following question:

- **Does the currently available evidence provide support for the continued use of $PM_{2.5}$ as the mass-based indicator for fine particles?**

As noted above, the selection of $PM_{2.5}$ to characterize respirable particles in 1997 was driven mainly by considerations related to measurement techniques available at the time rather than dosimetry. In this review, the ISA notes, "[c]urrently, cut points other than 2.5 μm are

attainable and frequently put into use…[m]ost commonly, however, $PM_{2.5}$ is used as an indicator of respirable particles" (US EPA, 2009a, p. 3-3). Recently, there has been increasing interest in examining the relationship between the particle number concentration by size and health effects. However, several instruments are needed to provide size distribution measurements (number and size) over the several orders of magnitude of particle diameters of interest (US EPA, 2009a, section 3.4.1.5, p. 3-29). These techniques, while widely used in aerosol research, have not yet been widely used in health effects studies.

As discussed in section 2.2.1, currently available scientific information providing evidence of associations between fine particles and a broad range of health outcomes has been substantially strengthened in this review. Epidemiological evidence continues to provide the strongest support for standards to protect public health from long- and short- term fine particle exposures. Measurements from community-based ambient monitors have generally been used for time-series and longitudinal epidemiological studies, and may be used for panel studies as well (US EPA, 2009a, p. 3-176). New epidemiological studies available in this review have considered a much larger set of air quality data than was available in the last review based primarily on ambient measurement data from the existing $PM_{2.5}$ monitoring networks.[26] This includes consideration of air quality measurements reported in more recent years. These data have improved our understanding of the spatiotemporal distribution of $PM_{2.5}$ (US EPA, 2009a, sections 3.5 and 3.9).

As presented in the ISA, epidemiological studies linking cardiovascular and respiratory effects as well as mortality with short- and long-term fine particle exposures continue to be largely indexed by $PM_{2.5}$ (US EPA, 2009a, chapters 6 and 7). Thus, we reach the preliminary conclusion that it is reasonable to retain $PM_{2.5}$ as an indicator for fine particles. We then pose additional questions to aid in considering whether the currently available scientific evidence provides support for supplementing the current $PM_{2.5}$ mass-based indicator by considering whether there is sufficient evidence to support a standard with a different size fraction or whether there is sufficient evidence to establish distinct standards focused on regulating specific $PM_{2.5}$ components or sources of fine particles.

- **To what extent does the currently available information provide support for considering a separate indicator for ultrafine particles as a subfraction of fine particles?**

[26] The network of $PM_{2.5}$ Federal Reference Methods (FRM) monitors has been operational since 1999. This network currently includes over 900 monitoring stations around the U.S. FRM-like air quality data are available from continuous monitors required in metropolitan statistical areas (MSAs) that have an FRM/Federal Equivalent (FEM) monitor. The network of continuous $PM_{2.5}$ monitors has grown to over 700 locations throughout the U.S. While $PM_{2.5}$ continuous monitors primarily support forecasting and reporting for the Air Quality Index (AQI), they are also used in interpreting the diurnal characterization of $PM_{2.5}$.

In considering whether or not the currently available evidence provides support for an additional size-based indicator by focusing on ultrafine particles (UFPs)[27], we recognize that a number of studies have focused on UFPs as a subset of $PM_{2.5}$. In the last review, limited evidence was available suggesting that the ultrafine subset of fine particles (generally including particles with a nominal aerodynamic diameter less than 0.1 μm) was associated with adverse health effects (US EPA, 2004, pp. 8-66 to 8-68). In this review, the ISA notes that there are many reasons for looking more closely at effects associated with this size fraction including, the particle number and large surface area of UFPs per unit of mass. Particle number is most highly concentrated in the UFP fraction with volume (or mass) most concentrated in the larger size fractions (US EPA, 2009a, p. 3-2) Furthermore, per unit mass, UFPs may have more opportunity to interact with cell surfaces due to their greater surface area and their greater particle number compared with larger particles (US EPA, 2009a, p. 5-3). Greater surface area increases the potential for soluble components to adbsorb to UFPs and be transported into the body (US EPA, 2009a, p. 6-83). Many studies suggest that the surface of particles or substances released from the surface (e.g., transition metals, organics) interact with biological substrates, and that surface-associated free radicals or free radical-generating systems may be responsible for toxicity, resulting in greater toxicity of UFPs per particle surface area than larger particles. In addition, evidence available in this review suggests that the ability of particles to enhance allergic sensitization is associated more strongly with particle number and surface area than particle mass (US EPA, 2009a, p. 6-127). Evidence is also available in this review suggesting that smaller particles may have a greater potential to cross cell membranes and epithelial barriers. The ISA notes that, for UFPs, "enhanced translocation to interstitial compartments or to the circultaon may be important sequelae" (US EPA, 2009a, p. 5-6). More information on possible modes of action for effects associated with UFPs exposures is discussed in sections 5.1 and 5.4 of the ISA.

With respect to ambient concentrations of UFPs, at present, there is no national network of UFP samplers, thus, only episodic and/or site-specific data sets exist (US EPA, 2009a, p. 2-2).[28] Therefore, a national characterization of concentrations, temporal and spatial patterns, and trends is not possible, and the availability of ambient UFPs data to support health studies are extremely limited. In general, UFP particle number concentrations are highly dependent on monitor location and therefore, more subject to exposure error than accumulation mode particles (US EPA, 2009a, p. 2-22). The UFP number concentrations fall off sharply downwind from sources, as UFPs may grow into the accumulation mode by coagulation or condensation (US

[27] Ultrafine particles (UFPs) are emitted directly to the atmosphere or are formed by nucleation of gaseous constituents in the atmosphere (US EPA, 2009a, p. 3-3).

[28] The ISA contains a review of the current scientific information related to measurements of UFPs (US EPA, 2009a, sections 3.5.1 and 3.5.2).

EPA, 2009a, p. 3-89). Limited studies of UFP ambient measurements suggest these particles exhibit a high degree of spatial and temporal heterogeneity driven primarily by differences in nearby source characteristics (US EPA, 2009a, p. 3-84). Internal combustion engines and therefore, on-road roadways are a notable source of UFPs, so concentrations of UFPs near roadways can generally be expected to be elevated (US EPA, 2009a, p. 2-3). Concentrations of UFPs have been reported to drop off much more quickly with distance from roadways than larger particle sizes (US EPA, 2009a, p. 3-84).

Additional but still limited health evidence available in this review, primarily from controlled human exposure and toxicological studies, provide evidence for UFP-induced cardiovascular and respiratory effects. This evidence is largely related to studies focused on exposure to diesel exhaust (DE), "[a]s a result, it is unclear if the effects observed are due to UFP, larger particles (i.e., $PM_{2.5}$), or the gaseous components of DE" (US EPA, 2009a, p. 2-22). The ISA notes uncertainty associated with the controlled human exposure studies as concentrated ambient particle (CAP) systems have been shown to modify the composition of UFPs (US EPA, 2009a, p. 2-22, see also section 1.5.3). In addition, relatively few epidemiologic studies have examined the potential cardiovascular and respiratory effects associated with short-term exposures to UFPs. These studies have reported inconsistent and mixed results (US EPA, 2009a, section 2.3.5).

In considering the body of scientific evidence available in this review, the ISA concludes that the currently available evidence is suggestive of a causal association between short-term exposures to UFPs and cardiovascular and respiratory effects. Furthermore, the ISA concludes that evidence is inadequate to infer a causal association between short-term exposure to UFPs and mortality as well as long-term exposure to UFPs and all outcomes evaluated (US EPA, 2009a, sections 2.3.5, 6.2.12.3, 6.3.10.3, 6.5.3.3, 7.2.11.3, 7.3.9, 7.4.3.3, 7.5.4.3, and 7.6.5.3; Table 2-6). Thus, while new evidence expands our understanding of effects associated with UFPs, we reach the preliminary conclusion that this information is still too limited to support a distinct PM standard for UFPs.

- **To what extent does the currently available information provide support for considering a separate indicator for a specific $PM_{2.5}$ component or source category of fine particles? Conversely, to what extent does the currently available information provide support for eliminating any component or source category from the mix of fine particles included in the $PM_{2.5}$ indicator?**

In the last review, EPA recognized the availability of a limited number of epidemiologic studies that explored associations with various components within the mix of fine particles and adverse effects (US EPA, 2004, section 9.2.2.1.1, Table 9–3) as well as several studies that used $PM_{2.5}$ speciation data to evaluate the association between mortality and particles from different

categories of fine particle sources (US EPA, 2004, section 8.2.2.5). As discussed in the last review, different patterns of associations of various $PM_{2.5}$ components (e.g., sulfates, nitrates, metals, organic compounds, elemental carbon (EC)) or source categories of fine particles with total or cardiovascular mortality were observed in various short-term exposure studies (US EPA, 2004, section 8.2.2.5. Tables 8-3, 8-4, 9-3). However, as noted in the last review, "many PM components are correlated with each other and also with PM mass, making it difficult to distinguish effects of the various components. Also, different PM components or characteristics would be expected to be more closely linked with different health outcomes" (US EPA, 2004, p. 9-30). In addition, a limited number of studies evaluated in the last review used $PM_{2.5}$ speciation data to assess the effects of air pollutant combinations or mixtures using factor analysis or source apportionment methods to link effects with different $PM_{2.5}$ source types (Schwartz, 2003; Mar et al., 2003; and Tsai et al., 2000). These studies reported that fine particles from combustion sources, including motor vehicle emissions, coal combustion, oil burning and vegetative burning, were associated with increased mortality. No significant increase in mortality was reported with a source factor representing crustal material in fine particles (US EPA, 2004, section 8.2.2.5.3). The EPA concluded that these studies indicated that exposure to fine particles from combustion sources, but not crustal material, was associated with mortality (US EPA, 2004, p. 8-85; US EPA, 2005, p. 3-16).

Overall, EPA concluded in the last review that the available evidence suggested "that many different chemical components of fine particles and a variety of different types of source categories are all associated with, and probably contribute to, mortality, either independently or in combinations'' (US EPA, 2004,p. 9-31). Conversely, scientific evidence available in the last review provided no basis to conclude that any individual fine particle component could not be associated with adverse health effects (US EPA, 2005, p. 5–17). This evidence provided the basis for EPA to reach the final decision that "there was not sufficient evidence that would lead EPA to select one or more $PM_{2.5}$ component as being primarily responsible for effects associated with fine particles, nor was there sufficient evidence to suggest that any component should be eliminated from the indicator for fine particles" (71 FR 61163/1, October 17, 2006).

In addressing the issue of particle composition in this review, the ISA concludes that, "[f]rom a mechanistic perspective, it is highly plausible that the chemical composition of PM would be a better predictor of health effects than particle size" (US EPA, 2009a, p. 6-202). Heterogeneity of ambient concentrations of $PM_{2.5}$ constituents (e.g., elemental carbon (EC), organic carbon (OC), sulfate (SO_4^{2-}), and nitrate) observed in different geographical regions as well as regional heterogeneity in $PM_{2.5}$-related health effects reported in a number of epidemiologic studies are consistent with this hypothesis (US EPA, 2009a, section 6.6).

With respect to the availability of ambient measurement data for fine particle components, we recognize that, in this review, there are more extensive ambient $PM_{2.5}$ speciation measurement data available through the Chemical Speciation Network (CSN).[29] Data from the CSN monitoring network provide further evidence of spatial and seasonal variation in both $PM_{2.5}$ mass and composition among cities/regions (US EPA, 2009a, pp. 3-50 to 3-60; Figures 3-12 to 3-18; Figure 3-47). Some of this variation may be related to "regional differences in meteorology, sources, and topography" (US EPA, 2009a, p. 2-3). While the network of approximately 200 CSN monitoring sites provides valuable data for development and tracking of control strategies, its use for providing $PM_{2.5}$ speciation data to support epidemiological studies is somewhat limited. The CSN sites provide measurement data on a one-in-three or one-in-six day schedule and do not capture data every day. Health researchers have expressed a strong interest in having access to $PM_{2.5}$ speciation measurements collected more frequently.[30]

The currently available epidemiologic, toxicological, and controlled human exposure studies have evaluated the health effects associated with ambient $PM_{2.5}$ constituents and categories of fine particle sources, using a variety of quantitative methods applied to a broad set of $PM_{2.5}$ constituents, rather than selecting a few constituents a priori (US EPA, 2009a, p. 2-26). Epidemiological studies have used measured ambient $PM_{2.5}$ speciation data, including monitoring data from the CSN, while all of the controlled human exposure and most of the toxicological studies have used CAPs, and analyzed the constituents therein (US EPA, 2009a, p. 6-203).[31]

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[29]The CSN consists of 54 Speciation Trends Network (STN) sites as well as about 150 SLAMS supplemental sites across the country measuring over 40 chemical species. A limited number of CSN monitors began collecting ambient data in 2000 with the majority of sites collecting data starting in 2001. These sites collect aerosol samples over 24 hours on filters that are analyzed for $PM_{2.5}$ mass, trace elements, major ions (e.g., sulfates, nitrates, ammonium), and organic and elemental carbon.

[30] As outlined in section 6.6.2.11of the ISA, some investigators have circumvented the issue of less than daily speciation data by using the $PM_{2.5}$ chemical species data in a second stage regression to explain the heterogeneity in PM_{10} or $PM_{2.5}$ mortality risk estimates across cities and assuming that the relative contributions of $PM_{2.5}$ have remained the same over time (US EPA, 2009a, p. 6-206). In April 2008, EPA co-sponsored a workshop to discuss modifications to the current ambient air quality monitoring networks that would advance our understanding of the impacts of PM exposures on public health/welfare in the most meaningful way, including improving our understanding of components of fine particles. This workshop was a major step in a series of interactions to foster improved long-term communication between external stakeholders, including air quality monitoring experts and health researchers. A summary of the workshop recommendations, including recommendations for daily $PM_{2.5}$ speciation measurements in large urban areas, is available at www.epa.gov/ORD/npd/pdfs/FINAL-April-2008-AQ-Health-Research-Workshop-Summary-Dec-2008.pdf. Follow-up for a number of the workshop recommendations is on-going.

[31] Most studies considered between 7 and 20 ambient $PM_{2.5}$ constituents, with EC, OC, SO_4^{2-}, nitrate, and metals most commonly measured. Many of the studies reduced the number of ambient $PM_{2.5}$ constituents by grouping them with various factorization or source apportionment techniques to examine the relationship between the grouped $PM_{2.5}$ constituents and various health effects. However, not all studies labeled the constituent groupings according to their presumed source and a small number of controlled human exposure and toxicological studies did not apply any kind of grouping to the ambient $PM_{2.5}$ speciation data. In addition, there were differences in the type and grouping

With respect to epidemiological studies evaluating short-term exposures to fine particle constituents, several new multi-city studies are now available. These studies continue to show an association between mortality and cardiovascular and/or respiratory morbidity effects and short-term exposures to various $PM_{2.5}$ components including nickel (Ni), vanadium (V), elemental carbon (EC), organic carbon (OC), and sulfates (US EPA, 2009a, sections 6.5.2.5 and 6.6). Lippmann et al. (2006); Dominici et al. (2007) evaluated the heterogeneity in the PM_{10}–mortality association as evaluated in the NMMAPS data by analyzing the $PM_{2.5}$ speciation data. Nickel (Ni) and Vanadium (V) were identified as significant predictors of variation in PM_{10}-related mortality across cities, with Ni levels in New York City being reported as particularly high (US EPA, 2009a, section 6.5.2.5; Figure 6-31).[32] Bell et al. (2009) and Peng et al. (2009) conducted similar analyses focusing on the variation in $PM_{2.5}$-related cardiovascular and respiratory hospital admissions in older adults. Peng et al. (2009) focused on the components that make up the majority of $PM_{2.5}$ mass and found that in multi-pollutant models only EC and OC were significantly associated with risk of hospitalization for cardiovascular disease. Bell et al. (2009) used data from twenty $PM_{2.5}$ components and found that EC, Ni, and V were most positively and significantly associated with the risk of $PM_{2.5}$-related hospitalizations suggesting that the observed associations between $PM_{2.5}$ and hospitalizations may be primarily due to particles from oil combustion and traffic (US EPA, 2009a, section 6.2.10.1). In a study of 25 U.S. cities, Franklin et al. (2008) focused on a time-series regression of mortality related to $PM_{2.5}$ mass by season and also examined effect modification due to various $PM_{2.5}$ species. They concluded that Al, As, Ni, Si and SO_4^{2-} were significant effect modifiers of $PM_{2.5}$ mortality risk estimates, and "simultaneously including Al, Ni, and SO_4^{2-} together or Al, Ni, and As together further increased explanatory power. Of the species examined, Al and Ni explained the most residual heterogeneity" (US EPA, 2009a, p. 6-194; Table 6-17).[33] Furthermore, Ostro et al (2006) examined associations between $PM_{2.5}$ components and mortality in six California counties and found an association between mortality, especially cardiovascular-related mortality and several $PM_{2.5}$ components including EC, OC, nitrate, Fe, K, and Ti at various lags (US EPA, 2009a, p. 6-195).

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of $PM_{2.5}$ constituent data used in the various studies and analyses conducted resulting in important limitations in interpreting these studies together (US EPA, 2009a, p. 6-203).

[32] However, as noted in the ISA, in a sensitivity analysis when selectively removing cities from the overall estimate, the significant association between the PM_{10} mortality risk estimate and the $PM_{2.5}$ Ni fraction was diminished upon removing New York City from the analysis, which is consistent with the results presented by Dominici et al. (2007) (US EPA, 2009a, section 6.5.2.5; Figure 6-32).

[33] Of note, New York City was not included in the 25 cities examined by Franklin et al. (2008).

Limited evidence is available to evaluate the health effects associated with long-term exposures to $PM_{2.5}$ components (US EPA, 2009a, section 7.6.2). The most significant new evidence is provided by a study that evaluated multiple $PM_{2.5}$ components and an indicator of traffic density in an assessment of health effects related to long-term exposure to $PM_{2.5}$ (Lipfert et al., 2006). Using health data from a cohort of U.S. military veterans and $PM_{2.5}$ data from EPA's CSN, Lipfert et al. (2006) reported positive associations between mortality and long-term exposures to nitrates, EC, Ni and V as well as traffic density and peak O_3 concentrations. Additional evidence from a long-term exposure study conducted in a Dutch cohort provides supportive evidence that long-term exposure to traffic-related particles is associated with increased mortality (Breelen et al., 2008).

With respect to source categories of fine particles associated with a range of health endpoints, the ISA reports that currently available evidence suggests associations between cardiovascular effects and a number of specific $PM_{2.5}$ –related source categories, specifically oil combustion, wood or biomass burning, motor vehicle emissions, and crustal or road dust sources (US EPA, 2009a, section 6.6; Table 6-18). In addition, a few studies have evaluated associations between $PM_{2.5}$–related source categories and mortality. These studies included a reported association between mortality and a $PM_{2.5}$ coal combustion factor (Laden et al., 2000), while others linked mortality to a secondary SO_4^{2-} long-range transport $PM_{2.5}$ source (Ito et al., 2006; Mar et al., 2006) (US EPA, 2009a, section 6.6.2.1). There is less consistency in associations observed between $PM_{2.5}$ sources and respiratory health effects, which may be partially due to the fact that fewer studies have been conducted that evaluated respiratory-related outcomes and measures. However, there is some evidence for associations with secondary SO_4^{2-}.and decrements in lung function in asthmatic and healthy adults (US EPA, 2009a, p. 6-211; Gong et al., 2005; Lanki et al., 2006). Respiratory effects relating to the crustal/soil/road dust and traffic sources of PM have been observed in asthmatic children and adults (US EPA, 2009a, p. 6-205; Gent et al., 2009; Penttinen et al., 2006).

Recent studies have shown that source apportionment methods have the potential to add useful insights into which sources and/or PM constituents may contribute to different health effects. Of particular interest are several epidemiologic studies that compared source apportionment methods and reported consistent results across research groups (US EPA, 2009a, p. 6-211; Hopke et al., 2006; Ito et al., 2006; Mar et al., 2006; Thurston et al., 2005). These studies reported associations between total mortality and secondary sulfate in two cities for two different lag times. The sulfate effect was stronger for total mortality in Washington D.C. and for cardiovascular-related morality in Phoenix (US EPA, 2009a, p. 6-204). These studies also found some evidence for associations with mortality and a number of source categories (e.g., biomass/wood combustion, traffic, copper smelter, coal combustion, sea salt) at various lag times

(US EPA, 2009a, p. 6-204). Sarnat et al., (2008) compared three different source apportionment methods and reported consistent associations between ED visits for cardiovascular diseases with mobile sources and biomass combustion as well as increased respiratory-related ED visits associated with secondary sulfate (US EPA, 2009a, pp. 6-204 and 6-211; Sarnat et al., 2008).

In summary, in considering the currently available evidence for health effects associated with chemical components and source categories of $PM_{2.5}$ as presented in the ISA, we reach the preliminary conclusion that additional information available in this review continues to provide evidence that many different constituents of the fine particle mixture as well as specific source categories of fine particles are linked to adverse health effects. However, as noted in the ISA, while "[t]here is some evidence for trends and patterns that link particular ambient PM constituents or sources with specific health outcomes…there is insufficient evidence to determine whether these patterns are consistent or robust" (US EPA, 2009a, p. 6-210). Furthermore, the ISA concludes that "the evidence is not yet sufficient to allow differentiation of those constituents or sources that are more closely related to specific health outcomes" (US EPA, 2009a, pp. 2-26 and 6-212). Therefore, we reach the preliminary conclusion that the currently available evidence is not sufficient to support consideration of a separate indicator for a specific $PM_{2.5}$ component or source category of fine particles. Furthermore, we also reach the preliminary conclusion that the evidence is not sufficient to support eliminating any component or source from the mix of fine particles included in the $PM_{2.5}$ indicator.

We recognize that much research supported by EPA, the Health Effects Institute (HEI), the Electric Power Research Institute (EPRI), and others is underway to evaluate the role of $PM_{2.5}$ components/sources and agree that additional research is needed to improve future understanding of the role of specific fine particle components and/or sources of fine particles.

Summary

In considering whether currently available evidence provides support for retaining, revising, or supplementing the current $PM_{2.5}$ mass-based indicator, we first reach the preliminary conclusion that it is appropriate to retain $PM_{2.5}$ as the indicator for fine particles. Secondly, we reach the preliminary conclusion that the currently available evidence does not provide a sufficient basis for supplementing the mass-based $PM_{2.5}$ indicator by considering a separate indicator for ultrafine particles as a subfraction of fine particles. Furthermore, we also reach the preliminary conclusion that the currently available evidence is too limited to provide support for considering a separate indicator for a specific $PM_{2.5}$ component or source category of fine particles or for eliminating any individual component or source category from the mix of fine particles included in the $PM_{2.5}$ mass-based indicator.

2.3.2 Averaging Times

In the last review, EPA recognized that the available information related to exposure periods of concern was generally consistent and supportive of the conclusions reached in the review completed in 1997. In that review, the Agency retained two $PM_{2.5}$ standards, based on annual and 24-hour averaging times in order to provide protection for health effects associated with short- and long-term exposure periods (71 FR 61164, October 17, 2006). In this review, in evaluating alternative fine particle standards, we first address the element of the standard related to averaging time by asking the following question:

- **To what extent does the currently available information continue to provide support for the current 24-hour and annual averaging times?**

In considering whether the information available in this review supports consideration of different averaging times for $PM_{2.5}$ standards, we note that the available information is generally consistent with and supportive of the conclusions reached in the previous reviews to set a suite of $PM_{2.5}$ standards including standards with both annual and 24-hour averaging times. The overwhelming majority of studies conducted since the last review continue to utilize 24-hour and annual averaging times, and largely contribute to the body of evidence for health effects related to both short-term (from less than 1 day to up to several days) and long-term (from a year to several years) measures of $PM_{2.5}$. Consequently, our preliminary conclusion is that the currently available evidence continues to provide support for a 24-hour and annual averaging time.

With respect to a standard with an annual averaging time, we recognize that an annual standard would provide effective protection against both annual and multi-year, cumulative exposures that are associated with an array of health effects. With regard to providing protection for short-term fine particle exposures, we note that the large majority of short-term epidemiologic studies report associations based on 24-hour averaging times or on multiple-day averages (i.e., distributed lag). Furthermore, we recognize that a 24-hour standard can effectively protect against episodes lasting several days, as well as providing some degree of protection from potential effects associated with shorter duration peak levels of $PM_{2.5}$, and from episodes that result in localized or seasonal $PM_{2.5}$ exposures of concern in areas where the highest 24-hour-to-annual mean $PM_{2.5}$ ratios are appreciably above the national average. In consideration of the currently available evidence, we have focused on evaluating alternative standards in the quantitative risk assessment conducted for this review that retained the averaging times of the current standards (i.e, 24-hour and annual averaging times) (US EPA, 2010a)

In summary, we reach the preliminary conclusion that there is strong support in this review for retaining the current 24-hour and annual averaging times. We have then considered if

the currently available evidence provides support for supplementing the current averaging times with additional standards focused on subdaily, multi-day, or seasonal exposures by posing two more specific questions.

- **To what extent does the currently available scientific evidence provide support for considering a standard with an averaging time less than 24 hours to address health effects associated with subdaily fine particle exposures?**

In the last review, we recognized the availability of limited evidence of effects associated with exposure periods shorter than 24-hours (e.g., one to several hours) (US EPA, 2004, section 3.5.5.1) and concluded that, while this evidence was "too limited to serve as the basis for establishing a shorter-than-24-hour fine particle primary standard," it provided "added weight to the importance of a standard with a 24-hour averaging time" (71 FR 61164/2; US EPA, 2005, section 5.3.3). More specifically, the AQCD noted that while few epidemiological studies had used ambient PM concentrations averaged over time intervals shorter than 24 hours, several epidemiological studies reported statistically significant associations between 2- to 4-hour $PM_{2.5}$ concentrations and cardiovascular health endpoints, including myocardial infarction (MI) incidence and heart rate variability (HRV) (US EPA 2004, pp. 8-162 to 8-165). In particular, Peters et al (2001) reported effect estimates for MI incidence with $PM_{2.5}$ averaged over 2- and 24- hours that were similar in magnitude and statistically significant (US EPA 2004, p. 8-165).

In this review, a much larger body of more recent studies provide additional evidence of cardiovascular effects associated with exposure periods shorter than 24 hours (US EPA, 2009a, section 6.2). In this review, two studies that assessed sub-daily and daily exposures did not observe an association between $PM_{2.5}$ and risk of MI, however no association was evident with 24-hour exposures to $PM_{2.5}$ as well (US EPA, 2009a, p. 6-67; Sullivan et al., 2005; Peters et al., 2005). One study found a strong positive association between self-reported exposure to traffic and the onset of an MI within one hour, although this study did not directly measure traffic-related pollution (US EPA 2009a, p. 6-67; Peters et al. 2004). For cardiac arrests witnessed by bystanders, another study found a significant association with $PM_{2.5}$ exposure during the hour of the arrest, with even larger risk estimates for older adults (ages 60-75) or those that presented with asystole, a particular form of cardiac arrest when electrical activity in the heart stops (US EPA 2009a, p. 6-77; Rosenthal et al. 2008).

With respect to heart rate and HRV, epidemiological studies reported effects associated with pollutant concentrations lagged as short as 1 to 2 hours, but more consistently with lags of 24 to 48 hours. The results of several new controlled human exposure studies provide limited evidence to suggest that acute exposures (2-hour) to near ambient levels of concentrated ambient particles, or CAPs ($PM_{2.5}$, $PM_{10-2.5}$ and ultrafine particles) may be associated with small changes in HRV (USEPA, 2009a, p. 6-10). Changes in HRV parameters, however, are variable with

some showing increased parasympathetic activity relative to sympathetic activity and others showing the opposite. One study reported adverse associations of 2-hour exposures to PM_{10} with implantable cardiac defibrillator-detected ventricular arrythmias (US EPA, 2009a, p. 6-15; Ljungman et al., 2008). Two panel studies of elderly subjects found electrocardiogram changes typically representative of cardiac ischemia (S-T segment depression) significantly associated with exposures to $PM_{2.5}$ of less than 24 hours (US EPA 2009a, p. 6-21; Gold et al., 2005; Lanki et al. 2008).

With respect to vasomotor function, the systemic vasculature is likely to be a target organ. Endothelial dysfunction is a factor in many diseases and may contribute to the origin and/or exacerbation of perfusion-limited diseases, such as MI or ischemic heart disease (IHD), as well as hypertension. Endothelial dysfunction is also a characteristic feature of early and advanced atherosclerosis. Six studies found effects of exposures of 2 hours or less on other vasomotor outcomes.[34] The evidence on blood pressure changes is more mixed, with one panel study (Dales et al., 2007; EPA 2009, p. 6-35) finding no association with blood pressure changes with 2-hour exposures to traffic-related $PM_{2.5}$; while one panel and two controlled human exposure studies (US EPA, p. 6-37; Chuang et al., 2005; Urch et al., 2005 and Fakhri et al., 2009) reported changes in blood pressure from 1- to 3-hour exposures to submicrometer particles, and 2-hour exposures to a combination of O_3 and CAPs, respectively.

One panel study that investigated associations between ambient PM and markers of systemic inflammation among senior citizens ($\geq$ 60 years of age) (US EPA, 2009a, p. 6-41; Dubowsky et al., 2006), found positive associations between daily $PM_{2.5}$ levels and measures of C-reactive protein (CRP), interleukin-6 (IL-6), and white blood cells (WBCs). When the analysis was limited to exposures that occurred only on daily bus trips (2 hours), the effect estimates were similar in direction to the main analysis but were smaller in magnitude, with the authors expressing the view that this was likely due to greater measurement error. Another panel study assessed the effects of in-vehicle exposure to $PM_{2.5}$ of healthy young non-smoking male state troopers working from 3 PM to midnight (US EPA, 2009a, p. 6-41 and 6-48; Riediker et al., 2004). This study concluded that $PM_{2.5}$ originating from speed-changing traffic modulates the autonomic control of the heart rhythm, increases the frequency of premature supraventricular beats and elicits proinflammatory and pro-thrombotic responses in healthy young men. New studies involving controlled human exposures to various particle types have provided limited and inconsistent evidence of a PM-induced increase in markers of systemic inflammation (US EPA,

[34] Two studies (Dales et al. 2007; Rundell et al. 2007; US EPA 2009a, p. 6-25) found reductions in flow mediated dilatation (FMD) with 30-minute and 2-hour exposures to $PM_{2.5}$, respectively. Four other studies (Peretz et al., 2008; Lund et al., 2009; Rundell and Caviston, 2008; and Shah et al., 2008; US EPA 2009a, p. 6-28 to 6-29) found effects of exposures of 2 hours or less on other vasomotor outcomes, including brachial artery diameter (BAD), circulating levels of endothelin-1, and reactive hyperemia, respectively.

2009a, p. 6-46). New findings for hemostasis, thrombosis and coagulation from controlled human exposure studies have provided in consistent evidence that short-term exposure to PM at near ambient levels may have small, yet statistically significant effects on hemostatic markers in healthy subjects or people with coronary artery disease (US EPA, 2009a, p. 6-50).

With respect to respiratory health outcomes, in the last review, evidence of association between respiratory symptoms and subdaily exposures to PM_{10} was available from two US panel studies of symptoms in asthmatic subjects (US EPA 2004, section 8.3.3.1.1). These two studies used 1-hour and 24-hour average concentrations. The PM_{10} 1-hour outcome was larger than the 24-hour outcome for lower respiratory illness in one study, but the reverse was true for cough in the other study.

In this review, evidence of subdaily $PM_{2.5}$ exposures associated with respiratory diseases continues to be limited. The ISA concludes that for several studies of hospital admissions or medical visits for respiratory diseases, the strongest associations were observed with 24-hour average or longer exposures, not with less then 24-hour exposures (US EPA, 2009a, section 6.3). A study that examined evidence of respiratory effects associated with subdaily $PM_{2.5}$ exposures in two New York City communities by assessing the association between 24-hour and 1-hour maximum $PM_{2.5}$ levels and ED visits. This study reported an increase in asthma-related ED visits that was similar for the two time periods (New York State Department of Health, 2006). These results were robust to adjustment for copollutants. However, a panel study found an association between a 10 $\mu g/m^3$ increase in morning maximum 1-hour mean, but not daily, $PM_{2.5}$ concentrations and increased likelihood of rescue medication use in asthmatic children (US EPA 2009a, p. 6-90; Rabinovitch et al., 2006). Another study examined the association between a marker for pulmonary inflammation (exhaled nitric oxide, or eNO), and ambient $PM_{2.5}$ concentrations. Each 10 $\mu g/m^3$ increase in 1-hour mean $PM_{2.5}$ concentration was associated with a statistically significant increase in eNO among asthmatic children not taking inhaled corticosteroids (US EPA 2009, p. 6-101; Mar et al., 2005).

In summary, there is a rapidly growing body of studies that provide evidence for cardiovascular effects associated with subdaily exposure to PM, especially effects related to HRV, cardiac ischemia, and vasomotor function, and also of changes in markers of systemic inflammation, hemostasis, thrombosis and coagulation. Because these studies have used different indicators (e.g., $PM_{2.5}$, PM_{10}, $PM_{10-2.5}$, ultrafine particles), averaging times, and health outcomes, it is difficult to draw conclusions about cardiovascular effects associated specifically with subdaily exposures to $PM_{2.5}$. Although there is additional evidence of respiratory effects associated with $PM_{2.5}$ exposure periods shorter than 24-hours (e.g., one to several hours), this evidence is much sparser than for cardiovascular effects. Considering the currently available evidence, we reach the preliminary conclusion that this information is too unclear, with respect

to the indicator, averaging time and health outcome, to serve as a basis for establishing a shorter-than-24-hour $PM_{2.5}$ primary standard at this time. However, this evidence does provide added weight to the importance of a standard with a 24-hour averaging time. We recognize that the assessment of health effects associated with shorter-than-24-hour exposure is an important area of research that could provide a basis for the consideration of a subdaily PM standard in the future. We note that the availability of hourly $PM_{2.5}$ concentrations from the $PM_{2.5}$ continuous monitors reporting to the AQS should provide the basis for a clearer assessment of the effects of subdaily exposure to $PM_{2.5}$ in the future.

- **To what extent does the currently available scientific evidence provide support for considering separate standards with distinct averaging times to address effects associated with seasonal fine particle exposures?**

With regard to health effects associated with $PM_{2.5}$ exposure across varying seasons in this review, Bell et al. (2008) reported higher $PM_{2.5}$ risk estimates for hospitalization for cardiovascular and respiratory diseases in the winter compared to other seasons in a large, national multi-city study. In comparison to the winter season, smaller statistically significant associations were also reported between $PM_{2.5}$ and cardiovascular morbidity for spring and autumn, and a positive non-significant association was observed for the summer months. In the case of mortality, Zanobetti and Schwartz (2009) reported in their multi-city US based study a 4-fold higher effect estimate for $PM_{2.5}$ associated mortality for the spring as compared to the winter. These results suggest individuals are at greater risk of dying from higher exposures to $PM_{2.5}$ in the warmer months, and at greater risk of PM associated hospitalization for cardiovascular and respiratory diseases during colder months of the year. Overall, we observe that there are few studies presently available to deduce a general pattern in $PM_{2.5}$ risk across seasons. In addition, these studies utilized 24-hour exposure periods within each season to assess the $PM_{2.5}$ associated health effects, and do not provide information on health effects associated with a season-long exposure to $PM_{2.5}$. Due to these limitations in the currently available evidence, we reach the preliminary conclusion that there is no basis to consider a seasonal averaging time separate from a 24-hour averaging time.

Summary

In summary, we recognize that the currently available evidence informs our understanding of exposure durations of concern and continues to provide strong support for standards that provide protection for both short- and long-term exposures. In considering the possibility of effects associated with subdaily $PM_{2.5}$ exposures (i.e., less than 24-hour exposures) we recognize that there is additional evidence available in this review, primarily focused on cardiovascular effects with more limited evidence for respiratory effects. However, because these studies have used different indicators of PM exposure (e.g., $PM_{2.5}$, PM_{10}, UFPs), averaging times, and a broad

range of health outcomes, it is difficult to use this evidence to serve as a basis for establishing a standard with a shorter-than-24-hour averaging time. With respect to seasonal effects, while we recognize there is some new evidence for $PM_{2.5}$-related effects differentiated by season, we reach the preliminary conclusion that this evidence is, at this point, too limited to use as a basis for establishing a $PM_{2.5}$ standard with a seasonal averaging time. Based on the above considerations, we initially conclude that the currently available information provides strong support for retaining the current annual and 24-hour averaging times but does not provide support for alternative averaging times of less than 24-hours or for seasons

2.3.3 Forms

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. In this review, staff are evaluating whether currently available information support consideration of alternative forms for the annual or 24-hour $PM_{2.5}$ standards.

2.3.3.1 Form of the Annual Standard

In 1997, EPA established the form of the annual $PM_{2.5}$ standard as an annual arithmetic mean, averaged over 3 years, from single or multiple community-oriented monitors. This form was intended to represent a relatively stable measure of air quality and to characterize area-wide $PM_{2.5}$ concentrations. The arithmetic mean served to represent the broad distribution of daily air quality values, and a 3-year average provided a more stable risk reduction target than a single-year annual average. When setting the initial fine particle standards in 1997, the level of the annual $PM_{2.5}$ standard was to be compared to measurements made at the community-oriented monitoring site recording the highest level, or, if specific constraints were met[35], measurements from multiple community-oriented monitoring sites could be averaged (62 FR 38671 to 38672, July 18, 1997). The constraints for allowing the use of spatially averaged measurements were intended to limit averaging across poorly correlated or widely disparate air quality values to ensure that spatial averaging would not result in inequities in the level of protection provided by the $PM_{2.5}$ standards against health effects associated with short- and long-term $PM_{2.5}$ exposures (62 FR 38672). This approach was judged to be consistent with the epidemiologic studies on which the $PM_{2.5}$ standard was primarily based, in which air quality data were generally averaged across multiple monitors in an area or were taken from a single monitor that was selected to represent community-wide exposures, not localized "hot spots."

[35] The original criteria for spatial averaging included: (1) the annual mean concentration at each site shall be within 20 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 0.6 for each calendar quarter.

In the last review, in considering the form of the primary annual $PM_{2.5}$ standard, EPA posed the question as to whether an annual standard that allowed for spatial averaging, within the original specified or alternative constraints, would provide appropriate public health protection. Analyses conducted in the last review, based on a much larger set of $PM_{2.5}$ air quality data than was available for the review completed in 1997, assessed both aggregate population risk across an entire urban area and the potential for disproportionate impacts on potentially vulnerable populations within an area. The results of these analyses provided evidence concerning the potential for disproportionate impacts on potentially vulnerable populations, noting "the highest concentrations in an area tend to be measured at monitors located in areas where the surrounding population is more likely to have lower education and income levels, and higher percentages of minority populations" (71 FR 61166/2, see also US EPA, 2005, section 5.3.6.1; Schmidt et al., 2005, Attachment A/Analysis 7).[36]

In addition, the effect of allowing the use of spatial averaging on aggregate population risk was considered as part of the sensitivity analyses included in the health risk assessment conducted for the last review (US EPA, 2005, section 4.2.2). In that analysis, changing the basis of the annual standard design value from the concentration at the highest monitor to the average concentration across all monitors reduced the air quality adjustment needed to just meet the current or alternative annual standards. As expected, the estimated risks remaining upon attainment of the current annual standard in areas where the annual standards was the "controlling standard" were greater when spatial averaging was used than when the highest monitor was used (i.e., the estimated reductions in risk associated with just attaining the current or alternative annual standards are less when spatial averaging was used). The estimated mortality incidence associated with long-term exposure in most cases ranged from about 10 to 60% higher when spatial averaging was used, and estimated mortality incidence associated with short-term exposure in most cases ranged from about 5 to 25% higher. In light of these analyses, EPA retained the form of the standard as an annual arithmetic mean, averaged over 3 years with modifications that strengthened the standard by tightening the criteria for use of spatial averaging[37] to provide increased protection for vulnerable populations exposed $PM_{2.5}$.

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[36] As summarized in footnote 29 at 71 FR 61166/2, the 2004 AQCD noted that some epidemiologic studies, most notably the ACS study of associations between long-term $PM_{2.5}$ exposure and mortality, reported larger effect estimates in the cohort subgroup with lower education levels (US EPA, 2004, p 8-103). The 2004 AQCD also noted that lower education level may be a marker for lower socioeconomic status (SES) that may be related to increased vulnerability to the effects of fine particle exposures, for example, as a result of greater exposure from proximity to sources such as roadways and industry, as well as other factors such as poorer health status and access to health care (US EPA, 2004, section 9.2.4.5).

[37] The current criteria for spatial averaging include: (1) the annual mean concentration at each site shall be within 10 percent of the spatially averaged annual mean, and (2) the daily values for each monitoring site pair shall yield a correlation coefficient of at least 0.9 for each calendar quarter (71 FR 61167/2-3, October 17, 2006).

In this review, the currently available evidence provides stronger support that socioeconomic status (SES), measured using surrogates such as educational attainment, residential location, and income level, modifies the association between PM and morbidity and mortality outcomes. Thus, as discussed in section 2.2.1, the ISA concludes that susceptible populations include persons with lower SES levels. In light of this information and the analyses conducted for the last review as discussed above, we believe that the existing constraints on spatial averaging, as modified in 2006, may not be adequate to avoid substantially greater exposures in some areas, potentially resulting in disproportionate impacts on persons with lower SES levels. Therefore, we are reconsidering the appropriateness of continuing to allow spatial averaging across monitors as part of the form of the annual $PM_{2.5}$ standard. Recognizing that it is the link between the form and the level of a standard that determines the degree of public health protection the standard affords, we discuss consideration for eliminating the spatial averaging provisions from the form of the annual $PM_{2.5}$ standard in conjunction with consideration of alternative levels to address health effects related to long-term $PM_{2.5}$ exposures in section 2.3.4 below.

2.3.3.2 Form of the 24-Hour Standard

In 1997, EPA established the form of the 24-hour $PM_{2.5}$ standard as the 98th percentile of 24-hour concentrations at each population-oriented monitor within an area, averaged over three years (62 FR at 38671 to 38674, July 18, 1997). In making that decision, EPA recognized that a concentration-based form gave proportionally greater weight to days when concentrations were well above the level of the standard than to days when the concentrations were just above the standard. Further, a concentration-based form better compensated for missing data and less-than-every-day monitoring; and, when averaged over 3 years, it had greater stability and, thus, facilitated the development of more stable implementation programs. The Agency selected the 98^{th} percentile as an appropriate balance between adequately limiting the occurrence of peak concentrations and providing increased stability and robustness. In addition, by basing the form of the standard on concentrations measured at population-oriented monitoring sites, EPA intended to provide protection for people residing in or near localized areas of elevated concentrations.

In the last review, in conjunction with considering alternative 24-hour standard levels, EPA concluded it was appropriate to retain a concentration-based form that was defined in terms of a specific percentile of the distribution of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area, averaged over 3 years. In that review, in considering retaining the 98^{th} percentile form or revising the standard to a 99^{th} percentile from, the Agency evaluated the combination of form and level to provide appropriate public health protection and, in

particular, considered: (1) the relative risk reduction afforded by alternative forms at the same standard level, (2) the relative year-to-year stability of the air quality statistic to be used as the basis for the form of a standard, and (3) the implications from a public health communication perspective of the extent to which either form allows different numbers of days in a year to be above the level of the standard in areas that attain the standard. Based on these considerations, the Administrator concluded it was appropriate to retain the 98th percentile form of the 24-hour standard in conjunction with lowering the level of the standard. In reaching this final decision, EPA recognized a technical problem associated with a potential bias in the method used to calculate the 98th percentile concentration for this form. As such, EPA adjusted the sampling frequency requirement in order to reduce this bias. Accordingly, the Agency modified the final monitoring requirements such that areas that are within 5 percent of the standards are required to increase the sampling frequency to every day (71 FR 61164 to 61165, October 17, 2006).

In this first draft PA, we have focused consideration of alternative 24-hour $PM_{2.5}$ standards on alternative levels only, as discussed in section 2.3.5. In the second draft PA, we intend to explore more fully information regarding peak air quality concentrations to better inform our understanding of the implications of retaining or modifying the current form of the 24-hour standard.

2.3.4 Alternative Levels to Address Health Effects Related to Long-term $PM_{2.5}$ Exposures

In considering alternative $PM_{2.5}$ standards that would provide protection against health effects related to long-term exposures, we have taken into account both evidence-based and risk-based considerations. As discussed below, we first evaluate the available evidence from long-term $PM_{2.5}$ exposure studies, as well as the uncertainties and limitations in that evidence as presented in the ISA, to assess the degree to which alternative annual $PM_{2.5}$ standards can be expected to provide protection against effects related to long-term exposures (section 2.3.4.1). Secondly, we have considered the quantitative risk estimates associated with long-term $PM_{2.5}$ exposure, as discussed in the second draft RA, to assess the extent to which alternative standards can be expected to reduce the estimated risks attributable to long-term exposure to $PM_{2.5}$ (section 2.3.4.2). With respect to the suite of $PM_{2.5}$ standards, our preliminary integrated conclusions presented in section 2.3.6 are based in part on the conclusions from this section and in part on preliminary staff conclusions from section 2.3.5, in which alternative $PM_{2.5}$ standards to address health effects related to short-term $PM_{2.5}$ exposures are discussed.

2.3.4.1 Evidence-based Considerations

In taking into account evidence-based considerations for informing our understanding of alternative levels to address health effects related to long-term fine particle exposures, we have

initially focused on long-term $PM_{2.5}$ exposure studies conducted in the U.S. and Canada and placed the greatest weight on associations that have been judged in the ISA to be causal or likely causal. We have also considered the evidence for a broader range of health outcomes judged in the ISA to have suggestive evidence of a causal association or that focus on specific susceptible populations to evaluate whether this evidence provides support for considering lower alternative levels. Collectively, we have integrated the currently available evidence to address the following question:

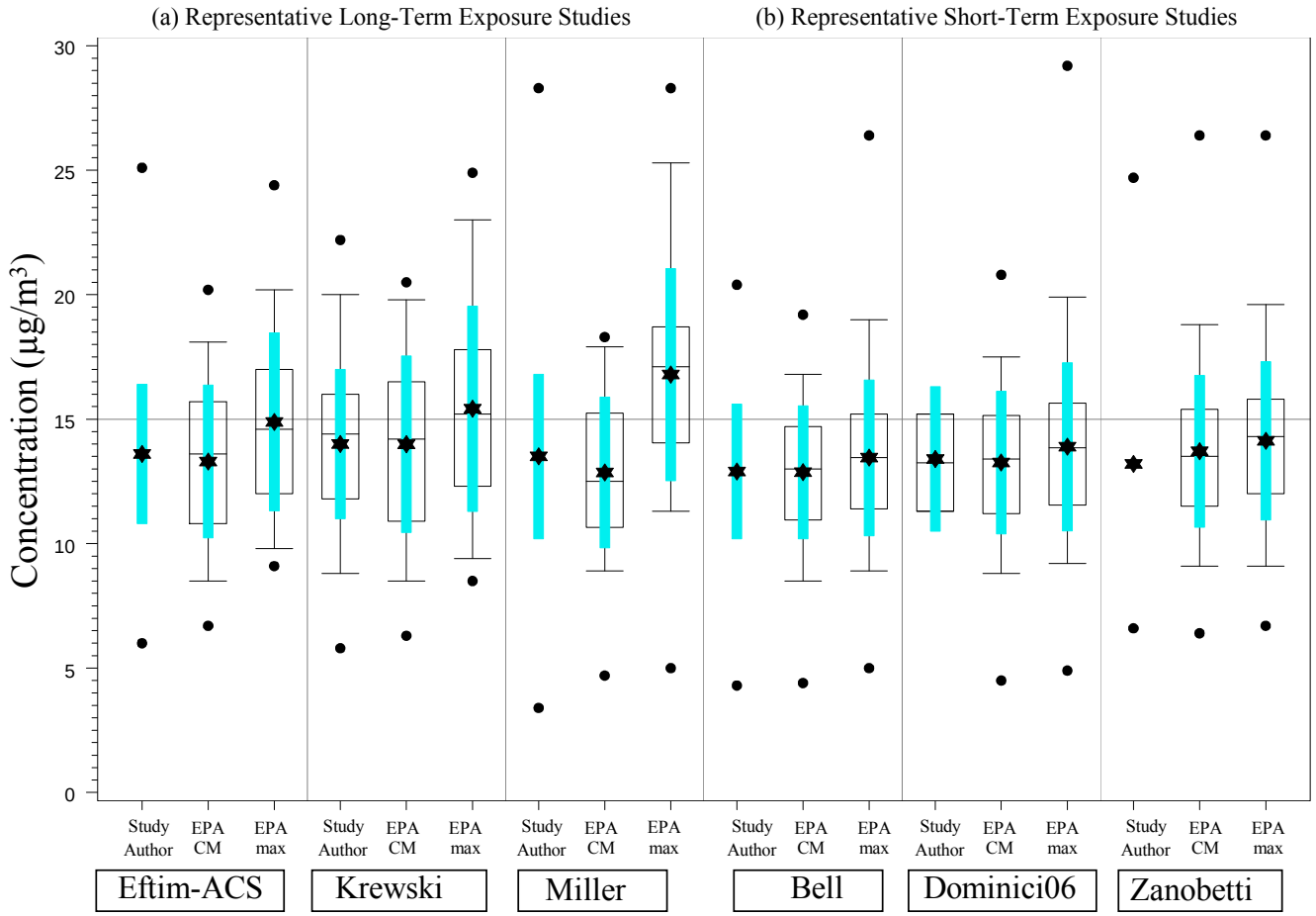
- **To what extent does the currently available evidence provide support for revising the current suite of standards to provide protection for long-term fine particle exposures?**

In looking first at evidence from long-term $PM_{2.5}$ exposure studies of mortality (causal association), we note, as discussed in section 2.2.1, that the extended follow-up analyses of the ACS and Harvard Six Cities studies, have confirmed and strengthened evidence of associations reported in the last review at lower air quality levels. In addition, new cohort studies, including the WHI evaluating cardiovascular-related mortality in postmenopausal women and analyses of mortality in a Medicare cohort, provide further evidence of effects associated with long-term $PM_{2.5}$ exposures at air quality levels in the same range as the more recent years of air quality data evaluated in the ACS and Harvard Six Cities extended follow-up studies.

As outlined in Figure 2-1 long-term mean $PM_{2.5}$ concentrations across all cities evaluated in each of these studies range from 10.7 to 16.4 $\mu g/m^3$.[38] In looking first at the long-term exposure mortality studies, we note that the long-term mean $PM_{2.5}$ concentration in the extended follow-up of the Harvard Six Cities study was 16.4 $\mu g/m^3$. As noted in section 2.2.1, in focusing on the extended follow-up period (1990-1998), we estimate an aggregate long-term mean $PM_{2.5}$ concentration across the six cities of 14.8 $\mu g/m^3$ (Laden, 2009). Eftim et al., (2008) evaluated mortality in a Medicare cohort consisting of adults age 65 and older, a susceptible population, within the same six cities using more recent air quality with a long-term mean of 14.1 $\mu g/m^3$. In the extended ACS study, the mean for the more recent time period used in the analysis (1999 to 2000) was 14.0 $\mu g/m^3$. In looking at the association based on the air quality for both time periods, the long-term mean $PM_{2.5}$ concentration was 17.1 $\mu g/m^3$ (Pope et al., 2004). Analysis of mortality associated with long-term $PM_{2.5}$ exposure using a Medicare cohort and the ACS locations using more recent air quality reported a long-term mean $PM_{2.5}$ concentration of 13.6 $\mu g/m^3$ (Eftim et al., 2008). Additional evidence of mortality associated with long-term $PM_{2.5}$ exposure in the MCAPS study across a larger number of counties (668 vs. 110 counties) using more extensive air quality data, provides evidence of effects in older adults, a susceptible population, at similar levels. This study included effect estimates for three geographic areas (i.e.,

[38] We note that Figure 2-1 also includes studies with substantially higher long-term mean $PM_{2.5}$ concentrations.

Figure 2-2. Distribution of study-specific area mean $PM_{2.5}$ concentrations.



Left plots represent the study author results; middle plots represent EPA replication results using a community monitor, CM, (spatial average) approach; and right plots represent EPA replication results using a maximum value approach (max monitor mean for each year averaged over the study timeframe). Black outlined boxes denote inter-quartile range and medians, stars denote means with cyan rectangles spanning +/- one standard deviation from the mean, and dots represent the minimum and maximum values.

eastern, central, western) with long-term median $PM_{2.5}$ concentrations ranging from 10.7 to 14.0 $\mu g/m^3$ (Zeger et al., 2008). In evaluating the air quality data considered in this study, we believe it is most appropriate to focus on the long-term median concentration across all cities which was reported as 13.2 $\mu g/m^3$ (Zeger et al., 2008). A cystic fibrosis cohort study of mortality reported a positive but not statistically significant mortality association with an aggregate long-term mean $PM_{2.5}$ concentration of 13.7 $\mu g/m^3$ in a susceptible population (Goss et al., 2004)

In considering new evidence for cardiovascular effects associated with long-term $PM_{2.5}$ exposure (causal association), we note the WHI reported positive and statistically significant effects at a long-term average across cities of 13.5 $\mu g/m^3$ (Miller et al, 2007). As noted above in section 2.2.1, this study considered the associations between long-term exposure to $PM_{2.5}$ and cardiovascular-related mortality as well as cardiovascular morbidity in post-menopausal women with no previous history of cardiac disease.

Furthermore, with respect to respiratory effects associated with long-term $PM_{2.5}$ exposure (likely causal association), the continued follow-up of the Southern California CHS's cohort study provides stronger evidence of decreased lung function growth in children, a susceptible population, that persisted into early adulthood at a long-term mean $PM_{2.5}$ concentration across 12 communities of 13.8 $\mu g/m^3$. McConnell et al., (2003) also reported a positive and statistically significant effect between long-term $PM_{2.5}$ concentrations and bronchitic symptoms as part of the Southern California CHS. These results are supported by a single-city cross-sectional study of bronchitic symptoms in school-aged children reported a positive and statistically significant association with long-term $PM_{2.5}$ concentrations of 12 $\mu g/m^3$ (Kim et al., 2004).

In considering alternative levels for an annual standard that would provide protection with an adequate margin of safety, we believe it is also appropriate to take into account evidence of effects for which the reported associations provide only suggestive evidence of a causal association, including, but not limited to, evidence of reproductive and developmental effects. With respect to emerging evidence on low birth weight and infant mortality, especially related to respiratory causes during the post-neonatal period, the ISA concludes that effects become "more precise and consistently positive in locations with mean $PM_{2.5}$ concentrations of 15 $\mu g/m^3$ and above" (US EPA, 2009a, p. 2-13; section 7.4). In particular, we note a recent study of postneonatal infant mortality which observed a positive and statistically significant association with an aggregate long-term mean $PM_{2.5}$ concentration of 14.8 $\mu g/m^3$ (Woodruff et al., 2008). We recognize that these effects are serious in nature and that data are continuing to emerge related to reproductive and developmental outcomes. At this time, however, the $PM_{2.5}$ concentrations reported in studies evaluating these effects report ambient levels that are equal to or greater than ambient levels observed in studies reporting mortality and cardiovascular and respiratory effects. Therefore, in selecting alternative levels, we note that in providing protection

for mortality and cardiovascular and respiratory effects, it is reasonable to anticipate that protection will also be provided for reproductive and developmental effects.

With respect to characterizing the concentration-response relationship for mortality associated with long-term $PM_{2.5}$ exposures, we first note, that in the last review, evidence was available to support a linear relationship. Using data from the ACS cohort, Pope et al., (2002) reported that the associations for all-cause, cardiovascular, and lung cancer mortality "were not significantly different from linear." In that study, the confidence intervals began to expand significantly starting around 13 to 12 $\mu g/m^3$, indicating greater uncertainty about the shape of the reported concentration-response relationship at and below this level (US EPA, 2004, Figure 8-7; US EPA 2005, Figure3-4). In this review, additional evidence supports a linear concentration-response relationship. Schwartz et al. (2008) used a variety of statistical methods and reported "the concentration-response curve was linear, clearly continuing below the level of the current U.S. air quality standard of 15 $\mu g/m^3$" (US EPA, 2009a, p. 7-92). No new evidence is available in this review to inform our understanding of the confidence intervals around the estimated concentration-response functions.

In considering what alternative levels would provide protection for effects observed in such long-term $PM_{2.5}$ exposure studies, we first recognize that the ISA has concluded that no discernable threshold for an effect associated with long-term $PM_{2.5}$ exposure can be identified based on the currently available evidence (US EPA 2009a, section 2.4.3). We recognize that health effects may occur over the full range of concentrations observed in the studies, however, we believe it is reasonable to conclude the evidence of association is strongest down to somewhat below the aggregated mean concentration, such as down to one standard deviation below the mean or to the lower end of the interquartile range, which includes the range in which the data in the study are most concentrated. This approach is consistent with considering the serious nature of the observed effects, including, but not limited to, mortality and cardiovascular effects for which there is strong evidence of a causal association as well as respiratory effects, for which there is strong evidence of a likely causal relationship. It also includes consideration of the range of long-term average concentrations across cities and the point where the data become less robust, suggestive of a concentration below which the association becomes appreciably more uncertain. In evaluating the long-term exposure studies, we recognize that the overall density of air quality concentrations becomes noticeable sparse below the range of air quality levels represented by the lower interquartile range or one standard deviation below the mean. In our view, an annual standard set below this range would be highly precautionary, giving little weight to the remaining uncertainties in the broader body of evidence, including the limited number of cities included in the long-term epidemiologic studies that reported long-term below the lower interquartile range.

As discussed in section 1.2.1, this approach is relevant to inform judgments about providing an adequate margin of safety to prevent pollution levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. As presented in Figure 2-1, the lower interquartile range of long-term average concentrations or one standard deviation below study mean air quality levels as reported in the long-term mortality studies for the most recent years evaluated, report air quality concentrations in the range from about 10 to 11 $\mu g/m^3$. With respect to considering air quality levels reported in the extended follow-up to the Southern California CHS, we recognize that using this approach, air quality levels one standard deviation below the mean across communities is significantly lower, about 6 $\mu g/m^3$, and close to or below the LML reported in the majority of the long-term mortality studies.

In considering not only the level but also the form of the annual standard[39], we acknowledge that there may be differences between mean $PM_{2.5}$ concentrations averaged across monitors within a city/county as is typically considered in epidemiologic studies, compared to the current form of the annual $PM_{2.5}$ standard which typically focuses on ambient measurements from the highest reporting community-oriented monitor. As such, we requested additional air quality distribution data from authors of specific epidemiologic studies in order to effectively place key epidemiologic studies in a policy-relevant context (Hassett-Sipple and Stanek, 2009). Data were received for some but not all studies for which information was requested. To broaden this data base, OAQPS conducted additional analyses for selected long-term $PM_{2.5}$ exposure studies to better understand air quality distributions averaged across monitors in comparison to air quality levels focused on the highest reporting monitors (Schmidt, 2010). These analyses focused on selected long-term mortality studies and, as presented in Table 2-4 Figure 2-2a, reported composite monitor values close to the long-term mean concentrations reported by the study authors.[40] As was expected, estimated air quality levels for the highest reported monitors, within a range of 14.9 $\mu g/m^3$ (Eftim et al., 2008) to 16.8 $\mu g/m^3$ (Miller et al, 2007), were higher than for the composite monitor values, within a range of 12.9 $\mu g/m^3$ (Miller et al., 2007) to 14.0 $\mu g/m^3$ (Krewski et al., 2009),. The most notable difference was reported for the WHI study which assessed only one year of air quality data (2000) for 36 study areas

[39] As summarized in section 2.3.3, the level of the annual $PM_{2.5}$ standard is to be compared to measurements made at the community-oriented monitoring site recording the highest level, or if specific constraints are met, measurements from multiple community-oriented monitoring sites could be averaged ("spatial averaging").

[40] As noted by Schmidt (2010), differences between long-term mean concentrations reported by the study authors and the parallel values in the EPA analyses may be related to the EPA assessment only encompassing Federal Reference and Federal Equivalent Method air quality data while the study authors may have included additional (non-reference/equivalent) data. Also, there may be additional differences in the sets of monitoring sites utilized due to uncertainties associated with the geographical area boundary definitions.

Table 2-4. Comparison of Air Quality Data for Selected Epidemiological Studies – Long-term Mean Concentrations[41]

Author Reported Data						EPA Analysis (Schmidt 2010)							
						Composite Monitor				Maximum Monitor			
Study	Cite	Years	Mean (SD)	Mean -1 SD	Range	Mean (SD)	Mean - 1SD	Lower end of IQR range (25%)	Range	Mean (SD)	Mean - 1SD	Lower end of IQR range (25%)	Range
Long-term Exposure Studies													
ACS - extended follow-up	Krewski et al 2009	1999-2000	14.0 (3.0)	11.0	5.8 - 22	14.0 (3.5)	10.5	10.9	6-21	15.4 (4.1)	11.3	12.3	9-25
Medicare -ACS	Eftim et al 2008	2000-2002	13.6 (2.8)	10.8	6-25	13.3 (3.1)	10.2	10.8	7-20	14.9 (3.6)	11.3	12.0	9-24
Women's Health Initiative	Miller et al 2007	2000	13.5 (3.3)	10.2	3.4 – 28	12.9 (3.0)	9.9	10.8	5-18	16.8 (4.3)	12.5	14.2	5-28
Short-term Exposure Studies													
MCAPS -Original	Dominici et al 2006	1999-2002	13.4 (2.9)	10.5	11.3-15.2 (IQR)*	13.3 (2.9)	10.4	11.2	5-21	13.9 (3.4)	10.5	11.6	5-29
-Extended	Bell et al 2008	1999-2005	12.9 (2.7)	10.2	4-20	12.9 (2.7)	10.2	11.0	4-19	13.4 (3.1)	10.3	11.4	5-26
National Mortality Study	Zanobetti & Schwartz, 2009	1999-2005	13.2 (2.9)	10.3	7-25	13.7 (3.0)	10.7	11.6	6-26	14.1 (3.2)	10.9	12.0	7-26

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[41] All concentrations reported as µg/m^3. * IQR = interquartile range

(average across monitors and across cities (composite monitor) of 12.9 $\mu g/m^3$, compared to an average of the highest reporting monitors across cities of 16.8 $\mu g/m^3$). When more study areas were considered and/or more years of air quality data were evaluated, the difference between the long-term mean for the composite monitor across cities compared to the long-term mean for the highest reporting monitor across cities was decreased.

In considering the currently available evidence, we reach the preliminary conclusion that the long-term $PM_{2.5}$ exposure studies provide a basis for considering alternative levels for the annual $PM_{2.5}$ standard within a range of about 13 $\mu g/m^3$ down to about 10 $\mu g/m^3$. A standard in the range of 13 to12 $\mu g/m^3$ would reflect placing weight on setting a level somewhat below the long-term mean $PM_{2.5}$ concentrations evaluated in long-term $PM_{2.5}$ exposure studies that show associations with mortality and cardiovascular and respiratory morbidity over a lower range of air quality levels than had been observed in the studies available in the last review. A standard in the range of 11 to 10 $\mu g/m^3$ would be consistent with a judgment that, recognizing the serious nature of the effects and that no discernable threshold for these effects can be identified, appreciable weight should be accorded to considering the lower interquartile range of long-term average concentrations within a study, or a range within one standard deviation around the study mean of either the composite monitor or the highest reporting monitor.

Furthermore, recognizing that there is a link between the form and the level of a standard that determines the degree of public health protection the standard affords, and in light of stronger evidence available in this review identifying persons with lower SES levels as a susceptible population as discussed in section 2.2.1, we recognize that the existing constraints on spatial averaging, as modified in 2006, may not be adequate to avoid substantially greater exposures in some areas, potentially resulting in disproportionate impacts on persons with lower SES levels. Therefore, we reach the preliminary conclusion that it is appropriate to consider a form of the annual $PM_{2.5}$ standards that does not allow for the use of spatial averaging across monitors such that the annual $PM_{2.5}$ standard would be compared to measurements made at monitoring sites that represent "community-wide air quality" recording the highest levels only. We plan to conduct additional air quality analyses to explore this issue to inform the second draft PA.

2.3.4.2 Risk-based Considerations

Beyond looking directly at the relevant epidemiologic evidence, staff have also considered the extent to which specific levels of alternative $PM_{2.5}$ standards are likely to reduce the estimated mortality risks attributed to long-term exposure to $PM_{2.5}$ and the uncertainties in the estimated risk reductions. We have based this evaluation on the results of the quantitative risk assessment presented in the second draft RA (US EPA, 2010a) and posed a series of questions to

aid in considering how the current suite of $PM_{2.5}$ standards might be revised to provide requisite public health protection.

- **To what extent do alternative standards reduce estimated risks associated with long-term $PM_{2.5}$ exposure compared to risks associated with simulating air quality to just meet the current standards? What roles do the current 24-hour and annual standards have in simulating the risks remaining upon just meeting the alternative suites of standards considered in the quantitative risk assessment? What level of confidence is associated with these risk estimates?**

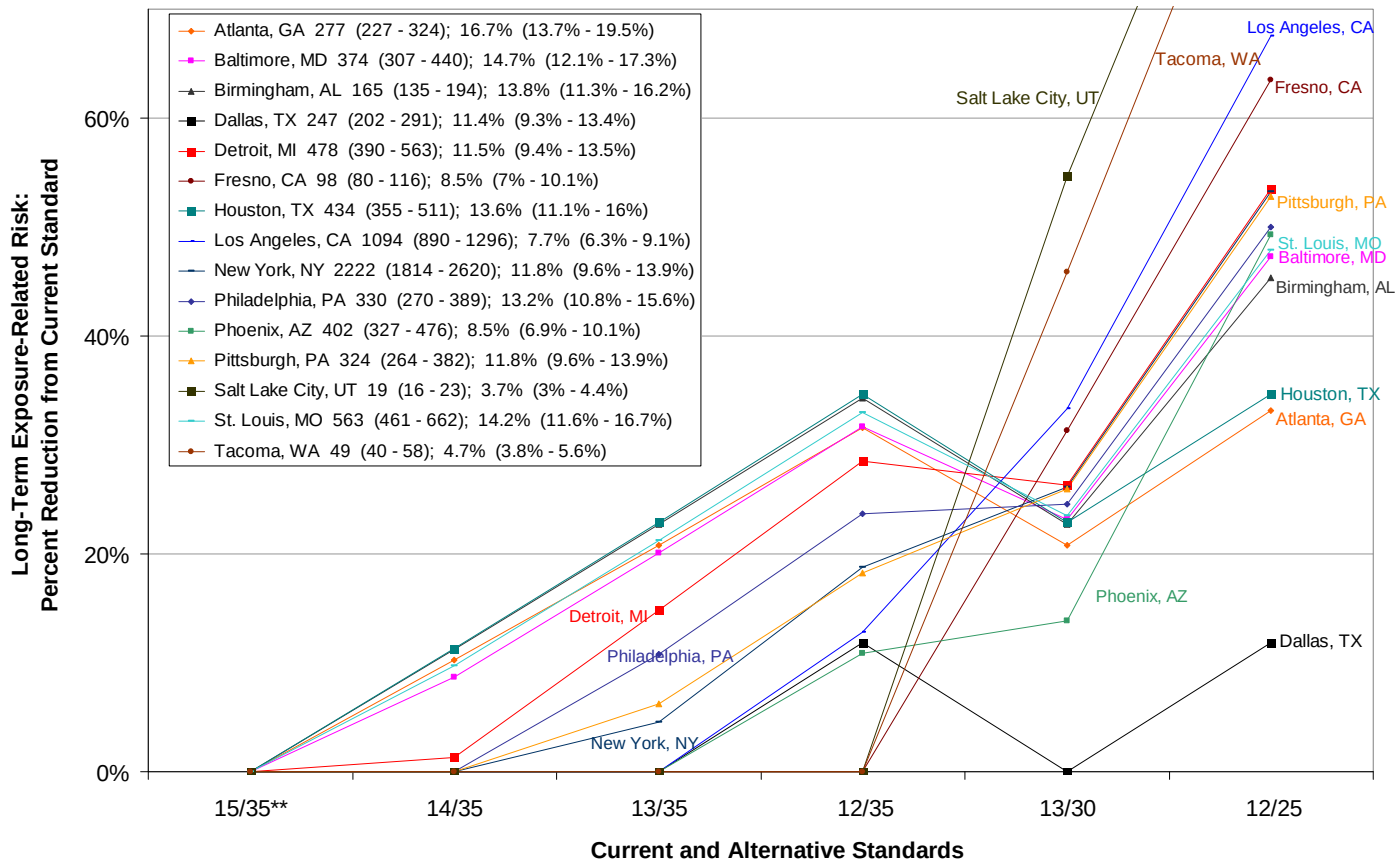
As noted in section 2.1.1, in summarizing risk estimates associated with long-term exposure-related mortality, we focus on IHD-related mortality due to greater overall support for a causal association with this endpoint. However, we note that risk estimates were also generated for all-cause, cardiopulmonary and lung cancer-related mortality. In presenting these results, we focus first on the degree of risk reduction (and estimates of risk remaining) upon simulation of the alternative annual standard levels considered in the risk assessment. We then discuss the nature and magnitude of risk reductions associated with alternative 24-hour standard levels. Contrasting the degree of risk reduction provided by the suites of alternative annual and 24-hour standards is covered in the overall summary discussion presented at the end of this section.

Risk reduction associated with alternative annual standards (14/35, 13/35, and 12/35)

In evaluating alternative standards, we first focused on consideration of different levels for the annual $PM_{2.5}$ standard (e.g., 14 $\mu g/m^3$, 13 $\mu g/m^3$, 12 $\mu g/m^3$) in conjunction with retaining the current level of the 24-hour standard (35 $\mu g/m^3$). We observed a consistent pattern of increasing risk reduction with decreasing alternative annual standard levels, both in terms of the number of urban study areas experiencing risk reductions and the magnitude of those reductions (US EPA, 2010a, section 6.2.2). Specifically, 5 of the 15 urban study areas experienced risk reductions under the alternative annual standard level of 14 $\mu g/m^3$, with percent reductions in $PM_{2.5}$-attributable long-term exposure-related mortality (relative to risk under the current suite of standards) ranging from 9% (Baltimore) to 12% (Houston and Birmingham) (Figure 2-3 and US EPA, 2010a, Appendix E, Table E-27). For an annual standard level of 12 $\mu g/m^3$, 12 of the 15 urban study areas experience risk reductions, with percent reductions (relative to risk under the current suite of standards) ranging from 11% (Phoenix) to 35% (Houston and Birmingham) (Figure 2-3 and US EPA, 2010a, Appendix E, Table E-27). Note, that even in the 12/35 case, three of the urban study areas (Tacoma, Fresno and Salt Lake City) did not experience any decreases in risk, although risk reductions were seen for these three study areas when alternative 24-hour standards were considered, as discussed below.

Figure 2-3. Percent reduction in long-term exposure-related mortality risk

(alternative standards relative to the current standards) (Note: inset shows $PM_{2.5}$ related incidence and percent of total incidence for IHD mortality under the current suite of standards)



*Based on Krewski et al. (2009), exposure period from 1999 – 2000. The legend contains, for each urban area, the incidence estimate (and 95% CI) and the estimate of percent of total incidence (and 95% CI) under the current standards.

**The current standards consist of an annual standard of 15 $\mu g/m^3$ and a daily standard of 35 $\mu g/m^3$. Combinations of an annual standard (n) and a daily standard (m) are denoted n/m in this figure.

***The percent reductions for Salt Lake City and Tacoma at the 12/25 standard are 100% and 93%, respectively.

While there is a consistent pattern of risk reduction across the alternative annual standards with lower standard levels resulting in more urban study areas experiencing increasingly larger risk reductions, there is considerable variability in the magnitude of these reductions across urban study areas for a given alternative annual standard level (e.g., as noted above, for the alternative annual standard level of 12 $\mu g/m^3$, risk reduction ranged from 11% for Phoenix to 35% for Houston). The variability in risk estimates reflects differing degrees of reduction in annual average $PM_{2.5}$ concentrations across the study areas. The differences in annual average concentrations result, in part, because the study areas begin with varying annual-average $PM_{2.5}$ concentrations after simulating just meeting the current suite of standards. Therefore, even if study areas have similar "ending" annual average $PM_{2.5}$, because the starting point in the calculation (i.e., the annual-average $PM_{2.5}$ concentrations upon just meeting the current suite of standards) is often variable, the overall reduction in annual-average $PM_{2.5}$ concentrations across the standards is also variable.[42]

The sensitivity analysis involving application of peak shaving rollback reveals that the pattern of reductions in ambient $PM_{2.5}$ concentrations upon just meeting the current suite of standards can impact the magnitude of additional risk reductions estimated for just meeting alternative (lower) annual standard levels. Specifically, for those study areas with more peaky $PM_{2.5}$ distributions[43], application of peak shaving rollback will result in higher annual-average $PM_{2.5}$ levels remaining upon just meeting the current suite of standards. If proportional rollback is then used to simulate just meeting alternative annual standard levels, a greater degree of reduction in annual-average $PM_{2.5}$ concentrations will result, since the "starting point" for the calculation (annual-average $PM_{2.5}$ levels upon just meeting the current suite of standards) will be higher. This translates into larger reductions in risk simulated for alternative annual standards when more localized patterns of $PM_{2.5}$ reduction are involved with simulating just meeting the current suite of standards. In instances where an urban study area has relatively peaky $PM_{2.5}$ concentrations, the difference in projected risk reduction for an alternative annual standard can be substantial. For example, with Los Angeles which has fairly peaky $PM_{2.5}$ levels, we predict a 13% reduction in long-term exposure-related mortality with the 12 $\mu g/m^3$ alternative annual standard (relative to risk under the current suite of standards) if we assume a regional pattern of $PM_{2.5}$ reductions for simulating just meeting the current standard as reflected in the application

[42] We note that additional variation in the risk estimates, in terms of both risk reduction across standard levels and residual risk for each of the alternative annual standard levels, results from differences across study areas in the relationship between the *maximum monitor annual-averages values* used in estimating percent reductions under an alternative standard and the *composite monitor annual-average values* used in estimating long-term exposure-related risk.

[43] The term "peaky" as used here, refers to urban study areas with relatively high 24-hour design values and lower annual average design values.

of proportional rollback. By contrast, we predict a 48% reduction in long-term exposure-related mortality risk if we assume a more localized pattern of reduction in ambient $PM_{2.5}$ levels, as reflected in the application of peak-shaving rollback (US EPA 2010a, section 6.2.2).

Regarding the magnitude of risk estimated to remain after simulation of alternative annual standards, the four study areas displaying the greatest degree of risk reduction across the range of alternative annual standard levels considered (Atlanta, Baltimore, Birmingham and Houston) have $PM_{2.5}$-related IHD mortality estimates (under the lowest alternative annual standard of 12/35) ranging from 85-110 (Birmingham) to 220-280 (Houston) (US EPA, 2010a, Appendix E, Table E-21 and E-30). The two urban study areas with the greatest degree of $PM_{2.5}$-related risk in absolute terms (Los Angeles and New York) do not exhibit significant reductions in risk until the lowest annual standard level of 12/35 is considered, with $PM_{2.5}$-related IHD mortality estimated at 750-950 and 1,420-1,800, respectively under that alternative standard (US EPA, 2010a, Appendix E, Table E-21 and E-30). In terms of the percentage of long-term mortality attributable to $PM_{2.5}$, we see the following levels for the alternative annual standard levels. For an annual standard level of 14 $\mu g/m^3$, the percent of total incidence of IHD mortality attributable to $PM_{2.5}$ in the 5 urban study areas experiencing risk reductions ranges from 9-11.3% (Detroit) to 11.8-14.9% (Atlanta) (US EPA 2010a, Appendix E, Tables E-24 and E-33). For an annual standard of 12 $\mu g/m^3$, estimated risk remaining in the 12 urban study areas experiencing risk reductions ranges from 6-7.6% (Phoenix) to 9-11.4% (Atlanta), again for $PM_{2.5}$-attributable long-term exposure-related mortality (US EPA 2010a, Appendix E, Tables E-24 and E-33).

We note that there is considerably less variability in the estimates of risk remaining after simulation of the alternative annual standards levels, compared with the magnitude of risk reductions across the study areas. This reflects the fact that study areas experiencing risk reductions under the alternative annual standards will have similar annual-average $PM_{2.5}$ levels given that this simulation involves annual standard levels that are controlling (i.e., these study areas have their annual-average $PM_{2.5}$ levels lowered to meet the same annual standard level).

Observations made earlier in section 2.1.1 in the context of the current suite of standards regarding uncertainty and its impact on risk estimates apply in this context as well. Specifically, given the results of the sensitivity analysis examining the form of the C-R functions for long-term exposure-related mortality, combined with only modeling risk down to the LML, we have increased confidence that we have not overstated either the magnitude of risk reductions across alternative standard levels, or the magnitude of risk remaining for a given standard level.

Risk reduction associated with alternative 24-hour standards (13/30 and 12/25)

We then focused on evaluating risks associated with long-term $PM_{2.5}$ exposures when varying the level of the 24-hour standard while holding the level of the annual standard constant.

Comparing risks associated with just meeting the 13/35 and 13/30 suites of alternative standards (which reflect a 5 $\mu g/m^3$ reduction in the 24-hour standard, while holding the annual fixed at 13$\mu g/m^3$), we see considerable variation in the magnitude of risk reduction across urban study areas. For example, St Louis, under the 13/35 suite of alternative standards has IHD mortality risk attributable to $PM_{2.5}$ reduced by 22% relative to risk under the current suite of standards. Very little additional risk reduction (increasing from 22% to 24%) is estimated under the 13/30 alternative suite of standards. In contrast, with Salt Lake City, we estimate that the 13/35 suite of alternative standards will produce no risk reduction relative to the current suite of standards, while the 13/30 suite would produce a 55% reduction in IHD mortality risk relative to risk under the current standard level (see Figure 2-3 and US EPA 2010a, Table E-27 in Appendix E).

The additional risk reduction provided by an alternative 24-hour standard is more substantial in comparing the 12/25 and 12/35 alternative suites of standards, although there is also greater variability in the magnitude of risk reductions across study areas. For example, Atlanta, which had a 32% reduction in risk under the 12/35 suite of standards (relative to the current standard level) only sees an marginal increase to 34% under the 13/25 suite of standards. By contrast, Salt Lake City, which has no reduction in risk under the 12/35 suite of standards (relative to the current suite of standards), sees a ~100% reduction in risk under the alternative suite of 12/25 (see Figure 2-3 and US EPA, 2010a, Appendix E, Table E-27). The reduction for Salt Lake City reflects a very high 24-hour design value which, when reduced to meet the 24-hour standard of 25 μg/m3 produced a substantial reduction in the annual design value (given application of the proportional adjustment to simulate rollback), such that the value was very close to 5.8 μg/m3 (the LML below which long-term exposure-related mortality is not estimated). The specific pattern of risk reduction reflects whether the 24-hour or annual standard was controlling (see discussion below regarding patterns of risk reduction). We also note, that under the 12/25 alternative suite of standards, we see that nine of the study areas (Detroit, Fresno, Los Angeles, New York, Philadelphia, Phoenix, Pittsburgh, Salt Lake City and Tacoma) have reductions in risk that are at least twice as large as for the 12/35 suite of alternative standards, with some substantially larger (see Figure 2-3 and US EPA, 2010a, Table E-27 in Appendix E).

Regarding risk remaining after simulation of the suite of alternative 24-hour standards, the four study areas displaying the greatest degree of reduction across these two alternative suites of standards (Tacoma, St. Louis, Los Angeles and Fresno), have $PM_{2.5}$-related IHD mortality estimates (under the 12/25 case) ranging from 3-4 (Tacoma) to 290-360 (Los Angeles) (US EPA, 2010a, Appendix E, Table E-21 and E-30). The other urban study area with the greatest degree of $PM_{2.5}$-related risk in absolute terms besides New York (New York) has $PM_{2.5}$-related all-cause mortality estimated at 820-1,040 under the 12/25 case. In terms of the percentage of long-term

mortality attributable to $PM_{2.5}$, we see that under the 13/30 suite of standards, the percent of total incidence of IHD mortality attributable to $PM_{2.5}$ ranges from 1.3 to 1.7% (Salt Lake City) to 10.4 to 3.2% (Atlanta) (US EPA, 2010a, Appendix E, Tables E-24 and E-33). Under the 12/25 alternative suite, risks for this metric range from ~0 to 0.3% (Salt Lake City) to 8.8 to 11.1% (Atlanta).

The observations presented above highlight variability both in the magnitude of risk reduction as well as in the risk remaining upon simulation of just meeting alternative 24-hour standards. This reflects the fact that, as noted earlier, alternative 24-hour standards can produce different degrees of reduction in the annual-average $PM_{2.5}$ concentrations, depending on the relationship between 24-hour and annual design values at a particular location. It is these annual-average $PM_{2.5}$ levels that drive changes in long-term exposure-related mortality. Those study areas with relatively peaky $PM_{2.5}$ levels, such as Salt Lake City, can see a substantial reduction in annual-average $PM_{2.5}$ levels under simulation of alternative 24-hour standards. By contrast, study areas with less peaky $PM_{2.5}$ levels, such as St. Louis, see substantially smaller reductions in annual-average $PM_{2.5}$ levels under the suite of alternative 24-hour standards and consequently lower degrees of risk reduction.

In addition, as noted earlier, in those instances where alternative 24-hour standards produce larger reduction in annual-average $PM_{2.5}$ levels (and consequently greater reductions in risk), often these reductions involve relatively low annual-average $PM_{2.5}$ levels. In some cases, such as with Salt Lake City, these annual-average $PM_{2.5}$ levels can approach the LML, which reduces our overall confidence in estimates of long-term exposure-related mortality for these locations.

Observations made earlier regarding the impact of variability in simulating changes in $PM_{2.5}$ distributions using different rollback approaches, and its impact on the degree of risk reduction, also hold for these simulations of alternative 24-hour standards. Specifically, in those instances where $PM_{2.5}$ distributions are more peaky, application of peak shaving rollback (reflecting more localized patterns of ambient $PM_{2.5}$ reduction) would result in smaller reductions in annual-average $PM_{2.5}$ concentrations and consequently, smaller reductions in estimates of long-term exposure-related mortality. For example, with Salt Lake City, which has a peaky $PM_{2.5}$ distribution, under the 12/25 suite of standards application of proportional rollback results in an annual average $PM_{2.5}$ concentration of 5.7 $\mu g/m^3$, while application of peak shaving results in an estimate of 8.9 $\mu g/m^3$ (as noted earlier, differences in annual-average $PM_{2.5}$ levels translate into differences in risk). In contrast, simulation of the 12/25 suite of standards for Baltimore, which has a less peaky $PM_{2.5}$ distribution, results in an annual average $PM_{2.5}$ concentration of 10.7 $\mu g/m^3$ for proportional rollback compared to 10.8 $\mu g/m^3$ with peak

shaving, implying that there would be little difference in risk (see US EPA, 2010a, Table F-49 in Appendix F).

Observations made earlier regarding overall confidence in the estimates of long-term exposure-related mortality also hold for these estimates (i.e., the sensitivity analysis results combined with the fact that we modeled risk down to LML result in our concluding that it is unlikely we have overstated either the degree of risk reduction or the degree of residual risk).

Summary

The results discussed above show that simulating just meeting alternative annual standard levels in the range of 14 to 12 $\mu g/m^3$ can produce substantial reductions in long-term exposure-related mortality risk (with the magnitude of risk reduction increasing as lower annual standards in this range are considered). Furthermore, the results suggest that alternative 24-hour standard levels in the range of 30 to 25 $\mu g/m^3$ can produce substantial reductions in estimated risk, beyond that produced by simulations of just meeting lower annual standard level down to 12 $\mu g/m^3$ (combined with a 24-hour standard of 35 $\mu g/m^3$). This results from the simulation of the alternative 24-hour standard levels producing substantially lower annual-average $PM_{2.5}$ concentrations, which drive reductions in both long-term and short-term exposure-related risk. However, the results also show that there can be considerable variability across study areas in the degree to which alternative 24-hour standard levels produce reductions in annual average $PM_{2.5}$ concentrations and, consequently, reductions in risk. This variability depends on the peakiness of the $PM_{2.5}$ distribution in an area and on the pattern of reductions in ambient $PM_{2.5}$ levels associated with just meeting the current and alternative suites of standards. Conversely, the analysis also suggests that more consistent annual-average $PM_{2.5}$ concentrations, and thus more consistent reductions in estimated risk and more uniform levels of public health protection would likely result from simulating just meeting alternative annual standards at levels below 12 $\mu g/m^3$ (i.e., below the lowest annual standard level considered in this assessment).

Furthermore, because the alternative 24-hour standard levels assessed resulted in lower simulated annual-average $PM_{2.5}$ levels (often approaching the LML used in modeling risk for long-term exposure-related mortality), we also conclude that there is greater uncertainty associated with risk estimates derived for the alternative 24-hour standards, relative to risks estimated for the alternative annual standards.

2.3.5 Alternative Levels to Address Health Effects Related to Short-term $PM_{2.5}$ Exposures

In considering alternative $PM_{2.5}$ standards that would provide protection against health effects related to short-term exposures, staff has taken into account both evidence-based and risk-based considerations. First, as discussed in section 2.1.3, it is our view that the evidence from studies of short-term exposure to $PM_{2.5}$ can help inform consideration of the protection afforded

by both a 24-hour and an annual standard (section 2.3.5.1). Secondly, we have considered the results of the quantitative risk assessment presented in the second draft RA (US EPA, 2010a) to assess the extent to which alternative annual and/or 24-hour standards can be expected to reduce the estimated risks attributable to short-term exposure to $PM_{2.5}$ (section 2.3.5.2). With respect to considering the protection afforded by the suite of $PM_{2.5}$ standards, our preliminary integrated conclusions presented in section 2.3.6 are based in part on the preliminary staff conclusions from this section and in part on preliminary staff conclusions from section 2.3.4 in which we discuss alternative standards to address health effects related to long-term $PM_{2.5}$ exposures.

2.3.5.1 Evidence-based Considerations

In taking into account evidence-based considerations for informing our understanding of alternative levels to address health effects related to short-term fine particle exposures, we initially focused on short-term multi-city $PM_{2.5}$ exposure studies. We observe that multi-city studies assessed $PM_{2.5}$-associated health effects among larger study populations, providing enhanced power to detect $PM_{2.5}$-associated health effects. In addition, short-term multi-city $PM_{2.5}$ exposure studies generally provide spatial coverage for different regions across the country, reflecting differences in $PM_{2.5}$ sources, composition, and potentially other factors which might impact $PM_{2.5}$-related risk. We have also evaluated short-term single-city $PM_{2.5}$ exposure studies that provide additional insights on associated health effects occurring at or below the $PM_{2.5}$ concentrations reported in the short-term multi-city $PM_{2.5}$ exposure studies, specifically in areas that may have unusually high peak-to-mean ratios of $PM_{2.5}$ concentrations, possibly associated with strong local or seasonal sources of fine particles.

In considering a range of health outcomes, we place the greatest weight on associations that have been judged in the ISA to be causal or likely causal, while being mindful of evidence that informs our understanding of impacts on susceptible populations.[44] We have considered a number of factors including: (1) the extent to which these studies report statistically significant and relatively precise relative risk estimates; (2) the extent to which the reported associations are robust to co-pollutant confounding; and (3) the extent to which the studies used relatively reliable air quality data. In particular, we focused on those specific studies conducted in the U.S. and Canada, briefly summarized in section 2.2.1 and presented in more detail in chapter 6 of the ISA, that provide evidence of associations in areas that would likely have met the current 24-

[44] In contrast to causal inferences for effects associated with long-term $PM_{2.5}$ exposures, the ISA has not identified any health outcomes as having evidence *suggestive* of a causal association with short-term $PM_{2.5}$ exposures. Thus, the discussion of evidence-based considerations in this section focuses on those effects for which the ISA has determined there is a causal or likely causal association with short-term $PM_{2.5}$ exposures only.

hour $PM_{2.5}$ standards during the time of the study.[45] We believe that this body of evidence can serve as a basis for considering alternative 24-hour and annual $PM_{2.5}$ standards that would provide appropriate protection for health effects associated with short-term $PM_{2.5}$ exposures.

Collectively, we have considered the evidence to address the following question:

- **To what extent does the currently available evidence provide support for revising the current suite of standards to provide protection from short-term fine particle exposures?**

In considering what alternative levels would provide protection for effects associated with short-term $PM_{2.5}$ exposure, we first recognize that the ISA has concluded that no discernable threshold, or lowest-observed-effect levels, can be identified based upon the currently available evidence (US EPA, 2009a. section 2.4.3). Being mindful of the challenges posed by issues relating to threshold and background concentrations, we have considered two alternative approaches for using the evidence from short-term exposures studies to inform preliminary staff conclusions regarding alternative standard levels. First, in considering an approach in which the 24-hour standard to set to be the primary means for providing protection for health effects associated with short-term exposures to $PM_{2.5}$, we considered evidence from short-term exposure epidemiological studies as a basis for an alternative 24-hour $PM_{2.5}$ standard. Specifically, we focused on the upper end of the distributions of 24-hour $PM_{2.5}$ concentrations, particularly in terms of the highest 98^{th} percentile values for a location, reflecting the form of the current 24-hour standard.

Alternatively, we have also considered an approach in which the annual standard is set to be the primary means for providing protection for effects associate with both long and short-term $PM_{2.5}$ exposures. This approach recognizes that, as noted in previous reviews, much of the risk related to daily exposures, when aggregated on an annual basis, results from the large number of days during which the 24-hour average concentrations are in the low- to mid-range of the entire distribution. Thus, to reduce the aggregate short-term exposure-related risk, it is necessary to shift the bulk of the distribution to lower concentrations, not just to limit the concentrations on days when the $PM_{2.5}$ concentrations are relatively high (US EPA, 2005, p. 4-67, Figure 4-10; Abt, 1996, section 7.1, p.79, Exhibit 7.6). This approach reflects consideration for allowing the annual standard to serve in most areas as the target for control programs designed to be effective in lowering the broad distribution of $PM_{2.5}$ concentrations, thus protecting not only against effects associated with long-term exposures but also effects associated with short-term

[45] As noted in section 2.3.4.1 above, we requested additional air quality distribution data from authors of specific epidemiological studies. To inform alternative standard levels to provide protection for effects associated with short-term $PM_{2.5}$ exposures, we were particularly interested in 98^{th} percentile and long-term mean $PM_{2.5}$ concentrations considered in short-term exposure studies. In focusing on the current forms of the 24-hour and annual standards, we were also interested in information related to the highest reporting monitors.

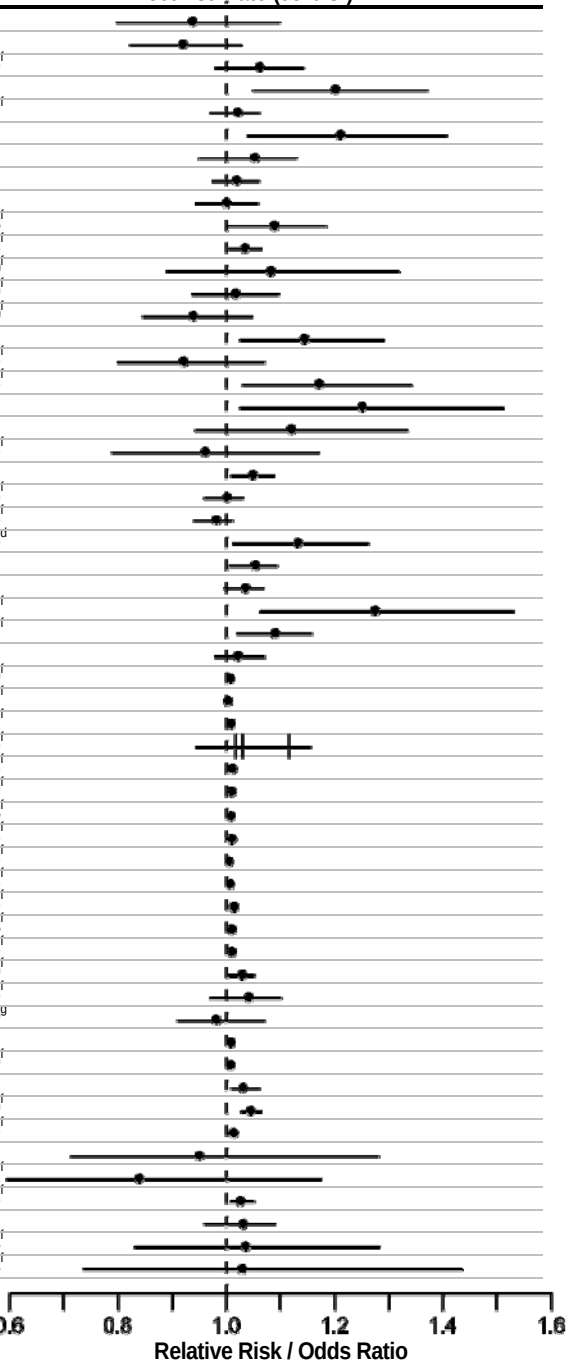
exposures. This judgment reflects the recognition that changes in $PM_{2.5}$ air quality designed to meet an annual standard would likely result not only in changes in lower annual average concentration but also in fewer and lower peak 24-hour concentrations. In exploring this alternative approach, we considered the evidence from the currently available short-term exposure studies, specifically the long-term mean $PM_{2.5}$ concentrations from these studies as a basis to inform preliminary conclusions for alternative levels for an annual $PM_{2.5}$ standard. Furthermore, we recognize that if the primary purpose of the annual standard was to provide protection for effects associated with both long- and short-term exposures, the purpose of the 24-hour standard would than shift. In that case, the primary purpose of the 24-hour standard would be to serve to provide supplemental protection to provide additional protection beyond the protection afforded by the annual standard in areas with unusually high peak-to-mean ratios of $PM_{2.5}$ concentrations, possibly associated with strong local or seasonal sources.

In first considering the approach of using the 24-hour standard as the primary means for providing protection for health effects associated with short-term exposures to $PM_{2.5}$, we look to the 98th percentile air quality values for specific short-term exposure studies to inform our consideration of alternative standard levels (see Figure 2-4). With respect to mortality evidence (causal association) from multi-city short-term exposure studies, we note that, as discussed in section 2.2.1, Zanobetti and Schwartz (2009) and Burnett et al. (2004) reported a 24-hour 98th percentile $PM_{2.5}$ concentration averaged across all cities and all years of 34.3 $\mu g/m^3$ and 38.0 $\mu g/m^3$, respectively. As presented in the ISA, despite large differences in air quality concentrations, Zanobetti and Schwartz (2009) reported "all-cause mortality risk estimates that were fairly uniform across the climatic regions, except for the 'Mediterranean' region"[46] (US EPA, 2009a, p. 6-178, Figure 6-24).

With regard to the evidence from studies assessing short-term exposure to $PM_{2.5}$-associated with cardiovascular (causal association) and respiratory (likely causal association) morbidity effects, recent multi-city analysis of MCAPS data by Dominici et al. (2006a) and Bell et al. (2008) reported an overall 24-hour average 98th percentile $PM_{2.5}$ concentration across all cities and all years of 34.8 $\mu g/m^3$ and 34.2 $\mu g/m^3$, respectively. As noted in section 2.2.1, an unpublished sub-analysis of Dominici et al (2006a) restricted to days with 24-hour average concentrations at or below the level of the current 24-hour standard (35 $\mu g/m^3$) indicated that, in spite of a reduced statistical power from a smaller number of study days, statistically significant associations were still observed between short-term $PM_{2.5}$ exposure and hospital admissions for cardiovascular and respiratory diseases (Dominici, 2006b).

[46] The Mediterranean region included cities in OR, CA, and WA.

Study	Outcome	Mean[a]	98th[a]
Chimonas & Gessner (2007, 093261)	Asthma HA	6.1	
	LRI HA	6.1	
Lisabeth et al. (2008, 155939)	Ischemic Stroke/TIA HA	7.0[e]	23.6[f]
Slaughter et al. (2005, 073854)	Asthma Exacerbation	7.3[e]	
Rabinovitch et al. (2006, 088031)	Asthma Medication Use	7.4	17.2[f]
Chen et al. (2004, 087262)	COPD HA	7.7	
Chen et al. (2005, 087942)	Respiratory HA	7.7	
Fung et al. (2006, 089789)	Respiratory HA	7.7	
Villeneuve et al. (2003, 055051)	Nonaccidental Mortality	7.9	
Stieb et al. (2000, 011675)	CVD ED Visits	8.5	27.3[f]
	Respiratory ED Visits	8.5	27.3[f]
Villeneuve et al. (2006, 090191)	Hemhrgc Stroke HA	8.5	24.0[f]
	Ischemic Stroke HA	8.5	24.0[f]
	TIA HA	8.5	24.0[f]
Lin et al. (2005, 087828)	RTI HA	9.6	
Mar et al. (2004, 057309)	Respiratory Symptoms (any)	9.8[c]	25.8[f]
	Respiratory Symptoms (any)	9.8[c]	25.8[f]
Rich et al. (2005, 079620)	Ventricular Arrhythmia	9.8[e]	
Dockery et al. (2005, 078995)	Ventricular Arrhythmia	10.3[e]	
Rabinovitch et al. (2004, 096753)	Asthma Exacerbation	10.6[d]	29.3[f]
Pope et al. (2006, 091246)	IHD HA	10.7[c]	
Slaughter et al. (2005, 073854)	CVD HA	10.8	29.6[f]
	Respiratory ED Visits	10.8	29.6[f]
Pope et al. (2008, 191969)	CHF HA	10.8	44.5[d]
Zanobetti and Schwartz (2006, 090195)	MI HA	11.1[e]	
	Pneumonia HA	11.1[e]	
Peters et al. (2001, 016546)	MI	12.1	28.2[f]
Delfino et al. (1997, 082687)	Respiratory HA (summer)	12.1	31.2[f]
Sullivan et al. (2005, 050854)	MI	12.8	
Burnett et al. (2004, 086247)	Nonaccidental Mortality	12.8	38.0[f]
Bell et al. (2008, 156266)	Respir HA	12.9[d]	34.2[f]
	CVD HA	12.9[d]	34.2[f]
Wilson et al. (2007, 157149)	CVD Mortality	13.0	31.6[f]
Zanobetti & Schwartz (2009, 188462)	Nonaccidental Mortality	13.2[d]	34.3[f]
Burnett and Goldberg (2003, 042798)	Nonaccidental Mortality	13.3	38.9[f]
Dominici et al. (2006, 088398)	CBVD HA	13.3	34.8[f]
	PVD HA	13.3	34.8[f]
	IHD HA	13.3	34.8[f]
	Dysrhythmia HA	13.3	34.8[f]
	CHF HA	13.3	34.8[f]
	COPD HA	13.3	34.8[f]
	RTI HA	13.3	34.8[f]
Fairley (2003, 042850)	Nonaccidental Mortality	13.6	59.0[f]
Zhang et al. (2009, 191970)	ST Segment Depression	13.9[j]	37.6[f]
O'Connor et al. (2008, 156818)	Wheeze/Cough	14.0[c]	39.0[g]
Klemm and Mason (2003, 042801)	Nonaccidental Mortality	14.7[e,j]	
Franklin et al. (2008, 097426)	Nonaccidental mortality	14.8	43.0[f]
NYDOH (2006, 090132)	Asthma ED Visits	15.0[k]	
Ito et al. (2007, 156594)	Asthma HA	15.1	39.0[f]
Franklin et al. (2007, 091257)	Non-accidental Mortality	15.6	45.8[f]
Rich et al. (2006, 089814)	Ventricular Arrhythmia	16.2[e]	
Symons et al. (2006, 091258)	CHF HA	16.5[d]	50.1[f]
Sheppard (2003, 042826)	Asthma HA	16.7	46.6[f]
NYDOH (2006, 090132)	Asthma ED Visits	16.7[l]	
Burnett et al. (1997, 084194)	Respiratory HA (summer)	16.8	47.4[f]
	CVD HA (summer)	16.8	47.4[f]



a μg/m^3
b Study did not present mean; median presented.
c Mean estimated from data in study.
d Mean value slightly different from those reported in the published study or not reported in the published study; mean was either provided by study authors or calculated from data provided by study authors.
e Mean value not reported in study; median presented.
f 98th percentile of $PM_{2.5}$ distribution was either provided by study authors or calculated from data provided by study authors.
g 98th estimated from data in study.
h Averaged annual values for years in study from data provided by study author.
i Air quality data obtained from original study: Schwartz et al. (1996, 077325).
j Mean $PM_{2.5}$ concentration reported is for lag 0-2.
k Bronx; TEOM data.
l Manhattan; TEOM data.
m Study does not present an overall effect estimate; the vertical lines represent the effect estimate for each of the areas of Phoenix examined.

Figure 2-4. Summary of Effect Estimates (per 10 μg/m^3) and Air Quality Distributions for Short-term Exposure Studies

Source: US EPA, 2009a, Figure 2-1.

In looking at short-term single-city $PM_{2.5}$ exposure studies conducted in areas that would have met the current level of the 24-hour standard, we recognize that these studies can provide additional insights regarding impacts on susceptible populations and/or on areas with isolated peak concentrations that could occur in areas that attain the current 24-hour and annual standards. We first consider studies that report positive and statistically significant associations. One short-term single-city $PM_{2.5}$ exposure study conducted since the last review reported a positive statistically significant association for short-term $PM_{2.5}$ exposures in relation to respiratory symptoms among children in Phoenix with an average 98th percentile value of 25.8 $\mu g/m^3$ (Mar et al., 2004). In addition, another short-term single-city $PM_{2.5}$ exposure a study noted in the last review also reported a positive statistically significant association between short-term exposure to $PM_{2.5}$ and myocardial infarction in Boston with an average 98th percentile value of 28.2 $\mu g/m^3$ (Peters et al., 2001).

In also considering short-term single-city $PM_{2.5}$ exposure studies that report positive but statistically non-significant associations for cardiovascular and respiratory endpoints in areas that would have met the current 24-hour $PM_{2.5}$ standard, we note a number of studies conducted in Montreal (respiratory hospital admissions; Delfino et al., 1997), Saint John (CVD and respiratory hospital admissions; Steib et al., 2000), Phoenix (CVD mortality; Wilson et al., 2007), Denver (asthma medication use; Rabinovitch et al., 2006), Edmonton (hemorrhagic and ischemic stroke hospital admissions; Villeneuve et al., 2006), and Nueces County, TX (ischemic stroke/transient ischemic attack; Lisabeth et al., 2008). We note that the 98th percentile values reported in these studies averaging across monitors in a city/county range from approximately 17.2 $\mu g/m^3$ (Rabinovitch et al., 2006) in Denver to 31.6 $\mu g/m^3$ (Wilson et al, 2007) in Phoenix. However, other short-term single-city $PM_{2.5}$ exposure studies report null findings for health effects noted above (i.e., cardiovascular and respiratory morbidity) as being positively associated with short-term exposure to $PM_{2.5}$ in areas that would have met the current level of the 24-hour $PM_{2.5}$ standard, including Phoenix (respiratory symptoms in adults; Mar et al., 2004); Spokane (CVD hospital admissions and respiratory ED visits; Slaughter et al. 2005), Denver (asthma exacerbation; Rabinovitch et al., 2004) and Edmonton (ischemic stroke and transient ischemic attack hospital admissions; Villeneuve et al., 2006).

In considering information from both multi- and single-city short-term $PM_{2.5}$ exposure studies as summarized in Figure 2-4, we believe that the range of alternative 24-hour $PM_{2.5}$ standards appropriate for consideration should extend below the range of 98th percentile values averaged across cities from the multi-city studies identified above so as to provide protection from effects associated with short-term $PM_{2.5}$ exposure. In light of the mixed findings reported in single-city studies, particularly for studies conducted in areas such as Phoenix, Denver, and Edmonton that report both positive and null findings, we place comparatively greater weight on

the results from multi-city studies for the reasons previously noted at the beginning of this section. Specifically, the heightened statistical power of multi-city studies to detect $PM_{2.5}$ associated health effects in aggregated analysis across cities and greater spatial coverage for different regions across the country to account for variations in $PM_{2.5}$ composition, sources, and potentially other factors which might impact $PM_{2.5}$-related risk. However, we note that 98th percentile values reported in single-city studies may provide additional insights for consideration in identifying alternative standards to provide protection for potentially susceptible populations. Specifically, as noted above, Mar et al. (2004) provides evidence of a statistically significant association between a 98th percentile $PM_{2.5}$ level of 25.8 $\mu g/m^3$ and respiratory symptoms among children.

In recognition that the current form of the 24-hour standard discussed in section 2.3.3.2 applies to the measurements made at each population-oriented monitor, OAQPS conducted additional air quality analyses for selected multi-city short-term $PM_{2.5}$ exposure studies to better understand air quality distributions averaged across monitors by the study investigators in comparison to air quality levels focused on the highest reporting monitors (Schmidt, 2010). These analyses, as noted in section 2.3.4.1, focused on selected mortality and hospitalization studies and, as presented in Table 2-5 and Figure 2-5, yielded composite monitor values close to the 98th percentile concentrations reported to the EPA by the study authors (ranging from 34.2 $\mu g/m^3$ (Bell et al 2008) to 34.8 $\mu g/m^3$ (Dominici et al., 2006).[47] As was expected, estimated air quality levels for the highest reported monitors, ranging from 35.4 $\mu g/m^3$ (Bell et al, 2008) to 38.9 $\mu g/m^3$ (Dominici et al 2007) were higher than for the composite monitor values, ranging from 33.5 $\mu g/m^3$ (Bell et al, 2008) to 36.5 $\mu g/m^3$ (Zanobetti and Schwartz, 2009). When more study areas were considered and/or more years of air quality data were evaluated, the difference between the 98th percentile values for the composite monitor across cities compared to the 98th percentile for the highest reporting monitor across cities was decreased.

Based on the epidemiological evidence and air quality analyses summarized above, in considering the 24-hour standard to be the primary means to provide protection for short-term $PM_{2.5}$ exposures, we reach the preliminary conclusion that alternative levels could be considered in the range of approximately 35 to 25 $\mu g/m^3$. A level selected at the upper end of this range would reflect consideration of a level somewhat below the 98th percentile values for the highest reporting monitors in the multi-city studies (ranging from about 35 to 39 $\mu g/m^3$) and just below the 98th percentile values averaged across all cities and all years in these studies (in the range of

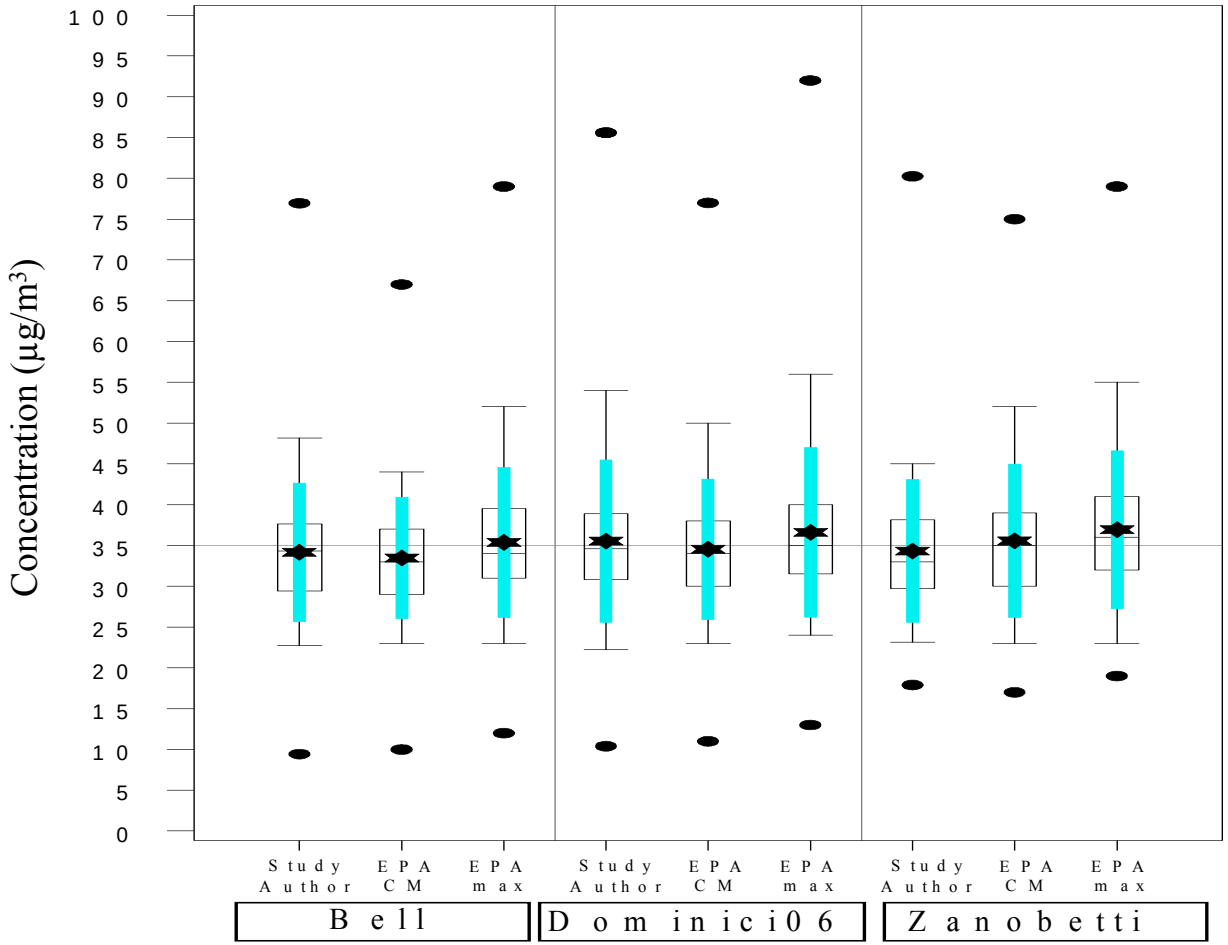
[47] As noted by Schmidt (2010), differences between 24-hour 98th percentile and long-term mean concentrations reported by the study authors and the parallel values in the EPA analyses may be related to the EPA assessment only encompassing Federal Reference and Federal Equivalent Method air quality data while the study authors may have included additional (non-reference/equivalent) data. Also, there may be additional differences in the sets of monitoring sites utilized due to uncertainties associated with the geographical area boundary definitions.

Table 2-5. Comparison of Air Quality Data for Selected Epidemiological Studies– 98 Percentile Values[48]

Author Reported Data					EPA Analysis (Schmidt 2010)			
					Composite Monitor		Maximum Monitor	
Study	**Cite**	**Years**	**98%**	**Range**	**98%**	**Range**	**98%**	**Range**
MCAPS -Original	Dominici et al 2006	1999-2002	34.8	10-86	34.5	11-77	36.6	13-92
-Extended	Bell et al 2008	1999-2005	34.2	9-77	33.5	10-67	35.4	12-79
National Mortality Study	Zanobetti & Schwartz, 2009	1999-2005	34.3	18-80	35.6	17-75	36.9	19-79

[48] All concentrations reported as μg/m^3.

Figure 2-5. Distribution of Study-specific 98th Percentile Concentrations



Left plots represent the study author results; middle plots represent EPA replication results using a community monitor, CM, (spatial average) approach; and right plots represent EPA replication results using a maximum value approach (max monitor 98th percentile for each year averaged over the study timeframe). Black outlined boxes denote inter-quartile range and medians, stars denote means with cyan rectangles spanning +/- one standard deviation from the mean, and dots represent the minimum and maximum values.

about 34 to 35 $\mu g/m^3$). A level selected at the lower end of this range would reflect consideration of a level just below the lowest 98th percentile value associated with statistically significant effects in a single-city study reporting effects in children, identified as a susceptible population (Mar et al., 2004, 25.8 $\mu g/m^3$).

Alternatively, in considering the approach of using the annual standard as the primary means for providing protection for both long- and short-term $PM_{2.5}$ exposures, we look to the long-term mean $PM_{2.5}$ concentrations from short-term $PM_{2.5}$ exposure studies to inform considerations of alternative annual standard levels. Using this approach, the same short-term multi- and single-city $PM_{2.5}$ exposure studies briefly described above were evaluated. In focusing on multi-city short-term $PM_{2.5}$ exposure studies of cardiovascular and respiratory mortality, the ISA concludes that associations are generally consistent and precise at long-term mean $PM_{2.5}$ concentrations of 12.8 $\mu g/m^3$ and above (see Figure 2-4; US EPA, 2009a, pp. 2-9 to 2-11). More specifically, with respect to mortality effects, Zanobetti and Schwartz (2009) report associations with an overall annual average across all 112 cities of 13.2 $\mu g/m^3$ and Burnett et al.(2004) report associations with an overall annual average across 12 Canadian cities of 12.8 $\mu g/m^3$. With regard to cardiovascular effects, Zhang et al. (2009) reported positive statistically non-significant association between an average $PM_{2.5}$ concentration of 13.9 $\mu g/m^3$ and ST segment depression among participants of the Women's Health Initiative.

In considering $PM_{2.5}$-related hospital admissions for cardiovascular and respiratory effects in older adults, an identified susceptible population, Dominici et al. (2006a) and Bell et al. (2008) report an overall annual average across 204 and 202 counties of 13.3$\mu g/m^3$ and 12.9 $\mu g/m^3$, respectively (US EPA, 2009a, Figure 2-1). In looking at short-term single-city $PM_{2.5}$ exposure studies, similarly to the discussion of the 24-hour standard, Mar et al. (2004) (average $PM_{2.5}$ concentration of 9.8 $\mu g/m^3$) and Peters et al. (2001) (average $PM_{2.5}$ concentration of 12.1 $\mu g/m^3$) report statistically significant associations for areas currently meeting the annual $PM_{2.5}$ standard. Several short-term single-city $PM_{2.5}$ exposure studies report positive but non-statistically significant associations in areas that would have met the current level of the annual standard for respiratory and cardiovascular morbidity and mortality endpoints associated with long-term mean $PM_{2.5}$ concentrations ranging from 7.0 $\mu g/m^3$ to 13.6 $\mu g/m^3$ (Figure 2-4). However, as noted in the discussion of this evidence with regard to alternatives levels for the 24-hour standard, investigators also reported null (Slaughter et al. 2005; Rabinovitch et al., 2004) and mixed (Mar et al. 2004, Villeneuve et al., 2006) results for similar endpoints in which positive associations were noted above for areas with annual levels ranging from 8.5 $\mu g/m^3$ to 10.8 $\mu g/m^3$ (Figure 2-4). These inconsistent findings suggest the potential for localized events influencing the observed associations in single-city short-term $PM_{2.5}$ exposure studies. Consequently, we observe that the results of short-term $PM_{2.5}$ exposure studies could potentially

inform judgments on a 24-hour $PM_{2.5}$ concentration set at the 98th percentile that provides adequate protection in areas with unusually high peak-to-mean ratios of $PM_{2.5}$ levels. However, due to the possibility that these studies represent air quality distributions that may be influenced by localized events and not be representative of air quality across the country, we reach the preliminary conclusion that these single-city short-term $PM_{2.5}$ exposure studies do not provide support for informing an alternative annual standard levels that would apply across the entire U.S.

In considering not only the level but also the form of the annual standard, we acknowledge, as was discussed in section 2.3.4.1, that there may be differences between mean $PM_{2.5}$ concentrations averaged across monitors within a city/county as is typically considered in epidemiological studies, compared to the current form of the annual $PM_{2.5}$ standard which typically focuses on ambient measurements from the highest reporting community-oriented monitor. As further discussed in section 2.3.4.1, OAQPS conducted additional air quality analyses to better understand air quality distributions considered in selected short-term exposure studies to compare long-term mean concentrations averaged across monitors in comparison to air quality levels focused on the highest reporting monitors (Schmidt, 2010). This analysis, as presented in Figure 2-2, reported composite monitor values close to the long-term mean concentrations reported by the study authors. As was expected, estimated air quality levels for the highest reported monitors were higher, ranging from 13.4 $\mu g/m^3$ (Bell et al.., 2008) to14.8 $\mu g/m^3$ (Dominici et al., 2007), than for the composite monitor values, ranging from12.9 $\mu g/m^3$ (Bell et al.., 2008) to13.7 $\mu g/m^3$ (Zanobetti and Schwartz, 2009). When more study areas were considered and/or more years of air quality data were evaluated, the difference between the long-term mean concentrations for the composite monitor across cities compared to the long-term mean concentrations for the highest reporting monitor across cities was decreased. Of particular interest, is that the difference between the composite monitor and the high monitor is even less when focusing on air quality estimates one standard deviation below the long-term mean across cities for each of these short-term exposure studies. With concentrations ranging from 10.2 $\mu g/m^3$ (Bell et al., 2008) to 10.7 $\mu g/m^3$ (Zanobetti and Schwartz, 2009) based one standard deviation below the long-term mean averaged across monitors and across cities/counties and concentrations ranging from 10.3 $\mu g/m^3$ (Bell et al., 2008) to 11.0 $\mu g/m^3$ (Zanobetti and Schwartz, 2009) based on one standard deviation below the long-term mean at the highest reporting monitor averaged across cities/counties.

In considering the currently available evidence, we reach the preliminary conclusion that the short-term $PM_{2.5}$ exposure studies provide a basis for considering alternative levels for the annual standard within a range below 13 $\mu g/m^3$ down to about 10 $\mu g/m^3$. A standard in the range of 13 to 12 $\mu g/m^3$ would reflect placing greater weight on setting a level somewhat below the

long-term mean concentrations reported in the short-term exposure studies (ranging from12.8 $\mu g/m^3$ and above). A standard in the range of 11 to 10 $\mu g/m^3$ would be consistent with a judgment that, recognizing the serious nature of the effects and that no discernable threshold for these effects can be identified, appreciable weight should be accorded to considering the lower end of the interquartile range of long-term mean concentrations reported in these studies, or a range within one standard deviation around the study mean of either the composite or the highest reporting monitor (ranging from about 10 to 11 $\mu g/m^3$).

As recognized above, an annual standard used as the primary means for providing protection for effects associated with both long- and short-term $PM_{2.5}$ exposures cannot be expected to offer an adequate margin of safety against the effects of all short-term $PM_{2.5}$ exposures, especially in areas with high peak-to-mean ratios of $PM_{2.5}$ concentrations, possibly associated with strong local or seasonal sources of fine particles. In considering a basis for setting an alternative standard levels for a 24-hour standard that would provide supplemental protection against days with high peak concentrations associated with localized "hotspots" and risk arising from seasonal emissions that might not be well controlled by a national annual standard, we intend to conduct air quality analyses of the relationships between annual and 24-hour concentrations to include in the second draft PA.

2.3.5.2 Risk-based Considerations to Inform Alternative Levels

This discussion considers the impact of alternative suites of standard levels on short-term exposure-related mortality and morbidity. As such, it is intended to address the following policy-related questions:

- **To what extent do alternative standards reduce estimated risks associated with short-term $PM_{2.5}$ exposure compared to risks associated with simulating air quality to just meet the current standards? What roles do the current 24 hour and annual standards have in simulating the risks remaining upon just meeting the alternative suites of standards considered in the risk assessment? What level of confidence is associated with these risk estimates?**

As was done above for long-term exposure-related mortality, we have divided the discussion of risk for short-term exposure-related mortality and morbidity, between (a) reductions in risk associated with simulation of the three alternative annual standard levels and (b) reductions in risk associated with the two alternative 24-hour standard levels.

Risk reduction associated with alternative annual standards (14/35, 13/35, and 12/35)

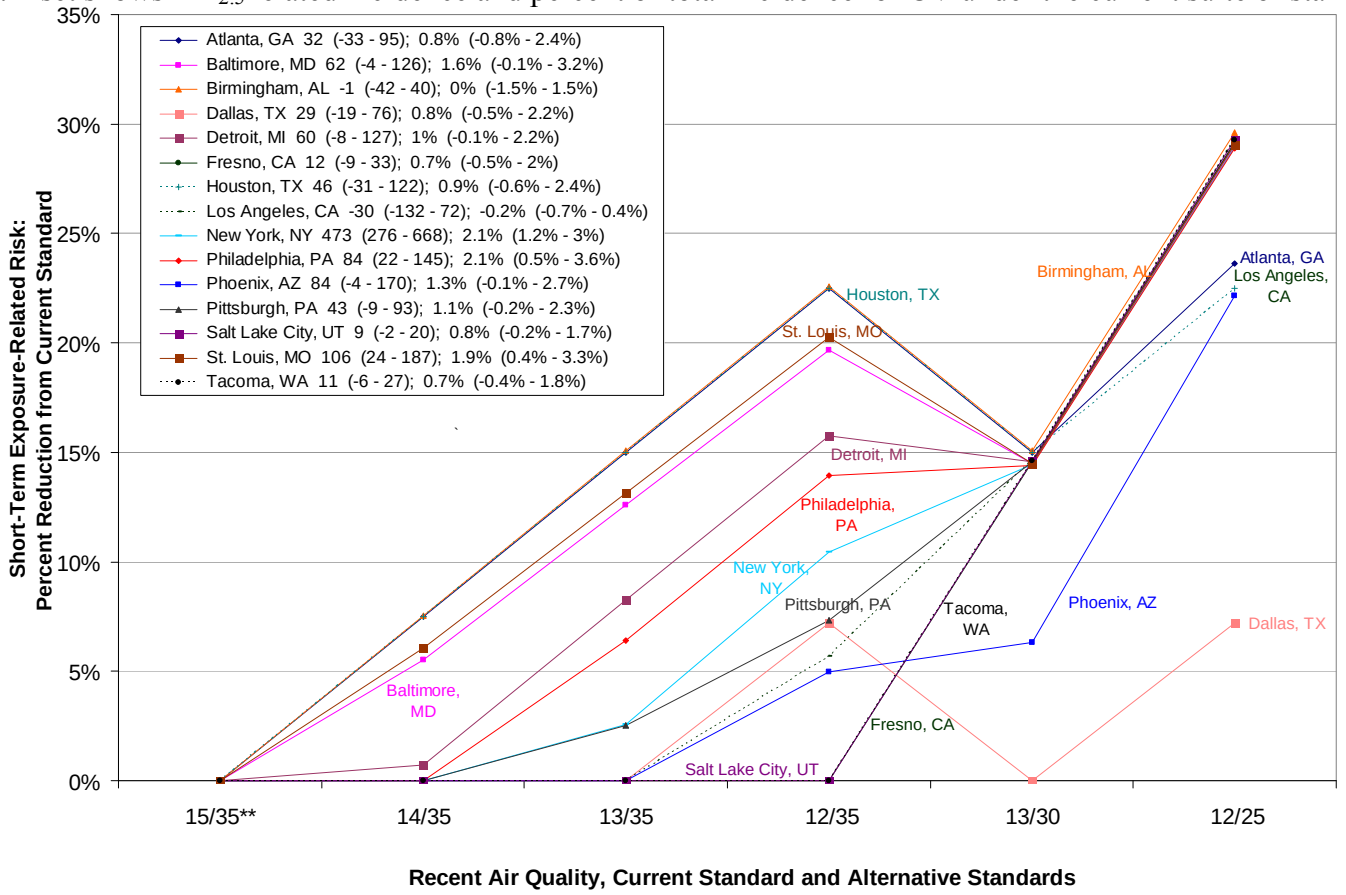
Reductions in risk for short-term exposure-related mortality and morbidity exhibits considerable variability across study areas for the alternative suite of annual standards (compared with risk under the current suite of standards) (see section 2.2.1.1). For the 12 urban study areas

experiencing reductions in short-term exposure-related CV mortality under the lowest alternative annual standard level assessed (12/35), reductions in risk compared to risk under the current suite of standards ranged from 5% (Phoenix) to 23% (Atlanta and Birmingham) (see Figure 2-3 and US EPA, 2010a, Appendix E, Table E-90). Estimates of risk reduction for CV-related HA's exhibited a similar pattern across the study areas for the lowest annual standard level assessed (see Figure 2-6 and US EPA, 2010a, Appendix E, Table E-108).

Regarding the magnitude of risk estimated to remain after simulation of the alternative annual standards, the four study areas displaying the greatest degree of reduction across the alternative annual standards (Atlanta, Baltimore, Houston and St. Louis) have $PM_{2.5}$-related CV mortality estimates (under the lowest alternative annual standard of 12/35) ranging from 25 (Atlanta) to 84 (St. Louis - see US EPA, 2010a, Appendix E, Table E-84). The urban study area with the greatest degree of $PM_{2.5}$-related risk in absolute terms (New York) did not exhibit significant reductions in risk until the lowest annual standard level of 12/35 was considered, at which point we estimate a reduction in $PM_{2.5}$-related CV mortality of 424 cases (see US EPA, 2010a, Appendix E, Table E-84). In terms of the percentage of mortality attributable to short-term $PM_{2.5}$ exposure, the four study areas experiencing the greatest degree of risk reduction across the four alternative annual standard levels had estimates (for the alternative annual standard of 12 $\mu g/m^3$) ranging from 0.6% (Atlanta) to 1.3% (Baltimore – US EPA, 2010a, Appendix E, Table E-87). For CV-related HA's related to short-term $PM_{2.5}$ exposure, estimates for this same group of four study areas (for the lowest alternative annual standard assessed) ranged from 32 (Atlanta) to 142 (St. Louis - RA Appendix E, Table E-102). This translated into a percentage of CV HA's attributable to $PM_{2.5}$ ranging from 0.28% (Atlanta) to 1.07% (Baltimore – US EPA, 2010a, Appendix E, Table E-105).

As with long-term exposure-related mortality, variation in risk reduction across urban study areas for both short-term exposure-related mortality and morbidity reflect to a great extent varying degrees of reduction in annual-average $PM_{2.5}$ levels. This in turn results from the initial simulation of the current 24-hour standard level which can produce varying degrees of reduction in annual-average $PM_{2.5}$ levels depending on a number of factors (i.e., peakiness of the $PM_{2.5}$ monitoring data, specific mix of annual and 24-hour design values for a given location and the spatial pattern of reduction in ambient $PM_{2.5}$ levels that is assumed). We note however, that there is greater variability in the levels of risk remaining after simulation of alternative annual standard levels for short-term exposure-related health endpoints compared with long-term exposure-related mortality. This primarily reflects the fact that we are able to specify C-R functions separately by urban area or region for short-term exposure related mortality and morbidity endpoints, while a single C-R function was used in modeling long-term exposure-related mortality by endpoint across all urban study areas.

Figure 2-6. Percent Reduction in Short-term Exposure-related Mortality and Morbidity Risk
(alternative standards relative to the current standards)
(Note: inset shows $PM_{2.5}$ related incidence and percent of total incidence for CV under the current suite of standards)



*Based on Zanobetti and Schwartz (2009). The legend contains, for each urban area, the incidence estimate (and 95% CI) and the estimate of percent of total incidence (and 95% CI) under the current standards.

**The current standards consist of an annual standard of 15 $\mu g/m^3$ and a daily standard of 35 $\mu g/m^3$. Combinations of an annual standard (n) and a daily standard (m) are denoted n/m in this figure.

As noted earlier, given increased emphasis placed in this analysis on long-term exposure-related mortality, the uncertainty analyses completed for this health endpoint category are somewhat more comprehensive than those conducted for short-term exposure-related mortality and morbidity, which to some extent reflects limitations in study data available for addressing uncertainty in the later category. However, C-R functions used in generating estimates for short-term exposure-related mortality and morbidity are well-supported in the literature.

Risk reduction associated with alternative 24-hour standards (13/30 and 12/25)

Comparing risks associated with just meeting the 13/35 and 13/30 suites of alternative standards (which reflect a 5 $\mu g/m^3$ reduction in the 24-hour standard, while holding the annual fixed at 13 $\mu g/m^3$), we see variation in the magnitude of risk reduction across urban study areas. For example, Baltimore, CV mortality risk attributable to $PM_{2.5}$ under the 13/35 suite of alternative standards was reduced by 14% relative to risk under the current suite of standards. Very little additional risk reduction (increasing from 14% to 15%) is estimated under the 13/30 alternative suite of standards. In contrast, with Salt Lake City, we estimate that the 13/35 suite of alternative standards will produce no risk reduction relative to the current suite of standards, while the 13/30 suite would produce a 15% reduction in CV mortality risk relative to risk under the current standard level (see Figure 2-6 and US EPA, 2010a, Table E-90 in Appendix E).

The additional risk reduction provided by an alternative 24-hour standard is more substantial in comparing the 12/25 and 12/35 alternative suites of standards, although there is also greater variability in the magnitude of risk reductions across study areas. For example, Atlanta, which had a 23% reduction in risk under the 12/35 suite of standards (relative to the current standard level) only sees a marginal increase to 24% under the 13/25 suite of standards. By contrast, Salt Lake City, which has no reduction in risk under the 12/35 suite of standards (relative to the current suite of standards), sees a 29% reduction in risk under the alternative suite of 12/25 (see Figure 2-3 and US EPA, 2010a, Appendix E, Table E-90). The pattern of risk reduction for CV-related HA's is very similar to what is presented here for CV-related mortality (see Figure 2-6 and US EPA, 2010a, Appendix E, Table E-108).

We note that while considerable reductions in risk are seen for short-term exposure-related mortality across many of the study areas, these are smaller than reductions seen for long-term exposure-related mortality. This reflects primarily the fact that risk is modeled down to PRB for short-term exposure-related mortality, while it is only modeled down to LML for long-term exposure-related mortality. Therefore, the incremental reductions in risk associated with short-term exposure-related mortality when we consider alternative suites of standards involve a smaller fraction of total risk compared with long-term exposure-related mortality.

Regarding risk remaining after simulation of the suite of alternative 24-hour standards, $PM_{2.5}$-related CV mortality estimates (under the 12/25 case) ranging from 6 (Salt Lake City) to 336 (New York) (see US EPA, 2010a, Appendix E, Table E-84). Estimates of CV-related HA under the 12/25 suite of standards range from 7 (Salt Lake City) to 534 (New York) (see Appendix E, Table E-102). In terms of the percentage of short-term mortality attributable to $PM_{2.5}$, we see that under the 13/30 suite of standards, the percent of total incidence of CV mortality attributable to $PM_{2.5}$ ranges from ~0% (Los Angeles, Birmingham) to 1.8% (New York, Philadelphia) (US EPA, 2010a, Appendix E, Table E-87). Under the 12/25 alternative suite, risks for this metric range from ~0% (Birmingham, Los Angeles) to 1.1% (Baltimore).

The observations presented above highlight variability both in the magnitude of risk reduction as well as in the risk remaining upon simulation of just meeting alternative 24-hour standards. This reflects the fact that, as noted earlier, alternative 24-hour standards can produce different degrees of reduction in the annual-average $PM_{2.5}$ concentrations, depending on the relationship between 24-hour and annual design values at a particular location. As noted before, it is these annual-average $PM_{2.5}$ levels that drive changes in long-term exposure-related mortality. In addition, as noted earlier, modeling of risk for short-term exposure-related mortality and morbidity involves a combination of urban study area- and regional-specific C-R functions, which adds additional variability to risk estimates generated across the study areas.

As noted earlier, given increased emphasis placed in this analysis on long-term exposure-related mortality, the uncertainty analyses completed for this health endpoint category are somewhat more comprehensive than those conducted for short-term exposure-related mortality and morbidity, which to some extent reflects limitations in study data available for addressing uncertainty in the later category. However, C-R functions used in generating estimates for short-term exposure-related mortality and morbidity are well-supported in the literature.

Summary

The results discussed above show that simulating just meeting alternative annual standard levels in the range of 14 to 12 $\mu g/m^3$ can produce substantial reductions in short-term exposure-related mortality and morbidity risk (with the magnitude of risk reduction increasing as lower annual standards in this range are considered). Furthermore, the results suggest that alternative 24-hour standard levels in the range of 30 to 25 $\mu g/m^3$ can produce additional reductions in estimated risk, beyond that produced by simulations of just meeting lower annual standard level down to 12 $\mu g/m^3$ (combined with a 24-hour standard of 35 $\mu g/m^3$). However, we note that the magnitude of estimated reductions in short-term exposure-related mortality are substantially lower than estimates for long-term exposure-related mortality (when comparing risks for the same urban study area and suite of standards).

In addition, while we would expect alternative 24-hour standards to produce more variable reduction in risk estimates and consequently in public health protection relative to alternative annual standards (for the same reasons presented earlier for long-term exposure-related mortality), we see that risk estimates for both annual and 24-hour standards are fairly variable for short-term exposure-related health effects categories. This reflects in part the fact that we use urban area-differentiated and regionally-differentiated C-R functions in modeling short-term exposure-related mortality and morbidity, which introduces additional variability across study areas in terms of both risk reduction and the magnitude of risks remaining after simulation of alternative suites of standards.

2.3.6 Preliminary Staff Conclusions on Alternative Levels to Address Health Effects Related to Long- and Short-term $PM_{2.5}$ Exposures

In reaching preliminary staff conclusions on alternative standard levels to address health effects related to both long- and short-term $PM_{2.5}$ exposures, we have considered the currently available scientific information including: epidemiologic evidence, including evidence of effects in susceptible populations; air quality analyses; and estimates of risk reductions associated with alternative annual and/or 24-hour standard levels, as well as the related limitations and uncertainties associated with this information as presented in sections 2.3.4 and 2.3.5 and discussed more fully in the ISA and second draft RA (US EPA, 2009a; US EPA, 2010a). As outlined in section 2.1.3, we believe it is most appropriate to consider the protection against $PM_{2.5}$-related mortality and morbidity effects, associated with long- and short-term exposures, afforded by the annual and 24-hour standards taken together, rather than to consider each standard separately. The extent to which these two standards are interrelated in any given area depend in large part on the relative levels of the standards, the peak-to-mean ratios that characterize air quality patterns in an area, and whether changes in air quality designed to meet a given suite of standards is of a more regional or localized nature.

In looking first at the nature of the associations between long- and short-term $PM_{2.5}$ exposures and a range of health outcomes, we have considered not only the causal inferences presented in the ISA but also at what air quality concentrations these effects have been observed. In evaluating these data, we are mindful that the ISA has concluded that no discernable threshold for an effect associated with long- or short-term $PM_{2.5}$ exposures can be identified based on the currently available evidence (US EPA, 2009a, section 2.4.3). We have considered a number of different air quality metrics to inform our preliminary conclusions regarding alternative levels that should be considered including:

- Long-term mean ambient $PM_{2.5}$ concentrations reported in long- and short-term exposure studies;

- Ambient $PM_{2.5}$ concentrations down to one standard deviation below the long-term mean concentrations or the lower end of the interquartile range of air quality data evaluated in the long- and short-term exposure studies;
- The range of long-term $PM_{2.5}$ mean concentrations and the point were the data become more sparse or where the confidence interval becomes notably wider, suggestive of a concentration below which the association becomes appreciably more uncertain and the possibility that an effects threshold may exist becomes more likely;
- Differences between long-term mean $PM_{2.5}$ concentrations averaged across monitors within a city/county as is typically considered in epidemiologic studies, compared to the current form of the annual $PM_{2.5}$ standard which typically focuses on ambient measurements from the highest reporting community-oriented monitor;
- 98^{th} percentile 24-hour ambient $PM_{2.5}$ concentrations identified for short-term exposure studies; and
- Differences between 98^{th} percentile 24-hour ambient $PM_{2.5}$ concentrations averaged across monitors within a city/county compared to the current form of the 24-hour $PM_{2.5}$ standard which focuses on ambient measurements from the highest reporting community-oriented monitor

In considering the results of quantitative risk assessments conducted for this and previous reviews, specifically the estimated risk remaining upon simulation of just meeting alternative suites of standards, we note the following:

- Long-term exposure to $PM_{2.5}$ has been shown to produce substantially larger mortality risk (in terms of overall incidence and percent of total mortality) compared to short-term $PM_{2.5}$ exposure (section 2.2.2; US EPA, 2010a, p. 6-1).

- Much of the risk related to daily exposures, when aggregated on an annual basis, results from the large number of days during which the 24-hour average concentrations are in the low- to mid-range of the entire distribution. Thus, to reduce the aggregate short-term exposure-related risk, it is necessary to shift the bulk of the distribution to lower concentrations, not just to limit the concentrations on days when the $PM_{2.5}$ concentrations are relatively high (US EPA, 2005, p. 4-67, Figure 4-10; Abt, 1996, section 7.1, p.79, Exhibit 7.6).

- Alternative annual standard levels produced more consistent levels of risk reduction (and consequently public health protection) with generally higher levels of confidence when compared with alternative 24-hour standards. Considerable variability exists across urban study areas with respect to the degree to which alternative 24-hour standard levels produce reductions in annual average $PM_{2.5}$ concentrations and, consequently, reductions in risk (section 2.3.4.2).

Taken together, we believe the best way to provide requisite protection for effects associated with both long- and short-term $PM_{2.5}$ exposures is to define a suite of standards that will provide generally consistent protection across the country. In considering the roles that each

standard might be expected to play in the protection afforded by alternative suites of standards, we believe it is appropriate to select a policy approach where the annual standard is the "generally controlling" standard. This approach would reflect consideration for allowing the annual standard to serve in most areas as the target for control programs designed to be effective in lowering the broad distribution of $PM_{2.5}$ concentrations, thus protecting not only against effects associated with long-term exposures but also effects associated with short-term exposures. This approach reflects the recognition that changes in $PM_{2.5}$ air quality designed to meet an annual standard would likely result not only in changes in lower annual average concentrations but also in fewer and lower peak 24-hour concentrations.

In addition, we recognize that an annual standard cannot be expected to offer an adequate margin of safety against the effects of all short-term $PM_{2.5}$ exposures, especially in areas with unusually high peak-to-mean ratios of $PM_{2.5}$ levels, possibly associated with strong local or seasonal sources, or for potential $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods (noted above in section 2.3.2). As a result, in conjunction with an annual standard that may be adopted as the generally controlling standard, in part to provide protection against effects associated with short-term exposures, we believe it is appropriate to use the 24-hour $PM_{2.5}$ standard to provide supplemental protection against days with high peak concentrations associated with localized "hotspots" and risk arising from seasonal emissions that might not be well controlled by a national annual standard.

Thus, we reach the preliminary conclusion that it is appropriate to consider defining the annual $PM_{2.5}$ standard as the generally controlling standard and the 24-hour $PM_{2.5}$ standard as a "backstop" to provide additional protection, where needed. We believe selecting a suite of standards using this approach will provide a more uniform level of protection across the U.S. compared to using an approach where the 24-hour standard is the generally controlling standard. This preliminary conclusion is consistent with the approach used to set the original $PM_{2.5}$ standards in 1997 (see section 2.1.1.1).

In integrating the preliminary staff conclusions reached in sections 2.3.4 and 2.3.5 regarding alternative levels to provide protection for long- and short-term $PM_{2.5}$ exposures, respectively, with the proposed approach outlined above, we have reached preliminary conclusions regarding alternative levels for both the annual and 24-hour standards. The body of scientific evidence upon which these preliminary conclusions are based includes consideration of effects in susceptible populations, including evidence of mortality (causal association), cardiovascular effects (causal association) and/or respiratory effects (likely causal association) in various populations including the life stages of children and older adults, people with pre-existing cardiovascular and respiratory disease, and people with lower socioeconomic status. As outlined in section 2.3.4.1, in considering alternative levels for an annual standard that would

provide protection with an adequate margin of safety, we believe it is also appropriate to take into account evidence of effects for which the ISA has determined the evidence is suggestive of an association with long-term $PM_{2.5}$ exposure including reproductive and developmental effects and carcinogencity, mutagenicity, and genotoxicity. At this time, $PM_{2.5}$ concentrations reported in these studies are equal to or greater than ambient concentrations identified in studies reporting associations with mortality, cardiovascular effects, or respiratory effects. Therefore, in selecting alternative levels, we note that, in providing protection for mortality and cardiovascular and respiratory effects, it is reasonable to anticipate that protection will also be provided for a broader range of health outcomes.

Based on the currently available scientific evidence, we believe there is support for a "generally controlling" $PM_{2.5}$ annual standard in the range of 13 to 10 $\mu g/m^3$ to provide protection for effects associated with both long- and short-term $PM_{2.5}$ exposures in conjunction with a generally "non-controlling" 24-hour $PM_{2.5}$ standard in the range of approximately 30 to 35 $\mu g/m^3$ to limit peak concentrations in areas with relatively high peak-to-mean $PM_{2.5}$ ratios. Selecting a suite of standards with an annual standard in the range of 13 to 12 $\mu g/m^3$ in conjunction with a 24-hour standard in the range of 35 to 30 $\mu g/m^3$ would reflect placing greater weight on setting standard levels just below the $PM_{2.5}$ concentrations (long-term mean and 98^{th} percentile value) reported in the epidemiologic studies reporting associations with mortality and cardiovascular and respiratory effects. It would also recognize consideration for setting a standard with an adequate margin of safety by selecting standard levels based on ambient concentrations averaged across monitors as is typically done in epidemiologic studies and applying those levels using the forms of the current annual and 24-hour $PM_{2.5}$ standards which generally focus on the ambient concentrations reported at the highest reporting monitors.

Alternatively, selecting a suite of standards with an annual standard in the range of 11 to 10 $\mu g/m^3$ in conjunction with a 24-hour standard of 30 to 25 $\mu g/m^3$ would reflect a more precautionary approach. This approach would be consistent with a judgment that, recognizing the serious nature of the effects and that no discernable threshold for these effects can be identified, appreciable weight should be accorded to recognizing that health effects may occur over the full range of concentrations observed in the epidemiologic studies. Using this approach, we believe that it is reasonable to conclude that the evidence of association is strongest down to somewhat further below the aggregate long-term mean concentrations reported in the long- and short-term exposure studies, such as down to one standard deviation below the mean or to the lower end of the interquartile range, which includes the range in which the data in the study are most concentrated. To serve as an effective "backstop" for an alternative annual standard set at the lower end of the preliminary range, we reach the preliminary conclusion that it would be

appropriate to set the level of the 24-hour $PM_{2.5}$ standard somewhat lower than the current standard.

We recognize that it is the link between the form and the level of the standard that determines the degree of public health protection the standard affords. As discussed in section 2.3.3.1, the current form of the annual standard allows for spatial averaging across monitors within constraints that were narrowed in 2006. In light of the currently available scientific evidence discussed in section 2.2.1 providing stronger support that socioeconomic status (SES)[49] modifies the association between PM and morbidity and morality outcomes, we believe that eliminating the spatial averaging provisions from the form of the annual $PM_{2.5}$ standard in conjunction with consideration of alternative levels for the annual standard discussed above is appropriate for identifying a standard that provides requisite protection with an adequate margin of safety. In the second draft of this Policy Assessment, we intend to explore more fully information on the peak to mean air quality concentrations relating the 24-hour 98th percentile $PM_{2.5}$ concentrations relative to the mean annual concentrations to better inform our understanding of the implications of retaining or modifying the current form of the annual standard.

2.4 PRELIMINARY STAFF CONCLUSIONS ON ALTERNATIVE FINE PARTICLE STANDARDS

In reaching preliminary conclusions on potential alternative standards to provide requisite protection for health effects associated with long- and short-term fine particle exposures, staff has considered these standards in terms of the basic elements of the NAAQS: indicator, averaging time, form, and level. In considering the scientific and technical information, we reflect upon the information available in the last review integrated with information that is newly available since the last review as assessed and presented in the ISA and second draft RA (US EPA, 2009a; US EPA 2010a) and as summarized in sections 2.2 and 2.3.

As outlined in sections 2.1.3 and 2.3.6, in this review, our approach to reaching conclusions about the adequacy of the current suite of $PM_{2.5}$ standards and potential alternative standards that are appropriate for consideration is broader and more integrative than approaches used in past reviews. In applying this approach, we recognize that there are various ways to combine the suite of standards to achieve an appropriate degree of public health protection. Such an approach to standard setting, which integrates a much expanded body of health effects evidence, more extensive air quality data and analyses, and a more comprehensive quantitative risk assessment and considers the combined protection afforded by the annual and 24-hour standards, has the potential to result in a more effective and efficient suite of standards than an

[49] Measured using surrogates such as educational attainment, residential location, and income level.

approach that only considers long- and short-term exposures evidence, analyses, and standards independently.

In presenting our preliminary conclusions regarding alternative suites of primary standards and ranges of levels for consideration, we summarize conclusions presented in sections 2.3.1 through 2.3.6. We emphasize that these are preliminary conclusions that reflect consideration of the scientific and technical information assessed and presented in the ISA and second draft RA (US EPA, 2009a; US EPA, 2010a). We note that staff conclusions to be presented in the final RA and second draft PA will be based, in part, on input received from CASAC and the public on the second draft RA and this first draft PA, as well as additional analyses that we are conducting that will help inform our consideration of alternative forms and levels as noted in sections 2.3.3, 2.3.4, and 2.3.5.

We recognize that selecting from among alternative standards will necessarily reflect consideration of the qualitative and quantitative uncertainties inherent in the relevant evidence and in the assumptions that underlie the quantitative risk assessment. In identifying these alternative suites of primary standards and ranges of levels for consideration, we are mindful that the Clean Air Act requires standards to be set that are requisite to protect public health with an adequate margin of safety, such that the standards are to be neither more nor less stringent than necessary. Thus, the Act does not require that the NAAQS be set at zero-risk levels, but rather at levels that avoid unacceptable risks to public health.

(1) Consideration should be given to revising the current $PM_{2.5}$ primary standards to provide increased public health protection from the effects of both long- and short-term exposures to fine particles in the ambient air. This preliminary conclusion is based in general on the evaluation in the ISA of the currently available epidemiologic, toxicologic, dosimetric, and exposure-related evidence, and more specifically on the evidence of mortality and cardiovascular and respiratory morbidity effects in areas where the current standards were met, together with judgments as to the public health significance of the estimated incidence of effects upon just meeting the current suite of standards.

(2) The indicator for fine particle standards should continue to be $PM_{2.5}$. This observation reflects our preliminary conclusions that the available evidence does not provide a sufficient basis for replacing or supplementing the $PM_{2.5}$ indicator with an indicator defined in terms of ultrafine particles or for any specific fine particle component or source category of fine particles, nor does it provide a basis for excluding any component or source category from the mix of particles included in the $PM_{2.5}$ indicator.

(3) Averaging times for $PM_{2.5}$ standards should continue to include annual and 24-hour averages to protect against health effects associated with long-term (seasons to years) and short-term (hours to days) exposure periods. Consideration of other averaging times, including an averaging time less than 24 hours to address health effects associated with subdaily fine particle exposures or a longer averaging time to address effects associated with seasonal fine particle exposures, was limited by the relatively small amount of relevant information available in this review.

(4) Consideration should be given to retaining or revising the form of the annual standard. Consideration should be given to revising the form of the annual standard to one based on the highest community-oriented monitor in an area rather than a form that would allow averaging across monitors (e.g., spatial averaging). The form of the 24-hour standard should continue to be defined in terms of the 98^{th} percentile of the distribution of 24-hour $PM_{2.5}$ concentrations, averaged over three years.

(5) Consideration should be given to alternative suites of $PM_{2.5}$ standards to provide protection against effects associated with both long- and short-term exposures, taking into account both evidence-based and risk-based considerations. Further, we conclude it is appropriate to consider setting the levels of the annual and 24-hour standards such that the annual standard would be the "generally controlling" standard to provide protection for both long- and short-term $PM_{2.5}$ exposures in conjunction with a 24-hour standard to provide supplemental protection against days with high peak concentrations associated with localized "hotspots" and risk arising from seasonal emissions that might not be well controlled by a national annual standard. Integrated preliminary conclusions on ranges of alternative suites of standards that, when considered together, would provide requisite protection against effects associated with both long- and short-term exposures include:

(a) Consideration of a revised annual $PM_{2.5}$ standard within the range of 13 to 12 $\mu g/m^3$, together with either retaining or revising the 24-hour $PM_{2.5}$ standard within the range of 35 to 30 $\mu g/m^3$.

(b) Consideration of a revised annual $PM_{2.5}$ standard, within the range of 11 to 10 $\mu g/m^3$, together with revising the 24-hour $PM_{2.5}$ standard within a range of 30 to 25 $\mu g/m^3$.

2.5 KEY UNCERTAINTIES AND AREAS FOR FUTURE RESEARCH AND DATA COLLECTION

[This topic will be discussed in the second draft Policy Assessment.]

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3 REVIEW OF THE PRIMARY STANDARD FOR THORACIC COARSE PARTICLES

This chapter presents preliminary staff conclusions with regard to the adequacy of the current primary PM_{10} standard, which is intended to protect public health against exposures to thoracic coarse particles ($PM_{10-2.5}$), and potential alternative primary standards for consideration in this review. Our assessment of these issues is framed by a series of key policy-relevant questions, which expand upon those presented in the IRP (US EPA, 2008a) at the outset of this review. The answers to these questions will inform decisions on whether, and if so how, to revise the current PM_{10} standard.

Staff notes that final decisions regarding the primary PM_{10} standard will draw upon scientific information about health effects, as well as judgments about how to deal with the range of uncertainties that are inherent in the scientific evidence. Ultimately, the final decisions are largely public health policy judgments. Our approach to informing these judgments, discussed more fully below, recognizes that the available health effects evidence reflects a continuum consisting of ambient levels at which scientists generally agree that health effects are likely to occur through lower levels at which the likelihood and magnitude of the response become increasingly uncertain

Our current approach for reviewing the primary PM_{10} standard is presented in section 3.1. Our preliminary conclusions regarding the adequacy of the current PM_{10} standard are presented in section 3.2. Section 3.3 presents our preliminary considerations and conclusions with respect to potential alternative standards, focusing on each of the basic elements of the standards: pollutant indicator (section 3.3.1), averaging time (section 3.3.2), and form and level (section 3.3.3). The next draft of this chapter will also include an initial overview of key uncertainties and suggested future research areas and data collection efforts.

3.1 APPROACH

Staff's approach for reviewing the current primary PM_{10} standard builds upon the approaches used in previous PM NAAQS reviews. Our current approach is based on the updated scientific and technical information in the ISA.[1] The past and current approaches described below are all based most fundamentally on using information from epidemiologic studies to inform the selection of PM standards that, in the Administrator's judgment, protect public health with an adequate margin of safety. In the case of thoracic coarse particles, such information is in

[1]As described below, given limitations in the health effects data and in the monitoring network, we have not conducted a quantitative risk assessment in this review for thoracic coarse particles.

the form of $PM_{10-2.5}$ and PM_{10} air quality distributions over which health effect associations have been reported. In light of limitations in $PM_{10-2.5}$ epidemiologic studies, dosimetric and toxicological information also play an important role, especially in considerations related to the appropriate indicator for a standard meant to protect against exposures to thoracic coarse particles. Evidence-based approaches to using information from epidemiologic studies to inform decisions on PM standards are complicated by the recognition that no population threshold, below which it can be concluded with confidence that PM-related effects do not occur, can be discerned from the available evidence. As a result, any approach to reaching decisions on what standards are appropriate requires judgments about how to translate the information available from the epidemiologic studies into a basis for appropriate standards, which includes consideration of how to weigh the uncertainties in reported associations across the distributions of PM concentrations in the studies. Such approaches are consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

3.1.1 Approaches Used in Previous Reviews

3.1.1.1 Reviews Completed in 1987 and 1997

The PM NAAQS have always included some type of a primary standard to protect against effects associated with exposures to thoracic coarse particles. In 1987, when EPA first revised the PM NAAQS, EPA changed the indicator for PM from Total Suspended Particles (essentially applicable to particles smaller than 25-45 micrometers) to focus on inhalable particles, those which can penetrate into the trachea, bronchi, and deep lungs (52 FR 24634). EPA changed the PM indicator to PM_{10} based on evidence that the risk of adverse health effects associated with particles of 10 micrometers or less was significantly greater than that associated with larger particles (52 FR at 24639).

In the 1997 review, in conjunction with establishing new fine particle (i.e., $PM_{2.5}$) standards (see above, sections 1.2.3, 2.1.1), EPA concluded that continued protection remained warranted against potential effects associated with thoracic coarse particles in the size range of 2.5 to 10 μm. This conclusion was based on particle dosimetry, toxicological information, and on limited epidemiologic evidence from studies that measured PM_{10} in areas where coarse particles were likely to dominate the distribution (62 FR 38677, July 18, 1997). Thus, EPA concluded that the PM_{10} standards would provide protection against effects associated with particles in the narrower size range of 2.5 to 10 μm. Although a more narrowly defined indicator was considered in that review (i.e., $PM_{10-2.5}$), EPA concluded that it was more appropriate, based on existing evidence, to continue to use PM_{10} as the indicator for standards to control thoracic

coarse particles. This decision was based, in part, on the recognition that the only studies of clear quantitative relevance to health effects most likely associated with thoracic coarse particles used PM_{10} in areas where the coarse fraction was the dominant fraction of PM_{10}, namely two studies conducted in areas that substantially exceeded the 24-hour PM_{10} standard (62 FR 38679). In addition, this decision reflected the fact that there were only very limited ambient air quality data then available specifically for thoracic coarse particles, in contrast to the extensive monitoring network already in place for $PM_{10,}$ Therefore, it was more administratively feasible to use PM_{10} as an indicator. EPA also stated that the PM_{10} standards would work in conjunction with the $PM_{2.5}$ standards by regulating the portion of particulate pollution not regulated by the $PM_{2.5}$ standards.[2]

3.1.1.2 Review Completed in 2006

In the review of the PM NAAQS that concluded in 2006, EPA considered the growing, but still limited, body of evidence supporting associations between health effects and thoracic coarse particles measured as $PM_{10\text{-}2.5}$.[3] The new studies available in the 2006 review included epidemiologic studies that reported associations with health effects using direct measurements of $PM_{10\text{-}2.5}$, as well as dosimetric and toxicological studies. In light of this growing body of evidence, staff concluded that it was appropriate to revise the PM_{10} standards and to base any revised standards principally on available evidence and air quality information for $PM_{10\text{-}2.5}$. Staff also concluded that it was appropriate to consider evidence from studies that measured PM_{10} in locations where the majority of PM_{10} was in the $PM_{10\text{-}2.5}$ fraction (US EPA, 2005, section 5.4.1) and that the level of protection afforded by the existing 1987 PM_{10} standard remained

[2]As explained in chapter 1, in May 1998, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit found "ample support" for EPA's decision to regulate coarse particle pollution, but vacated the 1997 PM_{10} standards, concluding that EPA had failed to adequately explain its choice of PM_{10} as the indicator for thoracic coarse particles pointing to the lack of reasoned explanation for the variable level of allowable concentrations of thoracic coarse particles (varying by levels of $PM_{2.5}$) and the consequent double regulation of $PM_{2.5}$. *American Trucking Associations v. EPA* , 175 F. 3d 1027, 1054-56 (D.C. Cir. 1999).. The court also rejected considerations of administrative feasibility as justification for a NAAQS, which are based exclusively on health and welfare considerations. Id. at 1054. Pursuant to the court's decision, EPA removed the vacated 1997 PM_{10} standards from the Code of Federal Regulations (CFR) (69 FR 45592, July 30, 2004) and deleted the regulatory provision [at 40 CFR section 50.6(d)] that controlled the transition from the pre-existing 1987 PM_{10} standards to the 1997 PM_{10} standards (65 FR 80776, December 22, 2000). The pre-existing 1987 PM_{10} standards remained in place. Id. at 80777. As noted in chapter 1 and in more detail above, in the 2006 review of the PM NAAQS, EPA re-addressed the appropriateness of using PM_{10} as an indicator for a standard meant to protect against exposures to thoracic coarse particles, and the decision to use PM_{10} as the indicator was upheld on judicial review. American Farm Bureau Federation v. EPA, 559 F. 3d 512, 533-38 (D.C. Cir. 2009).

[3]The PM Staff Paper (US EPA, 2005) also presents results of a quantitative assessment of health risks for $PM_{10\text{-}2.5}$. However, staff concluded that the nature and magnitude of the uncertainties and concerns associated with this risk assessment weighed against its use as a basis for recommending specific levels for a thoracic coarse particle standard.

appropriate (US EPA, 2005, p. 5-67). Responding to CASAC advice, staff also recommended that the indicator for thoracic coarse particles be urban coarse particles in the size range of 10-2.5 micrometer range, thus focusing on those thoracic coarse particles that are generally present in urban environments (US EPA, 2005, p. 5-71). The agency proposed to retain a standard for a subset of thoracic coarse particles, proposing a qualified $PM_{10-2.5}$ indicator to focus on the mix of thoracic coarse particles generally present in urban environments. More specifically, the revised thoracic coarse particle standard would have applied only to an ambient mix of $PM_{10-2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and/or by industrial and construction sources. The revised standard would not have applied to any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils. In addition, agricultural sources, mining sources, and other similar sources of crustal material would not have been subject to control in meeting the standard (71 FR 2667 to 2668, January 17, 2006).

The Agency received a large number of comments that were overwhelmingly opposed to the proposed qualified $PM_{10-2.5}$ indicator (71 FR 61188 to 61197). After careful consideration of the scientific evidence and the recommendations contained in the 2005 Staff Paper, the advice and recommendations from CASAC, the public comments received regarding the appropriate indicator for coarse particles, and after extensive evaluation of the alternatives available to the Agency, the Administrator decided it would not be appropriate to adopt a qualified $PM_{10-2.5}$ indicator. Underlying this determination was the decision that it was requisite to provide protection from exposure to all thoracic coarse PM, regardless of its origin, rejecting arguments that there are no health effects from community-level exposures to coarse PM in non-urban areas (71 FR 61189). The EPA concluded that dosimetric, toxicological, occupational and epidemiologic evidence supported retention of a primary standard for short-term exposures that included all thoracic coarse particles (i.e. both urban and non-urban), consistent with the Act's requirement that primary NAAQS provide an adequate margin of safety. Given the serious potential effects, the large numbers of persons exposed, and the need for a standard to provide an adequate margin of safety, the agency concluded it was appropriate to retain a standard applying to all coarse particles (71 FR 61197). At the same time, the agency concluded that the standard should target protection toward urban areas, where the evidence of health effects from exposure to $PM_{10-2.5}$ was strongest (71 FR at 61193, 61197). The proposed indicator was not suitable for that purpose. Not only did it inappropriately provide no protection at all to many areas, but it failed to identify many areas where the ambient mix was dominated by coarse particles contaminated with urban/industrial types of coarse particles for which evidence of health effects was strongest (71 FR 61193).

The agency ultimately concluded that the existing indicator, PM_{10}, was most consistent with the evidence. Although PM_{10} includes both coarse and fine PM, it remained an appropriate indicator for thoracic coarse particles because fine particle levels are generally higher in urban areas and, therefore, a PM_{10} standard set at a single unvarying level will generally result in lower allowable concentrations of thoracic coarse particles in urban areas than in non-urban areas. This was considered to be an appropriate targeting of protection given that the strongest evidence for effects associated with thoracic coarse particles came from epidemiologic studies conducted in urban areas and that elevated fine particle concentrations in urban areas could result in increased contamination of coarse fraction particles by $PM_{2.5}$, potentially increasing the toxicity of thoracic coarse particles in urban areas (71 FR 61195-96). Given the evidence that the existing PM_{10} standard afforded requisite protection with an ample margin of safety, the Agency retained the level and form of the 24-hour standard.[4]

The Agency also revoked the annual PM_{10} standard, in light of the conclusion in the PM Criteria Document (US EPA, 2004) that the available evidence does not suggest an association with long-term exposure to $PM_{10-2.5}$ and the conclusion in the Staff Paper (US EPA, 2005) that there is no quantitative evidence that directly supports an annual standard.

In the same rulemaking, EPA also included a new Federal Reference Method (FRM) for the measurement of $PM_{10-2.5}$ in the ambient air (71 FR 61212 to 61213). Although the standards for thoracic coarse particles do not use a $PM_{10-2.5}$ indicator, the new FRM for $PM_{10-2.5}$ was established 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.

3.1.2 Litigation of 2006 Final Rule for thoracic coarse particles

A number of groups filed suit in response to the final decisions made in the 2006 review. See *American Farm Bureau Federation and the National Pork Producers Council v. EPA* (DC Cir. 2009). Among the petitions for review were challenges from industry groups on the decision to retain the PM_{10} indicator and the level of the PM_{10} standard and from environmental and public health groups on the decision to revoke the annual PM_{10} standard. The court upheld both the daily PM_{10} standard and the decision to revoke the annual standard.

First, the court upheld EPA's decision for a standard to cover all thoracic coarse PM,, both of urban and non-urban origin. The court rejected arguments that the evidence showed there are no risks from exposure to non-urban coarse PM. The court further found that EPA had a reasonable basis not to set separate standards for urban and non-urban coarse PM, namely the

[4] Thus, the level of 150 $\mu g/m^3$ is met when this level is not exceeded more than once per year on average over a three-year period measured at each monitor within an area.

inability to reasonably define what ambient mixes would be included under either 'urban' or 'non-urban;' and that the evidence in the record supported EPA's cautious decision to provide "some protection from exposure to thoracic coarse particles… in all areas." 559 F. 3d at 532-33. Specifically, the court stated,

> Although the evidence of danger from coarse PM is, as EPA recognizes, "inconclusive," (71 FR 61193, October 17, 2006), the agency need not wait for conclusive findings before regulating a pollutant it reasonably believes may pose a significant risk to public health. The evidence in the record supports the EPA's cautious decision that "some protection from exposure to thoracic coarse particles is warranted in all areas." *Id.* As the court has consistently reaffirmed, the CAA permits the Administrator to "err on the side of caution" in setting NAAQS. 559 F. 3d at 533.

The court also upheld EPA's decision to retain the level of the standard at 150 $\mu g/m^3$ and to use PM_{10} as the indicator for a standard meant to protect against exposures to thoracic coarse particles. In upholding the level of the standard, the court referred to the conclusion in the Staff Paper that there is "little basis for concluding that the degree of protection afforded by the current PM_{10} standards in urban areas is greater than warranted, since potential mortality effects have been associated with air quality levels not allowed by the current 24-hour standard, but have not been associated with air quality levels that would generally meet that standard, and morbidity effects have been associated with air quality levels that exceeded the current 24-hour standard only a few times." 559 F. 3d at 534. The court also rejected arguments that a PM_{10} standard established at an unvarying level will result in arbitrarily varying levels of protection given that the level of coarse PM would vary based on the amount of fine PM present. The court agreed that the variation in allowable coarse PM accorded with the strength of the evidence: typically less coarse PM would be allowed in urban areas (where levels of fine PM are typically higher), in accord with the strongest evidence of health effects from coarse particles. 559 F. 3d at 535-36. In addition, such regulation would not impermissibly double regulate fine particles, since any additional regulation of fine particles (beyond that afforded by the primary $PM_{2.5}$ standard) would be for a different purpose; to prevent contamination of coarse particles by fine particles. 559 F. 3d at 535, 536. These same explanations explained the choice of PM_{10} as an indicator, and provided the reasoned explanation for that choice lacking in the record for the 1997 standard. 559 F. 3d at 536.

With regard to the challenge from environmental and public health groups, the court upheld EPA's decision to revoke the annual PM_{10} standard. Specifically, the court stated,

> The EPA reasonably decided that an annual coarse PM standard is not necessary because, as the Criteria Document and the Staff Paper make clear, the latest scientific data do not indicate that long-term exposure to coarse particles poses a health risk. The CASAC also agreed that an annual coarse PM standard is unnecessary.
> 559 F. 3d at 538-39.

3.1.3 Approach in the Current Review

The staff's approach in this review is consistent with the approaches ultimately taken in previous reviews. We have taken into account evidence-based considerations, including consideration of the uncertainties associated with the evidence, to inform our preliminary conclusions related to the adequacy of the current PM_{10} standard and potential alternative standards. In so doing, we are seeking to provide as broad an array of options as is supportable by the available evidence, recognizing that the selection of a specific approach to reaching final decisions on the primary PM_{10} standard will reflect the judgments of the Administrator as to what weight to place on different aspects of the evidence and associated uncertainties. As discussed in more detail in the *Quantitative Health Risk Assessment for Particulate Matter – Second External Review Draft (second draft RA,* US EPA, 2010a), we have not conducted a quantitative assessment of health risks associated with $PM_{10-2.5}$. Staff concluded that limitations in the monitoring network and in the health studies that rely on that monitoring network, which would be the basis for characterizing $PM_{10-2.5}$ exposures and risks, would introduce significant uncertainty into a $PM_{10-2.5}$ risk assessment such that the risk estimates generated would be of limited utility in informing review of the standard. Therefore, staff concluded in the second draft RA that a quantitative risk assessment for $PM_{10-2.5}$ is not supportable at this time (US EPA, 2010a, p. 2-6).

For the purposes of this first draft Policy Assessment (PA), we have drawn from the assessment and integration of the studies evaluated in the *Integrated Science Assessment for Particulate Matter (Final Report)* (ISA, US EPA, 2009a). The discussions presented in this chapter consider evidence from epidemiologic studies, controlled human exposure studies, and toxicological studies evaluating short- or long-term exposures to thoracic coarse particles; as discussed in chapters 6 and 7, respectively, with supporting information related to dosimetry and potential mode of action (MOA) evidence as presented in chapters 4 and 5, respectively, as well as the integration of evidence across disciplines presented in chapter 2 of the ISA.

With respect to these evidence-based considerations, we have considered causal inferences identified in the ISA based on consideration of the body of scientific evidence for effects related to short- and long-term $PM_{10-2.5}$ exposures. In considering these causal inferences,

we take into account evidence of effects for which the reported associations provide suggestive evidence of a causal association. In considering the evidence, we have relied most heavily on the epidemiologic evidence, including our understanding of air quality distributions of $PM_{10-2.5}$ and PM_{10} present during the times of the studies. While being mindful of the inherent limitations and uncertainties in the currently available evidence, we have developed preliminary conclusions as to the adequacy of the current 24-hour PM_{10} standard to protect against health effects associated with exposure to $PM_{10-2.5}$ and the degree to which alternative standards could be expected to protect against the reported health effects.

In focusing on the key policy-relevant questions by which we have structured the current review, our preliminary conclusions reflect upon our understanding of evidence-based considerations to inform two overarching questions related to: (1) the adequacy of the current 24-hour PM_{10} standard to protect against effects associated with exposure to thoracic coarse particles and (2) what potential alternative standard(s), if any, should be considered in this review. In addressing these broad questions, we have organized the discussions below around a series of more specific questions reflecting different aspects of each overarching question. When evaluating the health protection afforded by the current or any alternative standards considered, we have taken into account the four basic elements of the NAAQS (e.g., indicator, averaging time, level, and form).

We believe that the approach outlined above, when presented in the final PA, will provide a comprehensive basis to help inform the judgments required of the Administrator in reaching decisions about the current and potential alternative primary standards meant to protect public health against exposures to thoracic coarse particles.

3.2 ADEQUACY OF THE EXISTING PM_{10} STANDARD

In considering the adequacy of the current 24-hour PM_{10} standard to protect against effects associated with exposures to thoracic coarse particles, staff addresses the following overarching question:

Does the currently available scientific evidence, as reflected in the ISA, support or call into question the appropriateness of maintaining a standard to protect against effects associated with exposure to thoracic coarse particles and the adequacy of the protection afforded by the current 24-hour PM_{10} standard against those effects?

To inform our consideration of this overarching question, we consider below the evidence for a link between thoracic coarse particle exposures and adverse health effects (3.2.1), including the evidence for the link between $PM_{10-2.5}$ and mortality and morbidity; impacts on susceptible populations; evidence for $PM_{10-2.5}$-related health effects in locations that meet the

current PM_{10} standard; and uncertainties in the evidence. Preliminary staff conclusions regarding the adequacy of the current standard are presented in section 3.2.2. In considering the scientific information, we reflect upon both the information available in the last review and information that is newly available since the last review as assessed and presented in the ISA (US EPA, 2009a).

3.2.1 Evidence of Effects Related to Ambient Thoracic Coarse Particles

In the 2006 review of the PM NAAQS, the AQCD (US EPA, 2004, p. 9-48) concluded the following regarding thoracic coarse particles:

> For $PM_{10-2.5}$, less evidence is available [than for $PM_{2.5}$ or PM_{10}], but the studies using short-term exposures have reported results that are of the same magnitude as those for PM_{10} and $PM_{2.5}$, though less often statistically significant and thus having less strength, and the associations are generally robust to alternative modeling strategies or consideration of potential confounding by co-pollutants. This evidence is suggestive of associations for morbidity with short-term changes in $PM_{10-2.5}$.

In contrast, the AQCD concluded that "[l]ittle evidence is available to allow conclusions to be drawn about long-term $PM_{10-2.5}$ exposures and morbidity" (US EPA, 2004, p. 9-46). In considering these conclusions, the Administrator judged that "short-term exposure to thoracic coarse particles can have an important public health impact" and that available evidence "suggests that there is a lack of such effects associated with long-term exposure to thoracic coarse particles" (71 FR 61185/1, October 17, 2006). As noted above, the Administrator judged that the then-existing body of scientific evidence supported retaining a standard to protect against health effects associated with short-term exposures to all thoracic coarse particles. Specifically, the Administrator noted the following (71 FR 61185/1):

> EPA continues to believe that the health evidence, including dosimetric, toxicologic, and epidemiologic study findings, supports retaining a standard to protect against effects associated with short-term exposure to thoracic coarse particles. As noted above and summarized in section III.A of the proposal, there is a growing body of evidence suggesting causal associations between short-term exposure to thoracic coarse particles and morbidity effects, such as respiratory symptoms and hospital admissions for respiratory diseases, and possibly mortality.

In considering the current body of scientific evidence for health effects of thoracic coarse particles, we have considered the following question:

- **To what extent does the newly available scientific evidence and related uncertainties strengthen or call into question evidence of associations between ambient thoracic coarse particle exposures and health effects?**

We note that since the conclusion of the last review, the Agency has developed a more formal framework for reaching causal inferences from the body of scientific evidence, as discussed above in section 2.2.1. Application of this framework draws upon the evaluation and synthesis of evidence from across epidemiologic, controlled human exposure, and toxicological studies. This framework uses a five-level hierarchy that classifies the overall weight of evidence and causality using the following categorizations: causal relationship, likely to be a causal relationship, suggestive of a causal relationship, inadequate to infer a causal relationship, and not likely to be a causal relationship (ISA, section 1.5, Table 1-3).

Applying this framework to thoracic coarse particles, the ISA concludes that the existing evidence is suggestive of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects (US EPA, 2009a, section 2.3.3; see Table 3-1 below). Several large multi-city epidemiologic studies, as well as a number of single-city studies, have been conducted in the U.S. and Canada since the last review. These studies have generally reported positive associations between ambient $PM_{10-2.5}$ and morbidity and/or mortality (US EPA, 2009a, section 2.3.4). The plausibility of associations reported in these epidemiologic studies is supported by some experimental evidence, primarily from controlled human exposure studies of heart rate variability and pulmonary inflammation, and by dosimetry studies which show that a large proportion of inhaled particles in the 3-6 micron (d_{ae}) range can reach and deposit in the lower respiratory tract, particularly the tracheobronchial (TB) airways (ISA, Figures 4-3 and 4-4).

However, important uncertainties remain with regard to the interpretation of this evidence. For example, experimental support for the associations reported in epidemiologic studies has been somewhat limited. Controlled human exposure studies have not reported effects of thoracic coarse particles on pulmonary endpoints including lung function or respiratory symptoms. In addition, toxicological studies have not generally assessed inhalation of thoracic coarse particles due to the technical challenges associated with conducting a $PM_{10-2.5}$ inhalation study in rodents. These studies have used intratracheal instillation and so provide only limited support for the biological plausibility of the associations reported in epidemiologic studies (US EPA, 2009a, section 2.3.4). Beyond the limitations in experimental support, limitations in the $PM_{10-2.5}$ monitoring network, uncertainties in the ambient $PM_{10-2.5}$ concentrations reported in epidemiologic studies, the relatively small number of epidemiologic studies that have evaluated co-pollutant models to address the potential for confounding by co-pollutants, variability in the

chemical and biological composition of $PM_{10-2.5}$, and limited evidence regarding effects of the various components of $PM_{10-2.5}$, are also important sources of uncertainty (US EPA, 2009a, sections 2.3.3, 2.3.4).

With respect to effects associated with long-term $PM_{10-2.5}$ exposures, the ISA concludes that available evidence is *inadequate to infer a causal relationship* with all health outcomes evaluated (US EPA, 2009a, section 2.3). Specifically, similar to the judgment made in the AQCD (US EPA, 2004), the ISA states, "To date, a sufficient amount of evidence does not exist in order to draw conclusions regarding the health effects and outcomes associated with long-term exposure to $PM_{10-2.5}$" (US EPA, 2009a, section 2.3.4; see Table 3-1 below).

Table 3-1. Summary of Causality Determinations for $PM_{10-2.5}$

Exposure Duration	Outcome	Causal Determination
Short-term	Cardiovascular Effects	Suggestive
	Respiratory Effects	Suggestive
	Mortality	Suggestive
	Central Nervous System Effects	Inadequate
Long-term	Cardiovascular Effects	Inadequate
	Respiratory Effects	Inadequate
	Mortality	Inadequate
	Reproductive and Developmental Effects	Inadequate
	Cancer Mutagenicity, Genotoxicity Effects	Inadequate

Source: adapted from US EPA, 2009a; Table 2-6

Therefore, in considering the health evidence more specifically below we have focused on mortality, cardiovascular effects, and respiratory effects associated with short-term exposures to thoracic coarse particles.

Mortality

We note that, in the last review, a limited number of studies, mostly single-city analyses, were evaluated that examined thoracic coarse PM for its association with mortality (US EPA, 2004). Of those studies, a small number examined both $PM_{2.5}$ and $PM_{10-2.5}$ effects, and reported some evidence for $PM_{10-2.5}$ effects of the same magnitude as $PM_{2.5}$. Studies conducted in Phoenix (Mar et al., 2003) and Coachella Valley (Ostro et al., 2003) reported positive and statistically significant associations between $PM_{10-2.5}$ and mortality while other single-city studies reported $PM_{10-2.5}$ effect estimates that were positive, but not statistically significant. Multiple

limitations were identified in these studies including measurement and exposure uncertainties for $PM_{10-2.5}$ and the correlation between $PM_{2.5}$ and $PM_{10-2.5}$. These limitations decreased the precision of effect estimates and increased the uncertainty surrounding the concentrations at which $PM_{10-2.5}$-mortality associations were observed (US EPA, 2009a, section 6.5.2.3).

Evidence that has become available since the last review provides additional support for the link between exposure to thoracic coarse particles and mortality, though important uncertainties remain regarding the extent to which $PM_{10-2.5}$ itself contributes to reported effects and the thoracic coarse particle concentrations at which associations occur (discussed below in more detail). The ISA assesses several recent studies that have evaluated associations between mortality and $PM_{10-2.5}$, most of which have reported positive, and in some cases, statistically significant $PM_{10-2.5}$ effect estimates (US EPA, 2009a, Figure 6-30). This includes a recent U.S.-based multicity study (Zanobetti and Schwartz, 2009) and a Canadian multi-city study (Burnett et al., 2004), both of which reported positive associations (though in the case of the Canadian study, not statistically significant) between $PM_{10-2.5}$ and mortality. In the U.S. study, a significant association with $PM_{10-2.5}$ was reported for all-cause, cardiovascular, and respiratory mortality (US EPA, 2009a, section 6.5.2.3). The effect estimate for all-cause mortality remained "relatively robust" (US EPA, 2009a, p. 6-82) and statistically significant in a two-pollutant model that included $PM_{2.5}$, while the effect estimates for cause-specific mortality remained positive but not statistically significant. When examining the city-specific effect estimates for the 47 cities included in the thoracic coarse particle analysis, statistically significant increases in mortality were associated with $PM_{10-2.5}$ in St. Louis, MO; Salt Lake City, UT; Chicago, IL; Pittsburgh, PA; Detroit, MI; and Birmingham, AL. Positive, but not statistically significant, associations were reported for all cause and/or cause-specific mortality in the remaining cities (US EPA, 2009a, Figure 6-29). A number of additional studies have also reported positive, but not significant, associations between $PM_{10-2.5}$ and mortality (US EPA, 2009a, Figure 6-30). Considered as a whole, the ISA notes that epidemiologic studies that have evaluated thoracic coarse particles have reported consistent, positive associations between $PM_{10-2.5}$ and mortality (US EPA, 2009a, section 6.5.2.3).

Cardiovascular effects

With regard to cardiovascular morbidity, we note that the evidence evaluating associations with short-term concentrations of $PM_{10-2.5}$ was limited in the last review. Single-city epidemiologic studies found generally positive associations, with some reaching statistical significance, between $PM_{10-2.5}$ and cardiovascular-related hospital admissions in Toronto (Burnett et al., 1997; 1999) and Detroit, MI (Ito, 2003). In the Detroit study, the $PM_{10-2.5}$ effect estimates for ischemic heart disease (IHD) remained positive and statistically significant in two-

pollutant models that included gaseous co-pollutants (US EPA, 2009a, Figure 6-5), while effect estimates remained positive and relatively unchanged in magnitude, but not statistically significant, for congestive heart failure (CHF). Effect estimates in the Toronto study (Burnett et al., 1997) were decreased and became non-significant in two-pollutant models that included gaseous co-pollutants (US EPA, 2009a, ISA, Figure 6-5). In addition, one study considered in the last review reported a positive, but not significant, association between onset of myocardial infarction (MI) and short-term $PM_{10-2.5}$ concentrations in Boston (Peters et al., 2001) and, although not a study of $PM_{10-2.5}$ specifically, Schwartz et al. (1997) reported a statistically significant association between PM_{10} and increased hospitalizations for cardiovascular disease in Tucson, AZ, an urban area where thoracic coarse particles comprise a much greater fraction of PM_{10} than fine particles. No controlled human exposure or animal toxicological studies of $PM_{10-2.5}$ and cardiovascular endpoints were presented in the 2004 AQCD (US EPA, 2004).

In addition to these cardiovascular morbidity studies considered in the last review, the ISA assesses a recent multi-city study evaluating hospital admissions and emergency department visits for cardiovascular disease in Medicare patients (Peng et al., 2008). In this study of older adults, the authors reported a positive and statistically significant association between 24-hour $PM_{10-2.5}$ concentrations and cardiovascular disease hospitalizations in a single pollutant model using air quality data for 108 U.S. counties with one or more co-located $PM_{2.5}$ and PM_{10} monitors. The effect estimate was reduced only slightly, though it was no longer statistically significant, in two-pollutant models that included $PM_{2.5}$ (US EPA, 2009a, sections 2.3.3, 6.2.10.9). In addition to this U.S. multi-city study, positive associations reported for short-term $PM_{10-2.5}$ and cardiovascular morbidity reached statistical significance in a multi-city study in France (Host et al., 2007) and associations were positive, but often did not reach statistical significance, in several other locations (US EPA, 2009a, Figures 6-1 to 6-3, 6-5). In considering the available epidemiologic evidence, the ISA concludes that single- and multi-city epidemiologic studies generally report positive associations between short-term $PM_{10-2.5}$ concentrations and hospital admissions or emergency department visits for cardiovascular causes (US EPA, 2009a, section 2.3.3, 6.2.12.2).

The generally positive associations between $PM_{10-2.5}$ and cardiovascular morbidity reported in these studies are supported by several recent epidemiologic studies that have examined dust storm events and reported increases in cardiovascular-related emergency department visits and hospital admissions[5]; by studies reporting positive associations with

[5]Such dust storm studies are also important because they provide evidence that cardiovascular effects are associated with exposures to particles of non-urban origin. As discussed more fully below, this evidence has implications for

cardiovascular mortality; by reported associations with other cardiovascular health effects including supraventricular ectopy and changes in heart rate variability; and by a limited number of controlled human exposure studies that have reported alterations in heart rate variability following exposure to $PM_{10-2.5}$ (US EPA, 2009a, sections 2.3.3, 6.2.12.2). As noted above, the few toxicological studies that examined the effect of $PM_{10-2.5}$ on cardiovascular health effects used intratracheal instillation and, as a result, provide only limited evidence on the biological plausibility of $PM_{10-2.5}$ induced cardiovascular effects (US EPA, 2009a, sections 2.3.3, 6.2.12.2).

Respiratory effects

With respect to respiratory effects associated with short-term $PM_{10-2.5}$ exposures, we first note that, in the last review, epidemiologic studies reported generally positive associations between $PM_{10-2.5}$ and respiratory-related hospitalizations or emergency department visits (e.g., for pneumonia, chronic obstructive pulmonary disease, and respiratory diseases combined) (US EPA, 2004). Support for these associations came from a small number of studies that examined respiratory-related mortality and respiratory symptoms. Experimental evidence for respiratory effects of $PM_{10-2.5}$ was limited to a few animal toxicology studies and no controlled human exposure studies.

In the current review, the ISA notes that a number of recent epidemiologic studies have reported consistent, positive associations between short-term ambient $PM_{10-2.5}$ concentrations and respiratory-related emergency department visits and hospital admissions (US EPA, 2009a, section 2.3.3). In a French multi-city study (Host et al., 2008), 24-hour ambient $PM_{10-2.5}$ concentrations were positively associated with respiratory-related hospital admissions among children, with an effect estimate larger than that for $PM_{2.5}$. A U.S. multi-city study of Medicare patients (Peng et al., 2009) reported a positive, but not statistically significant, effect estimate for respiratory-related hospital admissions. A number of additional, mostly single-city, studies have also reported positive, and in some cases statistically significant, $PM_{10-2.5}$ effect estimates for respiratory-related hospital admissions and emergency department visits (ISA, Figures 6-10 to 6-15). In epidemiologic studies of respiratory effects, the strongest relationships with $PM_{10-2.5}$ were observed among children, with less consistent evidence for adults and older adults (i.e., age 65 and older) (US EPA, 2009a, section 2.3.3.1). A limited number of epidemiologic studies have focused on specific respiratory morbidity outcomes and found no evidence of an association with lower respiratory symptoms, wheeze, and medication use (US EPA, 2009a, sections 2.3.3.1 and 6.3.1.1). While controlled human exposure studies have not observed an

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decisions on the appropriateness of the current PM_{10} standard as well as on the choice of indicator for thoracic coarse particles.

effect on lung function or respiratory symptoms in healthy or asthmatic adults in response to short-term exposure to $PM_{10-2.5}$, healthy volunteers have exhibited an increase in markers of pulmonary inflammation. Toxicological studies using inhalation exposures are still lacking, but pulmonary injury and inflammation has been observed in animals after intratracheal instillation exposure (US EPA, 2009a, section 6.3.5.3) and, in some cases, $PM_{10-2.5}$ was found to be more potent than $PM_{2.5}$.

Some studies of $PM_{10-2.5}$ and respiratory morbidity have investigated potential confounding by co-pollutants through the application of co-pollutant models (US EPA, 2009a, section 6.3.8.5, Figure 6-15). Several of these studies have reported positive and statistically significant $PM_{10-2.5}$ effect estimates in co-pollutant models that included gaseous pollutants (e.g., Lin et al., 2002; Yang et al., 2004; Chen et al., 2005; Lin et al., 2005). Several other studies report that $PM_{10-2.5}$ effect estimates remain positive, though not always statistically significant, in co-pollutant models that include gaseous pollutants or $PM_{2.5}$ (US EPA, 2009a, Figure 6-15).

Summary

In considering the extent to which newly available scientific evidence strengthens or calls into question evidence of associations identified in the last review between ambient thoracic coarse particle concentrations and adverse health effects, we recognize that the available epidemiologic and experimental evidence now includes several recent multi-city epidemiologic studies conducted in the U.S., Canada, and Europe which have reported associations of $PM_{10-2.5}$ with cardiovascular and respiratory morbidity and mortality, several studies of dust storm events reporting associations with particles of non-urban origin, as well as some controlled human exposure studies reporting effects of $PM_{10-2.5}$ exposure on heart rate variability and pulmonary inflammation. While uncertainties identified in the last review remain (see below), these recent studies provide important information not available in that review on the link between $PM_{10-2.5}$ and mortality and morbidity, and they have broadened our understanding of this link with particles from different types of sources and in a variety of locations. Thus, our preliminary conclusion is that there is additional support, beyond that available in the last review, for associations between adverse health effects (mortality, morbidity) and short-term exposures to $PM_{10-2.5}$ from a broad mix of sources and a variety of locations.

Having reached this preliminary conclusion, we then consider how the new evidence informs our understanding of susceptible populations by asking the following question:

- **To what extent does the newly available scientific evidence expand our understanding of susceptible populations, including identification of new susceptible populations?**

Our understanding of populations that are more susceptible to PM exposures is discussed above in chapter 2 (section 2.2.1). This includes populations that have a greater likelihood of

experiencing health effects related to exposure to PM due to a variety of factors including, but not limited to, genetic or developmental factors, race, gender, life stage, lifestyle (e.g., smoking status and nutrition), preexisting disease, or population-level factors that can increase an individual's exposure to PM (e.g., socioeconomic status, reduced access to health care, low educational attainment, residential location). Although these studies have primarily evaluated exposures to $PM_{2.5}$ or PM_{10}, the available evidence suggests that the identified factors may also enhance susceptibility to $PM_{10-2.5}$ (US EPA, 2009a, section 2.4.1). Given this, the discussion in section 2.2.1 of this document, which summarizes the evidence from the ISA as well as staff considerations and conclusions on susceptible populations, will not be repeated here. Rather, with regard to $PM_{10-2.5}$, we note the overall conclusion from the ISA that "the epidemiologic, controlled human exposure, and toxicological studies evaluated in this review provide evidence for increased susceptibility for various populations, including children and older adults, people with pre-existing cardiopulmonary diseases, and people with lower SES" (US EPA, 2009a, p. 2-24). As discussed in more detail in section 2.2.1, these populations, which are of particular concern with regard to effects linked to PM exposures, are similar to the at-risk populations considered in the last review of the PM NAAQS.

We next consider how the available evidence informs our understanding of air quality concentrations associated with mortality and morbidity by asking the following question:

- **To what extent does the newly available scientific evidence report associations that extend to air quality levels that are lower than had previously been observed or that are observed in areas that would likely meet the current PM_{10} standard?**

As discussed in more detail in chapter 2, the ISA concluded that there is no evidence to support the existence of a discernable threshold below which PM-associated effects would not occur (US EPA, 2009a, section 2.4.3). Therefore, when considering the level of protection provided by the current 24-hour PM_{10} standard against exposures to thoracic coarse particles, we consider whether available evidence provides support for associations between $PM_{10-2.5}$ and mortality or morbidity in locations with PM_{10} concentrations that would be allowed by the current 24-hour PM_{10} standard. In this section, in considering air quality concentrations at which health effects have been reported, we have focused on effects for which the evidence is suggestive of a causal relationship, as described in the ISA. Where sufficient air quality data are available, we have evaluated air quality concentrations using the form of the current 24-hour PM_{10} standard.[6]

[6] The current form of the 24-hour PM_{10} standard is one expected exceedance per year, averaged over 3 years.

In the last review of the PM NAAQS, the Staff Paper (US EPA, 2005; section 5.4.1) noted that statistically significant associations between thoracic coarse particles and mortality had been reported in studies conducted in areas that did not meet the PM_{10} standard during the time periods of the studies, including Phoenix (Mar et al., 2000, 2003), Coachella Valley, CA (Ostro et al., 2000, 2003), and Steubenville (as part of the Harvard Six Cities study, Schwartz et al., 1996; Klemm et al., 2003). In contrast, the Staff Paper noted that "[i]n areas with lower $PM_{10-2.5}$ concentrations, no statistically significant associations were reported with mortality, though many were positive but not statistically significant" (US EPA, 2005, p. 5-49).

The Staff Paper also noted that epidemiologic studies of PM_{10}, in areas where PM_{10} is typically dominated by the coarse fraction, provided additional supportive evidence for associations between coarse fraction particles and health effects in areas with concentrations generally not meeting the PM_{10} standard levels. These studies included reports of associations with hospitalization for cardiovascular diseases in Tucson, AZ (Schwartz, 1997); hospitalization for chronic obstructive pulmonary disease in Reno/Sparks, NV (Chen et al., 2000); medical visits for asthma or respiratory diseases in Anchorage, AK (Gordian et al., 1996; Choudhury et al., 1997); and significant associations with mortality, respiratory hospital admissions, and respiratory symptoms in the Utah Valley area (e.g., Pope et al., 1989; 1991; 1992).

We have re-examined the issue of the PM_{10} concentrations at which associations between $PM_{10-2.5}$ and mortality and morbidity have been reported in light of currently available evidence and air quality information. In so doing, we have characterized PM_{10} concentrations reported in EPA's Air Quality System (AQS)[7] from several U.S. study locations (see US EPA, 2009a, Figure 2-3). Specifically, consistent with the form of the current PM_{10} standard, we consider the second highest 24-hour average PM_{10} concentration for each year of the study, from each monitoring site in the study location. In an attempt to gain insight into whether the PM_{10} air quality concentrations in a particular study location were above or below those allowed by the current standard, we compare these second highest 24-hour PM_{10} concentrations to the level of the standard, 150 $\mu g/m^3$.[8]

PM_{10} concentrations from U.S. study locations where positive and statistically significant $PM_{10-2.5}$ effect estimates have been reported (e.g., US EPA, 2009a, Figures 2-3; 6-5; 6-24; 6-30) are presented in Table 3-2 below for Detroit (Lippman, 2000; Ito et al., 2003; Zanobetti and Schwartz, 2009), Phoenix (Mar et al., 2003), Seattle (Sheppard, 2003), Birmingham (Zanobetti

[7] http://www.epa.gov/ttn/airs/airsaqs/detaildata/downloadaqsdata.htm

[8] We recognize that this is not the exact approach taken in making attainment and non-attainment designations for the PM_{10} standard, which also involves estimating expected exceedances for areas with less than daily monitoring, but it does provide important insights into the PM_{10} air quality in study areas, and into whether measured PM_{10} air quality concentrations would, or would not, be permitted under the current standard.

and Schwartz, 2009), Coachella Valley (Ostro et al., 2003), Chicago (Zanobetti and Schwartz, 2009), Pittsburgh (Zanobetti and Schwartz, 2009), Salt Lake City (Zanobetti and Schwartz, 2009), and St. Louis (Zanobetti and Schwartz, 2009).[9]

Table 3-2. PM_{10} Concentrations in Cities with Statistically Significant $PM_{10-2.5}$ Effect Estimates

City	Second highest 24-hour PM_{10} concentration for each study location and study year ($\mu g/m^3$)									
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Birmingham	152	157	130	160	178	166	179			
Coachella Valley	576	278	189	108	91	84	133	155	157	114
Chicago	120	123	124	106	103	84	88			
Detroit (Zanobetti and Schwartz)	126	113	114	96	157	139	87			
Detroit (Lippman; Ito)[10]	107	113	129							
Pittsburgh	120	123	133	107	145	153	142			
Phoenix	160	130	301							
Salt Lake City	113	117	156	123	209	149	123			
Seattle	134	138	140	131	114	119	83			
St. Louis	91	92	186	224	161	191	196			

Of these cities for which positive and statistically significant $PM_{10-2.5}$ effect estimates have been reported, PM_{10} concentrations in Birmingham, Phoenix, and St. Louis were higher than allowed by the current PM_{10} standard during most of the study periods and concentrations in Coachella Valley were higher than allowed during about half of the study period. In contrast, ambient PM_{10} concentrations were below those allowed by the current standard during the entire

[9]We have evaluated air quality in study locations for which single-city effect estimates are presented and for which air quality data during the study period are available. Some important U.S. multi-city studies (e.g., Peng et al., 2008) are not included in Table 3-2 because they did not present single-city effect estimates. We also note that there are several key studies conducted in Canadian cities; however, we were unable to obtain air quality information for individual monitors in these study locations.

[10]These studies in Detroit presented effect estimates for two separate time frames. Because PM_{10} FRM/FEM data is not available prior to 1988, we have focused here on the latter time frame used in the studies (1992-1994).

study periods for the studies conducted in Chicago, Detroit, Seattle, and Pittsburgh and during most of the study period in Salt Lake City.[11]

We also note that two of the studies included in Table 3-2 evaluated $PM_{10-2.5}$ effect estimates in co-pollutant models. Specifically, as discussed above, the associations reported by Ito et al. (2003) for $PM_{10-2.5}$ and pneumonia hospital admissions in Detroit remained after adjustment for gaseous co-pollutants. In addition, the ISA reported that the overall $PM_{10-2.5}$ effect estimate for all-cause mortality in the multi-city study by Zanobetti and Schwartz (2009), which included Chicago, Detroit, Seattle, Pittsburgh, and Salt Lake City, remained "relatively robust" (US EPA, 2009a, p. 6-82) and statistically significant in a two-pollutant model that included $PM_{2.5}$, though co-pollutant models were not reported for individual cities. As indicated in the ISA (Figure 6-15), several other studies (e.g., those conducted in Canada) have also reported robust and statistically significant $PM_{10-2.5}$ effect estimates in co-pollutant models, however, we were unable to obtain air quality data for these other study locations and, therefore, as described above, they were not included in Table 3-2.

In addition to the statistically significant results in the cities noted above, several studies have reported positive, but not statistically significant, $PM_{10-2.5}$ effect estimates in locations with PM_{10} concentrations below those allowed by the current standard. Specifically, Zanobetti and Schwartz (2009) reported positive $PM_{10-2.5}$ effect estimates for mortality in cities with a range of $PM_{10-2.5}$ concentrations, even down to the lowest $PM_{10-2.5}$ concentrations estimated in the study (ISA, figure 6-29). Many of these cities, where positive associations with mortality were reported, attained the current PM_{10} standard during the time period of the study.[12] In addition, Fairley et al. (2003) reported a positive, but not statistically significant, association between $PM_{10-2.5}$ and mortality in Santa Clara County, CA (ISA, Figure 6-30). Though some 24-hour PM_{10} concentrations in this location did exceed 150 $\mu g/m^3$ (i.e., authors report concentrations up to 165 $\mu g/m^3$), an analysis of Santa Clara air quality during the study period reveals that the 2nd highest 24-hour PM_{10} concentration did not exceed 150 $\mu g/m^3$ during any of the study years (range was 58-147 $\mu g/m^3$). Peters et al. (2001) reported a positive, but not statistically significant, association between $PM_{10-2.5}$ and hospital admissions for myocardial infarction in

[11]We considered the number of times per year that 24-hour PM_{10} concentrations exceeded 150 $\mu g/m^3$. For the studies in Chicago, Detroit, Seattle, and Pittsburgh, the average number of days per year with 24-hour PM_{10} concentrations above 150 $\mu g/m^3$ did not exceed 1 for any 3-year period. For Salt Lake City, year 3 of the study had 2 exceedances of 150 $\mu g/m^3$ and year 5 had 3 exceedances. Therefore, the average number of exceedances over years 3-5 was greater than 1. The average over other 3 year periods during the study did not exceed 1.

[12] See http://www.epa.gov/oaqps001/greenbk/pindex.html for information on attainment status of specific locations and http://www.epa.gov/airtrends/values.html for information on design values for PM.

Boston, a location where the 2nd highest 24-hour PM_{10} concentration did not exceed 150 $\mu g/m^3$ during either of the study years (52 and 80 $\mu g/m^3$).

A series of studies conducted in Atlanta have reported mixed results, but none statistically significant, for $PM_{10-2.5}$ and mortality and respiratory-related emergency department visits. Specifically, Klemm et al. (2004), Metzger et al. (2004), Peel et al. (2005), and Tolbert et al. (2007) reported both positive and negative $PM_{10-2.5}$ effect estimates for mortality and emergency department visits (ISA, Figure 2-3). The 2nd highest 24-hour PM_{10} concentrations in a year over the range of years encompassed by these studies did not exceed 150 $\mu g/m^3$ (maximum was 111 $\mu g/m^3$).

Summary

When viewed as a whole, these U.S. studies provide evidence for associations between ambient $PM_{10-2.5}$ concentrations and increased mortality and morbidity in several locations with ambient PM_{10} concentrations below those allowed by the current PM_{10} standard. Staff's preliminary conclusions regarding the potential implications of these studies for a decision on the adequacy of the current PM_{10} standard are discussed below.

We next consider the important uncertainties in the available evidence by asking the following question:

- **What are the important uncertainties associated with the currently available scientific evidence that should be considered in evaluating the adequacy of the current PM_{10} standard? Have these uncertainties changed or been reduced since the last review?**

The majority of the health evidence supporting the link between thoracic coarse particle exposures and adverse cardiovascular and respiratory effects comes from epidemiologic studies. Staff notes that, while several new studies have become available since the last review, little progress has been made in reducing some of the important uncertainties inherent in these studies. These uncertainties, and their implications for interpreting the scientific evidence, are discussed below in more detail.

The ISA (sections 2.3.3, 2.3.4) concludes that an important uncertainty in the $PM_{10-2.5}$ epidemiologic literature is that associated with the air quality estimates used in these studies. Specifically, the ISA concludes that there is greater error in estimating ambient concentrations of $PM_{10-2.5}$ than in estimates for $PM_{2.5}$ and, therefore, that such uncertainty is a particularly relevant consideration when interpreting $PM_{10-2.5}$ epidemiologic studies. Contributing to this uncertainty is the relatively limited spatial coverage provided by existing $PM_{10-2.5}$ monitors (US EPA, 2009a, sections 2.2.3, 2.3.3, 2.3.4). Currently, a national network to monitor $PM_{10-2.5}$ is not in place, limiting the spatial area over which $PM_{10-2.5}$ concentrations are measured. Specifically, of the

3,225 counties in the U.S., only 40 (1%), incorporating less than 5% of the population, met completeness and co-location criteria during the years 2005-2007, allowing analysis of $PM_{10-2.5}$ air quality in the ISA (US EPA, 2009a, section 3.5.1.1). In addition, based on the limited available evidence, the ISA concluded that "there is greater spatial variability in $PM_{10-2.5}$ concentrations than $PM_{2.5}$ concentrations, resulting in increased exposure error for the larger size fraction" (US EPA, 2009a, p. 2-8) and that available measurements do not provide sufficient information to adequately characterize the spatial distribution of $PM_{10-2.5}$ concentrations (US EPA, 2009a, section 3.5.1.1). As noted in the ISA, these limitations in estimates of ambient $PM_{10-2.5}$ concentrations "would tend to increase uncertainty and make it more difficult to detect effects of $PM_{10-2.5}$ in epidemiologic studies" (US EPA 2009a, p. 2-21).

Uncertainty also results from the different approaches taken to estimate $PM_{10-2.5}$ concentrations in epidemiologic studies. The ISA notes that ambient concentrations of $PM_{10-2.5}$ are generally determined by the subtraction of $PM_{2.5}$ from PM_{10} measurements, with different studies using different methods. For example, one important multi-city study (e.g., Peng et al., 2008) estimated $PM_{10-2.5}$ by taking the difference between collocated PM_{10} and $PM_{2.5}$ monitors while another important multi-city study (e.g., Zanobetti and Schwartz, 2009) used the difference between county average PM_{10} and $PM_{2.5}$ concentrations. A small number of studies have directly measured $PM_{10-2.5}$ concentrations with dichotomous samplers (e.g., Burnett et al., 2004; Villeneuve et al., 2003; Klemm et al., 2004). It is not clear how computed $PM_{10-2.5}$ measurements, such as those used by Zanobetti and Schwartz, compare with the $PM_{10-2.5}$ concentrations obtained in other studies either by direct measurement with a dichotomous sampler or by calculating the difference using co-located samplers (US EPA, 2009a, section 6.5.2.3).[13] Given the use of these different approaches to estimating $PM_{10-2.5}$ concentrations across studies, and their inherent limitations, the distributions of thoracic coarse particle concentrations over which reported health outcomes occur remain highly uncertain.

The ISA also notes that the potential for confounding by co-occurring pollutants has been addressed in only a relatively small number of $PM_{10-2.5}$ epidemiologic studies, introducing additional uncertainty into the interpretation of these studies (US EPA, 2009a, section 2.3.3). As discussed above, most studies that have evaluated co-pollutant models have reported that $PM_{10-2.5}$ effect estimates remain positive, but often lose precision and become statistically non-significant (US EPA, 2009a, Figures 6-5, 6-9, 6-15). In the U.S. multi-city study by Zanobetti and Schwartz (2009) effect estimates for all-cause mortality remained statistically significant in a

[13]In addition, when the difference between $PM_{2.5}$ and PM_{10} is calculated, the potential for differences among operational flow rates and temperatures for PM_{10} and $PM_{2.5}$ monitors add to the potential for exposure misclassification.

two-pollutant model that included $PM_{2.5}$ while effect estimates for cause-specific mortality remained positive but were not statistically significant. Effect estimates for $PM_{10-2.5}$ were also positive, but not statistically significant, in co-pollutant models that included $PM_{2.5}$ in the studies by Peng et al. (2008) (cardiovascular and respiratory hospital admissions) and Chen et al. (2004) (respiratory hospital admissions). In the Canadian multi-city study by Burnett et al. (2004) the $PM_{10-2.5}$ effect estimates for respiratory-related hospital admissions remained positive, but not statistically significant, in a co-pollutant model that also included NO_2, though the $PM_{10-2.5}$ effect estimate remained statistically significant in co-pollutant models with other gaseous pollutants. In other studies (e.g., see Lin et al., 2002; Ito et al., 2003; Chen et al., 2005) $PM_{10-2.5}$ effect estimates remained relatively unchanged, and in some cases statistically significant, in co-pollutant models that included gaseous pollutants.

Summary

As discussed above, important uncertainties remain in the evidence for associations between $PM_{10-2.5}$ and mortality and morbidity. In considering these uncertainties, we reach the preliminary conclusion that, although a number of studies have been conducted since the last review, the important uncertainties present in that review remain. The implications of these uncertainties for decisions on the adequacy of the PM_{10} standard are discussed below.

3.2.2 Preliminary Staff Conclusions on Adequacy of Current PM_{10} Standard

Collectively, taking into consideration the responses to specific questions focusing on different ways to inform a decision on the adequacy of the current 24-hour PM_{10} standard , we revisit the overarching question:

- **Does the currently available scientific evidence, as reflected in the ISA, support or call into question the appropriateness of maintaining a standard to protect against effects associated with exposure to thoracic coarse particles and the adequacy of the protection afforded by the current 24-hour PM_{10} standard against those effects?**

As an initial matter, we note that the current PM_{10} standard is meant to protect the public health against effects associated with exposures to all $PM_{10-2.5}$. As discussed above, this was judged in the last review to be appropriate given the "growing body of evidence suggesting causal associations between short-term exposure to thoracic coarse particles and morbidity effects, such as respiratory symptoms and hospital admissions for respiratory diseases, and possibly mortality" (71 FR 61185, October 17, 2006). In considering the currently available scientific evidence on thoracic coarse particles, we conclude that newly available studies conducted since the last review of the PM NAAQS strengthen this conclusion. As discussed

above, the newly available epidemiologic and experimental evidence, combined with evidence available in the last review, includes the following:

- Several multi-city epidemiologic studies conducted in the U.S., Canada, and Europe which have reported associations of $PM_{10-2.5}$ with cardiovascular and respiratory morbidity and mortality
- Studies that have reported that $PM_{10-2.5}$ effect estimates remain positive, and in some cases statistically significant, in co-pollutant models
- Studies that have reported positive associations between dust storm events and cardiovascular effects, broadening the available evidence for associations between adverse health effects and particles from a variety of sources, including non-urban sources
- Controlled human exposure studies of heart rate variability and pulmonary inflammation.

While uncertainties identified in the last review remain, these recent studies support those available in the last review and provide important information on the link between $PM_{10-2.5}$ and cardiovascular and respiratory effects, including mortality. In addition, several recent dust storm studies provide evidence not available in the last review regarding associations between particles of non-urban origin and adverse health effects. Therefore, consistent with the previous reviews, we judge that it is appropriate to maintain a standard to protect the public health against effects associated with exposures to all thoracic coarse particles.

In drawing preliminary conclusions regarding the adequacy of the level of protection afforded by the current PM_{10} standard, we have considered the ambient PM_{10} concentrations in locations where epidemiologic studies of thoracic coarse particles have been conducted as well as the uncertainties associated with the broader body of scientific evidence. Specifically, we note that several recent U.S. studies have reported generally positive, and in some cases statistically significant, $PM_{10-2.5}$ effect estimates in locations with 24-hour PM_{10} concentrations below those permitted by the current standard. This includes single-city and multi-city studies, and studies that have reported that $PM_{10-2.5}$ effect estimates remain positive, and in some cases robust and statistically significant, in co-pollutant models. As described above, the decision in the last review to retain the existing PM_{10} standard was based, in part, on the conclusion that the strongest evidence for the link between $PM_{10-2.5}$ and health effects came from studies conducted in locations with PM_{10} concentrations above those allowed by the standard. Given that recent epidemiologic studies have reported statistically significant $PM_{10-2.5}$ effect estimates in several locations with PM_{10} concentrations below those allowed by the standard, a similar conclusion would not be supported by the currently available evidence. Therefore, to the extent that the

approach to considering the adequacy of the current standard in this review is similar to the approach used in the last review, it would be appropriate to conclude that the current 24-hour PM_{10} standard does not provide adequate public health protection and that it should be revised in order to increase protection against effects associated with short-term exposures to thoracic coarse particles. If this approach to considering the evidence were adopted, a conclusion that the current standard is not adequate could be supported by the following observations:

- A number of epidemiologic studies have reported positive, and in some cases statistically significant, $PM_{10-2.5}$ effect estimates for mortality and morbidity in a variety of locations, including in several U.S. cities with 24-hour PM_{10} concentrations below those allowed by the current PM_{10} standard.
- Studies that have evaluated co-pollutant models have generally reported that $PM_{10-2.5}$ effect estimates remain robust and, in some cases, statistically significant when $PM_{2.5}$ or gaseous co-pollutants are added to the model.
- Uncertainties in the extent to which ambient $PM_{10-2.5}$ concentrations used in epidemiologic studies reflect population exposures tend to bias the results of those studies toward the null hypothesis. Therefore, given limitations in $PM_{10-2.5}$ monitoring, the generally positive $PM_{10-2.5}$ effect estimates reported across epidemiologic study locations, even in locations for which effect estimates were not significant, provide evidence for associations between $PM_{10-2.5}$ and mortality and morbidity.
- Controlled human exposure studies and, to a lesser extent, animal toxicological studies have reported cardiovascular and respiratory effects following exposures to thoracic coarse particles, thereby providing some support for the biological plausibility of the associations reported in epidemiologic studies.

However, as discussed above, a decision on the adequacy of the level of public health protection provided by the current PM_{10} standard will be a public health policy judgment in which the Administrator weighs the available evidence and its inherent uncertainties. Thus, depending on the emphasis placed on different aspects of the evidence and its associated uncertainties, different conclusions could be supported. Specifically, as discussed above, we note that many of the important uncertainties from the last review remain. In considering the evidence as well as these uncertainties, the ISA concluded that the evidence is "suggestive" of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects. These conclusions contrast with those for associations between $PM_{2.5}$ and health effects, which were judged to be either "causal" or "likely causal" for mortality and cardiovascular and respiratory effects associated with short- and long-term $PM_{2.5}$ exposures. Among the specific uncertainties noted in the ISA (US EPA, 2009a, sections 2.3.3, 2.3.4) are the following:

- Limited monitoring for $PM_{10-2.5}$ results in uncertainty in the ambient $PM_{10-2.5}$ concentrations at which effects reported in epidemiologic studies occur.
- The number of epidemiologic studies that have employed co-pollutant models to address the potential for confounding remains relatively limited. Therefore, the extent to which $PM_{10-2.5}$ itself contributes to reported health effects, rather than one or more co-pollutants, remains uncertain.
- Only a limited number of experimental studies provide support for the associations reported in epidemiologic studies.
- The chemical and biological composition of $PM_{10-2.5}$, and the effects associated with the various components, remains uncertain.

To the extent a decision on the adequacy of the current PM_{10} standard were to emphasize the uncertainties that contributed to the ISA conclusion that the evidence is "suggestive" of a causal relationship for $PM_{10-2.5}$, rather than indicating a "likely causal" or "causal" relationship, it would be reasonable to conclude that the available evidence does not provide a basis for reaching a fundamentally different conclusion from the one reached in the previous review (i.e., to retain the current 24-hour PM_{10} standard). Therefore, our preliminary conclusion is that the available evidence could support either revising the current PM_{10} standard to increase public health protection against exposures to thoracic coarse particles or retaining the current PM_{10} standard, depending on the emphasis placed on different aspects of the evidence and associated uncertainties.

3.3 CONSIDERATION OF POTENTIAL ALTERNATIVE STANDARDS

Having reached the conclusion that, depending on the approach to considering the available evidence, the adequacy of the current 24-hour PM_{10} standard to protect against effects associated with exposures to thoracic coarse particles could be called into question, staff considers a second overarching question:

What alternative standard(s) to protect against exposures to $PM_{10-2.5}$ could be supported by the currently available scientific evidence, as reflected in the ISA?

To inform the answer to this overarching question, we consider how the currently available scientific evidence could inform decisions regarding the basic elements of the NAAQS: indicator (section 3.3.1), averaging time (section 3.3.2), and form and level (section 3.3.3). In considering the appropriateness of potential alternative standards, we consider both the evidence available in the last review and the evidence that is newly available since the last review, as assessed and presented in the ISA (US EPA, 2009a).

3.3.1 Indicator

As noted in section 3.2 of the ISA, unlike gaseous pollutants such as O_3, SO_2, and CO, "which are well-defined chemical entities, atmospheric PM varies in size, shape, and chemical composition" (US EPA, 2009a, p. 3-1). The selection of PM_{10} as an indicator of thoracic particles was originally based in large part on dosimetry (U.S. EPA, 1996a) with evidence suggesting that a large proportion of inhaled coarse particles in the 3-6 μm (d_{ae}) range can reach and deposit in the lower respiratory tract, particularly the tracheobronchial airways, while the fraction deposited decreases as particle size increases (US EPA, 2009a, Figures 4-3 and 4-4). Currently, it is most common to use PM_{10} as an indicator of thoracic particles and $PM_{10-2.5}$ as an indicator of the thoracic component of coarse particles, sometimes referred to as thoracic coarse particles. As such, the majority of available health evidence for coarse particles links health effects to $PM_{10-2.5}$ and/or PM_{10}. As discussed in section 3.1.1, in the review of the PM NAAQS completed in 1997, and again in the review completed in 2006, EPA concluded that the purpose of the PM_{10} standard would be to provide protection against effects associated with $PM_{10-2.5}$. This section considers the issue of the appropriate indicator for a standard meant to protect against exposures to thoracic coarse particles. Considerations related to indicator in the review completed in 2006 are discussed in section 3.3.1.1; evidence-based considerations to inform our understanding of indicator in the current review are discussed in section 3.3.1.2; and preliminary staff conclusions regarding indicator are discussed in section 3.3.1.3.

3.3.2 Consideration of Indicator in the Review Completed in 2006

In the last review, the Administrator's decision on the indicator for a standard meant to protect against exposures to thoracic coarse particles took into consideration the potential for particles originating in different types of environments (i.e., urban versus non-urban), and with different compositions, to possess different degrees of toxicity. At the time, most of the studies supporting the link between exposure to thoracic coarse particles and adverse health effects had been conducted in urban locations. Epidemiologic studies had reported positive, and in some cases statistically significant, associations between ambient concentrations of thoracic coarse particles and adverse health effects in studies conducted in cities both inside and outside the U.S. In contrast, very little evidence was available to suggest that thoracic coarse particles from non-urban areas posed a threat to human health and a few studies reported that exposure to crustal material from non-urban locations did not result in the types of effects that had been linked with exposures to urban particles. Specifically, several toxicological studies reported that volcanic ash from Mt. St. Helens (an example of natural crustal material of geologic origin) caused very little toxicity in animal or *in vitro* model systems (e.g., see US EPA, 2005, section 5.4.2.1

for discussion). In addition, an epidemiologic study in Spokane, WA specifically assessed whether mortality was increased on dust-storm days using case-control analysis methods. The average PM_{10} concentration on dust storm days was more than 200 $\mu g/m^3$ higher than on control days; however, the authors reported no evidence of increased mortality on these specific days (Schwartz et al., 1999). In addition, studies conducted in several areas in the western U.S. reported that associations between PM_{10} and mortality or morbidity remained unchanged or became larger and more precise when days indicative of wind-blown dust were excluded from the analyses (Pope et al., 1999; Schwartz, 1997; Chen et al., 2000; Hefflin et al., 1994). In the last review, this group of studies was interpreted as suggesting that health effects associated with thoracic coarse particles are not driven by the types of natural crustal materials that would typically form a major fraction of coarse particles in non-urban or rural areas.[14]

In 2006, the Administrator noted that the apparent differences in toxicity of particles from urban versus non-urban locations could result from the different contaminants present in urban versus non-urban environments. Specifically, he stated the following

> [T]he observed toxicity of coarse particles in urban and industrial areas comes from the kind of coarse particles found in these environments, for example direct emissions from industrial sources or materials released to road dust from motor vehicles such as brake and tire wear, as well as from the contamination of coarse particles that can occur. This contamination can come from both mobile and stationary sources. In particular, specific components, such as byproducts of incomplete combustion (*e.g.* polycyclic aromatic hydrocarbons) most commonly emitted from motor vehicles and other sources in the form of $PM_{2.5}$, as well as metals and other contaminants emitted from other anthropogenic sources, appear in higher levels in urban areas (EPA, 2004a, p. 8–344; 71 FR 2665). Many of these contaminants in $PM_{10–2.5}$ come originally from fine particles, which may become attached in the atmosphere or be deposited and mixed into coarse materials on the ground. Thus the greater the concentration of $PM_{2.5}$, with higher levels typically found in urban areas, the greater the level of contamination of coarse particles by fine particles. This contamination increases the potential health risk posed by those coarse particles. For that reason, it is logical to allow lower levels of coarse particles when fine particle concentrations are high (71 FR 61196, October 17, 2006).

Given the available evidence and the above considerations, the Administrator judged in the last review that two primary objectives were appropriate to consider when making a decision on the standard indicator. Specifically, given the preponderance of evidence from studies conducted in urban areas, the Administrator judged it appropriate to have the level of protection reflect the varying degree of public health concern presented by the different ambient mixes of

[14]Although Ostro (2003) found that rural coarse particles primarily of crustal origin were associated with mortality effects, as noted by both CASAC and the Administrator (71 FR 61190).

thoracic coarse particulate matter by allowing lower ambient thoracic coarse particle concentrations in locations with higher fine particle concentrations (e.g., urban areas, where the evidence indicates the public health risks to be significant) and higher concentrations of ambient thoracic coarse particles in locations with lower fine particle concentrations (e.g., non-urban areas, where the evidence related to thoracic coarse particles is more limited). In addition, though there was little evidence at the time to suggest that thoracic coarse particles in non-urban locations posed a threat to human health, the Administrator judged that, given uncertainties in the interpretations of some of the studies of non-urban particles,[15] it was appropriate to take a cautious approach by setting a standard that provides some measure of protection against exposures to all ambient mixes of thoracic coarse particles, regardless of source of origin or composition (71 FR 61197/3).

The Administrator evaluated several different potential indicators by considering the extent to which each would contribute to achieving these objectives. Specifically, the Administrator considered a $PM_{10-2.5}$ indicator, either qualified so as to exclude some sources and locations (see below) or unqualified with no such exclusions, and a PM_{10} indicator, either adjusted to account for the $PM_{2.5}$ component of PM_{10} or unadjusted. Each of these options, and the Administrator's consideration of them in the last review, is discussed below.

In considering the extent to which a $PM_{10–2.5}$ indicator would achieve the objectives for public health protection described above, the Administrator evaluated both a qualified indicator, which would have exempted specific sources (e.g., agricultural and mining sources) and/or locations (e.g., rural areas), and an unqualified indicator. With regard to the qualified indicator, the Administrator concluded that, although it would permit the level of protection to reflect the varying degree of public health concern presented by the different ambient mixes of thoracic coarse particles, it would clearly not meet the goal of providing some measure of protection against all ambient mixes of thoracic coarse particles for the evident reason that it would have explicitly excluded certain types of sources and locations. In contrast, with regard to the unqualified indicator the Administrator noted that, though it would provide protection against exposures to all ambient mixes of thoracic coarse particles, "if such an indicator were utilized as part of a standard with a single unvarying level, it would not reflect the critical difference in evidence regarding the relative public health risks associated with urban and non-urban thoracic coarse particles" (71 FR 61195). That is, he concluded that if the level were selected to provide appropriate protection against effects associated with exposure to the ambient mixes typical of

[15] The final decision in the review completed in 2006 noted that uncertainties in interpreting these and other studies relevant to the consideration of effects associated with non-urban particles (e.g., changing activity patterns on high dust days in epidemiologic studies) suggested that it remained appropriate to provide some measure of protection against all thoracic coarse particles, even those from non-urban areas.

urban or industrial areas, the standard could be judged to be more stringent than necessary to protect against effects associated with exposure to the ambient mixes in non-urban areas. Conversely, if a less stringent level were adopted on the grounds that there is less certainty that the ambient mix in non-urban areas poses a health risk, then the standard could be judged not to provide sufficient protection from the ambient mix found in urban or industrial areas. In both instances a $PM_{10-2.5}$ standard could be judged not to be requisite (i.e., ''not lower or higher than is necessary'' *Whitman*, 531 U.S. at 476.) to protect the public health with an adequate margin of safety. In considering a potential approach to addressing this issue, the Administrator also concluded that it would not be appropriate to set different $PM_{10-2.5}$ standard levels for urban versus non-urban locations given the "lack of evidence to support establishing specific quantitative distinctions in level based on variations in coarse particle composition and differential toxicity" (71 FR 61195). Given all of these considerations, the Administrator concluded that it would not be appropriate to set a standard with a $PM_{10-2.5}$ indicator at the time of the last review.

In considering the extent to which a PM_{10} indicator would achieve the objectives for public health protection described above, the Administrator evaluated both an adjusted indicator, to account for the $PM_{2.5}$ component of PM_{10}, and an unadjusted indicator. For the adjusted indicator, the mass of $PM_{2.5}$ monitored in excess of the 24-hour standard for $PM_{2.5}$ would have been subtracted from monitored PM_{10} mass in order to avoid the double regulation of $PM_{2.5}$ in the situations where this would have had the most regulatory consequence. Under this option, on days when the measured concentration of PM_{10} exceeded the level of the standard and the measured concentration of $PM_{2.5}$ exceeded the level of the 24-hour $PM_{2.5}$ standard, the amount of $PM_{2.5}$ in excess of the 24-hour $PM_{2.5}$ standard would have been subtracted from the total PM_{10} mass (71 FR 61197). This option was judged by the Administrator to not be appropriate for two reasons. First, as noted above, the Administrator had determined that there should be less allowable coarse particulate matter as $PM_{2.5}$ levels increase because these are the conditions under which $PM_{10-2.5}$ tends to become more contaminated and could become more harmful. Furthermore, this indicator would have inappropriately relaxed the level of protection afforded by the existing 24-hour PM_{10} standard because it would have allowed higher total PM_{10} levels on days with high $PM_{2.5}$ levels. This indicator was thus directionally backwards; it decreased protection when conditions warranted increased protection. For both of these reasons, the Administrator rejected the adjusted PM_{10} indicator.

In his final decision in the review completed in 2006, the Administrator judged that the continued use of the unadjusted and unqualified PM_{10} indicator was appropriate for a standard meant to protect against effects associated with exposures to $PM_{10-2.5}$. In reaching this judgment,

the Administrator concluded that the PM_{10} indicator appropriately maintains some protection from all ambient mixes of thoracic coarse particles and provides a level of protection that reflects the varying degree of public health concern presented by the different ambient mixes. Specifically, the Administrator noted that both $PM_{2.5}$ and $PM_{10-2.5}$ contribute to PM_{10} mass. Therefore, he noted that that the PM_{10} standard would be expected to allow lower concentrations of thoracic coarse particles in locations with higher concentrations of $PM_{2.5}$ (i.e., urban areas) and higher concentrations of thoracic coarse particles in locations with lower concentrations of $PM_{2.5}$ (i.e, non-urban areas). As discussed above, this was judged appropriate because the available evidence indicated the potential for significant public health risks associated with exposures to thoracic coarse particles in urban areas, which generally have higher fine particle concentrations than rural areas, but provided much less certainty regarding risks in non-urban areas.

Given the Administrator's conclusion that these elevated fine particle concentrations in urban locations could result in greater fine particle contamination of coarse particles resulting in increased potential health risks posed by coarse particles in urban areas, he noted the following:

> To the extent that use of a PM_{10} indicator would result in any reduction in $PM_{2.5}$ concentrations in an area, this would reduce the potential health risk from coarse particles in the area as well. There is no certainty that the contribution of $PM_{2.5}$ to the health risk associated with exposure to contaminated coarse particles would be appropriately addressed through the fine particle standards alone. Thus, to the extent that the inclusion of the $PM_{2.5}$ fraction in the PM_{10} indicator amounts to double regulation of $PM_{2.5}$, its inclusion is non-duplicative and reasonable (71 FR 61196).

In reaching these judgments on the standard indicator, the Administrator recognized that the relationship between allowable thoracic coarse particle concentrations and fine particle concentrations is qualitative. That is, the varying coarse particle concentrations allowed under the PM_{10} standard do not precisely correspond to the likely variations in toxicity of thoracic coarse particles in different areas. However, the Administrator concluded that, while currently available information does not allow a more precise adjustment for relative toxicity, the PM_{10} standard is expected to generally ensure that the coarse particle levels allowed will appropriately be lower in urban areas and higher in non-urban areas. Given all of the above considerations, the Administrator judged in the last review that the unqualified and unadjusted PM_{10} indicator was appropriate for a standard meant to protect against exposures to $PM_{10-2.5}$.[16]

[16]As discussed above (section 3.1.2), this decision was upheld on review by the D.C. Circuit, which endorsed every aspect of the Administrator's rationale in reaching its decision. 559 F. 3d at 533-538.

3.3.3 Evidence-Based Consideration of Indicator in the Current Review

In the current review, in considering potential alternative standards, we have considered the following question with regard to indicator:

- **To what extent does the currently available information provide support for retaining or revising the current PM_{10} indicator?**

As in the last review, a critical issue in selecting an appropriate indicator for a standard meant to protect against exposures to thoracic coarse particles remains the extent to which available evidence supports the appropriateness of a standard that allows lower concentrations of $PM_{10-2.5}$ in urban areas than rural areas. In considering this issue, we note that the ISA assesses several epidemiologic studies of short-term exposures to thoracic coarse particles that have been conducted since the last review (US EPA, 2009a, Chapter 6). Similar to the studies considered in the previous review, as described above in more detail, most of these more recent studies have been conducted in urban locations in the U.S., Canada, and Europe. However, a few recent studies have examined the health impacts of dust storm events, where crustal material was generally indicated using PM_{10} (US EPA, 2009a, section 6.2.10.1). Specifically, a study of a dust storm in the Gobi desert, which transported PM across the Pacific Ocean reaching the western U.S. in the spring of 1998, reported no excess risk of cardiac or respiratory hospital admissions in the population of British Columbia's Lower Fraser Valley despite hourly PM_{10} concentrations greater than 100 $\mu g/m^3$ and daily average concentrations several times greater than normal (Bennett et al., 2006). In contrast, Middleton et al. (2008) reported that dust storms in Cyprus were associated with a 4.7% (95% CI: 0.7-9.0) and 10.4% (95% CI: -4.7 to 27.9) increase in risk of hospitalization for all causes and cardiovascular disease, respectively. PM_{10} concentrations in this study were much higher than typically reported in non-dust storm studies, with hourly PM_{10} concentrations during dust storms frequently approaching 300 to 400 $\mu g/m^3$ and a maximum 24-hour average PM_{10} concentration during the study almost 10-fold higher than the level of the current PM_{10} standard (i.e., 1,371 $\mu g/m^3$). In addition, Chan et al. (2008) studied the effects of Asian dust storms on cardiovascular hospital admissions in Taipei, Taiwan and reported significant adverse effects during 39 Asian dust events. Daily PM_{10} concentrations exceeded 150 $\mu g/m^3$ on several occasions during the study period and reached a maximum of between 200 and 250 $\mu g/m^3$ (see Figure 1 in Chan et al., (2008)). Bell et al. (2008) analyzed these data independently and concluded that Asian dust storms were positively associated with risk of hospitalization for ischemic heart disease. In addition, Yang et al. (2009) reported that hospitalizations for congestive heart failure were elevated during or immediately following 54 Asian dust storm events, though effect estimates were not statistically significant. Maximum 24-

hour PM_{10} concentrations were not reported but the mean 24-hour concentration due to dust storm events was 112 $\mu g/m^3$. In a dust storm study where $PM_{10-2.5}$ was specifically evaluated, Perez et al. (2008) tested the hypothesis that outbreaks of Saharan dust exacerbate the effects of $PM_{10-2.5}$ on daily mortality in Spain. During Saharan dust days, the $PM_{10-2.5}$ effect estimate was larger than on non-dust days, and it became statistically significant whereas it was not statistically significant on non-dust days. On Saharan dust days, mean $PM_{10-2.5}$ concentrations were about 10% higher than on non-Saharan dust days. Several animal toxicological studies have also reported that exposure to $PM_{2.5}$ from dust storms increased pulmonary inflammation and blood pressure (Lei et al., 2004; Chang et al., 2007; US EPA, 2009a, sections 6.2.5.3, 6.3.3.3).

In considering the implications of these studies for a decision on the indicator of a standard meant to protect against exposures to thoracic coarse particles, we first consider the following question:

- **To what extent is it appropriate to maintain an indicator that provides some measure of protection against all thoracic coarse particles?**

With regard to this question, we note that, though most of the evidence for associations with morbidity and mortality continues to come from studies conducted in urban areas,[17] associations reported in a small number of recent dust storm studies suggest that caution is warranted in drawing conclusions about the relative toxicity of thoracic coarse particles from urban versus non-urban environments. These studies of dust storm events, discussed above, raise credible concerns regarding the potential for non-urban particles to cause adverse health effects, though the dust storm-related PM_{10} concentrations tend to be higher than those in many locations where recent U.S. and Canadian studies have reported associations with $PM_{10-2.5}$. At a minimum, these recent dust storm studies indicate that exposure to relatively high concentrations of non-urban particles is associated with health effects that are similar to those that, in other studies, have been associated with urban particles.

Given the above considerations, as an initial matter we reach the preliminary conclusion that, for a standard meant to protect against exposures to thoracic coarse particles, it remains appropriate to provide some measure of protection against exposures to all ambient mixes of thoracic coarse particles, regardless of their source of origin or composition. In drawing this preliminary conclusion, we recognize the results of epidemiologic studies assessed in the ISA, which have reported positive, and in some cases statistically significant, effect estimates for

[17]Though in some cases study locations extended into areas surrounding urban centers and likely included some non-urban (e.g., suburban) areas.

thoracic coarse particles in a variety of locations, including studies of dust storm events where high particle concentrations were due to windblown crustal material. We also recognize that the causality judgments for thoracic coarse particles in the ISA were made for "$PM_{10-2.5}$ as a whole regardless of origin, since $PM_{10-2.5}$-related effects have been demonstrated for a number of different environments" (US EPA, 2009a, p. 2-19). Given these considerations, we note that either a PM_{10} or a $PM_{10-2.5}$ indicator would be expected to provide protection against all ambient mixes of thoracic coarse particles, as long as these indicators were not qualified so as to exclude certain types of sources or locations.

In addition, we have considered the following question with regard to indicator:

- **To what extent does it remain appropriate to draw distinctions between thoracic coarse particles from urban and non-urban environments when making a decision on the indicator for a standard meant to protect against exposures to those particles?**

In considering this question, we note that recent studies do provide some evidence for the toxicity of particles from a variety of environments, including particles of non-urban origin. Given these studies, it could be judged reasonable to adopt an indicator that does not allow different concentrations of thoracic coarse particles in urban and rural areas. As discussed above, a $PM_{10-2.5}$ indicator would accomplish this. In contrast, given the generally higher fine particle concentrations in urban areas compared to rural areas, a PM_{10} indicator would be expected to allow lower $PM_{10-2.5}$ concentrations in urban areas than in rural areas. Therefore, to the extent that it is judged appropriate to set a standard that does not allow different concentrations of thoracic coarse particles in different types of environments, it would be appropriate to consider a $PM_{10-2.5}$ indicator.

However, as discussed above, we also note that most of the evidence for positive associations between $PM_{10-2.5}$ and morbidity and mortality, particularly evidence for these associations at relatively low concentrations of $PM_{10-2.5}$, continues to come from studies conducted in locations where the $PM_{10-2.5}$ is expected to be largely of urban origin. While recent studies of dust storm events have provided some additional information on the health effects associated with particles of non-urban origin, the PM_{10} concentrations due to dust storm events in these studies are generally higher, and in at least some cases considerably higher, than those in the U.S. and Canadian cities where positive and statistically significant associations have been reported in recent studies. To the extent that these considerations are emphasized in a decision on the indicator for a standard, a reasonable conclusion would be that recent studies have not fundamentally changed our understanding of the relative toxicity of urban versus non-urban particles, and that available evidence continues to support the conclusion that thoracic coarse

particles of urban origin, where fine particle concentrations tend to be highest, are of particular concern.

Given this conclusion, it would be reasonable to consider an indicator that focuses control on areas with ambient mixes known with greater certainty to be associated with adverse health effects (i.e., mixes generally present in urban areas) since such an indicator could provide public health benefits with the greatest degree of certainty. With regard to this, as discussed in more detail above, we note that the varying levels of thoracic coarse particles allowed by a PM_{10} indicator would be expected to target protection to those locations (i.e., urban or industrial areas) where the strongest evidence has been observed for associations between adverse health effects and exposures to thoracic coarse particles. Therefore, under this approach to considering the evidence, a reasonable conclusion would be that a PM_{10} indicator remains appropriate for a standard meant to protect against exposures to thoracic coarse particles. Thus, as with a decision on the adequacy of the current standard, different decisions on indicator could be judged to be appropriate, depending on the emphasis placed on different aspects of the evidence and its associated uncertainties.

3.3.4 Averaging Time

In considering the appropriate averaging time(s) for the PM_{10} standard in the last review, the Administrator considered several epidemiologic studies that had reported statistically significant associations between short-term (24-hour) exposure to $PM_{10-2.5}$ and various morbidity effects as well as mortality. Based primarily on these studies, he concluded that the available evidence continued to support a 24-hour averaging time for a standard intended to control thoracic coarse particles. In contrast, given the relative lack of studies supporting a link between long-term exposures to thoracic coarse particles and morbidity or mortality, and given the conclusion reached in the AQCD that the available evidence did not suggest a link between morbidity or mortality and long-term exposure to $PM_{10-2.5}$ (US EPA, 2004a, p. 9–79), the Administrator further concluded that an annual coarse particle standard was not warranted at that time. In reaching this decision, the Administrator also noted that a 24-hour standard would be expected to provide protection against any as yet unidentified potential effects of long-term exposure at ambient concentrations. Thus, in the 2006 review the Administrator retained the 24-hour PM_{10} standard and revoked the annual PM_{10} standard (71 FR 61198-61199).

In the current review, we reconsider the extent to which the available evidence continues to support these decisions by considering the following question:

- **To what extent does the available evidence continue to support a 24-hour averaging time for a standard meant to protect against effects associated with short-term exposures to $PM_{10-2.5}$?**

With regard to this question, we note the conclusions from the ISA regarding the weight of evidence for different averaging times as well as the studies on which those conclusions are based. Specifically, as discussed above (see Table 3-1 above), the ISA concludes that the existing evidence is *suggestive of a causal relationship* between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects (ISA, section 2.3.3). This conclusion is based largely on epidemiologic studies which have primarily evaluated associations between 24-hour $PM_{10-2.5}$ concentrations and morbidity and mortality (e.g., see ISA, Figure 2-3), though a smaller number of controlled human exposure studies have reported effects following shorter exposures (i.e., 2-hours) to $PM_{10-2.5}$ (e.g., see ISA, sections 6.2.1.2, 6.3.3.2). In contrast, with respect to long-term exposures, the ISA concludes that available evidence is *inadequate to infer a causal relationship* with all health outcomes evaluated (US EPA, 2009a, section 2.3). Specifically, the ISA states, "To date, a sufficient amount of evidence does not exist in order to draw conclusions regarding the health effects and outcomes associated with long-term exposure to $PM_{10-2.5}$" (US EPA, 2009a, section 2.3.4; see Table 3-1 below).

In considering the weight of evidence determinations in the ISA, we conclude that, at a minimum, they suggest the importance of having a standard that protects against short-term exposures to thoracic coarse particles. In considering the averaging times used in the short-term epidemiologic studies, we note that the majority of the evidence supporting the link between $PM_{10-2.5}$ and morbidity and mortality is based on 24-hour average thoracic coarse particle concentrations. Therefore, our preliminary conclusion is that the evidence available in this review continues to support the appropriateness of a 24-hour averaging time for a PM_{10} standard meant to protect against short-term exposures to $PM_{10-2.5}$, including potential effects associated with exposures of shorter duration than 24-hours. We further note that, given the ISA conclusion that "a sufficient amount of evidence does not exist in order to draw conclusions regarding the health effects and outcomes associated with long-term exposure to $PM_{10-2.5}$" (ISA, p. 2-19) the evidence does not support the appropriateness of an annual thoracic coarse particle standard at this time. In reaching this conclusion, we note that, to the extent a short-term standard requires areas to reduce their 24-hour ambient particle concentrations, long-term concentrations would also be expected to decrease. Therefore, a 24-hour standard meant to protect against short-term exposures to thoracic coarse particles would also be expected to provide protection against any as yet unidentified potential effects of long-term exposures at ambient concentrations.

3.3.5 Level and Form

Given the conclusions above regarding the adequacy of the current PM_{10} standard (i.e., that, depending on the approach to considering the available evidence, the adequacy of the

current 24-hour PM_{10} standard to protect against effects associated with exposures to thoracic coarse particles could be called into question) and the appropriate indicator (i.e., that, depending on how the evidence is considered, either a PM_{10} or $PM_{10-2.5}$ indicator could be judged appropriate), we next consider whether different standard levels and/or forms for a 24-hour PM_{10} or $PM_{10-2.5}$ standard could be supported by the available evidence. To inform our consideration of this issue, we have considered the following question:

- **To what extent does new information support consideration of an alternative form and/or level?**

In considering this question, we have taken into account the scientific evidence from studies of the link between short-term exposure to $PM_{10-2.5}$ and mortality, cardiovascular morbidity, and respiratory morbidity, as assessed in the ISA, including the uncertainties and limitations in that evidence.

In the 2006 review, the Administrator concluded that "the level of protection afforded by the current 24-hour PM_{10} standard of 150 $\mu g/m^3$, one-expected-exceedance form, continues to be appropriate for the types of thoracic coarse particles typically found in urban or industrial areas" (71 FR 61202). In support of this decision, the Administrator noted that "mortality effects observed in epidemiologic studies for [thoracic] coarse particles are generally associated with exposure levels that exceed the current standards, and morbidity effects are generally associated with exposure levels that exceeded the current standards on only a few occasions" (71 FR 61202). Given this evidence, the Administrator concluded that the level of protection afforded by the existing PM_{10} standard was not greater than warranted. In addition, the Administrator concluded that uncertainties in population exposures in available morbidity studies[18] suggested that there was little basis for concluding that a greater degree of protection was warranted. Therefore, the Administrator retained the existing level of 150 $\mu g/m^3$ for the 24-hour PM_{10} standard, and the existing one-expected exceedance form.

In the sections below, we discuss the approach that will be used to identify potential alternative forms and a range of potential alternative levels for a standard meant to protect against exposures to thoracic coarse particles. These potential alternative standard forms and levels will be presented and considered in the second draft PA document.

[18]Analysis of air quality information in Detroit (Ito, 2003) and Coachella Valley (Ostro et al., 2003) suggested that population exposure concentrations in these areas could be appreciably higher (Detroit) or lower (Coachella Valley) than indicated by the air quality information used in the studies (See US EPA, 2005, pp. 5-64 to 5-66).

3.3.6 Form

As discussed in more detail above, in the 2006 review the Administrator concluded that "the degree of protection afforded by the current 24-hour PM_{10} standard is requisite to protect public health with an adequate margin of safety" (71 FR 61201). Given the overall decision in that review to provide the same protection as provided by the existing 24-hour standard, the Administrator concluded "it is best to retain both the form and the level of the current primary 24-hour PM_{10} standard" (71 FR 61202). Therefore, the one-expected-exceedance form was retained.

This decision is being examined in the current review within the context of the overall decision on whether to retain or revise the current 24-hour PM_{10} standard. While the selection of a specific form must be made within the context of a decision on the other elements of the standard, EPA generally favors the concentration-based form for short-term standards. In 1997 EPA established 98th percentile form for the 24-hour $PM_{2.5}$ standard and, most recently, in 2010 EPA established 98th percentile form for the 1-hour NO_2 standard (62 FR 38671; 75 FR 6474). In making these decisions, EPA judged that, as compared to an exceedance-based form, such as that used for the current PM_{10} standard, a concentration-based form is more reflective of the health risks posed by elevated pollutant concentrations because it gives proportionally greater weight to days when concentrations are well above the level of the standard than to days when the concentrations are just above the standard. Further, a concentration-based form better compensates for missing data and less than-daily monitoring. In addition, when averaged over 3 years, it has greater stability than an exceedance-based form and, therefore, it facilitates the development of more stable implementation programs. In these previous reviews, after considering different concentration percentiles (95th to the 99th for $PM_{2.5}$ and 98th and 99th for NO_2), EPA selected the 98th percentile as an appropriate balance between adequately limiting the occurrence of peak concentrations and providing increased stability and robustness.

In considering these decisions, our preliminary conclusion is that a similar logic applies in the case of the 24-hour PM_{10} standard. For this reason, to the extent that it is judged appropriate to revise the current 24-hour standard in the current review, we will give preliminary consideration to a range of alternative standard options based on 98th percentile concentrations of PM_{10} and/or $PM_{10-2.5}$, as discussed below.

3.3.7 Level

As noted above, depending on the approach taken in this review to consider the evidence for the adequacy of the current PM_{10} standard, it could be judged that this standard does not provide adequate public health protection. If this is judged to be the case, we will consider

potential alternative standard levels for a 24-hour standard that, in conjunction with a 98th percentile form as described above, would provide increased public health protection against effects associated with exposures to $PM_{10-2.5}$. Given the conclusion above that the continued use of the PM_{10} indicator could be judged appropriate for a standard meant to protect against exposures to $PM_{10-2.5}$, we will consider a range of potential alternative standard levels for a PM_{10} standard. However, as is also discussed above, a $PM_{10-2.5}$ indicator could potentially be judged appropriate. While the air quality information available to inform the identification of a range of potential alternative standard levels will be more limited for a $PM_{10-2.5}$ standard than for a PM_{10} standard, we recognize that some such information exists. Therefore, to the extent that feedback received during the review of this first draft Policy Assessment justifies consideration of a $PM_{10-2.5}$ standard, we will discuss potential alternative levels for such a standard in the second draft document.

In considering potential alternative standard levels, staff will consider the available information on PM_{10}, and possibly $PM_{10-2.5}$, concentrations in locations where health studies have evaluated the link between short-term $PM_{10-2.5}$ concentrations and mortality, cardiovascular morbidity, and respiratory morbidity, as well as the uncertainties and limitations in that evidence. In so doing, we will focus on U.S. studies, as described above in our consideration of the adequacy of the current standard. Specifically, we will consider the extent to which these studies report positive and relatively precise effect estimates; the extent to which the reported associations are robust in co-pollutant models; and the extent to which the studies used relatively reliable air quality data. In particular, we will focus on those specific studies, briefly summarized above and presented in more detail in chapter 6 of the ISA, that provide evidence of associations between $PM_{10-2.5}$ and mortality and morbidity in areas that would likely have met the current 24-hour PM_{10} standard during the time of the study. Staff believes that this body of evidence can serve as a basis for identifying and considering potential alternative 24-hour PM_{10} and/or $PM_{10-2.5}$ standards that would provide increased protection against effects related to short-term exposures to $PM_{10-2.5}$.

As an initial matter, we recognize, as discussed above, that these short-term exposure studies provide no evidence of clear thresholds, or lowest-observed-effects levels, in terms of 24-hour average concentrations. As a consequence, this body of evidence is difficult to translate directly into a specific 24-hour standard that would independently protect against all effects associated with short-term exposures. In the absence of an apparent threshold, for purposes of identifying the range of standard levels potentially supported by the epidemiologic evidence, we will focus on the range of PM_{10} and/or $PM_{10-2.5}$ concentrations that have been measured in locations where key health studies have reported associations with $PM_{10-2.5}$. Specifically, we will focus on the upper end of the distributions of daily PM concentrations,

particularly in terms of the 98th percentile of the yearly distribution of 24-hour PM_{10} and/or $PM_{10-2.5}$ concentrations, reflecting the considerations above for the appropriate form of the 24-hour standard. As noted above, this analysis of potential alternative standard levels will be presented in the second draft PA document.

3.4 KEY UNCERTAINTIES AND AREAS FOR FUTURE RESEARCH AND DATA COLLECTION

[This topic will be discussed in the second draft Policy Assessment.]

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4 REVIEW OF THE SECONDARY STANDARDS FOR VISIBILITY-RELATED EFFECTS

This chapter presents preliminary staff conclusions with regard to the adequacy of the current suite of secondary PM standards to protect against PM-related visibility impairment as well as the alternative secondary PM standards that are appropriate for consideration in this review. Our assessment of these issues is framed by a series of key policy-relevant questions, which expand upon those presented in the Integrated Review Plan (IRP) (US EPA, 2008a) at the outset of this review. The answers to these questions will inform decisions on whether, and if so how, to revise the current suite of secondary PM standards for the purpose of providing appropriate protection from PM-related visibility impairment.

In presenting preliminary staff conclusions on alternative secondary standard that are appropriate for consideration, we note that the final decision is largely a public welfare policy judgment. A final decision must draw upon scientific information and analyses about PM-related visibility impairment and related impacts on public welfare, as well as judgments about how to deal with the range of uncertainties that are inherent in the scientific evidence and analyses. Our approach to informing these judgments is discussed more fully below. This approach is consistent with the requirements of the NAAQS provisions of the Act and with how EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish secondary standards that, in the Administrator's judgment, 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 Act does not require that secondary standards be set at a zero-risk level, but rather at a level that avoids unacceptable public welfare impacts.

Information on the approaches used to set the secondary PM standards in past reviews as well as our current approach for this review are presented in section 4.1. Our preliminary conclusions regarding the adequacy of the current suite of secondary PM standards to protect against PM-related visibility impairment are presented in section 4.2. Section 4.3 presents our preliminary conclusions with respect to alternative PM standards by focusing on each of the basic elements of the standards: pollutant indicator (section 4.3.1), averaging time (section 4.3.2), and level and form (section 4.3.3). The performance of alternative standards, with a focus on the uniformity of protection from visibility impairment afforded by the alternative standards, is evaluated in section 4.3.4. Section 4.4 summarizes all preliminary staff conclusions on the secondary PM standards for visibility protection. The next draft of this chapter will conclude with an initial overview of areas of key uncertainties and suggested future research areas and data collection efforts (section 4.5)

4.1 APPROACH

Staff's approach for reviewing the current secondary PM standards builds upon and broadens the approaches used in previous PM NAAQS reviews. We first present a brief summary of the approaches used to establish and review secondary PM standards in the last two reviews of the PM NAAQS (section 4.1.1). Recent litigation on the 2006 standards has resulted in the remand of the secondary annual and 24 hour $PM_{2.5}$ NAAQS to EPA as discussed in section 4.1.2. Our current approach for evaluating the secondary $PM_{2.5}$ standards using both evidence- and impact assessment-based considerations is outlined in section 4.1.3.

4.1.1 Approaches Used in Previous Reviews

The original suite of $PM_{2.5}$ standards was established in 1997 and revisions to those standards were made in 2006. The approaches used in making final decisions on secondary standards in those reviews, as well as the current review, utilize different ways to consider the underlying body of scientific evidence. They also reflect an evolution in our understanding of the multi-faceted nature of the public welfare visibility effect, from a more narrow focus on Class I area visibility to non-Class I area visibility, including urban areas, and public perception, valuation and impacts on personal comfort and well being.

4.1.1.1 Review Completed in 1997

In 1997, EPA revised the identical primary and secondary PM_{10} NAAQS in part by establishing new identical primary and secondary $PM_{2.5}$ standards. In revising the secondary standards, EPA recognized that PM produces adverse effects on visibility and that impairment of visibility was experienced throughout the U.S., in multi-state regions, urban areas, and remote mandatory Class I Federal areas alike. However, in considering an appropriate level for a secondary standard to address adverse effects of PM on visibility, EPA concluded that the determination of a single national level was complicated by regional differences in several factors that influence visibility such as background and current levels of PM, composition of PM, and average relative humidity. Variations in these factors could thus result in situations where attaining even a low concentration of fine particles might or might not provide adequate protection, depending on these factors. The EPA also determined that there was insufficient information at that time to establish a level for a national secondary standard that would represent a threshold above which visibility conditions would always be adverse and below which visibility conditions would always be acceptable.

Based on these considerations, EPA assessed potential visibility improvements in urban areas and on a regional scale that would result from attainment of the new primary standards for $PM_{2.5}$. The agency concluded that the spatially averaged form of the annual $PM_{2.5}$ standard was well suited to the protection of visibility, which involves effects of PM throughout an extended

viewing distance across an urban area. Based on air quality data available at that time, many urban areas in the northeast, midwest, and southeast, as well as Los Angeles, were expected to see perceptible improvement in visibility if the annual $PM_{2.5}$ primary standard was attained. The EPA also concluded that in some areas attainment of the 24-hour $PM_{2.5}$ standard would be expected to reduce, to some degree, the number and intensity of ''bad visibility'' days, i.e., the 20% of days having the greatest impairment over the course of a year.

Having concluded that attainment of the annual and 24-hour $PM_{2.5}$ primary standards would lead to visibility improvements in many eastern and some western urban areas, EPA also considered whether these standards could provide potential improvements to visibility on a regional scale. Based on information available at the time, EPA concluded that attainment of $PM_{2.5}$ secondary standards set identical to the primary standards would be expected to result in visibility improvements in the eastern U.S. at both urban and regional scales, but little or no change in the western U.S., except in and near certain urban areas.

The EPA then considered the potential effectiveness of a regional haze program, required by sections 169A and 169B of the Act[1] to address the widespread, regionally uniform type of haze caused by a multitude of sources, to address those effects of PM on visibility that would not be addressed through attainment of the primary $PM_{2.5}$ standards. The structure and requirements of sections 169A and 169B of the Act provide for visibility protection programs that can be more responsive to the factors contributing to regional differences in visibility than can programs addressing a nationally applicable secondary NAAQS. The regional haze visibility goal was more protective than a secondary NAAQS since the goal addresses any man-made impairment rather than just impairment at levels determined to be adverse. Thus, an important factor considered in the 1997 review was whether a regional haze program, in conjunction with secondary standards set identical to the suite of $PM_{2.5}$ primary standards, would provide appropriate protection for visibility in non-Class I areas. The EPA concluded that the two programs and associated control strategies should provide such protection due to the regional approaches needed to manage emissions of pollutants that impair visibility in many of these areas.

For these reasons, EPA concluded that a national regional haze program, combined with a nationally applicable level of protection achieved through secondary $PM_{2.5}$ standards set identical to the primary $PM_{2.5}$ standards, would be more effective in addressing regional variations in the adverse effects of $PM_{2.5}$ on visibility than establishing national secondary

[1] In 1977, Congress established as a national goal ''the prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Class I Federal areas which impairment results from manmade air pollution'', section 169A(a)(1) of the Act. The EPA is required by section 169A(a)(4) of the Act to promulgate regulations to ensure that ''reasonable progress'' is achieved toward meeting the national goal.

standards for PM at lower levels than the primary $PM_{2.5}$ standards. The EPA further recognized that people living in certain urban areas may place a high value on unique scenic resources in or near these areas, and as a result might experience visibility problems attributable to sources that would not necessarily be addressed by the combined effects of a regional haze program and $PM_{2.5}$ secondary standards. The EPA concluded that in such cases, State or local regulatory approaches, such as past action in Colorado to establish a local visibility standard for the City of Denver, would be more appropriate and effective in addressing these special situations because of the localized and unique characteristics of the problems involved. Visibility in an urban area located near a mandatory Class I Federal area could also be improved through State implementation of the current visibility regulations, by which emission limitations can be imposed on a source or group of sources found to be contributing to ''reasonably attributable'' impairment in the mandatory Class I Federal area.

Based on these considerations, EPA set secondary $PM_{2.5}$ standards identical to the primary $PM_{2.5}$ standards, in conjunction with a regional haze program under sections 169A and 169B of the Act, as the most appropriate and effective means of addressing the welfare effects associated with visibility impairment. Together, the two programs and associated control strategies were expected to provide appropriate protection against the effects of PM on visibility and enable all regions of the country to make reasonable progress toward the national visibility goal.

4.1.1.2 Review Completed in 2006

In 2006, EPA revised the secondary PM standards by once again making them identical to the revised primary standards. The EPA's decision to revise the secondary PM standards reflected a number of new developments and sources of information that had occurred and/or become available following the 1997 review. First, EPA promulgated a regional haze program in 1999 (65 FR 35713) which required States to establish goals for improving visibility in Class I areas and to adopt control strategies to achieve these goals. Second, extensive new information from visibility and fine particle monitoring networks had become available, allowing for updated characterizations of visibility trends and PM levels in urban areas, as well as Class I areas. These new data allowed EPA to better characterize visibility impairment in urban areas and the relationship between visibility and $PM_{2.5}$ concentrations. Finally, additional studies in the U.S. and abroad provided the basis for the establishment of standards and programs to address specific visibility concerns in a number of local areas. These studies (e.g., in Denver, Phoenix, British Columbia) produced reasonably consistent results in terms of the visual ranges found to be generally acceptable by the participants in the various studies. These studies utilized photographic representations of visibility impairment, which were useful in characterizing the nature of particle-induced haze. Based largely on this information, the Administrator concluded

that it was appropriate to revise the secondary PM standards to provide increased protection from visibility impairment principally in urban areas, in conjunction with the regional haze program for protection of visual air quality in Class I areas.

In so doing, the Administrator recognized that PM-related visibility impairment is principally related to fine particle levels, such that it was appropriate to focus the review on whether the current secondary $PM_{2.5}$ standards should be revised. The Administrator also recognized that perception of visibility impairment is most directly related to instantaneous levels of visual air quality, such that in considering whether the current suite of secondary standards would provide the appropriate degree of protection, he concluded that it was appropriate to revise just the 24-hour secondary $PM_{2.5}$ standard to provide requisite protection.

The EPA then considered whether $PM_{2.5}$ remained the appropriate indicator for a secondary standard to protect visibility primarily in urban areas. One of the key issues in the 1997 review was the extent to which the differences in humidity between East and West complicated the establishment of a nationally uniform $PM_{2.5}$ secondary standard for urban areas. With the substantial addition to the air quality and visibility data made possible by the national urban $PM_{2.5}$ monitoring networks, an analysis conducted for the 2006 review found that, in urban areas, visibility levels showed far less difference between eastern and western regions on a 24-hour or shorter time basis than implied by the largely non-urban data available in the 1997 review. In analyzing how well $PM_{2.5}$ concentrations correlated with visibility in urban locations across the U.S., the 2005 Staff Paper concluded that clear correlations existed between 24-hour average $PM_{2.5}$ concentrations and reconstructed light extinction, which is directly related to visual range. These correlations were similar in the eastern and western regions of the U.S. Particles in the coarse mode generally contributed only marginally to visibility impairment in urban areas. Further, because hygroscopic components of fine particles, in particular sulfates and nitrates, contribute disproportionately to visibility impairment under high humidity conditions, these correlations were less influenced by relative humidity and more consistent across regions when $PM_{2.5}$ concentrations are averaged over shorter, daylight time periods (e.g., 4 to 8 hours) when relative humidity was generally lower and less variable. The 2005 Staff Paper noted that a standard set at any specific $PM_{2.5}$ concentration would necessarily result in visual ranges that vary somewhat in urban areas across the country, reflecting the variability in the correlations between $PM_{2.5}$ concentrations and light extinction. Thus, the 2005 Staff Paper concluded that it was appropriate to use $PM_{2.5}$ as an indicator for standards to address visibility impairment in urban areas, especially when the indicator is defined for a relatively short period (e.g., 4 to 8 hours) of daylight hours. Based on their review of the Staff Paper, most CASAC Panel members also endorsed such a $PM_{2.5}$ indicator for a secondary standard to address visibility impairment (Henderson, 2005a). Based on the above considerations, the Administrator

concluded that $PM_{2.5}$ should be retained as the indicator for fine particles as part of a secondary standard to address visibility protection, in conjunction with averaging times from 4 to 24 hours.

In considering what level of protection against PM-related visibility impairment would be appropriate, the Administrator took into account the results of the public perception and attitude surveys in the U.S. and Canada, State and local visibility standards within the U.S., and visual inspection of photographic representations of several urban areas across the U.S. In the Administrator's judgment, these sources provided useful but still quite limited information on the range of levels appropriate for consideration in setting a national visibility standard primarily for urban areas, given the generally subjective nature of the public welfare effect involved. Based on photographic representations of varying levels of visual air quality, public perception studies, and local and State visibility standards, the 2005 Staff Paper concluded that 30 to 20 $\mu g/m^3$ $PM_{2.5}$ represented a reasonable range for a national visibility standard primarily for urban areas, based on a sub-daily averaging time. The upper end of this range was below the levels at which illustrative scenic views are significantly obscured, and the lower end was around the level at which visual air quality generally appeared to be good based on observation of the illustrative views. This concentration range generally corresponded to median visual ranges in urban areas within regions across the U.S. of approximately 25 to 35 km, a range which was bounded above by the visual range targets selected in specific areas where State or local agencies placed particular emphasis on protecting visual air quality. In considering a reasonable range of forms for a $PM_{2.5}$ standard within this range of levels, the 2005 Staff Paper concluded that a concentration-based percentile form was appropriate, and that the upper end of the range of concentration percentiles should be consistent with the 98^{th} percentile used for the primary standard and that the lower end of the range should be the 92^{nd} percentile, which represented the mean of the distribution of the 20 percent most impaired days, as targeted in the regional haze program. While recognizing that it was difficult to select any specific level and form based on then currently available information (Henderson, 2005a), the CASAC Panel was generally in agreement with the ranges of levels and forms presented in the 2005 Staff Paper.

The Administrator also considered the level of protection that would be afforded by the proposed suite of primary $PM_{2.5}$ standards (71 FR 2681), on the basis that although significantly more information was available than in the 1997 review concerning the relationship between fine PM levels and visibility across the country, there was still little available information for use in making the relatively subjective value judgment needed in selecting the appropriate degree of protection to be afforded by such a standard. In so doing, the Administrator compared the extent to which the proposed suite of primary standards would require areas across the country to improve visual air quality with the extent of increased protection likely to be afforded by a standard based on a sub-daily averaging time. Based on such an analysis, the Administrator

observed that the predicted percent of counties with monitors not likely to meet the proposed suite of primary $PM_{2.5}$ standards was actually somewhat greater than the predicted percent of counties with monitors not likely to meet a sub-daily secondary standard with an averaging time of 4 daylight hours, a level toward the upper end of the range recommended in the 2005 Staff Paper, and a form within the recommended range. Based on this comparison, the Administrator concluded that revising the secondary 24-hour $PM_{2.5}$ standard to be identical to the proposed revised primary $PM_{2.5}$ standard (and retaining the current annual secondary $PM_{2.5}$ standard) was a reasonable policy approach to addressing visibility protection primarily in urban areas. In proposing this approach, the Administrator also solicited comment on a sub-daily (4- to 8-hour averaging time) secondary $PM_{2.5}$ standard (71 FR 2675-2781).

In commenting on EPA's proposal, the CASAC requested that a sub-daily standard to protect visibility be favorably reconsidered (Henderson, 2006). The CASAC noted three cautions regarding the Agency's proposed reliance on a secondary $PM_{2.5}$ standard identical to the proposed 24-hour primary $PM_{2.5}$ standard: (1) $PM_{2.5}$ mass measurement is a better indicator of visibility impairment during daylight hours, when relative humidity is generally low; the sub-daily standard more clearly matches the nature of visibility impairment, whose adverse effects are most evident during the daylight hours; using a 24- hour standard as a proxy introduces error and uncertainty in protecting visibility; and sub-daily standards are used for other NAAQS and should be the focus for visibility; (2) CASAC and its monitoring subcommittees have repeatedly commended EPA's initiatives promoting the introduction of continuous and near-continuous PM monitoring, and expanded deployment of continuous $PM_{2.5}$ monitors is consistent with setting a sub-daily standard to protect visibility; (3) The analysis showing a similarity between percentages of counties not likely to meet what they considered to be a lenient 4- to 8-hour secondary standard and a secondary standard identical to the proposed 24-hour primary standard was a numerical coincidence that was not indicative of any fundamental relationship between visibility and health. The CASAC Panel further stated that "visual air quality is substantially impaired at $PM_{2.5}$ concentrations of 35 $\mu g/m^3$" and that ''it is not reasonable to have the visibility standard tied to the health standard, which may change in ways that make it even less appropriate for visibility concerns."

In reaching a final decision, the Administrator focused on the limitations in the available hourly air quality data and in the studies of public perception and attitudes regarding the acceptability of various degrees of visibility impairment in urban areas, as well as on the subjective nature of the public welfare judgment required. In so doing, the Administrator concluded that caution was warranted in establishing a distinct secondary standard for visibility impairment and that the available information did not warrant adopting a secondary standard that

would provide either more or less protection against visibility impairment in urban areas than would be provided by secondary standards set equal to the proposed primary PM2.5 standards.

4.1.2 Remand of Secondary $PM_{2.5}$ Standards

Several parties filed petitions for review following promulgation of the revised PM NAAQS in 2006. These petitions challenged several aspects of the final rule including EPA's decision to set the secondary NAAQS for fine PM, which protect the public welfare from adverse visibility effects, at the same level as the primary NAAQS, which protect public health 42 U.S.C. 7607(d)(9).

On judicial review, the D.C. Circuit remanded for reconsideration the secondary NAAQS for fine PM to EPA because the Agency's decision was unreasonable and contrary to the requirements of 42 U.S. C. section 7409 (b)(2). The petitioners argued that EPA's decision lacked a reasoned basis. First, they asserted, EPA never determined what level of visibility was "requisite to protect the public welfare" 42 U.S.C. section 7409(b)(2). They argued that EPA unreasonably rejected the target level of protection provided by its staff, while failing to provide a target level of its own. The D.C. Circuit court concurred stating "the EPA's failure to identify such a level when deciding where to set the level of air quality required by the revised secondary fine PM NAAQS is contrary to the statute and therefore unlawful. Furthermore, the failure to set any target level of visibility protection deprived the EPA's decisionmaking of a reasoned basis." American Farm Bureau Federation v. EPA, 559 F. 3d 512, (D.C. Cir. 2009).

Second, the petitioners challenged EPA's method of comparing the protection expected from potential standards. They contend that the EPA relied on a meaningless numerical comparison, ignored the effect of humidity on the usefulness of a standard using a daily averaging time, and unreasonably concluded that the primary standards would achieve a level of visibility roughly equivalent to the level the EPA staff and CASAC deemed "requisite to protect the public welfare." Again, the court found that EPA's equivalency analysis failed on its own terms. The same table showing the alternative secondary standard used for comparison to the alternative primary to show equivalency also included six other standards within the recommended CASAC range that would be more "protective" under EPA's definition than the primary standards. Two thirds of the potential standards within the CASAC's recommended range would be substantially more protective than the primary standards. The EPA failed to explain why it looked only at one of the few potential standards that would be less protective-and only slightly so- than the primary standards. More fundamentally, however, EPA's equivalency analysis demonstrated nothing about the relative protection offered by the different standards. The tables simply offer no valid information about the relative visibility protection provided by the standards.

Finally, the Staff Paper made clear that a visibility standard using a daily averaging time will be confounded by regional differences in humidity. The EPA acknowledged this problem, yet did not address this issue at all in concluding that the primary standards would be sufficiently protective of visibility. Therefore, the court granted the petition for review and remanded for reconsideration the secondary PM NAAQS. American Farm Bureau Federation, 559 F. 3d at 520-24.

4.1.3 Current Approach

The staff's approach in this review broadens the general approaches used in the last two PM NAAQS reviews by utilizing, to the extent available, enhanced tools, methods, and data to more comprehensively characterize visibility impacts. As such, staff is taking into account both evidence-based and impact-based considerations to inform staff conclusions related to the adequacy of the current secondary standards and alternative standards that are appropriate for consideration in this review. In so doing, we are seeking to provide as broad an array of options as is supportable by the available information, recognizing that the selection of a specific approach to reaching final decisions on the secondary $PM_{2.5}$ standards will reflect the judgments of the Administrator as to what weight to place on the various approaches and types of information presented in the final PA.

For the purposes of this first draft Policy Assessment (PA), staff has drawn from the qualitative evaluation of all studies evaluated in the *Integrated Science Assessment for Particulate Matter (Final Report)* (ISA, USEPA, 2009a). The discussions presented in this chapter consider the extensive new air quality and source apportionment information available from the regional planning organizations, long-standing evidence of PM effects on visibility, and public preference studies from four urban areas, as discussed in chapter 9 of the ISA, as well as the integration of evidence across disciplines presented in chapter 2 of the ISA. In addition, limited information that has become available regarding the characterization of public preferences in urban areas has provided some new perspectives on the usefulness of this information in informing the selection of target levels of urban visibility protection. On these bases, we are again focusing our assessments in this review on visibility conditions in urban areas.

Our preliminary conclusions reflect our understanding of both evidence-based and impact-based considerations to inform two overarching questions related to: (1) the adequacy of the current suite of $PM_{2.5}$ standards and (2) what potential alternative standards, if any, should be considered in this review to provide appropriate protection from PM-related visibility impairment. In addressing these broad questions, we have organized the discussions below around a series of more specific questions reflecting different aspects of each overarching

question. When evaluating the visibility protection afforded by the current or any alternative standards considered, we have taken into account the four basic elements of the NAAQS (e.g., indicator, averaging time, level, and form).

We believe that the approach outlined above, when presented in the final PA, will provide a comprehensive basis to help inform the judgments required of the Administrator in reaching decisions about the current and potential alternative secondary PM standards for the purpose of providing appropriate protection from PM-related visibility impairment and in responding to the remand of the 2006 secondary $PM_{2.5}$ standards.

4.2 ADEQUACY OF CURRENT STANDARDS

In considering the adequacy of the current suite of $PM_{2.5}$ standards, staff addresses the following overarching question:

Does the currently available scientific evidence and visibility impact information, as reflected in the ISA and UFVA, support or call into question the adequacy of the visibility protection afforded by the current suite of fine particle standards?

To inform the answer to this overarching question, we have posed a series of more specific questions to aid in considering the currently available scientific evidence and the results of recent quantitative visibility impact analyses in a policy-relevant context, as discussed below. In considering the scientific and technical information, we reflect upon both the information available in the last review and information that is newly available since the last review as assessed and presented in the ISA and UFVA (US EPA, 2009a; US EPA, 2010b).

4.2.1 Evidence-based Considerations

In reviewing the adequacy of the current suite of $PM_{2.5}$ standards, we have taken into account evidence-based considerations, primarily as presented in the ISA, by considering causal inference, impacts on susceptible populations, and whether visibility effects have been observed in urban areas that would likely meet the current standards.

- **To what extent does the newly available scientific evidence strengthen or call into question evidence of associations between ambient fine particle exposures and visibility effects?**

New research conducted by regional planning organizations in support of the Regional Haze Rule, as discussed in chapter 9 of the ISA, continues to support and refine our understanding of the nature of the PM visibility effect and the source contributions to that effect in rural and remote locations. Additional byproducts of this research include new insights regarding the regional source contributions to urban visibility and better characterization of the urban excess that occurs in many cities above regional background. Ongoing urban $PM_{2.5}$

speciated and mass monitoring has produced new information that has allowed for updated characterization of visibility trends and current levels in urban areas. Information from both of these sources of PM data, while useful, has not however changed the fundamental and long understood science characterizing the contribution of PM, especially fine particles, to visibility impairment from the last review. This science, briefly summarized below, provides the basis for the ISA designation of the relationship between PM and visibility impairment as causal.

Visibility impairment is caused by the scattering and absorption of light by suspended particles and gases in the atmosphere. The combined effect of light scattering and absorption by both particles and gases is characterized as light extinction, (i.e. the fraction of light that is scattered or absorbed per unit of distance in the atmosphere). Light extinction is measured in units of 1/distance, which is often expressed in the technical literature as 1/(million meters) or inverse megameters (abbreviated Mm^{-1}). When PM is present in the air, its contribution to light extinction typically greatly exceeds that of gases.

The amount of light extinction contributed by PM depends on the particle size distribution and composition, as well as its concentration. If details of the ambient particle size distribution and composition (including the mixing of components) are known, Mie theory can be used to accurately calculate PM light extinction (ISA chapter 9). However, routine monitoring rarely includes measurements of particle size and composition information with sufficient detail for such calculations. A much simpler algorithm can be used to estimate light extinction using routinely monitored fine particle ($PM_{2.5}$) speciation and coarse particle mass ($PM_{10-2.5}$) data, plus relative humidity information needed to estimate the contribution by liquid water in solution with hygroscopic PM components (ISA section 9.2.2.2 and UFVA chapter 3).

The concentration of each of the major aerosol components is multiplied by a dry extinction efficiency value and for the hygroscopic components (e.g., ammoniated sulfate and ammonium nitrate) an additional multiplicative term to account for the water growth to estimate that components contribution to light extinction. Both the dry extinction efficiency and water growth terms are developed by some combination of empirical assessment and theoretical calculation using typical particle size distributions associated with each of the major aerosol components, and they are evaluated by comparing the algorithm estimates of light extinction with coincident optical measurements. Summing the contribution of each component gives the estimate of total light extinction. The most commonly used of these is referred to as the IMPROVE algorithm because it was developed specifically to use the IMPROVE aerosol monitoring data and was evaluated using IMPROVE optical measurements at the subset of sites that make those measurements (Malm et al., 1994). The formula for the traditional IMPROVE algorithm is shown below.

$b_{ext} \approx$ 3 x f(RH) x [Sulfate]
+ 3 x f(RH) x [Nitrate]
+ 4 x [Organic Mass]
+ 10 x [Elemental Carbon]
+ 1 x [Fine Soil]
+ 0.6 x [Coarse Mass]
+ 10

Light extinction (b_{ext}) is in units of Mm^{-1}, the mass concentrations of the components indicated in brackets are in $\mu g/m^3$, and *f(RH)* is the unitless water growth term that depends on relative humidity. The dry extinction efficiency for particulate organic mass is larger than those for particulate SO_4^{2-} and nitrate principally because the density of the dry inorganic compounds is higher than that assumed for the PM organic mass components. Since IMPROVE does not include ammonium ion monitoring, the assumption is made that all SO_4^{2-} is fully neutralized ammonium sulfate and all nitrate is assumed to be ammonium nitrate. Though often reasonable, neither assumption is always true (see Section 9.2.3.1). In the eastern U.S. during the summer there is insufficient ammonia in the atmosphere to neutralize the SO_4^{2-} fully. Fine particle nitrates can include sodium or calcium nitrate, which are the fine particle fraction of generally much coarser particles due to nitric acid interactions with sea salt at near-coastal areas (sodium nitrate) or nitric acid interactions with calcium carbonate in crustal aerosol (calcium nitrate). Despite the simplicity of the algorithm, it performs reasonably well and permits the contributions to light extinction from each of the major components (including the water associated with the SO_4^{2-} and nitrate compounds) to be separately approximated.

The *f(RH)* terms inflate the particulate SO_4^{2-} and nitrate light scattering for high relative humidity conditions. For relative humidity below 40% the *f(RH)* value is 1, but it increases to 2 at ~66%, 3 at ~83%, 4 at ~90%, 5 at ~93% and 6 at ~95% relative humidity. The result is that both particulate SO_4^{2-} and nitrate are more efficient per unit mass than any other aerosol component for relative humidity above ~85% where its total light extinction efficiency exceeds the $10 m^2/g$ associated with EC. Based on this algorithm, particulate SO_4^{2-} and nitrate are estimated to have comparable light extinction efficiencies (i.e., the same dry extinction efficiency and *f(RH)* water growth terms), so on a per unit mass concentration basis at any specific relative humidity they are treated as equally effective contributors to visibility effects.

Inspection of the PM component-specific terms in the simple algorithm shows that most of the $PM_{2.5}$ components contribute 5 times or more light extinction than a similar concentration of $PM_{10-2.5}$. We also know that 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. PM containing elemental or black carbon absorbs light as well as scattering it,

making it the component with the greatest light extinction contributions per unit of mass concentration, except for the hygroscopic components under high relative humidity conditions.

As a result of better characterization of PM in rural and remote locations, refinements in the original IMPROVE algorithm have been made to better account for the aging of the organic aerosols that occurs during transport to these more distant areas, and to add a component for sea salt. Since urban areas contain a higher proportion of newly emitted aerosols that have not aged, the assessments done in support of this review have relied on the original IMPROVE algorithm.

As mentioned above, particles are not the only contributor to ambient visibility conditions. Light scattering by gases also occurs in ambient air. Under pristine atmospheric conditions, naturally occurring gases such as N_2 and O_2, cause what is known as Rayleigh scattering. Rayleigh scattering, which depends on the density of air as a function primarily of the elevation above sea level, can be treated as a site-dependent constant. Rayleigh contribution to light extinction is only significant under pristine conditions. The only other commonly occurring atmospheric gas to appreciably absorb light in the visible spectrum is NO_2. NO_2 forms in the atmosphere from NO emissions associated with combustion processes. These combustion processes also emit PM at levels that generally contribute much higher light extinction than the NO_2 (i.e. NO_2 absorption is generally less than ~ 5% of the light extinction, except where emission controls remove most of the PM prior to releasing the remaining gases to the atmosphere). The remainder of this document focuses on the contribution of PM, which is typically much greater than that of gases, to ambient light extinction, unless otherwise specified.

- **To what extent does the available evidence inform our understanding of the temporal nature of the PM visibility effect, including relevant exposure periods, associated atmospheric conditions, and diurnal patterns of exposure?**

Diurnal Periods of Interest

Typically, we think of visibility associated with daytime periods. We recognize, however, that PM light extinction behaves the same at night as during the day, enhancing the scattering of anthropogenic light, contributing to the "skyglow" within and over populated areas, adding to the total sky brightness, and contributing to the reduction in contrast of stars against the background. These effects produce the visual result of a reduction of the number of visible stars and the disappearance of diffuse or subtle phenomena such as the Milky Way. The extinction of starlight is a secondary and minor effect also caused by increased PM scattering and absorption.

However, there are significant and important differences between daytime and nighttime visual environments that potentially make the nighttime period inappropriate to address at this time. First, daytime visibility has dominated the attention of those who have studied the visibility effects of air pollution. As a result, little research has been conducted on nighttime visibility and the state of the science is not yet comparable to that associated with daytime visibility impairment. Second, in addition

to air pollution, nighttime visibility is affected by the addition of light into the sight path from numerous sources, including anthropogenic light sources such as artificial outdoor lighting, which varies dramatically across space, and natural sources including the Moon, planets, and stars. Light sources and ambient conditions are typically five to seven orders of magnitude dimmer at night than in sunlight. Moonlight, like sunlight, introduces light throughout an observer's sight path at a constant angle. On the other hand, dim starlight emanates from all over the celestial hemisphere while artificial lights are concentrated in cities and illuminate the atmosphere from below. These different light sources will yield variable changes in visibility as compared to what has been established for the daytime scenario, in which a single source, the sun, is by far the brightest source of light. Third, the human psychophysical response (e.g., how the human eye sees and processes visual stimuli) at night is expected to differ (ISA, section 9.2.2).

Given the above, we do not believe that the science is available at this time to support adequate characterization of nighttime PM light extinction effects. In addition, we are not aware of preference or valuation studies providing information on public preferences for nighttime visual air quality (VAQ). Thus, we limit our consideration of PM visibility impacts to all daylight hours only.

Exposure Durations of Interest

Very little is known about the role exposure duration plays in determining the acceptability or unacceptability of a given level of VAQ on the public welfare. We do know from preference and/or valuation studies that atmospheric visibility conditions can be quickly assessed and preferences determined. These studies show that a momentary glance at an image of a scene (i.e. less than a minute) is enough for study participants to consistently judge the acceptability or unacceptability of the viewed visual air quality conditions. Outside these controlled settings, we are unaware of any studies that characterize the extent to which different frequencies and durations of exposure to visibility conditions contribute to the degree of public welfare impact that occurs.

In some circumstances, such as infrequent visits to scenic vistas in natural or urban environments, people are motivated specifically to take the opportunity to view a valued scene and are likely to do so for many minutes to hours to appreciate various aspects of the vista they choose to view. In such circumstances, the viewer may consciously evaluate how the VAQ at that time either enhances or diminishes the experience/view. However, the public also has many more opportunities to notice visibility conditions on a daily basis in settings/surroundings associated with performing daily routines (e.g. during commutes, while walking the dog, or when taking out the recyclables). These scenes, whether iconic or generic, may not be consciously viewed for their scenic value, but their VAQ can still affect a person's sense of wellbeing. Research has demonstrated that people are emotionally affected by low VAQ, that

perception of pollution is correlated with stress, annoyance and symptoms of depression, and that VAQ is deeply intertwined with a "sense of place," affecting peoples sense of the desirability of a neighborhood (ISA section 9.2.4). Though we do not know the extent to which these emotional effects are linked to different periods of exposure to poor VAQ, providing additional protection against even short term exposures to levels of VAQ considered unacceptable would be expected to provide some degree of improvement in the public's "sense of wellbeing".

Some people have mostly intermittent opportunities on a daily basis (e.g. during morning and/or afternoon commutes) to experience ambient visibility conditions as they spend much of their time indoors without access to windows. For such people a view of poor VAQ during their morning commute may provide their perception of the day's visibility conditions until the next time they venture outside during daylight hours later or perhaps the next day. Other people have exposure to visibility conditions throughout the day, so that a day with multiple hours of visibility impairment would likely be judged a having a greater impact on their wellbeing than a day with just one such hour.

We have no information or studies on the fraction of the public that has only one or a few opportunities to experience visibility during the day, or information or studies on the duration of the effect on wellbeing from exposure to different durations of poor VAQ conditions. However, it is logical to conclude that people with limited opportunities to experience visibility conditions on a daily basis would receive the entire impact of the day's VAQ based on the visibility conditions that occur during the short time period when they can see it. On the basis of this rationale, the segment of the population with infrequent access to visibility could be characterized as a sensitive subpopulation. Since this group could be affected on the basis of observing VAQ conditions for periods as short as one hour or less, we believe it is appropriate to consider characterizing PM visibility conditions in terms of the worst or maximum hourly value during daylight hours for each day for purposes of evaluating the adequacy of the current suite of secondary standards.

For another group of observers, those who have access to visibility conditions often or continuously throughout the day, the entire impact of the day's visibility conditions may be based on the varying visibility conditions they observe throughout the day. For this group, it might be more appropriate to evaluate the adequacy of the current suite of secondary standards in terms of all daylight hours in the day.

While both the maximum daily and all hour averaging times were assessed in the UFVA for the PM light extinction indicator, only the maximum daily 1 hour average is assessed for the PM mass concentration indicator (below and Appendix A). In looking at the UFVA assessment of PM light extinction, we noticed a close correspondence between the level of protection afforded for all 15 urban areas in the assessment by the maximum daily daylight1-hour with 90th

percentile and the all daylight 1-hour with the 98th percentile (UFVA section 4.1.4). Thus, at these percentiles, either form of the standard provides protection of welfare effects to both the fraction of the public with rare opportunities and to those with ample opportunities to experience visibility. For consistency between $PM_{2.5}$ mass and PM light extinction and because the daily maximum daylight 1-hour is thought to be more protective of those with limited opportunities to experience visibility, only the daily maximum form results will be displayed here.

Temporal Variations of Visibility Impacts

While visibility conditions can change quickly (i.e., less than a minute), atmospheric sight path averaged light extinction which is pertinent to visibility impacts generally changes more slowly (i.e. tens of minutes generally). Sub-hourly variations in light extinction determined at any point in the atmosphere are likely the result of small scale spatial pollution features (i.e. plumes) being transported by the wind across that point. At typical wind speeds found in U.S. cities, an hour corresponds to a few tens of kilometers of air flowing past a point, which is similar to visibility sight path lengths of interest in urban areas.

PM concentrations and light extinction in urban environments vary from hour to hour throughout the day due to a combination of diurnal meteorological conditions and systematic changes in emissions activity (e.g. rush hour traffic). Generally low mixing heights at night and during the early morning hour tend to trap locally produced emissions, which are diluted as the mixing height increases due to heating during the day. Low temperatures and high relative humidity at night are conducive to the presences of ammonium nitrate particles and water growth by hygroscopic particles compared with the generally higher temperatures and lower relative humidity later in the day. These combine to make early morning the most likely time for peak urban visibility impacts. Superimposed on such systematic time of day variations are the effects of synoptic meteorology (i.e., those associated with changing weather) and regional scale air quality that can generate peak visibility impacts any time of day. The net effects of the systematic urban and larger scale variations are that peak daytime PM light extinction can occur any time of day though more often in early morning hours (UFVA section 3.4.2 and 3.4.3 and shown in Figures 3-9, 3-10 and 3-12). Use of multi-hour averaging of PM light extinction would suppress peak hourly conditions that are expected to represent peak visibility impacts.

Meteorological Causes of Visibility Impacts

Visibility is also reduced directly by the presence of precipitation and fog regardless of the presence or absence of PM. A secondary PM NAAQS is not meant to protect against such sources of visibility impairment not related to PM. Therefore, one consideration in the development of alternative standard forms (discussed below in section 4.3) was the inclusion of a

relative humidity screen in an effort to avoid misinterpretation of the direct effect of meteorological conditions on visibility and those caused by PM air quality.

- **Based on currently available information, what range of levels of visibility impairment is reasonable to consider in reaching judgments about the adequacy of the current NAAQS?**

In order to identify levels of visibility impairment appropriate for consideration in setting secondary PM NAAQS to protect the public welfare, we comprehensively examined information that was available in this review regarding people's stated preferences for acceptable and unacceptable visual air quality.

Light extinction is an atmospheric property that by itself does not directly translate into a public welfare effect. Instead, light extinction becomes meaningful in the context of the impact of visibility on the human observer. This has been studied in terms of the acceptability or unacceptability expressed for it by a human observer. The perception of the visibility impact of a given level of light extinction occurs in conjunction with the associated characteristics and lighting conditions of the viewed scene. Thus, a given level of light extinction may be perceived differently by an observer looking at a different scene or the same scene with different lighting characteristics. Likewise, different observers looking at the same scene with the same lighting may have different preferences regarding the associated VAQ. When scene and lighting characteristics are held constant, the perceived appearance of a scene (i.e., how well the scenic features can be seen and the amount of visible haze) depends only on changes in light extinction. This has been demonstrated using the WinHaze model that uses image processing technology to apply user-specified changes in light extinction values to the same base photograph with set scene and lighting characteristics.

Much of what we know about the acceptability of levels of visibility comes from survey studies in which participants were asked questions about their preference or the value they place on various visibility levels as displayed to them in scenic photographs and/or WinHaze images with a range of known light extinction levels. Urban visibility preference studies for four urban areas were reviewed in the UFVA (chapter 2) to assess the light extinction levels judged by the participant to have acceptable visibility. While the results differed among the four urban areas, results from a rating exercise showed that within each preference study, survey participants consistently distinguish between different levels of light extinction and prefer and value visibility associated with lower light extinction levels among the scenic images they are shown.

The reanalysis included three completed urban visibility preference survey studies plus a pair of smaller focus studies designed to explore and further develop urban visibility survey instruments. The three western studies included Denver, Colorado (Ely et al., 1991), one in the lower Fraser River valley near Vancouver, British Columbia (BC), Canada (Pryor, 1996), and

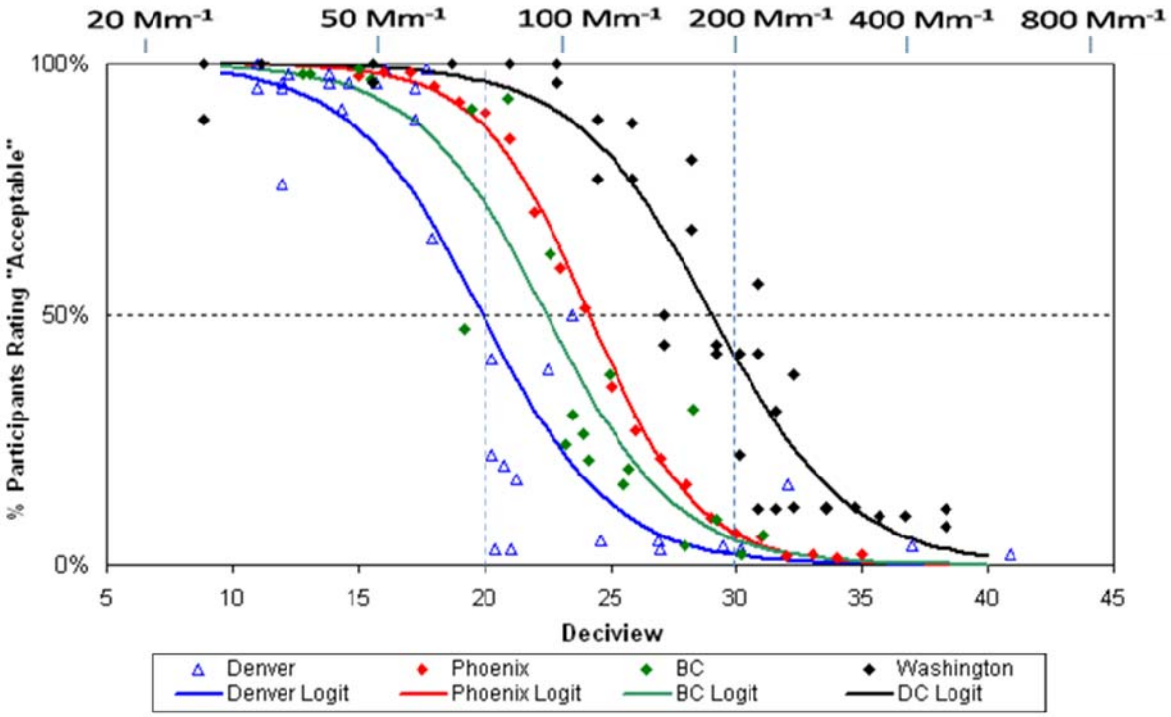
one in Phoenix, Arizona (BBC Research & Consulting, 2003). A pilot focus group study was also conducted for Washington, DC (Abt Associates Inc., 2001). In response to an EPA request for public comment on the Scope and Methods Plan (74 FR 11580, March 18, 2009), we received comments (Smith, 2009) about the results of a new Washington, DC focus group study that had been conducted using methods and approaches similar to the method and approach employed in the EPA pilot study (Smith and Howell, 2009). When taken together, these studies from the four different urban areas included a total of 852 individuals, with each individual responding to a series of questions answered while viewing a set of images of various urban VAQ conditions.

The approaches used in the four studies are similar and are all derived from the method first developed for the Denver urban visibility study. In particular, the studies all used a similar group interview type of survey to investigate the level of visibility impairment that participants described as "acceptable. While each study asked the basic question, "What level of visibility degradation is acceptable?", the term "acceptable" was not defined, so that each person's response was based on his/her own values and preferences for VAQ. Given the similarities in the approaches used, we concluded that it is reasonable to compare the results to identify overall trends in the study findings and that this comparison can usefully inform the selection of a range of levels for use in further analyses. However, variations in the specific materials and methods used in each study introduce uncertainties that should also be considered when interpreting the results of these comparisons. Key differences between the studies include: 1) image presentation methods (e.g., projected slides of actual photos, projected images generated using WinHaze (a significant technical advance in the method of presenting VAQ conditions), use of computer monitor screen; 2) number of participants in each study; 3) participant representativeness of the general population of the relevant metropolitan area; and 4) specific wording used to frame the questions used in the group interview process.

In the UFVA, each study was evaluated separately and figures developed to display the percentage of participants that rated each photograph as "acceptable". The horizontal axis was in terms of light extinction (deciview) and the vertical axis in terms of percent of participants rating "acceptable". Ely et al. (1991) introduced a "50% acceptability" criteria analysis of the Denver preference study results. The 50% acceptability criteria is designed to identify the VAQ level that best divides the photographs into two groups: those with a VAQ rated as acceptable by the majority of the participants, and those rated not acceptable by the majority of participants. We adopted the criteria as a useful index for comparison between studies. The results of each individual analysis were then combined graphically to allow for visual comparison. Figure 4-1 (Figure 2-16 in UFVA) presents the graphical summary of the results of the studies in the four cities and draws on results previously presented in Figures 2-3, 2-5, 2-7 and 2-11 of chapter 2 in

the UFVA. Figure 4-1 also contains lines at 20 dv and 30 dv that effectively and pragmatically identify a range where the 50% acceptance criteria occur across all four of the urban preference studies. Out of the 114 data points shown in Figure 4-1, only one photograph (or image) with a VAQ below 20 dv was rated as acceptable by less than 50% of the participants who rated that photograph.[2] Similarly, only one image with a VAQ above 30 dv was rated acceptable by more than 50% of the participants who viewed it.[3]

Figure 4-1 Summary of results of urban visibility studies in four cities, showing the identified range of the 50% acceptance criteria .[4]



As can be seen in the figure, each urban area has a separate and unique response curve that appears to indicate that it is distinct from the others. These curves are the result of a logistical regression analysis using a logit model of the greater than 19,000 ratings of haze images as acceptable or unacceptable. The model results can be used to estimate the VAQ deciview values where the estimated response functions cross the 50% acceptability level, as

[2] Only 47% of the BC participants rated a 19.2 dv photograph as acceptable.
[3] In the 2001 Washington, D.C. study, a 30.9 dv image was used as a repeated slide. The first time it was shown 56% of the participants rated it as acceptable, and 11% rated it as acceptable the second time it was shown. The same VAQ level was rated as acceptable by 42% of the participants in the 2009 study (Test 1).
[4] Top scale shows light extinction in inverse megameter units; bottom scale in deciviews. Logit analysis estimated response functions are shown as the color-coded curved lines for each of the four urban areas

well as any alternative criteria levels. Selected examples of these are shown in Table 4-1 (Table 2-4 in UFVA, Chapter 2). These results show that the logit model data also support the upper and lower ends of the range of 50th percentile acceptability values (e.g. near 20 dv for Denver and near 30 dv for Washington, DC) already identified in Figure 4-1 (see Table 2-4 UFVA).

Table 4-1 Logit model estimated VAQ values corresponding to various percent acceptability values for the four cities.

	Denver	British Columbia	Phoenix	Washington, DC
90% Acceptability criteria	14.21	16.80	24.15	23.03
75% Acceptability criteria	17.05	19.63	21.80	26.03
50% Acceptability Criteria	**19.90**	**22.45**	**24.15**	**29.03**
25% Acceptability criteria	22.74	25.28	26.51	32.03
10% Acceptability criteria	25.59	28.10	28.87	35.03

Based on the composite results and the effective range of 50th percentile acceptability across the four urban preference studies shown in Figure 4-1 and Table 4-1, benchmark levels have been selected in a range from 20 dv to 30 dv (74 Mm^{-1} to 201 Mm^{-1}) for the purpose of provisionally assessing whether visibility conditions would be considered acceptable (i.e., less than the low end of the range), unacceptable (i.e., greater than the high end of the range) or potentially acceptability (within the range). A midpoint of 25 dv (122 Mm^{-1}) was also selected for use in the assessment. This level is also very near to the 50th percentile criteria value from the Phoenix study (i.e. 24.3 dv), which is by far the best of the four studies in terms of least noisy preference results and the most representative selection of participants. Based on the currently available information, we conclude that the use of 25 dv to represent the middle of the distribution of results seems well supported.

These three benchmark values provide a low, middle, and high set of light extinction conditions that are used to provisionally define daylight hours with urban haze conditions that have been judged unacceptable by the participants of these preference studies. As discussed above, PM light extinction is taken to be light extinction minus the Rayleigh scatter (i.e. light scattering by atmospheric gases which is on average about 10 Mm^{-1}), so the low, middle and high levels correspond to PM light extinction levels of about 64 Mm^{-1}, 112 Mm^{-1} and 191 Mm^{-1}. In the UFVA, these three levels were called Candidate Protection Levels (CPLs). We continue to use this term in this document. However, it is important to note that the degree of protection

provided by a secondary NAAQS is not determined solely by the level of the standard but by all the components (e.g., indicator, form, level, averaging time) being applied together. Therefore, the reader should keep in mind that the term CPL is meant only to indicate levels within a range that we feel are appropriate for consideration that could, in conjunction with other aspects of the standard, provide an appropriate degree of visibility protection.

In characterizing our degree of confidence in each CPL and across the range, a number of issues were considered. Looking first at the two studies that define the upper and lower bounds of the range, we considered whether they represent a true regional distinction in preferences for urban visibility conditions between Western and Eastern U.S.. There is little information available to help sort this out, especially given that we have preference studies in only one Eastern urban area. Smith and Howell (2009) found little difference in preference response to Washington, DC haze photographs between the study participants from Washington, DC and those from Houston, TX. This provides some limited evidence that the value judgment of the public in different areas of the country may not be an important factor in explaining the differences in these study results.

In further considering what factors could explain the observed differences in preferences across the four urban areas, we noted that the urban scenes used in each study had different characteristics. For example, each of the Western urban visibility preference study scenes included mountains in the background while the single Eastern urban study did not. It's also true that each of the Western scenes included objects at greater distances from the camera location than in the Washington, DC study. There's no question that objects at a greater distance have a greater sensitivity to perceived visibility changes as light extinction is changed compared to otherwise similar scenes with objects at a shorter range. This alone might explain the difference between the results of the Washington DC, study and those from the Western urban studies. Also it's intuitively likely that people value the views of mountains in the background more than generic distant buildings in the foreground of the Western scenes; just as it seems obvious that the Capital Mall and Washington Monument were the likely objects of greatest interest for the Washington, DC study base photograph. Having scenes with the object of greatest intrinsic value nearer and hence less sensitive for Washington compared with more distant objects of greatest intrinsic value in the Western urban areas could further explain the difference in preference results.

Another question that we considered was whether the high CPL value that is based on the Washington DC preference results is likely to be generally representative of urban areas that do not have associated mountains or other valued objects visible in the distant background. Such areas would include the middle of the country and many areas in the eastern US. In order to examine this issue, an effort would have to be made to see if scenes in such areas could be found

that would be generally comparable to the western scenes (e.g., contain valued scenic elements at more sensitive distances than that used in the Washington, DC study). This is only one of a family of issues concerning how exposure to urban scenes of varying sensitivity affects public perception, for which no information is currently available. Additional urban visibility preference studies employing images selected of potentially more sensitive scenes could help evaluate whether a lower value for the high CPL is supportable. Other investigations to determine how common such scenes are in various regions of the country would also be informative. Until such information becomes available, the high end of the CPL range (30 dv) seems to be an appropriate level to consider.

With respect to the low end of the range, we considered factors that might further refine our understanding of the robustness of this level. We concluded that additional urban preference studies, especially with a greater variety in types of scenes, including potentially more sensitive Western urban scenes, could help evaluate whether a lower CPL value than the currently selected 20 dv is supportable. Further, the reason for the noisiness in data points around the curves apparent in both the Denver and British Columbia results compared to the smoother curve fit of Phoenix study results could be explored. One possible explanation that we identified is that these older studies used photographs taken at different times of day and on different days to capture the range of light extinction levels needed for the preference studies. By contrast, the use of WinHaze in the Phoenix (and Washington, DC) study, reduced variations in scene appearance that affects preference rating and avoided the uncertainty inherent in using ambient measurements to represent sight path averaged light extinction values. Reducing these sources of noisiness and uncertainty in the results of future studies of sensitive urban scenes could provide more certainty in the selection of a low CPL value.

- **To what extent does the available information demonstrate or suggest that PM-related visibility impairment (within the range of CPLs) is occurring at current ambient conditions or at levels that would meet the current standards?**

Current Visibility Levels

Chapter 3 of the UFVA characterized current visibility conditions in terms of both $PM_{2.5}$ and light extinction levels for the 15 urban areas selected and compared them to the CPLs identified above.

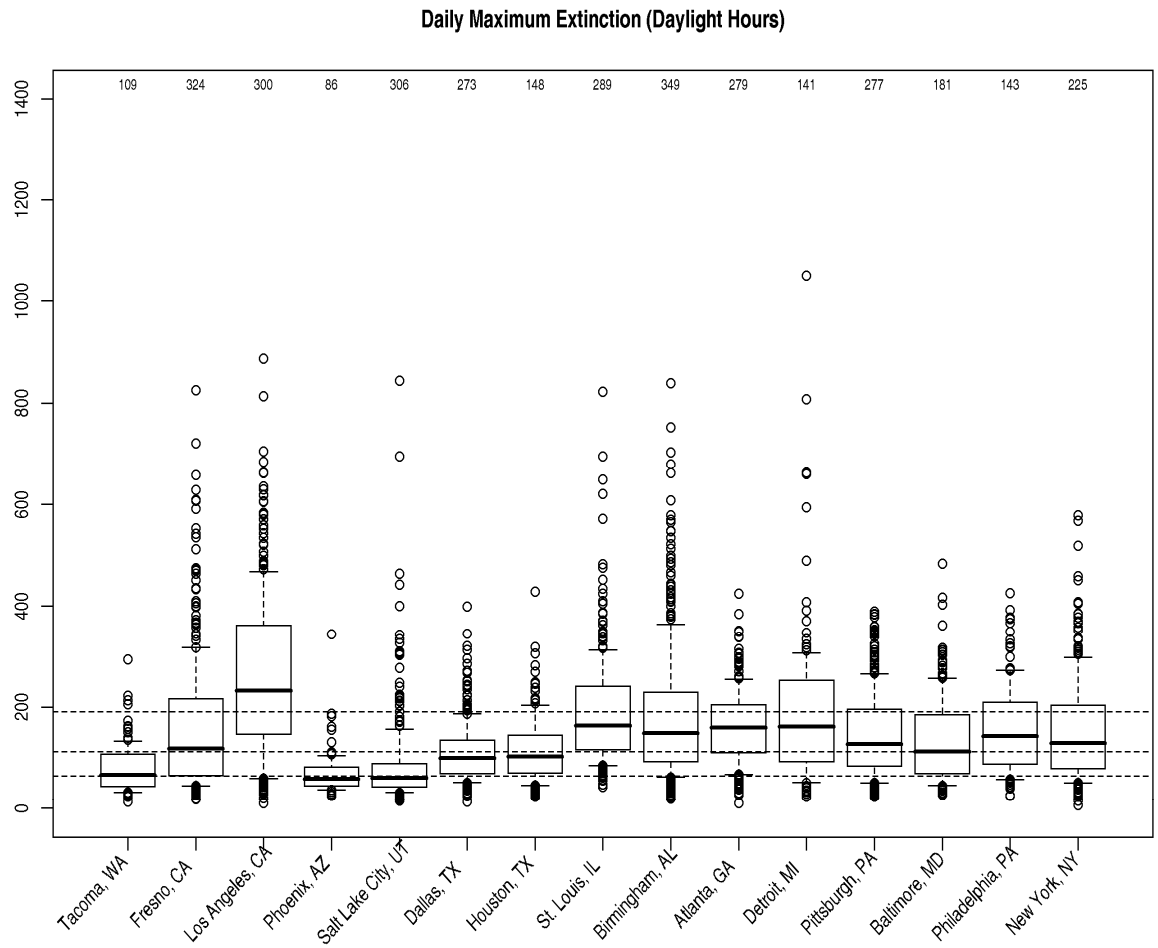
As an initial matter, we note that PM is not necessarily the primary source of visibility impairment during periods with fog or precipitation. In order to avoid precipitation and fog confounding estimates of PM visibility impairment, and as advised by CASAC as part of its comments on the first public review draft of the UFVA, we restricted our assessment of visibility conditions to daylight hours with relative humidity less than or equal to 90% (UFVA section

3.3.5 and Appendix G). However, not all periods with relative humidity above 90% have fog or precipitation. Removing those hours from application of a secondary PM standard involves a tradeoff between the benefits of avoiding many of the hours with meteorological causes of visibility impacts and the cost of not counting some hours with high relative humidity without fog or precipitation, where the growth of hygroscopic PM into large solution droplets results in enhanced PM visibility impacts. For the 11 urban areas included in the assessment for which updated meteorological data was obtained, a 90% relative humidity cutoff criterion is effective in that on average less than 6% of the hours are removed from consideration, yet those hours have on average twelve times the likelihood of meteorological causes of reduced visibility compared with hours with 90% or lower relative humidity.

Figure 4-2 (Figure 3-8 in UFVA) presents box-and-whisker plots to illustrate the distributions of the estimates of daylight 1-hour reconstructed PM light extinction levels in each area in each year during the 2005-2007 time period. The distribution of the daily maximum 1-hour values is shown. The horizontal dashed lines in the plots represent the low, middle, and high CPLs for PM light extinction of 64, 112, and 191 Mm^{-1}, corresponding to the benchmark VAQ values of 20 dv, 25 dv and 30 dv as discussed above. Table 4-2 (Table 3-7 in UFVA) provides the percentages of days (across all of 2005-2007, unweighted) in which the daily maximum daylight 1-hour PM light extinction level was greater than each of the three CPLs (excluding hours with relative humidity greater than 90 percent).

From these displays it can be seen that among the 15 urban areas, those in the East and in California tend to have a higher frequency of visibility conditions above the high CPL compared with those in the Western US. Both Figure 4-2 and Table 4-2 indicate that all 15 urban areas have daily maximum hourly PM light extinctions that exceed even the highest CPL some of the time. Again, the non-California western urban locations have the lowest frequency of maximum hourly PM light extinction with values in excess of the high CPL for 8 percent or fewer of the days. Except for the two Texas and the non-California western urban areas, all of the other urban areas exceed that high CPL from about 20 percent to over 60 percent of the days. Based on these estimated maximum hourly PM light extinction estimates, all 15 of the urban areas exceed the low CPL for about 40 percent to over 90 percent of the days. Based on all of the above, we conclude that current levels of PM light extinction associated with recent PM air quality exceed levels that could reasonably be considered as protective of the public welfare.

Figure 4-2. Distribution of estimated maximum daily daylight 1-hour PM light extinction across the 2005-2007 period, by study area (excluding hours with relative humidity greater than 90 percent). (Adapted from Figure 3-8 in UFVA)*



****In thel box-and-whisker plot, the box represents the 25th to 75th percentile range and the whiskers represent the 10th and 90th percentile points of the data; individual data points below the 10th percentile and above the 90th percentile are graphed as small circles. The three dashed horizontal lines represent the three CPL levels of 64, 112, and 191 Mm^{-1}.***

Table 4-2 Percentage of daily maximum hourly values of daylight PM light extinction exceeding CPLs (excluding hours with relative humidity greater than 90 percent). (adapted from Table 3-7 in UFVA)

Study Area	Number of Days with Estimates	Candidate Protection Level		
		64 Mm^{-1}	112 Mm^{-1}	191 Mm^{-1}
		(a) Percentage of Daily Maximum Hourly Values Exceeding CPL		
Tacoma	109	52	22	4
Fresno	324	75	52	30
Los Angeles	300	90	83	62
Phoenix	86	42	7	1
Salt Lake City	306	44	17	8
Dallas	273	80	41	10
Houston	148	79	45	11
St. Louis	289	98	78	40
Birmingham	349	89	65	34
Atlanta	279	91	75	31
Detroit	141	87	68	43
Pittsburgh	277	85	57	26
Baltimore	181	80	50	23
Philadelphia	143	86	64	31
New York	225	83	59	28
Average	***229***	***77***	***52***	***26***

Visibility Levels That Just Meet Current Standards

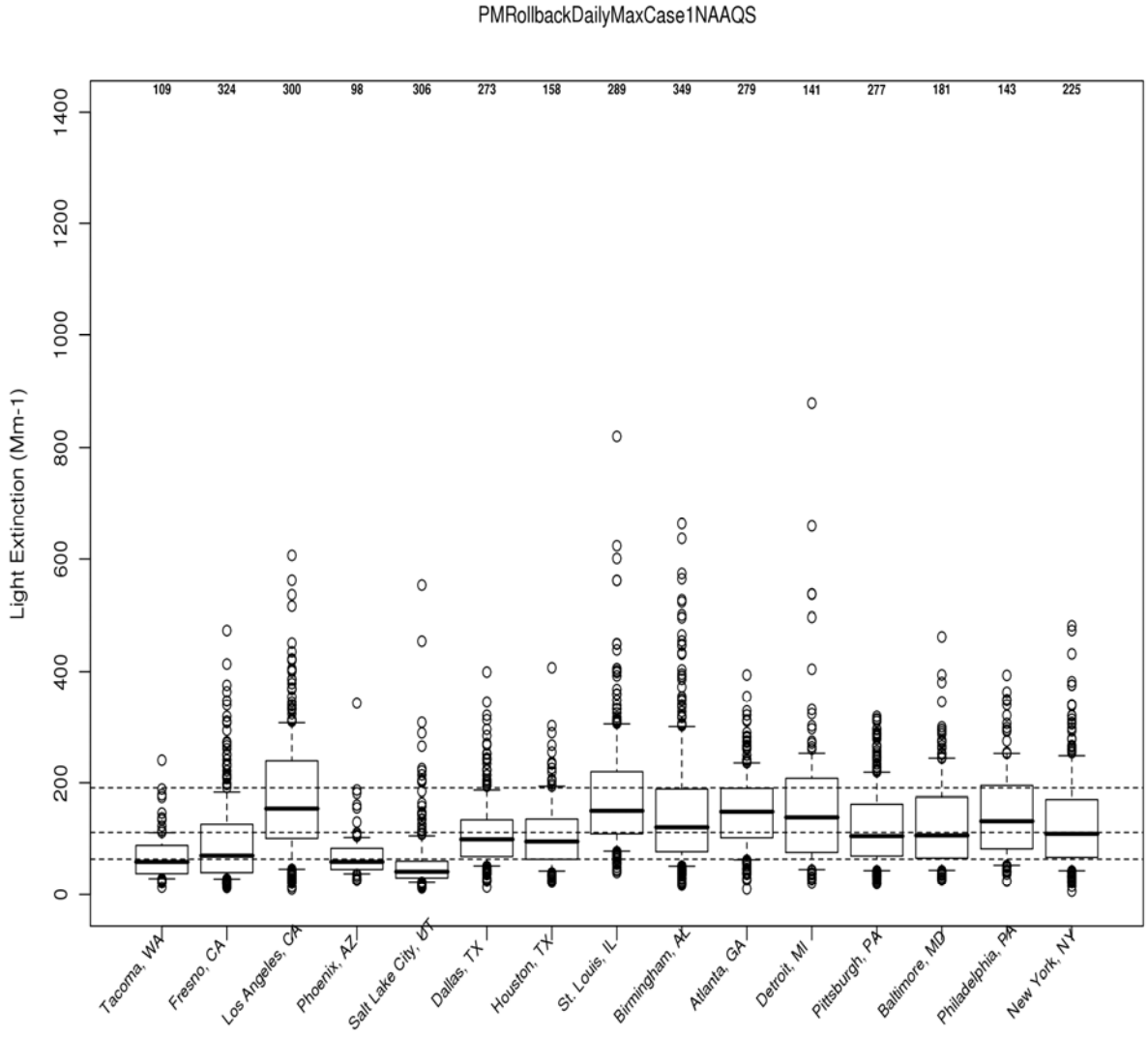
In the second draft of the UFVA, we modeled the "what if" scenario based on simulating just meeting the current suite of $PM_{2.5}$ secondary standards: 15 $\mu g/m^3$ annual average $PM_{2.5}$ concentration and 35 $\mu g/m^3$ 24-hour average $PM_{2.5}$ concentration with a 98^{th} percentile form, averaged over three years. The steps needed to model the "what if" conditions involve explicit consideration of changes in $PM_{2.5}$ components and are described here. First, we applied proportional rollback to all the $PM_{2.5}$ monitoring sites in each study area, taking into account PRB $PM_{2.5}$ mass, to "just meet" the NAAQS scenario for the area as a whole, not just at the visibility assessment study site. The health risk assessment document (EPA 2010a) describes this procedure in detail. The degree of rollback is controlled by the highest annual or 24-hour design value, which in most study areas is from a site other than the site used in this visibility assessment. The relevant result from this analysis is the percentage reduction in non-PRB $PM_{2.5}$ mass need to "just meet" the NAAQS scenario, for each study area. These percentage reductions

are shown in Table 4-4 of the UFVA. Note that Phoenix and Salt Lake City meet the 15/35 NAAQS scenario under current conditions, and require no reduction. $PM_{2.5}$ levels in these two cities were not "rolled up." Second, for each day and hour for each $PM_{2.5}$ component, we subtracted the PRB concentration from the current conditions concentration, to determine the non-PRB portion of the current conditions concentration. Third, we applied the percentage reduction from step 1 to the non-PRB portion of each of the five $PM_{2.5}$ components and added back the PRB portion of the component. Finally, we re-applied the IMPROVE algorithm, using the reduced $PM_{2.5}$ component concentrations, the current conditions $PM_{10-2.5}$ concentration for the day and hour, and relative humidity for the day and hour. We then included the term for Rayleigh scattering.

Figure 4-3 and Table 4-3 display the results of the rollback procedure as a box and whisker plot of daily maximum daylight 1-hour PM light extinction and the percentage of daily maximum hourly PM light extinction values exceeding the CPLs when just meeting the current $PM_{2.5}$ NAAQS scenario of 15/35 $\mu g/m^3$ (excluding hours with relative humidity greater than 90 percent. These displays show that at the current PM NAAQS level (i.e., 15/35) all of the eastern urban areas and Los Angeles exceed the least restrictive CPL more than 10% of the time and that only Tacoma would not exceed the least restrictive CPL more than 2% of the time.

Figure 4-3. Distribution of daylight 1-hour PM light extinction when rolled back to just meet current PM fine NAAQS across the 2005-2007 period, by study area (excluding hours with relative humidity greater than 90 percent). *

NAAQS Scenario: 15 µg/m^3 annual; 35 µg/m^3 24-hour
Displayed: Daily Max Daylight Light Extinction (excluding hours >90% RH)



**** In thel box-and-whisker plot, the box represents the 25th to 75th percentile range and the whiskers represent the 10th and 90th percentile points of the data; individual data points below the 10th percentile and above the 90th percentile are graphed as small circles. The three dashed horizontal lines represent the three CPL levels of 64, 112, and 191 Mm^{-1}***

Table 4-3 Percentage of daily maximum hourly values of daylight PM light extinction exceeding CPLs when "just meeting" the current $PM_{2.5}$ NAAQS (15/35 μg/m^3) (excluding hours with relative humidity greater than 90 percent). (Adapted from Table 4-7 in UFVA).

Study Area	Number of Days with Estimates	Candidate Protection Level		
		64 Mm^{-1}	112 Mm^{-1}	191 Mm^{-1}
		(a) Percentage of Daily Maximum Hourly Values Exceeding CPL		
Tacoma	109	43	10	1
Fresno	324	54	30	10
Los Angeles	300	85	69	39
Phoenix	86	44	6	1
Salt Lake City	306	24	9	4
Dallas	273	81	41	10
Houston	148	75	41	11
St. Louis	289	97	74	36
Birmingham	349	84	55	24
Atlanta	279	90	71	25
Detroit	141	80	61	33
Pittsburgh	277	78	48	16
Baltimore	181	78	48	19
Philadelphia	143	85	61	28
New York	225	76	45	19
Average	***229***	**72**	**45**	**18**

4.2.2 Summary

In summary, we reach the preliminary conclusion that the available information in this review, as described above and in the UFVA and ISA, clearly calls into question the adequacy of the current suite of $PM_{2.5}$ standards in the context of public welfare protection from unacceptable levels of visibility impairment, primarily in urban areas, and supports consideration of alternative standards to provide appropriate protection.

This preliminary conclusion is based first on the large percentage of days that exceed the range of CPLs identified for consideration under both current and just meet PM air quality conditions. In particular, under just meet conditions for the suite of secondary PM NAAQS (i.e. 15/35 μg/m^3) greater than 10% of the days exceed the highest, least protective CPL of 191 Mm^{-1}

for 10 of the 15 urban areas. When the middle CPL of 112 Mm^{-1} is considered, 12 of the 15 cities have greater than 10% of their days exceeding with a range of 30 to 74% of days exceeding this level. At the lowest CPL of 64 Mm^{-1}, the percentage of days exceeding range from 24 to 97% across the 15 urban areas.

Second, we have reached the preliminary conclusion that the averaging times associated with the current suite of PM NAAQS are not well suited to protect against PM-related visibility impairment on the basis that short term exposures (e.g., 1 hour or less) is sufficient for an unacceptable level of visual air quality to be observed and the associated impacts of that observation to be registered by the observer. Since some portion of the population may only have the opportunity to observe one hour or less of ambient daylight visibility conditions, relying on an averaging time as long as that of the current 24 hour and annual PM standards would make it difficult to identify a requisite level of protection that would translate into appropriate protection against the maximum daily value. In addition, these longer averaging times also result in the inclusion of nighttime conditions, for which the science needed to support identification of appropriate levels of visibility protection is not well developed or understood.

In reaching the preliminary conclusion that the current suite of $PM_{2.5}$ standards are inadequate to provide the appropriate protection of the public welfare from known and/or anticipated adverse effects by calling into question the adequacy of the current levels and averaging times, it also seems reasonable to consider whether the current indicator of $PM_{2.5}$ remains useful in relating ambient PM to its public welfare effect of visibility impairment. Section 4.3 below discusses these and other considerations in its discussion of alternative standards for consideration.

4.3 CONSIDERATION OF ALTERNATIVE STANDARDS

Having reached the conclusion that just meeting the current suite of $PM_{2.5}$ standards continues to allow levels of PM visual air quality that, based on the scientific evidence and information available in this review, can reasonably be considered adverse to the public welfare, this section will discuss alternative standards that could potentially provide requisite public welfare protection from known and/or anticipated adverse effects. Any PM standard that results in emissions reductions can be expected to result in visibility improvements, though meeting that standard does not ensure an adequate or uniform degree of protection from adverse visibility conditions. A requisite level of public welfare protection can be facilitated by adopting a standard specifically designed with indicator, averaging time and form that better mimics the characteristics of the effect of interest.

4.3.1 Nature of the Indicator

- **To what extent does information provide support for considering a different pollution indicator(s) for PM to replace or supplement the $PM_{2.5}$ mass based indicator?**

EPA staff is considering two alternative indicators: $PM_{2.5}$ mass and PM light extinction. $PM_{2.5}$ mass is taken here to be the same indicator as is used by the current suite of PM NAAQS. PM light extinction is the contributions to light extinction by PM_{10} under ambient conditions. EPA staff believes that the use of PM light extinction as an indicator is justified because it is a physically meaningful measure of the PM quantity that is most relevant and directly related to visibility effects. The basis for considering each indicator is discussed below.

PM Light Extinction Indicator

PM light extinction is highly related to light extinction, which is the property of the atmosphere that is most directly related to visibility effects. It differs from light extinction by the nearly constant contributions for Rayleigh (or clean air) light scattering and the minor contributions by NO_2 light absorption. Most importantly, there are no confounding issues associated with particle size or composition, including PM water. PM light extinction can be directly measured under ambient conditions by several instrumental methods, some of which have been used for decades to routinely monitor the two components of PM light extinction (light scattering and absorption) or to jointly measure both as total light extinction (from which Rayleigh scattering is subtracted to get PM light extinction).

EPA staff also recognizes that while $PM_{2.5}$ light extinction can be accurately measured by a number of commercially available instruments, it is technically more challenging to measure the $PM_{10-2.5}$ component of light extinction. This issue many not be of concern for many regions of the country where the $PM_{10-2.5}$ contributions to light extinction are minor (see UFVA section 3.4.5). However for some regions (e.g. Phoenix), the $PM_{10-2.5}$ contributions to light extinction are substantial and may need to be accounted for by some other methodology (e.g. estimation from $PM_{10-2.5}$ mass concentration measurements). As an alternative to direct measurements, light extinction can be estimated from PM speciation and relative humidity data (see section 4.2). There are a number of reasons for preferring direct measurements to algorithm-estimates of PM light extinction for use in a secondary standard. These include the greater accuracy of direct measurements, the ability to have short averaging times and the overall simplicity absent when multiple measured parameters need to be processed to generate the indicator for a standard.

There currently is no FRM for PM light extinction monitoring. Development of such an FRM could take one to two years. There is no routinely operated PM light extinction monitoring program in urban areas. Deploying such a network will required time and resources. As a result,

the selection of PM light extinction as an indicator could reasonably be expected to extend the time required for promulgation/implementation of a secondary PM NAAQS.

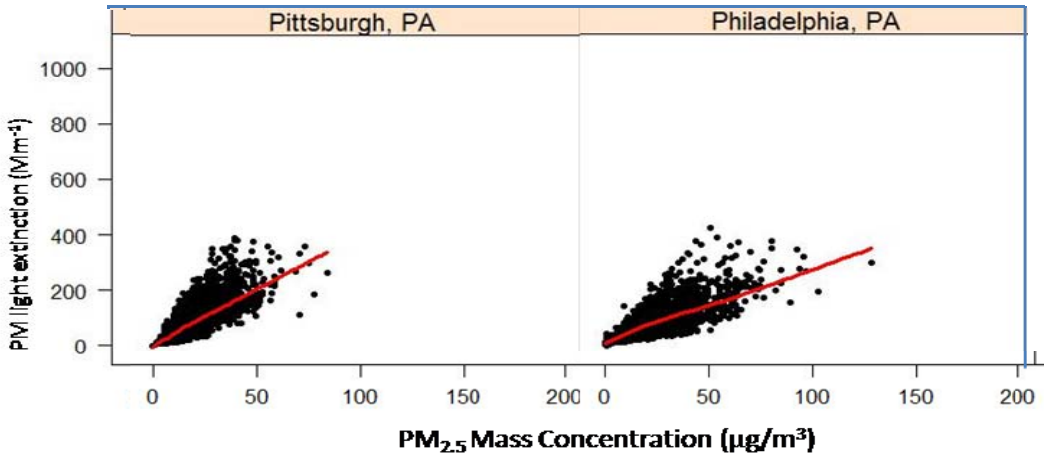
$PM_{2.5}$ Mass Indicator

$PM_{2.5}$ mass is responsible for most of the visibility impairment in the majority of urban areas. In these areas, the contribution of $PM_{10-2.5}$ is a minor contributor to visibility impairment most of the time. However, at some locations (see UFVA Figure 3-13 for Phoenix) $PM_{10-2.5}$ is a major contributor to urban visibility effects. In those cities, a $PM_{2.5}$ standard alone may not provide adequate visibility protection. In the absence of PM air quality information from a much larger number of urban areas across the country, it is not possible at this time to know how many urban areas fall into this category, though it is reasonable to presume that other urban areas in the desert southwestern region of the country may have conditions similar to the conditions shown for Phoenix. A possible solution to this issue would be to add a companion $PM_{10-2.5}$ standard to control under those circumstances. This latter refinement has not been developed for this review.

PM mass monitoring methods are in wide spread use, including the Federal Reference Method (FRM) involving the collection of periodic (1 day in 6 and 1 day in 3) 24-hour filter samples. These samples are then subsequently analyzed to determine 24-hour PM fine mass. The Chemical Speciation Network and continuous $PM_{2.5}$ monitoring produce hourly average mass concentrations and are conducted at many locations. At a few locations, continuous speciation sampling produces measures some of the major $PM_{2.5}$ chemical components. These routine monitoring activities do not include measurement of the water content of the ambient PM that contributes, often significantly, to visibility impacts. Further, the PM mass concentration monitoring does not provide information on the composition of the PM which also contributes to the variability in the amount of visibility impact associated with any ambient PM mass concentration.

The overall performance of $PM_{2.5}$ mass as a predictor of visibility effects as indicated by PM light extinction can be seen in scatter plots shown in Figure 4.3-1 for Pittsburgh and Philadelphia, PA (Similar plots for all 15 urban areas are in Appendix D, Figure D-2). These demonstrate the variation in hourly PM light extinction corresponding to any specific level of $PM_{2.5}$ mass concentration as well as statistical differences of the average relationships (depected as the best fit lines) between cities. While this degree of variation is an important factor in considering the appropriateness of a $PM_{2.5}$ mass indicator, we note that correctly identifying each hour's visibility conditions is not required to estimate the extent to which the distribution of visibility conditions may negatively impact public welfare.

Figure 4.3-1 Scatter plots of PM light extinction versus $PM_{2.5}$ mass concentration of two cities (from UFVA Appendix D, Figure D2).



4.3.2 Averaging and Applicable Times

Consideration of an appropriate averaging time and factors with respect to the timing over which a secondary standard should apply were informed by consideration of the nature of PM visibility effects.

Nighttime visibility impacts, described in the ISA (section 9.2.2) are significantly different from daytime impacts and not sufficiently well understood to be included at this time. As a result, a secondary standard to protect visibility would best only apply to daylight hours. In the UFVA daylight hours were defined to be those morning hours having no minutes prior to local sunrise and afternoon hours having no minutes after local sunset. This definition ensures the exclusion of periods of time where the sun is not the primary outdoor source of light to illuminate scenic features.

PM is not necessarily the primary source of visibility impairment during periods with fog or precipitation. By excluding daylight hours with average relative humidity above 90% for inclusion in a secondary PM standard, the likely occurrence of visibility effects from fog and precipitation is significantly reduced (UFVA section 3.3.5 and Appendix G). However not all periods with relative humidity above 90% have fog or precipitation. So removing those hours from application of a secondary PM standard involves a tradeoff between the benefits if avoiding many of the hours with meteorological causes of visibility impacts and not counting some hours without fog or precipitation, but where the growth of hygroscopic PM to large solution droplets results in enhanced PM visibility impacts. For the 11 urban areas included in the assessment for

which updated meteorological data was obtained,[5] a 90% relative humidity cutoff criterion is effective in that on average less than 6% of the hours are removed from consideration, yet those hours have on average twelve times the likelihood of meteorological causes of reduced visibility compared with hours with 90% or lower relative humidity.

As discussed above (section 4.2.1) selection of an appropriate averaging time takes into account both how quickly people experience and judge visibility conditions, as well as the typical rate of change of the path averaged PM light extinction over urban areas. While perception of visibility change can occur in less than a minute, meaningful changes to path averaged light extinction occur more slowly and can be well represented by hourly averaging. Multi-hour averaging times would have the effect of reducing the magnitude of hourly peak visibility impacts which can change significantly from one daylight hour to the next (see UFVA Figure 3-12). Reduction of peak values through multi-hour averaging reduces the ability of the indicator to accurately characterize the visibility effects experienced by the segment of the population that has infrequent short-term exposure during peak periods.

4.3.3 Alternative Levels/Forms

Candidate Protection Levels

The results from the visibility preferences studies conducted in four urban areas define a range of low, middle and high CPLs of 20 dv, 25 dv and 30 dv which are equivalent to PM light extinction of values of 64 Mm^{-1}, 112 Mm^{-1}, and 191 Mm^{-1}(see section 4.2 above). With only the four preference study results, the individual low and high CPL are in fact reflective of the results from the Denver and Washington, DC studies in particular, and the middle CPL is very near to the 50^{th} percentile criteria result from Phoenix.

Determining $PM_{2.5}$ mass concentration values that correspond to the low, middle and high CPL is complicated by the lack of a one-to-one relationship between PM light extinction and $PM_{2.5}$ mass. By considering a range of extinction efficiency values (i.e., the ratio of PM light extinction to $PM_{2.5}$ mass) from 3 m^2/g to 10 m^2/g, a range of $PM_{2.5}$ concentration levels that crudely corresponds to a low estimate of the low CPL and high estimate of the high CPL values can be determined. The full range is from ~6 $\mu g/m^3$ to ~60 $\mu g/m^3$. Keeping in mind that there is no exact one-to-one correspondence between PM mass concentration and PM light extinction, no individual value in this range of conditions corresponds to the CPL values expressed in terms of PM light extinction, so a number of alternate values within the range were selected for assessing their visibility protection performance when combined with alternative forms (as described

[5] Through an oversight, EPA staff did not obtain NWS data for Los Angeles, St. Louis, Houston, and Detroit in time for processing. These data will be added in the final UFVA.

below). Five alternative $PM_{2.5}$ mass concentration values were selected for this purpose: 10 $\mu g/m^3$, 20 $\mu g/m^3$, 30 $\mu g/m^3$, 40 $\mu g/m^3$ and 60 $\mu g/m^3$.

Alternative Forms

The form of the current 24-hour $PM_{2.5}$ NAAQS entails comparing the level of the standard to the three consecutive year average of the annual 98th percentile of the measured indicator. The purpose in averaging for three years is to provide stability from the occasional effects of inter-annual meteorological variability that can result in unusual high pollution levels for a particular year that is otherwise typical. The use of a percentile form makes the standard less subject to the possibility of inappropriate violations caused by statistical outlier indicator values. For consistency with the current PM NAAQS and to provide stability from unusual years or outlier indicator data, the secondary PM standard should consider incorporating the use of a three year average of a specified percentile.

The urban visibility preference studies that provided results leading to the range of CPLs being considered in this document, offer no information that addresses the frequency of time that visibility levels should be below those values. Based on this and the nature of the public welfare effect being one of aesthetics and/or feelings of wellbeing, we believe that it is not necessary or appropriate to consider eliminating all such exposures and that allowing some number of hours/days with reduced visibility can reasonably be considered. . In the UFVA, 90th, 95th and 98th percentile annual values are included in the PM light extinction NAAQS scenarios (Chapter 4). The hourly PM mass concentration scenarios that are described and assessed below and in Appendix A include only the 90th and 95th percentile forms.[6]

Another aspect of the form that needs to be considered is whether to include all daylight hours or only the maximum daily daylight 1-hour. The maximum daily daylight 1-hour form is more appropriate for protecting the welfare of people who have rare intermittent exposure to visibility during the day (e.g. during commutes), but spend most of their time isolated from outdoor views. For such people a view of poor visibility during their morning commute may represent their perception of the day's visibility conditions until the next time they venture outside during daylight, hours later or perhaps the next day. Other people have exposure to visibility conditions throughout the day. For those people it might be more effective to include every daylight hour into assessing compliance with a standard, since a day with multiple hours with visibility impairment is likely to be judged a greater impact on their wellbeing than a day with just one such hour.

[6] Assessment of the 98th percentile was thought to be unnecessarily restrictive, so it was not conducted at this time to simply and speed the assessment process.

We do not know the fraction of the public that has only one or a few opportunities to experience visibility during the day, nor do we have information or studies on the duration of the effects on wellbeing associated with visibility conditions. However, it is logical that people with limited opportunities to experience visibility conditions on a daily basis would experience the entire impact associated with visibility based on their short term exposure. The impact of visibility for those who have access to visibility conditions often or continuously during the day may be based on varying conditions throughout the day. Based on these considerations, the segment of the population with infrequent access to visibility could be characterized as a susceptible population relative to peak visibility impairment, while those with longer exposures are a susceptible population for longer-term visibility impairment.

In light of these considerations, the UFVA assessment of the various PM light extinction scenarios included both forms and noticed a close correspondence between the level of protection afforded for all 15 urban areas in the assessment by the maximum daily daylight1-hour with 90^{th} percentile and the all daylight 1-hour with 98^{th} percentile (UFVA section 4.1.4). In this sense, the reductions in visibility impairment required to meet either form of the standard provides protection to both the fraction of the public with rare opportunities and to those with ample opportunities to be affected by PM-related visibility impairment.

Both forms are assessed for the PM light extinction indicator (UFVA), but only the maximum daily form is assessed for the PM mass concentration indicator (below and Appendix A). For consistency between the two indicators and because the daily maximum daylight 1-hour is thought to be more protective of those with limited opportunities to experience visibility, only the daily maximum form results will be displayed here.

4.3.4 Performance of Alternative Standards

We conducted assessments of alternative standards based both on hourly PM light extinction as the indicator (see Chapter 4 of the UFVA) and on hourly PM mass concentration indicator (see Appendix A in this document). There are nine PM light extinction alternative standards discussed here (i.e., daily maximum daylight 1-hour PM light extinction at the low, middle and high CPL for each of the 90^{th}, 95^{th} and 98^{th} percentile forms) and there are ten $PM_{2.5}$ mass concentration alternative standards (i.e., five concentration levels for each of the 90^{th} and 95^{th} percentile forms). In both cases the assessment involves rolling back non-policy relevant background (PRB) PM light extinction or PM mass concentration values until these specific alternative standards are just met.

In considering the performance of alternative standards, we focused on the uniformity across the 15 urban areas of the resulting visibility conditions, as measured in terms of light extinction, when the alternative scenarios are just met. Because of the one-to-one

correspondence light extinction and PM light extinction,[7] the PM light extinction indicator based standards should produce visibility conditions exactly as prescribed. The ability to structure a PM light extinction based alternative standard to the level of visibility protection desired is an advantage because it could affords the most uniform degree of visibility protection nationwide.

Figures similar to 4.3-1 for the other PM light extinction scenarios are shown in Appendix F of the UFVA. Table 4.3-1 shows the design values for the 9 scenarios based on maximum daily 1-hour PM light extinction. When an area just meets a scenario, its design value in principle should exactly equal the NAAQS level, so preparation of this table serves as a check against calculation errors. Note that the design values in Table 4.3-1, resulting from the rollback steps described in section 4.1.4 of the UFVA, in some cases do not exactly equal the assumed level of the NAAQS, although all are quite close. In some cases (e.g. Phoenix for 191 Mm^{-1}/90th and 95th percentile), current conditions already meet the scenario specifications so no rollback was necessary and current design values are shown in Table 4.3-1 and reflected in box and whisker plot figures. The minor differences between prescribed and assessed design values seen for some applications of the rollback assessment are due to hours switching in the PM light extinction frequency distribution that is purely an artifact of the rollback methodology as described in the UFVA (section 4.3). These discrepancies were judged too small to justify iterative rollback that could have been used to eliminate them.

[7] In this assessment **light extinction = PM light extinction + 10Mm^{-1}**, where the last term is Rayleigh or clean air light scattering that in fact can range from about 8Mm^{-1} to 12Mm^{-1} depending on average sight path elevation above sea level.

Figure 4.3-2 Daily maximum daylight 1-hour light extinction after rollback to just meet a scenario with daily maximum of 112 Mm^{-1} for the 90th percentile excluding hours with relative humidity greater than 90 percent.

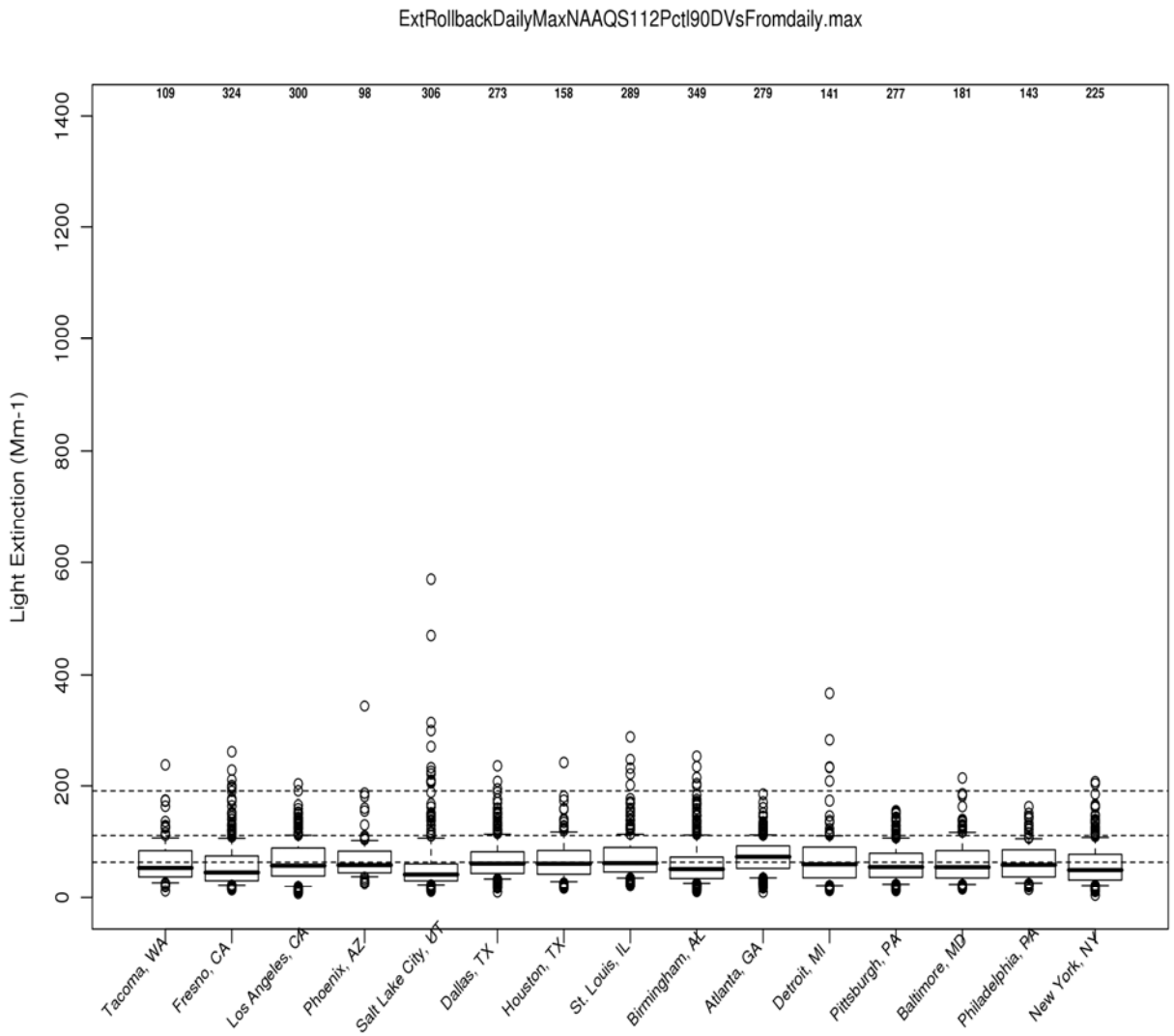


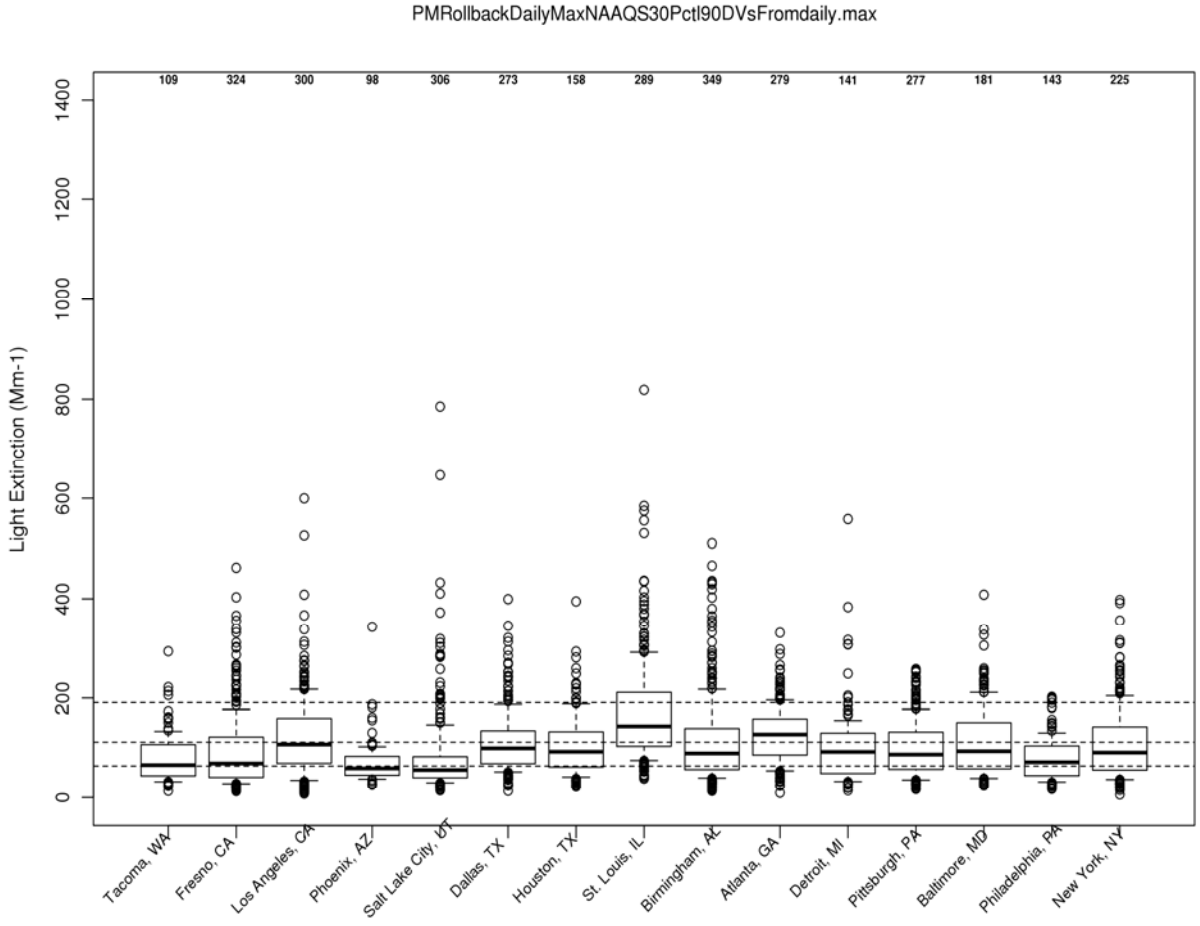
Table 4.3-1. PM light extinction design values for "just meeting" secondary NAAQS scenarios based on measured PM light extinction (excluding hours with relative humidity greater than 90 percent)

	Secondary NAAQS Scenarios Based on Daily Maximum								
	(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**	**(h)**	**(i)**
Level (Mm^{-1})	**191**	**191**	**191**	**112**	**112**	**112**	**64**	**64**	**64**
Percentile Form	**90th**	**95th**	**98th**	**90th**	**95th**	**98th**	**90th**	**95th**	**98th**
	PM light extinction Design Value (based on same percentile form as the NAAQS scenario)								
Tacoma, WA	140	157	191	112	112	108	66	70	60
Fresno, CA	191	191	191	112	112	112	64	64	64
Los Angeles, CA	191	191	191	112	112	112	65	64	64
Phoenix, AZ	105	144	185	105	112	112	64	64	64
Salt Lake City, UT	164	191	191	112	112	112	64	64	64
Dallas, TX	183	191	191	113	113	112	64	66	66
Houston, TX	191	191	191	115	112	112	67	61	67
St. Louis, IL	191	191	191	113	112	112	65	64	64
Birmingham, AL	191	192	191	113	114	112	64	66	64
Atlanta, GA	191	191	191	112	111	112	64	63	65
Detroit, MI	191	191	191	112	112	112	64	64	65
Pittsburgh, PA	191	191	191	112	112	112	64	64	64
Baltimore, MD	191	191	191	111	112	112	63	64	65
Philadelphia, PA	191	191	191	112	112	112	65	64	64
New York, NY	192	191	191	113	112	112	65	64	64

A complete description of the rollback assessment for the ten maximum daily 1-hour PM mass concentration scenarios is available in Appendix A of this document. The process used is very similar to that used in the UFVA for rollback of the PM light extinction based scenarios.

Since PM mass does not have a one-to-one correspondence to light extinction, the PM light extinction conditions resulting from just meeting standards based on PM mass are not as uniform as those shown above for PM light extinction scenarios. This is demonstrated in the box and whisker plot of the maximum daily 1-hour PM light extinction for the 30 $\mu g/m^3$, 90^{th} percentile scenario shown below (Figure 4.3-2), which shows greater variation from among the urban areas than the PM light extinction based scenarios. Similar plots for all ten PM mass based scenarios are shown in Appendix A (Figure A-2).

Figure 4.3-3 Maximum daily daylight 1-hour PM light extinction under "just meet" conditions for a NAAQS scenario based on 1-hour $PM_{2.5}$ mass of 30 $\mu g/m^3$, 90th percentile, excluding relative humidity >90%.



The 90th percentile PM light extinction design values corresponding to the 90th percentile PM mass concentration based scenarios for the five mass concentration levels are shown in Table 4.3-2. Values in the table that exceed each of the CPL values are highlighted using different colors. The values in the table are the same for some urban areas for the less restrictive PM mass concentration standard (e.g. Tacoma at 60 μg/m^3 and 40 μg/m^3, or Phoenix at 60 μg/m^3, 40 μg/m^3, 30 μg/m^3 and 20 μg/m^3), because those areas required no rollback to meet the less restrictive PM mass concentration standards. In order for most or all urban areas to achieve even the highest CPL at the 90th percentile, a $PM_{2.5}$ mass based standard set below 40 μg/m^3 would be necessary. The higher $PM_{2.5}$ mass levels of 60 μg/m^3 and 40 μg/m^3 clearly are not sufficiently protective, since they permit 11 and 10 of the 15 areas, respectively, to have design values larger than 191 Mm^{-1}. At the 20 μg/m^3 $PM_{2.5}$ standard level, all areas meet the highest CPL benchmark, except for St. Louis, which doesn't attain the highest CPL even when a 10 μg/m^3 standard is imposed. We believe that this latter case may have occurred because the coarse mass data in St. Louis may not be representative of the metropolitan area.[8] The 30 μg/m^3 standard is marginally above the high CPL at three cities and only exceeds it substantially at St. Louis.

[8] The data set used to determine hourly PM mass and composition data for St. Louis may not be representative of the St. Louis metropolitan areas. See the discussion in the UFVA section 3.2.1.

Table 4.3-2 90th percentile maximum daily 1-hour PM light extinction design values (Mm^{-1}) after rollback to meet alternative standard of 60 $\mu g/m^3$, 40 $\mu g/m^3$, 30 $\mu g/m^3$,20 $\mu g/m^3$ and 10 $\mu g/m^3$ maximum daylight 1-hour PM mass concentration for the 90th percentile.*

	60 $\mu g/m^3$	40 $\mu g/m^3$	30 $\mu g/m^3$	20 $\mu g/m^3$	10 $\mu g/m^3$
Tacoma, WA	140 Mm^{-1}	140 Mm^{-1}	140 Mm^{-1}	128 Mm^{-1}	82 Mm^{-1}
Fresno, CA	338 Mm^{-1}	248 Mm^{-1}	190 Mm^{-1}	132 Mm^{-1}	74 Mm^{-1}
Los Angeles, CA	403 Mm^{-1}	284 Mm^{-1}	220 Mm^{-1}	156 Mm^{-1}	105 Mm^{-1}
Phoenix, AZ	105 Mm^{-1}	105 Mm^{-1}	105 Mm^{-1}	105 Mm^{-1}	86 Mm^{-1}
Salt Lake City, UT	164 Mm^{-1}	164 Mm^{-1}	153 Mm^{-1}	107 Mm^{-1}	59 Mm^{-1}
Dallas, TX	183 Mm^{-1}	183 Mm^{-1}	183 Mm^{-1}	146 Mm^{-1}	80 Mm^{-1}
Houston, TX	194 Mm^{-1}	194 Mm^{-1}	179 Mm^{-1}	125 Mm^{-1}	73 Mm^{-1}
St. Louis, IL	307 Mm^{-1}	307 Mm^{-1}	277 Mm^{-1}	241 Mm^{-1}	206 Mm^{-1}
Birmingham, AL	357 Mm^{-1}	266 Mm^{-1}	208 Mm^{-1}	152 Mm^{-1}	102 Mm^{-1}
Atlanta, GA	249 Mm^{-1}	249 Mm^{-1}	191 Mm^{-1}	134 Mm^{-1}	76 Mm^{-1}
Detroit, MI	291 Mm^{-1}	202 Mm^{-1}	157 Mm^{-1}	120 Mm^{-1}	88 Mm^{-1}
Pittsburgh, PA	278 Mm^{-1}	243 Mm^{-1}	185 Mm^{-1}	127 Mm^{-1}	69 Mm^{-1}
Baltimore, MD	246 Mm^{-1}	246 Mm^{-1}	201 Mm^{-1}	138 Mm^{-1}	76 Mm^{-1}
Philadelphia, PA	258 Mm^{-1}	175 Mm^{-1}	134 Mm^{-1}	98 Mm^{-1}	63 Mm^{-1}
New York, NY	306 Mm^{-1}	281 Mm^{-1}	212 Mm^{-1}	141 Mm^{-1}	74 Mm^{-1}

Colored highlighting shows which of the CPL levels the values are near, using the following definitions: PM light extinction equal or above the high CPL $\geq$191 Mm^{-1}; above the middle CPL, 112 Mm^{-1} – 190 Mm^{-1}; above the low CPL, 64 Mm^{-1} – 111 Mm^{-1}; below the low CPL, < 64 Mm^{-1}. Values without color highlighting indicate no rollback, so no information about the effectiveness of the hourly PM mass based alternative standards

Aside from St. Louis, the range of 90th percentile PM light extinction design levels resulting from rollback to just meet a 90th percentile 20 $\mu g/m^3$ PM mass concentration is from 98 Mm^{-1} for Philadelphia to 156 Mm^{-1} for Los Angeles with most values near the middle CPL value of 112 Mm^{-1}. A similar range, excluding St. Louis for the 30 $\mu g/m^3$ PM mass concentration is from 134 Mm^{-1} to 220 Mm^{-1} for the same two cities. This demonstrates the amount of variability in visibility conditions that would likely result from using a standard with PM mass concentration instead of PM light extinction as the indicator. While this degree of variation is not particularly large, it does mean that some areas would be required to further control emissions to meet a secondary standard though they have visibility conditions that are as good or better than other areas which meet the PM mass based standard. Some measure of the extent to

which this occurs may be gained by comparing the percent rollback values required to meet the various PM mass and PM light extinction values.

Based on inspection of the design values shown in Table 4.3-2, among the $PM_{2.5}$ mass concentration levels that were assessed, 30 $\mu g/m^3$ provides protection most comparable to the high CPL (191 Mm^{-1}), 20 $\mu g/m^3$ provides protection most comparable to the middle CPL (112 Mm^{-1}) and 10 $\mu g/m^3$ provides protection most comparable to the low CPL (64 Mm^{-1}).

Care must be taken to avoid misinterpretation of this suggestion of approximate comparability of protection afforded the various urban areas by PM mass at the three concentration levels in terms of the three CPLs. The values in Table 4.3-2 are the 90th percentile values of the PM light extinction distribution that results from transforming the hourly PM mass and composition values of the rolled back PM distributions for each urban area. Hours with values above the 90th percentile of PM mass do not necessarily have PM light extinction above the 90th percentile and visa versa. As discussed earlier (section 4.3.1) for any individual hourly PM mass concentration there is a substantial range of corresponding PM light extinction values possible. However when used as the indicator for a secondary PM standard, hourly $PM_{2.5}$ mass need only predict the response of the distribution of hourly visibility conditions to produce requisite levels of protection for visibility welfare effects.

4.4 PRELIMINARY STAFF CONCLUSIONS ON ALTERNATIVE SECONDARY PM STANDARDS FOR VISIBILITY-RELATED EFFECTS

In reaching preliminary conclusions on potential alternative standards to provide requisite protection of PM-related visibility impairment, staff has considered the basic elements of the NAAQS: indicator, averaging time, form and level. In considering the scientific and technical information, we reflect upon the information available in the last review integrated with information that is newly available since the last review as assessed and presented in the ISA and the second draft UFVA (US EPA, 2010b) and as summarized in sections 4.2, 4.3, and Appendix A.

As outlined in section 4.1.3, in this review we emphasize a policy approach that broadens the general approaches used in the last two PM NAAQS reviews by utilizing, to the extent available, enhanced tools, methods, and data to more comprehensively characterize visibility impacts. As such, we take into account both evidence-based and impact assessment-based considerations to inform our conclusions related to the adequacy of the current $PM_{2.5}$ secondary standards and alternative standards that are appropriate for consideration in this review. In so doing, we are seeking to provide as broad an array of options as is supportable by the available information, recognizing that the selection of a specific approach to reaching final decisions on the secondary PM standards for protection from PM-related visibility impairment will reflect the

judgments of the Administrator as to what weight to place on the various approaches and types of information presented in the final PA.

In presenting our preliminary conclusions regarding alternative secondary standards and ranges of levels for consideration, we summarize conclusions presented in sections 4.3.1 through 4.3.4. We emphasize that these are preliminary conclusions that reflect consideration of the scientific and technical information assessed and presented in the ISA and second draft UFVA (US EPA, 2009a; US EPA, 2010b). We note that staff conclusions to be presented in the final UFVA and second draft PA will be based, in part, on input received from CASAC and the public on the second draft UFVAA and this first draft PA.

We recognize that selecting from among alternative standards will necessarily reflect consideration of the qualitative and quantitative uncertainties inherent in the relevant evidence and in the assumptions that underlie the quantitative visibility impact assessment. In identifying these alternative secondary standards and ranges of levels for consideration, we are mindful that the Clean Air Act requires standards to be set that are requisite to protect public welfare from any known or anticipated adverse effects, such that the standards are to be neither more nor less stringent than necessary. Thus, the Act does not require that the NAAQS be set at zero-risk levels, but rather at levels that avoid unacceptable risks to public welfare.

(1) Consideration should be given to revising the current suite of $PM_{2.5}$ secondary standards to provide increased public welfare protection from PM-related visibility impairment, primarily in urban areas. This preliminary conclusion is based in general on the evaluation in the ISA of the currently available information, including a more extensive characterization of the sources contributing to visibility impairment in both rural and urban locations, a refined understanding of the contributions of various PM components in such areas, exposure-related evidence supporting a causal relationship between ambient PM and impaired VAQ, and more specifically, on the evidence that a significant number of days with levels of VAQ that could reasonably be considered unacceptable based on the preference studies would continue to occur in areas where the current standards were met, together with judgments as to the public welfare significance of these occurrences upon just meeting the current suite of $PM_{2.5}$ standards.

(2) With regard to indicator, consideration should be given to establishing a new PM light extinction indicator; alternatively, consideration can be given to retaining the current $PM_{2.5}$ indicator. This preliminary conclusion takes into consideration the available evidence that demonstrates a one-to-one correspondence between measured ambient PM light extinction and PM-related visibility impairment as well as the significant degree of variability in visibility protection across the U.S. allowed by a $PM_{2.5}$ indicator, while also

recognizing that either indicator could be used as a basis for a standard that could provide appropriate protection from PM-related visibility impairment.

(3) With regard to averaging time, consideration should be given to selecting an alternative averaging time for a secondary PM standard to protect against daytime PM-related visibility impairment that takes into account the short term (instantaneous) nature of the perception of visibility impairment, short term variability in PM-related VAQ (partial hour to hourly), and the short-term nature of relevant exposure periods for the viewing public (partial hour to multiple hours). Recognizing that the current 24-hour and annual averaging times do not appropriately reflect these exposure characteristics, consideration should be given to a one-hour averaging time based on the maximum hour in the daylight period or on all daylight hours.

(4) In conjunction with considering a 1-hour averaging time, consideration should be given to a form defined in terms of the 90^{th}, 95^{th} or 98^{th} percentile of the distribution of 1-hour PM light extinction or $PM_{2.5}$ concentrations, averaged over three years. We believe it is appropriate to consider allowing some number of days/hours with visibility impairment above the target level of protection, such that consideration of the 90^{th} or 95^{th} percentile forms is appropriate. In addition, consideration should be given to applying a 90% relative humidity screen to remove hours in which fog or precipitation is much more likely to contribute to the observed visibility impairment.

(5) Consideration should be given to selecting a target level in terms of PM light extinction. Further, consideration should be given to alternative candidate levels, with a particular focus on a level of 112 Mm^{-1} as well as levels down to 64 Mm^{-1} and up to 191 Mm^{-1} to provide appropriate protection against PM-related visibility impairment. Based on the assessment conducted in this review, we judge that a reasonably consistent correspondence exists between these PM light extinction benchmark levels and $PM_{2.5}$ mass concentrations, with a particular focus on a level of 10 $\mu g/m^3$ as well as levels down to 20 $\mu g/m^3$ and up to 30 $\mu g/m^3$, which would be appropriate to consider in conjunction with consideration of a $PM_{2.5}$ indicator.

(6) Consideration should be given to the following alternative secondary PM standards to provide protection against PM-related visibility impairment during daylight hours:

(a) Consideration of a new 1-hour daily maximum PM light extinction standard set at a level within the range of 64 to 191 Mm^{-1} (e.g. 20 – 30 deciviews (dv)) with a 90^{th} or 95^{th} percentile form.

(b) Consideration of a revised 1-hour daily maximum $PM_{2.5}$ standard set at a level within the range of 10 to 30 $\mu g/m^3$ with a 90^{th} or 95^{th} percentile form.

(c) Alternatively, consideration could also be given to a standard based on all daylight hours with either indicator, in conjunction with consideration of a 98^{th} percentile form.

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Appendix A

Information Regarding the 1-hour $PM_{2.5}$ Mass Indicator

This Appendix presents information on 2005-2007 levels of 1-hour $PM_{2.5}$ mass concentrations in the 15 urban study areas and on the "what if" PM light extinction conditions that would exist if the study areas met each of 10 alternative secondary PM NAAQS scenarios based on a 1-hour $PM_{2.5}$ mass indicator. With respect to the latter subject, this Appendix is therefore similar to Chapter 4 of the Particulate Matter Urban-Focused Visibility Assessment (UFVA), which presented similar information for 18 secondary PM NAAQS scenarios based on PM light extinction as the indicator, for the current annual and 24-hour $PM_{2.5}$ NAAQS, and for a scenario with an annual NAAQS of 12 $\mu g/m^3$ and a 24-hour NAAQS of 25 $\mu g/m^3$.

1.0 Indicator and Monitoring Method

As in Chapter 4 of the PM UFVA, this Appendix excludes from all NAAQS scenarios and results all non-daylight hours and all daylight hours with relative humidity greater than 90 percent. This applies to both the definition of 10 secondary NAAQS scenarios, and to graphics and tables that characterize ambient conditions. While ambient humidity should not affect conventional measurement approaches for 1-hour $PM_{2.5}$ mass, the issue of co-occurrence of high humidity levels with light extinction due to natural conditions would still apply. See section 3.3.5 of the UFVA. The assumed hours of daylight are the same as those used in the UFVA, as shown in Table 3-5 of the UFVA.

All values for 1-hour $PM_{2.5}$ mass concentration in this appendix come from the continuous instruments at the 15 urban study sites, with no adjustment to make these values consistent with the collocated 24-hour FRM measurement of $PM_{2.5}$ mass. Appendix A of the UFVA provides details on the type of continuous instrument at each study site. TEOMs were used at all sites except for beta attenuation instruments in Fresno and Philadelphia, nephelometer instruments in Tacoma and Phoenix, and an FDMS instrument in Salt Lake City.

For conciseness in this first public review draft, only the daily maximum daylight 1-hour $PM_{2.5}$ mass concentration indicator is considered in this Appendix. It would also be possible to construct alternative NAAQS scenarios of an all-hours type, which could be analyzed in the same manner as presented in this Appendix.

2.0 Current Conditions of 1-hour $PM_{2.5}$ Mass

Figure A-1 is a box plot of 2005-2007 daily maximum daylight 1-hour $PM_{2.5}$ mass concentrations for the 15 study areas, excluding hours with relative humidity greater than 90 percent, to give a sense of the range and central tendency of this parameter. The horizontal reference lines are at 10, 20, 30, 40 and 60 $\mu g/m^3$. The relative positions of the 90 percentile concentrations (indicated by the horizontal stroke at the top of the whisker) are generally consistent with the relative ranking of these sites according to their design values for the 24-hour

$PM_{2.5}$ NAAQS (see Table 3-2 of the UFVA); similarly, the relative positions of the median concentrations are generally consistent with the annual $PM_{2.5}$ design values. Table A-1, based on the same data as Figure A-1, presents the percentage of days in 2005-2007 on which the daily maximum daylight 1-hour $PM_{2.5}$ concentration exceeded the reference levels represented by the horizontal lines in Figure A-1.

Figure A-1. 2005-2007 daily maximum daylight 1-hour $PM_{2.5}$ mass concentrations (µg/m^3) for the 15 study areas (excluding hours with relative humidity greater than 90 percent)

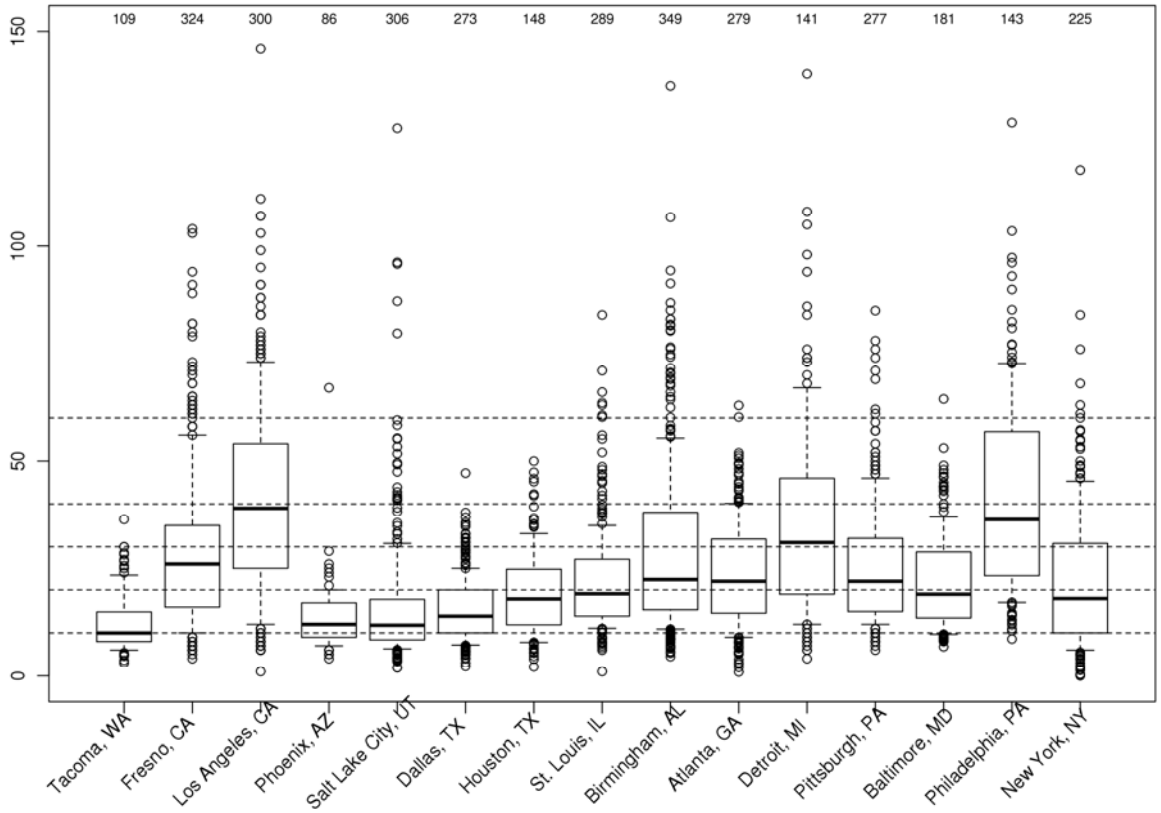


Table A-1. Percentage of days with daily maximum daylight 1-hour $PM_{2.5}$ mass concentration exceeding reference levels in 2005-2007 (excluding hour with relative humidity greater than 90 percent)

		1-hour $PM_{2.5}$ Mass Reference Level ($\mu g/m^3$)				
Study Area	Number of Days with Estimates	10	20	30	40	60
Tacoma	109	50	11	1	0	0
Fresno	324	88	62	37	20	8
Los Angeles	300	92	81	67	46	20
Phoenix	86	60	8	1	1	1
Salt Lake City	306	64	20	11	7	2
Dallas	273	75	25	5	0	0
Houston	148	80	42	14	5	0
St. Louis	289	93	47	18	7	2
Birmingham	349	92	60	37	23	8
Atlanta	279	86	56	28	10	1
Detroit	141	92	72	52	36	13
Pittsburgh	277	94	57	28	15	3
Baltimore	181	90	46	22	8	1
Philadelphia	143	99	84	63	45	20
New York	225	75	43	25	13	3

3.0 Alternative NAAQS Scenarios Based on 1-hour $PM_{2.5}$ Mass as the Indicator

To ensure examination of a wide enough range of alternative standards based on 1-hour $PM_{2.5}$ mass to encompass the range of standards that might be considered as alternatives to the PM light extinction NAAQS scenarios examined in Chapter 4 of the UFVA, we considered levels of 10, 20, 30, 40, and 60 $\mu g/m^3$. Only the daily maximum daylight hour form was considered. Each level was combined with two statistical forms: the three-year average of the annual 90th percentile value and the three-year average of the annual 95th percentile value. For ease of reference, these scenarios are designated by letters from "aa" to "jj" and listed in Table A-2. Looking somewhat ahead to results presented below, the scenarios are arranged in Table A-2 in order of least to most stringent in terms of the reductions in ambient $PM_{2.5}$ needed from current levels to meet the current and alternative NAAQS levels and forms.

Table A-2. Alternative NAAQS scenarios based on daily maximum daylight 1-hour $PM_{2.5}$ mass, averaged over three years (excluding hours with relative humidity greater than 90 percent)

NAAQS Scenario	Level ($\mu g/m^{3)}$	Statistical Form
aa	60	3-year average of 90th percentile
bb	60	3-year average of 95th percentile
cc	40	3-year average of 90th percentile
dd	40	3-year average of 95th percentile
ee	30	3-year average of 90th percentile
ff	30	3-year average of 95th percentile
gg	20	3-year average of 90th percentile
hh	20	3-year average of 95th percentile
ii	10	3-year average of 90th percentile
jj	10	3-year average of 95th percentile

4.0 Approach to Modeling "What If" Conditions of PM Light Extinction for Alternative Secondary NAAQS Based on 1-hour $PM_{2.5}$ Mass

Before modeling "what if" conditions, we augmented the data set described in Table 4 of the UFVA in the same manner as described in Section 4.1.4 of the UFVA, to achieve seasonal balance despite the lack of monitoring data for one quarter in each of Houston and Phoenix. In Tacoma and Phoenix, which had data only for two years in the 2005-2007 period, we averaged the percentile values from the only two available years rather than the three years defined for the statistical form of the NAAQS scenarios.

The modeling of daily maximum daylight 1-hour $PM_{2.5}$ mass under each of the scenarios listed in Table A-2 used a rollback approach that combined relevant concepts and steps from the rollback methods described in sections 4.1.4 (for PM light extinction scenarios) and 4.2.2 (for scenarios based on annual average and 24-hour average $PM_{2.5}$) of the UFVA. The following are the steps in the modeling.

1. Identify the 90th percentile daily maximum daylight 1-hour $PM_{2.5}$ mass value in each of 2005, 2006, and 2007 for a study area. Average these to determine the design value for that percentile

form. Repeat for the 95th percentile form. These design values are presented in Table A-3. They range from 22 to 81 $\mu g/m^3$ indicating that some study areas meet some of the NAAQS scenarios under current conditions. In such cases, $PM_{2.5}$ concentrations were not adjusted, i.e., there was no "roll up" for any area in any scenario.

2. Using the same days and hours as contributed by the three annual 90th percentile values for actual 1-hour $PM_{2.5}$ mass, find the three corresponding values of policy relevant background (PRB) 1-hour $PM_{2.5}$ mass. Average these three annual values of PRB 1-hour $PM_{2.5}$ to obtain the PRB portion of the actual 1-hour $PM_{2.5}$ design value for the 90th percentile form. Repeat for the 95th percentile form.

In the modeling for the NAAQS scenarios examined in the UFVA, PRB for 1-hour $PM_{2.5}$ mass was not explicitly calculated because it was not needed in the rollback modeling for the scenarios addressed in the UFVA. Therefore, it was necessary to reconstruct this parameter by adding the values for the PRB concentrations of the five components of $PM_{2.5}$: nitrate, sulfate, elemental carbon, organic carbon material, and soil. The method for estimating PRB for these five components is described in Appendix C of the UFVA.9

3. Subtract the value from step 2 from the value from step 1, to determine the non-PRB portion of the 1-hour $PM_{2.5}$ mass design value.

4. Calculate the percentage reduction required in non-PRB 1-hour $PM_{2.5}$ mass in order to reduce the design value to the level that defines the NAAQS scenario, using the following equation:

Percent reduction required = 1 – (NAAQS level – PRB portion of the design value)/(non-PRB portion of the design value)

The percentage reductions determined in step 4 are shown in Table A-4. Note that for some combinations of area and scenario no reduction is required because the 2005-2007 design value already meets the NAAQS scenario.

5. Turning to the entire set of day/hour-specific actual and PRB daylight 1-hour concentrations of the five $PM_{2.5}$ components for the three (or two) year period, determine the non-PRB portion of each of the five components in an hour by subtracting the PRB value from actual value, reduce it by the percentage determined in step 4, and add back in the PRB 1-hour concentration of the component.

6. Finally, re-construct PM light extinction using the reduced values of the five components, the original value of 1-hour $PM_{10-2.5}$, and the 1-hour value of f(RH), according to the following equation for PM light extinction (see section 3.2.3 of the UFVA for an explanation of the variables in this equation).

[9] Table C-1 of the UFVA presents the annual average of all daylight hour PRB $PM_{2.5}$ mass. The 90th and 95th percentile values of daily maximum PRB $PM_{2.5}$ mass were of course higher than shown in that table.

b_{extPM} = 3 x f(RH) x [Sulfate]
+ 3 x f (RH) x [Nitrate]
+ 4 x [Organic Mass]
+10 x [Elemental Carbon]
+ 1 x [Fine Soil]
+ 0.6 x [Coarse Mass]

These steps assume that in order to meet a PM NAAQS scenario based on 1-hour $PM_{2.5}$ as the indicator, each component of $PM_{2.5}$ is reduced by an equal percentage, across the five components and across all hours. In actual implementation of such a NAAQS, each state would develop an attainment strategy, which might result in unequal percentage reductions of the components. If the strategy emphasized reductions in the fine soil component, for example, PM light extinction levels would remain high relative to those estimated by these steps, because fine soil is not efficient in terms of reducing visibility compared to the other four components on a dry mass-to-mass basis. On the other hand, a strategy that involves relatively large reductions in sulfate or nitrate would achieve greater reductions in PM light extinction than estimated by these steps. The uncertainty in how the results of this rollback method compare to the results of actual attainment strategies should be kept in mind when comparing the results of "what if" scenarios for NAAQS based on $PM_{2.5}$ mass as the indicator versus scenarios based on PM light extinction. Unlike the effect of humidity variation between areas, this source of uncertainty is not reflected in any of the results presented in this Appendix and will not be apparent in comparisons of results in this Appendix to results presented in the PM UFVA for NAAQS scenarios based on PM light extinction.

These steps also assume no change in $PM_{10-2.5}$ concentrations between current conditions and "what if" conditions. While reductions in $PM_{10-2.5}$ would not be needed to meet a secondary NAAQS based on 1-hour $PM_{2.5}$ mass, it is possible that strategies to control $PM_{2.5}$ concentrations might also achieve reductions in $PM_{10-2.5}$ concentrations because some source emit both and some control methods achieve some reductions in both. However, in most of the 15 study areas, $PM_{10-2.5}$ makes a small contribution to estimated PM light extinction, in part because in many of the areas no local data on $PM_{10-2.5}$ concentrations were available and the method used to fill this gap (application of a factor to $PM_{2.5}$ concentration) simply could not produce a high estimate of $PM_{10-2.5}$.

Table A-3. 2005-2007 design values for 1-hour $PM_{2.5}$ mass ($\mu g/m^3$)

Study Area	Percentile Form	
	90th	95th
Tacoma	22	27
Fresno	55	66
Los Angeles	72	81
Phoenix	20	24
Salt Lake City	32	45
Dallas	26	29
Houston	33	37
St. Louis	36	44
Birmingham	55	74
Atlanta	40	45
Detroit	64	79
Pittsburgh	46	51
Baltimore	37	43
Philadelphia	67	77
New York	44	55

Table A-4. Percentage reductions in non-PRB $PM_{2.5}$ components required to meet NAAQS scenarios based on 1-hour $PM_{2.5}$ mass

Scenario	aa	bb	cc	dd	ee	ff	gg	hh	ii	jj
Level ($\mu g/m^3$)	60	60	40	40	30	30	20	20	10	10
Percentile Form	90	95	90	95	90	95	90	95	90	95
Study Area	Percentage Reduction									
Tacoma	0	0	0	0	0	0	11	27	60	69
Fresno	0	10	28	40	46	55	65	71	83	86
Los Angeles	17	26	45	51	59	64	73	76	87	88
Phoenix	0	0	0	0	0	0	0	15	51	58
Salt Lake City	0	0	0	12	7	34	39	56	70	78
Dallas	0	0	0	0	0	0	23	34	64	69
Houston	0	0	0	0	9	20	40	49	71	78
St. Louis	0	0	0	10	16	33	45	56	74	79
Birmingham	0	19	28	46	46	60	65	74	84	87
Atlanta	0	0	0	12	25	34	51	57	77	80
Detroit	7	24	38	50	54	63	70	75	85	88
Pittsburgh	0	0	13	22	35	42	57	62	79	81
Baltimore	0	0	0	8	19	31	47	55	74	78
Philadelphia	10	22	40	49	55	62	71	75	86	88
New York	0	0	8	28	32	46	55	65	78	83

5.0. 1-hour $PM_{2.5}$ Mass Results for "Just Meeting" Alternative Secondary NAAQS Scenarios Based on 1-hour $PM_{2.5}$ Mass

As a check on the reasonableness of the rollback method described in section 4.0 and on the accuracy of the code used to implement it, it is of interest to examine the distribution of the levels of 1-hour $PM_{2.5}$ that result from the method. Ideally, after rollback any area that had a non-zero required reduction should have a post-rollback design value for 1-hour $PM_{2.5}$ mass that is exactly equal to the target design value. Also, there should be a progression of reductions in 1-hour $PM_{2.5}$ medians and other percentile points on the distribution as progressively more stringent scenarios are modeled.

Table A-5 shows the post-rollback 1-hour $PM_{2.5}$ mass design values for the scenarios, with percentile forms matched. Design values for area-scenario combinations for which the required reductions were zero have been omitted, because the current conditions design values for these combinations would not be expected to reflect the target design value. It can be seen that the design values progress as expected and are in the vicinity of the target design values, but are not always exactly equal to the targets. EPA staff attributes this to the fact that PRB concentrations of 1-hour $PM_{2.5}$ mass vary from hour to hour. It is possible for the daily maximum $PM_{2.5}$ mass concentration on a certain day in 2005 with a percentile rank of, for example, 96^{th} to have a relatively small PRB portion and a large non-PRB portion compared to the daily maximum concentration that ranks 95^{th}. When an equal reduction is made to the non-PRB portion of each total concentration, the two values may switch rank positions, and so a new day and hour becomes the 2005 contributor to the rolled back three-year design value. Since this day and hour was not used to determine the required percentage reduction, the resulting design value will not exactly meet the target design value. It would be possible to iterate with higher and lower percentage reductions until the rolled back design value exactly matched the target design value, but EPA considered this degree of refinement to be unnecessary in order to meet the objectives of the Policy Assessment Document, given other uncertainties in the underlying data and in the assumptions used to estimate PM light extinction values.

EPA staff also generated and examined box plots of daily maximum daylight 1-hour $PM_{2.5}$ mass concentrations as a check for conceptual or programming, and found them to match expectations. They are not included here, for conciseness.

Table A-5. Post-rollback design values for daily maximum 1-hour $PM_{2.5}$ mass. Design values are shown only for combinations of study area and scenario for which the study area does not meet the scenario under current conditions, such that reductions were made during the rollback modeling.

Scenario	aa	bb	cc	dd	ee	ff	gg	hh	ii	jj
Level ($\mu g/m^3$)	60	60	40	40	30	30	20	20	10	10
Statistical Form	90th	95th	90th	95th	90th	95th	90th	95th	90th	95th
Study Area	Corresponding Design Value ($\mu g/m^3$) (same percentile form as the scenario)									
Tacoma							20	21	11	12
Fresno		63	40	42	30	31	20	21	10	10
Los Angeles	53	53	35	35	26	26	18	18	9	9
Phoenix								19	10	10
Salt Lake City				38	29	28	19	19	10	10
Dallas							23	23	12	11
Houston					29	27	19	18	10	9
St. Louis				39	31	29	21	19	10	10
Birmingham		58	42	39	32	29	21	20	11	10
Atlanta				36	28	27	19	18	10	10
Detroit	52	59	34	39	26	29	17	20	9	10
Pittsburgh			33	33	24	25	16	17	8	9
Baltimore				38	31	28	21	19	10	10
Philadelphia	46	44	31	30	23	22	16	15	8	8
New York			42	40	32	30	21	20	11	10

6.0 PM Light Extinction Results for "Just Meeting" Alternative Secondary NAAQS Scenarios Based on 1-hour $PM_{2.5}$ Mass

The rollback steps described in section 4.0 resulted in estimates of PM light extinction for each day and hour in each study area, for each of the 10 NAAQS scenarios based on 1-hour $PM_{2.5}$ mass as the indicator. Two summaries of these conditions are presented here.

Figure A-2 presents a box plot of daily maximum daylight 1-hour PM light extinction for each NAAQS scenario based on 1-hour $PM_{2.5}$ mass. These can be compared to Figure 3-8(a) of the UFVA representing pre-rollback daily maximum PM light extinction, and to the upper panel of the figures in Appendix F of the UFVA representing the daily maximum PM light extinction levels resulting from the 20 NAAQS scenarios examined in the UFVA (18 scenarios based on PM light extinction as the indicator, the current annual and 24-hour $PM_{2.5}$ NAAQS, and a scenario with an annual NAAQS of 12 $\mu g/m^3$ and a 24-hour NAAQS of 25 $\mu g/m^3$). It can be seen that the distribution of $PM_{2.5}$ mass in a given study area shifts downward as the NAAQS scenarios progress from least to most stringent (as indicated by the required percentage reduction) and in most cases become more similar to other areas (once the progression of scenarios begins to require reductions in a given area). St. Louis is an obvious exception, in that it retains many relatively high values even under the most stringent NAAQS scenario. This is due to the fact that many hours and days in St. Louis have a large estimated $PM_{10-2.5}$ concentration contribution to estimated PM light extinction, as visualized in the light extinction budgets presented in Figure 3-13 of the UFVA. The rollback approach does not change $PM_{10-2.5}$ concentrations. Recall from section 3.3.2 and Appendix A of the UFVA that for St. Louis, PM_{10-}

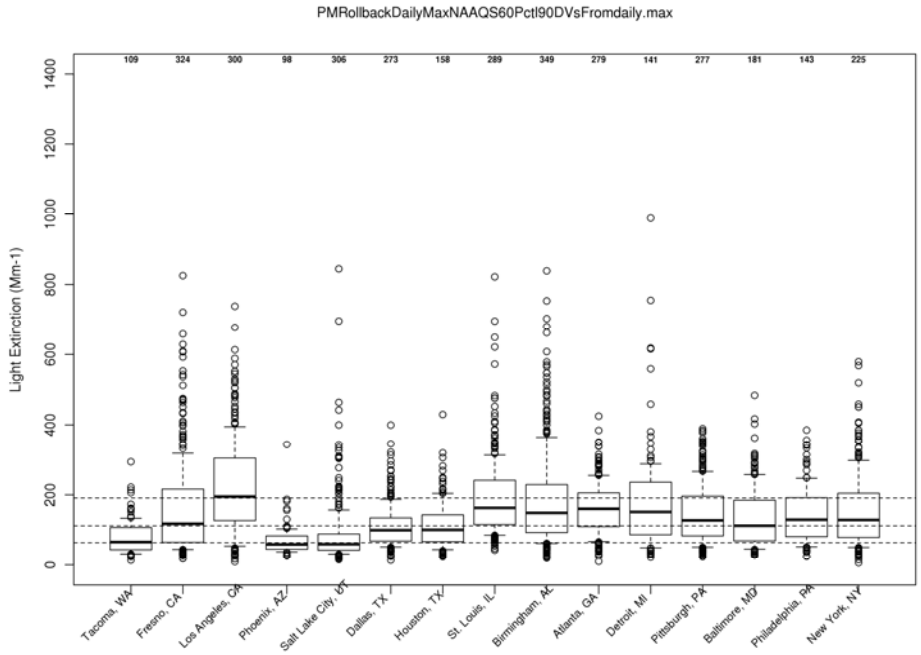
$_{2.5}$ concentrations were estimated based on a PM_{10} instrument located very near a recycling/municipal works yard and a $PM_{2.5}$ instrument in another less industrial location. As such, those estimated concentrations of $PM_{10-2.5}$ may not represent a large portion of the St Louis urban area.

$PM_{10-2.5}$ was also a notable contributor to the estimated light extinction budgets in Los Angeles on a number of days, although to a lesser degree than in St. Louis. This is reflected in the box plots, which show a number of high values of PM light extinction regardless of the level of the hypothetical $PM_{2.5}$ mass NAAQS. Recall from section 3.3.2 and Appendix A of the UFVA that for Los Angeles, $PM_{10-2.5}$ concentrations were estimated based on a PM_{10} instrument located in Victorville, California which is a considerable distance from the site in Rubidoux, California and is perhaps a dustier area than most of the Los Angeles airshed.

Table A-6 presents the percentage of days in 2005-2007 on which daily maximum 1-hour PM light extinction exceeded each of the CPL, under each of the 10 secondary PM NAAQS scenarios based on 1-hour $PM_{2.5}$ mass. These percentages are necessarily based on the days for which data to estimate PM light extinction were available, but are best estimates of the percentage of all days in the year given that the days with data were well distributed across the year on either a one-in-three or one-in-six sampling schedule. These percentages can be compared to the same-basis percentages presented in Table 4-7 of the UFVA.

Figure A-2. Distributions of maximum daily daylight 1-hour PM light extinction under "just meet" conditions for NAAQS scenarios based on 1-hour $PM_{2.5}$ mass (excluding hours >90% RH)

(aa) NAAQS Scenario
60 µg/m3
90th percentile



(bb) NAAQS Scenario
60 µg/m3
95th percentile

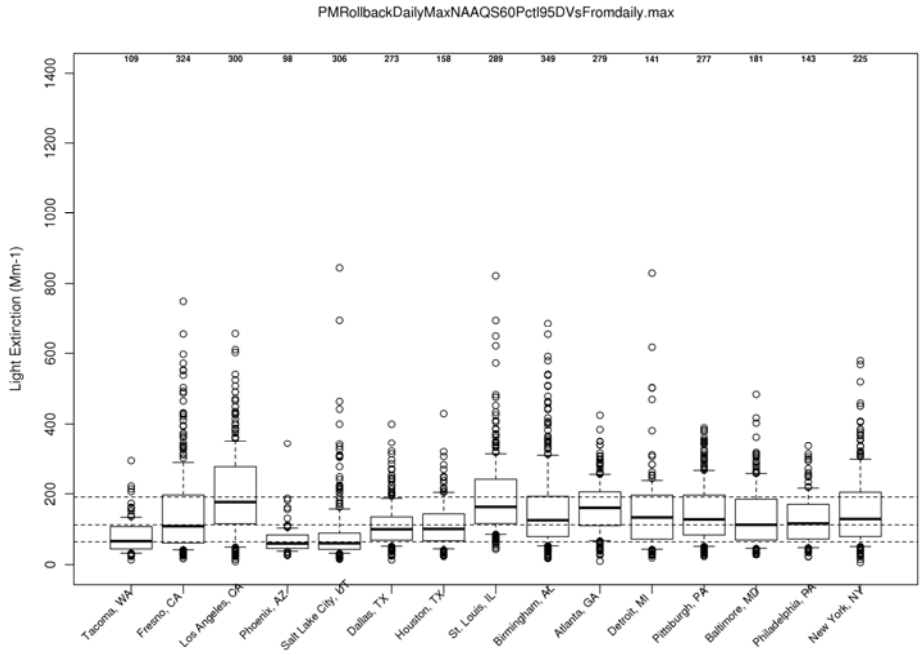
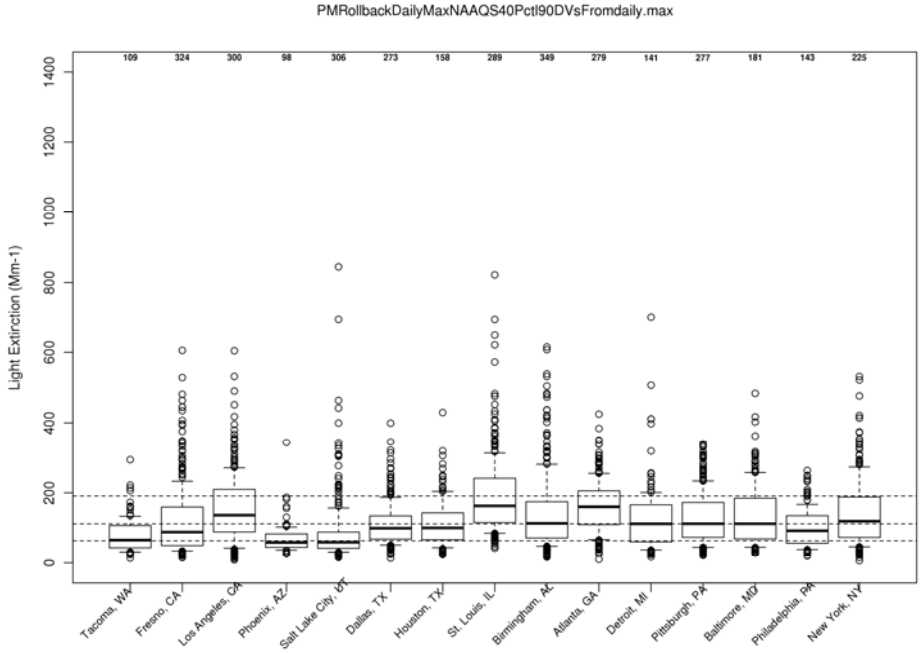


Figure A-2. Distributions of maximum daily daylight 1-hour PM light extinction under "just meet" conditions for NAAQS scenarios based on 1-hour $PM_{2.5}$ mass (excluding hours >90% RH) (continued)

(cc) NAAQS Scenario
40 µg/m3
90th percentile



(dd) NAAQS Scenario
40 µg/m3
95th percentile

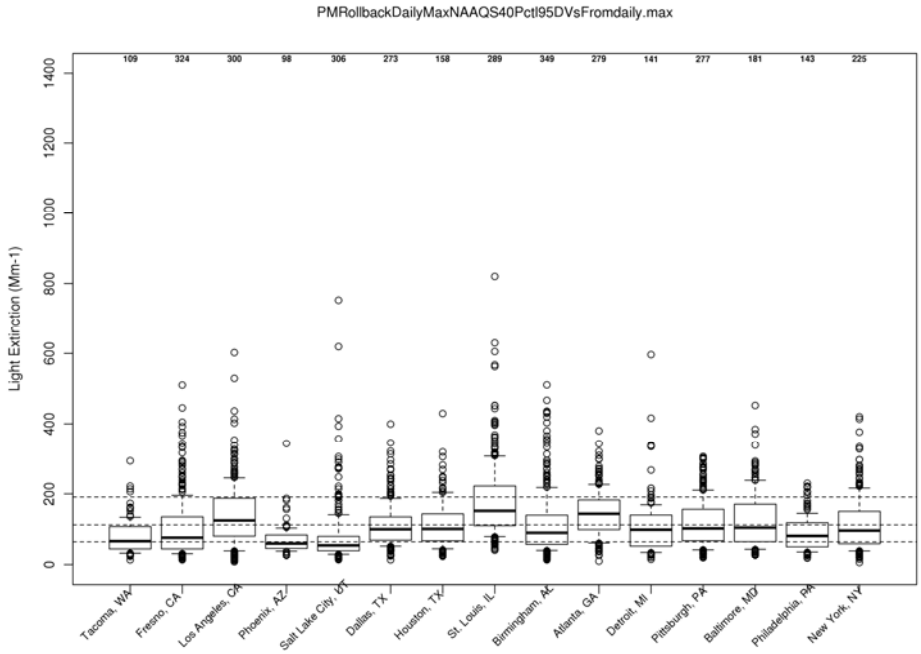
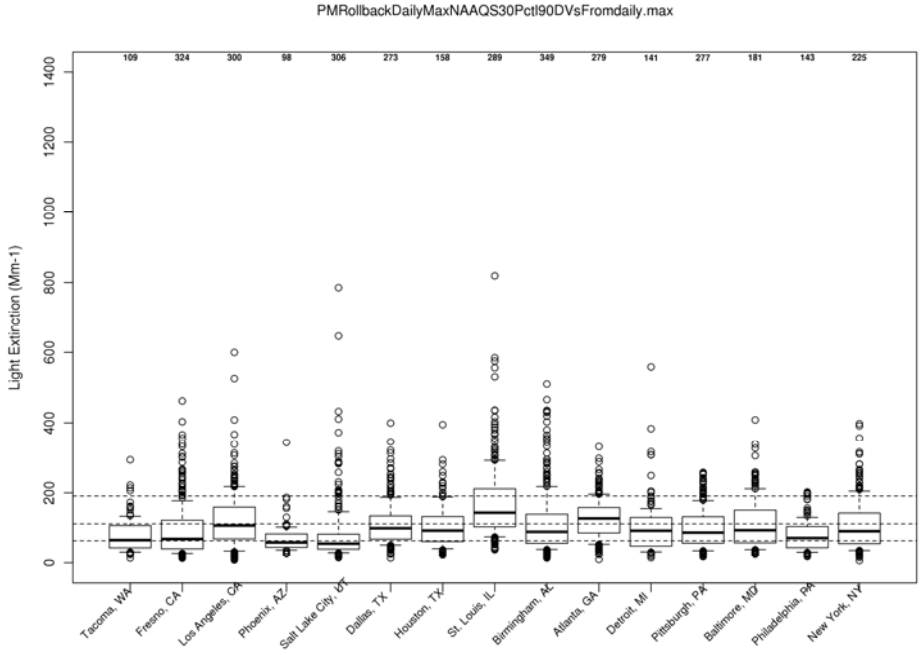


Figure A-2. Distributions of maximum daily daylight 1-hour PM light extinction under "just meet" conditions for NAAQS scenarios based on 1-hour $PM_{2.5}$ mass (excluding hours >90% RH) (continued)

(ee) NAAQS Scenario
30 µg/m3
90th percentile



(ff) NAAQS Scenario
30 µg/m3
95th percentile

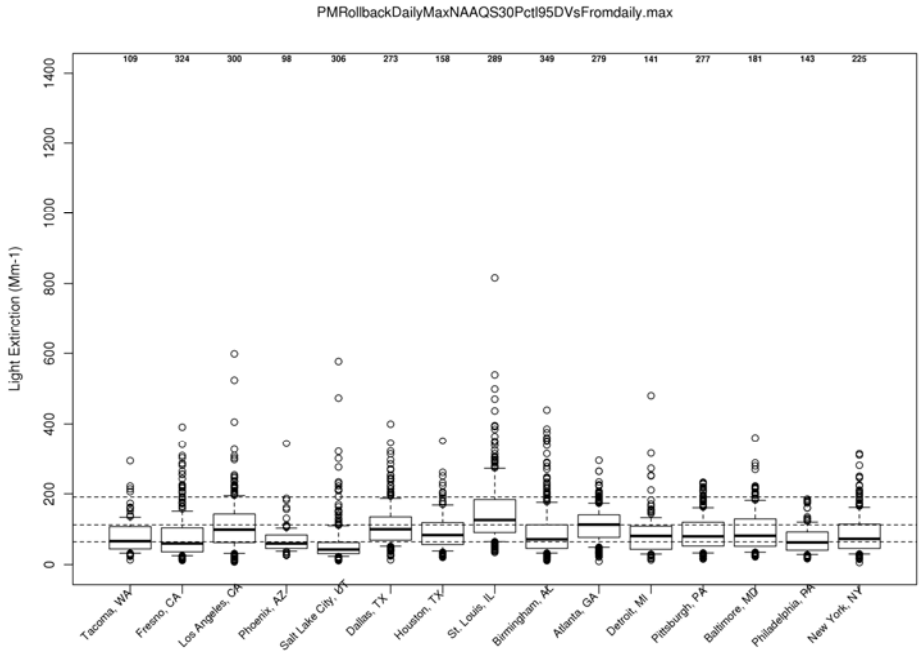
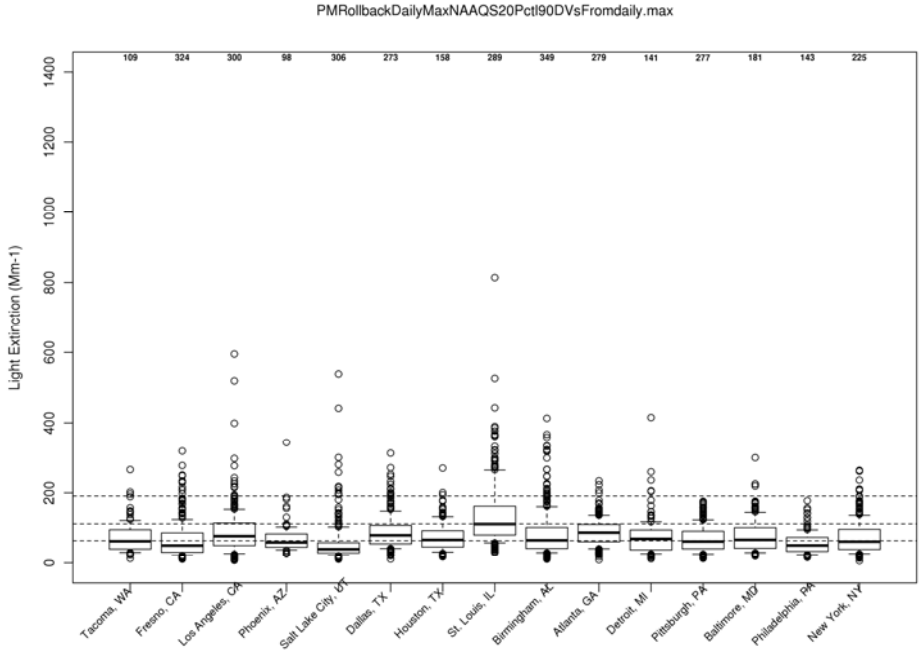


Figure A-2. Distributions of maximum daily daylight 1-hour PM light extinction under "just meet" conditions for NAAQS scenarios based on 1-hour $PM_{2.5}$ mass (excluding hours >90% RH) (continued)

(gg) NAAQS Scenario
20 µg/m3
90th percentile



(hh) NAAQS Scenario
20 µg/m3
95th percentile

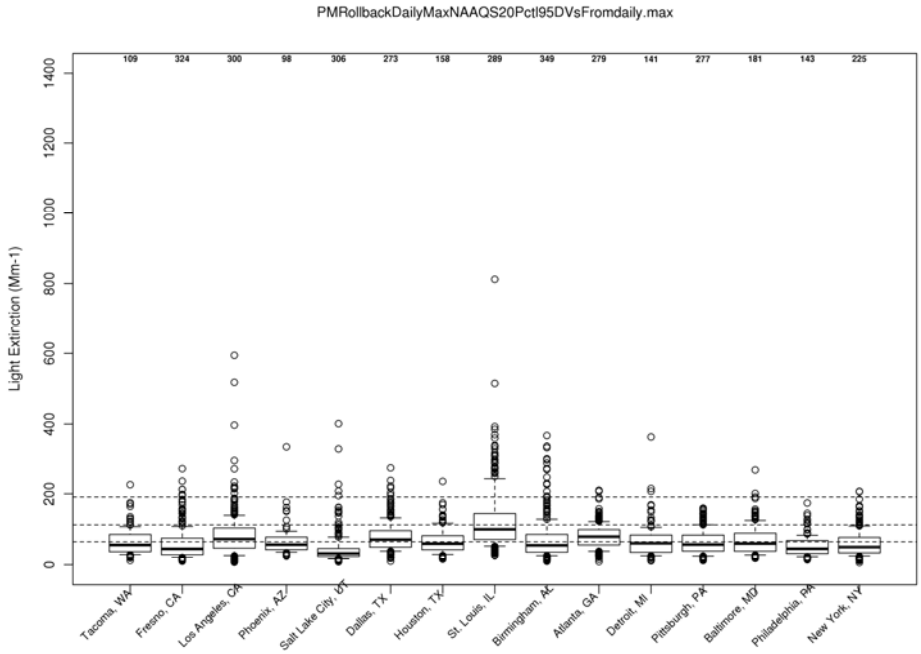
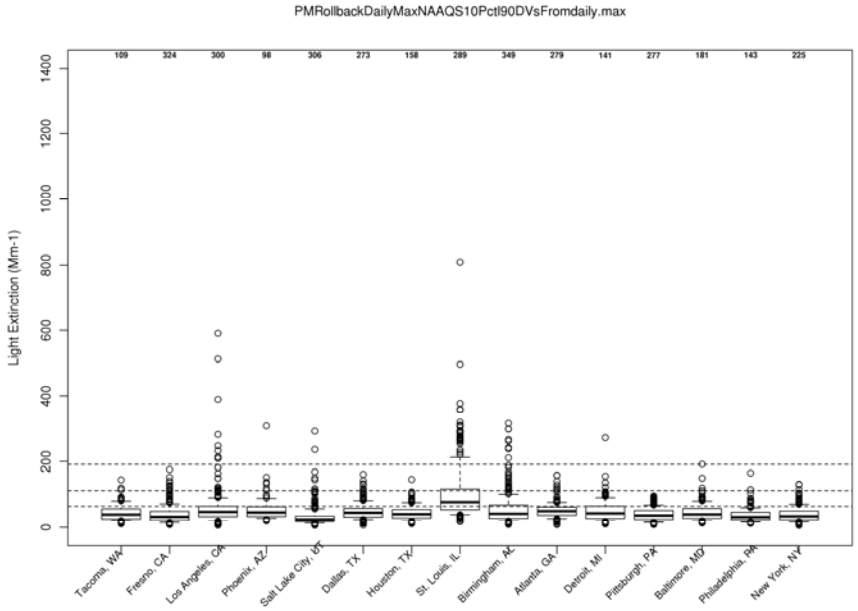


Figure A-2. Distributions of maximum daily daylight 1-hour PM light extinction under "just meet" conditions for NAAQS scenarios based on 1-hour $PM_{2.5}$ mass (excluding hours >90% RH) (continued)

(ii) NAAQS Scenario
Daily Max
10 µg/m3
90th percentile



(jj) NAAQS Scenario
Daily Max
10 µg/m3
95th percentile

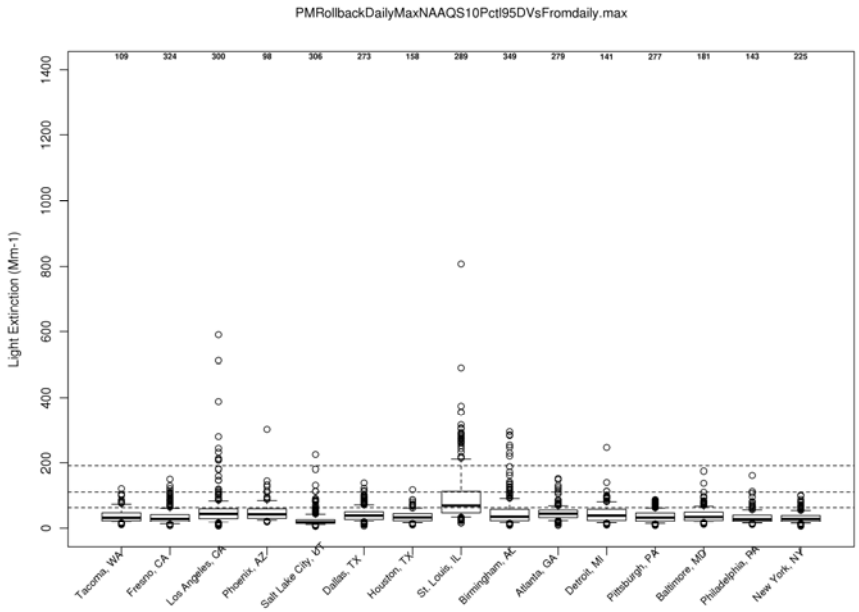


Table A-6. Percentage of days across three years (two in the case of Phoenix and Houston) with maximum 1-hour daylight PM light extinction above CPLs when "just meeting" NAAQS scenarios based on 1-hour $PM_{2.5}$ mass. Blue shading indicates no reduction required from current conditions.

	Days with max hour above 64 Mm^{-1}										Days with max hour above 112 Mm^{-1}										Days with max hour above 191 Mm^{-1}									
Scenario	**aa**	**bb**	**cc**	**dd**	**ee**	**ff**	**gg**	**hh**	**ii**	**jj**	**aa**	**bb**	**cc**	**dd**	**ee**	**ff**	**gg**	**hh**	**ii**	**jj**	**aa**	**bb**	**cc**	**dd**	**ee**	**ff**	**gg**	**hh**	**ii**	**jj**
NAAQS Level (µg/m3)	60	60	40	40	30	30	20	20	10	10	60	60	40	40	30	30	20	20	10	10	60	60	40	40	30	30	20	20	10	10
NAAQS Percentile Form	90	95	90	95	90	95	90	95	90	95	90	95	90	95	90	95	90	95	90	95	90	95	90	95	90	95	90	95	90	95
Area	**Percentage of days**										**Percentage of days**										**Percentage of days**									
Tacoma	53	53	53	53	53	53	53	53	43	35	23	23	23	23	23	23	23	23	11	6	4	4	4	4	4	4	4	4	1	1
Fresno	76	73	65	57	69	60	55	44	28	17	52	48	37	31	44	32	29	18	9	4	30	27	17	11	23	12	10	5	1	0
Los Angeles	89	87	84	81	84	79	74	69	41	30	78	76	65	57	65	53	41	31	11	7	52	46	30	24	30	19	11	6	3	3
Phoenix	44	44	44	44	44	44	44	44	37	32	6	6	6	6	6	6	6	6	6	6	1	1	1	1	1	1	1	1	1	1
Salt Lake City	45	45	45	37	45	45	45	26	17	10	17	17	17	15	17	17	17	11	8	5	8	8	8	7	8	8	8	5	2	1
Dallas	81	81	81	81	81	81	81	71	41	29	41	41	41	41	41	41	41	32	8	5	10	10	10	10	10	10	10	7	0	0
Houston	79	79	79	79	79	79	74	65	32	27	44	44	44	44	44	44	35	28	6	3	11	11	11	11	11	11	9	6	1	0
St. Louis	98	98	98	97	98	97	95	89	73	67	78	78	78	74	78	75	64	55	34	29	40	40	40	36	40	38	27	20	13	13
Birmingham	89	85	80	68	87	80	72	62	41	34	65	56	51	36	58	51	40	30	15	12	34	26	21	13	30	20	15	11	4	3
Atlanta	91	91	91	89	91	89	82	77	47	34	75	75	75	68	74	66	51	35	3	3	31	31	31	21	31	19	5	3	0	0
Detroit	84	80	74	72	76	73	65	60	40	33	67	57	51	43	53	48	34	21	9	6	43	28	13	7	14	9	6	4	1	1
Pittsburgh	85	85	81	77	81	77	63	55	27	19	57	57	51	45	52	44	29	22	3	0	26	26	18	14	21	13	6	2	0	0
Baltimore	81	81	81	76	81	74	64	56	31	20	51	51	51	45	51	44	31	23	4	3	23	23	23	18	23	16	8	2	1	1
Philadelphia	84	78	71	62	72	63	55	43	17	10	60	54	33	29	37	31	16	10	3	3	26	17	8	5	8	5	0	0	0	0
New York	83	83	80	71	81	73	63	56	27	19	60	60	56	39	56	40	32	22	6	3	29	29	25	16	25	17	9	5	0	0
Average	**78**	**76**	**74**	**70**	**75**	**71**	**66**	**58**	**36**	**28**	**52**	**49**	**45**	**40**	**47**	**41**	**33**	**25**	**9**	**6**	**24**	**22**	**17**	**13**	**19**	**14**	**9**	**5**	**2**	**2**

5 REVIEW OF THE SECONDARY STANDARDS FOR OTHER WELFARE EFFECTS

This chapter presents preliminary staff conclusions with regard to the current suite of secondary PM standards to protect against PM-related welfare effects other than visibility impairment. Specifically, staff has assessed the relevant information related to effects of atmospheric PM on the environment, including effects on climate, ecological effects, and effects on materials. Our assessment is framed by a series of key policy-relevant questions, which expand upon those presented in the Integrated Review Plan (IRP) (US EPA, 2008a, section 3.2). The answers to these questions will inform decisions on whether to retain or revise the current suite of secondary PM standards.

In presenting preliminary staff conclusions with regard to the current secondary standards relative to PM-related effects on climate, ecological effects, and materials, we note that the final decision is largely a public welfare policy judgment. A final decision must draw upon scientific information and analyses about non-visibility PM-related effects and related impacts on public welfare, as well as judgments about how to deal with the range of uncertainties that are inherent in the scientific evidence and analyses. Our approach to informing these judgments is discussed more fully below. This approach is consistent with the requirements of the NAAQS provisions of the Act and with how EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish secondary standards that, in the Administrator's judgment, 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 Act does not require that secondary standards be set at a zero-risk level, but rather at a level that avoids unacceptable public welfare impacts.

Information on the approaches used to set the secondary PM standards in past reviews as well as our current approach for this review are presented in section 5.1. A discussion of the scope of the review as related to non-visibility welfare effects of PM is included in section 5.1.2. This chapter considers each of the non-visibility welfare effects separately. The discussion of PM-associated effects on climate (section 5.2), ecological effects (section 5.3), and materials (section 5.4) are each followed by a consideration of key uncertainties and areas for future research and data collection.

5.1 APPROACH

Background information on the approaches used to establish the PM secondary standards in 1997 and revisions to those standards in 2006 are summarized below. This section also includes a discussion of the ongoing joint review of ecological effects of oxides of nitrogen and sulfur (NOx/SOx secondary review) for clarity, since depositional effects of PM components of NOx and SOx to ecosystems were historically considered as a component of the PM secondary review. Lastly, there is a discussion of the current approach for evaluating the effects of PM on climate, ecosystems, and materials using evidence-based considerations to inform our understanding of the key policy-relevant issues.

5.1.1 Approaches Used in Previous Reviews

5.1.1.1 Review Completed in 1997

In the 1997 review, as discussed in section 2.1.1.1, EPA determined that for the primary standard the fine and coarse fractions of PM_{10} should be considered separately and added a suite of new primary standards, using $PM_{2.5}$, as the indicator for fine particles, and retaining PM_{10} as the indicator for regulating thoracic coarse particles. The EPA established two new $PM_{2.5}$ standards: an annual standard of 15 $\mu g/m^3$, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors; and a 24-hour standard of 65 $\mu g/m^3$, based on the 3-year average of the 98^{th} percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area (62 FR 38652, July 18, 1997).

With respect to the secondary PM standards, EPA concluded in 1997, that the available evidence on effects of PM on non-visibility welfare endpoints was not sufficient to warrant a separate secondary standard. Therefore, the secondary standards were set equal to the primary $PM_{2.5}$ and PM_{10} standards in the final rule to provide protection against effects on visibility as well as materials damage and soiling effects related to fine and coarse particles (62 FR 38683).

5.1.1.2 Review Completed in 2006

In 2006, the Administrator concluded that there was insufficient information to consider a distinct secondary standard based on PM-related impacts to ecosystems, materials damage and soiling, and climatic and radiative processes (71 FR 61144, October 17, 2006). Specifically, there was a lack of evidence linking various non-visibility welfare effects to specific levels of ambient PM. To provide a level of protection for welfare-related effects, the secondary standards were set equal to the revised primary standards to directionally improve the level of protection afforded vegetation, ecosystems and materials (71 FR 61210).

In the last review, the 2004 AQCD concluded that regardless of size fraction, particles containing nitrates and sulfates have the greatest potential for widespread environmental significance (US EPA, 2004, sections 4.2.2 and 4.2.3.1). Considerable supporting evidence was available that indicated a significant role of NOx, SOx, and transformation products in acidification and nutrient enrichment of terrestrial and aquatic ecosystems (71 FR 61209). The recognition of these ecological effects, coupled with other considerations detailed below, led EPA to initiate a joint review of the NO_2 and SO_2 secondary NAAQS that will consider the gaseous and particulate species of NOx and SOx with respect to the ecosystem-related welfare effects that result from the deposition of these pollutants and transformation products.

5.1.2 Scope of Current NAAQS Reviews

Non-visibility welfare-based effects of oxides of nitrogen and sulfur are divided between two NAAQS reviews; (1) the PM NAAQS review and, (2) the joint NOx/SOx secondary NAAQS review. The scope of each document and the components of N and S considered in each review are detailed in this section and summarized in Table 5-1.

Table 5-1. Scope of the current secondary PM NAAQS review and current NOx/SOx secondary review.

	NOx/SOx Secondary Review		**PM Secondary Review**				
Welfare Effect	Acidifying deposition, nutrient enrichment	Direct effects of gas-phase NOx/SOx on vegetation	Visibility impairment	Climate Forcing effects	Ecological effects	Materials	
						Damage	Soiling
Documents							
ISA	NOx/SOx	NOx/SOx	PM	PM	PM	PM and NOx/SOx Annex E	PM
REA	NOx/SOx	NOx/SOx	PM (Urban focused visibility assessment)				
PA	NOx/SOx	NOx/SOx	PM	PM	PM	PM	PM
Components	Deposited particulate and gaseous forms of oxides of nitrogen and sulfur and related N and S containing compounds.	Gaseous forms of oxides of nitrogen and sulfur and related N and S containing compounds in the ambient air.	All particles 10 microns or smaller in the ambient air.	Climate-related particles (aerosols) in the ambient air.	Deposited components of PM, including metals and organics but not N and S containing compounds.	Particles and gases associated with ambient NOx and SOx including NOy, NH_3 and NHx.	Deposited particles

5.1.2.1 Scope of the Current Secondary PM NAAQS Review

In reviewing the current suite of secondary PM standards to address visibility impairment (chapter 4), climate forcing effects (section 5.2), and other welfare-related effects (sections 5.3 and 5.4), all PM-related effects that are not being covered in the NOx/SOx review are considered. With regard to the materials section (5.4), the discussion has been expanded to include particles and gases that are associated with the presence of ambient NOx and SOx, as well as NOy, NH_3 and NH_X for completeness. By excluding the effects associated with deposited particulate matter components of NOx and SOx and their transformation products which are addressed fully in the NOx/SOx secondary review, as outlined below, the discussion of ecological effects of PM has been narrowed to focus on effects associated with the deposition of metals and, to a lesser extent, organics (section 5.3).

5.1.2.2 Scope of the Current NOx/SOx Secondary NAAQS Review

This is the first time since the NAAQS were established in 1971 that a joint review of the secondary NAAQS for NOx and SOx, has been conducted. This review is being conducted because the atmospheric chemistry and environmental effects of NOx, SOx, and their associated transformation products are linked, and because the National Research Council (NRC) has recommended that EPA consider multiple pollutants, as appropriate, in forming the scientific basis for the NAAQS. The NOx/SOx secondary review focuses on the welfare effects associated with exposures from deposited particulate and gaseous forms of oxides of nitrogen and sulfur and related N and S containing compounds and transformation products on ecosystem receptors. An assessment of the complex ecological effects associated with N deposition requires consideration of multiple forms of N. These include evaluation of data on inorganic reduced forms of N (e.g., ammonia [NH_3] and ammonium ion [NH^4+]), inorganic oxidized forms (e.g., NOx, nitric acid [HNO_3], nitrous oxide [N_2O], nitrate [NO^3-]), and organic N compounds (e.g., urea, amines, proteins, nucleic acids). In addition to acidification and N-nutrient enrichment, other welfare effects related to deposition of N-and S-containing compounds are discussed, such as SOx interactions with mercury (Hg) methylation. In addition, the NOx/SOx secondary review includes evidence related to direct ecological effects of gas-phase NOx and SOx since the direct effects of gas-phase SOx on vegetation formed a primary basis for the initial establishment of the secondary NAAQS for SO_2.

Effects of acidifying deposition associated with particulate N and S are covered in the recent *Integrated Science Assessment for Oxides of Nitrogen and Sulfur-Ecological Criteria* (*Final Report* (US EPA, 2008c). The *Risk and Exposure Assessment for Review of the Secondary National Ambient Air Quality Standards for Oxides of Nitrogen and Oxides of Sulfur*

(Final)(NOx/SOx REA) (US EPA, 2009h) considers four main targeted ecosystem effects considered in the review of secondary effects of NOx and SOx: (1) aquatic acidification due to N and S, (2) terrestrial acidification due to N and S, (3) aquatic nutrient enrichment, including eutrophication and (4) terrestrial nutrient enrichment. In the draft *Policy Assessment for Review of the Secondary National Ambient Air Quality Standards for Oxides of Nitrogen and Oxides of Sulfur* (US EPA 2010c) ecologically-based indicators that link atmospheric concentrations to deposition are being considered.

5.1.3 Current Approach

The remainder of this chapter summarizes and highlights key aspects of the policy relevant information from the ISA to help inform the Administrator's judgments regarding the adequacy of the current suite of secondary PM NAAQS in relation to climate processes, ecological effects, and materials damage. The ISA uses a five-level hierarchy that classifies the weight of evidence for causation, not just association, into a qualitative statement about the overall weight of evidence and causality (US EPA, 2009a, section 1.5.5, Table 1-3): causal relationship; likely to be a causal relationship; suggestive of a causal relationship; inadequate to infer a causal relationship; not likely to be a causal relationship (see US EPA, 2009a, Table 1-3).

Staff is evaluating evidence-based considerations primarily by assessing the evidence of associations identified in the ISA. All relationships between PM and climate, ecological effects, and materials damage effects identified in the ISA are considered to be either "likely causal" or "causal". The staff's approach in this review of non-visibility welfare effects of PM is to consider information regarding particulate matter effects on climate, ecological endpoints and materials. This includes new literature available since the last review as well as existing, relevant information as presented in the ISA (US EPA 2009a).

5.2 CLIMATE

5.2.1 Scope

Information and conclusions about what is currently known about the role of PM in climate is summarized in Chapter 9 of the PM ISA (US EPA, 2009a). The ISA concludes; "that a causal relationship exists between PM and effects on climate, including both direct effects on radiative forcing and indirect effects that involve cloud feedbacks that influence precipitation formation and cloud lifetimes" (US EPA, 2009a, section 9.3.10). Material from the climate section of the ISA is principally drawn from the U.S. Climate Change Science Program Synthesis and Assessment Product 2.3, *Atmospheric Aerosol Properties and Climate Impacts*, by Chin et al., (CCSP 2009) and Chapter 2, *Changes in Atmospheric Constituents and in Radiative Forcing*,(Forster et al., 2007) in the comprehensive *Working Group I report in the Fourth*

Assessment Report (AR4) from the Intergovernmental Panel on Climate Change (IPCC), Climate Change 2007: The Physical Science Basis. Sections 9.3.7 (Fire as a Special Source of PM Welfare Effects), 9.3.9 (Other Special Sources and Effects), 9.3.9.1 (Glaciers and Snowpack) and 9.3.9.3 (Effects on Local and Regional Climate) of the ISA were written by NCEA staff. This section of the PA summarizes and synthesizes the policy-relevant science in the ISA for the purpose of helping to inform consideration of climate aspects in the review of the secondary PM NAAQS.

Atmospheric PM (referred to as aerosols[1] in the remainder of this section to be consistent with the ISA) affects multiple aspects of climate. These include absorbing and scattering of incoming solar radiation, alterations in terrestrial radiation, effects on the hydrological cycle, and changes in cloud properties (US EPA, 2009a, section 9.3.1). Major aerosol components that contribute to climate processes include black carbon (BC), organic carbon (OC), sulfates, nitrates and mineral dusts. There is a considerable ongoing research effort focused on understanding aerosol contributions to changes in global mean temperature and precipitation patterns. The Climate Change Research Initiative identified research on atmospheric concentrations and effects of aerosols as a high research priority (National Research Council, 2001) and the IPCC 2007 *Summary for Policymakers* states that anthropogenic contributions to aerosols remain the dominant uncertainty in radiative forcing (IPCC 2007). The current state of the science of climate alterations attributed to PM is in flux as a result of continually updated information.

5.2.2 Adequacy of the Current Standard

In considering the adequacy of the suite of secondary standards, staff addresses the following overarching question:

Does currently available scientific information, as reflected in the ISA, support or call into question the adequacy of the protection for climate effects afforded by the current suite of secondary PM standards?

To inform the answer to this overarching question, staff has posed specific questions to aid in assessing the available scientific evidence as related to climate effects attributed to aerosols. In considering the currently available scientific and technical information, we included both the information available from the last review and information that is newly available since the last review synthesized in Chapter 9 of the ISA (US EPA, 2009).

- **What new techniques are available to improve our understanding of climate effects of aerosols?**

[1] In the sections of the ISA included from IPCC AR4 and CCSP SAP2.3, 'aerosols' is more frequently used than "PM" and that word is retained.

Global climate change has increasingly been the focus of intense international research endeavors. Major efforts are underway to understand the complexities inherent in atmospheric aerosol interactions and to decrease uncertainties associated with climate estimations. Two recent reports, the US CCSP Product 2.3 and sections of the IPCC AR4 were combined to form the climate discussion in the ISA (CCSP 2009; Forster et al., 2007). A review of the most recently available techniques for assessing climate-aerosol relationships is presented in the ISA. Aerosol measurement capabilities reviewed in the ISA include a discussion of the increasingly sophisticated instrumentation and techniques available for quantifying aerosols, the enhanced sensing capabilities of satellites, development of remote sensing networks and synergy of measurements with model simulations (US EPA 2009a, section 9.3.2). Advances in measured aerosol properties as related to modeling as well as outstanding issues remaining in these measurement-based studies are elaborated in the ISA (US EPA 2009a sections 9.3.3 and 9.3.4). Section 9.3.6 of the ISA, "Global Aerosol Modeling" considers the capabilities of climate modeling that have developed over the last decade and limitations of the techniques currently in use (US EPA 2009a).

- **To what extent does newly available evidence improve our understanding of the nature and magnitude of climate responses to PM (aerosols)?**

Aerosols have direct and indirect effects on climate processes. The direct effects of aerosols on climate result mainly from particles scattering light away from earth into space, directly altering the radiative balance of the Earth-atmosphere system. This reflection of solar radiation back to space decreases the transmission of visible radiation to the surface of the earth and results in a decrease in the heating rate of the surface and the lower atmosphere. At the same time, absorption of either incoming solar radiation or outgoing terrestrial radiation by particles, primarily BC, results in an increased heating rate in the lower atmosphere. Global estimates of aerosol direct radiative forcing (RF) were recently summarized using a combined model-based estimate (Forster et al., 2007). The overall, model-derived aerosol direct RF was estimated in the IPCC AR4 as -0.5 (-0.9 to -0.1) watts per square meter (W/m^2), with an overall level of scientific understanding of this effect as "medium low" (Forster et al., 2007), indicating a net cooling effect in contrast to greenhouse gases (GHGs) which have a warming effect.

The contribution of individual aerosol components to total aerosol direct radiative forcing is more uncertain than the global average (US EPA, 2009a, section 9.3.6.6). The direct effect of radiative scattering by atmospheric particles exerts an overall net cooling of the atmosphere, while particle absorption of solar radiation leads to warming. For example, the presence of OC and sulfates decrease warming from sunlight by scattering shortwave radiation back into space. Such a perturbation of incoming radiation by anthropogenic aerosols is designated as aerosol climate forcing, which is distinguished from the aerosol radiative effect of the total aerosol

(natural plus anthropogenic). The aerosol climate forcing and radiative effect are characterized by large spatial and temporal heterogeneities due to the wide variety of aerosol sources, the spatial non-uniformity and intermittency of these sources, the short atmospheric lifetime of aerosols (relative to that of the greenhouse gases), and processing (chemical and microphysical) that occurs in the atmosphere. For example, OC can be warming (positive forcer) when deposited on or suspended over a highly reflective surface such as snow or ice but, on a global average, is a negative forcer in the atmosphere.

More information has also become available on indirect effects of aerosols. Particles in the atmosphere indirectly affect both cloud albedo (reflectivity) and cloud lifetime by modifying the cloud amount, and microphysical and radiative properties (US EPA, 2009a, section 9.3.6.4). The RF due to these indirect effects (cloud albedo effect) of aerosols is estimated in the IPCC AR4 to be -0.7(-1.8 to -0.3) W/m^2 with the level of scientific understanding of this effect as "low" (Forster et al., 2007). Aerosols act as cloud condensation nuclei (CCN) for cloud formation. Increased particulates in the atmosphere available as CCN with no change in moisture content of the clouds have resulted in an increase in the number and decrease in the size of cloud droplets in certain clouds that can increase the albedo of the clouds (the Twomey effect). Smaller particles slow the onset of precipitation and prolong cloud lifetime. This effect, coupled with changes in cloud albedo, increase the reflection of solar radiation back into space. The altitude of clouds also effects cloud radiative forcing. Low clouds reflect incoming sunlight back to space but do not effectively trap outgoing radiation, thus, cooling the planet, while higher elevation clouds reflect some sunlight but more effectively can trap outgoing radiation and act to warm the planet (US EPA, 2009a, section 9.3.3.5).

The total negative RF due to direct and indirect effects of aerosols computed from the top of the atmosphere, on a global average, is estimated at -1.3 (-2.2 to -0.5) W/m^2 in contrast to the positive RF of +2.9 (+3.2 to +2.6) W/m^2 for anthropogenic GHGs (IPCC 2007, pg. 200).

The understanding of the magnitude of aerosol effects on climate has increased substantially in the last decade. Data on the atmospheric transport and deposition of aerosols indicate a significant role for PM components in multiple aspects of climate. Aerosols can impact glaciers, snowpack, regional water supplies, precipitation and climate patterns (US EPA 2009a section 9.3.9). Aerosols deposited on ice or snow can lead to melting and subsequent decrease of surface albedo (US EPA 2009a, section 9.3.9.2). Aerosols are potentially important agents of climate warming in the Arctic and other locations (US EPA, 2009a, section 9.3.9). Incidental fires and biomass burning are being recognized as having a significant impact on $PM_{2.5}$ concentrations and climate forcing. Intermittent fires can occur at large enough scales to affect hemispheric aerosol concentrations (US EPA 2009a, section 9.3.7).

A series of studies available since the last review examine the role of aerosols on local and regional scale climate processes (US EPA, 2009a, section 9.3.9.3). Studies on the South Coast Air Basin (SCAB) in California indicate aerosols may reduce near-surface wind speeds, which, in turn reduce evaporation rates and increase cloud lifetimes. The overall impact can be a reduction in local precipitation (Jacobson and Kaufmann, 2006). Conditions in the SCAB impact ecologically sensitive areas including the Sierra Nevadas. Precipitation suppression due to aerosols in California (Givati and Rosenfield, 2004) and other similar studies in Utah and Colorado found that orographic precipitation decreased by 15-30% downwind of pollution sources. Evidence of regional-scale impacts of aerosols on meteorological conditions in other regions of the U.S. are lacking.

- **To what extent does the currently available information provide evidence of association between specific PM constituents (i.e. BC, OC, sulfates) and climate-related effects?**

Advances in the understanding of aerosol components and how they contribute to climate change have enabled refined global forcing estimates of individual PM constituents. The global mean radiative effect from individual components of aerosols was estimated for the first time in the IPCC AR4 where they were reported to be (all in W/m^2 units): -0.4 ($\pm$0.2) for sulfate, -0.05 ($\pm$0.05) for fossil fuel-derived OC, +0.2 (+0.15) for fossil fuel derived BC, +0.03 ($\pm$0.12) for biomass burning, -0.1 ($\pm$0.1) for nitrates, and -0.1 ($\pm$0.2) for mineral dust (US EPA, 2009a, section 9.3.10). Sulfate and fossil fuel-derived OC cause negative forcing whereas BC causes positive forcing because of its highly absorbing nature (US EPA, 2009a, 9.3.6.3). Although BC comprises only a small fraction of anthropogenic aerosol mass load and aerosol optical depth (AOD), its forcing efficiency (with respect to either AOD or mass) is an order of magnitude stronger than sulfate and particulate organic matter (POM), so its positive shortwave forcing largely offsets the negative direct forcing from sulfate and POM (IPCC, 2007; US EPA 2009a, 9.3.6.3). Global loadings for nitrates and anthropogenic dust remain very difficult to estimate, making the radiative forcing estimates for these constituents particularly uncertain (US EPA, 2009a, section 9.3.7).

Improved estimates of anthropogenic emissions of some aerosols, especially BC and OC, have promoted the development of improved global emissions inventories and source-specific emissions factors useful in climate modeling (Bond et al. 2004). Recent data suggests that BC is one of the largest individual warming agents after carbon dioxide (CO_2) and perhaps methane (CH_4) (Jacobson 2000; Sato et al., 2003; Bond and Sun 2005). There are several studies modeling BC effects on climate and/or considering emission reduction measures on anthropogenic warming detailed in section 9.3.9 of the ISA. Fires release large amounts of BC, CO_2, CH_4 and OC (US EPA, 2009a, section 9.3.7).

5.2.3 Preliminary Staff Conclusions

- Aerosols alter climate processes directly through radiative forcing and by indirect effects on cloud brightness, changes in precipitation and possible changes in cloud lifetimes.
- Individual components of aerosols differ in their reflective properties, and direction of climate forcing. Overall, aerosols have a net climate cooling effect.
- Most climate model simulations are based on global scale scenarios. These models may fail to consider the local variations in climate forcing due to emissions sources and local meteorological patterns.
- Aerosols that are warming are co-emitted with aerosols that are cooling. The relative mix of these components will vary in areas across the U.S. and over time.

Collectively taking into consideration the responses to specific questions regarding the adequacy of the current secondary PM standards for climate effects, we revisit the overarching question: "does available scientific information, as reflected in the ISA, support or call into question the adequacy of the protection for climate effects afforded by the current suite of secondary PM standards?" As an initial matter, we considered the appropriateness of the current secondary standard defined in terms of $PM_{2.5}$ and PM_{10} indicators, for providing protection against potential climate effects of aerosols. Newly available scientific information on climate-aerosol relationships has improved our understanding of direct and indirect effects of aerosols and aerosol properties. The major aerosol components that contribute to climate processes include BC, OC, sulfate, nitrate and mineral dusts. These components vary in their reflectivity, forcing efficiencies and even in the direction of climate forcing. The current standards that are defined in terms of aggregate size mass cannot be expected to appropriately target controls on components of fine and coarse particles that are related to climate forcing effects. Thus, the current mass-based $PM_{2.5}$ and PM_{10} secondary standards are not an appropriate or effective means of focusing protection against PM-associated climate effects due to these differences in components.

Overall, there is a net climate cooling associated with aerosols in the global atmosphere (US EPA, 2009a, section 9.2.10). Staff recognizes that some individual aerosol components, such as BC, are positive climate forcers, whereas others, such as OC and sulfates, are negative climate forcers. However, aerosols that are warming are co-emitted with aerosols that are cooling. The relative mix of components will vary in areas across the U.S. and over time. Due to 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, it is not currently feasible to conduct a quantitative analysis for the purpose of informing revisions of the current NAAQS PM standard based on climate.

Based on these considerations, we reach the preliminary conclusion that there is insufficient information at this time to base a national ambient standard on climate impacts associated with current ambient concentrations of PM or its constituents[2].

5.2.4 Key Uncertainties and Areas for Future Research and Data Collection

Although considerable progress is being made in estimating aerosol contributions to climate fluctuations, significant uncertainties remain that preclude consideration of climate effects as a basis for establishing a separate NAAQS secondary standard. A major impediment at this time to establishing a secondary standard for PM based on climate is the lack of accurate measurement of aerosol contributions, specifically quantification of aerosol absorption and inability to separate the anthropogenic component from total aerosol forcing. Section 9.3.4 of the ISA details the current limitations in aerosol measurement. Most measurement studies focus on the sum of natural and anthropogenic contributions under clear sky conditions, however, this scenario is simplistic when effects of cloud cover and differing reflective properties of land and ocean are considered. Satellite measurements do not currently have the capability to distinguish anthropogenic from natural aerosols. Due to a lack of data on the vertical distribution of aerosols, above-cloud aerosols and profiles of atmospheric radiative heating are poorly understood (US EPA, 2009a, section 9.3.4).

Another uncertainty in considering climate effects of PM in the NAAQS review is the spatial and temporal heterogeneity of aerosols. In regions having high concentrations of anthropogenic aerosols, aerosol forcing is greater than the global average, and can exceed warming by GHGs, locally reversing the sign of the forcing (US EPA, 2009a, section 9.3.1). Emissions of carbonaceous aerosols from intermittent fires and volcanic activity can further complicate regional climate forcing estimates (US EPA, 2009a, sections 9.3.7 and 9.3.8). Individual components of aerosols may either be positive or negative climate forcers. Airborne PM components may be directly emitted or undergo a variety of physical and chemical interactions and transformations. These result in changes in particle size, structure and composition which alter aerosol reflective properties. Aerosols can grow in size in the atmosphere because ambient water vapor condenses on individual particles, a phenomenon known as hygroscopic growth (US EPA, 2009a, section 9.3.6.2). Atmospheric lifetimes of individual aerosol components vary greatly confounding tracking source receptor relationships.

Improved representation of aerosols in climate models is essential to more accurately predict the role of PM in climate forcing (US EPA, 2009a, section 9.3.6.7). The influence of

[2] Given the reasons discussed above, this conclusion would apply for both the secondary (welfare based) and the primary (health based) standards.

aerosols on climate is not yet adequately taken into account in computer predictions although considerable progress in being made in this area. For example, PM components underrepresented or missing from many models include nitrate aerosols and anthropogenic secondary aerosols (US EPA, 2009a, section 9.3.6.7). The modeling of aerosol indirect effects and absorption are difficult due to the high level of uncertainty associated with these climate factors.

The interaction of PM with clouds remains a large source of uncertainty in climate estimates. The interactions of aerosols with clouds and linkages between clouds and the overall climate system are complex and limit the feasibility of conducting quantitative analysis for the purpose of establishing a secondary PM standard based on welfare effects on climate processes.

5.3 ECOLOGICAL EFFECTS

5.3.1 Scope

Information on what is currently known about ecological effects of PM is summarized in Chapter 9 of the ISA (US EPA 2009a). Four main categories of ecological effects are identified in the ISA: direct effects, effects of PM-altered radiative flux, indirect effects of trace metals and indirect effects of organics. Exposure to PM for direct effects occur via deposition (e.g. wet, dry or occult) to vegetation surfaces, while indirect effects occur via deposition to ecosystem soils or surface waters where the deposited constituents of PM then interacts with biological organisms. Both fine and coarse-mode particles may affect plants and other organisms; however, PM size classes do not necessarily relate to ecological effects (U.S. EPA, 1996). More often the chemical constituents drive the ecosystem response to PM (Grantz et al., 2003). The trace metal constituents of PM considered in the ecological effects section of the ISA are cadmium (Cd), copper (Cu), chromium (Cr), mercury (Hg), nickel (Ni) and zinc (Zn). Ecological effects of lead (Pb) in particulate form are covered in the Air Quality Criteria Document for Lead (US EPA, 2006). The organics included in the ecological effects section of the ISA are persistent organic pollutants (POPs), polyaromatic hydrocarbons (PAHs) and polybromiated diphenyl ethers (PBDEs).

Ecological effects of PM include direct effects to metabolic processes of plant foliage; 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. It is important to emphasize that the metal and organic constituents of PM contribute to total metal and organic loads in ecosystems.

The ISA states that overall, ecological evidence is 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 based on information from the previous review and limited new findings in this review (US EPA 2009a, sections 2.5.3 and 9.4.7). However the ISA also finds, in many cases, it is difficult to characterize the nature and magnitude of effects and to quantify relationships between ambient concentrations of PM and ecosystem response due to significant data gaps and uncertainties as well as considerable variability that exists in the components of PM and their various ecological effects.

Ecological effects of PM must then be evaluated to determine if they are known or anticipated to have an adverse impact on public welfare. Characterizing a known or anticipated adverse effect to public welfare is an important component of developing any secondary NAAQS. The most recent secondary NAAQS reviews have assessed changes in ecosystem structure or processes using a weight-of-evidence approach that uses both quantitative and qualitative data. For example, the 2008 ozone (O_3) final rule and 2010 O_3 proposal conclude that a determination of what constitutes an "adverse" welfare effect in the context of secondary NAAQS review can appropriately occur by considering effects at higher ecological levels (populations, communities, ecosystems) as supported by recent literature. In the 2008 rulemaking and current ozone proposal, the interpretation of what constitutes an adverse effect on vegetation can vary depending on the location and intended use of the plant. The degree to which O_3-related effects are considered adverse depends on the intended use of the vegetation and its significance to public welfare (73 FR 16496). Therefore, effects (e.g. biomass loss, foliar injury, impairment of intended use) may be judged to have a different degree of impact on public welfare depending, for example, on whether that effect occurs in a Class I area, a city park, commercial cropland or private land.

A paradigm useful in evaluating ecological adversity is the concept of ecosystem services. Ecosystem services identify the varied and numerous ways that ecosystems are important to human welfare. Ecosystems provide many goods and services that are of vital importance for the functioning of the biosphere and provide the basis for the delivery of tangible benefits to human society. An EPA initiative to consider how ecosystem structure and function can be interpreted through an ecosystem services approach has resulted in the inclusion of ecosystem services in the NOx/SOx REA (US EPA, 2009h). The Millennium Ecosystem Assessment (MEA) defines these to include supporting, provisioning, regulating and cultural services (Hassan et al., 2005):

- Supporting services are necessary for the production of all other ecosystem services. Some examples include biomass production, production of atmospheric O_2, soil formation and retention, nutrient cycling, water cycling, and provisioning of habitat. Biodiversity is a supporting service that is increasingly recognized to sustain many of the goods and services that humans enjoy from ecosystems. These provide a basis for three higher-level categories of services.

- Provisioning services, such as products (Gitay et al., 2001) i.e., food (including game, roots, seeds, nuts, and other fruit, spices, fodder), fiber (including wood, textiles), and medicinal and cosmetic products (including aromatic plants, pigments).
- Regulating services that are of paramount importance for human society such as (a) C sequestration, (b) climate and water regulation, (c) protection from natural hazards such as floods, avalanches, or rock-fall, (d) water and air purification, and (e) disease and pest regulation.
- Cultural services that satisfy human spiritual and aesthetic appreciation of ecosystems and their components.

An important consideration in evaluating biologically adverse effects of PM and linkages to ecosystem services is that many of the MEA categories overlap and any one pollutant may impact multiple services. For example, deposited PM may alter the composition of soil-associated microbial communities, which may affect supporting services such as nutrient cycling. Changes in available soil nutrients could result in alterations to provisioning services such as timber yield and regulating services such as climate regulation. If enough information is available, these alterations can be quantified based upon economic approaches for estimating the value of ecosystem services. Valuation may be important from a policy perspective because it can be used to compare the benefits of altering versus maintaining an ecosystem. Knowledge about the relationships linking ambient concentrations and ecosystem services can be used to inform a policy judgment on a known or anticipated adverse public welfare effect.

This review seeks to build upon and focus this body of science using the concept of ecosystem services to qualitatively evaluate linkages between biologically adverse effects and particulate deposition. This approach is similar to that taken in the NOx/SOx REA in which the relationship between air quality indicators, deposition of N and S, ecologically relevant indicators and effects on sensitive receptors are linked to changes in ecosystem structure and services (US EPA, 2009h). This approach considers the benefits received from the resources and processes that are supplied by ecosystems. Ecosystem components (e.g. plants, soils, water, wildlife) are impacted by PM air pollution, which may alter the services provided by the ecosystems in question. The goals of this policy assessment are to (1) identify ecological effects associated with PM deposition that can be linked to ecosystem services and (2) qualitatively evaluate ecological endpoints when possible. Keeping these goals and guidelines in mind, limited new data on PM effects on plants, soil and nutrient cycling, wildlife and water are evaluated in the context of ecosystem services to qualitatively evaluate linkages between biologically adverse effects and particulate deposition for the purpose of evaluating the adequacy of the current standard.

5.3.2 Adequacy of the Current Standard

In considering the adequacy of the suite of secondary standards, staff addresses the following overarching question:

Does available scientific information, as reflected in the ISA support or call into question the adequacy of the protection afforded by the current suite of secondary PM standards for vegetation and ecosystems from the effects of deposited particulate metals and organics?

To inform the answer to this overarching question, staff has posed specific questions to aid in assessing the available scientific evidence as related to ecosystem effects attributed to PM deposition as presented in the ISA (US EPA, 2009a).

- **To what extent has key scientific evidence become available to improve our understanding of the nature and magnitude of ecosystem responses, the variability associated with these responses, and the impact of PM on ecosystem services?**

Key scientific evidence regarding PM effects on plants, soil and nutrient cycling, wildlife and water available since the last review is summarized below to evaluate how this information has improved our understanding of ecosystem responses to PM.

Plants

As primary producers, plants play a pivotal role in energy flow through ecosystems. Ecosystem services derived from plants include all of the categories (supporting, provisioning, regulating, cultural) identified in the MEA (Hassan et al., 2005). Vegetation supports other ecosystem processes by cycling nutrients through food webs and serving as a source of organic material for soil formation and enrichment. Trees and plants provide food, wood, fiber, and fuel for human consumption. Flora help to regulate climate by sequestering CO_2, control flooding by stabilizing soils and cycling water via uptake and evapotranspiration. Plants are significant in aesthetic, spiritual and recreational aspects of human interactions.

Particulate matter can adversely impact plants and ecosystem services provided by plants by deposition to vegetative surfaces (US EPA, 2009a, section 9.4.3). Particulates deposited on the surfaces of leaves and needles can block light, altering the radiation received by the plant. PM deposition can obstruct stomata limiting gas exchange, damage leaf cuticles and increase plant temperatures. This level of PM accumulation is typically observed near sources of heavy deposition such as smelters and mining operations (US EPA, 2009a, section 9.4.3). Plants growing on roadsides exhibit impact damage from near-road PM deposition, having higher levels of organics and heavy metals, and accumulate salt from road de-icing during winter months (US EPA, section 2009a, sections 9.4.3.1 and 9.4.5.7).

In addition to damage to plant surfaces, deposited PM can be taken up by plants from soil or foliage. The ability of vegetation to take up heavy metals and organics is dependent upon the amount, solubility and chemical composition of the deposited PM. Uptake of PM by plants from

soils and vegetative surfaces can disrupt photosynthesis, alter pigments and mineral content, reduce plant vigor, decrease frost hardiness and impair root development. The ISA indicates that there are little or no effects on foliar processes at ambient levels of PM (sections 9.4.3 and 9.4.7) however, damage due to atmospheric pollution can occur near point-sources or under conditions where plants are subjected to multiple stressors.

Though all heavy metals can be directly toxic at sufficiently high concentrations, only Cu, Ni, and Zn have been documented as being frequently toxic to plants (U.S. EPA, 2004), while toxicity due to Cd, Co, and Pb has been observed less frequently (Smith, 1990; US EPA 2009a, section 9.4.5.3). In general, plant growth is negatively correlated with trace metal and heavy metal concentration in soils and plant tissue (Audet and Charest, 2007). Trace metals, particularly heavy metals, can influence forest growth. Growth suppression of foliar microflora has been shown to result from Fe, Al, and Zn. These three metals can also inhibit fungal spore formation, as can Cd, Cr, Mg, and Ni (see Smith, 1990). Metals cause stress and decreased photosynthesis (Kucera et al., 2008) and disrupt numerous enzymes and metabolic pathways (Strydom et al., 2006). Excessive concentrations of metals result in phytotoxicity through: (i) changes in the permeability of the cell membrane; (ii) reactions of sulfydryl (-SH) groups with cations; (iii) affinity for reacting with phosphate groups and active groups of ADP or ATP; and (iv) replacement of essential ions (Patra et al., 2004).

New information since the last review provides additional evidence of plant uptake of organics (US EPA, 2009a, section 9.4.6). An area of active study is the impact of PAHs on provisioning ecosystem services due to the potential for human and other animal exposure via food consumption (US EPA, 2009a, section 9.4.6 page 9-190). The uptake of PAHs depends on the plant species, site of deposition, physical and chemical properties of the organic compound and prevailing environmental conditions. It has been established that most bioaccumulation of PAHs by plants occurs via leaf uptake, and to a lesser extent, through roots. Differences between species in uptake of PAHs confound attempts to quantify impacts to ecosystem provisioning services. For example, zucchini (*Cucurbita pepo*) accumulated significantly more PAHs than related plant species (Parrish et al., 2006).

Plants as ecosystem regulators can serve as passive monitors of pollution (US EPA, 2009a, section 9.4.2.3). Lichens and mosses are sensitive to pollutants associated with PM and have been used with limited success to show spatial and temporal patterns of atmospheric deposition of metals (US EPA, 2009a, section 9.4.2.3). For example, the presence or absence of a specific species of lichen can be used as a bioindicator of metal or organics contamination. PBDEs detected in moss and lichens in Antarctica indicate long-range transport of PM components (Yogui and Sericano 2008). In the U.S. Blue Ridge Mountains, a study linked metal concentrations in mosses to elevation and tree canopy species at some sites but not with

concentrations of metals in the O horizon of soil (Schilling, 2002). A limitation to employing mosses and lichens to detect for the presence of air pollutants is the difference in uptake efficiencies of metals between species. The European Moss Biomonitoring Network has been shown to be useful in Europe for estimating general trends in metal concentrations and identification of some sources of trace contaminants, however, quantification of ecological effects is not possible due to the variability of species responses (US EPA, 2009a, section 9.4.2.3).

A potentially important regulating ecosystem service of plants is their capacity to sequester contaminants (US EPA, 2009a, section 9.4.5.3). Ongoing research on the application of plants to environmental remediation efforts are yielding some success in removing heavy metals and organics from contaminated sites (phytoremediation) with tolerant plants such as the willow tree (*Salix* spp.) and members of the family Brassicaceae (US EPA, 2009a, section 9.4.5.3). Tree canopies can be used in urban locations to capture particulates and improve air quality (Freer-Smith et al., 2004). Plant foliage is a sink for Hg and other metals and this regulating ecosystem service may be impacted by atmospheric deposition of trace metals.

An ecological endpoint (phytochelatin concentration) associated with presence of metals in the environment has been correlated with the ecological effect of tree mortality (Grantz et al., 2003). Metal stress may be contributing to tree injury and forest decline in the Northeastern U.S. where red spruce populations are declining with increasing elevation. Quantitative assessment of PM damage to forests potentially could be conducted by overlaying PM sampling data and elevated phytochelatin levels. However, limited data on phytochelatin levels in other species currently hinders use of this peptide as a general biomarker for PM.

The presence of PM in the atmosphere affects ambient radiation as discussed in the ISA which can impact the amount of sunlight received by plants (US EPA, 2009a, section 9.4.4). Atmospheric PM can change the radiation reaching leaf surfaces through attenuation and by converting direct radiation to diffuse radiation. Diffuse radiation is more uniformly distributed in a tree canopy, allowing radiation to reach lower leaves. The net effect of PM on photosynthesis depends on the reduction of photosynthetically active radiation (PAR) and the increase in the diffuse fraction of PAR. Decreases in crop yields (provisioning ecosystem service) have been attributed to regional scale air pollution, however, global models suggest that the diffuse light fraction of PAR can increase growth (US EPA, 2009a, section 9.4.4).

Soil and Nutrient Cycling

Many of the major indirect plant responses to PM deposition are chiefly soil-mediated and depend on the chemical composition of individual components of deposited PM. Major ecosystem services impacted by PM deposition to soils include support services such as nutrient cycling, products such as crops and regulating flooding and water quality. Upon entering the soil

environment, PM pollutants can alter ecological processes of energy flow and nutrient cycling, inhibit nutrient uptake to plants, change microbial community structure and, affect biodiversity. Accumulation of heavy metals in soils depends on factors such as local soil characteristics, geologic origin of parent soils, and metal bioavailability. It can be difficult to assess the extent to which observed heavy metal concentrations in soil are of anthropogenic origin (US EPA, 2009a, section 9.4.5.1). Trace element concentrations are higher in some soils that are remote from air pollution sources due to parent material and local geomorphology.

Heavy metals such as Zn, Cu, and Cd and some pesticides can interfere with microorganisms that are responsible for decomposition of soil litter, an important regulating ecosystem service that serves as a source of soil nutrients (US EPA, 2009a, sections 9.4.5.1 and 9.4.5.2). Surface litter decomposition is reduced in soils having high metal concentrations. Soil communities have associated bacteria, fungi, and invertebrates that are essential to soil nutrient cycling processes. Changes to the relative species abundance and community composition can be quantified to measure impacts of deposited PM to soil biota. A mutualistic relationship exists in the rhizophere (plant root zone) between plant roots, fungi, and microbes. Fungi in association with plant roots form mycorrhizae that are essential for nutrient uptake by plants. The role of mychorrizal fungi in plant uptake of metals from soils and effects of deposited PM on soil microbes is discussed in section 9.4.5.2 of the ISA.

Wildlife

Animals play a significant role in ecosystem function including nutrient cycling and crop production (supporting ecosystem service), and as a source of food (provisioning ecosystem service). Cultural ecosystem services provided by wildlife include bird and animal watching, recreational hunting and fishing. Impacts on these services are dependent upon the bioavailability of deposited metals and organics and their respective toxicities to ecosystem receptors. Pathways of PM exposure to fauna include ingestion, absorption and trophic transfer. Bioindicator species (known as sentinel organisms) can provide evidence of contamination due to atmospheric pollutants. Use of sentinel species can be of particular value because chemical constituents of deposited PM are difficult to characterize and have varying bioavailability (US EPA, 2009a, section 9.4.5.5). Snails readily bioaccumulate contaminants such as PAHs and trace metals. These organisms have been deployed as biomonitors for urban pollution and have quantifiable biomarkers of exposure including growth inhibition, impairment of reproduction, peroxidomal proliferation and induction of metal detoxifying proteins (metallothioneins) (Gomet-de Vaufleury, 2000; Regoli, 2006). Earthworms have also been used as sensitive indicators of soil metal contamination.

Evidence of deposited PM effects on animals is limited (US EPA, 2009a, section 9.4.5.5). Trophic transfer of pollutants of atmospheric origin has been demonstrated in limited studies.

PM may also be transferred between aquatic and terrestrial compartments. There is limited evidence for biomagnifications of heavy metals up the food chain except for Hg which is well known to move readily through environmental compartments (US EPA, 2009a section 9.4.5.6). Bioconcentration of POPs and PBDEs in the Arctic and deep-water oceanic food webs indicates the global transport of particle-associated organics (US EPA, 2009a, section 9.4.6). Salmon migrations are contributing to metal accumulation in inland aquatic systems, potentially impacting the provisioning and cultural ecosystem service of fishing (US EPA, 2009a, section 9.4.6). Stable isotope analysis can be applied to establish linkages between PM exposure and impacts to food webs, however, the use of this evaluation tool is limited for this ecological endpoint due to the complexity of most trophic interactions (US EPA 2009a, section 9.4.5.6). Foraging cattle have been used to assess atmospheric deposition and subsequent bioaccumulation of Hg and trace metals and their impacts on provisioning services (US EPA, 2009a, section 9.4.2.3).

Water

New limited information on impacts of deposited PM on receiving water bodies indicate that the ecosystem services of primary production, provision of fresh water, regulation of climate and floods, recreational fishing and water purification are adversely impacted by atmospheric inputs of metals and organics (US EPA, 2009a, sections 9.4.2.3 and 9.4.5.4). Deposition of PM to surfaces in urban settings increases the metal and organic component of storm water runoff (US EPA, 2009a, sections 9.4.2.3). This atmospherically-associated pollutant burden can then be toxic to aquatic biota.

Atmospheric deposition can be the primary source of some organics and metals to watersheds. The contribution of atmospherically deposited PAHs to aquatic food webs was demonstrated in high elevation mountain lakes with no other anthropogenic contaminant sources (US EPA, 2009a, section 9.4.6). Metals associated with PM deposition limit phytoplankton growth, impacting aquatic trophic structure. Long-range atmospheric transport of 47 pesticides and degradation products to the snowpack in seven national parks in the Western U.S. was recently quantified indicating PM-associated contaminant inputs to receiving waters during spring snowmelt (Hageman et al., 2006).

- **What new techniques are available to improve our understanding of ecosystem effects associated with metal and organic components of PM?**

Regionally-based comprehensive ecological studies

The recently completed Western Airborne Contaminants Assessment Project (WACAP) is the most comprehensive database on contaminant transport and PM depositional effects on sensitive ecosystems in the U.S. In this project, the transport, fate, and ecological impacts of

anthropogenic contaminants from atmospheric sources were assessed from 2002 to 2007 in seven ecosystem components (air, snow, water, sediment, lichen, conifer needles and fish) in eight core national parks (Landers et al., 2008). The goals of the study were to identify where the pollutants were accumulating, identify ecological indicators for those pollutants causing ecological harm, and to determine the source of the air masses most likely to have transported the contaminants to the parks (US EPA, 2009a, section 9.4.6). Collected data were analyzed to identify probable local, regional and/or global sources of deposited PM components and their concurrent effects on ecological receptors. The study concluded that bioaccumulation of semi-volatile organic compounds (SOCs) was observed throughout park ecosystems (Landers et al., 2008). Findings from this study included the observation of an elevational gradient in PM deposition with greater accumulation at higher altitude areas of the parks. Furthermore, specific ecological indicators were indentified in the WACAP that can be useful in assessing contamination on larger spatial scales. For example, quantification of concentrations of selected pesticides in second-year conifer needles served as a method for regional-scale comparison of pollutant distribution (Landers et al., 2008).

In the WACAP study, bioaccumulation and biomagnification of airborne contaminants were demonstrated on a regional scale in remote ecosystems in the Western United States. Contaminants were shown to accumulate geographically based on proximity to individual sources or source areas, primarily agriculture and industry (Landers et al., 2008). This finding was counter to the original working hypothesis that most of the contaminants found in western parks would originate from eastern Europe and Asia (Landers et al., 2008 p 6-8). The WACAP study represents an experimental design in which ecological effects could be correlated to ambient pollutant levels on a regional scale. Although this assessment focuses on chemical species that are components of PM, it does not specifically assess the effects of particulates versus gas-phase forms; therefore, in most cases it is difficult to apply the results to this assessment based on particulate concentration and size fraction (US EPA, 2009a, section 9.4.6). There is a need for ecological modeling of PM components in different environmental compartments to further elucidate links between PM and ecological indicators.

Europe and other countries are using the critical load approach to assess pollutant effects at the level of the ecosystem. This type of assessment requires site-specific data and information on individual species responses to PM. In respect to trace metals and organics, there are insufficient data for the vast majority of U.S. ecosystems to calculate critical loads, however, a methodology is being presented in the NOx/SOx Secondary REA (US EPA 2009h) to calculate atmospheric concentrations from deposition that may be applicable to other environmental contaminants.

- **Is there currently available information on ambient levels of PM that cause adverse effects on ecosystem components?**

As reviewed above, there is considerable data on impacts of PM on ecological receptors, but few studies that link ambient PM levels to observed effect. This is due, in part, to the nature, deposition, transport and fate of PM in ecosystems. PM is not a single pollutant, but a heterogeneous mixture of particles differing in size, origin and chemical composition (US EPA, 2009a, section 9.4.1). The heterogeneity of PM exists not only within individual particles or samples from individual sites, but to even a greater extent, between samples from different sites. Since vegetation and other ecosystem components are affected more by particulate chemistry than size fraction, exposure to a given mass concentration of airborne PM may lead to widely differing plant or ecosystem responses, depending on the particular mix of deposited particles.

Many of the PM components bioaccumulate over time in organisms or plants making correlations to ambient levels of PM impossible. For example, in the WACAP study, SOC accumulation in vegetation and air showed different patterns, possibly because each medium absorbs different types of SOCs with varying efficiencies (Landers et al., 2008).

Bioindicator organisms demonstrated biological effects including growth inhibition, metallothionein induction and reproductive impairment when exposed to complex mixtures of ambient air pollutants (US EPA 2009a, section 9.4.5.5). Other studies quantify uptake of metals and organics by plants or animals. However, due to the difficulty in correlating individual PM components to a specific physiological response, these studies are limited. Furthermore, there may be differences in uptake between species such as differing responses to metal uptake observed in mosses and lichens (US EPA 2009a, section 9.4.2.3). PM may also biomagnify across trophic levels confounding efforts to link atmospheric concentrations to physiological endpoints (US EPA, 2009a, section 9.4.5.6).

Evidence of PM effects that are linked to a specific ecological endpoint can be observed when ambient levels are exceeded. Most direct ecosystem effects associated with particulate pollution occur in severely polluted areas near industrial point sources (quarries, cement kilns, metal smelting) (US EPA, 2009a, sections 9.4.3 and 9.4.5.7) . Extensive research on biota near point sources provide some of the best evidence of ecosystem function impacts and demonstrates that deposited PM has the potential to alter species composition over long time scales. Ecological field studies conducted in proximity to Cu-Ni smelter in Harjavalta, Finland indicated ecological structure and community composition are altered in response to PM and these effects decrease with increasing distance from the point source (US EPA 2009a, section 9.4.5.7). The ISA indicates at 4 km distance, species composition of vegetation, insects, birds, and soil microbiota changed, and within 1 km only the most resistant organisms were surviving (US EPA, 2009a, section 9.4.5.7). Heavy metal concentrations were quantified in understory plant

species growing at varying distance from the Harjavalta smelter (Salemaa et al., 2004). Heavy metal concentrations were highest in bryophytes, followed by lichens and were lowest in vascular plants. At the Harjavalta smelter there are clear links between PM deposition levels, ecological endpoints and compromised ecosystem structure. However, these conditions are not reflective of ambient concentrations of PM in the majority of US ecosystems (US EPA, 2009a, section 9.4.7).

5.3.3 Preliminary Staff Conclusions

- A number of significant environmental effects that either have already occurred or are currently occurring are linked to deposition of chemical constituents found in ambient PM.
- Ecosystem services can be adversely impacted by PM in the environment, including supporting, provisioning, regulating and cultural services.
- The lack of sufficient information to relate specific ambient concentrations of particulate metals and organics to a degree of impairment of a specific ecological endpoint hinders our ability to identify a range of appropriate indicators, levels, forms and averaging times of a distinct secondary standard to protect against associated effects.
- Data from regionally-based ecological studies can be used to establish probable local, regional and/or global sources of deposited PM components and their concurrent effects on ecological receptors.

Collectively taking into consideration the responses to specific questions regarding the adequacy of the current secondary PM standards for ecological effects, we revisit the overarching question: "does available scientific information, as reflected in the ISA, support or call into question the adequacy of the protection for ecosystems afforded by the current suite of secondary PM standards?" Staff reaches the preliminary conclusion that the available information is insufficient to assess the adequacy of the protection for ecosystems afforded by the current suite of PM secondary standards. Ecosystem effects linked to PM are difficult to determine because the changes may not be observed until pollutant deposition has occurred for many decades. Because the high levels necessary to cause injury occur only near a few limited point sources and/or on a very local scale, protection against these effects alone may not provide sufficient basis for considering a separate secondary NAAQS based on the ecological effects of particulate metals and organics. Data on ecological responses clearly linked with atmospheric PM is not abundant enough to perform a quantitative analysis although the WACAP study may represent an opportunity for quantification at a regional scale. At this time, we conclude that available evidence is not sufficient for establishing a distinct national standard for ambient PM based on ecosystem effects of particulates not addressed in the NOx/SOx secondary review (e.g. metals, organics).

Staff considered the appropriateness of continuing to use the $PM_{2.5}$ and PM_{10} size fractions as the indicators for protection of ecological effects of PM. Though the chemical constitution of individual particles can be strongly correlated with size, the relationship between particle size and particle composition can also be quite complex, making it difficult in most cases to use particle size as a surrogate for chemistry. At this time it remains to be determined as to what extent PM secondary standards focused on a given size fraction would result in reductions of the ecologically relevant constituents of PM for any given area.

5.3.4 Key Uncertainties and Areas for Future Research and Data Collection

The above discussions identify linkages between ecological effects of deposited PM and potential impacts to ecosystem services. Unfortunately, our ability to relate ambient concentrations of PM to ecosystem response is hampered by a number of significant data gaps and uncertainties. These limitations include the presence of multiple ecological stressors confounding attempts to link specific ecosystem responses to PM deposition. These stressors can be anthropogenic (e.g. habitat destruction, eutrophication, other pollutants) or natural (e.g. drought, fire, disease). Deposited PM interacts with other stressors to affect ecosystem patterns and processes. Furthermore, the environmental effects of deposited PM are decoupled in space and time from the point of emission confounding efforts to identify ecological perturbations attributed to PM deposition.

A second source of uncertainty lies in predicting the amount of PM deposited to sensitive receptors from measured concentrations of PM in the ambient air. This makes it difficult to relate a given air concentration to a receptor response, an important factor in being able to set a national ambient air quality standard. A multitude of factors such as the mode of deposition (wet, dry and occult), wind speed, surface roughness or stickiness, elevation, particle characteristics (e.g. size, shape, chemical composition), and relative humidity exert varying degrees of influence on the deposition velocities for different PM components in any point in time. Composition of ambient PM varies in time and space and the particulate mixture may have synergistic, antagonistic or additive effects on ecological receptors depending upon the chemical species present. Furthermore, presence of co-occurring pollutants make it difficult to attribute observed effects to ecological receptors to PM alone or one component of deposited PM.

Third, each ecosystem has developed within a context framed by the topography, underlying bedrock, soils, climate, meteorology, hydrologic regime, natural and land use history, and species composition that make it unique from all others. Sensitivity of ecosystem response is highly variable in space and time. Because of this variety and lack of sufficient baseline data on each of these features for most ecosystems, it is currently not possible to extrapolate with confidence any effect from one ecosystem to another.

5.4 MATERIALS

5.4.1 Scope

Welfare effects on materials associated with deposition of PM include both physical damage (materials damage effects) and impaired aesthetic qualities (soiling effects). Because the effects of PM are exacerbated by the presence of acidic gases and can be additive or synergistic due to the complex mixture of pollutants in the air and surface characteristics of the material, this discussion will also include those particles and gases that are associated with the presence of ambient NOx and SOx, as well as NH_3 and NH_X for completeness. Building upon the information presented in the last Staff Paper (US EPA, 2005), and including the limited new information presented in Chapter 9 of the PM ISA (US EPA, 2009a) and *Annex E. Effects of NOy, NHx, and SOx on Structures and Materials of the Integrated Science Assessment for Oxides of Nitrogen and Sulfur-Ecological Criteria* (NOx/SOx ISA) (US EPA, 2008c) the following sections consider the policy-relevant aspects of physical damage and aesthetic soiling effects of PM on materials including metal and stone.

The ISA concludes that evidence is sufficient to support a causal relationship between PM and effects on materials (US EPA, 2009a, sections 2.5.4 and 9.5.4). The deposition of PM can physically affect materials, adding to the effects of natural weathering processes, by potentially promoting or accelerating the corrosion of metals, by degrading paints and by deteriorating building materials such as stone, concrete and marble (US EPA, 2009a, section 9.5). Particles contribute to these physical effects because of their electrolytic, hygroscopic and acidic properties, and their ability to sorb corrosive gases (principally SO_2). In addition, the deposition of ambient PM can reduce the aesthetic appeal of buildings and objects through soiling. Particles consisting primarily of carbonaceous compounds cause soiling of commonly used building materials and culturally important items such as statues and works of art. Soiling is the deposition of particles on surfaces by impingement, and the accumulation of particles on the surface of an exposed material results in degradation of its appearance (US EPA 2009a, section 9.5). Soiling can be remedied by cleaning or washing, and depending on the soiled material, repainting.

5.4.2 Adequacy of the Current Standard

In considering the adequacy of the suite of secondary standards, staff addresses the following overarching question:

Does available scientific information, as reflected in the ISA support or call into question the adequacy of the protection for materials afforded by the current suite of secondary PM standards?

To inform the answer to this overarching question, staff has posed a specific question to aid in assessing the available scientific evidence as related to materials damage and soiling attributed to PM deposition as presented in the ISA (US EPA, 2009a).

- **What new evidence is available to improve our understanding of effects of PM on materials and linking ambient concentrations to materials damage?**

The majority of available new studies on materials effects of PM are from outside the U.S., however, they provide limited new data for consideration of the secondary standard.

Metal and stone are susceptible to damage by ambient PM. Considerable research has been conducted on the effects of air pollutants on metal surfaces due to the economic importance of these materials, especially steel, zinc, aluminum, and copper. Chapter 9 of the PM ISA and Annex E of the NOx/SOx ISA summarize the results of a number of studies on the corrosion of metals (US EPA, 2009a; US EPA, 2008c). Moisture is the single greatest factor promoting metal corrosion, however, deposited PM can have additive, antagonistic or synergistic effects. In general, SO_2 is more corrosive than NOx although mixtures of NOx, SO_2 and other particulate matter corrode some metals at a faster rate than either pollutant alone (US EPA, 2008c, Annex E.5.2). Information from both the PM ISA and NOx/SOx ISA suggest that the extent of damage to metals due to ambient PM is variable and dependent upon the type of metal, prevailing environmental conditions, rate of natural weathering and presence or absence of other pollutants.

The PM ISA and NOx/SOx ISA summarize the results of a number of studies on PM and stone surfaces. While it is clear from the available information that gaseous air pollutants, in particular SO_2, will promote the deterioration of some types of stones under specific conditions, carbonaceous particles (non-carbonate carbon) and particles containing metal oxides may help to promote the decay process. Studies on metal and stone summarized in the ISA do not show an association between particle size, chemical composition and frequency of repair.

A limited number of new studies available on materials damage effects of PM since the last review consider the relationship between pollutants and biodeterioration of structures associated with microbial communities that colonize monuments and buildings (US EPA 2009a, section 9.5). Presence of air pollutants may synergistically enhance microbial deterioration processes. The role of heterotrophic bacteria, fungi and cyanobacteria in biodeterioration varied by local meterological conditions and pollutant components. In a comparative study of biodeterioration processes on monuments in Latin America, limestone deterioration at the Mayan site of Uxmal was enhanced by biosolubilization by metabolic acids from bacteria and fungi while destruction of the Cathedral of La Plata was attributed primarily to atmospheric pollutants (Herrera and Videla, 2006).

PM deposition onto surfaces such as metal, glass, stone and paint can lead to soiling. Soiling results when PM accumulates on an object and alters the optical characteristics

(appearance). The reflectivity of a surface may be changed or presence of particulates may alter light transmission. These effects can impact the aesthetic value of a structure or result in reversible or irreversible damage to statues, artwork and architecturally or culturally significant buildings. Due to soiling of building surfaces by PM, the frequency and duration of cleaning may be increased. Soiling affects the aesthetic appeal of painted surfaces. In addition to natural factors, exposure to PM may give painted surfaces a dirty appearance. Pigments in works of art can be degraded or discolored by atmospheric pollutants, especially sulfates (US EPA, 2008c, Annex E-15).

Formation of black crusts due to carbonaceous compounds and buildup of microbial biofilms results in discoloration of surfaces. Black crust includes a carbonate component derived from building material and organic carbon (OC) and elemental carbon (EC). In limited new studies quantifying the OC and EC contribution to soiling by black crust, OC predominated over EC at almost all locations (Bonazza et al., 2005). Limited new studies suggest that traffic is the major source of carbon associated with black crust formation (Putaud, 2004) and that soiling of structures in Oxford, UK showed a relationship with traffic and NO_2 concentrations (Viles and Gorbushina, 2003). These findings attempt to link atmospheric concentrations of PM to observed damage. However, no data on rates of damage are available and all studies were conducted outside of the U.S.

5.4.3 Preliminary Staff Conclusions

Available evidence in regards to materials damage and soiling supports the following observations:

- Materials damage and soiling that occur through natural weathering processes are enhanced by exposure to atmospheric pollutants, most notably SO_2 and particulate sulfates.
- 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 damage have been established.
- While soiling associated with fine and course particles can result in increased cleaning frequency and repainting of surfaces, no quantitative relationships between particle characteristics and the frequency of cleaning or repainting have been established.
- Limited new data on the role of microbial colonizers in biodeterioration processes and contributions of black crust to soiling are not sufficient for quantitative analysis.
- While several studies in the PM ISA and NOx/SOx ISA suggest that particles can promote corrosion of metals there remains insufficient evidence to relate corrosive effects to specific particulate levels or to establish a quantitative relationship between ambient PM and metal degradation. With respect to damage to calcareous stone,

numerous studies suggest that wet or dry deposition of particles and dry deposition of gypsum particles can enhance natural weathering processes.

Revisiting the overarching policy question as to whether the available scientific evidence supports or calls into question the adequacy of the protection for materials afforded by the current suite of secondary PM standards, we reach the preliminary conclusion that no new evidence in this review calls into question the adequacy of the protection for materials afforded by the current standard. PM effects on materials can play no quantitative role in considering whether any revisions of the secondary PM NAAQS are appropriate at this time. However, in the absence of information that provides a basis for establishing a different level of control, observations continue to support retaining an appropriate degree of control on both fine and coarse particles to help address materials damage and soiling associated with PM.

5.4.4 Key Uncertainties and Areas for Future Research and Data Collection

Quantitative relationships are needed between particle size, concentration, chemical concentrations and frequency of repainting and repair. Deposition rates of airborne PM to surfaces would provide an indication of rate and degree of damage to surfaces. There is considerable uncertainty with regard to interaction of co-pollutants in regards to materials damage and soiling processes.

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