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

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

U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
Health and Environmental Impacts Division
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This Policy Assessment is the product of the Office of Air Quality Planning and Standards (OAQPS). It has been developed as part of the Environmental Protection Agency's (EPA) ongoing review of the national ambient air quality standards (NAAQS) for particulate matter (PM). The PM NAAQS review team has been led by Ms. Beth Hassett-Sipple. Dr. Karen Martin has managed the project. For the chapter on health effects associated with fine particle exposures and the primary $PM_{2.5}$ standards, the principal authors include Ms. Beth Hassett-Sipple, Dr. Pradeep Rajan, and Dr. Zach Pekar. For the chapter on health effects associated with thoracic coarse particle exposures and the primary PM_{10} standard, the principal author is Dr. Scott Jenkins. For the chapter on visibility-related effects and the secondary $PM_{2.5}$ standards, the principal authors include Dr. Marc Pitchford (National Oceanic and Atmospheric Administration, NOAA) and Mr. Phil Lorang. For the chapter on other welfare effects and secondary PM standards, the principal author is Dr. Meredith Lassiter. The principal contributors of ambient monitoring information, as presented in the introductory chapter, Appendix B, and other analyses, are Mr. Tim Hanley and Ms. Joann Rice. The authors would also like to acknowledge Mr. Mark Schmidt, Dr. Adam Reff, Dr. Michael Rizzo, and Mr. Mark Evangelista for conducting analyses on specific topics. Staff from other EPA offices, including the Office of Research and Development and the Office of General Counsel, also provided valuable comments and contributions.

Earlier drafts of this document were reviewed by the Clean Air Scientific Advisory Committee (CASAC) and made available for public comment. This final document has been informed by the expert advice and comments received from CASAC, as well as by public comments.

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AAMMS	Ambient Air Monitoring and Methods Subcommittee
ACS	American Cancer Society
AOD	Aerosol optical depth
ANPR	Advance notice of proposed rulemaking
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
BMA	Bayesian model averaging
C	Carbon
Ca	Calcium
CAA	Clean Air Act
CAPs	Concentrated ambient particles
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
CF	Cystic fibrosis
CFR	Code of Federal Regulations
CHD	Coronary heart disease
CHF	Congestive heart failure
CHS	Children's Health Study
CH_4	Methane
CO	Carbon monoxide
CO_2	Carbon dioxide
COPD	Chronic obstructive pulmonary disease
CPL	Candidate protection level
Cr	Chromium
C-R	Concentration-response

CSN	Chemical Speciation Network
Cu	Copper
CV	Cardiovascular
CVD	Cardiovascular disease
DE	Diesel Exhaust
DEP	Diesel Exhaust Particles
DHEW	US Department of Health, Education, and Welfare
DLEE	Dry light extinction efficiency
dv	deciview
EC	Elemental carbon
ED	Emergency department
EPA	Environmental Protection Agency
FEM	Federal Equivalent Method
FEV_1	Forced expiratory volume in one second, volume of air exhaled in first second of exhalation
FRM	Federal Reference Method
GHG	Greenhouse gas
HA	Hospital admissions
HEI	Health Effects Institute
HF	Hygroscopic fraction
Hg	Mercury
IHD	Ischemic heart disease
IMPROVE	Interagency Monitoring of Protected Visual Environment
IPCC	Intergovernmental Panel on Climate Change
IRP	Integrated Review Plan
ISA	Integrated Science Assessment
IT	Intratracheal
IUGR	Intrauterine growth restriction, intrauterine growth retardation
Km	Kilometer
LC	Local conditions
LML	Lowest measured level
µg	microgram
µm	micrometer, micron
$\mu g/m^3$	micrograms per cubic meter
MCAPS	Medicare Air Pollution Study

MEA	Millennium Ecosystem Assessment
MI	Myocardial infarction
MLEE	Moist light extinction efficiency
Mm	Megameter
Mm^{-1}	Inverse megameters, 1/(million meters)
MSA	Metropolitan Statistical Area
N	Nitrogen
NAAQS	National Ambient Air Quality Standards
NCEA	National Center for Environmental Assessment
NCore	National Core Monitoring Network
Ni	Nickel
NMMAPS	National Morbidity, Mortality, and Air Pollution Study
NO	Nitric oxide
NO_2	Nitrogen dioxide
NO_3^-	Nitrate
NOx	Nitrogen oxides ($NO+NO_2$)
NOAA	National Oceanic and Atmospheric Administration
NRC	National Research Council
O_3	Ozone
OAQPS	Office of Air Quality Planning and Standards
OAR	Office of Air and Radiation
OC	Organic carbon
OCM	Organic carbonaceous material
OMB	Office of Management and Budget
ORD	Office of Research and Development
PA	Policy Assessment
PAH	Polyaromatic hydrocarbon
Pb	Lead
PBDES	Polybrominated diphenyl ethers
PM	Particulate matter
$PM_{0.1}$	In general terms, particulate matter with a mobility diameter less than or equal to 0.1 μm; a measurement of ultrafine particles; since no reference method has been established, no 50% cut-point has been specified

$PM_{2.5}$	In general terms, particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 μm; a measurement of fine particles In regulatory terms, particles with an upper 50% cut-point of 2.5 μm aerodynamic diameter (the 50% cut point diameter is the diameter at which the sampler collects 50% of the particles and rejects 50% of the particles) and a penetration curve as measured by a reference method based on Appendix L of 40 CFR Part 50 and designated in accordance with 40 CFR Part 53, by an equivalent method designated in accordance with 40 CFR Part 53, or by an approved regional method designated in accordance with Appendix C of 40 CFR Part 58
PM_{10}	In general terms, particulate matter with an aerodynamic diameter less than or equal to a nominal 10 μm; a measurement of thoracic particles (i.e., that subset of inhalable particles thought small enough to penetrate beyond the larynx into the thoracic region of the respiratory tract) In regulatory terms, particles with an upper 50% cut-point of 10± 0.5 μm aerodynamic diameter (the 50% cut point diameter is the diameter at which the sampler collects 50% of the particles and rejects 50% of the particles) and a penetration curve as measured by a reference method based on Appendix J of 40 CFR Part 50 and designated in accordance with 40 CFR Part 53 or by an equivalent method designated in accordance with 40 CFR Part 53
$PM_{10-2.5}$	In general terms, particulate matter with an aerodynamic diameter less than or equal to a nominal 10 μm and greater than a nominal 2.5 μm; a measurement of thoracic coarse particulate matter or the coarse fraction of PM_{10} In regulatory terms, particles with an upper 50% cut-point of 10 μm aerodynamic diameter and a lower 50% cut-point of 2.5 μm aerodynamic diameter (the 50% cut point diameter is the diameter at which the sampler collects 50% of the particles and rejects 50% of the particles) as measured by a reference method based on Appendix O of 40 CFR Part 50 and designated in accordance with 40 CFR Part 53 or by an equivalent method designated in accordance with 40 CFR Part 53
POM	Particulate organic matter
POP	Persistant organic pollutants
PRB	Policy-relevant background
QAPP	Quality Assurance Project Plan
RA	Risk Assessment

REA	Risk and Exposure Assessment
RF	Radiative forcing
RH	Relative humidity
SANDWICH	Sulfate, Adjusted Nitrate, Derived Water, Inferred Carbonaceous mass approach
SCAB	South Coast Air Basin (CA)
SD	Standard deviation
SES	Socioeconomic status
S	Sulfur
SIP	State implementation plan
SLAMS	State and local air monitoring stations
SO_2	Sulfur dioxide
SO_x	Sulfur oxides
STN	Speciation Trends Network
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
W/m^2	Watts per square meter
WACAP	Western Airborne Contaminants Assessment Project
WHI	Women's Health Initiative
Zn	Zinc

EXECUTIVE SUMMARY

This Policy Assessment (PA) has been prepared by staff in the Environmental Protection Agency's (EPA) Office of Air Quality Planning and Standards (OAQPS) in conjunction with the Agency's ongoing review of the national ambient air quality standards (NAAQS) for particulate matter (PM), which include primary (health-based) and secondary (welfare-based) standards. It presents staff conclusions regarding the adequacy of the current suite of PM standards as well as potential alternative standards for consideration in this review.

Staff conclusions are based on the scientific and technical information, as well as uncertainties and limitations related to this information, assessed in other EPA documents, including the Integrated Science Assessment for Particulate Matter (Final Report) (ISA, US EPA, 2009a), the Quantitative Health Risk Assessment for Particulate Matter (Final Report) (RA, US EPA, 2010a) and the Particulate Matter Urban-Focused Visibility Assessment (Final Report) (UFVA, US EPA, 2010b). This PA is intended to "bridge the gap" between the relevant scientific evidence and technical information and the judgments required of the EPA Administrator in determining whether, and if so how, to revise the PM NAAQS. The current and potential alternative PM standards are considered in terms of the basic elements of the NAAQS: indicator, averaging time, form, and level.

Primary Standards for Fine Particles (Chapter 2):

In assessing the adequacy of the current suite of annual and 24-hour $PM_{2.5}$ standards meant to protect public health against long- and short-term exposures to fine particles, staff concludes that the currently available information clearly calls into question the adequacy of the current standards and that consideration should be given to revising the suite of standards to provide increased public health protection. In considering alternative $PM_{2.5}$ standards, staff concludes that protection from both long- and short-term $PM_{2.5}$ exposures can most effectively and efficiently be provided by relying primarily on the annual standard, with the 24-hour standard providing supplemental protection for days with high peak concentrations.

Taking into account both evidence-based and risk-based considerations, staff concludes that consideration should be given to revising the current annual $PM_{2.5}$ standard level of 15 $\mu g/m^3$ to a level within the range of 13 to 11 $\mu g/m^3$. Staff further concludes that the evidence most strongly supports consideration of an alternative annual standard level in the range of 12 to 11 $\mu g/m^3$. In conjunction with consideration of an annual standard in the range of 12 to 11 $\mu g/m^3$, staff concludes it is appropriate to consider retaining the current 24-hour $PM_{2.5}$ standard level at 35 $\mu g/m^3$. In conjunction with consideration of an annual standard level of 13 $\mu g/m^3$, staff concludes there is limited support to consider revising the 24-hour $PM_{2.5}$ standard level to somewhat below 35 $\mu g/m^3$, such as down to 30 $\mu g/m^3$.

In reaching these conclusions, staff recognizes that uncertainties and limitations remain in the currently available evidence and quantitative risk estimates. We note that no discernible thresholds have been identified for any health effects associated with long-

or short-term $PM_{2.5}$ exposures. Therefore, a primary focus of our consideration of alternative standard levels has been related to identifying the broader range of ambient $PM_{2.5}$ concentrations which has the most influence on generating health effect estimates in the epidemiological studies. We also recognize that there remain uncertainties in our understanding of the relationship between differences in the ambient $PM_{2.5}$ mixtures and/or exposure-related factors and the heterogeneity in health effects observed in the epidemiological evidence. Staff concludes that there is insufficient information at this time to consider supplementing the mass-based $PM_{2.5}$ indicator by considering a separate indicator for ultrafine particles or for a specific $PM_{2.5}$ component or group of components associated with any source categories of fine particles, or for eliminating any individual component or group of components from the mix of fine particles included in the $PM_{2.5}$ mass-based indicator.

Primary Standard for Thoracic Coarse Particles (Chapter 3):

In assessing the adequacy of the current primary 24-hour PM_{10} standard, which is meant to protect public health against short-term exposures to thoracic coarse particles (i.e., $PM_{10-2.5}$), staff concludes that it would be appropriate to consider either retaining or revising the current standard, depending on the relative weight placed on the evidence supporting associations with $PM_{10-2.5}$ and the uncertainties and limitations in this evidence. Important uncertainties and limitations include those associated with the air quality estimates used in $PM_{10-2.5}$ epidemiologic studies; the extent to which $PM_{10-2.5}$ air quality concentrations reflect exposures to $PM_{10-2.5}$; the extent to which $PM_{10-2.5}$ itself is responsible for health effects reported in epidemiologic studies; and the extent to which the chemical and/or biological composition of $PM_{10-2.5}$ affects particle toxicity.

To the extent consideration is given to revising the current standard, which has a one-expected-exceedance form and a level of 150 $\mu g/m^3$, staff concludes that consideration should be given to revising both the form and level. In this case, consideration should be given to a 98^{th} percentile form and a level within the range of 85 $\mu g/m^3$ down to about 65 $\mu g/m^3$, in conjunction with retaining the PM_{10} indicator and the 24-hour averaging time. Staff also concludes that standard levels in the upper part of this range are supported by the strongest evidence.

Secondary Standards for PM-related Visibility Impairment (Chapter 4):

In assessing the adequacy of the current suite of secondary annual and 24-hour $PM_{2.5}$ standards (which are identical to the primary $PM_{2.5}$ standards) meant to protect against PM-related visibility impairment, staff concludes that the currently available information clearly calls into question the adequacy of the current standards and that consideration should be given to revising the suite of standards to provide increased public welfare protection. Staff also concludes that the current $PM_{2.5}$ mass indicator is not appropriate for a national standard intended to protect against PM-related visibility impairment since such a standard is inherently confounded by regional differences in relative humidity and species composition of $PM_{2.5}$, which are critical factors in the relationship between ambient particles and associated visibility impairment.

Taking into account both evidence-based and impact assessment-based considerations, staff concludes that consideration should be given to establishing a new

standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator. Such an indicator would use speciated $PM_{2.5}$ mass and relative humidity data to calculate $PM_{2.5}$ light extinction, similar to how light extinction is now calculated in the Regional Haze Program. In conjunction with a calculated $PM_{2.5}$ light extinction indicator, staff concludes that consideration should be given to a 24-hour averaging time and a level of 28 deciviews (dv) or somewhat below, down to 25 dv. Staff concludes that it would also be appropriate to consider a multi-hour, sub-daily averaging period (e.g., 4 hours) to the extent that data quality issues that have recently been raised about data from continuous $PM_{2.5}$ monitors classified as Federal Equivalent Methods (FEMs) can be appropriately addressed. In conjunction with consideration of a standard with a 4-hour averaging time, staff concludes that consideration should be given to a level of 30 dv or somewhat below, down to 25 dv. In all cases, staff concludes that consideration should be given to a 90^{th} percentile form, averaged over three years.

Secondary Standards for Non-visibility Welfare Effects (Chapter 5):

In assessing the adequacy of the current suite of secondary PM standards (which are identical to the primary $PM_{2.5}$ and PM_{10} standards) meant to protect against PM-related effects other than visibility impairment, staff has considered PM-related effects on climate, ecological effects, and effects on materials. Staff concludes that the currently available information supports retaining control of both fine and coarse particles to address PM-related effects on ecosystems and materials damage and soiling, but that there is insufficient information to assess the adequacy of protection afforded by the current standards. Staff also concludes that there is insufficient information at this time to base a NAAQS on climate impacts associated with current ambient concentrations of PM or its constituents.

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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 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 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 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 and secondary PM standards will reflect the judgments of the Administrator.

In this 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 (Final Report)* (RA, US EPA, 2010a) and the *Particulate Matter Urban-Focused Visibility Assessment (Final Report)* (UFVA, 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.

Although this 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

[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.

contained in the ISA (US EPA, 2009a) and in the quantitative health risk and visibility assessment documents (US EPA, 2010a,b).

1.2 BACKGROUND

1.2.1 Legislative Requirements

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. section 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those air pollutants that in her "judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;" "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources;" and "for which . . . [the Administrator] plans to issue air quality criteria…" Air quality criteria are intended 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. 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 such 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 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 provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See *Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980), *cert. denied*, 449 U.S. 1042 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981), *cert. denied*, 455

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

[5] Welfare effects as defined in section 302(h) (42 U.S.C. § 7602(h)) include, but are not limited to, "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

U.S. 1034 (1982); *American Farm Bureau Federation v. EPA*, 559 F. 3d 512, 533 (D.C. Cir. 2009); *Association of Battery Recyclers v. EPA*, 604 F. 3d 613, 617-18 (D.C. Cir. 2010). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, see *Lead Industries v. EPA*, 647 F.2d at 1156 n.51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of sensitive 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. See *Lead Industries Association v. EPA*, 647 F.2d at 1161-62; *Whitman v. American Trucking Associations*, 531 U.S. 457, 495 (2001).

In setting primary and secondary standards that are "requisite" to protect public health and welfare, respectively, 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, 465-472, 475-76 (2001). Likewise, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards." *American Petroleum Institute v. Costle*, 665 F. 2d at 1185.

Section 109(d)(1) requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate . . . ." 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 . . . ." Since the early 1980's, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC).[6]

[6] Lists of CASAC members and of members of the CASAC PM Review Panel are available at: http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CommitteesandMembership?OpenDocument .

1.2.2 Previous PM NAAQS Reviews

The EPA initially established NAAQS for PM under section 109 of the CAA in 1971. Since then, the Agency has made a number of changes to these standards to reflect continually expanding scientific information, particularly with respect to the selection of indicator[7] and level. Table 1-1 provides a summary of the PM NAAQS that have been promulgated to date. These decisions are briefly discussed below.

In 1971, EPA established NAAQS for PM based on the original air quality criteria document (DHEW, 1969; 36 FR 8186, April 30, 1971). 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 an aerodynamic diameter less than or equal to a nominal 10 μm, which delineates thoracic particles (i.e., that subset of inhalable particles thought small enough to penetrate beyond the larynx into the thoracic region of the respiratory tract). 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 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).

[7] 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.

Table 1-1. Summary of National Ambient Air Quality Standards Promulgated for Particulate Matter 1971-2006[8]

Final Rule	Indicator	Averaging 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[9]
		Annual	15 µg/m^3	Annual arithmetic mean, averaged over 3 years[10,11]
	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[9]
		Annual	15 µg/m^3	Annual arithmetic mean, averaged over 3 years[11,12]
	PM_{10}	24-hour	150 µg/m^3	Not to be exceeded more than once per year on average over a 3-year period

[8] When not specified, primary and secondary standards are identical.
[9] The 24-hour standard NAAQS metric is defined as an integer (zero decimal places) as determined by rounding. For example, a 3-year average 98th percentile concentration of 35.49 µg/m^{3}would round to 35 µg/m^{3}and thus meet the 24-hour standard and a 3-year average of 35.50 µg/m^{3}would round to 36 µg/m^3 and hence, violate the 24-hour standard (40 CFR part 50 Appendix N).
[10] The annual standard NAAQS metric is defined to one decimal place (i.e., 15.0 µg/m^3) as determined by rounding. For example, a 3-year average annual mean of 15.04 µg/m^3 would round to 15.0 µg/m^3 and thus meet the annual standard and a 3-year average of 15.05 µg/m^3 would round to 15.1 µg/m^3 and hence, violate the annual standard.
[11] 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").
[12] 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, July 18, 1997). Most significantly, EPA determined that although the PM NAAQS should continue to focus on thoracic particles (PM_{10}), the fine and coarse fractions of PM_{10} should be considered separately. New standards were added, using $PM_{2.5}$ as the indicator for fine particles.[13] The PM_{10} standards were retained for the purpose of regulating the coarse fraction of PM_{10} (referred to as thoracic coarse particles or $PM_{10-2.5}$).[14] 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[15]; 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[16] 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

[13] $PM_{2.5}$ includes particles with an aerodynamic diameter less than or equal to a nominal 2.5 µm.
[14] See 40 CFR Parts 50, 53, and 58 for more information on reference and equivalent methods for measuring PM in ambient air.
[15] Monitoring stations sited to represent *community-wide* air quality will typically be at the neighborhood or urban-scale; however, where a population-oriented micro or middle-scale $PM_{2.5}$ monitoring station represents many such locations throughout a metropolitan area, these smaller scales may also be considered to represent community-wide air quality (40 CFR Part 58, Appendix D, 4.7.1(b)).
[16] *Population-oriented* monitoring (or sites) means residential areas, commercial areas, recreational areas, industrial areas where workers from more than one company are located, and other areas where a substantial number of people may spend a significant fraction of their day. (40 CFR Part 58, §58.1)

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). After CASAC and public review of several drafts, EPA's National Center for Environmental Assessment (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 Associates, 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 its review of the Staff Paper, CASAC provided advice to the Administrator on revisions to the PM NAAQS (Henderson, 2005a). In particular, most CASAC PM Panel members favored revising the level of the primary 24-hour $PM_{2.5}$ standard in the range of 35 to 30 $\mu g/m^3$ with a 98^{th} percentile form, in concert with revising the level of the primary 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 primary 24-hour $PM_{10-2.5}$ 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 primary 24-hour $PM_{2.5}$ standard to 35 $\mu g/m^3$; revising the form, but not the level, of the primary annual $PM_{2.5}$ standard by tightening the constraints on the use of spatial averaging; replacing the primary 24-hour PM_{10} standard with a 24-hour standard defined in terms of a new indicator, $PM_{10-2.5}$[17] set at a level of 70 $\mu g/m^3$ based on the 3-year average of the 98^{th} percentile of 24-hour $PM_{10-2.5}$ concentrations; revoking the primary annual PM_{10} 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.[18] 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 primary 24-hour $PM_{2.5}$

[17] 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 (71 FR 2667 to 2668).

[18] 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, considering alternative standard levels within a range of 20 to 30 $\mu g/m^3$ in conjunction with a form within a range of the 92^{nd} to 98^{th} percentile (71 FR 2685).

standard to 35 μg/m^3, retained the level of the primary annual $PM_{2.5}$ standard at 15 μg/m^3, and revised the form of the primary 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 particles, EPA retained the level and form of the 24-hour PM_{10} standard (such that the standard remained at a level of 150 μg/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 primary $PM_{2.5}$ annual standard, CASAC expressed serious concerns regarding the decision to retain the level of the standard at 15 μg/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 its advice to establish a distinct secondary standard for fine particles to address visibility impairment was not followed.

1.2.3 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, 520-27 (D.C. Cir. 2009). With regard to the

standards for PM_{10}, the court upheld EPA's decisions to retain the 24-hour PM_{10} standard to provide protection from thoracic coarse particle exposures and to revoke the annual PM_{10} standard. *American Farm Bureau Federation*, 559 F. 2d at 533-38. With regard to the secondary $PM_{2.5}$ standards, the court remanded the standards to EPA because the Agency failed to adequately explain why setting the secondary PM standards identical to the primary standards provided the required protection for public welfare, including protection from visibility impairment. *American Farm Bureau Federation*, 559 F. 2d at 528-32.

The decisions of the court with regard to these three issues are discussed further in chapters 2, 3 and 4, respectively (see sections 2.1.2, 3.1.2, and 4.1.2). The EPA is responding to the court's remands as part of the current review of the PM NAAQS.

1.2.4 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 34004, June 20, 2007).[19] These workshops provided an opportunity for a public discussion of 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 (US EPA, 2007). On November 30, 2007, EPA held a consultation with CASAC 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 (Henderson, 2008) and the public on the draft plan as well as input from senior Agency managers.[20]

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; 73 FR 77686, December 19, 2008) was reviewed by

[19] See workshop materials available at: 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.

[20] The process followed in this review varies from the NAAQS review process described in section 1.1 of the IRP (US EPA, 2008a). On May 21, 2009, EPA Administrator Jackson called for key changes to the NAAQS review process including reinstating a policy assessment document that contains staff analyses of the scientific bases for alternative policy options for consideration by senior Agency management prior to rulemaking. In conjunction with this change, EPA will no longer issue a policy assessment in the form of an advance notice of proposed rulemaking (ANPR) as discussed in the IRP. For more information on the overall process followed in this review including a description of the major elements of the process for reviewing NAAQS see Jackson (2009).

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; 74 FR 38185, July 31, 2009), 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 Risk and Exposure Assessment (REA) documents that build on the scientific evidence presented in the ISA, OAQPS released two planning documents: *Particulate Matter National Ambient Air 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; 74 FR 11580, March 18, 2009). 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 7688, February 19, 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 (74 FR 46586, September 10, 2009). Based on CASAC (Samet 2009c,d) and public comments, OAQPS staff revised these draft documents and released second draft assessment documents (US EPA, 2010d,e) in January and February 2010 (75 FR 4067, January 26, 2010) for CASAC and public review at a meeting held on March 10-11, 2010 (75 FR 8062, February 23, 2010). Based on CASAC (Samet, 2010a,b) and public comments on the second draft assessment documents, we revised these documents and released final assessment documents in June and July 2010 (US EPA, 2010a,b; 75 FR 39252, July 8, 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. CASAC's comments on the preliminary draft PA 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. These comments were considered in developing a first draft PA (US EPA, 2010c; 75 FR 4067, January 26, 2010) that built upon the information presented and assessed in the final ISA and second draft risk and visibility assessment documents. The EPA presented an overview of the first draft PA at a CASAC meeting on March 10, 2010 (75 FR 8062, February

23, 2010). The first draft PA was reviewed by CASAC and the public and discussed during public teleconferences on April 8 - 9, 2010 (75 FR 8062, February 23, 2010) and May 7, 2010 (75 FR 19971, April 16, 2010).

The CASAC (Samet, 2010c) and public comments on the first draft PA were considered by EPA staff in developing a second draft PA (US EPA, 2010f; 75 FR 39253, July 8, 2010) which was reviewed by CASAC at a meeting on July 26 - 27, 2010 (75 FR 32763, June 9, 2010). CASAC (Samet, 2010d, see Appendix A) and public comments on the second draft PA were considered by EPA staff in preparing this final PA.[21] This document includes final staff conclusions related to the adequacy of the current PM standards and the broadest range of alternative standards that are supported by the currently available scientific evidence and quantitative assessments.

1.3 CURRENT AMBIENT MONITORING NETWORKS FOR PM

In the U.S., state and local agencies operate the vast majority of PM monitors as part of the State and local air monitoring stations (SLAMS) network. The SLAMS network supports three major objectives: to provide air pollution data to the general public in a timely manner; to support compliance with ambient air quality standards and emissions strategy development; and to support air pollution research studies. PM monitors are deployed according to network design criteria described in Appendix D to 40 CFR Part 58. For comparison to the annual standard, $PM_{2.5}$ monitoring sites are required to represent community-wide air quality. For most urban locations this will result in siting monitors at the neighborhood scale[22] where $PM_{2.5}$ concentrations are reasonably homogeneous throughout an entire urban sub-region. At least one monitoring station representing community-wide air quality is also to be sited in a population-oriented area of expected maximum concentration. Sites that represent relatively unique population-oriented microscale,[23] or localized hot-spot, or unique population-oriented middle

[21] All written comments submitted to the Agency are available in the docket for this PM NAAQS review (EPA-HQ-OAR-2007-0429). Transcripts of public meetings and teleconferences held in conjunction with CASAC's reviews are also included in the docket.

[22] *Neighborhood scale for $PM_{2.5}$:* Measurements in this category would represent conditions throughout some reasonably homogeneous urban sub-region with dimensions of a few kilometers and of generally more regular shape than the middle scale. Homogeneity refers to the particulate matter concentrations, as well as the land use and land surface characteristics. Much of the $PM_{2.5}$ exposures are expected to be associated with this scale of measurement. In some cases, a location carefully chosen to provide neighborhood scale data would represent the immediate neighborhood as well as neighborhoods of the same type in other parts of the city. See 40 CRF Part 58 Appendix D, 4.7.1(c)(3).

[23] *Microscale for $PM_{2.5}$:* This scale would typify areas such as downtown street canyons and traffic corridors where the general public would be exposed to maximum concentrations from mobile sources. See 40 CFR Part 58 Appendix D, 4.7.1(c)(1).

scale[24] impact sites are only eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS. For PM_{10}, the network design criteria emphasize monitoring at middle[25] and neighborhood[26] scales to effectively characterize the emissions from both mobile and stationary sources, although not ruling out microscale monitoring in some instances (40 CFR Part 58 Appendix D, 4.6 (b)).

The sections below briefly summarize the monitoring networks for PM including $PM_{2.5}$ mass, $PM_{2.5}$ speciation, and PM_{10} mass, as well as the new $PM_{10-2.5}$ mass network which will be part of the forthcoming National Core Multipollutant Monitoring Network (NCore).[27] Additional information and maps of monitoring sites are provided in Appendix B.

1.3.1 $PM_{2.5}$ Mass

The $PM_{2.5}$ monitoring requirements provide for monitors in Metropolitan Statistical Areas[28] (MSAs) based on a combination of population and design value[29] (see Table D-5, 40 CFR Part 58) with higher populated locations having more polluted air required to have the most monitors. Background and transport monitors[30] are also required of each state with options for utilizing IMPROVE[31] and other $PM_{2.5}$ data to provide for flexibility in meeting the monitoring requirements.

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[24] *Middle scale for $PM_{2.5}$:* People moving through downtown areas, or living near major roadways, encounter particle concentrations that would be adequately characterized by this spatial scale. Thus, measurements of this type would be appropriate for the evaluation of possible effects associated with short-term exposures to $PM_{2.5}$. See 40 CFR Part 58 Appendix D, 4.7.1(c)(2).

[25] *Middle scale for PM_{10}*: Much of the short-term public exposure to coarse fraction particles (using PM_{10} as the indicator) is characterized on this scale and on the neighborhood scale. People moving through downtown areas or living near major roadways or stationary sources, may encounter particulate matter that would be adequately characterized by measurements of this spatial scale. See 40 CFR Part 58 Appendix D, 4.6(b)(2).

[26] *Neighborhood scale for PM_{10}*: Measurements in this category represent conditions throughout some reasonably homogeneous urban subregion with dimensions of a few kilometers and of generally more regular shape than the middle scale. Homogeneity refers to the particulate matter concentrations, as well as the land use and land surface characteristics. In some cases, a location carefully chosen to provide neighborhood scale data would represent not only the immediate neighborhood but also neighborhoods of the same type in other parts of the city. See 40 CFR Part 58 Appendix D, 4.6(b)(3).

[27] The NCore network is a multi-pollutant network that includes measurements of particles, gases, and meteorology (71 FR 61236, October 17, 2006). The network is intended to support integrated air program management needs. The NCore monitoring network is expected to be fully operational by January 1, 2011.

[28] Metropolitan and micropolitan statistical areas (metro and micro areas) are geographic entities defined by the U.S. Office of Management and Budget (OMB) for use by Federal statistical agencies in collecting, tabulating, and publishing Federal statistics. The term "Core Based Statistical Area" (CBSA) is a collective term for both metro and micro areas. A metro area contains a core urban area of 50,000 or more population, and a micro area contains an urban core of at least 10,000 (but less than 50,000) population. Each metro or micro area consists of one or more counties and includes the counties containing the core urban area, as well as any adjacent counties that have a high degree of social and economic integration (as measured by commuting to work) with the urban core.

[29] *Design values* are the metrics (i.e., statistics) that are compared to the NAAQS levels to determine compliance. For example, for $PM_{2.5}$, design values are calculated as shown in section 4.0 of Appendix N to 40 CFR Part 50.

[30] *Background and transport sites* are used to provide regional background and transport data. When evaluated in combination with urban sites, these locations help determine the local urban contribution to PM.

[31] The Interagency Monitoring of Protected Visual Environment (IMPROVE) program was established in 1985 to aid the creation of federal and state implementation plans for the protection of visibility in Class 1 areas (i.e., 155

The network of $PM_{2.5}$ FRM monitors includes over 900 monitoring stations throughout the country. The FRM is a manually operated sampler that is programmed to operate for a 24-hour period covering midnight to midnight local standard time. Although approximately 150 FRM sites operate every day, most operate every third or sixth day according to a national schedule provided by EPA.[32] The network of $PM_{2.5}$ continuous monitors has grown to approximately 800 locations throughout the country of which about 115 locations have Class III FEMs[33]. The number of $PM_{2.5}$ FRM monitors may decrease over the coming years as $PM_{2.5}$ continuous FEMs replace FRMs.

1.3.2 $PM_{2.5}$ Speciation

As part of the $PM_{2.5}$ NAAQS review completed in 1997, EPA established a $PM_{2.5}$ Chemical Speciation Network (CSN) to conduct routine speciation monitoring in primarily urban areas in the U.S. The $PM_{2.5}$ CSN consists of about 50 Speciation Trends Network (STN) sites and about 150 SLAMS supplemental sites. All STN sites operate on a one-in-three day sample collection schedule. A majority of the SLAMS supplemental sites operate on a one-in-six day sample collection schedule. These sites collect aerosol samples over 24 hours on filters that are analyzed for $PM_{2.5}$ mass, a number of trace elements, major ions (e.g., sulfate, nitrate, ammonium), and organic and elemental carbon. Similar to the CSN, the IMPROVE program[34] also provides $PM_{2.5}$ mass and speciation data for organic and elemental carbon, major ions, and trace elements; however, unlike CSN, IMPROVE also samples for PM_{10} mass.

1.3.3 PM_{10} Mass

PM_{10} monitoring stations have an urban focus and are required in MSAs according to Table D-4 of Appendix D to 40 CFR Part 58. Local considerations are a factor in determining the actual required number of monitoring sites. More stations are required in larger MSAs and areas with more evidence of poor air quality, while monitors are also required in "clean" MSAs of certain size. The network currently includes over 800 monitoring stations throughout the country with most metropolitan areas operating more PM_{10} monitors than the minimum required

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national parks and wilderness areas) as stipulated in the 1977 amendments to the CAA. The IMPROVE Network also supports goals set forth in the 1999 Regional Haze Rule (64 FR 35714. July 1, 1999). Additional information is available at http://www.epa.gov/visibility/program.html.

[32] The national sampling schedule calendar is available on the web at: http://www.epa.gov/ttn/amtic/calendar.html.

[33] *Class III equivalent method* means an equivalent method for $PM_{2.5}$ that is an analyzer capable of providing ambient air measurements representative of one hour or less integrated concentrations as well as 24-hour measurements determined as, or equivalent to, the mean of 24 one-hour consecutive measurements.

[34] IMPROVE is a cooperative measurement effort managed by a steering committee composed of representatives from federal, regional, and state organizations. See Appendix B and http://vista.cira.colostate.edu/improve/ for more information.

by current monitoring rules. Many PM_{10} monitoring stations operate FRMs on a mix of daily, one-in-two day, one-in-three day, or one-in-six day sampling, based on the relative concentrations measured at a specific monitoring site with respect to the 24-hour standard. There are also FEMs that are operated continuously, providing hourly PM_{10} measurements.

1.3.4 $PM_{10-2.5}$ Mass

Ambient measurements of $PM_{10-2.5}$ concentrations are not routinely measured and reported at present (US EPA, 2009a, section 3.5.1.1). The EPA has required $PM_{10-2.5}$ mass monitoring as part of the NCore network which began January 1, 2011 at approximately 80 stations. Urban NCore stations are to be generally located at an urban scale[35] or neighborhood scale to provide representative concentrations of exposure expected throughout the metropolitan area. Rural NCore stations are to be located, to the maximum extent practicable, at a regional[36] or larger scale, away from any large local emission source, so that they represent ambient concentrations over an extensive area.

1.4 GENERAL APPROACH AND ORGANIZATION OF THIS DOCUMENT

This PA includes staff's evaluation of the policy implications of the scientific assessment of the evidence presented and assessed in the ISA and the results of quantitative assessments based on that information presented and assessed in the REAs. Taken together, this information informs 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).[37] 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

[35] *Urban scale*: This class of measurement would be used to characterize PM concentrations over an entire metropolitan or rural area ranging in size from 4 to 50 kilometers. Such measurements would be useful for assessing trends in area-wide air quality, and hence, the effectiveness of large scale air pollution control strategies. Community-oriented $PM_{2.5}$ sites may have this scale (see 40 CFR Part 58, Appendix D, section 4.7.1(c)(4)).

[36] *Regional scale*: These measurements would characterize conditions over areas with dimensions as much as hundreds of kilometers. Such measurements provide information about PM emissions and atmospheric losses and transport (see 40 CFR Part 58, Appendix D, section 4.7.1(c)(5).

[37] Ultrafine particles generally include particles with a nominal serodynamic diameter less than or equal to 0.1 μm.

aid in considering whether there is support to consider standards with a different size fraction and/or distinct standards focused on regulating a specific $PM_{2.5}$ component or group of components associated with any source categories of fine particles.

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 conclusions related to review of the primary standards for fine and thoracic coarse particles, respectively. Each chapter includes background information on the rationale for previous reviews and the policy assessment approaches followed in the current review, focusing on evidence-based considerations and, as appropriate, quantitative risk-based considerations. 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 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 conclusions with regard to the adequacy of the current standards and the extent to which information is available to support consideration of alternative standards.

1.5 REFERENCES

Abt Associates (2005). Particulate Matter Health Risk Assessment for Selected Urban Areas. Final Report. Bethesda, MD. Prepared for the Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Contract No. 68-D-03-002. EPA 452/R-05-007A. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/data/PMrisk20051220.pdf

Henderson R (2005a). Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Honorable Stephen L. Johnson, Administrator, US EPA. CASAC PM Review Panel's Peer Review of the Agency's *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information* (Second Draft PM Staff Paper, January 2005). June 6, 2005. Available at: http://www.epa.gov/sab/pdf/casac-05-007.pdf.

Henderson, R (2005b). Clean Air Scientific Advisory Committee (CASAC) Review of the EPA Staff Recommendations Concerning a Potential Thoracic Coarse PM Standard in the *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information* (Final PM OAQPS Staff Paper, EPA-452/R-05-005, June 2005). September 15, 2005. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/3562FF25F05133FC85257084000B1B77/$File/sab-casac-05-012.pdf.

Henderson R (2006a). Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to the Honorable Stephen L. Johnson, Administrator, US EPA. Clean Air Scientific Advisory Committee Recommendations Concerning the Proposed National Ambient Air Quality Standards for Particulate Matter. March 21, 2006. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/CD706C976DAC62B3852571390081CC21/$File/casac-ltr-06-002.pdf.

Henderson R, Cowling E, Crapo JD, Miller FJ, Poirot RL, Speizer F, Zielinska B (2006b). Letter from Clean Air Scientific Advisory Committee to the Honorable Stephen L. Johnson, Administrator, US EPA. Clean Air Scientific Advisory Committee Recommendations Concerning the Final National Ambient Air Quality Standards for Particulate Matter. September 29, 2006. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/1C69E987731CB775852571FC00499A10/$File/casac-ltr-06-003.pdf.

Henderson R (2008). Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to the Honorable Stephen L. Johnson, Administrator, US EPA. Clean Air Scientific Advisory Committee Particulate Matter Review Panel's Consultation on EPA's Draft *Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter*. January 3, 2008. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/76D069B8191381DA852573C500688E74/$File/EPA-CASAC-08-004-unsigned.pdf

Jackson L (2009). Memo from Administrator Lisa P. Jackson to Elizabeth Craig, Acting Assistant Administrator for OAR and Lek Kadeli, Acting Assistant Administrator for ORD. Process for Reviewing the National Ambient Air Quality Standards. May 21, 2009. Available at: http://www.epa.gov/ttn/naaqs/pdfs/NAAQSReviewProcessMemo52109.pdf.

Samet J (2009a). Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to the Honorable Lisa P. Jackson, Administrator, US EPA. Consultation on EPA's *Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment*. May 21, 2009. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/723FE644C5D758DF852575BD00763A32/$File/EPA-CASAC-09-009-unsigned.pdf

Samet, J (2009b). Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to the Honorable Lisa P. Jackson, Administrator, US EPA. Consultation on EPA's *Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Urban Visibility Impact Assessment.* May 21, 2009. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/0F63D7995F5850D5852575BD0077869C/$File/EPA-CASAC-09-010-unsigned.pdf.

Samet J (2009c). Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to the Honorable Lisa P. Jackson, Administrator, US EPA. Review of *Risk Assessment to Support the Review of the Particulate Matter (PM) Primary National Ambient Air Quality Standards – External Review Draft* (September 2009). November 24, 2009. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/BC1ECC5D539EF72385257678006D5754/$File/EPA-CASAC-10-003-unsigned.pdf

Samet J (2009d). Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to the Honorable Lisa P. Jackson, Administrator, US EPA. Review of *Particulate Matter Urban-Focused Visibility Assessment* (External Review Draft, September 2009). November 24, 2009. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/15872217938041F685257678006A26E3/$File/EPA-CASAC-10-002-unsigned.pdf

Samet J (2010a). Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to the Honorable Lisa P. Jackson, Administrator, US EPA. CASAC Review of *Quantitative Health Risk Assessment for Particulate Matter – Second External Review Draft* (February 2010). April 15, 2010. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/BC4F6E77B6385155852577070002F09F/$File/EPA-CASAC-10-008-unsigned.pdf

Samet J (2010b). Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to the Honorable Lisa P. Jackson, Administrator, US EPA. *CASAC Review of Particulate Matter Urban-Focused Visibility Assessment - Second External Review Draft* (January 2010). April 20, 2010. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/0D5CB76AFE7FA77C8525770D004EED55/$File/EPA-CASAC-10-009-unsigned.pdf

Samet J (2010c). Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to the Honorable Lisa P. Jackson, Administrator, US EPA. CASAC Review of *Policy Assessment for the Review of the PM NAAQS – First External Review Draft* (March 2010). May 17, 2010. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/E504EE3276D87A9E8525772700647AFB/$File/EPA-CASAC-10-011-unsigned.pdf/.

Samet J (2010d). Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to the Honorable Lisa P. Jackson, Administrator, US EPA. CASAC Review of *Policy Assessment for the Review of the PM NAAQS – Second External Review Draft* (June 2010). September 10, 2010. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/CCF9F4C0500C500F8525779D0073C593/$File/EPA-CASAC-10-015-unsigned.pdf.

US Department of Health, Education and Welfare (DHEW). (1969). Air Quality Criteria for Particulate Matter. U.S. Government Printing Office, Washington DC, AP-49.

US EPA (2004). Air Quality Criteria for Particulate Matter. National Center for Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; report no. EPA/600/P-99/002aF and EPA/600/P-99/002bF. October 2004. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_cd.html.

US EPA (2005). Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. Research Triangle Park, NC 27711: Office of Air Quality Planning and Standards; report no. EPA EPA-452/R-05-005a. December 2005. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_sp.html.

US EPA (2007). Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter. National Center for Environmental Assessment and Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. Report No. EPA 452/P-08-006. October 2007. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pd.html.

US EPA (2008a). Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter. National Center for Environmental Assessment-RTP Division and Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. Report No. EPA 452/R-08-004. March 2008. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pd.html.

US EPA (2008b). Integrated Science Assessment for Particulate Matter: First External Review Draft. National Center for Environmental Assessment-RTP Division, Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA/600/R-08/139 and 139A. December 2008. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_isa.html.

US EPA (2009a). Integrated Science Assessment for Particulate Matter: Final Report. National Center for Environmental Assessment-RTP Division, Office of Research and Development, Research Triangle Park, NC. EPA/600/R-08/139F. December 2009. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_isa.html.

US EPA (2009b). Integrated Science Assessment for Particulate Matter: Second External Review Draft. National Center for Environmental Assessment-RTP Division, Office of Research and Development, Research Triangle Park, NC. EPA/600/R-08/139B. July 2009. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_isa.html.

US EPA (2009c). Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/P-09-002. February 2009. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pd.html.

US EPA (2009d). Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Urban Visibility Impact Assessment. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/P-09-001. February 2009. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pd.html.

US EPA (2009e). Risk Assessment to Support the Review of the PM Primary National Ambient Air Quality Standards - External Review Draft. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/P-09-006. September 2009. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

US EPA (2009f). Particulate Matter Urban-Focused Visibility Assessment – External Review Draft. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/P-09-005. September 2009. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

US EPA (2009g). Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards – Preliminary Draft. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/P-09-007. September 2009. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pa.html.

US EPA (2010a). Quantitative Health Risk Assessment for Particulate Matter – Final Report. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/R-10-005. June 2010. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

US EPA (2010b). Particulate Matter Urban-Focused Visibility Assessment – Final Report. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/R-10-004. July 2010. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

US EPA (2010c). Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards - First External Review Draft. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA 452/P-10-003. March 2010. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pa.html.

US EPA (2010d). Quantitative Risk Assessment for Particulate Matter – Second External Review Draft. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/P-10-001. February 2010. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

US EPA (2010e). Particulate Matter Urban-Focused Visibility Assessment – Second External Review Draft. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/P-10-002. January 2010. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

US EPA (2010f). Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards - Second External Review Draft. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA 452/P-10-007. June 2010. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pa.html.

2 REVIEW OF THE PRIMARY STANDARDS FOR FINE PARTICLES

This chapter presents 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 at the outset of this review in the IRP (US EPA, 2008a). Answers to these questions will inform decisions by the Administrator 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 made about how to deal with the 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 recognizes that the available health effects evidence generally reflects a continuum consisting of ambient levels at which scientists generally agree that health effects occur through lower levels at which the likelihood and magnitude of the response become appreciably more uncertain.

Our approach for reviewing the primary standards for fine particles is presented in section 2.1. Staff 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 conclusions with respect to alternative fine particle standards that are appropriate to consider, addressing each of the basic elements of the standards: indicator (section 2.3.1), averaging time (section 2.3.2), form (section 2.3.3), and level (section 2.3.4). Section 2.4 summarizes staff conclusions on the primary fine particle standards. Key uncertainties and areas for future research and data collection efforts are included in section 2.5.

2.1 APPROACH

Staff's general approach for reviewing the current primary $PM_{2.5}$ standards, which involves translating scientific and technical information into the basis for addressing key policy-relevant questions, takes into consideration the approaches used in previous PM NAAQS reviews (section 2.1.1) and the court's remand of the primary annual $PM_{2.5}$ standard set in 2006 (section 2.1.2). 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 (C-R) 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 general 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. This includes consideration of how to weigh the uncertainties in the reported associations across the distributions of PM concentrations in the studies and the uncertainties 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. Our current approach for evaluating the primary $PM_{2.5}$ standards using both evidence- and risk-based considerations is outlined in section 2.1.3.

2.1.1 Approaches Used in Previous Reviews

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 risk 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

[1] In so doing, EPA noted that because an annual standard would focus control programs on annual average $PM_{2.5}$ concentrations, it would not only control long-term exposure levels, but would also generally control the overall distribution of 24-hour exposure levels, resulting 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).

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, EPA evaluated but did not use an alternate approach that considered short- and long-term exposure evidence, analyses, and standards independently. The 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 a key observation from the quantitative risk assessment that most of the aggregated annual risk associated with short-term $PM_{2.5}$ exposures through a year results from the large number of days during which the 24-hour average concentrations are in the low- to mid-range, well 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 38668 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 $PM_{2.5}$ exposure-related effects occurs at concentrations near the long-term (e.g., annual) average in the short-term exposure studies. The 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 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 at that time, and because even small changes in annual means in this concentration range could make a 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[2], or a value resulting from an average of measurements from multiple community-wide air quality monitoring sites that met specific criteria and constraints (i.e., "spatial averaging"; 62 FR 38672). 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). The selection of the level of the 24-hour standard was done in conjunction with having selected the form of the 24-hour standard to be based on the concentration measured at each population-oriented monitor[3] within an area (62 FR 38674).

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 that would protect against effects associated with short-term exposures. The Administrator relied upon evidence from long-term exposure studies as the principal basis for

[2] As outlined in section 1.3, *community-wide* monitoring sites are considered beyond the zone of influence of a single source, and should have a neighborhood- to urban-scale zone of representation. The principal purpose of community-oriented monitoring sites is to approximate the long- and short-term exposures of large numbers of people where they live, work, and play. See 40 CFR part 58 for additional information.

[3] As outlined in section 1.3, *population-oriented* monitoring sites represent residential areas, commercial areas, recreational areas, industrial areas where workers from more than one company are located, and other areas where a substantial number of people may spend a significant fraction of their day. See 40 CFR part 58, and especially the definitions in section 58.1 and the provisions of section 58.30, for additional information.

selecting the level of the annual $PM_{2.5}$ standard that would protect against effects associated with long-term exposures.

With respect to quantitative risk-based considerations, 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 the levels of the revised standards (71 FR 61174/1-2). The Administrator more heavily weighed the implications of the uncertainties associated with the quantitative risk assessment than CASAC did in their comments on the proposed rulemaking. Specifically, in CASAC's request for reconsideration,[4] they 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 the primary annual $PM_{2.5}$ standard, the Administrator placed the greatest weight on the long-term means of the concentrations associated with mortality effects in 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 studies provided "evidence of generally robust associations and provide[d] a basis for greater confidence in the reported associations than in the last review," and the extended ACS study provided "new evidence of mortality related to lung cancer and further 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 (CHS), respectively (Dockery et al. 1996, Gauderman et al., 2002). 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 long-term mortality studies the Administrator regarded as "key" and "basically at the same level" as the long-term average concentrations in the long-term respiratory morbidity studies. In the judgment of the Administrator, the two long-term

[4] As summarized in section 1.2.2, subsequent to the January 17, 2006 proposed rule (71 FR 2620), CASAC provided additional advice to EPA in a letter to the Administrator requesting reconsideration of CASAC's recommendations, including its recommendation on the primary annual $PM_{2.5}$ standard (Henderson, 2006a).

respiratory morbidity studies of children 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 strengthened the standard by tightening the criteria for use of spatial averaging. Based on a much larger set of $PM_{2.5}$ air quality data than was available in the 1997 review, analyses were conducted concerning the potential for disproportionate impacts on potentially vulnerable populations. These 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).[5]

In revising 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 greatest weight on the much expanded body of epidemiological evidence from U.S. and Canadian short-term $PM_{2.5}$ exposure studies with more reliable air quality data that was reanalyzed to address statistical modeling issues. The Administrator recognized that these studies provided no evidence of clear effect thresholds or lowest-observed effect levels. Nonetheless, in focusing on the 98^{th} 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 $PM_{2.5}$ concentrations could reasonably be expected to be associated with serious health effects. The Administrator concluded 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 98^{th} percentile concentrations (71 FR 61168/3).

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

As noted above in section 1.2.3, 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 public health and environmental groups (American Lung

[5] 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 limited access to health care (US EPA, 2004, section 9.2.4.5).

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 Court of Appeals for the District of Columbia Circuit (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 primary 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*. In so holding, the court emphasized that the Administrator had failed to consider the short-term studies when setting the annual standard, and failed to provide a reasoned explanation of why it had done so. Id. at 521.

With respect to protection from long-term exposure to fine particles, the court found that EPA failed to adequately explain how the 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 the 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.

In remanding the primary annual $PM_{2.5}$ standard for reconsideration, the court did not vacate the standard. Id. at 530.

2.1.3 General Approach Used in Current Review

This review is based on an assessment of a much expanded body of epidemiological evidence, more extensive air quality data and analyses, and a more comprehensive quantitative risk assessment relative to the information available in past reviews, as presented in the ISA and RA. As a result, staff's general approach to reaching conclusions about the adequacy of the current suite of $PM_{2.5}$ standards and potential alternative standards that are appropriate to consider is broader and more integrative than in past reviews. Our general approach also reflects consideration of the issues raised by the court in its remand of the primary annual $PM_{2.5}$ standard, since decisions made in this review, and the rationales for those decisions, will comprise the Agency's response to the remand.

Our general approach takes into account both evidence-based and risk-based considerations, and the uncertainties related to both types of information, as well as advice from CASAC (Samet, 2010c,d) and public comments on the first and second draft PAs (US EPA, 2010c,f). In so doing, we are seeking to provide as broad an array of policy 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 this document.

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, as was done in the 1997 review, rather than to consider each standard separately, as was done in the 2006 review.[6] As EPA recognized in 1997, there are various ways to combine two standards to achieve an appropriate degree of public health protection. 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 are likely to be of a more regional or more localized nature.

[6] By utilizing this approach, the Agency would also be responsive to the remand of the 2006 standard. As noted in section 2.1.2 above, the D.C. Circuit, in remanding the 2006 primary annual $PM_{2.5}$ standard, concluded that the Administrator had failed to adequately explain why an annual standard was sufficiently protective in the absence of consideration of the long-term mean $PM_{2.5}$ concentrations in short-term exposure studies as well, and likewise had failed to explain why a 24-hour standard was sufficiently protective in the absence of consideration of the effect of an annual standard on reducing the overall distribution of 24-hour average $PM_{2.5}$ concentrations. 559 F. 3d at 520-24.

In considering the combined effect of annual and 24-hour standards, we recognize that changes in $PM_{2.5}$ air quality designed to meet an annual standard would likely result not only in lower annual average $PM_{2.5}$ concentrations but also in fewer and lower peak 24-hour $PM_{2.5}$ concentrations. We also recognize that changes designed to meet a 24-hour standard would result not only in fewer and lower peak 24-hour $PM_{2.5}$ concentrations but also in lower annual average $PM_{2.5}$ concentrations. Thus, either standard could be viewed as providing protection for both short- and long-term exposures, with the other standard serving to address situations where the daily peak and annual average concentrations are not consistently correlated.

With respect to the currently available evidence, we note the short-term exposure studies are primarily drawn from epidemiological studies that associated variations in area-wide effects with monitor(s) that gauged the variation in daily $PM_{2.5}$ concentrations over the course of several years. The strength of the associations in these data is demonstrably in the numerous "typical" days within the air quality distribution, not on the peak days. Furthermore, based on the quantitative risk assessments conducted for this and previous reviews, we recognize that much, if not most of the aggregated 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 (see section 2.2.2; US EPA, 2010a, section 3.1.2.2). In addition, there is no evidence suggesting that risks associated with long-term exposures are likely to be disproportionately driven by peak 24-hour concentrations.[7] For these reasons, strategies that focus primarily on reducing peak days are less likely to achieve reductions in $PM_{2.5}$ concentrations that are most strongly associated with the observed health effects compared to an approach that concentrates on reducing the more typical part of the air quality distribution. Furthermore, a policy approach that focuses on reducing peak exposures would most likely result in more uneven public health protection across the U.S. by either providing inadequate protection in some areas or overprotecting in other areas (US EPA, 2010a, section 5.2.3).

Staff concludes a policy goal of setting a "generally controlling" annual standard that will lower a wide range of ambient 24-hour $PM_{2.5}$ concentrations, as opposed to focusing on control of peak 24-hour $PM_{2.5}$ concentrations, is the most effective and efficient way to reduce total population risk and so provide appropriate protection. This approach would likely reduce aggregate risks associated with both long- and short-term exposures with more consistency than a generally controlling 24-hour standard and would likely avoid setting national standards that could result in relatively uneven protection across the country, due to setting standards that are either more or less stringent than necessary in different geographical areas.

[7] In confirmation, a number of studies that have presented analyses excluding higher PM concentration days reported a limited effect on the magnitude of the effect estimates or statistical significance of the association (e.g., Dominici, 2006b; Schwartz et al, 1996; Pope and Dockery, 1992).

However, we conclude that an annual standard intended to serve 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. As a result, in conjunction with a generally controlling annual standard, we conclude that it is appropriate to consider setting a 24-hour standard to provide supplemental protection, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods.

Our consideration of the protection afforded by the current and alternative suites of standards focuses on $PM_{2.5}$-related health effects associated with long-term exposures, for which the magnitude of quantitative estimates of risks to public health generated in the risk assessment is appreciably larger in terms of overall incidence and percent of total mortality or morbidity effects than for short-term $PM_{2.5}$-related effects. We also consider effects and estimated risks associated with short-term exposures. In both cases, we place greatest weight on health effects that have been judged in the ISA to have a *causal* or *likely causal relationship* with $PM_{2.5}$ exposures, while also considering health effects judged to be *suggestive of a causal relationship* or that focus on specific susceptible populations. We focus on epidemiological studies conducted in the U.S. and Canada, as studies in other countries reflect air quality and exposure patterns that are not necessarily typical of the U.S.,[8] 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 consider evidence from large multi-city studies, as well as single-city studies.

In translating information from epidemiological studies into the basis for reaching staff conclusions on the adequacy of the current suite of standards (section 2.2.1), we consider a number of factors. As an initial matter, we consider the extent to which the currently available evidence and related uncertainties strengthens or calls into question conclusions from the last review regarding associations between fine particle exposures and health effects. We also consider evidence on susceptible populations and potential impacts on such populations. Further, we explore the extent to which $PM_{2.5}$-related health effects have been observed in areas where air quality distributions extend to lower levels than previously reported or in areas that would likely have met the current suite of standards.

In translating information from epidemiological studies into the basis for reaching staff conclusions on alternative standard levels for consideration (section 2.3.4), we first recognize the absence of discernible thresholds in the C-R functions from long- and short-term $PM_{2.5}$ exposure

[8] Nonetheless, we recognize the importance of all studies, including international studies, in the ISA's assessment of the weight of the evidence that informs causality determinations.

studies (US EPA, 2009a, section 2.4.3). In the absence of any discernible thresholds, our general approach for identifying appropriate standard levels for consideration involves characterizing the range of $PM_{2.5}$ concentrations over which we have the most confidence in the associations reported in epidemiological studies. In so doing, we recognize that there is no single factor or criterion that comprises the "correct" approach, but rather there are various approaches that are reasonable to consider for characterizing the confidence in the associations and the limitations and uncertainties in the evidence. Identifying the implications of various approaches in reaching conclusions on the range of alternative standard levels that is appropriate to consider can help inform decisions that are made to either retain or revise the standards. Final decisions will necessarily also take into account public health policy judgments as to the degree of health protection that is to be achieved.

In reaching staff conclusions on the range of *annual standard levels* that is appropriate to consider, we focus on identifying an annual standard that provides protection for effects associated with both long- and short-term exposures, as discussed above. In so doing, we explore different approaches for characterizing the range of $PM_{2.5}$ concentrations over which our confidence in associations for both long- and short-term exposures is greatest, as well as the extent to which our confidence is reduced at lower $PM_{2.5}$ concentrations.

The approach that most directly addresses this issue considers studies that present confidence intervals around C-R relationships, and in particular, analyses that average across multiple C-R models rather than considering a single C-R model.[9] We explore the extent to which such analyses have been published for studies of health effects associated with long- or short-term $PM_{2.5}$ exposures. Such analyses could potentially be used to characterize a concentration below which uncertainty in a C-R relationship substantially increases or is judged to be indicative of an unacceptable degree of uncertainty about the existence of a continuing C-R relationship. We believe that identifying this area of uncertainty in the C-R relationship can be used to inform identification of alternative standard levels that are appropriate to consider.

We also take into account the general approach used in previous PM reviews which focused on consideration of alternative standard levels that were somewhat below the long-term mean $PM_{2.5}$ concentrations reported in epidemiological studies. This approach recognizes that the strongest evidence of $PM_{2.5}$-related associations occurs at concentrations near the long-term (i.e., annual) mean. In using this approach, we place greatest weight on those long- and short-

[9] This is distinct from confidence intervals around C-R relationships that are related to the magnitude of effect estimates generated at specific $PM_{2.5}$ concentrations (i.e., point-wise confidence intervals) and that are relevant to the precision of the effect estimate across the air quality distribution, rather than to our confidence in the existence of a continuing C-R relationship across the entire air quality distribution on which a reported association was based.

term exposure studies that reported statistically significant associations with mortality and morbidity effects.

In extending this approach, we also consider information beyond a single statistical metric of $PM_{2.5}$ concentrations (i.e., the mean) to the extent such information is available. In so doing, we employ distributional statistics (i.e., statistical characterization of an entire distribution of data) to identify the broader range of $PM_{2.5}$ concentrations that were most influential in generating health effect estimates in epidemiological studies. Thus, we consider the range of $PM_{2.5}$ concentrations where the data analyzed in the study (i.e., air quality and population-level data, as discussed below) are most concentrated, specifically, the range of $PM_{2.5}$ concentrations around the long-term mean over which our confidence in the associations observed in the epidemiological studies is greatest. We then focus on the lower part of this range and seek to characterize where in the distributions the data become appreciably more sparse and, thus, where our understanding of the associations correspondingly becomes more uncertain. We recognize there is no one percentile value within a given distribution that is the most appropriate or "correct" way to characterize where our confidence in the associations becomes appreciably lower. We judge that the range from the 25^{th} to 10^{th} percentiles is a reasonable range to consider as a region where we have appreciably less confidence in the associations.[10]

In considering distributional statistics from epidemiological studies, we first recognize that there are two types of population-level metrics that are useful to consider in identifying the $PM_{2.5}$ concentrations most influential in generating the health effect estimates reported in the epidemiological studies. The most relevant information is the distribution of health events (e.g., deaths, hospitalizations) occurring within a study population in relation to the distribution of $PM_{2.5}$ concentrations. However, in recognizing that access to health event data can be restricted, we also consider the number of study participants within each study area as a reasonable surrogate for health event data.[11]

In the absence of data on the number of health events or study participants, we consider the distribution of $PM_{2.5}$ concentrations across study areas in multi-city studies as representative of the $PM_{2.5}$ concentrations likely experienced by study participants, which are integral to the generation of effect estimates. This approach is particularly relevant for identifying the range of

[10] In the PM NAAQS review completed in 2006, staff recognized that the evidence of an association in any epidemiological study is "strongest at and around the long-term average where the data in the study are most concentrated. For example, the interquartile range of long-term average concentrations within a study [with a lower bound of the 25^{th} percentile] or a range within one standard deviation around the study mean, may reasonably be used to characterize the range over which the evidence of association is strongest" (US EPA, 2005, p. 5-22). A range of one standard deviation around the mean represents approximately 68% of normally distributed data, and, below the mean falls between the 25^{th} and 10^{th} percentiles.

[11] A limitation of applying population data as a substitute for the number of the health events occurring in a study area is the recognition that baseline incidence rates of health events will vary across study areas.

$PM_{2.5}$ concentrations most influential in generating the effect estimates in short-term exposure studies (e.g., time-series studies). In short-term exposure studies, a similar number of events are likely occurring on a daily basis and, thus, information on the $PM_{2.5}$ air quality distributions provides a better approximation of a study participant's likely exposure in relation to the observed health effects as compared to long-term exposure studies where individual study participant's exposures change over the course of the study follow-up period (Samet, 2010d, p. 2).

We recognize that an approach considering analyses of confidence intervals around C-R functions is intrinsically related to an approach that considers different distributional statistics. Both of these approaches can be employed to identify the range of $PM_{2.5}$ concentrations over which we have the most confidence in the associations reported in epidemiological studies.

In applying these approaches, we consider $PM_{2.5}$ concentrations from long- and short-term $PM_{2.5}$ exposure studies using *composite monitor distributions*.[12] For multi-city studies, this distribution reflects concentrations averaged across ambient monitors within each area included in a given study and then averaged across study areas for an overall study mean $PM_{2.5}$ concentration. Beyond considering air quality concentrations based on composite monitor distributions, in the second draft PA we also considered $PM_{2.5}$ concentrations based on measurements at the monitor within each area that records the highest concentration (i.e., *maximum monitor*) (US EPA, 2010f, sections 2.1.3 and 2.3.4.1).[13] Although consideration of alternative annual standard levels could be based on either composite or maximum monitor distributions, we conclude that it is reasonable to place more weight on an approach based on composite monitor distributions, which represent the $PM_{2.5}$ concentrations typically presented and used in epidemiological analyses. Such composite monitor distributions provide a direct link between $PM_{2.5}$ concentrations and the observed health effects reported in both long- and short-term exposure studies.

In reaching staff conclusions on alternative standard levels that are appropriate to consider, we have also included a broader consideration of the uncertainties related to the C-R relationships from multi-city long- and short-term exposure studies. Most notably, these uncertainties relate to our currently limited understanding of the heterogeneity of relative risk estimates in areas across the country, which may be attributed, in part, to the potential for

[12] Using the term "composite monitor" does not imply we can identify one monitor that represents the air quality evaluated in a specific study area.

[13] The maximum monitor distribution is relevant because it is generally used to determine whether a given standard is met in an area and the extent to which ambient $PM_{2.5}$ concentrations need to be reduced in order to bring an area into attainment with the standard. However, maximum monitor distributions represent a far less robust metric than composite monitor distributions for consideration of alternative annual standard levels because they are available for only a few epidemiological studies.

different components within the mix of ambient fine particles to differentially contribute to health effects observed in the studies and to exposure-related factors. In addition, uncertainties remain in more fully understanding the role of $PM_{2.5}$ in relationship to the roles of gaseous co-pollutants within complex ambient mixtures.

We recognize the level of protection afforded by the NAAQS relies both on the level and the form of the standard. We conclude that a policy approach that uses data based on composite monitor distributions to identify alternative standard levels, and then compares those levels to concentrations at maximum monitors to determine if an area meets a given standard, directionally has the potential to build in some margin of safety.[14] This conclusion is consistent with CASAC's comments on the second draft PA, in which CASAC expressed its preference for focusing on an approach using composite monitor distributions "because of its stability, and for the additional margin of safety it provides" when "compared to the maximum monitor perspective" (Samet, et al., 2010d, pp. 2 to 3).

In reaching staff conclusions on alternative *24-hour standard levels* that are appropriate to consider for setting a 24-hour standard intended to supplement the protection afforded by a generally controlling annual standard, we consider currently available short-term $PM_{2.5}$ exposure studies. The evidence from these studies informs our understanding of the protection afforded by the suite of standards against effects associated with short-term exposures. In considering the short-term exposure studies, we evaluate both the distributions of 24-hour $PM_{2.5}$ concentrations, with a focus on the 98^{th} percentile concentrations to match the form of the current 24-hour $PM_{2.5}$ standard, to the extent such data were available, as well as the long-term mean $PM_{2.5}$ concentrations reported in these studies. In addition to considering the epidemiological evidence, we also consider air quality information based on county-level 24-hour and annual design values to understand the policy implications of the alternative standard levels supported by the underlying science. In particular, we consider the extent to which different combinations of alternative annual and 24-hour standards would support the policy goal of focusing on a generally controlling annual standard in conjunction with a 24-hour standard that would provide supplemental protection. Based on the evidence-based considerations outlined above, we then develop integrated conclusions with regard to alternative suites of standards, including both annual and 24-hour standards that we conclude are appropriate to consider in this review based

[14] Statistical metrics (e.g., means) based on composite monitor distributions may be identical to or below the same statistical metrics based on maximum monitor distributions. For example, some areas may have only one monitor, in which case the composite and maximum monitor distributions will be identical in those areas. Other areas may have multiple monitors that may be very close to the monitor measuring the highest concentrations, in which case the composite and maximum monitor distributions could be similar in those areas. Still other areas may have multiple monitors that may be separately impacted by local sources in which case the composite and maximum monitor distributions could be quite different and the composite monitor distributions may be well below the maximum monitor distributions.

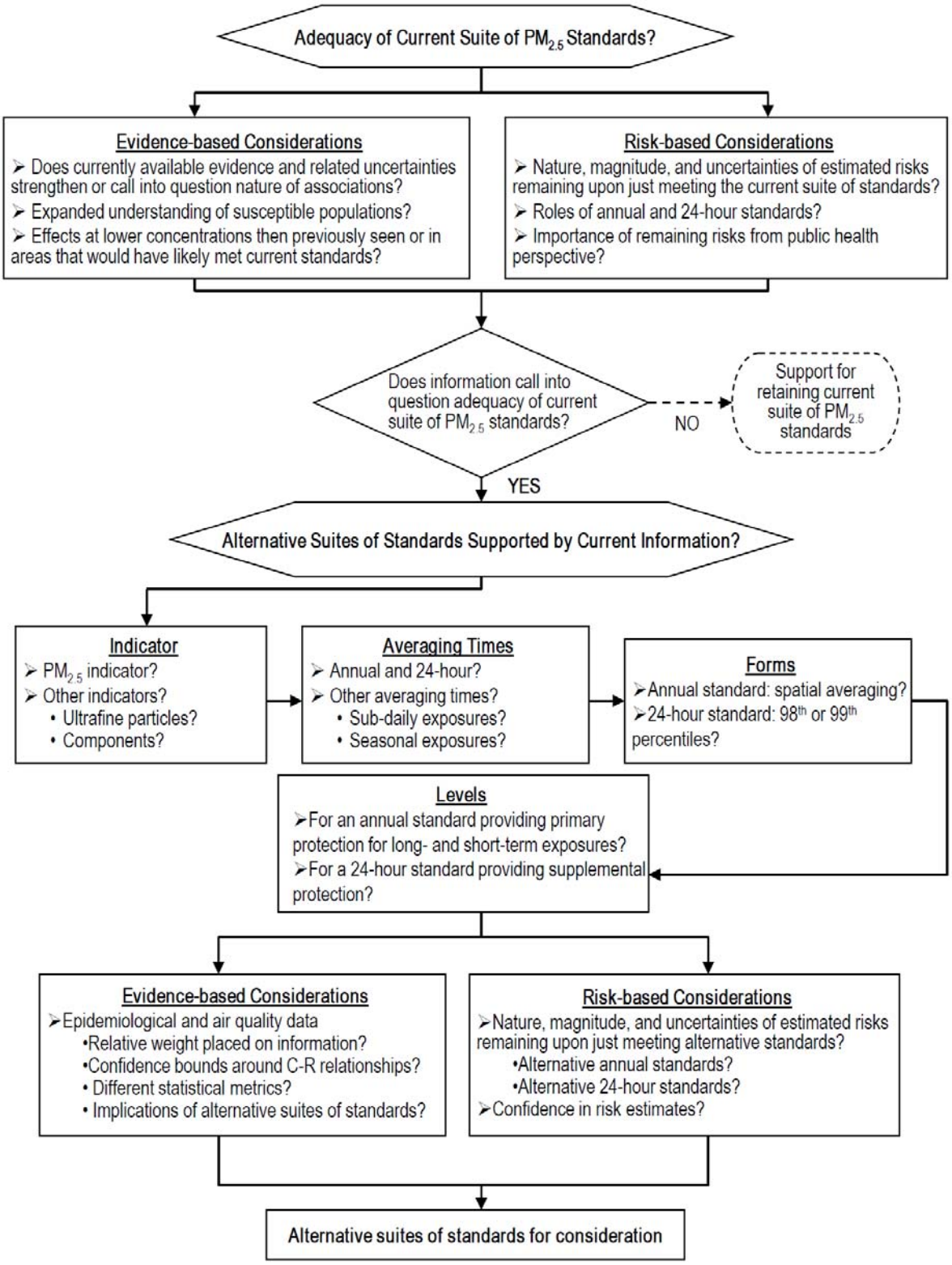
on the currently available evidence and air quality information. In so doing, we discuss the roles that each standard might be expected to play in the protection afforded by alternative suites of standards.

Beyond these evidence-based considerations, we also consider the quantitative risk estimates and the key observations presented in the 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- and short-term $PM_{2.5}$ exposures (US EPA, 2010a). As part of our risk-based considerations, we consider 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 also characterize 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 take 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 consider additional analyses characterizing the representativeness of the urban study areas within a broader national context to understand 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.

Staff conclusions related to the primary $PM_{2.5}$ standards 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) potential alternative standards, if any, that are appropriate to consider in this review to protect against 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: the indicator, averaging time, form, and level.

Figure 2-1 provides an overview of the policy relevant questions that frame our review, as discussed more fully below. We believe that this general approach provides a comprehensive basis to help inform the judgments required of the Administrator in reaching decisions about the current and potential alternative primary fine particle standards and in responding to the remand of the 2006 primary annual $PM_{2.5}$ standard.

Figure 2-1. Overview of Approach for Review of Primary $PM_{2.5}$ Standards



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 our consideration of this broad question, we address a series of more specific questions to aid in considering the currently available scientific evidence (section 2.2.1) and the results of recent quantitative risk analyses (section 2.2.2) 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 the RA (US EPA, 2009a; US EPA, 2010a). CASAC advice regarding the adequacy of the current suite of $PM_{2.5}$ standards is summarized in section 2.2.3. Staff conclusions regarding the adequacy of the current suite of $PM_{2.5}$ standards are presented in section 2.2.4.

2.2.1 Evidence-based Considerations

Our review of the adequacy of the current suite of primary $PM_{2.5}$ standards begins by considering the strength of the evidence, susceptible populations, and the air quality distributions over which health effects associations have been reported.

- **To what extent does the currently 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 long- and short-term exposures to $PM_{2.5}$ and health effects, we note that in the last review EPA concluded that there was "strong epidemiological evidence" for linking long-term $PM_{2.5}$ exposures with cardiovascular-related and lung cancer mortality and respiratory-related morbidity and for linking short-term $PM_{2.5}$ exposures with cardiovascular-related and respiratory-related mortality and 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 decision making 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 greatly expand and provide stronger support for a number of potential biologic mechanisms or pathways for cardiovascular and respiratory effects associated with long- and short-term PM exposures (US EPA, 2009a, p 2-17; chapter 5; Figures 5-4 and 5-5).

With regard to causal inferences described in the ISA, we note that since the last review EPA has developed a more formal framework for reaching causal determinations that draws upon the assessment and integration of evidence from across epidemiological, controlled human exposure, and toxicological studies, and the related uncertainties, that ultimately influence our understanding of the evidence (US EPA, 2009a, section 1.5). This framework employs 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).[15]

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 long- and short-term exposures to $PM_{2.5}$ and mortality and cardiovascular effects including cardiovascular-related mortality. The ISA also concludes that the collective evidence continues to support a *likely causal relationship* between long- and short-term $PM_{2.5}$ exposures and respiratory effects, including respiratory-related mortality. Further, the ISA concludes that the currently available 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 effects (e.g., lung cancer mortality). Table 2-1 summarizes these causal determinations (US EPA, 2009a, sections 2.3.1 and 2.6).

[15] Causal inferences, as discussed in the ISA, are based not only on the more expansive epidemiological evidence available in this review but also reflect consideration of important progress that has been made to advance our understanding of a number of potential biologic modes of action or pathways for PM-related cardiovascular and respiratory effects (US EPA 2009a, chapter 5).

Table 2-1. Summary of Causal 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, 2009a, Table 2-6.

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

With regard to *mortality*, the ISA concludes that newly available evidence significantly strengthens the link between 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, including 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 (US EPA, 2009a, section 7.6). For example, the Women's Health Initiative (WHI) study reported effects of $PM_{2.5}$ on cardiovascular-related mortality in post-menopausal women with no previous history of cardiac disease (Miller et al., 2007), based on one year of air quality data and multiple years of health event data. Additionally, multiple studies observed $PM_{2.5}$-associated mortality among older adults using Medicare data (Eftim et al., 2008; Zeger et al., 2007, 2008). Collectively, these new studies, along with 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).

The strength of the causal relationship between long-term $PM_{2.5}$ exposure and mortality is also built upon new studies providing evidence of improvement in community health following reductions in ambient fine particles. Pope et al. (2009) 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 reported that reductions in ambient fine particles 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, with the fine particle reductions reported to be associated with an estimated increase in mean life expectancy across the entire population 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 (Laden et al., 2006). Another extended follow-up to the Harvard Six Cities study investigated the delay between changes in ambient $PM_{2.5}$ concentrations and changes in mortality (Schwartz et al., 2008) and reported that the effects of changes in $PM_{2.5}$ were seen within the two years prior to death (US EPA, 2009a, p. 7-92; Figure 7-9). Looking more broadly across studies, the ISA concludes, "Generally, these results indicate a developing coherence of the air pollution mortality literature, suggesting that the health benefits from reducing air pollution do not require a long latency period and would be expected within a few years of intervention" (US EPA, 2009a, p. 7-95).

With regard to *cardiovascular effects,* several new 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 comes from 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 study (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) reported 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 for IHD-related mortality associated with long-term $PM_{2.5}$ exposure (US EPA, 2009a, p. 7-84, Figure 7-7).

With regard to *cardiovascular-related morbidit*y associated with long-term $PM_{2.5}$ exposures, studies were not available in the last review. Recent studies, however, 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). 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 cardiovascular

disease (CVD) and cerebrovascular disease (CBVD), including myocardial infarction (MI), coronary artery revascularization (e.g., bypass graft, angioplasty, stent, atherectomy), congestive heart failure (CHF), and stroke. The most important new evidence comes from the WHI study which provides evidence of nonfatal cardiovascular events including both coronary and cerebrovascular events (Miller et al., 2007; US EPA, 2009a, sections 7.2.9 and 7.6.1). Toxicological studies provide supportive evidence that the cardiovascular morbidity effects observed in long-term exposure epidemiological studies are biologically plausible and coherent with studies of cardiovascular-related mortality as well as with studies of cardiovascular-related effects associated with short-term exposures to $PM_{2.5}$, as described below (US EPA, 2009a, p 7-19).

With regard to *respiratory effects*, the ISA concludes that extended analyses of studies available in the last review as well as new epidemiological studies conducted in the U.S. and abroad provide stronger evidence of *respiratory-related morbidity* associated with long-term $PM_{2.5}$ exposure. The strongest evidence for respiratory-related effects available in this review is from studies that 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).[16] Specifically, extended analyses of the Southern California CHS provided evidence that clinically important deficits in lung function[17] associated with children's long-term exposure to $PM_{2.5}$ persisted into early adulthood (U.S., EPA, 2009a, p. 7-27; Gauderman et al., 2004). Additional analyses of the CHS cohort reported 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 of $PM_{2.5}$ on the association between lung function and asthma incidence (US EPA, 2009, 7-24; Islam et al., 2007). The outcomes observed in these more recent reports from the Southern California CHS, including evaluation of a broader range of endpoints and longer follow-up periods, were larger in magnitude and more precise than previously reported. 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 provided 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).

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[16] 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 growth in areas where PM_{10} is dominated by $PM_{2.5}$" (US EPA, 2009a, p. 2-12).

[17] 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, pp. 7-29 to 7-30). The primary NAAQS for SO_2 also includes this interpretation for FEV_1 (75 FR 35525, June 22, 2010).

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).

With regard to *respiratory-related mortality* associated with long-term $PM_{2.5}$ exposure, the ISA concludes that the evidence is "limited and inconclusive" (US EPA, 2009a, p. 7-41). The extended follow-up of the Harvard Six Cities study reported a positive but statistically nonsignificant association between long-term $PM_{2.5}$ exposure and respiratory-related mortality (Laden et al., 2006), whereas Pope et al. (2004) found no association in the ACS cohort (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 and infant mortality provide some support for the weak respiratory-related mortality effects observed.

Beyond effects considered to have causal or likely causal relationships with long-term $PM_{2.5}$ exposure as discussed above, the following health outcomes are classified as having evidence *suggestive of a causal relationship* with long-term $PM_{2.5}$ exposure: (1) reproductive and developmental effects and (2) cancer, mutagenicity, and genotoxicity effects (US EPA, 2009a, Table 2-6). With regard to *reproductive and developmental effects*, the ISA notes, "[e]vidence is accumulating for $PM_{2.5}$-related 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, and a significant association between postnatal exposure to $PM_{2.5}$ and 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). While toxicological studies provide some evidence that supports an association between long-term $PM_{2.5}$ exposure and adverse reproductive and developmental outcomes, there is "little mechanistic information or biological plausibility for an association between long-term PM exposure and adverse birth outcomes (e.g., low birth weight, infant mortality)" (US EPA, 2009a, p. 2-13).

With regard 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, p. 2-13 and 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) as did the extended follow-up to the Harvard Six Cities study when considering the entire 25-year follow-up period (Laden et al., 2006). 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), although toxicological studies of carcinogenicity, mutagenicity, and genotoxicity generally reported mixed results (US EPA, 2009a, section 7.5).

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 of the influence of local or regional 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*, new U.S. and Canadian multi-city and single-city $PM_{2.5}$ 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). In an analysis of the National Morbidity, Mortality, and Air Pollution Study (NMMAPS) data, Dominici et al. (2007a) reported associations between fine particle exposures and all-cause and cardiopulmonary-related mortality (US EPA, 2009a, p. 6-175, Figure 6-26). In a study of 112 U.S. cities, Zanobetti and Schwartz (2009) reported positive associations (in 99% of the cities) and frequently statistically significant associations (in 55% of the cities) between short-term $PM_{2.5}$ exposure and total (non-accidental) mortality (US EPA, 2009a, pp 6-176 to 6-179; Figures 6-23 and 6-24).[18] A Canadian 12-city study (Burnett et al., 2004) is generally

[18] Single-city Bayes-adjusted effect estimates for the 112 cities analyzed in Zanobetti and Schwartz (2009) were provided by the study author (personal communication with Dr. Antonella Zanobetti, 2009; see also US EPA, 2009a, Figure 6-24).

consistent with an earlier Canadian 8-city study (Burnett and Goldberg, 2003). Both studies reported a positive and statistically significant association between short-term $PM_{2.5}$ exposure and nonaccidental mortality (US EPA, 2009a, p 6-182, Figure 2-1), although the influence of NO_2 and limited $PM_{2.5}$ data for several years during the study period somewhat diminished the findings reported in the 12-city study. Collectively, these studies provide generally consistent and much stronger evidence for $PM_{2.5}$-associated mortality than the evidence available in the last review.

With regard to *cardiovascular effects*, new multi-city as well as single-city short-term $PM_{2.5}$ exposure studies conducted since the last review support a largely positive and frequently statistically significant association between short-term exposure to $PM_{2.5}$ and cardiovascular-related morbidity and mortality, substantiating prior findings. For example, among a multi-city cohort of older adults participating in the Medicare Air Pollution Study (MCAPS), investigators reported evidence of a positive association between short-term $PM_{2.5}$ exposures and hospital admissions related to cardiovascular outcomes (US EPA, 2009a, pp. 6-57 to 58; Dominici et al, 2006a; Bell et al, 2008). The strongest evidence for cardiovascular effects has been observed predominantly for hospital admissions and emergency department visits for IHD and 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 WHI study that reported a positive but statistically nonsignificant association between short-term exposure to $PM_{2.5}$ and electrocardiogram (ECG) measures of myocardial ischemia (Zhang et al., 2009).

In focusing on *respiratory effects*, the strongest evidence from short-term $PM_{2.5}$ exposure studies has been observed for respiratory-related emergency department visits and hospital admissions 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, 2009a, p. 2-10). Furthermore, the comparatively larger body of toxicological evidence since the last review is coherent with the evidence from epidemiological and controlled human exposure studies that examined short-term exposures to $PM_{2.5}$ and respiratory effects (US EPA 2009a, section 6.3.10.1).

Uncertainties in the Evidence

With respect to understanding the nature and magnitude of $PM_{2.5}$-related risks, as discussed above, we recognize that epidemiological studies evaluating health effects associated with long- and short-term $PM_{2.5}$ exposures have reported heterogeneity in responses both within and between cities and geographic regions across the U.S. This heterogeneity may be attributed, in part, to differences in the fine particle composition. However, the currently available evidence and limited availability of city-specific $PM_{2.5}$ speciation data does not allow conclusions to be drawn regarding the relative toxicity of $PM_{2.5}$ components, or group of components associated with any source categories of fine particles in different locations. Overall, the ISA concludes "that many constituents of $PM_{2.5}$ can be linked with multiple health effects, and 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, p. 2-17).

Exposure measurement error is also an important source of uncertainty (US EPA, 2009a, section 3.8.6). Variability in the associations observed across $PM_{2.5}$ epidemiological studies may be due in part to exposure error related to measurement-related issues, the use of central fixed-site monitors to represent population exposure to $PM_{2.5}$, models used in lieu of or to supplement ambient measurements, and our limited understanding of factors that may influence exposures (e.g., topography, the built environment, climate, source characteristics, ventilation usage, personal activity patterns, photochemistry). As noted in the ISA, exposure measurement error can introduce bias and increased uncertainty in associated health effect estimates (US EPA, 2009a, p. 2-17).

In particular, we note that there are challenges with interpreting differences in health effects observed in the eastern versus western parts of the U.S, including evaluating effects stratified by seasons. As noted in section 2.3.2 of the ISA, western U.S. counties tend to be larger and more topographically diverse than eastern U.S. counties. These characteristics may contribute to a higher likelihood of exposure measurement error influencing health effect estimates. Seasonal differences in effects may be related to $PM_{2.5}$ composition as well as regional differences in climate and infrastructure that may affect time spent outdoors or indoors, housing characteristics including air conditioning usage, and differences in baseline incidence rates (US EPA, 2009a, p. 3-182). In consideration of these differences, however, the ISA notes "…the available evidence and the limited amount of city-specific speciated $PM_{2.5}$ data does not allow conclusions to be drawn that specifically differentiate effects of PM in different locations" (US EPA 2009a, p. 2-17). Therefore, we recognize that important uncertainties remain in this review related to understanding the temporal and spatial variability in $PM_{2.5}$ concentrations, including $PM_{2.5}$ components, and associated health impacts across different geographic areas and seasons.

In addition, where $PM_{2.5}$ and other pollutants (e.g., O_3, NO_2, CO) are correlated, it can be difficult to distinguish the effects of the various pollutants in the ambient mixture (i.e, co-pollutant confounding).[19] The use of multipollutant models is generally used in air pollution epidemiological studies to provide insights into the potential for confounding or interaction among pollutants (US EPA, 2009a, p. 1-16). A number of research groups have found the effects of various indicators of PM, including $PM_{2.5}$, and gaseous copollutants to be independent of one another (US EPA, 2009a, Figures 6-9 and 6-15). Although many recent US multi-city studies did not analyze multipollutant models, evidence from single-city studies available in the last review suggest that gaseous copollutants do not confound the $PM_{2.5}$-related mortality association, which is further supported by studies that examined the PM_{10}-mortality relationship (US EPA, 2009a, p. 6-182 and 6-201).

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 long- and short-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 relationship between long- and short-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 relationship between long- and short-term exposure to $PM_{2.5}$ and respiratory effects. With respect to evidence suggestive of a causal relationship 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 conclude that there is stronger and more consistent and coherent support for associations between long- and short-term $PM_{2.5}$ exposure and a broader range of health outcomes than was available in the last review, providing the basis for fine particle standards 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 addressing the following question:

[19] A copollutant meets the criteria for potential confounding in PM-health associations if: (1) it is a potential risk factor for the health effect under study; (2) it is correlated with PM; and (3) it does not act as an intermediate step in the pathway between PM exposure and the health effect under study (US EPA, 2004, p. 8-10).

- **To what extent does the currently available scientific evidence expand our understanding of susceptible populations?**

Specific groups within the general population, referred to as susceptible populations, are at increased risk for experiencing adverse health effects related to PM exposures. These groups could exhibit a greater risk of PM-related health effects than the general population for a number of reasons including, being affected by lower concentrations of PM, experiencing a larger health impact at a given PM concentration, and/or being exposed to higher PM concentrations than the general population. Given the heterogeneity of individual responses to PM exposures, the severity of the health effects experienced by a susceptible population may be much greater than that experienced by the population at large.

As summarized below, the currently available epidemiological and controlled human exposure evidence expands our understanding of previously identified susceptible populations (i.e., children, older adults, and individuals with pre-existing heart and lung disease) and supports the identification of additional susceptible populations (e.g., persons with lower socioeconomic status (SES), genetic differences) (US EPA, 2009a, section 2.4.1, Table 8-2). In addition, toxicological studies provide underlying support for the biological mechanisms that potentially lead to increased susceptibility to PM-related health effects.

Lifestages: Children and Older Adults

Two different lifestages have been associated with increased susceptibility to PM-related health effects: childhood (i.e., less than 18 years of age) and older adulthood (i.e., 65 years of age and older). Childhood represents a lifestage where susceptibility to PM exposures may be related to the following observations: 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 the developing lung is prone to damage, including irreversible effects, from environmental pollutants as it continues to develop through adolescence (US EPA, 2009a, section 8.1.1.2). Older adults represent a lifestage where susceptibility to PM-associated health effects may be related to the higher prevalence of pre-existing cardiovascular and respiratory diseases found in this age group compared to younger age groups as well as the gradual decline in physiological processes that occur as part of the aging process (US EPA, 2009a, section 8.1.1.1).

With regard to mortality, recent epidemiological studies have continued to find that older adults are at greater risk of all-cause (nonaccidental) mortality associated with short-term exposure to both $PM_{2.5}$ and PM_{10}, providing consistent and stronger evidence of effects in this susceptible population compared to the last review. Epidemiological studies that examined the association between mortality and long-term exposure to $PM_{2.5}$ that stratified the results by age

(i.e., less than 65 years of age compared to aged 65 and older; different age groups within the aged 65 and older population) reported results that are generally consistent with the findings of these short-term exposure studies and also provided some evidence that the increased risk declined with increasing age starting at age 60, such that there was no evidence of an association among persons 85 years and older (US EPA, 2009a, Figure 7-7, section 8.1.1.1, Zeger et al., 2008).

With regard to morbidity effects, currently available studies provide evidence that older adults have heightened responses, especially for cardiovascular-related effects, and children have heightened responses for respiratory-related effects associated with long- and short-term $PM_{2.5}$ exposures. With regard to older adults, epidemiological studies provide evidence of increases in $PM_{2.5}$-related risk of MI, coronary revascularization,[20] and their combination with CHD-related death for participants free of CVD at baseline (Miller et al., 2007) as well as cardiovascular-related hospitalization (Dominici et al., 2006a; Bell et al., 2008). Further, 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, suggesting that older adults are at greater risk of PM-related respiratory health effects (US EPA, 2009a, section 8.1.1).

With regard to respiratory-related effects in children associated with long-term PM exposures, our understanding of effects on lung development has been strengthened based on newly available evidence that is consistent and coherent across different study designs, locations, and research groups. For example, the strongest evidence comes from the extended follow-up for the Southern California CHS which 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 persisting to young adulthood, respiratory symptoms (e.g., bronchitic symptoms), and respiratory disease incidence (US EPA, 2009a, section 7.3; McConnell et al, 2003; Gauderman et al., 2004; Islam et al., 2007). These analyses provide evidence that $PM_{2.5}$–related effects persist into early adulthood and are more robust and larger in magnitude than previously reported.

With regard to respiratory effects in children associated with short-term exposures to PM, currently available studies provide stronger evidence of respiratory-related hospitalizations with larger effect estimates observed among children. In addition, reductions in lung function (i.e., FEV_1) and increases in respiratory symptoms and medication use associated with PM exposures have been reported among asthmatic children (US EPA, 2009a, sections 6.3.1, 6.3.2.1, 8.4.9).

In addition, accumulating evidence suggests that the developing fetus may also represent an additional lifestage that is susceptible to PM exposures. The ISA notes that "[i]nfants and

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

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). Evidence is accumulating for $PM_{2.5}$-related effects on low birthweight and infant mortality, especially due to respiratory causes during the post-neonatal period (US EPA, 2009a, sections 2.3.1.2 and 7.4).

Pre-existing Diseases/Health Conditions

A number of health conditions have been found to put individuals at greater risk for adverse effects following exposure to PM. The currently available evidence confirms and strengthens evidence in the last review that individuals with underlying cardiovascular and respiratory diseases are more susceptible to PM exposures.

The majority of the epidemiological studies that examined associations between short-term PM exposures and cardiovascular outcomes focused on cardiovascular-related hospital admissions and emergency department visits (US EPA, section 8.1.6.1). There is some new evidence that individuals with pre-existing IHD are at greater risk of PM-associated hospital admissions and emergency department visits related to cardiovascular effects. Additional studies have focused on hypertension and on the effects of PM on cardiac function in individuals with dysrhythmia with mixed results. 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 MI, finding significant associations for mortality, CHF, and new hospitalization for MI.

With regard to individuals with pre-existing respiratory illnesses (e.g., asthma, COPD), the ISA presents and assesses a number of studies that evaluate a broad range of health outcomes (e.g., mortality, asthma symptoms) in response to PM exposures (US EPA, 2009a, section 8.1.6.2). Evidence in asthmatics is stronger and more consistent than previously reported, while studies of persons with COPD have reported mixed results. Epidemiological studies have examined the effect of short-term exposure to PM in asthmatics finding an increase in medication use, asthma attacks, and respiratory symptoms (i.e., cough, shortness of breath, chest tightness). Controlled human exposure studies reported healthy and asthmatic subjects exposed to fine, coarse, and ultrafine concentrated ambient particles (CAPs), exhibited similar respiratory responses, although these studies excluded moderate and severe asthmatics that would be expected to show increased susceptibility to PM exposure. Toxicological studies using diesel exhaust particles (DEPs) provide mechanistic support that PM exposure results in allergic sensitization, and individuals with allergic airway conditions are at greater risk of adverse effects

upon exposure to $PM_{2.5}$ (US EPA, 2009a, section 6.3.6.3). Further, there is emerging but limited evidence which suggests that non-allergic respiratory morbidities may also increase the susceptibility of an individual to PM-related respiratory effects (US EPA, 2009a, p. 8-12).

There is also emerging evidence that suggests the influence of additional pre-existing diseases or health conditions, including diabetes and obesity, on the manifestation of PM-related health effects. The ISA notes that additional research exploring the effect of PM exposures on obese individuals and identifying the biological pathway(s) that could increase the susceptibility of diabetic and obese individuals to PM could improve our understanding of these potentially susceptible populations (US EPA 2009a, pp. 2-23-2-24).

Socioeconomic Status

Stronger evidence is available in this review indicating that people from lower socioeconomic strata are a susceptible population relative to PM exposures (US EPA, 2009a, section 8.1.7). Persons with lower socioeconomic status (SES)[21] have been generally found to have a higher prevalence of pre-existing diseases; limited access to medical treatment; and increased nutritional deficiencies, which can increase this population's risk to PM-related effects. Evidence available in the last review from the ACS and Harvard Six Cities cohort studies indicated increased mortality risk with long-term exposure to $PM_{2.5}$ in the cohort subgroups with lower education levels (US EPA 2004, section 9.2.4.5). In this review, additional support is available to identify persons with lower SES as a susceptible population. For example, Krewski et al. (2009) found moderate evidence for increased lung cancer mortality in individuals with a high school education or less in response to long-term exposure to $PM_{2.5}$. However, IHD-related mortality associated with long-term $PM_{2.5}$ exposures was most strongly associated with individuals with higher education levels (US EPA, 2009a, p. 8-15).

Genetic Factors

Investigation of potential genetic susceptibility has provided evidence that individuals with null alleles or polymorphisms in genes that mediate the antioxidant response to oxidative stress (e.g., GSTM1), regulate enzyme activity (i.e., MTHFR and cSHMT), or regulate levels of procoagulants (i.e., fibrinogen) are more susceptible to PM-related effects. However, some evidence suggests that polymorphisms in genes (e.g., HFE) may provide protection for PM-related effects. Emerging evidence also suggests that PM exposure can impart epigenetic effects (i.e., DNA methylation) (US EPA, 2009a, p. 8-16). More research is needed to better understand the relationship between genetic effects and potential susceptibility to PM-related effects.

[21] SES is a composite measure that usually consists of economic status, measured by income; social status measured by education; and work status measured by occupation (US EPA, 2009a, p. 8-14).

Summary

In summary, we conclude that there are several susceptible populations that are likely to be at increased risk of PM-related effects, including the lifestages of childhood and older adulthood, those with preexisting heart and lung diseases, and those of lower SES. Evidence for PM-related effects in these susceptible populations has expanded and is stronger than previously observed. We also recognize that there is emerging, though still limited evidence for additional potentially susceptible populations, such as those with diabetes, people who are obese, or those with specific genetic factors. We note that the available evidence does not generally allow distinctions to be drawn between the PM indicators in terms of whether populations are more susceptible to a particular size fraction (i.e., $PM_{2.5}$ and $PM_{10-2.5}$).

- **To what extent does the currently 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?**

In focusing our attention on whether the available evidence supports consideration of standards that are more protective than the current suite of $PM_{2.5}$ standards, we first recognize that the ISA concludes there is no evidence to support the existence of a discernible population threshold below which effects would not occur (US EPA, 2009a, section 2.4.3). Next, we consider whether the evidence provides information for health effects associated with air quality concentrations that are lower than had previously been observed, or if epidemiological studies have reported effects in areas that would likely have met the current suite of $PM_{2.5}$ standards.

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

Extended follow-up analyses of the ACS and Harvard Six Cities studies provide consistent and stronger evidence of an association with mortality at lower air quality distributions than had previously been observed. The original and reanalysis of the ACS study reported positive and statistically significant effects associated with a long-term mean $PM_{2.5}$ concentration of 18.2 $\mu g/m^3$ across 50 metropolitan areas for 1979-1983 (Pope et al., 1995; Krewski et al., 2000).[22] In extended analyses, positive and statistically significant effects of approximately similar magnitude were associated with declining $PM_{2.5}$ concentrations, from an aggregate long-term mean in 58 metropolitan areas of 21.2 $\mu g/m^3$ in the original monitoring period (1979-1983) to 14.0 $\mu g/m^3$ for 116 metropolitan areas in the most recent years evaluated (1999-2000), with an overall average across the two study periods in 51 metropolitan areas of 17.7 $\mu g/m^3$ (Pope et al., 2002; Krewski et al., 2009). With regard to the Harvard Six Cities

[22] The study periods referred to in this document reflect the years of air quality data that were included in the analyses, whereas the study periods identified in the ISA reflect the years of health status data that were included.

Study, the original and reanalysis reported positive and statistically significant effects associated with a long-term mean $PM_{2.5}$ concentration of 18.0 $\mu g/m^3$ for 1980-1985 (Dockery et al., 1993; Krewski et al., 2000). In an extended follow-up of this study, the aggregate long-term mean concentration across all years evaluated was 16.4 $\mu g/m^3$ for 1980-1988[23] (Laden et al., 2006). In an additional analysis of the extended follow-up of the Harvard Six Cities Study, investigators reported the C-R relationship was linear and "clearly continuing below the level" of the current annual standard (US EPA, 2009a, p. 7-92; Schwartz et al., 2008).

We then consider new cohort studies that provide evidence of mortality associated with air quality distributions that are generally lower than those reported in the ACS and Harvard Six Cities studies, with effect estimates that were similar or greater in magnitude. The WHI study reported positive and most often statistically significant associations between long-term $PM_{2.5}$ exposure and cardiovascular-related mortality, with much larger relative risk estimates than in the ACS and Harvard Six Cities studies, as well as morbidity effects at an aggregate long-term mean $PM_{2.5}$ concentration of 12.9 $\mu g/m^3$ for 2000 (Miller et al., 2007).[24] Using the Medicare cohort, Eftim et al. (2008) reported somewhat higher effect estimates than in the ACS and Harvard Six Cities studies with aggregate long-term mean concentrations of 13.6 $\mu g/m^3$ and 14.1 $\mu g/m^3$, respectively, for 2000-2002. The MCAPS reported associations between long-term $PM_{2.5}$ exposure and mortality for the eastern region of the U.S. at an aggregated long-term $PM_{2.5}$ median concentration of 14.0 $\mu g/m^3$, although no association was reported for the western region with an aggregated long-term $PM_{2.5}$ median concentration of 13.1 $\mu g/m^3$ (US EPA, 2009a, p. 7-88; Zeger et al., 2008).[25] Premature mortality in children reported in a national infant mortality study as well as mortality in a cystic fibrosis cohort including both children and adults reported positive but statistically nonsignificant effects associated with long-term aggregate mean

[23] Aggregate mean concentration provided by study author (personal communication from Dr. Francine Laden, 2009).

[24] Miller et al. (2007) reported a long-term mean $PM_{2.5}$ concentration across study areas of 13.5 $\mu g/m^3$. This concentration was presented in the ISA (US EPA, 2009a) and discussed in the second draft PA (US EPA, 2010f). In response to a request from EPA for additional information on the air quality data used in selected epidemiological studies (Hassett-Sipple and Stanek, 2009), study investigators provided updated air quality data for the study period. The updated long-term mean $PM_{2.5}$ concentration provided by the study authors was 12.9 $\mu g/m^3$ (personal communication from Cynthia Curl, 2009; Stanek et al., 2010). We note that this updated long-term mean concentration matches the composite monitor approach annual mean calculated by EPA for the year of air quality data (i.e., 2000) considered by the study investigators (Hassett-Sipple et al., 2010, Attachment A, p. 6). Staff concludes it is most appropriate to include the updated air quality data in this final document.

[25] Zeger et al. (2008) also reported positive and statistically significant effects for the central region, with an aggregate long-term mean $PM_{2.5}$ concentration of 10.7 $\mu g/m^3$. However, in contrast to the eastern and western risk estimates, the central risk estimate increased with adjustment for COPD (used as a proxy for smoking status). Due to the potential for confounding bias influencing the risk estimate for the central region, we have not focused on the results reported in the central region to inform the adequacy of the current suite of standards or alternative annual standard levels discussed in section 2.3.4.1.

concentrations of 14.8 μg/m^3 and 13.7 μg/m^3, respectively (Woodruff et al., 2008; Goss et al., 2004).

With respect to respiratory morbidity effects associated with long-term $PM_{2.5}$ exposure, the across-city mean of 2-week average $PM_{2.5}$ concentrations reported in the initial Southern California CHS was approximately 15.1 μg/m^3 (Peters et al., 1999). These results were found to be consistent with results of cross-sectional analyses of the 24-Cities Study (Dockery et al., 1996; Raizenne et al., 1996), which reported a long-term cross-city mean $PM_{2.5}$ concentration of 14.5 μg/m^3. In this review, extended analysis of the Southern California CHS provided stronger evidence of $PM_{2.5}$-related respiratory effects, at lower air quality concentrations than had previously been reported, with a four-year aggregate mean concentration of 13.8 μg/m^3 across the 12 study communities (McConnell et al., 2003; Gauderman et al., 2004, US EPA, 2009a, Figure 7-4).

Broadening our consideration to effects for which evidence is suggestive of a causal relationship, we note a limited number of birth outcome studies that reported positive and statistically significant effects related to aggregate long-term mean $PM_{2.5}$ concentrations of approximately 12 μg/m^3 (US EPA, 2009a, Table 7-5; Bell et al., 2007; Liu et al., 2007; Parker et al, 2005). In contrast, Parker and Woodruff (2008) reported no overall association with birth weight with an aggregate long-term mean concentration of 13.5 μg/m^3 (US EPA, 2009a, section 7.4.1.1).

Collectively, the currently available evidence provides support for associations between long-term $PM_{2.5}$ exposure and mortality and morbidity effects that extend to air quality concentrations that are lower than had previously been observed, with aggregate long-term mean $PM_{2.5}$ concentrations extending to well below the level of the current annual standard. These studies evaluated a broader range of health outcomes in the general population and in susceptible populations 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.

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

In considering long-term average ambient concentrations from multi-city, short-term $PM_{2.5}$ exposure studies, a 12-cities Canadian study (Burnett et al 2004; aggregate long-term mean $PM_{2.5}$ concentration of 12.8 μg/m^3) provided evidence of an association between short-term $PM_{2.5}$ exposure and mortality at lower air quality distributions than had previously been observed in an 8-cities Canadian study (Burnett and Goldberg, 2003; aggregate long-term mean $PM_{2.5}$ concentration of 13.3 μg/m^3). In a multi-city time-series analysis of 112 U.S. cities, Zanobetti and Schwartz (2009) reported a positive and statistically significant association with

all-cause, cardiovascular-related (e.g., MI, stroke), and respiratory-related mortality and short-term $PM_{2.5}$ exposure, in which the aggregate long-term mean $PM_{2.5}$ concentration was 13.2 $\mu g/m^3$ (US EPA, 2009a, Figure 6-24). Furthermore, city-specific effect estimates in Zanobetti and Schwartz (2009) indicate the association between short-term exposure to $PM_{2.5}$ and total mortality and cardiovascular- and respiratory-related mortality is consistently positive for an overwhelming majority (99%) of the 112 cities across a wide range of air quality concentrations (ranging from 6.6 $\mu g/m^3$to 24.7 $\mu g/m^3$; US EPA, 2009a, Figure 6-24, p. 6-178 to 179). We note that for all-cause mortality, city-specific effect estimates were statistically significant for 55% of the 112 cities, with long-term city-mean $PM_{2.5}$ concentrations ranging from 7.8 $\mu g/m^3$ to 18.7 $\mu g/m^3$ and 24-hour $PM_{2.5}$ city-mean 98th percentile concentrations ranging from 18.4 to 64.9 $\mu g/m^3$ (personal communication with Dr. Antonella Zanobetti, 2009).[26]

With regard to cardiovascular and respiratory morbidity effects, in the first analysis of the MCAPS cohort conducted by Dominici et al. (2006a) across 204 U.S. counties, investigators reported a statistically significant association with hospitalizations for cardiovascular and respiratory diseases and short-term $PM_{2.5}$ exposure, in which the aggregate long-term mean $PM_{2.5}$ concentration was 13.4 $\mu g/m^3$. 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).[27] In an extended analysis of the MCAPS study, Bell et al. (2008) reported a positive and statistically significant increase in cardiovascular hospitalizations associated with short-term $PM_{2.5}$ exposure, in which the aggregate long-term mean $PM_{2.5}$ concentration was 12.9 $\mu g/m^3$. These results, along with the observation that approximately 50% of the 204 county-specific mean 98th percentile $PM_{2.5}$ concentrations in Dominici et al. (2006a) aggregated across all years were below the 24-hour standard of 35 $\mu g/m^3$, 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 (Bell, 2009, personal communication from Dr. Michelle Bell regarding air quality data for Bell et al., 2008 and Dominici et al., 2006a).

In considering single-city short-term $PM_{2.5}$ exposure studies that were conducted in areas that would likely have met the current suite of standards, the following studies reported positive and statistically significant associations: three studies noted in the last review, Mar et al. (2003)

[26] Single-city Bayes-adjusted effect estimates for the 112 cities analyzed in Zanobetti and Schwartz (2009) were provided by the study authors (personal communication with Dr. Antonella Zanobetti, 2009; see also US EPA, 2009a, Figure 6-24).

[27] 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 (personal communication with Dr. Francesca Dominici, 2006b).

reported a positive and statistically significant association for premature mortality in Phoenix and Peters et al. (2001) and Delfino et al. (1997) reported an association with short-term exposure to $PM_{2.5}$ and MI- and respiratory-related hospital admissions in Boston and Montreal, Canada, respectively, and one more recent study, Mar et al. (2004) reported an association for short-term $PM_{2.5}$ exposures in relation to respiratory symptoms among children in Spokane. Single-city studies that reported positive but statistically non-significant associations for cardiovascular and respiratory endpoints include a number of studies conducted in Saint John (Steib et al., 2000), Phoenix (Wilson et al., 2007), Denver (Rabinovitch et al., 2006), Edmonton (Villeneuve et al., 2006), and Nueces County, TX (Lisabeth et al., 2008). Other single-city short-term $PM_{2.5}$ exposure analyses reported null findings for cardiovascular and respiratory morbidity effects in association with short-term exposure to $PM_{2.5}$ in areas that would likely have met the current suite of standards, including Spokane (i.e., respiratory symptoms in adults, Mar et al., 2004; Slaughter et al. 2005), Denver (Rabinovitch et al., 2004), and Edmonton (Villeneuve et al., 2006). 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 in considering the adequacy of the current suite of standards.

Collectively, the findings from multi-city and single-city short-term $PM_{2.5}$ exposure studies provide evidence of $PM_{2.5}$-associated health effects occurring in areas that would likely have met the current suite of $PM_{2.5}$ standards. These findings are further bolstered by evidence of statistically significant $PM_{2.5}$ associated health effects occurring in analyses restricted to days in which 24-hour average $PM_{2.5}$ concentrations were below 35 $\mu g/m^3$ (Dominici, 2006b).

Summary

In evaluating the currently available scientific evidence, we conclude that the evidence from long and short-term $PM_{2.5}$ exposure studies clearly calls into question whether the current suite of primary $PM_{2.5}$ 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 conclude that this evidence provides strong support for considering fine particle standards that would afford 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-related and respiratory-related morbidity effects now available in this review both at lower concentrations of air quality than had previously been observed and at concentrations allowed by the current suite of $PM_{2.5}$ 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. For this review, we have estimated risk for a set of health effect endpoints based on a number of selection criteria (US EPA, 2010a, section 3.3.1). Specifically, we have estimated risks for (1) all-cause, IHD-related, cardiopulmonary- and lung cancer-related mortality associated with long-term $PM_{2.5}$ exposure, (2) non-accidental, cardiovascular-related, and respiratory-related mortality associated with short-term $PM_{2.5}$ exposure, and (3) cardiovascular-related and respiratory-related hospital admissions and asthma-related emergency department visits associated with short-term $PM_{2.5}$ exposure. In the discussion below, we focus on cardiovascular-related endpoints, since the causal relationship for these endpoints based on the currently available scientific evidence as assessed in the ISA is the strongest of the endpoints considered. The estimated risks for the broader set of health effect endpoints modeled are included in the RA (US EPA, 2010a).

As discussed below, three factors figure prominently in the interpretation of the risk estimates associated with simulating just meeting the current suite of standards, including: (1) the importance of changes in annual mean $PM_{2.5}$ concentrations for a specific study area in estimating changes in risks related to both long- and short-term exposures associated with recent air quality conditions and air quality simulated to just meet the current suite of $PM_{2.5}$ standards; (2) the ratio of peak- to-mean ambient $PM_{2.5}$ concentrations in a study area; and (3) the spatial pattern of ambient $PM_{2.5}$ reductions that result from using different approaches to simulate just meeting the current standard levels (i.e., rollback approaches). The latter two factors are interrelated and influence the degree of risk reduction estimated under the current suite of standards.

The magnitude of both long- and short-term exposure-related risk estimated to remain upon just meeting the current suite of standards is strongly associated with the simulated change in annual mean $PM_{2.5}$ concentrations. The role of annual mean $PM_{2.5}$ concentrations in driving long-term exposure-related risk estimates is intuitive given that risks are modeled using the annual mean air quality metric.[28] The fact that short-term exposure-related risk estimates are also driven by changes in long-term mean $PM_{2.5}$ concentrations is less intuitive, since changes in

[28] As noted in section 3.2.1 of the RA (U.S.EPA, 2010a), estimates of long-term exposure-related mortality are actually based on an annual mean $PM_{2.5}$ concentration that is the average across monitors in a study area (i.e., based on the composite monitor distribution). 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 alternative suite of standards considered. The annual mean at the highest reporting monitor (i.e., based on the maximum monitor distribution) for a study area is the annual design value. The annual design value is used to determine the percent reduction in $PM_{2.5}$ concentrations required to meet a particular standard. Both types of air quality estimates are provided in Table 3-4 of the RA and both are referenced in this discussion of core risk estimates, as appropriate.

mean 24-hour $PM_{2.5}$ concentrations are used to estimate changes in risk for this time period.[29] Analyses show 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 (US EPA, 2010a, section 3.1.2.2). Consequently, changes in annual mean $PM_{2.5}$ concentrations are related, to a large extent, to changes in short-term exposure-related risk. Therefore, we focus on changes in annual mean $PM_{2.5}$ concentrations to inform our understanding of patterns of both long- and short-term exposure-related risk estimates across the set of urban study areas evaluated in the quantitative risk assessment.

The ratio of peak-to-mean ambient $PM_{2.5}$ concentrations within a study area informs the type of rollback approach used to simulate just meeting the current suite of standards to determine the magnitude of the reduction in annual mean $PM_{2.5}$ concentrations for that study area and consequently the degree of risk reduction.[30] For example, study areas with relatively high peak-to-mean ratios are likely to have greater estimated risk reductions for the current suite of standards (depending on the combination of 24-hour and annual design values), and such locations can be especially sensitive to the type of rollback approach used, with the proportional rollback approach resulting in notably greater estimated risk reduction compared with the locally-focused rollback approach. In contrast, study areas with lower peak-to-mean ratios typically experience greater simulated risk reductions when simulating just meeting the current annual-standard level than with simulating just meeting the current 24-hour standard level (again depending on the combination of 24-hour and annual design values). In addition, the type of rollback approach used will tend to have less of an impact on the magnitude of risk reductions for study areas with lower peak-to-mean ratios. Rigorous consideration of these two factors, allowed us to better understand the nature and pattern of estimated risk reductions and risk remaining upon simulation of just meeting the current suite of standards across the urban study areas (see U.S.EPA, 2010a, section 5.2.1).

We have considered a series of questions to inform our understanding of the adequacy of the current suite of fine particle standards based on insights obtained from the quantitative risk assessment. We begin by considering the overall confidence associated with the quantitative risk assessment and the degree to which the set of urban study areas analyzed is representative of

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

[30] The peak-to-mean ratio of ambient $PM_{2.5}$ concentrations also has a direct bearing on whether the 24-hour or annual standard will be the controlling standard for a particular study area, with higher peak-to-mean ratios generally being associated with locations where the 24-hour standard is likely the controlling standard.

urban areas across the U.S. We then consider the nature and magnitude of risk estimated to remain based on simulating just meeting the current suite of standards.

- **What is the level of confidence associated with risk estimates generated for simulating just meeting the current suite of $PM_{2.5}$ standards?**

A number of design elements were included in the quantitative risk assessment to increase the overall confidence in the risk estimates generated for the 15 urban study areas. These elements included: (1) use of a deliberative process for specifying components of the risk model that reflects consideration of the latest research on $PM_{2.5}$ exposure and risk (US EPA, 2010a, section 5.1.1), (2) integration of key sources of variability into the design as well as the interpretation of risk estimates (U.S.EPA, 2010a, section 5.1.2), (3) assessment of the degree to which the urban study areas are representative of areas in the U.S. experiencing higher $PM_{2.5}$-related risk (U.S.EPA, 2010a, section 5.1.3), and (4) identification and assessment of important sources of uncertainty and the impact of these uncertainties on the core risk estimates (U.S.EPA, 2010a, section 5.1.4).[31] Two additional analyses examined potential bias and overall confidence in the risk estimates. The first analysis explored potential bias in the core risk estimates by considering a set of alternative reasonable risk estimates generated as part of a sensitivity analysis. The second analysis compared the annual mean $PM_{2.5}$ concentrations associated with simulating just meeting the current suite of standards with the air quality distribution used in deriving the C-R functions applied in modeling mortality risk.[32] Greater confidence is associated with risk estimates based on simulated annual mean $PM_{2.5}$ concentrations that are within the region of the air quality distribution used in deriving the C-R functions where the bulk of the data reside (e.g., within one standard deviation (SD) around the mean). Each of the design elements listed above together with the two additional analyses is discussed below.

Staff used a deliberative process to specify each of the key analytical elements comprising the core risk model, including: selection of urban study areas; selection of health endpoints, including specification of the C-R functions to use in modeling those endpoints; and choice of rollback approach used to simulate just meeting the current suite of standards. This deliberative process involved rigorous review of the currently available literature addressing both $PM_{2.5}$ exposure and risk combined with the application of a formal set of criteria to guide development of each of the key analytical elements in the quantitative risk assessment (US EPA, 2010a, section 5.1.1).[33] The application of this deliberative process increases our overall

[31] The "core" risk estimates produced in this assessment refer to those generated using the combination of modeling elements and input data sets in which we had the highest confidence. Alternative modeling elements were included as part of the sensitivity analyses.
[32] This analysis also considered simulations of alternative standard levels as discussed in section 2.3.4.2.
[33] In addition, as discussed in section 1.2.4, the quantitative risk assessment design reflects consideration of CASAC and public comments on the Scope and Methods Plan and two draft assessment documents.

confidence in the risk estimates by insuring that the estimates are based on the best available science and data characterizing $PM_{2.5}$ exposure and risk, and that they reflect consideration of input from external experts on PM exposure and risk through CASAC and public reviews.

We considered key sources of variability that can impact the nature and magnitude of risks associated with the current standard levels across the urban study areas. These sources of uncertainty include those that contribute to differences in risk across urban study areas, but do not directly affect the degree of risk reduction associated with the simulation of the current standard levels (e.g., differences in baseline incidence rates, demographics and population behavior). We also focused on factors that not only introduce variability into risk estimates across study areas, but also play an important role in determining the magnitude of risk reductions upon simulation of current standard levels (e.g., peak-to-mean ratios of ambient $PM_{2.5}$ concentrations within individual urban study areas and the nature of the rollback approach used to simulate just meeting the current standards – see earlier discussion).

Single and multi-factor sensitivity analyses were combined with a qualitative analysis to assess the impact of potential sources of uncertainty on the core risk estimates. The qualitative uncertainty analysis supplemented the quantitative sensitivity analyses by allowing coverage for sources of uncertainty that could not be readily included in the sensitivity analysis (US EPA, 2010a, section 3.5.3). The quantitative sensitivity analyses informed our understanding of sources of uncertainty that may have a moderate to large impact on the core risk estimates. With respect to the long-term exposure-related mortality risk estimates, the most important sources of uncertainty identified in the quantitative sensitivity analyses included: selection of C-R functions;[34] modeling risk down to policy-relevant background (PRB) versus lowest measured level (LML); and the choice of rollback approach used. With regard to the qualitative analysis of uncertainty, the following sources were identified as potentially having a large impact on core risk estimates for the long-term exposure-related mortality: characterization of inter-urban population exposures; impact of historical air quality; and potential variation in effect estimates reflecting differences in $PM_{2.5}$ composition. Together, the qualitative analysis of uncertainty and quantitative sensitivity analyses provided us with a comprehensive understanding of which sources of uncertainty could have a significant impact on the core risk estimates. This

[34] In the case of long-term exposure-related mortality, we considered both alternative C-R functions from the epidemiological study providing the C-R function used in the core analysis (i.e., alternative functions obtained from the Krewski et al. (2009) study involving the ACS dataset) as well as alternative C-R functions identified in other studies (i.e., C-R functions obtained from Krewski et al. (2000) based on a reanalysis of the Harvard Six Cities study).

information proved useful in interpreting core risk estimates and increased our overall confidence in the analysis.[35]

In addition to identifying sources of uncertainty with a moderate to large impact on the core risk estimates, the single and multi-element sensitivity analyses also produced a set of reasonable alternative risk estimates that allowed us to place the results of the core analysis in context with regard to uncertainty and potential bias.[36] Most of the alternative model specifications supported by the currently available scientific information produced risk estimates that are higher (by up to a factor of 2 to 3) than the core risk estimates. This was not unexpected. The C-R functions used in the core analysis for estimating mortality risks associated with long-term $PM_{2.5}$ exposures were selected from the extended analysis of the ACS study (Krewski et al., 2009). The C-R functions used in the sensitivity analysis were from the reanalysis and validation of the Harvard Six Cities study (Krewski et al., 2000). In generalizing the results of the extended analyses of the ACS and Harvard Six Cities studies across the broader national population, we recognize differences in the underlying populations enrolled in these long-term cohort studies, specifically related to SES, a factor in considering impacts on susceptible populations. As noted in the last review, the ACS study population has a higher SES status (e.g., educational status) relative to the Harvard Six Cities study population (12% versus 28% of the cohort had less than a high school education, respectively) (US EPA, 2004a, p. 8-118). The Harvard Six Cities cohort may provide a more representative sample of the broader national population than the ACS cohort.

As discussed above, lower SES groups have been identified as a susceptible population. Therefore, use of effect estimates reported in the ACS study which does not provide representative coverage for lower-SES groups, may result in risk estimates that are biased low. In contrast, risk estimates developed in the sensitivity analysis based on the Harvard Six Cities study data set provide better coverage for lower SES populations but give greater weight to eastern and Midwestern populations and, therefore, result in higher risk estimates (US EPA, 2010a, section 5.1.5).

While being mindful that the use of C-R functions from Krewski et al. (2009) introduces potential for low bias in the core risk estimates, we also recognize many strengths of this study

[35] Given increased emphasis placed in this analysis on long-term exposure-related mortality, the uncertainty analyses completed for this health endpoint category were more comprehensive than those conducted for analyses of short-term exposure-related mortality and morbidity. This reflects, to some extent, limitations in the epidemiological data available for addressing uncertainty in the latter categories (U.S.EPA 2010a, section 3.5.4.2).

[36] The alternative set of reasonable risk estimates were based on alternative model specifications compared to the core risk model. These alternative reasonable risk estimates were only generated for long-term exposure-related mortality and not for any of the short-term exposure-related mortality or morbidity endpoints. Consequently, consideration of overall confidence (and potential bias) in the core risk estimates based on consideration for these alternative risk estimates is limited to estimates of mortality associated with long-term $PM_{2.5}$ exposures.

and reasons for its continued use for generating the core risk estimates, including: consideration of a large number of metropolitan statistical areas (MSAs), inclusion of two time periods for the air quality data which allowed us to consider different exposure windows; and analysis of a wide range of C-R function models. Therefore, we concluded that C-R functions obtained from this study had the greatest overall support and should be used in the core risk model. Consideration of the alternative set of reasonable risk estimates provided several observations relevant to the interpretation of the core risk estimates including: (a) the core estimates are unlikely to underestimate risk and (b) the degree of potential bias in the core risk estimates could range up to at least a factor of 2-3 higher.[37]

In considering the overall confidence in the core risk estimates, we have compared the $PM_{2.5}$ concentrations simulated under the current suite of standard levels across the urban study areas to the distribution of $PM_{2.5}$ concentrations used in deriving the C-R functions used for long-term exposure-related mortality (as presented in Krewski et al., 2009). Specifically, this assessment compared the composite monitor annual mean $PM_{2.5}$ concentrations used in modeling long-term exposure-related mortality risk in the core analysis to the distribution of annual mean $PM_{2.5}$ concentrations from the 1999-2000 ACS exposure period.[38] Generally, when composite monitor annual mean concentrations were within one SD of the long-term mean concentration for the most recent years of air quality considered in the ACS dataset (i.e., in the range of 14+/-3 $\mu g/m^3$), we had relatively high confidence in the risk estimates, since they were based on $PM_{2.5}$ concentrations that roughly matched those used in deriving the C-R functions. However, as composite monitor annual mean $PM_{2.5}$ concentrations extend below this range, our confidence in the risk estimates decreased, with our confidence being significantly reduced when composite monitor annual mean concentrations approached the LML of the ACS data set (i.e., 5.8 $\mu g/m^3$).

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[37] We note that these findings regarding potential bias in the core risk estimates were based on modeling $PM_{2.5}$-attributable IHD and all-cause mortality associated with long-term $PM_{2.5}$ exposure for the current suite of standards. However, we would expect these observations regarding overall confidence in the core risk estimates to hold for other long-term exposure-related mortality endpoints modeled in the quantitative risk assessment for both the alternative annual and 24-hour standard levels considered in section 2.3.4.2. Furthermore, given increased emphasis placed in this analysis on long-term exposure-related mortality, as noted earlier, the uncertainty analyses completed for this health endpoint category are more comprehensive than those conducted for short-term exposure-related mortality and morbidity effects, which to some extent reflects limitations in study data available for addressing uncertainty in the latter category. Therefore, an alternative set of reasonable risk estimates was not generated to supplement core risk estimates generated for short-term $PM_{2.5}$ exposure.

[38] As discussed in sections 3.3.3 and 4.0 of the RA (U.S.EPA, 2010a), each category of long-term exposure-related mortality was estimated using separate C-R functions derived from the 1979-1983 and 1999-2000 ACS monitoring periods. For purposes of comparing composite monitor annual mean $PM_{2.5}$ concentrations to the ACS data sets used in deriving the C-R functions, we focused on the later monitoring period (1999-2000), since ambient $PM_{2.5}$ concentrations from this period more closely matched those associated with the study areas in our consideration of recent air quality conditions (2005-2007). The 1999-2000 ACS monitoring period had a mean $PM_{2.5}$ concentration of 14.0 $\mu g/m^3$, a SD of 3.0 $\mu g/m^3$ and an LML of 5.8 $\mu g/m^3$ (see Table 1 in Krewski et al., 2009).

- **How representative is the set of urban study areas for the broader set of urban areas in the U.S. expected to experience elevated risk from ambient $PM_{2.5}$ exposure?**

The goal in selecting urban study areas was to provide coverage for the range of larger urban areas in the U.S. expected to experience relatively elevated risk due to ambient $PM_{2.5}$ exposure and other factors associated with $PM_{2.5}$-related risk (e.g., elevated baseline incidence rates for relevant health endpoints, relatively larger susceptible populations). As part of considering our overall confidence in the quantitative risk assessment, we assessed the representativeness of the 15 urban study areas in the broader national context. Three separate analyses were used to explore representativeness:

- A comparison of $PM_{2.5}$-risk-related attributes of the 15 urban study areas against national distributions of these same attributes suggested that the urban study areas likely reflect the distribution of risk for the nation, with the potential for better characterization at the higher end of that distribution (US EPA, 2010a, section 4.4.1).[39]
- An analysis of the distribution of U.S. counties included in a national-scale mortality analysis suggested that counties associated with the 15 urban study areas are likely to experience elevated $PM_{2.5}$-related risk (US EPA, 2010a, section 4.4.2).
- An evaluation 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. This analysis suggested that (a) the 15 urban study areas reasonably captured the key groupings of urban areas in the U.S. likely to experience elevated risk due to $PM_{2.5}$ exposures and (b) we have included study areas likely to experience relatively greater degrees of $PM_{2.5}$-related risk (US EPA, 2010a, section 4.5.1).

Based on these analyses, we conclude that these study areas are generally representative of urban areas in the U.S. likely to experience relatively elevated levels of risk related to ambient $PM_{2.5}$ exposure.

- **What is the nature and magnitude of the *long-term* and *short-term* exposure-related risks remaining upon just meeting the current suite of $PM_{2.5}$ standards?**

In considering $PM_{2.5}$-related risks likely to remain upon just meeting the current $PM_{2.5}$ annual and 24-hour standards in the 15 urban study areas included in the quantitative RA, we focus on the 13 areas that would likely not have met the current standards based on recent air quality (2005-2007). These 13 areas have annual and/or 24-hour design values that are above the

[39] This representativeness 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 low $PM_{2.5}$ concentrations (e.g., urban areas in Florida) and consequently failure to include these areas in the set of urban study areas is unlikely to exclude high $PM_{2.5}$-risk locations.

levels of the current standards (see Tables 2-2 and 2-3).[40] Based on the core risk estimates for these areas, using the proportional rollback approach, we make the following key observations regarding the magnitude of risk remaining upon simulation of just meeting the current suite of standards:

- *Long-term exposure-related mortality risk remaining*: IHD-related mortality attributable to long-term $PM_{2.5}$ exposure was estimated to range from less than 100 to approximately 2,000 cases per year. The variability in these estimates reflects, to a great extent, differences in the size of study area populations. These estimates represent from 4 to 17% of all IHD-related mortality in a given year for the urban study areas, representing a measure of risk that takes into account differences in population size and baseline mortality rates (see Table 2-2).
- *Short-term exposure-related mortality risk remaining*: Cardiovascular (CV)-related mortality associated with short-term $PM_{2.5}$ exposure was estimated to range from less than 10 to 500 cases per year. These estimates represent approximately 1 to 2% of total CV-related mortality in a given year for the urban study areas (see Table 2-3).
- *Short-term exposure-related morbidity risk remaining:* CV-related hospitalizations were estimated to range from approximately 10 to 800 cases per year across the study areas, which is approximately equivalent to less than 1% of total CV-related hospitalizations (see Table 2-3).

Although long- and short-term exposure-related mortality rates have similar patterns in terms of the subset of urban study areas experiencing risk reductions for the current suite of standard levels, the magnitude of risk remaining is substantially lower for short-term exposure-related mortality. These findings were expected, since, as noted earlier, changes in annual mean $PM_{2.5}$ concentrations were expected to drive both long- and short-term exposure-related risk, resulting in similar overall patterns in risk reduction for both exposure periods (in terms of the subset of urban study areas experiencing risk reductions). We note, however, that the variability in the effect estimates used to model short-term exposure-related health endpoints across urban study areas introduced additional variation into the pattern of risk reduction across study areas.

[40] Of the 15 study areas, only Dallas and Phoenix have both annual and 24-hour design values below the levels of the current standards based on 2005-2007 air quality data.

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)

Urban Study Area	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]	
	Exposure Period: 1979-1983	Exposure Period: 1999-2000	Exposure Period: 1979-1983	Exposure Period: 1999-2000
Atlanta, GA	220 (180 - 258)	277 (227 - 324)	13.2% (10.9% - 15.5%)	16.7% (13.7% - 19.5%)
Baltimore, MD	297 (243 - 349)	374 (307 - 440)	11.7% (9.6% - 13.7%)	14.7% (12.1% - 17.3%)
Birmingham, AL	131 (107 - 154)	165 (135 - 194)	10.9% (8.9% - 12.9%)	13.8% (11.3% - 16.2%)
Dallas, TX	195 (159 - 230)	247 (202 - 291)	9% (7.3% - 10.6%)	11.4% (9.3% - 13.4%)
Detroit, MI	377 (308 - 445)	478 (390 - 563)	9.1% (7.4% - 10.7%)	11.5% (9.4% - 13.5%)
Fresno, CA	77 (63 - 92)	98 (80 - 116)	6.7% (5.5% - 8%)	8.5% (7% - 10.1%)
Houston, TX	344 (281 - 405)	434 (355 - 511)	10.7% (8.8% - 12.6%)	13.6% (11.1% - 16%)
Los Angeles, CA	860 (701 - 1018)	1094 (890 - 1296)	6.1% (4.9% - 7.2%)	7.7% (6.3% - 9.1%)
New York, NY	1755 (1435 - 2070)	2222 (1814 - 2620)	9.3% (7.6% - 11%)	11.8% (9.6% - 13.9%)
Philadelphia, PA	261 (214 - 308)	330 (270 - 389)	10.5% (8.6% - 12.3%)	13.2% (10.8% - 15.6%)
Phoenix, AZ	317 (258 - 374)	402 (327 - 476)	6.7% (5.5% - 7.9%)	8.5% (6.9% - 10.1%)
Pittsburgh, PA	256 (209 - 302)	324 (264 - 382)	9.3% (7.6% - 11%)	11.8% (9.6% - 13.9%)
Salt Lake City, UT	15 (12 - 18)	19 (16 - 23)	2.9% (2.4% - 3.4%)	3.7% (3% - 4.4%)
St. Louis, MO	446 (365 - 525)	563 (461 - 662)	11.2% (9.2% - 13.2%)	14.2% (11.6% - 16.7%)
Tacoma, WA	38 (31 - 46)	49 (40 - 58)	3.7% (3% - 4.4%)	4.7% (3.8% - 5.6%)

[1] The current primary $PM_{2.5}$ standards include an annual standard set at 15 $\mu g/m^3$ and a 24-hour standard set at 35 $\mu g/m^3$.
[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 $PM_{2.5}$ concentrations from 1979 - 1983 and from 1999-2000, respectively. Estimated incidence is presented for 30 years of age and older within each urban study area.

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)

Urban Study Area	Incidence of Cardiovascular Mortality Associated with Short-term Exposure to $PM_{2.5}$[3]	Incidence of Cardiovascular Hospitalizations Associated with Short-term Exposure to $PM_{2.5}$[4]	Percent of Incidence of Cardiovascular Mortality Associated with Short-term Exposure to $PM_{2.5}$[3]	Percent of Incidence of Cardiovascular Hospital Admissions Associated with Short-term Exposure to $PM_{2.5}$[4]
Atlanta, GA	32 (-33 - 95)	41 (-27 - 109)	0.8% (-0.8% - 2.4%)	0.4% (-0.2% - 1%)
Baltimore, MD	62 (-4 - 126)	216 (159 - 273)	1.6% (-0.1% - 3.2%)	1.3% (1% - 1.7%)
Birmingham, AL	-1 (-42 - 40)	16 (-11 - 43)	0% (-1.5% - 1.5%)	0.3% (-0.2% - 0.9%)
Dallas, TX	29 (-19 - 76)	28 (-18 - 73)	0.8% (-0.5% - 2.2%)	0.3% (-0.2% - 0.7%)
Detroit, MI	60 (-8 - 127)	233 (171 - 295)	1% (-0.1% - 2.2%)	1.1% (0.8% - 1.4%)
Fresno, CA	12 (-9 - 33)	23 (0 - 46)	0.7% (-0.5% - 2%)	0.5% (0% - 0.9%)
Houston, TX	46 (-31 - 122)	56 (-37 - 149)	0.9% (-0.6% - 2.4%)	0.3% (-0.2% - 0.8%)
Los Angeles, CA	-30 (-132 - 72)	258 (3 - 511)	-0.2% (-0.7% - 0.4%)	0.5% (0% - 0.9%)
New York, NY	473 (276 - 668)	752 (552 - 951)	2.1% (1.2% - 3%)	1.2% (0.8% - 1.5%)
Philadelphia, PA	84 (22 - 145)	203 (149 - 257)	2.1% (0.5% - 3.6%)	1.3% (0.9% - 1.6%)
Phoenix, AZ	84 (-4 - 170)	108 (1 - 215)	1.3% (-0.1% - 2.7%)	0.5% (0% - 1%)
Pittsburgh, PA	43 (-9 - 93)	140 (103 - 177)	1.1% (-0.2% - 2.3%)	1.1% (0.8% - 1.4%)
Salt Lake City, UT	9 (-2 - 20)	9 (0 - 18)	0.8% (-0.2% - 1.7%)	0.4% (0% - 0.7%)
St. Louis, MO	106 (24 - 187)	178 (131 - 225)	1.9% (0.4% - 3.3%)	1.3% (0.9% - 1.6%)
Tacoma, WA	11 (-6 - 27)	19 (-46 - 82)	0.7% (-0.4% - 1.8%)	0.5% (-1.3% - 2.3%)

[1] The current primary $PM_{2.5}$ standards include an annual standard set at 15 $\mu g/m^3$ and a 24-hour standard set at 35 $\mu g/m^3$.
[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 provided to EPA by the study authors (personal communication with Dr. Antonella Zanobetti, 2009).
[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.

- *Substantial variability exists in the magnitude of risk remaining across urban study areas:* Estimated risks remaining upon just meeting the current suite of standards vary substantially across study areas, even when considering risks normalized for differences in population size and baseline incidence rates. This variability is a consequence of the substantial differences in the annual mean $PM_{2.5}$ concentrations across study areas that result from simulating just meeting the current standards. This is important because, as discussed above, annual mean concentrations are highly correlated with both long- and short-term exposure-related risk. The variability in annual mean $PM_{2.5}$ concentrations occurred primarily in those study areas in which the 24-hour standard was the "controlling" standard. In such areas, the variability in estimated risks across study areas was largest when regional patterns of reductions in $PM_{2.5}$ concentrations were simulated, using the proportional rollback approach, as was done in the core analyses. Less variability was observed when more localized patterns of $PM_{2.5}$ reductions were simulated using the locally-focused rollback approach, as was done in a sensitivity analysis. When simulations were done using the locally-focused rollback approach, estimated risks remaining upon just meeting the current suite of standards were appreciably larger than those estimated in the core analysis (US EPA, 2010a, section 4.3.1.1).
- *Simulation of just meeting the current suite of standards results in annual mean $PM_{2.5}$ concentrations well below the current standard for some study areas:* In simulating just meeting the current suite of standards, the resulting composite monitor annual mean $PM_{2.5}$ concentrations ranged from about 15 $\mu g/m^3$ (for those study areas in which the annual standard was controlling) down to as low as about 8 $\mu g/m^3$ (for those study areas in which the 24-hour standard was controlling or the annual mean concentration was well below 15 $\mu g/m^3$ based on recent air quality). As discussed above, as the composite monitor annual mean $PM_{2.5}$ concentrations used in generating risk estimates extend below 11.0 $\mu g/m^3$ (one SD below the mean for the 1999-2000 ACS monitoring period, Krewski et al., 2009) we have increasingly less confidence in the risk estimates, with confidence decreasing significantly as composite monitor concentrations approach the LML for the ACS dataset (5.8 $\mu g/m^3$). Typically, for the 15 urban study areas assessed, the locations where the 24-hour standard was the controlling standard were simulated to have the lowest composite monitor annual mean $PM_{2.5}$ concentrations. We observe that all four of the urban study areas with simulated composite monitor annual mean $PM_{2.5}$ concentrations below 11 $\mu g/m^3$ are areas where the 24-hour standard is generally controlling (U.S.EPA, 2010a, Table 3-4). While such locations often are estimated to have the greatest risk reductions, there is also reduced confidence associated with these risk estimates.

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

Estimates of long-term exposure-related IHD mortality risk associated with simulating just meeting the current suite of standards range from less than 100 deaths per year for the urban study area with the lowest risk to approximately 2,000 deaths per year for the urban study areas with the greatest risk. Estimates of risk for the urban areas included in the quantitative risk

assessment suggest that IHD-related mortality associated with long-term $PM_{2.5}$ exposure would likely be in a range of thousands of deaths per year on a national scale. Based on these risk estimates for IHD-related mortality alone, we conclude that risks estimated to remain upon simulation of just meeting the current suite of standards are important from a public health standpoint. This reflects consideration of both the severity of the effect and the magnitude of the effect. We have also estimated risks for long-term exposure related mortality risk related to cardiopulmonary effects and lung cancer, which increase the total annual incidence of mortality attributable to long-term $PM_{2.5}$ exposure (see U.S. EPA, 2010a, section 4.2.1).

In addition to long-term exposure-related mortality, we estimated cardiovascular-related and respiratory-related mortality risk associated with short-term $PM_{2.5}$ exposure. We note that these mortality estimates are up to an order of magnitude smaller than estimates related to long-term exposure-related mortality.[41] As part of the quantitative risk assessment, we also estimated respiratory and cardiovascular-related hospital admissions as well as asthma-related emergency department visits associated with short-term exposure to $PM_{2.5}$, with estimates of cardiovascular-related and respiratory-related hospital admissions together ranging up to approximately 1,000 admissions per year across the urban study areas, with the estimated incidence of asthma-related emergency department visits being several fold higher. Further, as discussed in section 2.2.1, we recognize that the currently available scientific information includes evidence for a broader range of health endpoints and susceptible populations beyond those included in the quantitative risk assessment, including lung function growth and respiratory symptoms in children and reproductive and developmental effects. Taken together, the set of quantitative risk estimates related to long- and short-term $PM_{2.5}$ exposure, together with consideration of the health endpoints which could not be quantified, further strengthen the conclusion that risks estimated to remain following simulation of just meeting the current suite of $PM_{2.5}$ standards are important from a public health perspective, both in terms of severity and magnitude.

2.2.3 CASAC Advice

In our consideration of the adequacy of the current suite of $PM_{2.5}$ standards, in addition to the evidence and risk-based information discussed above, we have also considered the advice of CASAC, based on their review of drafts of the ISA, the RA, and this document, as well as comments from the public on earlier drafts of this document and the RA. In their comments on the second draft PA, CASAC stated agreement with EPA staff's conclusion that the "currently

[41] Estimates of short-term exposure-related and long-term exposure-related mortality should not be added because there is the potential for overlap (i.e., the long-term exposure-related mortality estimate may include some of the short-term exposure-related signal on a daily basis, aggregated over the year).

available information clearly calls into question the adequacy of the current standards" (Samet, 2010d, p. i). Further, in an earlier draft of this document, CASAC noted:

> With regard to the integration of evidence-based and risk-based considerations, CASAC concurs with EPA's conclusion that the new data strengthens the evidence available on associations previously considered in the last round of the assessment of the $PM_{2.5}$ standard. CASAC also agrees that there are significant public health consequences at the current levels of the standard that justify consideration of lowering the $PM_{2.5}$ NAAQS further (Samet, 2010c, p.12).

2.2.4 Staff Conclusions on Adequacy of Current Standards

Collectively, taking into consideration the responses to specific questions focused 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 currently available information strengthens the associations between $PM_{2.5}$ and mortality and cardiovascular-related and respiratory-related morbidity effects observed in the last review. This information also expands our understanding of a broader range of health outcomes as well as our understanding of effects in susceptible populations. The currently 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 providing the basis for consideration of alternative standards that would provide increased protection beyond that afforded by the current suite of $PM_{2.5}$ 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 simulations of just 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 conclude 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. We further conclude that these estimated risks provide strong support for consideration of alternative 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 and cardiovascular-related and respiratory-related effects observed in epidemiological and toxicological 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 effects in susceptible populations including children, older adults, individuals with pre-existing cardiovascular and respiratory disease, persons at lower SES, and persons with genetic susceptibility.

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 complexities 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 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 suite of 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 suites of fine particle standards are supported by the currently available scientific evidence and risk-based information, as reflected in the ISA and RA?

To address this overarching question, we have posed a series of more specific questions to inform 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 (section 2.3.4). These elements are considered collectively in evaluating the health protection afforded by alternative suites of standards under consideration. In taking into account 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 RA prepared for this review (US EPA, 2009a; US EPA, 2010a).

2.3.1 Indicator

In initially setting standards for fine particles in 1997, EPA concluded it was more appropriate to control fine particles as a group, rather than singling out any particular component or class of fine particles for which only very limited evidence was available. In establishing a

size-based indicator to distinguish fine particles from particles in the coarse mode, EPA noted that the available epidemiological studies of fine particles were based largely on $PM_{2.5}$ and also considered monitoring technology that was generally available. The selection of a 2.5 μm size cut reflected the regulatory importance of 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 and humidity 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 38666 to 38668, July, 18, 1997). In the last review, based on the same considerations, EPA again recognized that the available information supported retaining the $PM_{2.5}$ indicator and remained too limited to support a distinct standard for any specific $PM_{2.5}$ component or group of components associated with any source categories of fine particles (71 FR 61162 to 61164, October 17, 2006).

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

In this review, epidemiological studies linking cardiovascular and respiratory effects as well as mortality with long- and short-term fine particle exposures continue to be largely indexed by $PM_{2.5}$. Based on the same considerations that informed the last two reviews, summarized above in section 2.1.1, we again conclude that it is appropriate to retain a $PM_{2.5}$ indicator to provide protection associated with long- and short-term exposure to fine particles.

We also look to the expanded body of evidence available in this review to consider whether there is sufficient evidence to support a separate standard for ultrafine particles (UFPs)[42] and whether there is sufficient evidence to establish distinct standards focused on regulating specific $PM_{2.5}$ components or group of components associated with any source categories of fine particles, as addressed below.

- **To what extent does the currently available information provide support for considering a separate indicator for UFPs?**

A number of studies available in this review have evaluated potential health effects associated with short-term exposures to UFPs. As noted in the ISA, the enormous number and larger, collective surface area of UFPs are important considerations for focusing on this particle size fraction in assessing potential public health impacts (US EPA, 2009a, p. 6-83).[43] Per unit mass, UFPs may have more opportunity to interact with cell surfaces due to their greater surface

[42] Ultrafine particles, generally including particles with a mobility diameter less than or equal to 0.1 μm, are emitted directly to the atmosphere or are formed by nucleation of gaseous constituents in the atmosphere (US EPA, 2009a, p. 3-3).

[43] 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, Figure 3-1).

area and their greater particle number compared with larger particles (US EPA, 2009a, p. 5-3). Greater surface area also increases the potential for soluble components (e.g., transition metals, organics) to adsorb to UFPs and potentially cross cell membranes and epithelial barriers (US EPA, 2009a, p. 6-83). 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 with particle mass (US EPA, 2009a, p. 6-127).[44]

New evidence, primarily from controlled human exposure and toxicological studies, expands our understanding of UFP-related cardiovascular and respiratory effects. However, this evidence is still very limited and largely focused on exposure to diesel exhaust (DE), for which the ISA concludes it is unclear if the effects observed are due to UFPs, larger particles within the $PM_{2.5}$ mixture, or the gaseous components of DE (US EPA, 2009a, p. 2-22). In addition, the ISA notes uncertainties associated with the controlled human exposure studies as CAP systems have been shown to modify the composition of UFPs (US EPA, 2009a, p. 2-22, see also section 1.5.3). Relatively few epidemiological studies have examined 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).

Collectively, in considering the body of scientific evidence available in this review, the ISA concludes that the currently available evidence is *suggestive of a causal relationship* between short-term exposures to UFPs and cardiovascular and respiratory effects. Furthermore, the ISA concludes that evidence is *inadequate to infer a causal relationship* 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).

With respect to our understanding of ambient UFP concentrations, 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).[45] Therefore, a national characterization of concentrations, temporal and spatial patterns, and trends is not possible, and the availability of ambient UFP measurements to support health studies is extremely limited. In general, measurements of UFPs are highly dependent on monitor location and, therefore, more subject to exposure error than accumulation mode particles (US EPA, 2009a, p. 2-22). In addition, UFPs are often monitored based on numerical concentrations (i.e., particle counts), rather than mass concentrations, as UFP mass in ambient air is typically very low (US EPA, 2009a, section 3.4.1.4). The UFP number

[44] More information on possible modes of action for effects associated with UFP exposures is discussed in sections 5.1 and 5.4 of the ISA (US EPA, 2009a).
[45] 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).

concentrations fall off sharply downwind from sources, as UFPs may grow into the accumulation mode by coagulation or condensation (US 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, roadways are a notable source of UFPs, so concentrations of UFPs near roadways are generally 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 fine particles (US EPA, 2009a, p. 3-84).

In considering both the currently available health effects evidence and the air quality data for UFPs, we conclude that this information is still too limited to provide support for consideration of 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 group of components associated with any source categories of fine particles? Conversely, to what extent does the currently available information provide support for eliminating any component or group of components associated with any source categories from the mix of fine particles included in the $PM_{2.5}$ indicator?**

In addressing the issue of particle composition, 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), sulfates, nitrates) observed in different geographical regions as well as regional heterogeneity in $PM_{2.5}$-related health effects reported in a number of epidemiological 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 in this review, there are now more extensive ambient $PM_{2.5}$ speciation measurement data available through the CSN than in previous reviews (see section 1.3.2 and Appendix B, section B.1.3). Data from the CSN 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).

The currently available epidemiological, 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).[46] The CSN provides $PM_{2.5}$ speciation measurements generally on a one-in-three or one-in-six day sampling schedule and, thus, do not capture data every day at most sites. To expand our understanding of the role of specific $PM_{2.5}$ components and sources with respect to the observed health effects, researchers have expressed a strong interest in having access to $PM_{2.5}$ speciation measurements collected more frequently.[47]

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), EC, OC, and sulfates (US EPA, 2009a, sections 6.5.2.5 and 6.6). Lippmann et al. (2006) and 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 and 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).[48] 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 using multi-pollutant models reported 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,

[46] Most studies considered between 7 to 20 ambient $PM_{2.5}$ constituents, with EC, OC, sulfates, nitrates, and metals most commonly measured. Many of the studies grouped the constituents with various factorization or source apportionment techniques to examine the relationship between the grouped 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 use any constituent grouping. These differences across studies substantially limit any integrative interpretation of these studies (US EPA, 2009a, p. 6-203).

[47] As outlined in section 6.6.2.11 of 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 fine particle components. 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.

[48] 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).

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 sulfates were significant effect modifiers of $PM_{2.5}$ mortality risk estimates, and "simultaneously including Al, Ni, and sulfates 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).[49] Furthermore, Ostro et al (2007) 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, nitrates, iron (Fe), potassium (K), and titanium (Ti) at various lags (US EPA, 2009a, p. 6-195).

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 $PM_{2.5}$ measurement data from the 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 (Beelen et al., 2008).

With respect to source categories of fine particles associated with a range of health endpoints, the ISA reports that the 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 study that reported an association between mortality and a $PM_{2.5}$ coal combustion factor (Laden et al., 2000), while other studies linked mortality to a secondary sulfate 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 sources of fine particles and respiratory health effects, which may be partially due to the fact that fewer studies have evaluated respiratory-related outcomes and measures. However, there is some evidence for $PM_{2.5}$-related associations with secondary sulfate 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

[49] We note that New York City was not included in the 25 cities examined by Franklin et al. (2008).

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 epidemiological 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 emergency department visits for cardiovascular diseases with mobile sources and biomass combustion as well as increased respiratory-related emergency department visits associated with secondary sulfate (US EPA, 2009a, pp. 6-204 and 6-211).

Collectively, in considering the currently available evidence for health effects associated with specific $PM_{2.5}$ components or groups of components associated with any source categories of fine particles as presented in the ISA, we conclude that additional information available in this review continues to provide evidence that many different constituents of the fine particle mixture as well as groups of components associated with specific source categories of fine particles are linked to adverse health effects. 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 conclude that the currently available evidence is not sufficient to support consideration of a separate indicator for a specific $PM_{2.5}$ component or group of components associated with any source category of fine particles. We also conclude that the evidence is not sufficient to support eliminating any component or group of components associated with any source categories of fine particles from the mix of fine particles included in the $PM_{2.5}$ indicator.

Summary

In considering whether the currently available evidence provides support for retaining, revising, or supplementing the current $PM_{2.5}$ mass-based indicator, we first conclude that it is appropriate to consider retaining $PM_{2.5}$ as the indicator for fine particles. Secondly, we conclude 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. We also conclude that the currently available evidence is too limited to provide support for considering a separate indicator for a specific $PM_{2.5}$ component or group of components associated with any source categories of fine particles or for eliminating any individual component or group of components associated with any source categories from the mix of fine particles included in the $PM_{2.5}$ mass-based indicator.

In their review of the first draft PA, CASAC agreed with staff's conclusion that it is appropriate to consider retaining $PM_{2.5}$ as the indicator for fine particles and further asserted, "There [is] insufficient peer-reviewed literature to support any other indicator at this time" (Samet, 2010c, p. 12). CASAC expressed a strong desire for EPA to "look ahead to future review cycles and reinvigorate support for the development of evidence that might lead to newer indicators that may correlate better with the health effects associated with ambient air concentrations of PM …" (Samet, 2010c, p 2). We further conclude that consideration of alternative indicators (e.g., taking into account new evidence for UFP or $PM_{2.5}$ composition) in future reviews is desirable and could be informed by additional research and data collection efforts, as described in section 2.5 below.

2.3.2 Averaging Times

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

In this review, we consider whether the currently available information provides support for maintaining standards with annual and 24-hour averaging times and whether there is sufficient evidence to support setting standards with other averaging times to address sub-daily or seasonal exposures.

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

The overwhelming majority of studies conducted since the last review continue to utilize annual (or multi-year) and 24-hour averaging times, reflecting the averaging times of the current

$PM_{2.5}$ standards. These studies continue to provide evidence that health effects are associated with annual and 24-hour averaging times. Therefore, we conclude it is appropriate to retain the current annual and 24-hour averaging times to provide protection for effects associated with both long-term (from one year to several years) and short-term (from less than one day to up to several days) $PM_{2.5}$ exposures.

- **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 sub-daily fine particle exposures?**

Relative to information available in the last review, recent studies provide additional evidence for cardiovascular effects associated with sub-daily (e.g., one to several hours) exposure to PM, especially effects related to cardiac ischemia, vasomotor function, and more subtle changes in markers of systemic inflammation, hemostasis, thrombosis and coagulation (US EPA, 2009a, section 6.2).[50] Because these studies have used different indicators (e.g., $PM_{2.5}$, PM_{10}, $PM_{10-2.5}$, UFPs), averaging times (e.g., 1, 2, and 4 hours), and health outcomes, it is difficult to draw conclusions about cardiovascular effects associated specifically with sub-daily exposures to $PM_{2.5}$.

With regard to respiratory effects associated with sub-daily $PM_{2.5}$ exposures, the currently available evidence is much sparser than for cardiovascular effects and continues to be very 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 than 24-hour exposures (US EPA, 2009a, section 6.3).

We conclude that this information, when viewed as a whole, is too unclear, with respect to the indicator, averaging time and health outcome, to serve as a basis for consideration of establishing a primary $PM_{2.5}$ standard with an averaging time shorter than 24-hours at this time.

- **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 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, but statistically non-

[50] A limited number of additional studies have also provided evidence of reported ECG changes typically representative of cardiac ischemia (S-T segment depression) or reported changes in heart rate variability (HRV) (US EPA, 2009a, sections 6.2.1.2 and 6.2.12.1), however, these changes are often variable and difficult to interpret the $PM_{2.5}$ etiologically relevant mechanism underlying the observed effects.

significant association was observed for the summer months. In the case of mortality, Zanobetti and Schwartz (2009) reported a 4-fold higher effect estimate for $PM_{2.5}$ associated mortality for the spring as compared to the winter. Taken together, these results provide emerging evidence that individuals may be at greater risk of dying from higher exposures to $PM_{2.5}$ in the warmer months and may be at greater risk of $PM_{2.5}$-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 $PM_{2.5}$-related 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 conclude that there is no basis to consider a seasonal averaging time separate from a 24-hour averaging time.

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 long- and short- term exposures. In considering the possibility of effects associated with sub-daily $PM_{2.5}$ 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 national 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 conclude that this evidence is 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 conclude that the currently available information provides strong support for consideration for retaining the current annual and 24-hour averaging times but does not provide support for considering alternative averaging times. CASAC agreed with these conclusions and further noted, "[t]o the extent that EPA supplements or replaces 24-hour fine PM samplers with continuous monitors, it may become possible to conduct studies that demonstrate that other averaging times for acute responses may be more appropriate than 24-hour averages, for at least some effects" (Samet, 2010c, p. 13).

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, we

consider whether currently available information supports 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 level of the standard was to be compared to measurements made at the community-oriented monitoring site recording the highest concentration, or, if specific constraints were met, measurements from multiple community-oriented monitoring sites could be averaged[51] (62 FR 38671 to 38672, July 18, 1997). The constraints were intended to ensure that spatial averaging would not result in inequities in the level of protection provided by the standard (62 FR 38672). This approach was consistent with the epidemiological 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."

In the last review, EPA tightened the criteria for use of spatial averaging to provide increased protection for vulnerable populations exposed to $PM_{2.5}$.[52] This change was based in part on an analysis of the potential for disproportionate impacts on potentially vulnerable populations, which found that 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; US EPA, 2005, section 5.3.6.1).

In this review, we again consider the potential impact of allowing for spatial averaging, noting that persons from lower socioeconomic strata have been identified as an additional susceptible population (section 2.2.1).

- **Does the currently available evidence provide support for the continued use of spatial averaging as part of the form of the annual standard?**

In considering the potential for disproportionate impacts on potentially susceptible populations, we updated an air quality analysis conducted for the last review. This analysis focused on determining if the spatial averaging provisions, as modified in 2006, could introduce

[51] 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 (62 FR 38671 to 38672, July 18, 1997).
[52] 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).

inequities in protection for susceptible populations exposed to $PM_{2.5}$. Specifically, we evaluated whether persons with a lower SES (a susceptible population discussed in US EPA,2009a, section 8.1.7) are more likely than the general population to live in areas in which the monitors recording the highest air quality values in an area are located. Data used in this analysis included demographic parameters measured at the Census Block or Census Block Group level, including percent minority population, percent minority subgroup population, percent of persons living below the poverty level, percent of persons 18 years of age or older, and percent of persons 65 years of age and older. In each candidate geographic area, data from the Census Block(s) or Census Block Group(s) surrounding the location of the monitoring site (as delineated by radii buffers of 0.5, 1.0, 2.0, and 3.0 miles) in which the highest air quality value was monitored were compared to the area-wide average value in the area. This analysis looked beyond areas that would meet the current spatial averaging criteria and considered all urban areas (i.e., CBSAs) with at least two valid annual DV monitors (Schmidt et al., 2011a, Analysis A). Recognizing the limitations of such cross-sectional analyses, we observe that the highest concentrations in an area tend to be measured at monitors located in areas where the surrounding populations are more likely to live below the poverty line and to have higher percentage of minorities.

Based upon the analysis described above, staff concludes 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 susceptible populations of persons with lower SES levels and minorities. Therefore, we conclude that it is appropriate to consider revising the form of the annual $PM_{2.5}$ standard such that it does not allow for the use of spatial averaging across monitors. In doing so, the level of the annual $PM_{2.5}$ standard would be compared to measurements made at the monitoring site that represents community-wide air quality recording the highest $PM_{2.5}$ concentrations. CASAC agreed with staff conclusions that it is "reasonable" for EPA to eliminate the spatial averaging provisions (Samet, 2010d, p. 2). Further, in CASAC's comments on the first draft PA, they noted, "Given mounting evidence showing that persons with lower SES levels are a susceptible group for PM-related health risks, CASAC recommends that the provisions that allow for spatial averaging across monitors be eliminated for the reasons cited in the (first draft) *Policy Assessment*" (Samet, 2010c, p. 13).

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 98^{th} 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). The Agency selected the 98^{th} percentile as an appropriate balance between adequately limiting the occurrence of peak concentrations and

providing increased stability which, when averaged over 3 years, facilitated effective health protection through the development of more stable implementation programs. 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 lowering the level of the 24-hour standard, EPA retained this form based in part on a comparison with the 99th percentile form.[53]

In this review, we have again considered the relative stability of the 98th and 99th percentile forms.

- **Does the currently available evidence provide support for the continued use of the 98th percentile form of the 24-hour standard?**

We recognize that the selection of the appropriate form of the 24-hour standard includes maintaining adequate protection against peak 24-hour concentrations while also providing a stable target for risk management programs, which serves to provide for the most effective public health protection in the long run.[54] As in previous reviews, we recognize that a concentration-based form, compared to an exceedance-based form, is more reflective of the health risks posed by elevated pollutant concentrations because such a form 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 level of the standard. Further, staff concludes that a concentration-based form, when averaged over three years, provides an appropriate balance between limiting peak pollutant concentrations and providing a stable regulatory target, thus, facilitating the development of more stable implementation programs.

In revisiting the stability of a 98th versus 99th percentile form for a 24-hour standard intended to provide supplemental protection for a generally controlling annual standard, we consider air quality data reported in 2000 to 2008 to update our understanding of the ratio between peak-to-mean $PM_{2.5}$ concentrations.[55] As illustrated in Figure 2-2, the 98th percentile value is a more stable metric than the 99th percentile.

On this basis, we conclude that it is appropriate to consider retaining the current 98th percentile form of the 24-hour standard as it represents an appropriate balance between

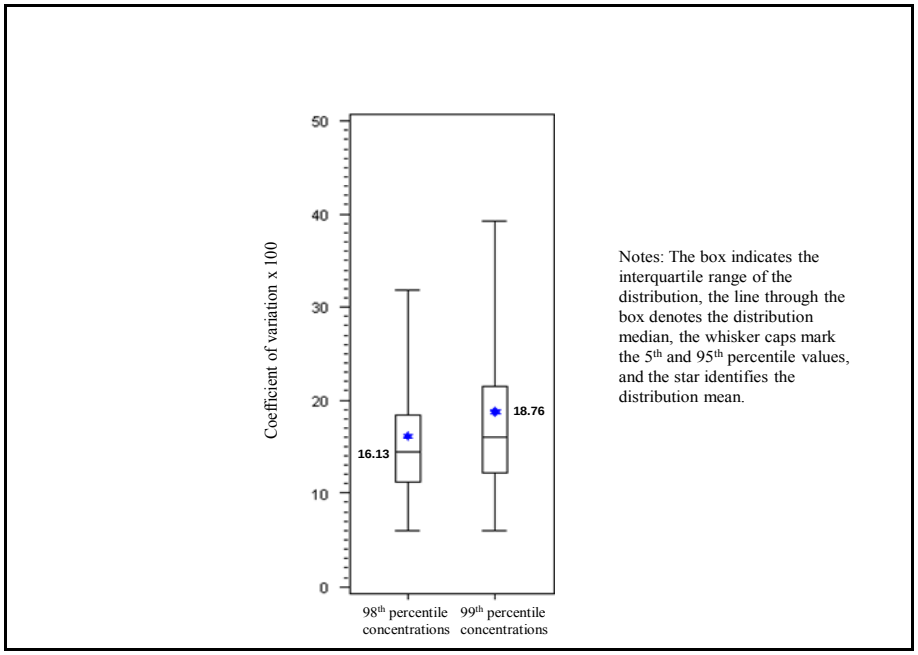
[53] In reaching this final decision, EPA recognized a technical problem associated with a potential bias in the method used to calculate the 98th percentile concentration for this form. The EPA adjusted the sampling frequency requirement in order to reduce this bias. Accordingly, the Agency modified 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).

[54] See *ATA III*, 283 F.3d at 374-375 which concludes it is legitimate for EPA to consider overall stability of the standard and its resulting promotion of overall effectiveness of NAAQS implementation programs in setting a standard that is requisite to protect the public health.

[55] We consider a coefficient of variation instead of simply the standard deviation because the 99th percentile values have higher concentration levels and dividing by the mean normalizes the data. In focusing on three years of recent air quality (2006 to 2008), we see a similar pattern of peak-to-mean ratios (Schmidt et al., 2010, Analysis 3).

adequately limiting the occurrence of peak concentrations and providing increased stability relative to an alternative 99th percentile form. In addition, by basing the form of the standard on concentrations measured at population-oriented monitoring sites, the standard would continue to focus on providing protection for people residing in or near localized areas of elevated concentrations.

Figure 2-2. Distribution of Site-level Variation in 98th and 99th Percentile Concentrations, as Measured by Coefficient of Variation (SD/Mean) Computed by Site Across Years, 2000-2008



Source: Schmidt et al., 2010, Analysis 3

2.3.4 Alternative Levels

In reaching staff conclusions for alternative standard levels that are appropriate to consider, we take into account both evidence-based (section 2.3.4.1) and risk-based considerations (section 2.3.4.2) as well as the related limitations and uncertainties associated with this information as presented and discussed more fully in the ISA and RA (US EPA, 2009a; US EPA, 2010a). CASAC advice on alternative standard levels is summarized in section 2.3.4.3. Staff conclusions based on the integration of the evidence-based and risk-based approaches as well as consideration of CASAC advice and public comments on the first and second draft PAs are presented in section 2.3.4.4.

Alternative levels are discussed in conjunction with staff conclusions on other elements of the standard presented above, notably, retaining $PM_{2.5}$ as the indicator for fine particles (section 2.3.1); retaining the current annual and 24-hour averaging times (section 2.3.2); modifying the current form of the annual standard to eliminate spatial averaging (section 2.3.3.1)

and retaining the current form of the 24-hour standard (section 2.3.3.2). Specifically, we address the following overarching question:

What alternative standard levels are appropriate to consider to provide requisite protection for health effects associated with long- and short-term $PM_{2.5}$ exposures?

2.3.4.1 Evidence-based Considerations

In translating information from epidemiological studies into the basis for reaching staff conclusions on alternative standard levels that are appropriate for consideration, we apply the policy framework outlined in section 2.1.3. In doing so, we focus on identifying levels for an annual standard and a 24-hour standard that, in combination, provide protection for health effects associated with both long- and short-term $PM_{2.5}$ exposures. We also consider the extent to which various combinations of annual and 24-hour standards reflect setting a generally controlling annual standard with a 24-hour standard providing supplemental protection. We conclude this policy goal results in the most efficient and effective way to provide appropriate public health protection.

As discussed in section 2.1.3, we recognize that there is no single factor or criterion that comprises the "correct" approach for reaching staff conclusions on alternative standard levels for consideration, but rather there are various approaches that are reasonable to consider. In reaching staff conclusions on the ranges of standard levels that are appropriate to consider, we address a series of specific questions beginning with consideration of the relative weight to place on different evidence.

In recognizing the absence of a discernible population threshold below which effects would not occur, our general approach for identifying *alternative annual standard levels* that are appropriate to consider focuses on characterizing the range of $PM_{2.5}$ concentrations over which we have the most confidence in the associations reported in the epidemiological studies, and conversely where our confidence in the association becomes appreciably lower. The most direct approach to address this issue is to consider epidemiological studies reporting confidence intervals around C-R relationships. We also explore other approaches that consider different statistical metrics to identify ranges of long-term mean $PM_{2.5}$ concentrations that were most influential in generating health effect estimates in long- and short-term epidemiological studies, placing greatest weight on those studies that reported positive and statistically significant associations.

With regard to identifying *alternative 24-hour standard levels* that are appropriate to consider, we look at the distributions of 24-hour $PM_{2.5}$ concentrations reported in short-term exposure studies, focusing on the 98^{th} percentile concentrations to match the form of the 24-hour standard (as discussed in section 2.3.3.2). In recognizing that the annual and 24-hour standards

work together to provide protection for effects associated with short-term $PM_{2.5}$ exposures, we also consider information on the long-term mean $PM_{2.5}$ concentrations from these studies. In addition to considering the epidemiological evidence, we also consider air quality information, specifically peak-to-mean ratios using county-level 24-hour and annual design values, to characterize air quality patterns in areas possibly associated with strong local or seasonal sources. These patterns help us understand the extent to which different combinations of annual and 24-hour standards would be consistent with the policy goal of setting a generally controlling annual standard with a 24-hour standard that provides supplemental protection.

- **What factors do we weigh in placing emphasis on epidemiological evidence to translate this information into staff conclusions on alternative standard levels?**

As discussed in section 2.1.3, we initially focus on long- and short-term $PM_{2.5}$ exposure studies conducted in the U.S. and Canada and place the greatest weight on health outcomes that have been judged in the ISA as having evidence to support a causal or likely causal relationship. We also consider the evidence for a broader range of health outcomes judged in the ISA to have evidence suggestive of a causal relationship, specifically studies that focus on effects in susceptible populations, to evaluate whether this evidence provides support for considering lower alternative standard levels.

We take several factors into account in placing relative weight on the body of available epidemiological studies, for example, study characteristics, including study design (e.g., time period of air quality monitoring, control for potential confounders); strength of the study (in terms of statistical significance and precision of results); and availability of population-level and air quality distribution data. We place greatest weight on information from multi-city epidemiological studies to inform staff conclusions regarding alternative annual standard levels. These studies have a number of advantages compared to single-city studies[56] that include providing representation of ambient $PM_{2.5}$ concentrations and potential health impacts across a range of diverse locations providing spatial coverage for different regions across the country, reflecting differences in $PM_{2.5}$ sources, composition, and potentially other exposure-related factors which might impact $PM_{2.5}$-related risks; lack of 'publication bias' (US EPA, 2004, p. 8-30); and consideration of larger study populations that afford the possibility of generalizing to the broader national population and provide higher statistical power than single-city studies to

[56] As discussed in section 2.2.1, we recognize that single-city studies provide ancillary evidence to multi-city studies in support of calling into question the adequacy of the current suite of standards. However, in light of the mixed findings reported in single-city short-term $PM_{2.5}$ exposure studies, and the likelihood that these results are influenced by localized events and not representative of air quality across the country, we place comparatively greater weight on the results from multi-city studies in considering alternative annual standard levels.

detect potentially statistically significant associations with relatively more precise effect estimates.

In reaching staff conclusions regarding alternative 24-hour standard levels that are appropriate to consider, we also take into account relevant information from single-city short-term $PM_{2.5}$ exposure studies. Although, as discussed above, multi-city studies have greater power to detect associations and provide broader geographic coverage in comparison to single-city studies, the extent to which effects reported in multi-city short-term $PM_{2.5}$ exposure studies are associated with the specific short-term air quality in any particular location is unclear, especially when considering short-term concentrations at the upper end of the air quality distribution (i.e., at the 98th percentile value) for a given study area. In contrast, single-city studies are more limited in terms of power and geographic coverage but the link between reported health effects and the air quality in a given study area is more straightforward to establish. Therefore, we consider the results of both multi-city and single-city short-term exposure studies to inform staff conclusions regarding alternative levels that are appropriate to consider for a 24-hour standard that is intended to provide supplemental protection in areas where the annual standard may not offer appropriate protection against the effects of all short-term exposures.

- **To what extent have confidence intervals around concentration-response relationships reported in epidemiological studies been characterized and to what extent do they inform the identification of alternative standard levels?**

Based on a thorough search of the available evidence, we identified three long-term $PM_{2.5}$ exposure studies reporting confidence intervals around C-R functions (i.e., Schwartz et al., 2008; Pope et al., 2002; Miller et al., 2007; see Figure 2-3).[57] In our assessment of these studies, we placed greater weight on analyses that averaged across multiple C-R models since this approach represents a more robust examination of the underlying C-R relationship than analyses considering a single C-R model. Although epidemiological studies reporting C-R functions and associated 95% confidence intervals provide information on the precision of the effect estimates at specific concentrations in the air quality distribution (i.e., point-wise confidence intervals), the concentration below which the confidence intervals for effect estimates becomes notably wider is intrinsically related to data density (an issue that is explored in the subsequent question), and not necessarily indicative of lower confidence in the underlying C-R relationship. Therefore, for the purposes of this discussion, we are interested in additional information that confidence intervals associated with C-R functions can provide, specifically as to the extent to which the confidence

[57] Subsequent to a thorough exploration of the published evidence, we were unable to identify any short-term $PM_{2.5}$ exposure studies that characterized confidence intervals around C-R relationships.

intervals around non-parametrically estimated C-R functions indicate appreciably less confidence that an association continues to exist at lower $PM_{2.5}$ concentrations.

Based on our review of the evidence and on our discussions with the investigators of the aforementioned three studies, we determined that these studies analyzed the C-R function primarily to determine if a linear curve most appropriately represented the C-R relationship, and not to characterize the confidence intervals associated with the underlying C-R relationship. Nonetheless, we consider what additional information beyond the shape of the C-R relationship these non-parametric curves can provide to inform our confidence in the association at lower $PM_{2.5}$ concentrations.

In the first study, Schwartz et al. (2008) used a variety of statistical methods to analyze the shape of the C-R relationship associated with long-term $PM_{2.5}$ exposure, and to investigate whether a mortality effect threshold exists among participants of the Harvard Six Cities cohort. The authors conducted a Bayesian Modeling Averaging (BMA) analysis that included 32 distinct models, some with the option for a threshold at 10 $\mu g/m^3$ and higher. Based on the BMA analysis, the C-R function reported by Schwartz et al. (2008) was found to be linear, with "….little evidence for a threshold in the association between exposure to fine particles and the risk of death…". Moreover, based on the BMA analysis (Figure 2-3a), EPA staff observed a widening of the confidence intervals around the C-R function for $PM_{2.5}$-related mortality. This widening of the confidence intervals occurred around the long-term mean concentration of approximately 10 $\mu g/m^3$ with continued broadening of the confidence intervals around the C-R function at lower $PM_{2.5}$ concentrations. This broadening is likely due in part to the comparative lack of data at the lower end of the air quality distribution considered in this analysis (i.e., 10.7 $\mu g/m^3$ is one standard deviation below the long-term mean concentration and the lower bound of the range of air quality considered was 8 $\mu g/m^3$). Consequently, we observe from this analysis that the widening of confidence intervals around C-R relationships at lower concentrations is due, in part, to the density of air quality data, reinforcing the view that one has most confidence in study results over the range of concentrations where the bulk of the data exist. In a separate analysis, Schwartz et al. (2008) also included point-wise confidence intervals for the association between $PM_{2.5}$ and mortality in a smoothing plot of a single nonparametric model (Figure 2-3b). However, since these point-wise confidence intervals relate specifically to the magnitude of effect estimates generated at specific $PM_{2.5}$ concentrations from a single model, we conclude that this analysis is not informative for characterizing confidence intervals associated with the underlying C-R relationship.

Figure 2-3. Confidence Intervals Around $PM_{2.5}$ Concentration-Response Relationships – Information from Multi-city Epidemiological Studies

a.

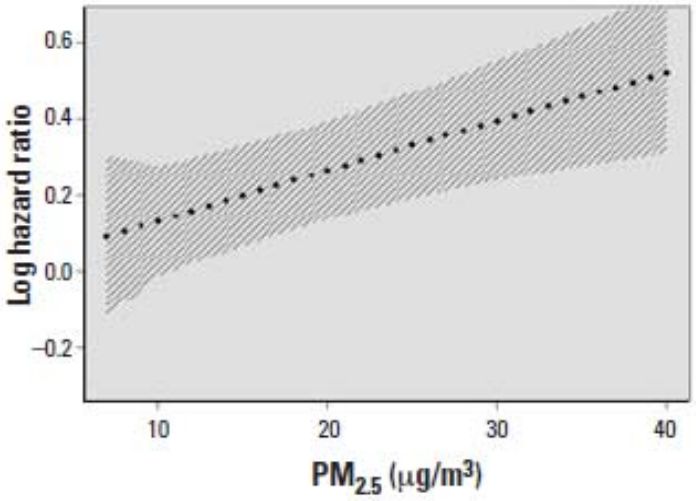


Figure 2. The estimated concentration–response relation between $PM_{2.5}$ and the risk of death in the Six Cities Study, based on averaging the 32 possible models that were fit. Also shown are the pointwise 95% CIs around that curve, based on jacknife estimates.

b.

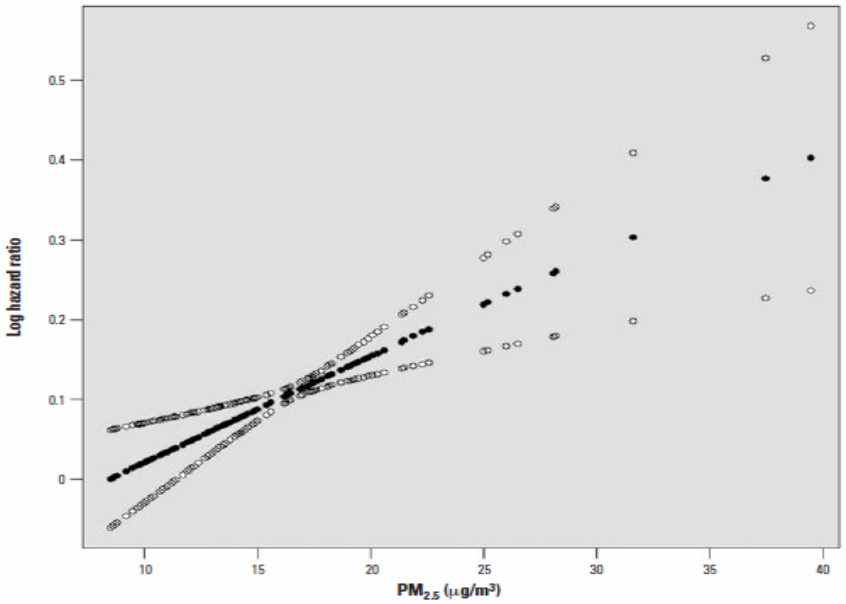
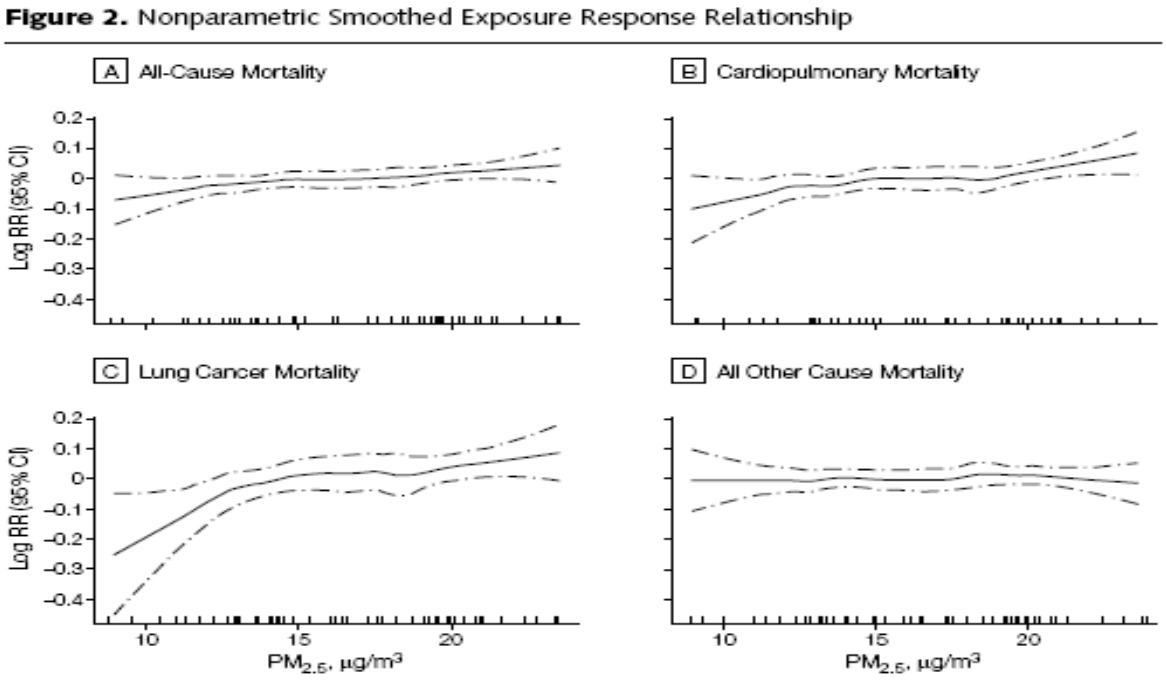


Figure 1. The estimated concentration–response relation between $PM_{2.5}$ and the risk of death in the Six Cities Study, using a penalized spline with 18 knots. Also shown are the pointwise 95% CIs.

Source: Schwartz et al., 2008

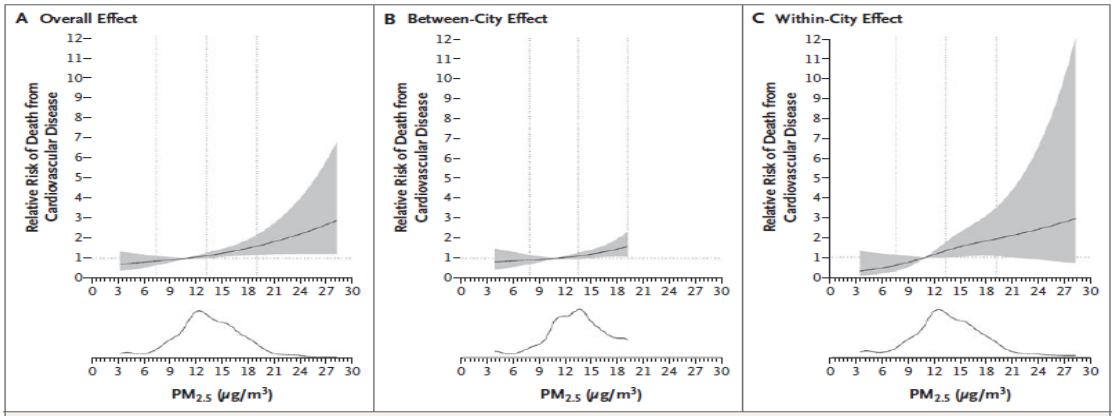
Figure 2-3. Confidence Intervals Around $PM_{2.5}$ Concentration-Response Relationships from Multi-City Epidemiological Studies (cont.)

c.



Source: Pope et al., 2002

d.



Source: Miller et al., 2007

In the second long-term $PM_{2.5}$ exposure study, Pope et al. (2002) utilized a nonparametric smoothing model to depict the shape of the C-R function and associated confidence intervals using mortality data from the ACS cohort. This exploratory analysis was conducted primarily to examine departures from linearity and to support the utilization of log-linear regression models. Goodness-of-fit testing indicated these data supported a log-linear C-R relationship. We observe (and observed in the last review) that there was an appreciable widening of point-wise confidence intervals on the smoothing plot for all-cause mortality beginning at approximately 13 to 12 $\mu g/m^3$ (Figure 2-3c; US EPA, 2005, p. 3-56; Figure 3-4) which is somewhat below where the bulk of the air quality distribution in the study occurs (i.e., 14 $\mu g/m^3$ is one standard deviation below the long-term mean concentration of 17.7 $\mu g/m^3$). However, similar to the single-model analysis presented in the discussion of the Schwartz et al. (2008) study (Figure 2-3b), this analysis was also generated from a single model, which resulted in point-wise confidence intervals that relate to the magnitude of effect estimates generated at specific $PM_{2.5}$ concentrations. Moreover, the widening of the confidence intervals in the smoothing plot is likely a consequence of the comparative lack of air quality data at lower $PM_{2.5}$ concentrations in this study, and does not suggest the possibility that an effects threshold may exist at lower $PM_{2.5}$ concentrations. It also remains unclear how representative this single model is of the underlying C-R relationship. Therefore, a potentially more robust approach to characterizing confidence intervals associated with C-R relationships may involve the generation of multiple C-R functions as was conducted by Schwartz et al. (2008), as just discussed.

The third long-term $PM_{2.5}$ exposure study provides information on the shape of the C-R function and associated confidence intervals using cardiovascular-related mortality and morbidity data from the WHI cohort (Miller et al., 2007; Figure 2-3d). This analysis of cardiovascular events in relation to long-term $PM_{2.5}$ exposure is indicative of a continued reduction in risk at lower concentrations of $PM_{2.5}$, with no evidence of a discernible effects threshold, and provides additional support for log-linear C-R relationships (US EPA, 2009a, section 2.4.3). We also recognize that the relative number of events occurring at the lower quintiles of exposure is similar to the number of events at the higher quintiles, indicating that there is statistical power to detect an association between $PM_{2.5}$ and mortality at the lower $PM_{2.5}$ concentrations. However, since the reference value for the C-R function in this analysis is 11$\mu g/m^3$, and effect estimates across the entire distribution are being compared to effect estimates at this concentration, this analysis does not identify a $PM_{2.5}$ concentration where there is an appreciable widening of confidence intervals and reduced confidence in the underlying C-R relationship in this study.

In summary, we recognize there are important differences in the statistical approaches utilized to create the C-R functions and associated confidence intervals reported in Schwartz et

al. (2008), Pope et al. (2002), and Miller et al. (2007) that inform our interpretation of these studies. Although these analyses of long-term exposure to $PM_{2.5}$ provide information on the lack of any discernible population threshold, only Schwartz et al. (2008) conducted a multi-model analysis to characterize confidence intervals around the estimated C-R relationship that can help inform at what $PM_{2.5}$ concentrations we have appreciably less confidence in the nature of the underlying C-R relationship. Although analyses of confidence intervals associated with C-R relationships can help inform consideration of alternative standard levels, we conclude that the single relevant analysis now available is too limited to serve as the principal basis for identifying alternative standard levels in this review.

- **How do we consider different statistical metrics for identifying alternative levels that are appropriate to consider for an annual standard?**

As outlined above, we recognize that health effects may occur over the full range of concentrations observed in the long- and short-term epidemiological studies and that the ISA concluded no discernible population threshold for any effects can be identified based on the currently available evidence (US EPA 2009a, section 2.4.3). In identifying alternative standard levels that are appropriate to consider, we first take into account the statistical metric used in previous reviews. This approach recognizes that the strongest evidence of associations occurs at concentrations around the long-term mean concentration. Thus, in earlier reviews, we focused on identifying standard levels that were somewhat below the long-term mean concentrations reported in $PM_{2.5}$ exposure studies. As outlined in section 2.1.3, the long-term mean concentrations represent air quality data typically used in epidemiological analyses and provide a direct link between $PM_{2.5}$ concentrations and the observed health effects. Further, these data are available for all long- and short-term exposure studies analyzed and, therefore, represent the data set available for the broadest set of epidemiological studies.

Consistent with CASAC's comments on the second draft PA, we also explore ways to take into account additional information from epidemiological studies, when available (Samet, 2010d, p. 2). We do this by evaluating different statistical metrics, beyond the long-term mean concentration, to characterize the range of $PM_{2.5}$ concentrations down through which we continue to have confidence in the associations observed in epidemiological studies and below which there is a comparative lack of data such that our confidence in the relationship is appreciably less. This would also be the range of $PM_{2.5}$ concentrations which have the most influence on generating the health effect estimates reported in epidemiological studies. As discussed in section 2.1.3, we recognize there is no one percentile value within a given distribution that is the most appropriate or "correct" way to characterize where our confidence in the associations becomes appreciably lower. We conclude that focusing on concentrations within the lower quartile of a distribution, such as the range from the 25^{th} to the 10^{th} percentile, is

reasonable to consider as a region within which we begin to have appreciably less confidence in the associations observed in epidemiological studies.[58] In staff's view, considering lower $PM_{2.5}$ concentrations, down to the lowest concentration observed in a study, would be a highly uncertain basis for selecting alternative standard levels.

As outlined in 2.1.3, we recognize that there are two types of population-level information to consider in identifying the range of $PM_{2.5}$ concentrations which have the most influence on generating the health effect estimates reported in epidemiological studies. The most relevant information to consider is the number of health events (e.g., deaths, hospitalizations) occurring within a study population in relation to the distribution of $PM_{2.5}$ concentrations likely experienced by study participants. Although not as directly relevant, the number of participants within each study area can be used as a surrogate for health event data in relation to the distribution of $PM_{2.5}$ concentrations.

In applying this approach, we focus on identifying the broader range of $PM_{2.5}$ concentrations which had the most influence on generating health effect estimates in epidemiological studies. As discussed below, in working with study investigators, we were able to obtain health event data for three large multi-city studies (Krewski et al., 2009; Zanobetti and Schwartz, 2009; Bell et al., 2008)[59] and population data for the same three studies and one additional long-term $PM_{2.5}$ exposure study (Miller et al., 2007); as documented in a staff memorandum (Rajan et al., 2011). In the absence of health event and population data, the distribution of $PM_{2.5}$ concentrations across study areas could be used to represent the $PM_{2.5}$ concentrations likely experienced by study participants. However, we were unable to determine from the methodologies published for these studies how the air quality was statistically weighted to account for variations in the availability of daily $PM_{2.5}$ measurements by study area. Consequently, we are unable to consider this type of information as part of our effort to identify the broader range of $PM_{2.5}$ concentrations that were most influential in generating the health effect estimates in epidemiological studies.

Figures 2-4 through 2-7 summarize policy-relevant epidemiological evidence. Long- and short-term exposure studies that evaluated endpoints classified in the ISA as having evidence of

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[58] In the last review, staff believed it was appropriate to consider a level for an annual $PM_{2.5}$ standard that was somewhat below the averages of the long-term concentrations across the cities in each of the key long-term exposures studies, recognizing that the evidence of an association in any such study was strongest at and around the long-term average where the data in the study are most concentrated. For example, the interquartile range of long-term average concentrations within a study and a range within one standard deviation around the study mean were considered reasonable approaches for characterizing the range over which the evidence of association is strongest (US EPA, 2005, p. 5-22). In this review, we note the interrelatedness of the distributional statistics and a range of one standard deviation around the mean which contains approximately 68% of normally distributed data, in that one standard deviation below the mean falls between the 25^{th} and 10^{th} percentiles.

[59] Effect estimates from Krewski et al. (2009), Zanobetti and Schwartz (2009), and Bell et al. (2008) were used to generate the core quantitative risk assessment results presented in the RA (US EPA, 2010a).

a *causal* or *likely causal relationship* (including studies with long-term mean $PM_{2.5}$ concentrations below 17 $\mu g/m^3$) are summarized in Figures 2-4 through 2-6.[60] Figures 2-4 and 2-6 provide summaries of long- and short-term exposure studies that evaluated mortality (evidence of a *causal relationship*); cardiovascular effects (evidence of a *causal relationship*); and respiratory effects (evidence of a *likely causal relationship*) in the general population, as well as older adults, a susceptible population. Figure 2-5 provides a summary of studies that evaluated respiratory effects (evidence of *a likely causal relationship*) in children, a susceptible population, as well as long-term exposure studies of children that evaluated developmental effects that are classified as having evidence *suggestive of a causal relationship*. Figure 2-7 presents cumulative frequency plots of the health events or number of study participants and corresponding long-term mean $PM_{2.5}$ concentrations for the four studies for which we were able to obtain such data (Krewski et al., 2009; Zanobetti and Schwartz, 2009; Bell et al., 2008; Miller et al., 2007). This figure highlights the range of $PM_{2.5}$ concentrations between the 25^{th} to 10^{th} percentiles of the distribution of health events or number of study participants. In general, we note that the long-term mean $PM_{2.5}$ concentrations based upon the distributions of health event and study population data are similar, and provide support for the utilization of data on the number of study participants as a surrogate for health event data (Rajan et al., 2011).

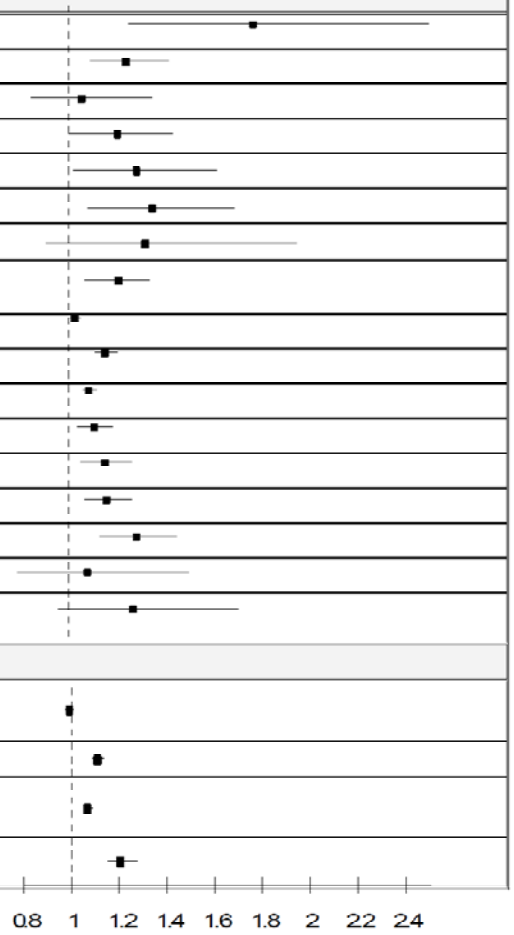
As outlined above in section 2.1.3, epidemiological studies typically report concentrations based upon a composite monitor distribution; that is, concentrations averaged across ambient monitors within each area included in a given study are averaged across study areas to calculate an overall study mean concentration. As noted above, a policy approach that uses data based on composite monitor distributions to identify alternative standard levels, and then compares those levels to concentrations at appropriate maximum monitors to determine if an area meets a given standard, directionally has the potential to build in some margin of safety.[61]

[60] We note that additional studies presented and assessed in the ISA report effects at higher long-term mean $PM_{2.5}$ concentrations.

[61] In analyses conducted by EPA staff based on selected long- and short-term exposure studies, we note that the differences between the maximum and composite distributions were greater for studies with fewer years of air quality data (i.e., 1 to 3 years) and smaller numbers of study areas (i.e., 36 to 51 study areas). The differences in the maximum and composite monitor distribution were much smaller for studies with more years of air quality data (i.e., up to 6 years) and larger numbers of study areas (i.e., 112 to 204 study areas) (Hassett-Sipple et al., 2010; US EPA, 2010f, section 2.3.4.1). Therefore, any margin of safety that may be provided by a policy approach that uses data based on composite monitor distributions to identify alternative standard levels, and then compares those levels to concentrations at appropriate maximum monitors to determine if an area meets a given standard, will vary depending upon the number of monitors and air quality distributions within a given area. See also footnote 14 in section 2.1.3 and associated text.

Figure 2-4. Summary of Effect Estimates (per 10 µg/m^3) and Air Quality Distributions for Multi-City, Long-term $PM_{2.5}$ Exposure Studies of the General Population and Older Adults

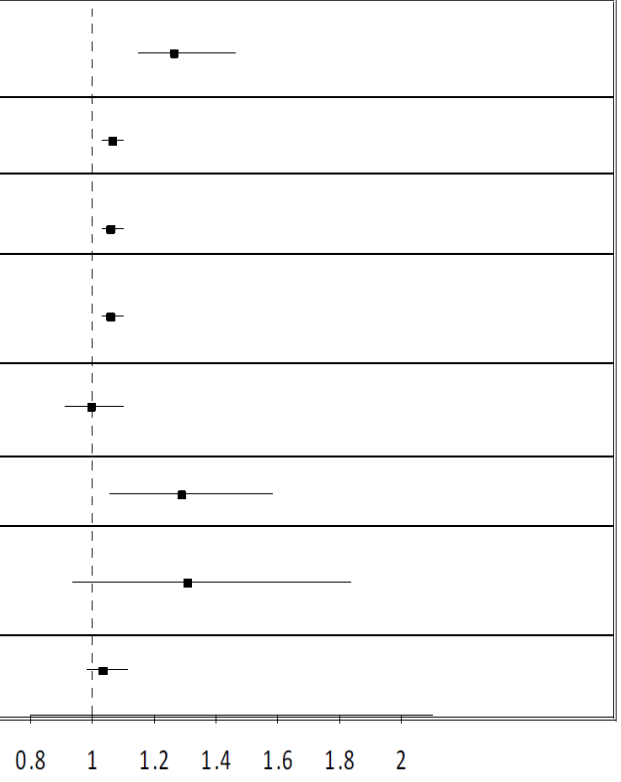
Study	Cite	Geographic Area	Years of Air Quality Data	Endpoint	Air Quality Data (µg/m³) Author Reported Data Mean	Mean - 1SD	Range	Effect Estimate (95% CI)
General Population								
WHI	Miller et al. (2007)	36 US cities	2000	Mortality-CV	12.9[a]	10.2	3.4 28.3	
				All CVD				
				Incident MI				
				Revascularization				
				Stroke				
				CBVD				
Cystic Fibrosis	Goss et al. (2004)[b]	6 US regions (NE, SE, NC, SC, NW, SW)	2000	Mortality-All-cause	13.7	9.5	11.8-15.9 (IQR)	
				Pulmonary exacerbation				
ACS-Reanalysis II	Krewski et al. (2009)	116 US MSAs	1999-2000	Mortality-all cause	14.0	11.0	5.8 - 22	
				Mortality-IHD				
				Mortality-CPD				
				Mortality-Lung cancer				
VA	Lipfert et al. (2006)		1999-2001	Mortality-all cause	14.3	11.3	5.0 - ?	
Harvard Six Cities (SCS)-Extended	Laden et al. (2006)	6 US cities (Northeast/ Midwest)	1979-1998	Mortality-all cause	16.4[c]	10.8	10-22	
				Mortality-CV				
				Mortality-Respiratory				
				Mortality-Lung cancer				
Older Adults								
MCAPS-Western US	Zeger et al. (2008)	62 US counties	2000-2005	Mortality-all cause	13.1[d]	-	10.4-18.5 (IQR)	
Medicare-ACS	Eftim et al. (2008)	51 US MSAs	2000-2002	Mortality-all cause	13.6	10.8	6.0-25.1	
MCAPS-Eastern US	Zeger et al. (2008)	421 US counties	2000-2005	Mortality-all cause	14.0[c]	-	12.3-15.3 (IQR)	
Medicare -SCS	Eftim et al. (2008)	6 US cities	2000-2002	Mortality-all cause	14.1	11.0	9.6-19. 1	



[a]Update of Miller et al. (2007) $PM_{2.5}$ data included in Curl, 2009
[b]Cohort included persons with cystic fibrosis age 6 and older, mean age: 18.4 yrs
[c]Estimated from data provided by study author (Laden, 2009)
[d]Median (IQR: Interquartile range); overall US reported median (IQR) of 13.2 µg/m³ (11.1-14.9)

Figure 2-5. Summary of Effect Estimates (per 10 µg/m^3) and Air Quality Distributions for Multi-City, Long-term $PM_{2.5}$ Exposure Studies of Children

Children								
Study	Cite	Geographic Area	Years of Air Quality Data	Endpoint	Air Quality Data (µg/m^3)			Effect Estimate (95% CI)
					Mean	Mean – 1SD	Range	
	Bell et al. (2007)	CT,MA	1998-2002	Low Birth Weight	11.9[a]	10.3		
	Liu et al. (2007)	3 Canadian cities	1985-1999	IUGR -1nd trimester	12.2	-	6.3-15	
				IUGR -2nd trimester				
				IUGR – 3rd trimester				
	Parker and Woodruff (2008)	Continental US	2000-2003	Low Birth Weight	13.5[a]	-	10.9-16.1 (IQR)	
S CA CHS	McConnell et al. (2003)	12 communities – S CA	1996-1999	Bronchitic Symptoms	13.8	6.1	6-29	
24-Cities	Dockery et al. (1996)	24 communities – US, Canada	1988-1991	Bronchitis	14.5	10.3	5.8-20.7	
	Woodruff et al. (2008)	96 US counties	1999-2002	Infant mortality	14.9[b]	--	12.0-18.6 (IQR)	



[a]Gestational mean

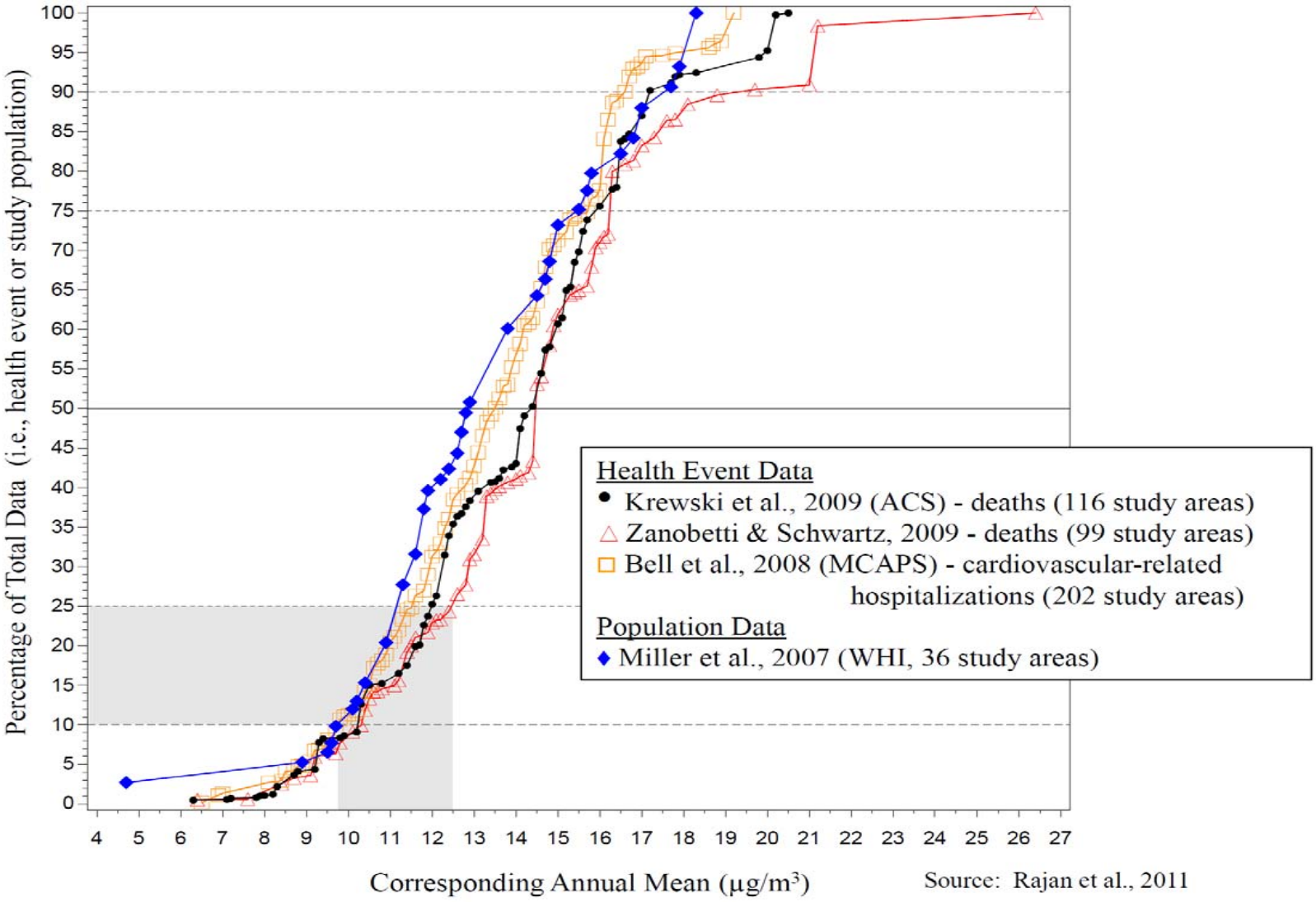
[b]Median for all cause mortality; median (IQR: interquartile range) for survivors = 14.8 (11.7-18.7) µg/m^3. Exposure period was first 2 months of life.

Figure 2-6. Summary of Effect Estimates (per 10 µg/m^3) and Air Quality Distributions for Multi-City, Short-term $PM_{2.5}$ Exposure Studies of the General Population and Older Adults

Study/Cite	Geographic Area	Years of Air Quality Data	Endpoint	Air Quality Data (µg/m³) Author Reported Data				Effect Estimate (95% CI)
				Mean	Mean - 1SD	Range	98th percentile	
General Population								
Burnett et al. (2004)	12 Canadian Cities	1981-1999	Nonaccidental mortality	12.8	-	-	38.0	
Zanobetti & Schwartz (2009)	112 US counties	1999-2005	Nonaccidental mortality	13.2[a]	10.3[a]	6.6-24.7	34.3	
Burnett & Goldberg (2003)	8 Canadian Cities	1986-1996	Nonaccidental mortality	13.3	3.9[b]	-	38.9[a]	
Harvard Six Cities/ Klemm and Mason (2003)	6 US cities (Northeast/ Midwest)	1979-1988	Nonaccidental mortality	14.7[c]	-	9-23 (IQR)	-	
Franklin et al. (2008)	25 US communities	2000-2005	Nonaccidental mortality	14.8[a]	-	9.9-27.4[a]	43.0	
Franklin et al. (2007)	27 US communities	1997-2002	Nonaccidental mortality	15.6[a]	-	8.8-23.9	45.8	
Older Adults/Children[d]								
MCAPS/Bell et al. (2008)	202 US counties	1999-2005	CVD HA	12.9[a]	10.2[a]	4-20	34.2	
			Resp HA					
MCAPS/Dominici et al. 2006	204 US counties	1999-2002	IHD HA	13.4[a]	10.5[a]	4-23	34.8	
			CHF HA					
			Dysrhythmia HA					
			CBVD HA					
			PVD HA					
			COPD HA					
			RTI HA					
O' Connor (2008)	7 US Cities	1998-2001	Wheeze/Cough	14.0	-	-	39.0[a]	

[a]Estimated from data provided by study author or published study
[b]Estimated from coefficient of variation reported in original study by Burnett et al. (2000)
[c]Mean value not reported in study, median presented from original study by Schwartz et al. (1996)
[d]MCAPS cohort included adults ≥ 65 yrs; O'Connor (2008) cohort included children, mean age: 7.7 yrs
IQR: interquartile range

Figure 2-7. Distribution of Population-Level Data and Corresponding $PM_{2.5}$ Concentrations for Selected Multi-City Epidemiological Studies



We initially consider distributional statistics for both long- and short-term exposure studies that evaluated mortality (*causal relationship*), cardiovascular effects (*causal relationship*) or respiratory effects (*likely causal relationship*). In looking first at the long-term mean concentrations in the long-term exposure studies, we observe positive and often statistically significant associations at long-term mean $PM_{2.5}$ concentrations ranging from 16.4 to 12.9 $\mu g/m^3$ (Laden et al., 2006; Lipfert et al., 2006; Krewski et al., 2009; Goss et al., 2004; Miller et al.; 2007; Zeger et al., 2008; Eftim et al., 2008; Dockery et al., 1996; McConnell et al., 2003; see Figures 2-4 and 2-5). In considering the one long-term $PM_{2.5}$ exposure study for which we have health event data (Krewski et al., 2009), we observe that the long-term mean $PM_{2.5}$ concentrations corresponding with study areas contributing to the 25^{th} and 10^{th} percentiles of the distribution of mortality data are 12.0 $\mu g/m^3$ and 10.2 $\mu g/m^3$, respectively. As identified above, although less directly relevant than event data, the number of participants within each study area can be used as a surrogate for health event data in relation to the distribution of $PM_{2.5}$ concentrations. The long-term mean $PM_{2.5}$ concentrations corresponding with study areas contributing to the 25^{th} and 10^{th} percentiles of the distribution of study participants for Miller et al. (2007) were 11.2 $\mu g/m^3$ and 9.7 $\mu g/m^3$, respectively (Rajan et al., 2011).

In then considering information from multi-city, short-term exposure studies reporting positive and statistically significant associations with these same broad health effect categories, we observe positive and statistically significant associations at long-term mean $PM_{2.5}$ concentrations in a similar range of 15.6 to 12.8 $\mu g/m^3$ (Franklin et al., 2007, 2008; Klemm and Mason, 2003; Burnett and Goldberg, 2003; Zanobetti and Schwartz, 2009; Burnett et al., 2005; Bell et al., 2008; Dominici et al., 2006a; see Figure 2-6).[62] In considering the two multi-city, short-term $PM_{2.5}$ exposure studies for which we have health event data, we observe that the long-term mean $PM_{2.5}$ concentrations corresponding with study areas contributing to the 25^{th} and 10^{th} percentiles of the distribution of deaths and cardiovascular-related hospitalizations are 12.5 $\mu g/m^3$ and 10.3 $\mu g/m^3$, respectively, for Zanobetti and Schwartz (2009), and 11.5 $\mu g/m^3$ and 9.8 $\mu g/m^3$, respectively, for Bell et al. (2008) (Rajan et al., 2011).

Taking into consideration additional studies of specific susceptible lifestages (i.e., childhood), we expand our evaluation of the long-term exposure studies to include a broader range of health outcomes judged in the ISA to have evidence *suggestive of a causal relationship*. This evidence is taken into account to evaluate whether it provides support for considering lower alternative levels than if weight were only placed on studies for which health effects have been

[62] When integrating evidence from short-term exposure studies reporting positive and statistically significant associations with mortality, cardiovascular, and respiratory effects, the ISA concluded that these associations are generally consistent and precise at long-term mean $PM_{2.5}$ concentrations of 12.8 $\mu g/m^3$ and above (US EPA, 2009a, pp. 2-10 to 2-11)

judged in the ISA to evidence supporting a causal or likely causal relationship. We make note of a limited number of studies that provide emerging evidence for $PM_{2.5}$-related low birth weight and infant mortality, especially related to respiratory causes during the post-neonatal period. This more limited body of evidence indicates positive and often statistically significant effects associated with long-term $PM_{2.5}$ mean concentrations in the range of 14.9 to 11.9 $\mu g/m^3$ (Woodruff et al., 2008; Liu et al., 2007; Bell et al., 2007; see Figure 2-5). As illustrated in Figure 2-5, although Parker and Woodruff (2008) did not observe an association between quarterly estimates of exposure to $PM_{2.5}$ and low birth weight in a multi-city U.S. study, other U.S. and Canadian studies did report positive and statistically significant associations between $PM_{2.5}$ and low birth weight at lower ambient concentrations (Bell et al., 2007; Liu et al., 2007).[63] There remain significant limitations (e.g., identifying the etiologically relevant time period) in the evaluation of evidence on the relationship between $PM_{2.5}$ exposures and birth outcomes (US EPA, 2009a, pp. 7-48 and 7-56) which should be taken into consideration in reaching judgments about how to weigh these studies of potential impacts on specific susceptible populations in considering alternative standard levels that provide protection with an appropriate margin of safety.

With respect to carcinogenicity, mutagenicity, and genotoxicity (evidence *suggestive of a causal relationship*), the strongest evidence currently available is from long-term prospective cohort studies that report positive associations between $PM_{2.5}$ and lung cancer mortality. At this time, the $PM_{2.5}$ concentrations reported in studies evaluating these effects generally included ambient concentrations that are equal to or greater than ambient concentrations observed in studies that reported mortality and cardiovascular and respiratory effects (US EPA, 2009a, section 7.5). 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 carcinogenicity, mutagenicity, and genotoxicity effects.

Summary of Evidence-based Considerations to Inform Annual Standard Level

In considering the currently available evidence and air quality information within the context of identifying potential alternative annual standard levels for consideration, we again note that the ISA concludes there is no evidence of a discernible population threshold below which effects would not occur. Thus, health effects may occur over the full range of concentrations observed in the epidemiological studies. In the absence of any discernible thresholds, our general approach for identifying alternative standard levels that would provide

[63] As noted in section 7.4 of the ISA, Parker et al. (2005) reported that over a 9 month exposure period (mean $PM_{2.5}$ concentration of 15.4 $\mu g/m^3$) a significant decrease in birth weight was associated with infants in the highest quartile of $PM_{2.5}$ exposure as compared to infants exposed in the lowest quartile.

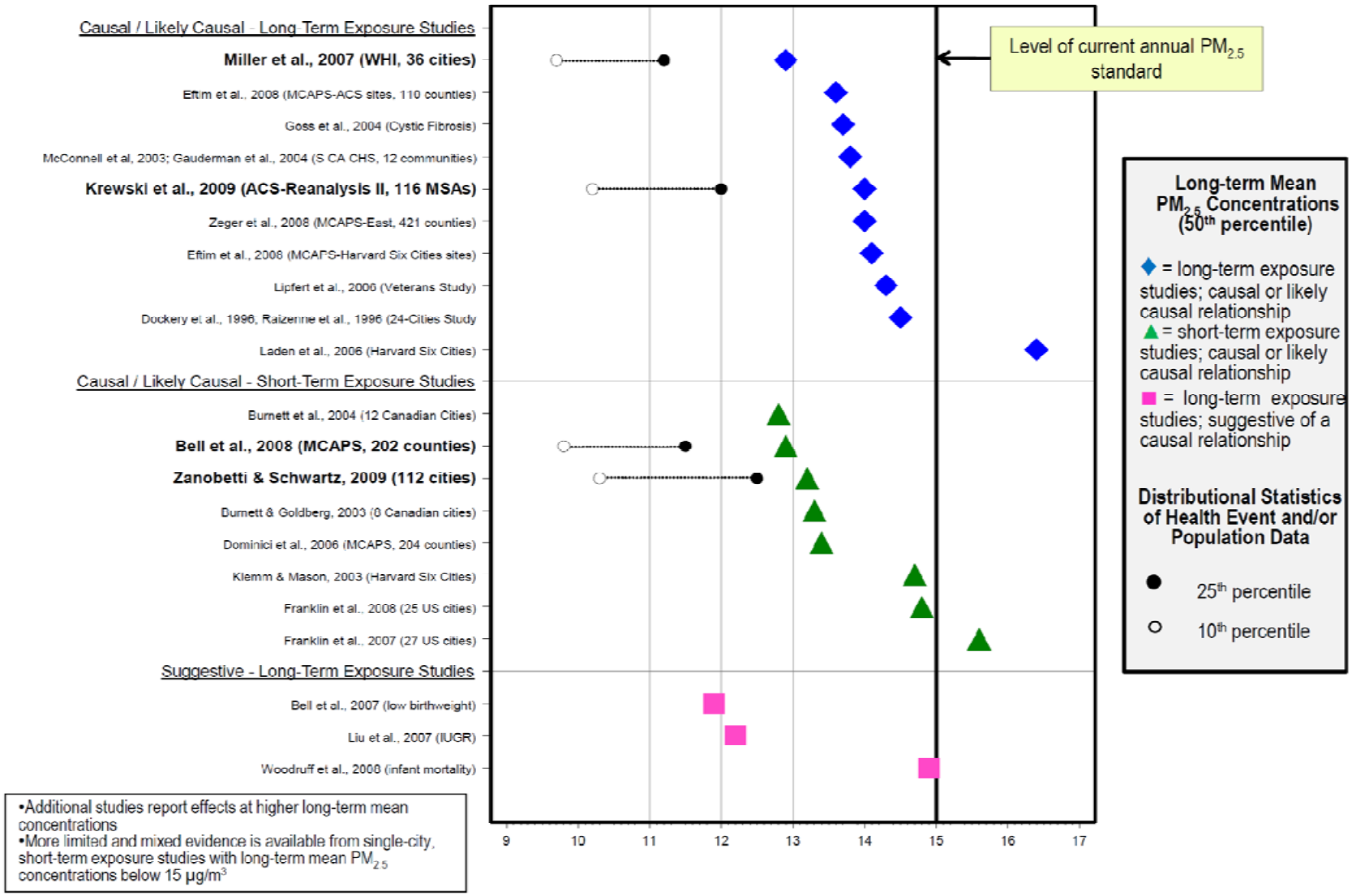
appropriate protection against effects observed in epidemiological studies has focused on the central question of identifying the range of $PM_{2.5}$ concentrations below the long-term mean concentrations where we continue to have confidence in the associations observed in epidemiological studies.

In considering the evidence, we recognize that NAAQS are standards set so as to provide requisite protection, neither more nor less stringent than necessary to protect public health with an adequate margin of safety. This judgment, ultimately made by the Administrator, involves weighing the strength of the evidence and the inherent uncertainties and limitations of that evidence. Therefore, depending on the weight placed on different aspects of the evidence and inherent uncertainties, considerations of different alternative standard levels could be supported.

As discussed in section 2.1.3, by applying the general policy approach used in previous reviews, one could focus on identifying alternative standard levels for the annual standard that are somewhat below the long-term mean $PM_{2.5}$ concentrations reported in the long- and short-term exposure studies. By expanding this approach to consider additional population-level information from epidemiological studies, one could also focus on the range of $PM_{2.5}$ concentrations below the long-term mean concentrations over which we continue to have confidence in the associations observed in epidemiological studies, as well as the extent to which our confidence in the associations is appreciably less at lower concentrations, to identify alternative annual standard levels. Figure 2-8 provides a summary of the long-term mean $PM_{2.5}$ concentrations for the long- and short-term exposure studies presented in Figures 2-4 through 2-6 as well as the range of $PM_{2.5}$ concentrations corresponding with the 25^{th} to 10^{th} percentiles of health event or number of study participants data from the four multi-city studies, for which distributional statistics are available and presented in Figure 2-7.

Given the currently available evidence and considering the various approaches discussed above, as an initial matter we conclude it is appropriate to focus on an annual standard level within a range of about 12 to 11 $\mu g/m^3$. As illustrated in Figure 2-8, a standard level of 12 $\mu g/m^3$, at the upper end of this range, is somewhat below the long-term mean $PM_{2.5}$ concentrations reported in all the multi-city long- and short-term exposure studies that provide evidence of positive and statistically significant associations with health effects classified as having evidence of a causal or likely causal relationship, including premature mortality and hospitalizations and emergency department visits for cardiovascular and respiratory effects as well as respiratory effects in children. Further, a level of 12 $\mu g/m^3$ would reflect consideration of additional population-level information from such epidemiological studies in that it is the $PM_{2.5}$ concentration generally corresponding with the 25^{th} percentile of the available distributions of health events data, which we consider to be at the high end of the range of $PM_{2.5}$ concentrations within which the data become appreciably more sparse and, thus, where our

Figure 2-8. Translating Epidemiological Evidence from Multi-City Exposure Studies into Annual $PM_{2.5}$ Standards



confidence in the associations observed in epidemiological studies starts to become appreciably less. In addition, a level of 12 $\mu g/m^3$ would reflect some consideration of studies that provide more limited evidence of reproductive and developmental effects, which are suggestive of a causal relationship, in that it is about at the same level as the lowest long-term mean $PM_{2.5}$ concentrations reported in such studies (see Figure 2-8).

Alternatively, an annual standard level of 11 $\mu g/m^3$, at the lower end of this range, is well below the lowest long-term mean $PM_{2.5}$ concentrations reported in all multi-city long- and short-term exposure studies that provide evidence of positive and statistically significant associations with health effects classified as having evidence of a causal or likely causal relationship. A level of 11 $\mu g/m^3$ would reflect placing more weight on the distributions of health event and population data, in that this level is within the range of $PM_{2.5}$ concentrations corresponding to the 25^{th} and 10^{th} percentiles of all the available distributions of such data. In addition, a level of 11 $\mu g/m^3$ is somewhat below the lowest long-term mean $PM_{2.5}$ concentrations reported in reproductive and developmental effects studies that are suggestive of a causal relationship. Thus, a level of 11 $\mu g/m^3$ would reflect an approach to translating the available evidence that places relatively more emphasis on margin of safety considerations than would a standard set at a higher level. Such a policy approach would tend to weigh uncertainties in the evidence in such a way as to avoid potentially underestimating $PM_{2.5}$-related risks to public health. Further, recognizing the uncertainties inherent in identifying any particular point at which our confidence in reported associations becomes appreciably less, we conclude that the available evidence does not provide a sufficient basis to consider alternative annual standard levels below 11 $\mu g/m^3$.

We have also considered the extent to which the available evidence provides a basis for considering alternative annual standard levels above 12 $\mu g/m^3$. As discussed below, we conclude that it could be reasonable to consider a standard level up to 13 $\mu g/m^3$ based on a policy approach that tends to weigh uncertainties in the evidence in such a way as to avoid potentially overestimating $PM_{2.5}$-related risks to public health, especially to the extent that primary emphasis is placed on long-term exposure studies as a basis for an annual standard level. A level of 13 $\mu g/m^3$ is somewhat below the long-term mean $PM_{2.5}$ concentrations reported in all but one of the long-term exposure studies providing evidence of positive and statistically significant associations with $PM_{2.5}$-related health effects classified as having a causal or likely causal relationship. As shown in Figure 2-8, the one long-term exposure study with a long-term mean $PM_{2.5}$ concentration just below 13 $\mu g/m^3$ is the WHI study (Miller et al., 2007).[64] We note that in comparison to other long-term exposure studies, the WHI study was more limited in that

[64] As noted in section 2.2.1 and Table 2-4, WHI study investigators provided EPA with updated air quality data indicating the long-term mean $PM_{2.5}$ concentration for this study was 12.9 $\mu g/m^3$, not 13.5 $\mu g/m^3$ as originally reported (Curl, 2009).

it was based on only one year of air quality data. Thus, to the extent that less weight is placed on the WHI study than on other long-term exposure studies with more robust air quality data, a level of 13 $\mu g/m^3$ could be considered as being protective of long-term exposure related effects classified as having a causal or likely causal relationship. In also considering short-term exposure studies, we note that a level of 13 $\mu g/m^3$ is below the long-term mean $PM_{2.5}$ concentrations reported in most such studies, but is above the long-term means of 12.8 and 12.9 $\mu g/m^3$ reported in Burnett et al. (2004) and Bell et al. (2008), respectively. In considering these studies, we find no basis to conclude that these two studies are any more limited or uncertain than the other short-term studies shown in Figure 2-8, noting in particular that Bell et al. (2008) is a large study of older adults, a susceptible population. On this basis, as discussed below, we conclude that consideration of an annual standard level of 13 $\mu g/m^3$ would have implications for the degree of protection that would need to be provided by the 24-hour standard, such that taken together the suite of $PM_{2.5}$ standards would provide appropriate protection from effects on public health related to short-term exposure to $PM_{2.5}$.

We also note that a standard level of 13 $\mu g/m^3$ would reflect a judgment that the uncertainties in the epidemiological evidence in general, including uncertainties related to the heterogeneity observed in the epidemiological studies in the eastern versus western parts of the U.S., the relative toxicity of $PM_{2.5}$ components, and the potential role of co-pollutants, are too great to warrant placing any weight on distributions of health event and population data that extend down below the mean into the lower quartile of the data. This level would also reflect a judgment that the evidence from reproductive and developmental effects studies that are suggestive of a causal relationship is too uncertain to support consideration of any lower level.

Taken together, staff concludes that consideration of alternative annual standard levels in the range of 13 to 11 $\mu g/m^3$ may be appropriate, although we also conclude that the currently available evidence most strongly supports consideration of an alternative annual standard level in the range of 12 to 11 $\mu g/m^3$. We conclude that an alternative level within the range of 12 to 11 $\mu g/m^3$ would more fully take into consideration the available information from all long- and short-term $PM_{2.5}$ exposure studies, including studies of susceptible populations, than would a higher level. This range would also reflect placing weight on information from studies that helps to characterize the range of $PM_{2.5}$ concentrations over which we continue to have confidence in the associations observed in epidemiological studies, as well as the extent to which our confidence in the associations is appreciably less at lower concentrations.

- **What alternative standard levels are appropriate to consider for a 24-hour standard intended to supplement the protection afforded by an annual standard?**

As recognized in section 2.1.3, an annual standard intended to serve as the primary means for providing protection for effects associated with both long- and short-term $PM_{2.5}$ exposures is

not expected to provide appropriate protection against the effects of all short-term $PM_{2.5}$ exposures. Of particular concern are areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods. As a result, we believe it is appropriate to consider alternative 24-hour $PM_{2.5}$ standard levels that would supplement the protection provided by an annual standard.

As outlined in section 2.1.3, we consider the available evidence from short-term $PM_{2.5}$ exposure studies, as well as the uncertainties and limitations in that evidence, to assess the degree to which alternative annual and 24-hour $PM_{2.5}$ standards can be expected to reduce the estimated risks attributed to short-term fine particle exposures. In considering the available epidemiological evidence, we take into account information from multi-city studies as well as single-city studies. We look both at the distributions of 24-hour $PM_{2.5}$ concentrations, focusing on the 98th percentile air quality values to match the form of the 24-hour standard (section 2.3.3.2), to the extent such data are available, as well as the long-term mean $PM_{2.5}$ concentrations.

In considering the information provided by the short-term exposure studies, we recognize that to the extent these studies were conducted in areas that likely did not meet one or both of the current standards, such studies do not help inform the characterization of the potential public health improvements of alternative standards set at lower levels.[65] Therefore, in considering the short-term exposure studies to inform staff conclusions regarding levels of the 24-hour standard that are appropriate to consider, we place greatest weight on studies conducted in areas that likely met both the current annual and 24-hour standards.

With regard to *multi-city studies* that evaluated effects associated with short-term $PM_{2.5}$ exposures, as summarized in Figure 2-6, we observe an overall pattern of positive and statistically significant associations in studies with 98th percentile values averaged across study areas in the range of 45.8 to 34.2 $\mu g/m^3$ (Burnett et al., 2004; Zanobetti and Schwartz, 2009; Bell et al., 2008; Dominici et al., 2006a, Burnett and Goldberg, 2003; Franklin et al., 2008).[66] We

[65] We recognize that in considering studies conducted in areas that likely did not meet the current annual standard, by reducing the long-term mean $PM_{2.5}$ concentrations in such areas to just meet the current annual standard, one could reasonably anticipate additional public health protection from short-term exposure (as well as long-term exposure). Further, we recognize that in considering studies conducted in areas that likely did not meet the current 24-hour standard, by reducing the upper end of the air quality distributions in order to meet the current 24-hour standard, one could similarly reasonably anticipate additional public health protection.

[66] We note that Figure 2-6 also includes one multi-city study conducted in areas that likely did not meet either the annual or 24-hour standards (Franklin et al., 2007). To the extent that changes in air quality designed to meet the current annual and/or 24-hour standard are undertaken, one could reasonably anticipate additional public health protection will occur in these study areas. Figure 2-6 also includes one multi-city study for which the ISA reports a long-term mean $PM_{2.5}$ concentration but does not report information on the 98th percentile value (Klemm and Mason, 2003). We do not know whether this study was conducted in areas that likely would have met the current

note that, to the extent air quality distributions were reduced to reflect just meeting the current 24-hour standard, additional protection would be anticipated for the effects observed in the three multi-city studies with 98th percentile values greater than 35 $\mu g/m^3$ (Burnett et al., 2004; Burnett and Goldberg, 2003; Franklin et al., 2008). In the three additional studies with 98th percentile values below 35 $\mu g/m^3$, specifically 98th percentile concentrations of 34.2, 34.3, and 34.8 $\mu g/m^3$, we note that these studies reported long-term mean $PM_{2.5}$ concentrations of 12.9, 13.2, and 13.4 $\mu g/m^3$, respectively (Bell et al., 2008; Zanobetti and Schwartz, 2009; Dominici et al., 2006a). To the extent that consideration is given to revising the level of the annual standard, as discussed above in section 2.3.4.1, we recognize that potential changes associated with meeting such an alternative annual standard would result in lowering risks associated with both long- and short-term $PM_{2.5}$ exposures. Consequently, in considering a 24-hour standard that would work in conjunction with an annual standard to provide appropriate public health protection, we note that to the extent that the level of the annual standard is revised to within a range of 13 to 11 $\mu g/m^3$, in particular in the range of 12 to 11 $\mu g/m^3$, as discussed above, additional protection would be provided for the effects observed in these multi-city studies.

Taken together, staff concludes that the multi-city, short-term exposure studies generally provide support for retaining the 24-hour standard level at 35 $\mu g/m^3$, specifically, in conjunction with an annual standard level revised to within a range of 12 to 11 $\mu g/m^3$. Alternatively, in conjunction with an annual standard level of 13 $\mu g/m^3$, we conclude that the multi-city studies provide limited support for revising the 24-hour standard level somewhat below 35 $\mu g/m^3$, such as down to 30 $\mu g/m^3$, based on one study (Bell et al., 2008) that reported positive and statistically significant effects with an overall 98th percentile value below the level of the current 24-hour standard in conjunction with an overall long-term mean concentration slightly less than 13 $\mu g/m^3$.

In reaching staff conclusions regarding alternative 24-hour standard levels that are appropriate to consider, we also take into account relevant information from *single-city studies* that evaluated effects associated with short-term $PM_{2.5}$ exposures. We recognize that these studies may provide additional insights regarding impacts on susceptible populations and/or on areas with isolated peak concentrations. Although, as discussed above, multi-city studies have advantages over single-city studies in terms of statistical power to detect associations and

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24-hour $PM_{2.5}$ standard and, therefore, this study does not inform staff conclusions regarding alternative standard levels that are appropriate to consider. Further, we note one study reported no association between $PM_{2.5}$ and respiratory symptoms in children in areas that likely would have met the current annual standard but not the current 24-hour standard (O'Connor et al., 2008). This study reported effects on lung function in asthmatic children associated with 5-day average $PM_{2.5}$ concentrations but not associated with 1-day average $PM_{2.5}$ concentrations (US EPA, 2009a, section 6.3.2.1).

broader geographic coverage as well as other factors such as less likelihood of publication bias, reflecting differences in $PM_{2.5}$ sources, composition, and potentially other factors that could impact $PM_{2.5}$-related effects, multi-city studies often present overall effect estimates rather than single-city effect estimates. Since short-term air quality can vary considerably across cities, the extent to which effects reported in multi-city studies are associated with short-term air quality in any particular location is uncertain, especially when considering short-term concentrations at the upper end of the distribution of daily $PM_{2.5}$ concentrations (i.e., at the 98th percentile value). In contrast, single-city studies are more limited in terms of power and geographic coverage but the link between reported health effects and the air quality in a given study area is more straightforward to establish. Therefore, we also consider evidence from single-city, short-term exposure studies to inform staff conclusions regarding alternative levels that are appropriate to consider for a 24-hour standard that is intended to provide supplemental protection in areas where the annual standard may not provide an adequate margin of safety against the effects of all short-term $PM_{2.5}$ exposures.

As discussed above for the multi-city studies, we look both at the 24-hour $PM_{2.5}$ concentrations in the single-city studies, focusing on the 98th percentile air quality values, as well as the long-term mean $PM_{2.5}$ concentrations. We consider single-city studies conducted in areas that would likely have met the current suite of $PM_{2.5}$ standards as most useful for informing staff conclusions related to the level of the 24-hour standard, as summarized in Figure 2-9.[67] We note that additional single-city studies summarized in Figure 2-9 were conducted *in areas that would likely have met one but not both of the current $PM_{2.5}$ standards*.[68] To the extent changes in air quality designed to just meet the current suite of $PM_{2.5}$ standards are undertaken, one could reasonably anticipate additional public health protection will occur in these study areas.

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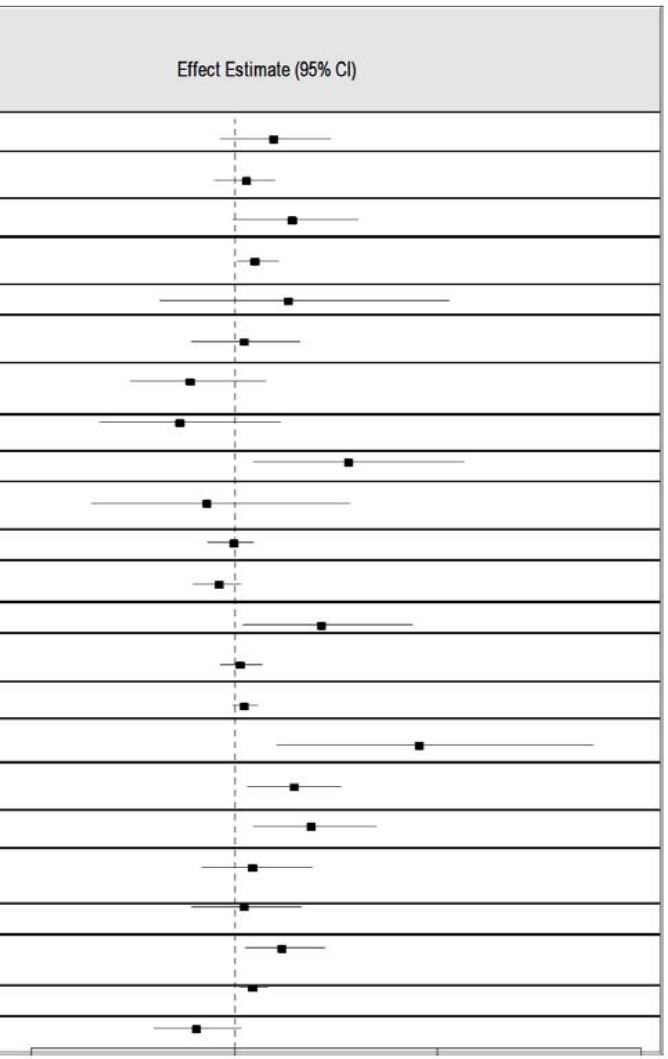
[67] We note there are additional single-city studies discussed in the ISA beyond the short-term exposure studies discussed in this section that were conducted in areas that would likely not have met both the current annual and 24-hour standards (e.g., Ito et al., 2007; Sheppard, 2003; Burnett, 1997). To the extent that changes in air quality designed to just meet the current annual and/or 24-hour standard are undertaken, one could reasonably anticipate additional public health protection will occur in these study areas For another group of studies, we have no information on the distribution of air quality concentrations, specifically information on the upper end of the distribution (i.e., the 98th percentile values) (e.g., NYDOH, 2006; Sullivan et al., 2005; Zanobetti and Schwartz, 2006; Pope et al., 2006; Dockery et al., 2005; Rich et al., 2005; Villeneuve et al, 2003; Fung et al., 2006; Chen et al, 2004; Chen et al., 2005 Slaughter et al, 2003; Chimonas and Gessner, 2007). Therefore, we do not know whether these studies were conducted in areas that would likely have met the current 24-hour $PM_{2.5}$ standard. Collectively, staff concludes these two groups of studies are not helpful to inform staff conclusions regarding alternative standard levels that are appropriate to consider.

[68] This group of studies included two studies conducted in areas that would likely have met the current annual standard but not the current 24-hour standard (Santa Clara, California and the Wasatch Front, UT) that reported positive and statistically significant associations between short-term $PM_{2.5}$ exposures and mortality and cardiovascular-related hospitalizations, respectively (Fairley, 2003; Pope et al., 2008) and one study conducted in an area that would likely have met the current 24-hour standard but not the current annual standard (Coachella Valley, California) that reported no association between short-term $PM_{2.5}$ exposures and cardiovascular –related mortality (Ostro et al., 2003).

Figure 2-9. Summary of Effect Estimates (per 10 µg/m^3) and Air Quality Distributions for Single-City, Short-term $PM_{2.5}$ Exposure Studies

Study/Cite	Geographic Area	Years of Air Quality Data	Endpoint	Air Quality Data (µg/m)		Effect Estimate (95% CI)
				Mean	98th percentile[a]	
Lisabeth et al. 2008	Nueces County, TX	2001-2005	Ischemic Stroke/TIA HA	7.0[b]	13.6	
Rabinovich et al. 2006	Denver	2 winters 2001-2003	Asthma Medication Use (children)	7.4	17.2	
Stieb et al. 2000	St. John, Canada	1992-1996	CV ED Visits	8.5	27.3	
			Respiratory ED Visits			
Villeneuve et al. 2006	Edmonton, Canada	1992-2002	Hemhrgc stroke HA	8.5	24.0	
			Ischemic stroke HA			
			TIA stroke HA			
Mar et al. 2004	Spokane	1997-1999	Respiratory Symp(any) adults	9.8[c]	25.8	
			Respiratory Symp (any) children			
Rabinovitch et al.2004	Denver	3 winters 1999-2002	Asthma exacerbation (children)	10.6[d]	29.3	
Slaughter et al. 2005	Spokane	1995-2001	CVD HA and ED visits	10.8	29.6	
			Respiratory HA and ED Visits			
Pope et al. 2008	Wasatch Front UT[e]	1993-2006	CHF HA	10.8c	44.5	
Schreuder et al.2006	Spokane	1995-2002	Cardiac HA	10.8[d]	29.6	
			Respiratory ED			
Peters et al. 2001	Boston	1995-1996	MI HA	12.1	28.2	
Delfino et al. 1997	Montreal	Summer 1993	Respiratory HA	12.1	31.2	
Wilson, et al. 2007	Phoenix-central	1995-1997	CV mortality	13.0	31.6	
	Phoenix-middle					
	Phoenix-outer					
Mar et al. 2003	Phoenix	1995-1997	CV mortality	13.5[d]	32.2	
Fairley 2003	Santa Clara Co, CA	1989-1996	Nonaccidental mortality	13.6	59.0	
Ostro et al. 2003	Coachella Valley, CA	1996-1998	CV mortality	15.8[d]	33.8	



[a]98th percentile of $PM_{2.5}$ distribution was either provided by study authors or calculated from data provided by authors. [b]Mean not reported in study; median presented [c]Mean estimated from data in study. [d]Mean value slightly different from value reported in published study; mean was either provided by study authors or calculated from data provided by study authors. [e]3 nearly contiguous metro areas: Ogden, Salt Lake City, Provo/Orem

Therefore, staff concludes that these studies are not helpful to inform staff conclusions regarding alternative standard levels that are appropriate to consider.

With regard to single-city studies that were *conducted in areas that would likely have met both the current 24-hour and annual standards*, we first look to studies that reported *positive and statistically significant associations* with short-term $PM_{2.5}$ exposures. In considering this group of studies, we note Mar et al. (2003) reported a positive and statistically significant association for premature mortality in Phoenix with a long-term mean concentration of 13.5 $\mu g/m^3$ in conjunction with a 98th percentile value of 32.2 $\mu g/m^3$. To the extent that consideration is given to revising the level of the annual standard, within a range of 13 to 11 $\mu g/m^3$, as discussed above, additional protection would be provided for the effects observed in this study.

Four additional studies reported *positive and statistically significant associations* with 98th percentile values within a range of 31.2 to 25.8 $\mu g/m^3$ and long-term mean concentrations within a range of 12.1 to 8.5 $\mu g/m^3$ (Delfino et al., 1997; Peters et al., 2001; Stieb et al., 2000; and Mar et al., 2004). Delfino et al. (1997) reported statistically significant associations between $PM_{2.5}$ and respiratory emergency department visits for older adults (greater than 64 years old) but not young children (less than 2 years old), in one part of the study period (summer 1993) but not the other (summer 1992). Peters et al. (2001) reported a positive and statistically significant association between short-term exposure to $PM_{2.5}$ (2-hour and 24-hour averaging times) and onset of acute MI in Boston.[69] Stieb et al. (2000) reported positive and statistically significant associations with cardiovascular- and respiratory-related emergency department visits in Saint John, Canada, in single pollutant models but not in multi-pollutant models (US EPA, 2004, pp 8-154 and 8-252 to 8-253). Mar et al. (2004) reported a positive and statistically significant association for short-term $PM_{2.5}$ exposures in relation to respiratory symptoms among children but not adults in Spokane, however, this study had very limited statistical power because of the small number of children and adults evaluated.

We then consider short-term single-city $PM_{2.5}$ exposure studies that reported *positive but nonstatistically significant associations* for cardiovascular and respiratory endpoints in *areas that would likely have met both the current 24-hour and annual standards*. The 98th percentile values reported in these studies ranged from 31.6 $\mu g/m^3$ to 17.2 $\mu g/m^3$ and the long-term mean concentrations ranged from 13.0 to 7.0 $\mu g/m^3$. These studies included consideration of cardiovascular-related mortality effects in Phoenix (Wilson et al., 2007), asthma medication use in children in Denver (Rabinovitch et al., 2006), hospital admissions for hemorrhagic and

[69] A King County, WA (Seattle) study using similar methods to Peters et al. (2001) reported no association with acute onset MI and $PM_{2.5}$ concentration with a long-term mean concentration of 12.8 $\mu g/m^3$ (Sullivan et al., 2005). We do not have information on the 98th percentile value for the Seattle study. It is unclear whether the differences observed in these two studies were due to regional differences in population characteristics and/or air pollution sources/$PM_{2.5}$ components (US EPA, 2009a, section 6.2.10.4).

ischemic stroke in Edmonton, Canada (Villeneuve et al., 2006), and hospital admissions for ischemic stroke/transient ischemic attack in Nueces County, TX (Lisabeth et al., 2008).

Lastly, we consider single-city studies conducted in *areas that would likely have met both the current 24-hour and annual standards* that reported *null findings*. The 98th percentile values reported in these studies ranged from 29.6 μg/m^3 to 24.0 μg/m^3 and the long-term mean concentrations ranged from 10.8 to 8.5 μg/m^3. These studies reported no associations with short-term $PM_{2.5}$ exposures and cardiovascular-related hospital admissions and respiratory-related emergency department visits (Slaughter et al., 2005) and cardiovascular-related emergency department visits (Schreuder et al., 2006) in Spokane; asthma exacerbation in children in Denver (Rabinovitch et al., 2004); and hospital admissions for transient ischemic attack in Edmonton, Canada (Villeneuve et al., 2006).

Viewing the evidence as a whole, we observe a limited number of single-city studies that reported positive and statistically significant associations for a range of health endpoints related to short-term $PM_{2.5}$ concentrations in areas that would likely have met the current suite of $PM_{2.5}$ standards. Many of these studies had significant limitations (e.g., limited statistical power, limited exposure data) as briefly identified above and discussed in more detail in the ISA (US EPA, 2009a, chapter 6). Other studies reported positive but not statistically significant results or null associations also in areas that would likely have met the current suite of $PM_{2.5}$ standards. In addition, still other studies (e.g., those conducted in Phoenix, Denver, and Edmonton) reported mixed results within the same study areas. Overall, the entire body of results from these single-city studies is mixed, particularly as 24-hour 98th percentile concentrations go below 35 μg/m^3.

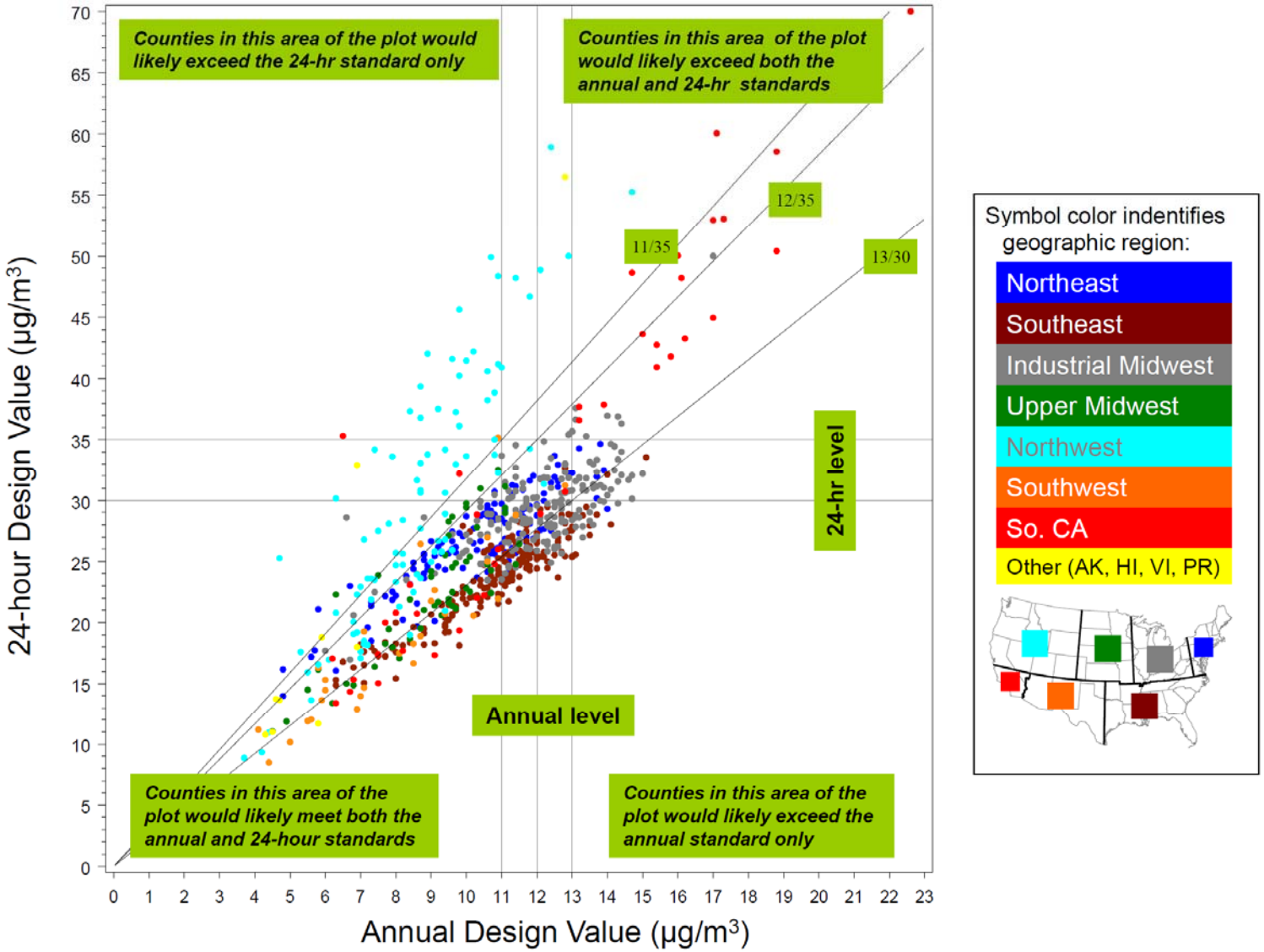
Although a number of single-city studies report effects at appreciably lower $PM_{2.5}$ concentrations than multi-city short-term exposure studies, the uncertainties and limitations associated with the single-city studies were greater and, thus, we have less confidence in using these studies as a basis for setting the level of a standard. Therefore, we conclude that the multi-city short-term exposure studies provide the strongest evidence to inform decisions on the level of the 24-hour standard, and the single city studies do not warrant consideration of 24-hour levels different from those supported by the multi-city studies.

In addition to considering the epidemiological evidence, we look to air quality information based on county-level 24-hour and annual design values to understand the implications of the alternative standard levels supported by the currently available scientific evidence, as discussed above. As outlined in section 2.1.3, we recognize that changes in $PM_{2.5}$ air quality designed to meet an annual standard would likely result not only in lower annual mean concentrations but also in fewer and lower peak 24-hour concentrations. We also recognize that changes designed to meet a 24-hour standard would result not only in fewer and lower peak 24-hour concentrations (especially when coupled with a high percentile-based form,

such as the 98th percentile) but also in lower annual mean concentrations. As discussed in section 2.1.3, we conclude that a policy goal which includes setting the annual standard to be the "generally controlling" standard in conjunction with setting the 24-hour standard to provide supplemental protection to the extent that additional protection is warranted, is the most effective and efficient way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures, resulting in more uniform protection across the U.S than the alternative of setting the 24-hour standard to be the controlling standard. Therefore, we consider the extent to which different combinations of alternative annual and 24-hour standard levels based on the evidence would support this policy goal.

Figure 2-10 presents a scatter plot of annual and 24-hour design values in urban areas across the U.S., color-coded by geographic region. This figure provides a visual perspective of whether the annual or 24-hour standard is likely to be the controlling standard for various combinations of standards. In Figure 2-10, the horizontal lines represent alternative 24-hour standard levels (i.e., 35 or 30 $\mu g/m^3$) with a 98th percentile form, averaged over three years, while the vertical lines represent alternative annual standard levels (i.e., 13, 12, or 11 $\mu g/m^3$), using an annual arithmetic mean averaged over three years. To understand this figure, we note that there are four quadrants that distinguish counties that are likely to have met or not met one or both of the $PM_{2.5}$ standards. The lower left quadrant characterizes counties that would likely meet both the annual and 24-hour standards. The lower right quadrant characterizes counties that would likely meet the 24-hour standard but not the annual standard, representing counties where the annual standard would be the controlling standard. The upper left quadrant characterizes counties that would likely exceed the 24-hour standard but not the annual standard, representing counties where the 24-hour standard would be the controlling standard. Finally, the upper right quadrant characterizes counties that would likely exceed both the annual and 24-hour standards. In this quadrant, the diagonal lines that intercept the origin and the intersection of a suite of alternative standard levels (e.g., the "11/35" line) represents the point of demarcation between those counties for which the 24-hour standard would be controlling (to the left of the diagonal line) and those for which the annual standard would be controlling (to the right of the diagonal line). More specifically, for counties to the left of the diagonal line, 24-hour concentrations would need to be reduced by a greater proportion to meet the 24-hour standard than the proportional reduction needed in the annual average concentrations to meet the annual standard.

Figure 2-10. County-level 24-hour DVs versus Annual DVs, 2007-2009



Source: Schmidt, 2011a, Analysis B

Using information on the relationship of the 24-hour and annual design values, we examine the implications of three alternative suites of $PM_{2.5}$ standards identified as appropriate to consider based on the currently available scientific evidence, as discussed above. As seen in Figure 2-10, an alternative suite of $PM_{2.5}$ standards that would include an annual standard level of 11 or 12 $\mu g/m^3$and a 24-hour standard with a level of 35 $\mu g/m^3$ (i.e., 11/35 or 12/35), would result in the 24-hour standard as the generally controlling standard in the Northwest (i.e., counties identified as light blue dots in Figure 2-10) but not generally in other regions across the country. These Northwest counties generally represent areas where the annual mean $PM_{2.5}$ concentrations have historically been low but where relatively high 24-hour concentrations occur, often related to seasonal wood smoke emissions. Alternatively, combining an alternative annual standard of 13 $\mu g/m^3$ with a 24-hour standard of 30 $\mu g/m^3$ would result in many more areas across the country in which the 24-hour standard would likely become the controlling standard than if an alternative annual standard of 12 or 11 $\mu g/m^3$ were paired with the current level of the 24-hour standard (i.e., 35 $\mu g/m^3$). This can be seen by comparing the area to the left of the "13/30" line to the areas to the left of the "12/35" and "11/35" lines, in particular in the upper right quadrant in Figure 2-10, which represents the regions on the graph in which the 24-hour standard would likely be controlling.

Summary of Evidence-based Considerations to Inform the 24-Hour Standard Level

In considering the currently available scientific information and air quality information within the context of identifying potential alternative standard levels for consideration we have identified a range of alternative 24-hour standard levels that is appropriate to consider based on the general approach outlined in section 2.1.3. Our general approach for identifying alternative 24-hour standard levels that would protect against effects observed in epidemiological studies has focused on setting a level somewhat below the 98^{th} percentile values where associations have been observed in epidemiological studies, particularly in areas that would meet alternative annual standard levels discussed above. In considering the available evidence, staff concludes it is appropriate to consider either retaining the level of the current 24-hour standard at 35 $\mu g/m^3$ or revising the level to somewhat below 35 $\mu g/m^3$, such as, down to 30 $\mu g/m^3$.

Consideration for retaining the level at 35 $\mu g/m^3$ would reflect placing greatest weight on evidence from multi-city studies that reported positive and statistically significant associations with health effects classified as having a *causal or likely causal relationship*. In conjunction with lowering the annual standard level, especially within a range of 12 to 11 $\mu g/m^3$, this alternative would recognize additional public health protection for effects associated with short-term $PM_{2.5}$ exposures would be provided by lowering the annual standard such that revision to the 24-hour standard would not be warranted. In addition, such combinations of 24-hour and

annual standards levels (i.e., 11/35 and 12/35) would be expected to result in the annual standard being the generally controlling standard, except in areas with particularly high peak-to-mean ratios (e.g., Northwest), with the annual standard providing protection against $PM_{2.5}$-related health effects associated with long- and short-term exposures, in conjunction with the 24-hour standard providing appropriate supplemental protection. These combinations would likely result in providing more uniform protection across the U.S than if the 24-hour standard were the generally controlling standard.

An alternative approach to considering the evidence would recognize that the currently available information provides some support for revising the level below 35 $\mu g/m^3$, perhaps as low as 30 $\mu g/m^3$. This alternative 24-hour standard level would be more compatible with an alternative annual standard of 13 $\mu g/m^3$ based on placing greater weight on one multi-city short-term exposure study (Bell et al., 2008) that reported positive and statistically significant effects at a 98th percentile value less than 35 $\mu g/m^3$ (i.e., 34.2 $\mu g/m^3$) in conjunction with a long-term mean concentration less than 13 $\mu g/m^3$ (i.e., 12.9 $\mu g/m^3$). However, in considering the implications of this combination (i.e., 13/30), staff recognizes that this option would likely result in the 24-hour standard being the controlling standard in a large number of areas in many geographic regions, potentially resulting in more uneven public health protection across the U.S. than if the annual standard was the generally controlling standard.

Taken together, while we consider it appropriate to consider an alternative 24-hour standard level within a range of 35 to 30 $\mu g/m^3$, staff concludes that the currently available evidence most strongly supports consideration for retaining the current 24-hour standard level at 35 $\mu g/m^3$ in conjunction with lowering the level of the annual standard within a range of 12 to 11 $\mu g/m^3$.

2.3.4.2 Risk-based Considerations

Beyond looking directly at the relevant epidemiologic evidence, staff has also considered the extent to which specific levels of alternative $PM_{2.5}$ standards are likely to reduce both long-term exposure-related mortality risk and short-term exposure-related mortality and morbidity risk. In addition to considering the nature and magnitude of $PM_{2.5}$-attributable risk remaining under each set of alternative standards, we have also considered the nature and magnitude of risk reductions under the alternative standards considered. These risk estimates for the set of alternative standard levels considered are based on the same methodology used in estimating risk for the current suite of standard levels as discussed above in section 2.2.2.

The quantitative risk assessment initially included analyses of alternative annual standard levels of 14, 13, and 12 $\mu g/m^3$ paired with either the current 24-hour standard level of 35 $\mu g/m^3$ or with alternative 24-hour standard levels of 30 and 25 $\mu g/m^3$. The specific combinations of

alternative standard levels assessed in the quantitative risk assessment included: (a) alternative suites of standards focusing on alternative annual standard levels in conjunction with the current 24-hour standard including combinations denoted by 14/35, 13/25, and 12/35and (b) alternative suites of standards reflecting combinations of alternative annual and 24-hour standard levels including combinations denoted by 13/30 and 12/25. This set of alternative annual and 24-hour standard levels was chosen prior to completion of the first draft RA and reflects consideration for evidence related to potential $PM_{2.5}$-related health effects as presented in the *Integrated Science Assessment for Particulate Matter: Second External Review Draft* (2^{nd} draft ISA) released in July, 2009 (US EPA, 2009b). The presentation of that evidence was refined in subsequent iterations of the PM ISA, culminating in the Final ISA released in December 2009 (US EPA, 2009a). The range of alternative standard levels discussed in section 2.3.4.1 above (i.e., annual standard levels within a range of 13 to 11 $\mu g/m^3$ and 24-hour standard levels within a range of 35 to 30 $\mu g/m^3$), reflects consideration of evidence as presented in the Final ISA and consequently differs somewhat from the set of alternative standard levels originally selected for modeling in the quantitative risk assessment. Subsequent to the release of the second draft RA (US EPA, 2010d), we expanded the range of alternative annual standard levels evaluated in the final RA to include an alternative annual standard level of 10 $\mu g/m^3$ and developed risk estimates for two additional combinations of alternative standards – 10/35 and 10/25 (US EPA, 2010a, Appendix J).

In simulating ambient $PM_{2.5}$ levels associated with these alternative standard levels, we included a more regional spatial pattern of reductions (reflected in the use of a proportional rollback approach) as well as more localized spatial patterns of reductions (reflected in the use of a hybrid approach and to an even greater extent in the use of a locally focused rollback approach) (see U.S. EPA, 2010a, section 3.2.3). While the proportional rollback approach was used in generating the core risk estimates, the other two more localized rollback approaches were considered as part of sensitivity analyses.

Results for the alternative suites of standards considered are presented in Figures 2-11 and 2-12, which depict patterns in risk reduction for long-term exposure-related risk (Figure 2-11) and short-term exposure-related risk (Figure 2-12) using different combinations of alternative standard levels relative to the estimated risks related to simulating just meeting the current standards. These figures include results for each of the 15 urban study areas, thereby allowing patterns in risk reduction across alternative standard levels and urban study areas to be considered together.[70] The discussion below of the magnitude of risk remaining under simulated

[70] *Patterns of risk reduction* across alternative annual standard levels (in terms of percent change relative to risk for the current annual standard level) are similar for all health endpoints modeled for a particular exposure duration (i.e., patterns of percent risk reduction will be similar for long-term exposure related all-cause, IHD-related and

attainment of the alternative standard levels is based on risk estimates presented in U.S.EPA, 2010a, section 4.2.2. The figures also depict the level of confidence, also discussed below, associated with risk estimates generated for the current suite of standard levels as well as alternative standard levels considered.

- **What is the nature and magnitude of risk associated with just meeting the alternative annual $PM_{2.5}$ standards considered?**

In characterizing estimates of $PM_{2.5}$-related risk associated with simulation of the alternative annual standards combined with the current 24-hour standard level (i.e., 14/35, 13/35 and 12/35), we estimated both the magnitude of risk reductions (relative to risk remaining upon just meeting the current suite of standards), as well as the risk estimated to remain upon just meeting the alternative annual standard levels.[71] We have greater overall confidence in our estimates of *risk reduction* with simulation of just meeting an alternative standard level (relative to risk associated with simulation of just meeting the current standards) than for estimates of *absolute risk remaining* upon simulation of just meeting that alternative standard level. In the context of long-term exposure-related mortality, this greater confidence primarily reflects the fact that we modeled risk down to the LML of the epidemiological study providing C-R functions (Krewski et al., 2009).[72] While this introduces the potential for underestimating the absolute risk remaining upon simulation of just meeting an alternative standard level (since the portion or exposure associated with ambient $PM_{2.5}$ concentrations below the LML is not translated into risk), it has little to no effect on the simulation of risk reduction for that alternative standard level, relative to risk estimated for the current standards (since this calculation involves ambient $PM_{2.5}$ concentrations that are typically above the LML and are therefore translated into risk). In the context of short-term exposure-related mortality and morbidity, while we modeled risk down to PRB, we still have greater uncertainty in estimating absolute risk remaining since this requires extrapolation of the C-R function to cover lower ambient $PM_{2.5}$ concentrations,

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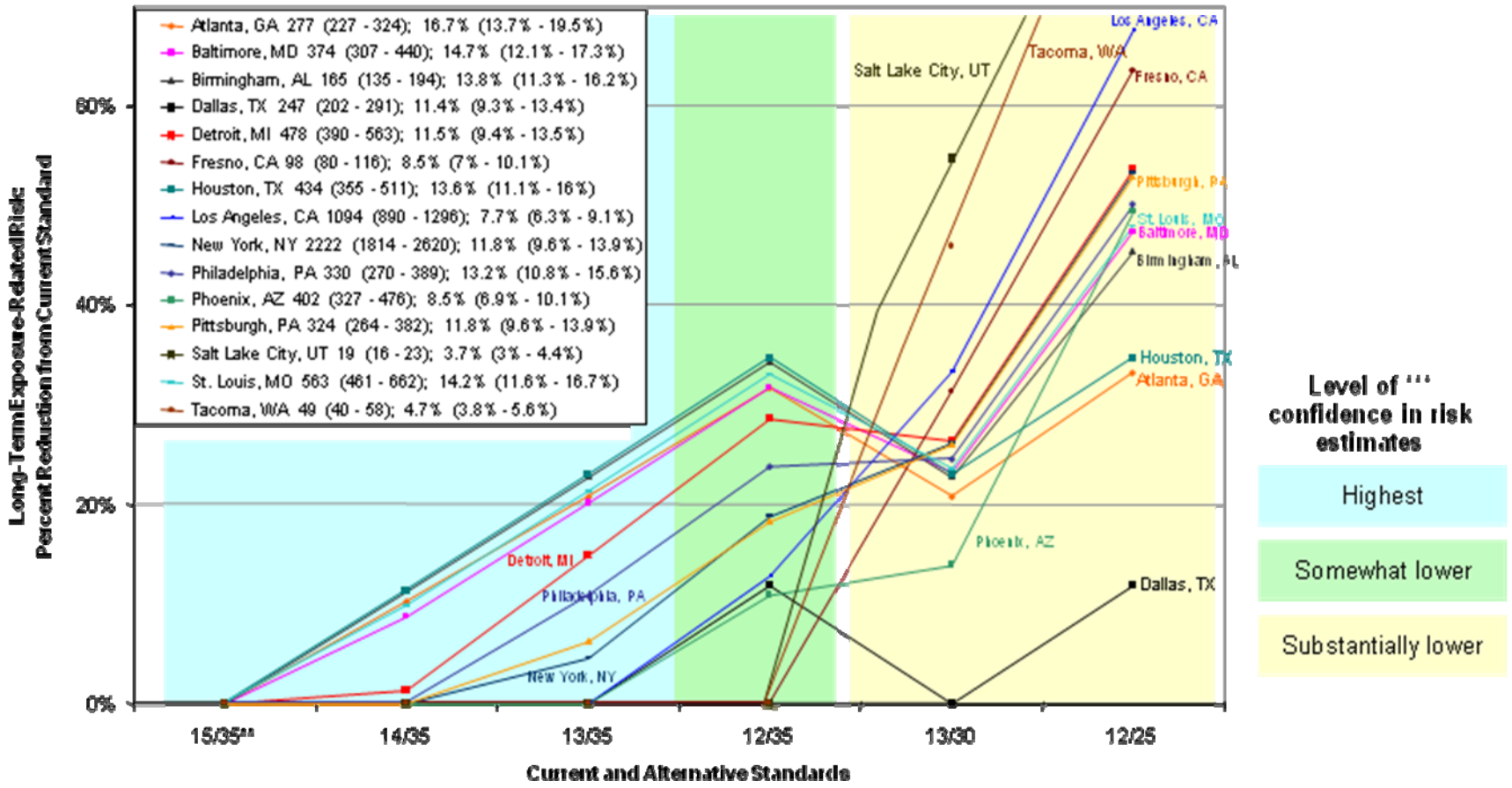
cardiopulmonary-related mortality). This reflects the fact that the C-R functions used in the quantitative risk assessment are close to linear across the range of ambient air concentrations evaluated. However, estimated *incidence* will vary by health endpoint.

[71] Our analysis also included the assessment of risk associated with an alternative annual standard level of 10 $\mu g/m^3$.US EPA, 2010a, Appendix J).

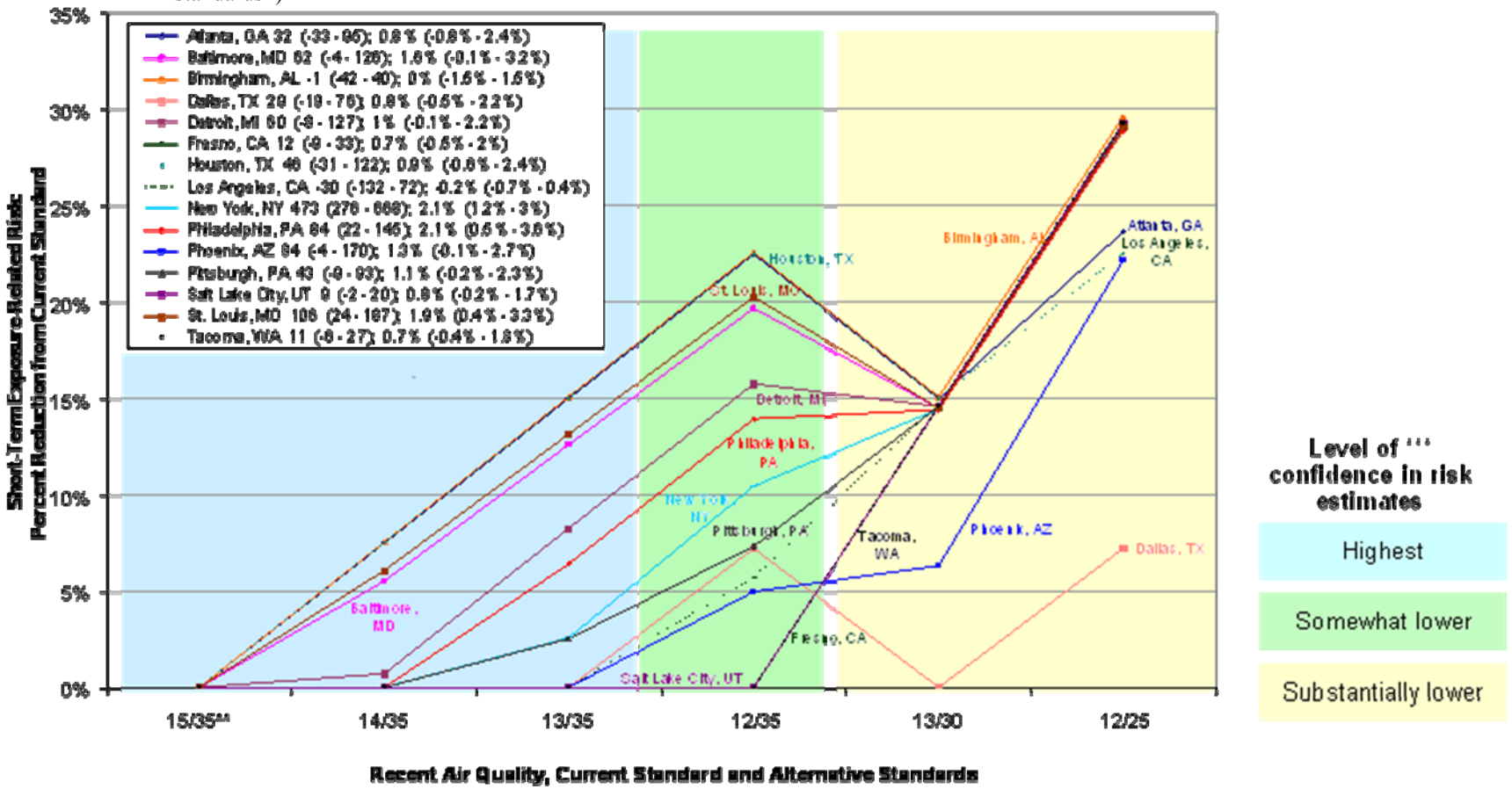
[72] As discussed in section 3.1.1 of the RA (U.S. EPA, 2010a), we did not model long-term exposure-related risk below the LML due to concerns over uncertainty in extrapolating the C-R functions below the range of $PM_{2.5}$ concentrations reflected in the epidemiological study providing those C-R functions. However, as stated in the ISA, there is no evidence for a discernible threshold (US EPA, 2009a, section 2.4.3) and our decision not to estimate risk below the LML should not be construed as support for the existence of a threshold. Therefore, the decision not to estimate risk below the LML, while reasonable given our desire to generate higher-confidence estimates of risk, does introduce low-bias into the estimate of absolute risk remaining upon simulation of each of the alternative standard levels considered, since evidence suggests that risk does extend to long-term $PM_{2.5}$ concentrations below the LML.

Figure 2-11 Percent reduction in long-term exposure-related mortality risk (alternative standards relative to the current standard)
(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. While incidence and percent of total incidence estimates are provided specifically for IHD-related mortality, the percent reduction plots provided in the figure apply to all long-term exposure-related mortality categories assessed – see text.
**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. Note, that the percent reductions for Salt Lake City and Tacoma at the 12/25 standard are 100% and 93%, respectively.
***Level of confidence reflects consideration for how the composite monitor annual mean $PM_{2.5}$ concentrations used in generating the risk estimates compare with the range of ambient $PM_{2.5}$ concentrations considered in fitting the C-R functions used (see accompanying text for additional detail).

Figure 2-12. 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 mortality 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. While incidence and percent of total incidence estimates are provided specifically for CV-related mortality, the percent reduction plots provided in the figure apply to all short-term exposure-related mortality and morbidity categories assessed – see text.

**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 24-hour standard (m) are denoted n/m in this figure.

*** Although short-term exposure-related risk estimates differ from long-term exposure-related risk estimates in that the former are estimated down to policy-relevant background, general observations regarding the level of confidence in risk estimates related to the composite monitor $PM_{2.5}$ levels involved in risk estimation (i.e., decreased confidence associated with lower composite monitor values) generally apply in the case of short-term exposure-related mortality and morbidity estimates.

relative to the estimation of risk reduction, which involves assessing risk for higher ambient $PM_{2.5}$ concentrations.

Because we have greater confidence in our estimates of the magnitude of risk reduction associated with alternative standard levels, we emphasize this risk metric in discussing risk estimates below. While we do present estimates of absolute risk remaining for each of the alternative standard levels, this is done with the caveat that, particularly in the context of long-term exposure-related mortality, these estimates may be biased low.

In discussing the estimated risks, we focus on the set of urban study areas experiencing risk reductions under each alternative annual standard modeled. Key policy-relevant observations associated with these risk estimates include:

- *Magnitude of estimated reductions in long-term exposure-related mortality risk:* Upon simulation of just meeting the alternative annual standard levels considered (14, 13, and 12 $\mu g/m^3$) in conjunction with the current 24-hour standard (35 $\mu g/m^3$, denoted as alternative suites of standards of 14/35, 13/35 and 12/35), the core analysis estimated reductions in long-term exposure-related mortality for 12 of the 15 urban study areas, with the degree of estimated risk reduction increasing incrementally across the alternative standard levels (both in terms of the number of study areas experiencing risk reduction and the magnitude of those reductions). For the alternative annual standard level of 12 $\mu g/m^3$ (in conjunction with the current 24-hour standard), the core analysis estimates that these study areas have reductions in risk (relative to risk remaining upon just meeting the current suite of standards) ranging from about 11 to 35%.

  For some of those areas in which the 24-hour standard is the generally controlling standard, larger risk reductions would have been estimated in this case (i.e., 12/35) if the locally-focused rollback approach had been used to simulate just meeting the current suite of standards. This result would be expected since the magnitude of risk remaining upon just meeting the current suite of standards would have been higher than that estimated based on the proportional rollback approach used in the core analysis. Therefore, while the absolute risks would not change, the percentage difference would have been greater if we had started with higher risks related to simulation of just meeting the current annual standard.

- *Long-term exposure-related mortality risk remaining:* For an annual standard level of 14 $\mu g/m^3$, the percent of total incidence of long-term exposure-related IHD mortality attributable to $PM_{2.5}$ (i.e., risk remaining) in the 5 urban study areas experiencing risk reductions ranged from an estimate of 9 to 15%. For an alternative annual standard of 12 $\mu g/m^3$, estimated risk remaining in the 12 urban study areas experiencing risk reductions ranged from 6 to 11% in terms of $PM_{2.5}$-attributable long-term exposure-related mortality. This translates into estimates of between 90 and 300 cases per year attributable to long-term $PM_{2.5}$ exposure for those study areas experiencing the greatest reductions in risk under the lowest alternative annual standard level simulated.

- *Short-term exposure-related mortality and morbidity risk*: For the alternative annual standard level of 12 $\mu g/m^3$ (in conjunction with the current 24-hour standard, 12/35), the core analysis estimated that reductions in both short-term exposure-related cardiovascular-related mortality and morbidity risk ranged from 5 to 23%.[73] In terms of risk remaining upon simulation of 12 $\mu g/m^3$ (in conjunction with the current 24-hour standard), the urban study areas with the greatest percent reduction have CV-related mortality estimates ranging from 25 to 50 deaths per year.
- *Simulation of risks for an alternative annual standard level below 12 $\mu g/m^3$:* Simulation of risks for an alternative annual standard of 10 $\mu g/m^3$ suggested that additional risk reductions could be expected with alternative annual standards below 12 $\mu g/m^3$. However, we recognize that there is potentially greater uncertainty associated with these risk estimates compared with estimates generated for the higher alternative annual standards considered in the quantitative risk assessment, since these estimates require simulation of relatively greater reductions in ambient $PM_{2.5}$ concentrations. As lower ambient $PM_{2.5}$ concentrations are simulated (i.e., ambient concentrations further from recent conditions), potential variability in such factors as the spatial pattern of ambient $PM_{2.5}$ reductions (rollback) increases, thereby introducing greater uncertainty into the simulation of composite monitor annual mean $PM_{2.5}$ concentrations and, consequently, risk estimates (US EPA, 2010a, Appendix J).
- *Substantial variability in magnitude of estimated risk reduction across urban study areas:* While there is a consistent pattern of estimated risk reduction across the alternative annual standards with lower alternative standard levels resulting in more urban study areas experiencing increasingly larger risk reductions, there is considerable variability in the magnitude of these reductions across study areas for a given alternative annual standard level. This variability reflects differing degrees of reduction in annual mean concentrations across the study areas, which results, in part, because the study areas began with varying annual mean $PM_{2.5}$ concentrations after simulating just meeting the current suite of standards. Therefore, even if study areas have similar "ending" annual mean $PM_{2.5}$ concentrations after simulation of just meeting a specific alternative annual standard, because the starting point in the calculation (the annual mean $PM_{2.5}$ concentrations upon just meeting the current suite of standards) can be variable, the overall reduction in annual mean $PM_{2.5}$ concentrations across the standards can also be variable. This translates into variation in reductions in long-term exposure-related risk upon just meeting alternative annual standard levels across the study areas.
- *The nature of the spatial pattern in $PM_{2.5}$ reductions (reflected in the rollback approach used) can impact the magnitude of estimated risk reductions:* The sensitivity analysis involving application of the locally focused rollback approach revealed 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.

[73] Because the same air quality metric (annual distributions of 24-hour $PM_{2.5}$ concentrations) was used in generating short-term exposure-related mortality and morbidity endpoints, patterns of risk reduction (as a percent of risk under the current suite of standards) are similar for both sets of endpoints (see US EPA, 2010a, section 4.2.2).

Specifically, for those study areas with higher peak-to-mean $PM_{2.5}$ ratios, application of the locally focused rollback approach resulted in higher annual mean $PM_{2.5}$ concentrations remaining upon just meeting the current suite of standards. If a proportional rollback approach was then used to simulate just meeting alternative annual standard levels, a greater degree of reduction in composite monitor annual mean $PM_{2.5}$ concentrations will result, since the starting point for the calculation (annual mean $PM_{2.5}$ concentrations upon just meeting the current suite of standards) would be higher. These findings highlight the important role played by variability in the spatial pattern of ambient $PM_{2.5}$ concentrations in influencing the magnitude of risk reductions under alternative annual standard levels.

- *Based on consideration of the composite monitor annual mean $PM_{2.5}$ concentrations involved in estimating long-term exposure-related mortality, we have varying levels of confidence in risk estimates generated for the alternative annual standard levels considered:* With the exception of one study area, those study areas estimated to have risk reductions under the alternative annual standards of 14 and 13 $\mu g/m^3$ had simulated composite monitor annual mean $PM_{2.5}$ concentrations ranging from just below 10.6 to over 13.3 $\mu g/m^3$ (see US EPA, 2010a, Table 3-4). In other words, these composite monitor annual mean $PM_{2.5}$ concentrations generally fell well within the range of ambient $PM_{2.5}$ concentrations considered in fitting the C-R functions used (i.e., within one SD of the mean $PM_{2.5}$ concentration from 1999-2000 ACS dataset, Krewski et al., 2009). The urban study areas estimated to have risk reductions under the lower alternative annual standard level of 12 $\mu g/m^3$ had lower composite monitor annual mean values ranging from 9.0 to over 11.4 $\mu g/m^3$. These values generally extend to below one SD of the mean of the ACS dataset and therefore, we have somewhat lower confidence in these risk estimates, relative to those generated for the higher alternative annual standards. By contrast, urban study areas estimated to have risk reductions under the alternative standard level of 10 $\mu g/m^3$ (paired with the current 24-hour standard) had simulated composite monitor annual estimates ranging from 7.6 to 8.9 $\mu g/m^3$ (see US EPA, 2010a, Appendix J). These concentrations are towards the lower end of the range of ACS data used in fitting the C-R functions (in some cases approaching the LML) and, therefore, we have substantially less confidence in these risk estimates, compared with those for the higher alternative annual standards assessed. The levels of confidence associated with risk estimates generated for the suites of alternative standard levels considered in the quantitative risk assessment are depicted in Figure 2-11. These confidence levels are repeated in presenting risk estimates for short-term exposure-related mortality and morbidity in Figure 2-12, since the general observation that confidence in risk estimates decreases as we consider lower composite monitor annual mean values also holds for the short-term exposure-related health endpoints.

- **What is the nature and magnitude of risk associated with simulating different combinations of alternative annual and 24-hour $PM_{2.5}$ standards?**

In characterizing $PM_{2.5}$-related risks associated with simulation of alternative annual standards combined with alternative 24-hour standards (i.e., 13/30 and 12/25), we estimated both the magnitude of risk remaining upon just meeting these alternative standards, as well as the

magnitude of risk reductions (relative to risk remaining upon just meeting the current suite of standards). While the alternative 24-hour standard levels considered did result in estimated risk reductions, we have substantially lower confidence in these risk estimates because of the relatively low annual-average $PM_{2.5}$ concentrations associated with simulation of these alternative standard levels.

Of the 11 urban study areas estimated to have risk reductions under the alternative 24-hour standard of 30 $\mu g/m^3$ (with the 24-hour standard controlling – see US EPA 2010a, Table 3-4), composite monitor annual mean $PM_{2.5}$ concentrations ranged from 6.6 to 11.3 $\mu g/m^3$ with most of the urban study areas having concentrations in the 8 to 10 $\mu g/m^3$ range. These concentrations extend into the lower range of $PM_{2.5}$ concentrations considered in the ACS study to fit the C-R functions and therefore, we have substantially lower confidence in these estimates.

When we consider composite monitor concentrations for urban study areas assessed to have risk reductions under the alternative 24-hour standard level of 25 $\mu g/m^3$ (again, where the 24-hour standard is controlling), we observed composite monitor annual mean $PM_{2.5}$ concentrations that are even lower, ranging from 5.6 to 11.2 $\mu g/m^3$ with most study areas having concentrations in the range of 7 to 9 $\mu g/m^3$. Because this range extends well into the lower range of $PM_{2.5}$ concentrations considered in the ACS study to fit the C-R functions (in some cases extending below the LML), we have substantially lower confidence in these risk estimates. Furthermore, we find that those urban study areas with the greatest degree of estimated risk reduction under these alternative 24-hour standard levels also had the lowest composite monitor annual average $PM_{2.5}$ levels, and therefore we have the lowest overall confidence in these results.

2.3.4.3 CASAC Advice

Based on its review of the second draft PA, CASAC concluded that the levels presented in that draft document (i.e., alternative annual standard levels within a range of 13 to 11 $\mu g/m^3$ and alternative 24-hour standard levels within a range of 35 to 30 $\mu g/m^3$) "are supported by the epidemiological and toxicological evidence, as well as by the risk and air quality information compiled" in the ISA, RA, and second draft PA. CASAC further noted that "[a]lthough there is increasing uncertainty at lower levels, there is no evidence of a threshold (i.e., a level below which there is no risk for adverse health effects)" (Samet, 2010d, p. ii).

Although CASAC supported the alternative standard level ranges presented in the second draft PA, they encouraged EPA to develop a clearer rationale for staff conclusions regarding annual and 24-hour standards that are appropriate to consider, including consideration of the combination of these standards supported by the available information. Specifically, CASAC encouraged staff to focus on information related to the concentrations that were most influential in generating the health effect estimates in individual studies to inform alternative annual

standard levels (Samet, 2010d, p. 2). CASAC also commented that the approach presented in the second draft PA to identify alternative 24-hour standard levels which focused on peak-to-mean ratios was not relevant for informing the actual level (Samet 2010d, p. 4). Further, they expressed the concern that the combinations of annual/24-hour standard levels discussed in the second draft PA (i.e., in the range of 13 to 11 $\mu g/m^3$ for the annual standard, in conjunction with retaining the current 24-hour $PM_{2.5}$ standard level of 35 $\mu g/m^3$; alternatively, revising the level of the 24-hour standard to 30 $\mu g/m^3$ in conjunction with an annual standard level of 11 $\mu g/m^3$) "may not be adequately inclusive" and encouraged EPA to more clearly explain its rationale for identifying the 24-hour/annual combinations that are appropriate for consideration (Samet 2010d, p. ii).

In considering CASAC's advice, we note that staff conclusions in this final PA regarding alternative standard levels that are appropriate to consider differ somewhat from the alternative standard levels discussed in the second draft PA (US EPA, 2010f, section 2.3.4), upon which CASAC based its advice. In commenting on draft staff conclusions in the second draft PA, CASAC did not have an opportunity to review the analyses of distributional statistics conducted by staff to identify the broader range of $PM_{2.5}$ concentrations that were most influential in generating health effect estimates in epidemiological studies (Rajan et al., 2011), as presented in section 2.3.4.1 above. In addition, CASAC was not aware of the revised long-term mean concentration in the WHI study as discussed in section 2.2.1, specifically, footnote 24.

2.3.4.4 Staff Conclusions on Alternative Standard Levels

In considering the epidemiological evidence, estimates of risk reductions associated with just meeting alternative annual and/or 24-hour standards, air quality analyses, and related limitations and uncertainties, staff concludes that there is clear support for considering revisions to the suite of current $PM_{2.5}$ standards to provide additional protection against health effects associated with long- and short-term exposures. We recognize that health effects may occur over the full range of concentrations observed in the long- and short-term epidemiological studies and that no discernible threshold for any effects can be identified based on the currently available evidence. In reaching staff conclusions regarding appropriate alternative standard levels to consider, we have examined where the evidence of associations is strongest and, conversely, where we have appreciably less confidence in the associations and in quantitative estimates of risk.

Based upon the currently available evidence, we conclude alternative annual standard levels in the range of 13 to 11 $\mu g/m^3$ are appropriate to consider. We further conclude that the evidence most strongly supports consideration of an alternative annual standard level in the range of 12 to 11 $\mu g/m^3$. An alternative level within the range of 12 to 11 $\mu g/m^3$ would more

fully take into consideration the available information from all long- and short-term $PM_{2.5}$ exposure studies, including studies of susceptible populations, than would a higher level. This range would also reflect placing weight on information from studies that helps to characterize the range of $PM_{2.5}$ concentrations over which we continue to have confidence in the associations observed in epidemiological studies, as well as the extent to which our confidence in the associations is appreciably less at lower concentrations.

In considering how the annual and 24-hour standards work together to provide appropriate public health protection, we conclude it is appropriate to consider retaining the current 24-hour standard level at 35 $\mu g/m^3$ in conjunction with an annual standard in the range of 12 to 11 $\mu g/m^3$, as well as to consider an alternative 24-hour standard level of 30 $\mu g/m^3$, particularly in conjunction with an annual standard level of 13 $\mu g/m^3$.

These conclusions reflect the much stronger body of scientific evidence available in this review supporting a causal relationship between long- and short-term $PM_{2.5}$ exposures and mortality and cardiovascular effects and a likely causal relationship between long- and short-term $PM_{2.5}$ exposures and respiratory effects, as well as evidence that is suggestive of a causal relationship with other health outcomes such as low reproductive and development effects (e.g., birth weight and infant mortality) and cancer, mutagenicity, and genotoxicity effects. In addition, we reflect upon the broad range of long- and short-term exposure studies that reported $PM_{2.5}$-related effects in areas that would likely have met the current suite of $PM_{2.5}$ standards, and specifically consider available information on the range of concentrations that were most influential in generating the health effect estimates in epidemiological studies.

Beyond evidence-based considerations, we have also considered the extent to which the quantitative risk assessment supports consideration of these alternative standard levels or provides support for lower levels. We first conclude that risks estimated to remain upon simulation of just meeting the current suite of standards are important from a public health perspective, considering both the severity and estimated magnitude of effects. In considering simulations of just meeting alternative annual standard levels within the range of 13 to 11 $\mu g/m^3$ in conjunction with the current 24-hour standard level of 35 $\mu g/m^3$, we conclude that important public health improvements are associated with risk reductions estimated for standard levels of 13 and 12 $\mu g/m^3$, noting that the level of 11 $\mu g/m^3$ was not included in the quantitative risk assessment. Our overall confidence in the quantitative risk estimates is strongest for the alternative annual standard level of 13 $\mu g/m^3$. We have somewhat lower confidence in risk estimates for the alternative annual standard level of 12 $\mu g/m^3$. We also estimated risks likely to remain upon just meeting an annual standard level of 10 $\mu g/m^3$, although we have substantially lower confidence in those estimates. With regard to level of the 24-hour standard, our overall confidence in the quantitative risk estimates is strongest for the current standard level of 35

$\mu g/m^3$. We have somewhat lower confidence in our risk estimates for an alternative 24-hour standard level of 30 $\mu g/m^3$, and substantially lower confidence in our estimates of risks for an alternative 24-hour standard level of 25 $\mu g/m^3$.

Based on the above considerations, we conclude that the quantitative risk assessment provides support for considering an alternative annual standard within a range of 13 to 11 $\mu g/m^3$, in conjunction with a 24-hour standard of 35 or 30 $\mu g/m^3$, but does not provide strong support for considering lower alternative levels.

In evaluating this range of alternative annual standard levels, staff has taken into consideration the importance of balancing the strength of the currently available evidence and risk-based information with the remaining uncertainties and limitations associated with this information. The upper end of the range of alternative annual standard levels (13 $\mu g/m^3$) reflects placing appreciably more weight on the uncertainties and limitations in the information which would serve to reduce the potential to overestimate public health risks and protection likely to be associated with just meeting a standard set at this level. This policy option would reflect placing greater weight on the remaining uncertainties in the evidence, including uncertainties associated with understanding the heterogeneity observed in the epidemiological studies such as those associated with the role of specific components, sources, and subfractions (e.g., UFPs) within the current $PM_{2.5}$ mass-based indicator; the role of fine particles and co-pollutants within the broader ambient mixture; and exposure-related factors that influence the magnitude and duration of fine particle exposures. The lower end of this range (11 $\mu g/m^3$) reflects placing much less weight on uncertainties and limitations in the information which would serve to reduce the potential to underestimate public health risks and protection likely to be associated with just meeting a standard set at this level. This policy option would reflect placing considerably more weight on limited evidence of serious effects in susceptible populations such as potential developmental effects, while recognizing that significant limitations remain in assessing the relationship between $PM_{2.5}$ exposures and these effects, specifically, understanding the nature of the association and exposure windows of concern. We recognize that air quality changes designed to meet alternative annual standards are an effective and efficient way to reduce not only long-term exposure-related mortality, but also short-term exposure-related risk. Thus, we judge it is appropriate to consider a policy goal of focusing on establishing a generally controlling annual standard intended to serve as the primary means for providing protection for effects associated with both long- and short-term $PM_{2.5}$ exposures in conjunction with a 24-hour standard that provides supplemental protection.

The alternative suites of $PM_{2.5}$ standards supported by the currently available evidence and quantitative risk assessment discussed above might reasonably be judged to provide appropriate public health protection. However, some combinations of standards are more likely

to provide more consistent protection, whereas other combinations are more likely to provide less uniform protection. Combining a need to provide requisite protection with a policy goal of providing such protection as uniformly as possible in areas across the U.S., we conclude it is most appropriate to consider revising the annual standard level within a range of 12 to 11 $\mu g/m^3$ in conjunction with retaining the 24-hour standard level at 35 $\mu g/m^3$. Such combinations of 24-hour and annual standards levels (i.e., 12/35 and 11/35) would be expected to result in the annual standard being the generally controlling standard, except in areas with particular high peak-to-mean ratios.

Alternatively, we also reach the conclusion that there is limited support for considering revising the annual standard level to 13 $\mu g/m^3$ in conjunction with revising the 24-hour standard level to somewhat below 35 $\mu g/m^3$, such as, down to 30 $\mu g/m^3$ (i.e., 13/30). In considering the implication of this alternative suite of standards, we conclude this combination would result in a large number of areas in many geographic areas where the 24-hour standard would likely become the controlling standard. Staff judges that this approach would likely provide less uniform protection in areas across the U.S.

To provide some perspective on the implications of applying various combinations of alternative annual and 24-hour standards, staff assessed (based on 2007 to 2009 air quality data) the percentage of counties, and the population in those counties, that would not likely attain various alternative suites of $PM_{2.5}$ standards (Schmidt, 2011a, Analysis C). This assessment, shown in Appendix C, Table C-1, was not considered as a basis for the above staff conclusions.

2.4 SUMMARY OF STAFF CONCLUSIONS ON PRIMARY FINE PARTICLE STANDARDS

In reaching conclusions on the adequacy of the current suite of $PM_{2.5}$ standards and potential alternative suites of standards to provide the appropriate 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 (sections 2.3.1 to 2.3.4). In considering the scientific and technical information, we reflect upon the information available in the last review integrated with information that is newly available as assessed and presented in the ISA and RA (US EPA, 2009a; US EPA, 2010a) and as summarized in sections 2.2 and 2.3. We also consider the issues raised by the court in its remand of the primary annual $PM_{2.5}$ standard as discussed in section 2.1.2.

As outlined in section 2.1.3, 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. Our approach 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 against $PM_{2.5}$-related mortality and morbidity effects associated with both long- and short-term exposures afforded by the suite of annual and 24-hour standards.

We recognize that selecting from among alternative suites of 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 reaching staff conclusions on alternative suites of standards that are appropriate to consider, we are mindful that the CAA requires primary 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 CAA does not require that the NAAQS be set at zero-risk levels, but rather at levels that reduce risk sufficiently so as to protect public health with an adequate margin of safety (section 1.2.1).

Based on the currently available scientific evidence and other information, staff reaches the following conclusions regarding the primary fine particle standards:

(1) Consideration should be given to revising the current suite of primary $PM_{2.5}$ 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 conclusion is based, in general, on the evaluation in the ISA of the currently available epidemiological, toxicological, dosimetric, and exposure-related evidence, and on air quality information and analyses related to the epidemiological evidence, together with judgments as to the public health significance of the estimated incidence of effects remaining upon just meeting the current suite of standards.

(2) It is appropriate to retain $PM_{2.5}$ as the *indicator* for fine particles. Staff concludes that the available evidence does not provide a sufficient basis for replacing or supplementing the $PM_{2.5}$ indicator with any other indicator(s) defined in terms alternative size fractions (i.e., UFPs) or for any specific fine particle component or group of components associated with any source categories of fine particles, nor does it provide a basis for excluding any component or group of components associated with any source categories from the mix of particles included in the $PM_{2.5}$ indicator.

(3) With regard to *averaging times* for the $PM_{2.5}$ standards, it is appropriate to retain annual and 24-hour averaging times to provide protection against health effects associated with long-term (seasons to years) and short-term (hours to days) exposure periods. The available evidence does not provide a sufficient basis for consideration of other averaging times, including an averaging time less than 24 hours to address health effects associated with sub-daily exposures or an averaging time to address effects associated with seasonal exposures, given the relatively small amount of relevant information available.

(4) It is appropriate to consider revising the *form of the annual standard* to one based on the highest appropriate monitor in an area rather than a form that allows averaging across monitors (i.e., spatial averaging) to provide increased protection for susceptible populations. Further, it is appropriate to retain the 98^{th} percentile *form of the current 24-hour standard*.

(5) Consideration should be given to revising the suite of $PM_{2.5}$ standards to provide increased protection against effects associated with both long- and short-term exposures, taking into account both evidence-based and risk-based considerations, with a particular focus on revising the annual standard level to provide protection for effects associated with both exposure periods. An emphasis on the annual standard would be consistent with the policy approach of setting a "generally controlling" annual standard to provide protection for both long- and short-term $PM_{2.5}$ exposures in conjunction with a 24-hour standard that provides supplemental protection against days with high peak concentrations. This would limit peak concentrations in areas with high peak-to-mean ratios, possibly associated with strong local or seasonal sources. This would also provide supplemental protection for potential $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods. Staff concludes that this policy goal is the most effective and efficient way to reduce total population risk associated with both long- and short-term exposures, and would provide relatively more uniform protection in areas across the country.

   (a) Taken together, staff concludes that the currently available evidence and information from a quantitative risk assessment and air quality analyses provide support for considering revision of the level of the *annual standard* to within a range of 13 to 11 $\mu g/m^3$. Staff further concludes that the evidence most strongly supports consideration of an alternative annual standard level in the range of 12 to 11 $\mu g/m^3$.

   (b) In conjunction with consideration of an annual standard level in the range of 12 to 11 $\mu g/m^3$, staff concludes it is appropriate to consider retaining the current *24-hour standard* level at 35 $\mu g/m^3$.

   (c) In conjunction with consideration of an annual standard level of 13 $\mu g/m^3$, staff concludes that there is limited support to consider revising the 24-hour standard level to somewhat below 35 $\mu g/m^3$, such as down to 30 $\mu g/m^3$.

2.5 KEY UNCERTAINTIES AND AREAS FOR FUTURE RESEARCH AND DATA COLLECTION

The uncertainties and limitations that remain in the review of the primary fine particle standards are primarily related to understanding the range of ambient concentrations over which we continue to have confidence in the health effects observed in the epidemiological studies, as well as the extent to which the heterogeneity observed in the epidemiological evidence is related to differences in the ambient fine particle mixture and/or exposure-related factors. In addition, uncertainties remain in more fully understanding the role of $PM_{2.5}$ in relationship to the roles of gaseous co-pollutants within complex ambient mixtures.

In this section, we highlight areas for future health-related research, model development, and data collection activities to address these uncertainties and limitations in the current body of scientific evidence. These efforts, if undertaken, could provide important evidence for informing future PM NAAQS reviews and, in particular, consideration of possible alternative indicators, averaging times, and/or levels. In some cases, research in these areas can go beyond aiding

standard setting to informing the development of more efficient and effective control strategies. We note, however, that a full set of research recommendations to meet standards implementation and strategy development needs is beyond the scope of this discussion.

As has been presented and discussed in the PM ISA, particularly in Chapters 4 through 8, the scientific body of evidence informing our understanding of health effects associated with long- and short-term exposures to fine particles has been broadened and strengthened since the last review. In reviewing the adequacy of the current suite of primary $PM_{2.5}$ standards and in evaluating alternative health-based fine particle standards appropriate for consideration, we identify the following key uncertainties and areas for future research and data collection efforts that have been highlighted in this review. We recognize that some research could be available to inform the next PM NAAQS review, while other research may require longer-term efforts.

Interpretation of Epidemiological Evidence

Additional research focused on identifying the most important factors contributing to the observed heterogeneity in the epidemiological evidence could provide insights for interpreting these studies. We encourage research and data collection efforts directed at improving our understanding of the nature of the exposures contributing to the observed health effects, for example, the role of specific components, sources, and different size fractions (e.g., UFPs) within the current $PM_{2.5}$ mass-based indicator and the role of fine particles and co-pollutants within the broader ambient mixture, as well as improving our understanding of exposure-related factors that influence the magnitude and duration of fine particle exposures. Much of this research may depend on the availability of increased monitoring data, as discussed below.

- Components/Sources. The currently available scientific evidence continues to be largely indexed by aggregate $PM_{2.5}$ mass-based concentrations which vary in composition both regionally and seasonally. Source characterization, exposure, epidemiological, and toxicological research could focus on improving our understanding of the relative toxicity of different fine particle components, properties, and sources that may be more closely linked with various health effects. Critical to this better understanding of the impacts of $PM_{2.5}$ components and their associated sources are data that refines the temporal and spatial variability of the fine particle mixture. This research would reduce the uncertainties in estimating risks. It could also inform consideration of alternative indicators in future PM NAAQS reviews as well as aid in the development of efficient and effective source control strategies for reducing health risks.
- Ultrafine Particles (UFPs). Additional monitoring methods development work, health research, and ambient monitoring data collection efforts are needed to expand the currently available scientific data base for UFPs. UFP measurements should include surface area as well as number, mass and composition. It would be most useful for an UFPs monitoring network to be designed to inform our understanding of the spatial and temporal variability of these particles, including in near-roadway environments. This information would improve

our ability to explore consideration of a separate indicator for UFPs in future PM NAAQS reviews.

- Co-pollutant Exposures. Research focused on furthering our understanding of the extent to which an association between fine particles and specific health effects can be modified by one or more co-pollutants would inform our ability to discern the role of PM in the complex ambient mixture. For example, does the magnitude of a $PM_{2.5}$-related effect estimate differ on days when O_3 concentrations are higher compared to days when O_3 concentrations are lower?
- Factors Influencing Exposures. Additional research and analyses would be useful to provide insights on population exposures, specifically in improving our understanding of intra-city and inter-city differences related to various $PM_{2.5}$ components, source contributions and personal and building-related factors that may enhance our interpretation of the epidemiological evidence. This could include time-activity data to support probabilistic scenario-based exposure models, such as additional activity diary data to incorporate into the Consolidated Human Activity Database (CHAD); air conditioning use; residence near roadways; and penetration rates to better characterize ambient $PM_{2.5}$ impacts on indoor microenvironments. This research could focus on different size fractions in $PM_{2.5}$ (i.e., UFPs) as well as components. Coordination between exposure and health studies could advance our understanding of exposure-related factors. For example, epidemiological panel studies might use various exposure measurements to explore differences in personal exposures related to (1) indoor generated fine particles, (2) fine particle exposures measured by community monitors, and (3) fine particle exposures not captured by community monitors (i.e., personal exposures during commuting).

Health Outcomes, Exposure Durations of Concern, and Susceptible Populations

New information available in this review reinforces and expands the evidence of associations between long- and short-term $PM_{2.5}$ exposures and mortality and a number of cardiovascular and respiratory effects. Less evidence is available to understand other health effects (e.g., developmental/reproductive effects; central nervous system effects). Additional research could expand our understanding of the associations between $PM_{2.5}$ and a broader range of health outcomes; reduce uncertainties associated with our current understanding of concentration-response relationships; improve our understanding of exposure durations of concern; and improve our understanding of the potential public health impacts of fine particle exposures in susceptible populations. Toxicological studies could provide additional evidence of coherence and biological plausibility for the effects observed in epidemiological studies as well as additional insights on possible mechanisms of action.

- Health Effects. Research on a broader range of cardiovascular and respiratory endpoints could improve our understanding of the mechanisms by which these effects occur. In addition, future research could expand the scientific data base for health effects that are currently less understood including effects categorized within the ISA as having evidence suggestive of a causal relationship or for which currently available evidence is inadequate to support a quantitative risk analysis. To the extent that research supports a link between fine

particles and adverse effects on the nervous system, reproduction, development, or other endpoints, such effects could play an increased role for informing future PM NAAQS reviews including expanding the health endpoints that could potentially be evaluated in future quantitative risk assessments.

- Concentration-Response Relationships. Research focused on improving our understanding of the shape of the C-R relationships, especially at lower ambient fine particle concentrations, as well as the confidence intervals around these C-R relationships, could reduce uncertainties associated with estimating and characterizing risks throughout the full range of air quality distributions. As more information becomes available on fine particle components and sources, it will be important to understand the C-R relationships for key constituents of the fine particle mixture, as well.
- Exposure Durations of Concern. Research should be directed at broadening the scientific data base to improve our understanding of health effects associated with short-term, peak exposures, such as those related to traffic-related sources, wildfires, agricultural burning, or other episodic events, as well as to improve our understanding of health effects associated with seasonal-length exposures, such as those related to wintertime wood-burning emissions. Additional quantitative measures of exposure might take into account factors including the magnitude and duration of sub-daily and seasonal length $PM_{2.5}$ exposures and the frequency of health impacts associated with repeated peak exposures. More research is needed to better understand effects that occur at longer lag times than have historically been studied (e.g., 0 to 2 day lags).
- Susceptible Populations. Improving our understanding of the populations that are more likely to experience adverse health effects related to fine particle exposures and the concentrations at which these effects may occur is important for informing future PM NAAQS reviews and for developing programs to reduce related public health risks. This evidence may also provide insights into the biologic modes of action for toxicity.
    - Pre-existing Health Conditions. While currently identified susceptible populations include persons with pre-existing cardiovascular and respiratory disease, evidence continues to emerge related to additional health conditions that may increase susceptibility to fine particle exposures (e.g., diabetes, obesity, neurological disorders). Research to replicate or extend these findings would enhance our understanding of these and other potentially susceptible populations.
    - Children. Epidemiological and toxicological studies provide evidence that children are more susceptible to PM exposures, primarily for respiratory-related effects. Evidence of developmental effects associated with PM exposures continues to emerge. Additional research exploring issues to better understand key windows of development impacted by PM exposures could enhance our understanding of this important susceptible lifestage.
    - Genetic Susceptibility. Research to expand our understanding of genetic susceptibility could inform our understanding of potentially susceptible populations and provide additional information for identifying the specific pathways and mechanisms of action by which PM initiates health effects.

- Socioeconomic status (SES). Additional research is needed to identity what factors (e.g., general health status, diet, medication, stress, unmeasured pollution) cause SES differences in response to pollution measured in communities.

Data Collection Needs and Methods Development Activities

Additional research and data collection efforts focused on expanding current monitoring methods and networks as well as continued development of exposure models to expand data available for health studies could improve our understanding of potential alternative indicators, averaging times, and levels to consider in future PM NAAQS reviews. In particular, staff encourages work to enhance our understanding of the temporal and spatial variability of $PM_{2.5}$, $PM_{2.5}$ components, and different size fractions (e.g., UFPs).

- Monitoring Measurements. In order to improve our understanding of the association between fine particles and health effects, more frequent measurement data could be collected. This would provide information that could inform our understanding of alternative lags.
    - $PM_{2.5}$ Components. With respect to improving our understanding of the impacts of $PM_{2.5}$ components, enhancements to the CSN, including more frequent measurement schedules and the development and deployment of continuous monitoring methods for specific fine particle components (e.g., EC/OC, sulfates), could enhance our understanding of the temporal and spatial variability of specific components. Furthermore, identifying chemical species within the mix of organic aerosols would improve our understanding of the artifacts associated with semi-volatile PM components and aid in designing toxicological experiments.
    - Ultrafine Particles. In order to improve our understanding of the public health impacts of UFPs, consideration should be given to establishing an FRM for UFPs and establishing a national UFP monitoring network.
    - Source Apportionment. Composition data with better time resolution (e.g., 1 to 6 hour) and better size resolution (e.g., UFPs, accumulation mode particles, coarse particles in $PM_{2.5}$ and $PM_{10-2.5}$) could provide more precise and accurate information on sources of fine particles to inform health research as well as development of more efficient and effective control strategies.
    - Spatial Variability. Some portion of the required $PM_{2.5}$ monitoring network could be dedicated to improving our ability to characterize spatial variability across urban areas including both at localized and area-wide scales.
- Model Development. Continuing work to improve models for estimating $PM_{2.5}$ mass and composition in areas with only every third or sixth day measurements, and by space where measurements are not available could enhance our understanding of the temporal and spatial variability of fine particles. Refinement of these models to finer spatial scales may improve exposure estimates in epidemiological studies as well as in quantitative risk and exposure assessments.
- Air Quality Distributions Reported in Epidemiological Studies. Most epidemiological studies provide some information on the distribution of ambient measurement data evaluated, however, published information is often generally limited in scope and the descriptive

statistics reported vary from one study to another. Understanding the air quality distributions at which effects have been observed is important for informing consideration of the adequacy of the current NAAQS as well as potential alternative indicators, averaging times, and levels to consider. Working with intramural and extramural research groups, we plan to encourage a more comprehensive and more consistent reporting of population-level and air quality data.

2.6 REFERENCES

Bell ML, Ebisu K, Belanger K (2007). Ambient air pollution and low birth weight in Connecticut and Massachusetts. Environ Health Perspect, 115: 1118-24.

Bell ML, Ebisu K, Peng RD, Walker J, Samet JM, Zeger SL, Dominic F (2008). Seasonal and regional short-term effects of fine particles on hospital admissions in 202 U.S. counties, 1999-2005. Am J Epidemiol, 168: 1301-1310.

Bell ML, Ebisu K, Peng R, Samet J, Dominici F (2009). Hospital Admissions and Chemical Composition of Fine Particle Air Pollution. Am J Respir Crit Care Med, 179: 1115-1120.

Bell ML (2009). Personal communication with Dr. Michelle Bell: Annual $PM_{2.5}$ levels used in Dominici et al. 2006 and Bell et al. 2008. December 7, 2009. Docket No. EPA-HQ-ORD-2007-0517-0087.

Beelen R, Hoek G, van den Brandt PA, Goldbohm RA, Fischer P, Schouten LJ, Jerrett M, Hughes E, Armstrong B, Brunekreef B (2008). Long-term effects of traffic-related air pollution on mortality in a Dutch cohort (NLCS-AIR study). Environ Health Perspect, 116: 196-202.

Burnett RT, Goldberg MS (2003) Size-fractionated particulate mass and daily mortality in eight Canadian cities. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 85-90. Available: http://www.healtheffects.org/news.htm [16 May, 2003].

Burnett RT, Stieb D, Brook JR, Cakmak S, Dales R, Raizenne M, Vincent R, Dann T (2004). Associations between short-term changes in nitrogen dioxide and mortality in Canadian cities. Arch Environ Occup Health, 59: 228-236.

Curl C (2009). Personal communication with Cynthia Curl, MESA Air Project Manager, University of Washington; email to Beth Hassett-Sipple, US EPA, OAQPS regarding request for PM air quality data. August 10, 2009. Docket No. EPA-HQ-ORD-2007-0517-0113.

Delfino RJ, Murphy-Moulton AM, Burnett RT, Brook JR, Becklake MR (1997). Effects of air pollution on emergency room visits for respiratory illnesses in Montreal, Quebec. Am J Respir Crit Care Med, 155: 568-576.

Dockery DW, Pope CA III, Xu X, Spengler JD, Ware JH, Fay ME, Ferris BG Jr, Speizer FE (1993). An association between air pollution and mortality in six US cities. NEJM 329: 1753-1759.

Dockery DW, Cunningham J, Damokosh AI, Neas LM, Spengler JD, Koutrakis P, Ware JH, Raizenne M, Speizer FE (1996). Health effects of acid aerosols on North American children: respiratory symptoms. Environ Health Perspect. 104(5):500-5.

Dominici F, Peng RD, Bell ML, Pham L, McDermott A, Zeger SL, Samet JM (2006a). Fine particulate air pollution and hospital admission for cardiovascular and respiratory diseases. JAMA, 295: 1127-1134.

Dominic F (2006b). Letter from Francesca Dominici, Associate Professor of Biostatistics, Bloomberg School of Public Health, Johns Hopkins University, comments to the proposed rule. Docket No. OAR-2001-0017-0988. March 21, 2006.

Dominici F, Peng RD, Zeger SL, White RH, Samet JM (2007a). Particulate air pollution and mortality in the United States: did the risks change from 1987 to 2000? Am J Epidemiol, 166: 880-8.

Dominici F, Peng RD, Ebisu K, Zeger SL, Samet JM, Bell ML (2007b). Does the effect of PM_{10} on mortality depend on PM nickel and vanadium content? A reanalysis of the NMMAPS data. Environ Health Perspect, 115: 1701-1703.

Eftim SE, Samet JM, Janes H, McDermott A, Dominici F (2008). Fine Particulate Matter and Mortality: A Comparison of the Six Cities and American Cancer Society Cohorts With a Medicare Cohort. Epidemiology, 19: 209- 216.

Fairley D (2003). Mortality and air pollution for Santa Clara County, California, 1989-1996, In: Revised analyses of time-series studies of air pollution and health. Special report. Health Effects Institute. Boston, MA. http://www.healtheffects.org/Pubs/TimeSeries.pdf.

Franklin M, Zeka A, Schwartz J (2007). Association between $PM_{2.5}$ and all-cause and specific-cause mortality in 27 US communities. J Expo Sci Enviorn Epidemiol, 17:279-287.

Franklin M, Koutrakis P, Schwartz J (2008). The role of particle composition on the association between $PM_{2.5}$ and mortality. Epidemiology, 19:680-689.

Gauderman WJ., McConnell R, Gilliland F, London S, Thomas D, Avol E, Vora H., Berhane K., Rappaport EB., Lurmann F, Margolis HG, Peters J. (2000). Association between air pollution and lung function growth in southern California children. Am. J. Respir. Crit. Care Med. 162: 1383-1390.

Gauderman WJ, Gilliland GF, Vora H, Avol E, Stram D, McConnell R, Thomas D, Lurmann F, Margolis HG, Rappaport, E. B., Berhane, K., Peters, J. M. (2002). Association between air pollution and lung function growth in southern California children: results from a second cohort. Am. J. Respir. Crit. Care Med. 166: 76-84.

Gauderman WJ, Avo, E, Gilliland F, Vora H, Thomas D, Berhane K, McConnell R, Kuenzli N, Lurmann F, Rappaport E, Margolis H, Bates D, Peters J (2004). The effect of air pollution on lung development from 10 to 18 years of age. NEJM 351:1057-67.

Gent JF, Koutrakis P, Belanger K, Triche E, Holford TR, Bracken MB, Leaderer BP (2009) Symptoms and medication use in children with asthma and traffic-related sources of fine particle pollution. Environ Health Perspect. 117:1168-74.

Gong H Jr, Linn WS, Clark KW, Anderson KR, Geller MD, Sioutas C (2005) Respiratory responses to exposures with fine particulates and nitrogen dioxide in the elderly with and without COPD. Inhal Toxicol. 17(3):123-32.

Goss CH, Newsom SA, Schildcrout JS, Sheppard L, Kaufman JD (2004). Effect of ambient air pollution on pulmonary exacerbations and lung function in cystic fibrosis. Am J Respir Crit Care Med, 169: 816-821.

Hassett-Sipple B and Stanek L (2009). Email to study authors of recent U.S, and Canadian epidemiological studies evaluating health effects associated with exposure to fine and thoracic coarse particles. May 2, 2009 and October 20, 2009. Docket ID number EPA-HQ-ORD-2007-0517-0050 and EPA-HQ-ORD-2007-0517-0104.

Hassett-Sipple, B, Rajan, P, Schmidt, M. (2010). Analyses of $PM_{2.5}$ Data for the PM NAAQS Review. Memorandum to PM NAAQS review docket. Docket ID number EPA-HQ-OAR-2007-0492-0077. March 29, 2010. Available: http://epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

Henderson R (2006a). Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to the Honorable Stephen L. Johnson, Administrator, US EPA. Clean Air Scientific Advisory Committee Recommendations Concerning the Proposed National Ambient Air Quality Standards for Particulate Matter. March 21, 2006. Available: http://yosemite.epa.gov/sab/sabproduct.nsf/CD706C976DAC62B3852571390081CC21/$File/casac-ltr-06-002.pdf.

Hopke PK, Ito K, Mar T, Christensen WF, Eatough DJ, Henry RC, Kim E, Laden F, Lall R, Larson TV, Liu H, Neas L, Pinto J, Stolzel M, Suh H, Paatero P, Thurston GD (2006). PM source apportionment and health effects: 1 Intercomparison of source apportionment results. J Expo Sci Environ Epidemiol, 16: 275-286.

Islam T, Gauderman WJ, Berhane K, McConnell R, Avol E, Peters JM, Gilliland FD (2007). The relationship between air pollution, lung function and asthma in adolescents. Thorax, 62: 957-963.

Ito K, Christensen WF, Eatough DJ, Henry RC, Kim E, Laden F, Lall R, Larson TV, Neas L, Hopke PK, Thurston GD (2006). PM source apportionment and health effects: 2 An investigation of intermethod variability in associations between source-apportioned fine particle mass and daily mortality in Washington, DC. J Expo Sci Environ Epidemiol, 16: 300-310.

Jerrett M, Burnett RT, Ma R: Pope CA, Kreski D, Newbold KB, Thurston G, Shi Y, Finkelstein N, Calle N, Thun MJ (2005) Spatial analysis of air pollution and mortality in Los Angeles. Epidemiology, 16: 727-36.

Krewski D, Burnett RT, Goldberg MS, Hoover K, Siemiatycki J, Jerrett M, Abrahamowicz M, White WH (2000). Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of particulate air pollution and mortality. A special report of the Institute's particle epidemiology reanalysis project. Cambridge, MA: Health Effects Institute. http://pubs.healtheffects.org/view.php?id=6

Krewski D, Jerrett M, Burnett RT, Ma R, Hughes E, Shi Y, Turner MC, Pope AC III, Thurston G, Calle EE, Thun MJ (2009). Extended Follow-Up and Spatial Analysis of the American Cancer Society Study Linking Particulate Air Pollution and Mortality. HEI Research Report 140, Health Effects Institute, Boston, MA. Available: http://pubs.healtheffects.org/view.php?id=315.

Laden F, Neas LM, Dockery DW, Schwartz J (2000). Association of fine particulate matter from different sources with daily mortality in six US cities. Environ Health Perspect, 108: 941-947.

Laden F, Schwartz J, Speizer FE, Dockery DW (2006). Reduction in fine particulate air pollution and mortality: extended follow-up of the Harvard Six Cities Study. Am. J. Respir. Crit. Care. Med. 173: 667-672.

Laden F (2009). Personal communication with Dr. Francine Laden: Annual $PM_{2.5}$ levels used in the update of the Harvard Six Cities Study. May 21, 2009. Docket No. EPA-HQ-OAR-2007-0492.

Lanki T, Pekkanen J, Aalto P, Elosua R, Berglind N, D'Ippoliti D, Kulmala M, Nyberg F, Peters A, Picciotto S, Salomaa V, Sunyer J, Tiittanen P, Von Klot S, Forastiere (2006). Associations of traffic-related air pollutants with hospitalization for first acute myocardial infarction: the HEAPSS study. Occup Environ Med, 63: 844-851.

Lipfert FW, Baty JD, Miller JP, Wyzga RE (2006). $PM_{2.5}$ constituents and related air quality variables as predictors of survival in a cohort of U.S. military veterans. Inhal Toxicol, 18: 645-657.

Lippmann M, Ito K, Hwang JS, Maciejczyk P, Chen LC (2006). Cardiovascular effects of nickel in ambient air. Environ Health Perspect, 114: 1662-1669.

Lisabeth LD, Escobar JD, Dvonch JT, Sanchez BN, Majersik JJ, Brown DL, Smith MA, Morgenstern LB (2008). Ambient air pollution and risk for ischemic stroke and transient ischemic attack. Ann Neurol, 64: 53-59.

Mar TF, Norris GA, Larson TV, Wilson WE, Koenig JQ (2003) Air pollution and cardiovascular mortality in Phoenix, 1995-1997. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute, pp. 177-182. Available: http://www.healtheffects.org/news.htm [16 May, 2003].

Mar TF, Larson TV, Stier RA, Claiborn C, Koenig JQ (2004). An analysis of the association between respiratory symptoms in subjects with asthma and daily air pollution in Spokane, Washington. Inhal Toxicol, 16: 809-815.

Mar TF, Ito K, Koenig JQ, Larson TV, Eatough DJ, Henry RC, Kim E, Laden F, Lall R, Neas L, Stölzel M, Paatero P, Hopke PK, Thurston GD (2006). PM source apportionment and health effects. 3. Investigation of inter-method variations in associations between estimated source contributions of $PM_{2.5}$ and daily mortality in Phoenix, AZ. J Expo Sci Environ Epidemiol. 16:311-20.

McConnell R, Berhane K, Gilliland F, Molitor J, Thomas D, Lurmann F, Avol E, Gauderman WJ, Peters JM (2003). Prospective study of air pollution and bronchitic symptoms in children with asthma. Am J Respir Crit Care Med, 168: 790-797.

Miller KA, Siscovick DS, Sheppard L, Shepherd K, Sullivan JH, Anderson GL, Kaufman JD (2007). Long-term exposure to air pollution and incidence of cardiovascular events in women. N Engl J Med, 356: 447-458.

Ostro BD, Broadwin R, Lipsett MJ (2003) Coarse particles and daily mortality in Coachella Valley, California. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 199-204. Available: http://www.healtheffects.org/news.htm [16 May, 2003].

Ostro B, Feng W, Broadwin R, Green S, Lipsett M (2007). The Effects of Components of Fine Particulate Air Pollution on Mortality in California: Results from CALFINE. Environ Health Perspect 115(1): 13-19.

Peng RD, Bell ML, Geyh AS, McDermott A, Zeger SL, Samet JM, Dominici F (2009). Emergency admissions for cardiovascular and respiratory diseases and the chemical composition of fine particle air pollution. Environ Health Perspect. 117:957-63.

Penttinen P, Vallius M, Tiittanen P, Ruuskanen J, Pekkanen J (2006). Source-specific fine particles in urban air and respiratory function among adult asthmatics. Inhal Toxicol, 18: 191-198.

Peters A., Dockery DW, Muller JE, Mittleman MA (2001). Increased particulate air pollution and the triggering of myocardial infarction. Circulation 103:2810-2815.

Peters J, Avol E, Gauderman WJ, Linn WS, Navidi W, London S, Margolis H, Rappaport E, Vora H, Gong H Jr, Thomas DC (1999). A study of twelve southern California communities with differing levels and types of air pollution II Effects on pulmonary function. Am J Respir Crit Care Med, 159: 768-775.

Pope CA 3rd, Dockery DW (1992). Acute health effects of PM_{10} pollution on symptomatic and asymptomatic children. Am Rev Respir Dis. 145(5):1123-8.Pope CA 3rd, Thun M.J., Namboodiri MM, Dockery DW, Evans JS, Speizer FE, Heath CW (1995). Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults. Am J Respir Crit Care Med. 151: 669-674.

Pope CA 3rd, Burnett RT, Thun MJ, Calle EE, Krewski D, Ito K, Thurston GD (2002). Lung cancer, cardiopulmonary mortality, and long-term exposure to fine particulate air pollution. J. Am. Med. Assoc. 287:1132-1141.

Pope CA 3rd, Burnett RT, Thurston GD, Thun MJ, Calle EE, Krewski D, Godleski JJ (2004). Cardiovascular mortality and long-term exposure to particulate air pollution: epidemiological evidence of general pathophysiological pathways of disease. Circulation, 109: 71-77.

Pope CA 3rd, Ezzati M, Dockery DW (2009). Fine-particulate air pollution and life expectancy in the United States. N Engl J Med, 360: 376-386.

Rabinovitch N, Zhang LN, Murphy JR, Vedal S, Dutton SJ, Gelfand EW (2004). Effects of wintertime ambient air pollutants on asthma exacerbations in urban minority children with moderate to severe disease. J Allergy Clin Immunol, 114: 1131-1137.

Rabinovitch N, Strand M, Gelfand EW (2006). Particulate levels are associated with early asthma worsening in children with persistent disease. Am J Respir Crit Care Med, 173: 1098-1105.

Raizenne M, Neas LM, Damokosh AI, Dockery DW, Spengler JD, Koutrakis P, Ware JH, Speizer FE (1996). Health effects of acid aerosols on North American children: pulmonary function. Environ Health Perspect, 104: 506-514.

Rajan P, Schmidt M, Hassett-Sipple B (2010). $PM_{2.5}$ Distributional Statistical Analyses. Memorandum to PM NAAQS review docket EPA-HQ-OAR-2007-0492. April 7, 2011. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

Samet J (2010c). Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to the Honorable Lisa P. Jackson, Administrator, US EPA. CASAC Review of *Policy Assessment for the Review of the PM NAAQS – First External Review Draft* (March 2010). May 17, 2010. Available: http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/E504EE3276D87A9E8525772700647AFB/$File/EPA-CASAC-10-011-unsigned.pdf/.

Samet J (2010d). Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to the Honorable Lisa P. Jackson, Administrator, US EPA. CASAC Review of *Policy Assessment for the Review of the PM NAAQS – Second External Review Draft* (June 2010). September 10, 2010. Available: http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/CCF9F4C0500C500F8525779D0073C593/$File/EPA-CASAC-10-015-unsigned.pdf

Schmidt M, Frank N, Mintz D, Rao T, McCluney L (2005). Analyses of particulate matter (PM) data for the PM NAAQS review. Memorandum to PM NAAQS Review Docket EPA-HQ-OAR-2001-0017. June 30, 2005. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_td.html.

Schmidt M, Hassett-Sipple B, Rajan P (2010). $PM_{2.5}$ Air Quality Analyses. Memorandum to PM NAAQS Review Docket EPA-HQ-OAR-2007-0492. July 22, 2010. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html

Schmidt M (2011a). $PM_{2.5}$ Air Quality Analyses – Update. Memorandum to the PM NAAQS Review Docket EPA-HQ-OAR-2007-0492. April 15, 2011. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html

Schwartz J Dockery DW, Neas LM. (1996). Is daily mortality associated specifically with fine particles? J Air Waste Manage Assoc 46: 927-939.

Schwartz J, Coull B, Laden F, Ryan L (2008). The effect of dose and timing of dose on the association between airborne particles and survival. Environ Health Perspect, 116: 64-69.

Slaughter JC, Kim E, Sheppard L, Sullivan JH, Larson TV, Claiborn C (2005). Association between particulate matter and emergency room visits, hospital admissions and mortality in Spokane, Washington. J Expo Sci Environ Epidemiol, 15: 153-159.

Stanek LW; Yang R, Hassett-Sipple B. (2010). Particulate Matter Air Quality Data Requested from Epidemiologic Study Authors. Memorandum to the PM NAAQS Review Dockets (EPA-HQ-ORD-2007-0517 and EPA-HQ-OAR-2007-0492). July 22, 2010. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

Thurston G, Ito K, Mar T, Christensen WF, Eatough DJ, Henry RC, Kim E, Laden F, Lall R, Larson TV, Liu H, Neas L, Pinto J, Stolzel M, Suh H, Hopke PK (2005). Results and implications of the workshop on the source apportionment of PM health effects. Epidemiology, 16: S134-S135.

Tolbert PE, Klein M, Peel JL, Sarnat SE, Sarnat JA (2007). Multipollutant modeling issues in a study of ambient air quality and emergency department visits in Atlanta. J Expo Sci Environ Epidemiol, 24: 938-945.

Tsai FC, Apte MG, Daisey JM (2000). An exploratory analysis of the relationship between mortality and the chemical composition of airborne particulate matter. Inhal Toxicol, 12: 121-135.

US EPA (2004). Air Quality Criteria for Particulate Matter. National Center for Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, report no. EPA/600/P-99/002aF and EPA/600/P-99/002bF. October 2004. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_cd.html.

US EPA (2005). Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. Research Triangle Park, NC 27711: Office of Air Quality Planning and Standards, report no. EPA EPA-452/R-05-005a. December 2005. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_sp.html.

US EPA (2008a). Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter. National Center for Environmental Assessment and Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. Report No. EPA 452/R-08-004. March 2008. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pd.html.

US EPA (2009a). Integrated Science Assessment for Particulate Matter (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-08/139F, December 2009. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_isa.html.

US EPA (2009b). Integrated Science Assessment for Particulate Matter: Second External Review Draft. National Center for Environmental Assessment-RTP Division, Office of Research and Development, Research Triangle Park, NC. EPA/600/R-08/139B. July 2009. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_isa.html.

US EPA (2010a). Quantitative Risk Assessment for Particulate Matter –Final Report. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/R-010-005. June 2010. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

US EPA (2010c). Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards - First External Review Draft. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA 452/P-10-003. March 2010. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pa.html.

US EPA (2010d). Quantitative Risk Assessment for Particulate Matter – Second External Review Draft. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/P-10-001. February 2010. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

US EPA (2010f). Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards- Second External Review Draft. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA 452/P-10-007. June 2010. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pa.html.

Villeneuve PJ, Chen L, Stieb D, Rowe BH (2006). Associations between outdoor air pollution and emergency department visits for stroke in Edmonton, Canada. Eur J Epidemiol, 21: 689-700.

Woodruff TJ, Darrow LA, Parker JD (2008). Air pollution and postneonatal infant mortality in the United States, 1999-2002. Environ Health Perspect, 116: 110-115.

Zanobetti, A. (2009). Personal communication with Dr.Antonella Zanobetti; email to Jason Sacks, US EPA, NCEA. June 1, 2009. Docket No. EPA-HQ-ORD-2007-0517-0064.

Zanobetti A, Schwartz J (2007). Particulate air pollution, progression, and survival after myocardial infarction. Environ Health Perspect, 115: 769-775.

Zanobetti A, Schwartz J (2009). The effect of fine and coarse particulate air pollution on mortality: A national analysis. Environ Health Perspect, 117: 1-40.

Zhang Z, Whitsel E, Quibrera P, Smith R, Liao D, Anderson G, Prineas R (2009). Ambient fine particulate matter exposure and myocardial ischemia in the Environmental Epidemiology of Arrhythmogenesis in the Women's Health Initiative (EEAWHI) study. Environ Health Perspect, 117: 751-756.

Zeger S, McDermott A, Dominicit F, Samet J (2007). Mortality in the Medicare population and chronic exposure to fine particulate air pollution. Johns Hopkins University. Baltimore. http://www.bepress.com/jhubiostat/paper133.

Zeger S, Dominici F, McDermott A, Samet J (2008). Mortality in the Medicare population and chronic exposure to fine particulate air pollution in urban centers (2000-2005). Environ Health Perspect, 116: 1614.

3 REVIEW OF THE PRIMARY STANDARD FOR THORACIC COARSE PARTICLES

This chapter presents 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). The answers to these questions will inform decisions on whether, and if so how, to revise the current PM_{10} standard.

Our approach for reviewing the primary PM_{10} standard is presented in section 3.1. Our considerations and conclusions regarding the adequacy of the current PM_{10} standard are presented in section 3.2. Section 3.3 presents our 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), form (section 3.3.3), and level (section 3.3.4). Section 3.4 summarizes staff conclusions on the current and potential alternative standards. Section 3.5 discusses 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. 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. Evidence-based approaches to 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 (US EPA, 2009a, section 2.4.3). As a result, any approach to reaching decisions on what standards are appropriate 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. Our approach to informing these decisions, 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. Such an approach is

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). The EPA changed the PM indicator to PM_{10} based on evidence that the risk of adverse health effects associated with particles with a nominal mean aerodynamic diameter less than or equal to 10 μm was significantly greater than risks 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 (discussed above in sections 1.2.2, 2.1.1.1), EPA concluded that continued protection was 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 epidemiological 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 existing PM_{10} standards would provide requisite protection against effects associated with particles in the size range of 2.5 to 10 μm. Although EPA considered a more narrowly defined indicator for thoracic coarse particles 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. 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, there were only very limited ambient air quality data then available specifically for $PM_{10-2.5}$, in contrast to the extensive monitoring network already in place for PM_{10}. Therefore, it was judged more administratively feasible to use PM_{10} as an indicator. The 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.

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 use of PM_{10} as the indicator for thoracic coarse PM, since NAAQS (and their elements) are to be 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.

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 $PM_{10-2.5}$.[1] The new studies available in the 2006 review included epidemiological studies that reported associations with health effects using direct measurements of $PM_{10-2.5}$, as well as dosimetric and toxicological studies. In considering this growing body of $PM_{10-2.5}$ evidence, as well as evidence from studies that measured PM_{10} in locations where the majority of PM_{10} was in the $PM_{10-2.5}$ fraction (US EPA, 2005, section 5.4.1), staff concluded that that the level of protection afforded by the existing 1987 PM_{10} standard remained appropriate (US EPA, 2005, p. 5-67), but recommended that the indicator for the standard be revised. Specifically, staff recommended replacing the PM_{10} indicator with an indicator of urban thoracic coarse particles in the size range of 10-2.5 μm (US EPA, 2005, pp. 5-70 to 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 proposed revised thoracic coarse particle standard would have applied only to an ambient mix of $PM_{10-2.5}$ dominated by resuspended dust from high-density traffic on paved roads and/or by industrial and construction sources. The proposed revised standard would not have applied to any ambient mix of $PM_{10-2.5}$ 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).

[1]The PM Staff Paper (US EPA, 2005) also presented results of a quantitative assessment of health risks for $PM_{10-2.5}$ (see also Abt Associates, 2005). 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 (US EPA, 2005, p.5-69).

The Agency received a large number of comments 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 epidemiological evidence supported retention of a primary standard for short-term exposures that included all thoracic coarse particles (i.e., particles of both urban and non-urban origin), consistent with the Act's requirement that primary NAAQS provide an adequate margin of safety. 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, the Agency concluded that it remained an appropriate indicator for thoracic coarse particles because, as reported by Schmidt et al. (2005), 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. The EPA considered this to be an appropriate targeting of protection given that the strongest evidence for effects associated with thoracic coarse particles came from epidemiological 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 adequate margin of safety, the Agency retained the level and form of the 24-hour PM_{10} standard.[2]

The Agency also revoked the annual PM_{10} standard, in light of the conclusion in the PM Criteria Document (US EPA, 2004, p. 9-79) that the available evidence does not suggest an

[2]Thus, the standard is met when a 24-hour average PM_{10} concentration of 150 $\mu g/m^3$ is not exceeded more than one day per year, on average over a three-year period.

association with long-term exposure to $PM_{10-2.5}$ and the conclusion in the Staff Paper (US EPA, 2005, p. 5-61) that there is no quantitative evidence that directly supports an annual standard.

In the same rulemaking, EPA also included a new FRM for the measurement of $PM_{10-2.5}$ in the ambient air (71 FR 61212 to 61213). Although the standard for thoracic coarse particles does not use a $PM_{10-2.5}$ indicator, the new FRM for $PM_{10-2.5}$ was established to provide a basis for approving FEMs and to promote the gathering of scientific data to support future reviews of the PM NAAQS (section 1.3.4).

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 decision to retain the 24-hour PM_{10} standard and the decision to revoke the annual standard.

First, the court upheld EPA's decision for a standard to encompass 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 inability to reasonably define what ambient mixes would be included under either 'urban' or 'non-urban;' and the evidence in the record that supported EPA's appropriately 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 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 control 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 justified 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 following:

> 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 General Approach Used in Current Review

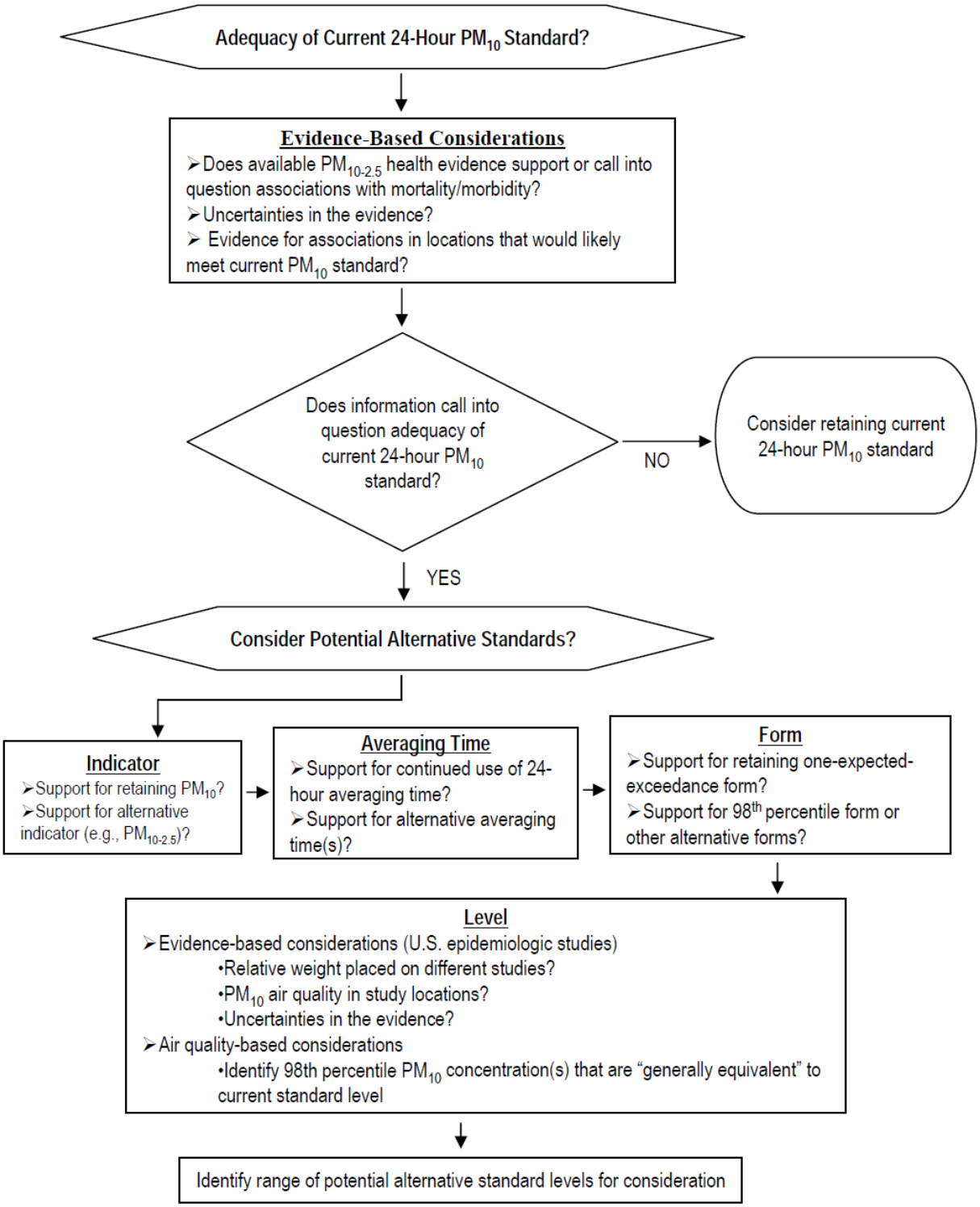
Our approach relies most heavily on the health evidence, primarily the epidemiological evidence, assessed in the ISA (US EPA, 2009a) and on available PM air quality information. As discussed in more detail in the *Quantitative Health Risk Assessment for Particulate Matter – Final* (RA, US EPA, 2010a), 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 estimating $PM_{10-2.5}$ health risks, would introduce significant uncertainty into a $PM_{10-2.5}$ risk assessment such that the risk estimates generated would be of limited value in informing review of the standard. Therefore, staff concluded in the RA that a quantitative risk assessment for $PM_{10-2.5}$ is not supportable at this time (US EPA, 2010a, p. 2-6).

For purposes of this policy assessment, we seek to provide as broad an array of options for consideration as is supportable by the available evidence and air quality information,

recognizing that the final decisions on the primary PM_{10} standard will reflect the judgments of the Administrator. In developing these options for consideration, we consider the available evidence and air quality information that informs overarching questions related to: (1) the adequacy of the current 24-hour PM_{10} standard to protect against effects associated with exposures 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 potential alternative standards, we have taken into account the four basic elements of the NAAQS: indicator, averaging time, form, and level.

Figure 3-1 provides an overview of the policy-relevant questions that frame our review, as discussed more fully below. We believe that this general approach provides 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.

Figure 3-1. Overview of Approach for Review of Primary PM_{10} Standard



3.2 ADEQUACY OF THE CURRENT 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, we address the following overarching question:

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

To inform our consideration of this overarching question, we consider the scientific evidence for associations between $PM_{10-2.5}$ and mortality and morbidity, evidence linking $PM_{10-2.5}$ toxicity to specific sources/locations, uncertainties in the evidence, and available PM_{10} air quality concentrations in $PM_{10-2.5}$ study locations (section 3.2.1). Evidence for populations that are particularly susceptible to PM exposures is discussed in detail in section 2.2.1 above, and is not repeated here. Staff conclusions regarding the adequacy of the current standard are presented in section 3.2.2.

3.2.1 Evidence-Based Considerations

In considering the currently available body of scientific evidence for health effects of thoracic coarse particles, we consider the following question:

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

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, this framework uses a five-level hierarchy that classifies the overall weight of evidence 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, 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). In contrast, the ISA concludes that available evidence is *inadequate to infer a causal relationship* between long-term $PM_{10-2.5}$ exposures and various health effects (US EPA, 2009a, section 2.3; Table 3-1 below). Similar to the judgment made in the AQCD regarding long-term exposures (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). Given these weight of evidence conclusions in the ISA, our evidence-based considerations regarding the adequacy of the current 24-hour PM_{10} standard focus on effects that have been linked with short-term exposures to $PM_{10-2.5}$.

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

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

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

As noted above, in the last review of the PM NAAQS, PM_{10} studies conducted in locations where PM_{10} is comprised predominantly of $PM_{10-2.5}$ were also considered (US EPA, 2005, pp. 5-49 to 5-50). However, PM_{10} studies are difficult to interpret within the context of a standard meant to protect against exposures to $PM_{10-2.5}$ because PM_{10} is comprised of both fine and coarse particles, even in locations with the highest concentrations of $PM_{10-2.5}$ (see below). In light of the considerable uncertainty in the extent to which PM_{10} effect estimates reflect associations with $PM_{10-2.5}$ versus $PM_{2.5}$, together with the availability in this review of several studies that evaluated associations with $PM_{10-2.5}$ and the fact that the ISA weight of evidence conclusions for thoracic coarse particles were based on studies of $PM_{10-2.5}$, we focus in this PA on studies that have specifically evaluated $PM_{10-2.5}$. The evidence supporting a link between short-term thoracic coarse particle exposures and adverse health effects is discussed in detail in the ISA (US EPA, 2009a, Chapter 6) and is summarized briefly below for mortality, cardiovascular effects, and respiratory effects.

Short-Term $PM_{10-2.5}$ and Mortality

The ISA assesses a number of multi-city and single-city epidemiological studies that have evaluated associations between mortality and short-term $PM_{10-2.5}$ concentrations (US EPA, 2009a, Figure 6-30 presents $PM_{10-2.5}$ mortality studies assessed in the last review and the current

review). Different studies have used different approaches to estimate ambient $PM_{10-2.5}$. Some studies have used the difference between PM_{10} and $PM_{2.5}$ mass, either measured at co-located monitors (e.g., Lipfert et al., 2000; Mar et al., 2003; Ostro et al., 2003; Sheppard et al., 2003; Wilson et al., 2007) or as the difference in county-wide average concentrations (Zanobetti and Schwartz, 2009), while other studies have measured $PM_{10-2.5}$ directly with dichotomous samplers (e.g., Burnett and Goldberg, 2003; Fairley et al., 2003; Burnett et al., 2004; Klemm et al., 2004). Despite differences in the approaches used to estimate ambient $PM_{10-2.5}$ concentrations, the majority of multi- and single-city studies have reported positive associations between $PM_{10-2.5}$ and mortality, though most of these associations were not statistically significant (US EPA, 2009a, Figure 6-30). When considered as a whole, the ISA concluded that epidemiological studies have reported consistent, positive associations between short-term $PM_{10-2.5}$ and mortality (US EPA, 2009a, section 6.5.2.3).

In considering specific mortality studies, we note that the U.S. multi-city study by Zanobetti and Schwartz (2009) reported positive and statistically significant associations with $PM_{10-2.5}$ for all-cause, cardiovascular-related, and respiratory-related mortality (US EPA, 2009a, section 6.5.2.3) while other multi-city studies have reported positive, but not statistically significant, $PM_{10-2.5}$ effect estimates for mortality (US EPA, 2009a, Figure 6-30, Burnett and Goldberg, 2003; Klemm et al., 2003; Burnett et al., 2004). In the study by Zanobetti and Schwartz, the effect estimates for all-cause and respiratory-related mortality remained statistically significant in co-pollutant models that included $PM_{2.5}$, while the effect estimate for cardiovascular-related mortality remained positive but not statistically significant. When risk estimates in this study were evaluated by climatic region (US EPA, 2009a, Figure 6-28), the "dry continental" region, which included areas with relatively high $PM_{10-2.5}$ concentrations such as Salt Lake City, Provo, and Denver, showed the largest risk estimates (see US EPA, 2009a, Figure 6-29; Schmidt and Jenkins, 2010; and discussion of regional differences in $PM_{10-2.5}$ concentrations below). However, the "dry" region, which included Phoenix and Albuquerque, two locations that also have relatively high $PM_{10-2.5}$ concentrations, did not show positive associations with all-cause or respiratory-related mortality and only a relatively small positive association for cardiovascular-related mortality. In addition, the "Mediterranean" region (which included cities in California, Oregon, and Washington) did not show positive associations while the other three regions (i.e., "hot summer, continental," "warm summer, continental," and "humid, subtropical and maritime"), which included cities that correspond to the mid-west, northeast, and southeast geographic regions, all showed positive associations (US EPA, 2009a, Figure 6-28).

The ISA also presents single-city empirical Bayes-adjusted effect estimates (Le Tertre et al., 2005) for the 47 cities evaluated by Zanobetti and Schwartz (US EPA, 2009a, Figure 6-29).

City-specific estimates were positive, though generally not statistically significant, for cardiovascular-related mortality in all 47 cities evaluated. Effect estimates were positive for all-cause and respiratory-related mortality in all cities except Los Angeles (negative association for all-cause and respiratory-related mortality) and Phoenix (negative association for respiratory-respiratory-related mortality) (US EPA, 2009a, Figure 6-29). In addition, positive and statistically significant associations between mortality (all-cause, cardiovascular-related, and/or respiratory-related) and $PM_{10-2.5}$ were reported for six locations (i.e., St. Louis, MO; Salt Lake City, UT; Chicago, IL; Pittsburgh, PA; Detroit, MI; and Birmingham, AL).

In considering single-city $PM_{10-2.5}$ mortality studies, we note that all of the studies included in Figure 6-30 of the ISA (US EPA, 2009a) reported positive $PM_{10-2.5}$ effect estimates, with three single-city studies reporting effect estimates that were statistically significant (Mar et al., 2003; Ostro et al., 2003; Wilson et al., 2007). One study reported a negative $PM_{10-2.5}$ effect estimate for respiratory-related mortality (Villeneuve et al., 2003), though effect estimates for all-cause and cardiovascular-related mortality were positive in this study (US EPA, 2009a, Figure 6-30).

Short-Term $PM_{10-2.5}$ and Cardiovascular Effects

The ISA assesses a number of studies that have evaluated the link between short-term ambient concentrations of thoracic coarse particles and cardiovascular effects. In considering the available epidemiological evidence, the ISA concludes that single- and multi-city epidemiological 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). Some of these studies have reported positive and statistically significant $PM_{10-2.5}$ effect estimates in co-pollutant models while others report that $PM_{10-2.5}$ effect estimates remain positive, but not statistically significant (US EPA, 2009a, Figure 6-5).

These studies include a recent U.S. multi-city study evaluating hospital admissions and emergency department visits for cardiovascular disease in Medicare patients (MCAPS, 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 co-located PM_{10} and $PM_{2.5}$ monitors. The magnitude of this effect estimate was larger in counties with higher degrees of urbanization (Peng et al., 2008). The effect estimate was reduced only slightly in a two-pollutant model that included $PM_{2.5,}$ but it was no longer statistically significant (US EPA, 2009a, sections 2.3.3, 6.2.10.9). County-specific analyses were not reported for the locations evaluated by Peng and, therefore, it is not possible to consider differences in $PM_{10-2.5}$

effect estimates in specific locations. Effect estimates for $PM_{10-2.5}$ were larger in the eastern U.S. than the western U.S., though this difference was not statistically significant (Peng et al., 2008). In addition to this U.S. multi-city study, positive associations reported for short-term $PM_{10-2.5}$ and cardiovascular-related morbidity reached statistical significance in a multi-city study in France (Host et al., 2007) and single-city studies in Detroit (Ito, 2003) and Toronto (Burnett et al., 1999) (US EPA, 2009a, Figures 6-2, 6-3). In contrast, associations were positive but not statistically significant in single-city studies conducted in Atlanta (Metzger et al., 2004; Tolbert et al., 2007;) and Boston (Peters et al., 2001) (and for some endpoints in Detroit) (US EPA, 2009a, Figures 6-1 to 6-3, 6-5).

The plausibility of the positive associations reported for $PM_{10-2.5}$ and cardiovascular-related hospital admissions and emergency department visits is supported by a small number of controlled human exposure studies that have reported alterations in heart rate variability following short-term exposure to $PM_{10-2.5}$ (Gong et al., 2004; Graff et al., 2009); by short-term $PM_{10-2.5}$ epidemiological studies reporting positive associations with cardiovascular-related mortality (see discussion above); by a small number of recent epidemiological studies that have examined dust storm events and reported increases in cardiovascular-related emergency department visits and hospital admissions (see below); and by associations with other cardiovascular effects including heart rhythm disturbances and changes in heart rate variability (US EPA, 2009a, sections 2.3.3, 6.2.12.2). 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).

Short-Term $PM_{10-2.5}$ and Respiratory Effects

The ISA also assesses a number of studies that have evaluated the link between short-term ambient concentrations of thoracic coarse particles and respiratory effects. This includes recent studies conducted in the U.S., Canada, and France (US EPA, 2009a, section 6.3.8), including the U.S. multi-city study of Medicare patients by Peng et al. (2009). As discussed above, Peng estimated $PM_{10-2.5}$ concentrations as the difference between PM_{10} and $PM_{2.5}$ concentrations measured by co-located monitors. The authors reported a positive, but not statistically significant, $PM_{10-2.5}$ effect estimate for respiratory-related hospital admissions. Single-city studies have reported positive, and in some cases statistically significant, $PM_{10-2.5}$ effect estimates for respiratory-related hospital admissions and emergency department visits (Lin et al., 2002; Ito, 2003; Sheppard et al., 2003; Chen et al., 2004; Yang et al., 2004; Chen et al., 2005; Lin et al., 2005; Peel et al., 2005; Slaughter et al., 2005; Fung et al., 2006; NYS DOH, 2006; Tolbert et al., 2007) (US EPA, 2009a, Figures 6-10 to 6-15). Some of these $PM_{10-2.5}$

respiratory morbidity studies have reported positive and statistically significant $PM_{10-2.5}$ effect estimates in co-pollutant models that included gaseous pollutants while others reported that $PM_{10-2.5}$ effect estimates remain positive, but not statistically significant, in such co-pollutant models (US EPA, 2009a, Figure 6-15).

A limited number of epidemiological studies have focused on specific respiratory morbidity outcomes and reported both positive and negative, but generally not statistically significant, associations between $PM_{10-2.5}$ and lower respiratory symptoms, wheeze, and medication use (US EPA, 2009a, sections 2.3.3.1 and 6.3.1.1; Figures 6-7, 6-8, 6-9). Although controlled human exposure studies have not observed an 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 reported 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 $PM_{2.5}$.

$PM_{10-2.5}$ Toxicity: Impacts of Sources and Composition

As discussed above, positive, and in some cases statistically significant, associations between short-term $PM_{10-2.5}$ concentrations and mortality and morbidity have been reported in a number of different locations. Little is known about how $PM_{10-2.5}$ composition varies across these locations and how that variation could affect particle toxicity (US EPA, 2009a, sections 2.3.3, 2.3.4, 2.4.4). However, the limited available evidence suggests that specific components of thoracic coarse particles tend to comprise different fractions of $PM_{10-2.5}$ mass in different environments (e.g., urban versus rural environments) (US EPA, 2009a, section 3.5.1.1; Schmidt et al., 2005; Edgerton et al., 2009). It is possible that such differences in particle composition affect particle toxicity, though the ISA concludes that currently available evidence is insufficient to draw distinctions in toxicity based on composition and notes that recent studies have reported that PM (both $PM_{2.5}$ and $PM_{10-2.5}$) from different sources, including crustal sources, is associated with adverse health effects (US EPA, 2009a, section 2.4.4). The evidence for associations with particles originating from different types of sources and in different locations is discussed briefly below.

As discussed above, most $PM_{10-2.5}$ epidemiological studies have been conducted in urban locations in the U.S., Canada, and Europe while a small number of studies have examined the health impacts of dust storm events (US EPA, 2009a, sections 6.2.10.1, 6.5.2.3). Although these dust storm studies do not link specific particle constituents to health effects, it is useful to consider them within the context of the toxicity of particles of non-urban crustal origin. Several

studies have reported positive and statistically significant associations between dust storm events and morbidity or mortality, including the following:

- Middleton et al. (2008) reported that dust storms in Cyprus were associated with a statistically significant increase in risk of hospitalization for all causes and a non-significant increase in hospitalizations for cardiovascular disease.

- Chan et al. (2008) studied the effects of Asian dust storms on cardiovascular-related hospital admissions in Taipei, Taiwan and reported a statistically significant increase associated with 39 Asian dust events. Evaluating the same data, Bell et al. (2008) also reported positive and statistically significant associations between hospitalization for ischemic heart disease and $PM_{10-2.5}$.

- 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.

In contrast to the studies noted above, some dust storm studies have reported associations that were not statistically significant. Specifically, Bennett et al. (2006) reported on a dust storm in the Gobi desert that transported PM across the Pacific Ocean, reaching western North America in the spring of 1998. The authors reported no excess risk of cardiovascular-related or respiratory-related hospital admissions associated with the dust storm in the population of British Columbia's Lower Fraser Valley (Bennett et al., 2006). 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. The implications of these studies for the current review, specifically for consideration of potential alternative indicators, are discussed below in section 3.3.1.

Next we consider uncertainties associated with the evidence by addressing 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?**

The majority of the health evidence supporting the link between short-term thoracic coarse particle exposures and mortality and morbidity comes from epidemiological studies. Although new studies have become available since the last review and have expanded our understanding of the association between $PM_{10-2.5}$ and adverse health effects (see above and U.S. EPA, 2009a, Chapter 6), important uncertainties remain. These uncertainties, and their implications for interpreting the scientific evidence, are discussed below.

The ISA (sections 2.3.3, 2.3.4) concludes that an important uncertainty in the $PM_{10-2.5}$ epidemiological literature is related to the air quality estimates used in these studies. Specifically, the ISA concludes that there is greater error in estimating ambient exposures to $PM_{10-2.5}$ than to $PM_{2.5}$ and that such uncertainty is a particularly relevant consideration when interpreting $PM_{10-2.5}$ epidemiological studies. Contributing to this uncertainty is the relatively limited spatial coverage provided by the existing $PM_{10-2.5}$ monitoring network (discussed in section 1.3.4 above; US EPA, 2009a, sections 2.2.3, 2.3.3, 2.3.4, 3.5.1.1). As discussed above, a national monitoring network for $PM_{10-2.5}$ is not in place, limiting the spatial area over which $PM_{10-2.5}$ concentrations are measured. 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). The net effect of these uncertainties on epidemiological studies of $PM_{10-2.5}$ is to bias the results of such studies toward the null hypothesis. That is, 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).

Given these limitations in the available $PM_{10-2.5}$ monitoring data, different epidemiological studies have employed different approaches for estimating $PM_{10-2.5}$ concentrations, further contributing to uncertainty in interpreting these studies. For example, as discussed above, the multi-city study by Peng et al. (2008) estimated $PM_{10-2.5}$ by taking the difference between collocated PM_{10} and $PM_{2.5}$ monitors while the study by 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).[3] Given the use of these different approaches to estimating $PM_{10-2.5}$

[3]In addition, several sources of uncertainty can be specifically associated with $PM_{10-2.5}$ concentrations that are estimated based on co-located monitors. For example, 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. As discussed in Appendix B, PM_{10} data are often reported at standard temperature and pressure (STP) while $PM_{2.5}$ is reported at local conditions (LC). In these cases, the PM_{10} data should be adjusted to local conditions when estimating $PM_{10-2.5}$ concentrations. In many of the epidemiological studies that estimated $PM_{10-2.5}$ concentrations based on co-located

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, particularly $PM_{2.5}$, has been addressed in only a relatively small number of $PM_{10-2.5}$ epidemiological studies, introducing additional uncertainty into the interpretation of these studies (US EPA, 2009a, section 2.3.3). This is a particularly important consideration given the relatively limited body of experimental evidence available to support the plausibility of associations between $PM_{10-2.5}$ itself and health effects reported in epidemiological studies. As discussed above, many epidemiological studies that have evaluated co-pollutant models have reported that $PM_{10-2.5}$ effect estimates remain positive, but lose precision and are not statistically significant in these models (US EPA, 2009a, Figures 6-5, 6-9, 6-15). The net effect of this limitation in the number of epidemiological studies that have evaluated co-pollutant models, combined with the limited number of supporting experimental studies, is to increase the uncertainty associated with estimates of the extent to which $PM_{10-2.5}$ itself, rather than one or more co-occurring pollutants, is responsible for the reported health effects.

Another uncertainty results from the relative lack of information on the chemical and biological composition of $PM_{10-2.5}$, and the effects associated with the various components (US EPA, 2009a, section 2.3.4). As discussed above, a few recent studies have evaluated associations between health effects and particles of non-urban, crustal origin by evaluating the health impacts of dust storm events. Though these studies provide some information on the health effects of particles that likely differ in composition from the particles of urban origin that are typically studied, without more information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations with health effects across locations is difficult to characterize (US EPA, 2009a, section 6.5.2.3).

As discussed above, a 24-hour PM_{10} standard is in place to protect the public health against exposures to thoracic coarse particles. Therefore, in further considering the adequacy of the current PM_{10} standard, we ask the following question:

- **To what extent does the available scientific evidence report associations between $PM_{10-2.5}$ and morbidity and mortality in areas that would likely meet the current PM_{10} standard?**

In addressing this question, we have used EPA's AQS[4] to characterize PM_{10} concentrations in U.S. locations where both single-city and multi-city $PM_{10-2.5}$ studies have been

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monitors, it is not made explicitly clear whether this adjustment was made, adding to the overall uncertainty in the $PM_{10-2.5}$ concentrations that are associated with health effects.

[4] Accessible at http://www.epa.gov/ttn/airs/airsaqs/

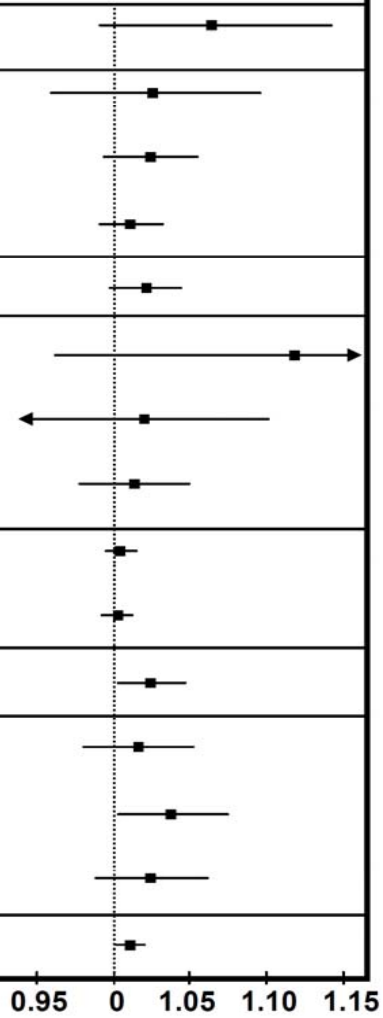
conducted (see U.S. EPA, 2009a, Figures 6-1 to 6-30 for studies). When compared to single-city studies, we note that multi-city studies assess $PM_{10-2.5}$-associated health effects among larger study populations, providing enhanced power to detect $PM_{10-2.5}$-associated health effects. In addition, multi-city studies often provide spatial coverage for different regions across the country, reflecting differences in $PM_{10-2.5}$ sources, composition, and potentially other factors that could impact $PM_{10-2.5}$-related effects. These factors make multi-city studies particularly important when drawing conclusions about health effect associations. However, multi-city studies often present overall effect estimates rather than single-city effect estimates, while short-term air quality can vary considerably across cities. Therefore, the extent to which effects reported in multi-city studies are associated with the short-term air quality in any particular location is uncertain, especially when considering short-term concentrations at the upper end of the distribution of daily concentrations for pollutants with relatively heterogeneous spatial distributions such as $PM_{10-2.5}$ and PM_{10} (US EPA, 2009a, section 2.1.1.2). In contrast, single-city studies are more limited in terms of power and geographic coverage but the link between reported health effects and the short-term air quality in a given city is more straightforward to establish. As a result, in considering 24-hour PM_{10} concentrations in locations of epidemiological studies, we have focused below primarily on single-city studies (Figures 3-2 and 3-3) and single-city analyses of the locations evaluated in the multi-city study by Zanobetti and Schwartz (US EPA, 2009a, Figure 6-29).

The current PM_{10} standard has a form of one-expected-exceedance per year, averaged over 3 years.[5] In order to compare PM_{10} concentrations in study locations to the level of the current standard, we have identified the PM_{10} 3-year expected exceedance concentration-equivalent design value for each study period (labeled "DV" in Figures 3-2 and 3-3 below) using the protocol specified in the PM_{10} State Implementation Plan (SIP) Development Guidelines (US EPA, 1987).[6] Some studies (indicated by a * in Figure 3-3) covered time periods of less than three years. For these study areas, to characterize ambient PM_{10} concentrations relative to concentrations allowed under the current PM_{10} standard, we averaged the second highest 24-hour

[5]The one-expected-exceedance form implies that the standard level is not to be exceeded more than once per year, on average over 3 years. Therefore, in areas that report 24-hour PM_{10} concentrations every day, the 4th highest 24-hour PM_{10} concentration measured during a three year period is compared to the standard level. In contrast, in areas that monitor PM_{10} every six days or every three days, the PM_{10} concentrations that are comparable to the standard level are, respectively, the highest and 2nd highest 24-hour PM_{10} concentrations measured during a three year period.
[6]Specifically, the PM_{10} 3-year expected exceedance concentration-equivalent design value is identified as the highest 24-hour average concentration (i.e., from a single monitor in the study area) over a 3-year period when there are 347 or fewer samples reported for that time-frame, the second highest 24-hour average concentration when there are 348 to 695 samples in the 3-year period, the third highest 24-hour average concentration when there are 696 to 1042 samples in the 3-year period, and the fourth highest 24-hour average concentration when there are 1043 or more samples reported over the 3-year period. Concentration-equivalent design values were not identified for study periods less than 3 years.

Figure 3-2. PM_{10} Air Quality and $PM_{10-2.5}$ Effect Estimates in Locations of U.S. Single-City $PM_{10-2.5}$ Mortality Studies[++]

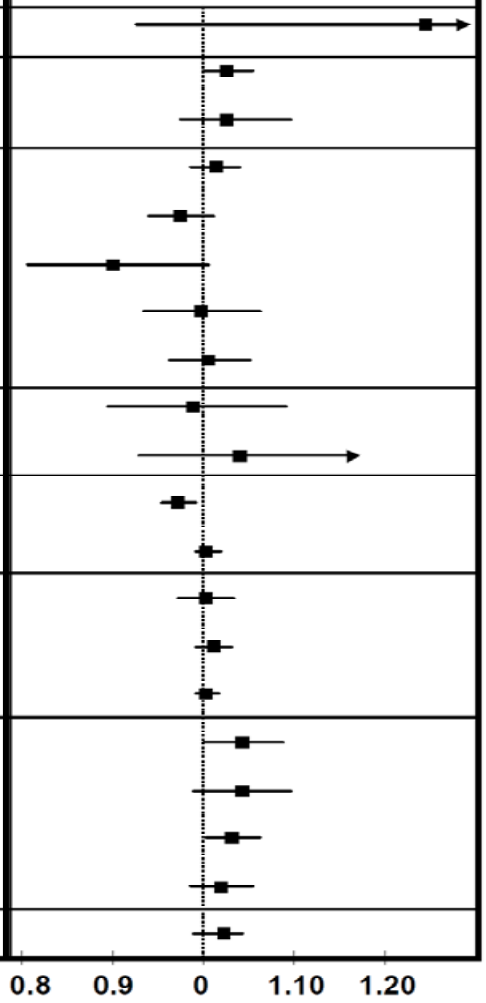
Study	Location	Mortality Endpoint	Time Period	Age	PM_{10} DV ($\mu g/m^3$)	Effect Estimate (95% CI)
Klemm, 2004	Atlanta	All Cause	1998-2000	65+	76	
Ito, 2003	Detroit	Respiratory	1992-1994	65+	123	
		Cardiovascular				
		All Cause				
Lipfert, 2000	Philadelphia	Cardiovascular	1992-1995	All	129	
Fairley, 2003	Santa Clara	Respiratory	1989-1996	All	130	
		Cardiovascular				
		All Cause				
Chock, 2000	Pittsburgh	All Cause	1989-1991	75+	199	
				<75		
Mar, 2003	Phoenix	Cardiovascular	1995-1997	All	307	
Wilson, 2007	Phoenix (outer)	Cardiovascular	1995-1997	25+	307	
	(central)					
	(inner)					
Ostro, 2003	Coachella Valley	Cardiovascular	1989-1998	All	315	



[++]Studies in Figures 3-2 and 3-3 are a combination of those assessed in the last review and those assessed in the ISA in the current review. Studies in these figures are ordered by increasing PM_{10} concentration-equivalent design values.

Figure 3-3. PM_{10} Air Quality $PM_{10-2.5}$ Effect Estimates in Locations of U.S. Single-City $PM_{10-2.5}$ Morbidity Studies

Study	Location	Morbidity Endpoint	Time Period	Age	PM_{10} DV (µg/m³)
Peters, 2001	Boston	MI HA	1995-1996	Mean 62	49*
NYS DOH, 2006	Bronx	Asthma HA	1999-2000	All	49*
	Manhattan				57*
Peel, 2005	Atlanta	URI ED visits	1993-2000	All	78
		Pneumonia ED visits		All	
		COPD ED visits		65+	
		Asthma ED visits		All	
		RD ED visits		All	
Metzger, 2004	Atlanta	IHD ED visits	1993-2000	All	78
		CHF ED visits			
Tolbert, 2007	Atlanta	RD ED visits	1993-2004	All	102
		CVD ED visits			
Slaughter, 2005	Spokane	COPD	1995-2001	65+	110
		Asthma		All	
		RD		All	
Ito, 2003	Detroit	RI HA	1992-1994	65+	123
		COPD HA			
		IHD HA			
		CHF HA			
Sheppard, 2003	Seattle	Asthma HA	1987-1994	All	136



* Concentration-equivalent design values were not identified for study periods less than three years. For study periods of less than three years, we averaged the second highest 24-hour PM_{10} concentrations for each year of the study (i.e., second highest concentration measured by the single monitor in the study area recording the highest such concentration).

PM_{10} concentrations for each year of the study (i.e., second highest concentration measured at the single monitor in the study area recording the highest such concentration). The identification of concentration-equivalent design values and second highest PM_{10} concentrations for each study area are described in more detail in Schmidt and Jenkins (2010) and Jenkins (2011).

In addition to the single-city studies included in Figures 3-2 and 3-3 above, multi-city averages of the 3-year expected exceedance concentration-equivalent design values for U.S. multi-city studies were 110 $\mu g/m^3$, for the locations evaluated by Zanobetti and Schwartz (2009) (see Jenkins, 2011 for PM_{10} air quality concentrations), and 100 $\mu g/m^3$, for the locations evaluated by Peng et al. (2008) (see Schmidt and Jenkins, 2010 for PM_{10} air quality concentrations). As discussed above, the extent to which overall $PM_{10-2.5}$ effect estimates reported in multi-city studies are associated with the air quality in any particular location is uncertain. However, the ISA also presents single-city Bayes-adjusted effect estimates for each of the cities evaluated by Zanobetti and Schwartz (US EPA, 2009a, Figure 6-29), providing the opportunity to consider associations between $PM_{10-2.5}$ and mortality, and to consider the PM_{10} air quality, in each of the individual cities evaluated in this study.

As discussed above, in single-city analyses in the locations evaluated by Zanobetti and Schwartz, $PM_{10-2.5}$ effect estimates for mortality were generally positive but not statistically significant, and most were similar in magnitude and precision, particularly for cardiovascular-related mortality, across a wide range of estimated $PM_{10-2.5}$ concentrations (US EPA, 2009a, Figure 6-29). Three-year PM_{10} expected exceedance concentration-equivalent design values in these cities ranged from 50 $\mu g/m^3$ (Davie, FL) to 283 $\mu g/m^3$ (Salt Lake City, UT). In most of the cities evaluated (37 of the 45 for which concentration-equivalent design values could be identified), concentration-equivalent design values were below 150 $\mu g/m^3$ (Jenkins, 2011). In the six cities where positive and statistically significant $PM_{10-2.5}$ mortality effect estimates were reported (see above), concentration-equivalent design values were as follows (Jenkins, 2011):

- Chicago: 113 $\mu g/m^3$
- Pittsburgh: 139 $\mu g/m^3$
- Birmingham[7]: 154 $\mu g/m^3$
- Detroit: 165 $\mu g/m^3$
- St. Louis: 165 $\mu g/m^3$
- Salt Lake City: 283 $\mu g/m^3$

Therefore, while $PM_{10-2.5}$ effect estimates in single-city analyses were not statistically significant for most locations evaluated by Zanobetti and Schwartz, including some locations with PM_{10}

[7]According to rounding convention for the PM_{10} standard, a 24-hour PM_{10} concentration of 154 $\mu g/m^3$ would round to 150 $\mu g/m^3$ (71 FR 61144). Therefore, based on the PM_{10} one-expected-exceedance concentration-equivalent design value, Birmingham would have been expected to just meet the current PM_{10} standard during the study period.

concentrations well above those allowed by the current 24-hour PM_{10} standard, positive and statistically significant $PM_{10-2.5}$ effect estimates were reported in two locations (Chicago, Pittsburgh) with concentration-equivalent design values below 150 $\mu g/m^3$.[7]

In considering $PM_{10-2.5}$ epidemiological studies conducted in Canada and elsewhere outside the U.S., we note that we generally do not have access to PM_{10} air quality information beyond that published by the study authors. Many of these studies report PM concentrations averaged across monitors, rather than from the highest monitor in the study area, and/or report only mean or median concentrations. Lin et al. (2002) reported positive and statistically significant associations between $PM_{10-2.5}$ and asthma hospital admissions in children in Toronto (US EPA, 2009a; Figures 6-12, 6-15). The authors reported a maximum PM_{10} concentration measured at a single monitor in the study area of 116 $\mu g/m^3$, indicating that the PM_{10} air quality in Toronto during this study would have been allowed by the current 24-hour PM_{10} standard. In contrast Middleton et al. (2008), who reported that dust storms in Cyprus were associated with a statistically significant increase in risk of hospitalization for all causes and a non-significant increase in hospitalizations for cardiovascular diseases, reported a maximum 24-hour PM_{10} concentration of 1,371 $\mu g/m^3$. Thus, the dust storm-associated increases in hospitalizations reported in this study occurred in an area with PM_{10} concentrations that were likely well above those allowed by the current standard. Other dust storm studies did not report maximum 24-hour PM_{10} concentrations from individual monitors, though the studies by Chan et al. (2008) and Bell et al. (2008), which reported positive and statistically significant associations between dust storm metrics and cardiovascular-related hospital admissions, reported that 24-hour PM_{10} concentrations, averaged across monitors, exceeded 200 $\mu g/m^3$. It is likely that peak concentrations measured at individual monitors in these studies were much higher and, therefore, 24-hour PM_{10} concentrations in these study areas were likely above those allowed by the current standard.

Summary of Evidence-Based Considerations

New evidence supporting an association between $PM_{10-2.5}$ and mortality and morbidity has become available since the last review of the PM NAAQS. The available evidence was judged in the ISA to be *suggestive of a causal relationship* between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects while the evidence was judged *inadequate to infer a causal relationship* with long-term $PM_{10-2.5}$ exposures for these same broad health effect categories as well as other effects considered in the ISA (US EPA, 2009a, section 2.3.3; see Table 3-1 above). The evidence supporting a link between short-term thoracic coarse particle exposures and adverse health effects comes primarily from epidemiological studies, with limited supporting evidence from controlled human exposure

studies and, to a lesser extent, animal instillation studies. This evidence includes several recent (i.e., published since the last review of the PM NAAQS) multi-city epidemiological studies conducted in the U.S., Canada, and Europe and a small number of recent studies of particles of non-urban origin. In general, epidemiological studies have reported positive, and in some cases statistically significant, $PM_{10-2.5}$ effect estimates. In the limited number of studies that have evaluated co-pollutant models that include either gaseous pollutants or fine particles, $PM_{10-2.5}$ effect estimates generally remained positive, and in a few cases statistically significant.

Positive associations between $PM_{10-2.5}$ and mortality and morbidity have been reported in a number of locations across the U.S. with a wide range of $PM_{10-2.5}$ and PM_{10} concentrations. Among single-city analyses, $PM_{10-2.5}$ effect estimates were positive and statistically significant in a few U.S. cities and at least one Canadian city with ambient PM_{10} concentrations that would be allowed by the current 24-hour PM_{10} standard. In addition, multi-city average PM_{10} one-expected-exceeded concentration-equivalent design values were below the level of the current PM_{10} standard when averaged across U.S. cities that have been evaluated in multi-city studies reporting positive, and in some cases statistically significant, associations between $PM_{10-2.5}$ and mortality and morbidity. However, most $PM_{10-2.5}$ effect estimates, even those reported in locations with PM_{10} concentrations above the concentrations allowed by the current standard, were not statistically significant.

3.2.2 CASAC Conclusions and Recommendations

Following their review of the first and second draft PAs, CASAC provided advice and recommendations regarding the current and potential alternative standards for thoracic coarse particles (Samet, 2010c; Samet, 2010d). With regard to the current PM_{10} standard, CASAC concluded that "the current data, while limited, is sufficient to call into question the level of protection afforded the American people by the current standard" (Samet, 2010d, p. 7). In drawing this conclusion, CASAC noted the positive associations in multi-city and single-city studies, including in locations with PM_{10} concentrations below those allowed by the current standard. In addition, CASAC gave "significant weight to studies that have generally reported that $PM_{10-2.5}$ effect estimates remain positive when evaluated in co-pollutant models" and concluded that "controlled human exposure $PM_{10-2.5}$ studies showing decreases in heart rate variability and increases in markers of pulmonary inflammation are deemed adequate to support the plausibility of the associations reported in epidemiologic studies" (Samet, 2010d, p. 7). Given all of the above conclusions CASAC recommended that "the primary standard for PM_{10} should be revised" in order to increase public health protection (Samet, 2010d, p. ii and p. 7).

3.2.3 Staff Conclusions on Adequacy of Current PM_{10} Standard

In light of the available $PM_{10-2.5}$ health evidence and the PM_{10} air quality concentrations in study locations, as discussed above, we revisit the overarching question: Does the currently available scientific evidence, as reflected in the ISA, and air quality information support or call into question the adequacy of the protection afforded by the current 24-hour PM_{10} standard against effects associated with exposures to thoracic coarse particles?

In considering the evidence and information as they relate to the adequacy of the current 24-hour PM_{10} standard we note that, as discussed above, this standard is meant to protect the public health against effects associated with short-term exposures to $PM_{10-2.5}$. In the last review, it was judged appropriate to maintain such a standard 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). Given the expanded body of evidence available in the current review, discussed in detail in the ISA (US EPA, 2009a, Chapter 6) and summarized above, we conclude that the evidence continues to support the appropriateness of a standard to protect the public health against effects associated with short-term exposures to $PM_{10-2.5}$. In addition, when considering the evidence for associations with $PM_{10-2.5}$ from different types of sources and in different locations (e.g., thoracic coarse particles of urban/industrial origin as well as windblown dust of non-urban origin), we conclude that it remains appropriate to provide some measure of protection against exposures to all thoracic coarse particles.

In considering the evidence, we note that a decision on the adequacy of the public health protection provided by the current PM_{10} standard will be a public health policy judgment in which the Administrator weighs that evidence and its inherent uncertainties. Therefore, depending on the emphasis placed on different aspects of the evidence and uncertainties, consideration of different conclusions on adequacy could be supported.

For example, one approach to considering the evidence and its associated uncertainties would be to place emphasis on the following:

- While important uncertainties are associated with the health evidence, several multi-city epidemiological studies conducted in the U.S., Canada, and Europe, as well as a number of single-city studies, have reported generally positive, and in some cases statistically significant, associations between short-term $PM_{10-2.5}$ concentrations and adverse health endpoints including mortality and cardiovascular-related and respiratory-related hospital admissions and emergency department visits.

- Both single-city and multi-city analyses, using different approaches to estimate ambient $PM_{10-2.5}$ concentrations, have reported positive $PM_{10-2.5}$ effect estimates in locations that would likely have met the current 24-hour PM_{10} standard. In some cases, these $PM_{10-2.5}$ effect estimates were statistically significant.

- While limited in number, studies that have evaluated co-pollutant models have generally reported that $PM_{10-2.5}$ effect estimates remain positive, and in a few cases statistically significant, when these models include gaseous pollutants or fine particles.

- Support for the plausibility of the associations reported in epidemiological studies is provided by a small number of controlled human exposure studies reporting that short-term (i.e., 2-hour) exposures to $PM_{10-2.5}$ decrease heart rate variability and increase markers of pulmonary inflammation.

Such an approach to considering the evidence would place substantial weight on the generally positive $PM_{10-2.5}$ effect estimates that have been reported for mortality and morbidity, even those effect estimates that are not statistically significant. This could be judged appropriate given that consistent results have been reported across multiple studies using different approaches to estimate ambient $PM_{10-2.5}$ concentrations and that exposure measurement error, which is likely to be larger for $PM_{10-2.5}$ than for $PM_{2.5}$, tends to bias the results of epidemiological studies toward the null hypothesis, making it less likely that associations will be detected. In contrast, such an approach would place relatively little weight on the uncertainties in the evidence that resulted in the ISA conclusions that the evidence is only "suggestive" of a causal relationship, rather than "likely causal" or "causal." To the extent that a decision on the adequacy of the current 24-hour PM_{10} standard were to place emphasis on the considerations noted above, it could be judged that the current 24-hour PM_{10} standard does not protect public health with an adequate margin of safety and that it should be revised in order to increase protection against effects associated with short-term exposures to thoracic coarse particles.

Another approach to considering the evidence and its uncertainties would be to place emphasis on the following:

- While most of $PM_{10-2.5}$ effect estimates reported for mortality and morbidity were positive, many were not statistically significant, even in single-pollutant models. This includes effect estimates reported in study locations with PM_{10} concentrations above those allowed by the current 24-hour PM_{10} standard.
- The number of epidemiological studies that have employed co-pollutant models to address the potential for confounding, particularly by $PM_{2.5}$, remains limited. Therefore, the extent to which $PM_{10-2.5}$ itself, rather than one or more co-pollutants, contributes to reported health effects remains uncertain.
- Only a limited number of experimental studies provide support for the associations reported in epidemiological studies, resulting in further uncertainty regarding the plausibility of the associations between $PM_{10-2.5}$ and mortality and morbidity reported in epidemiological studies.

- Limitations in $PM_{10-2.5}$ monitoring data and the different approaches used to estimate $PM_{10-2.5}$ concentrations across epidemiological studies result in uncertainty in the ambient $PM_{10-2.5}$ concentrations at which the reported effects occur.
- The chemical and biological composition of $PM_{10-2.5}$, and the effects associated with the various components, remains uncertain. Without more information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations across locations is difficult to characterize.
- In considering the available evidence and its associated 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 weight-of-evidence conclusions contrast with those for the relationships between $PM_{2.5}$ exposures and adverse health effects, which were judged in the ISA to be either "causal" or "likely causal" for mortality, cardiovascular effects, and respiratory effects.

To the extent that a decision on the adequacy of the current 24-hour PM_{10} standard were to place emphasis on the considerations noted above, it could be judged that, while it remains appropriate to maintain a standard to protect against short-term exposures to thoracic coarse particles, the available evidence suggests that the current 24-hour PM_{10} standard appropriately protects public health and that it provides an adequate margin of safety against effects that have been associated with $PM_{10-2.5}$. While this approach to considering the evidence would recognize the positive, and in some cases statistically significant, associations between $PM_{10-2.5}$ and mortality and morbidity by maintaining a standard to protect against exposures to thoracic coarse particles, it would place relatively greater emphasis on the limitations and uncertainties noted above, which tend to complicate the interpretation of that evidence.

Given all of the above, we conclude that it would be appropriate to consider either retaining or revising the current 24-hour PM_{10} standard, depending on the approach taken to considering the available evidence and information. Therefore, we judge that it is appropriate in this PA to consider what potential alternative standards, if any, could be supported by the available scientific evidence in order to increase public health protection against exposures to $PM_{10-2.5}$.

3.3 CONSIDERATION OF POTENTIAL ALTERNATIVE STANDARDS

Staff next considers the following overarching question:

What potential alternative standard(s) could be supported by the currently available scientific evidence and air quality information?

In addressing this overarching question, we consider how the currently available scientific evidence and air quality information could inform decisions regarding the basic elements of the NAAQS: indicator (section 3.3.1), averaging time (section 3.3.2), form (section 3.3.3), and level (section 3.3.4). These elements are considered collectively in evaluating the health protection afforded by potential alternative standards under consideration.

3.3.1 Indicator

As discussed above, PM_{10} includes both $PM_{10-2.5}$ and $PM_{2.5}$, with the relative contribution of each to PM_{10} mass varying across locations (see below). In the most recent review completed in 2006, EPA concluded that the PM_{10} indicator remained appropriate because a PM_{10} standard would be expected to provide appropriate protection against effects associated with exposures to $PM_{10-2.5}$. In particular, a PM_{10} indicator would be expected to target protection to urban areas, where the evidence of effects from exposure to coarse PM is the strongest (71 FR at 61196). In considering potential alternative standards in the current review, we have considered the following question with regard to indicator:

- **To what extent does the available evidence and/or air quality information provide support for retaining or revising the current PM_{10} indicator?**

  In addressing this question, we focus on the following considerations:

  - The extent to which PM_{10} is comprised of $PM_{10-2.5}$
  - The appropriateness of a standard that would be expected to allow lower $PM_{10-2.5}$ concentrations in areas with higher fine particle concentrations (i.e., urban areas) than areas with lower fine particle concentrations (i.e., rural areas)[8]

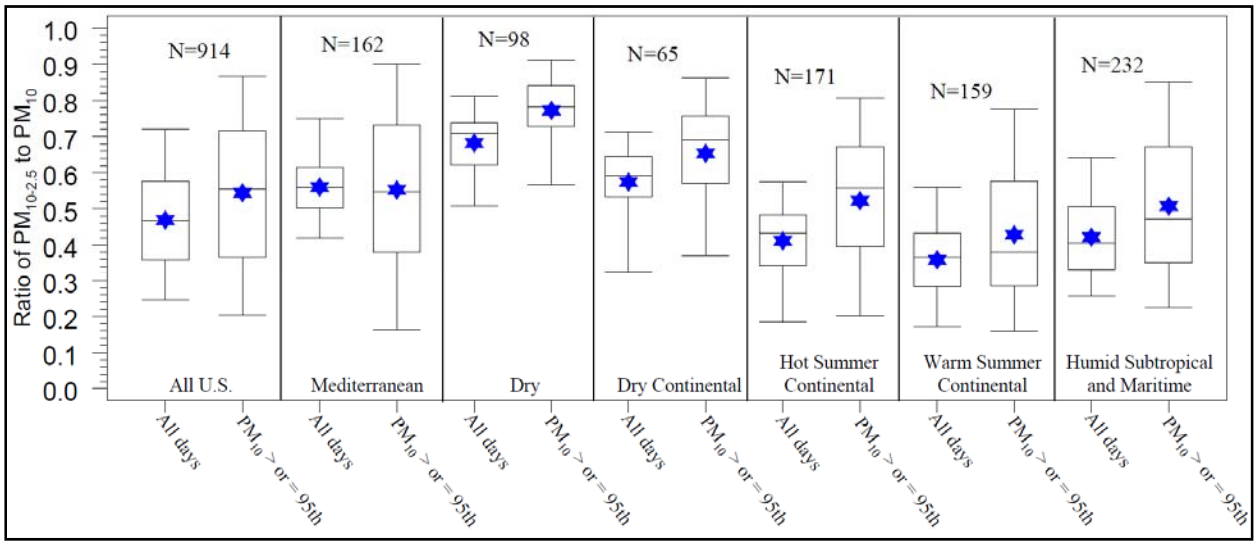
As an initial matter, we consider the proportion of PM_{10} mass in different regions of the U.S. that is $PM_{10-2.5}$ (see US EPA, 2009a, section 3.5.1.1; Schmidt and Jenkins, 2010). Schmidt and Jenkins (2010) divided the U.S. into climatic regions using the same approach as used in the multi-city epidemiological study by Zanobetti and Schwartz (2009) (see above).[9] Consistent

[8]For comparisons of $PM_{2.5}$ mass in urban and rural areas see Schmidt (2005, outputs for Attachment D).

[9]The Mediterranean region includes CA, OR, WA. The dry region includes NM, AZ, NV. The dry continental region includes MT, ID, WY, UT, CO. The hot summer continental region includes SD, NE, IA, IL, IN, OH. The warm summer continental region includes ND, MN, WI, MI, PA, NY, CT, RI, MA, VT, NH, ME. The humid

with the air quality analyses in the ISA (US EPA, 2009a, section 3.5.1.1) and the concentration estimates of Zanobetti and Schwartz (2009), $PM_{10-2.5}$ concentrations were higher in the dry, mediterranean, and dry continental regions, with the highest concentrations in the dry region, which included the southwestern U.S. (data not shown, from Schmidt and Jenkins, 2010). On average, ratios of $PM_{10-2.5}$ concentrations to PM_{10} concentrations were also higher in these regions than in the remainder of the U.S., with the dry region having the highest ratios. Consistent results were reported in the ISA analyses of PM air quality (US EPA, 2009a, compare Tables 3-9 and 3-10). While the same general pattern persisted when the analysis was restricted to days with PM_{10} concentrations at the high end of the distribution of 24-hour concentrations (i.e., at or above the 95th percentile values), ratios of $PM_{10-2.5}$ to PM_{10} on these days tended to be somewhat higher, on average, across most regions of the U.S. (see right-hand columns in Figure 3-4).

Figure 3-4. Site-Level Ratio of 24-Hour $PM_{10-2.5}$ to 24-Hour PM_{10} Concentrations*



*Blue stars represent mean concentrations, horizontal lines represent median concentrations, boxes represent 75% confidence intervals, and error bars represent 95% confidence intervals. N values equal the number of site years of monitoring data for each region.

Thus, on average across the U.S., $PM_{10-2.5}$ comprises a larger portion of PM_{10} on days with relatively high PM_{10} concentrations than on days with more typical PM_{10} concentrations. Given this, a PM_{10} standard that focuses on the upper end of the distribution of daily PM_{10} concentrations could effectively control ambient $PM_{10-2.5}$ concentrations.

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subtropical and maritime region includes FL, LA, TX, GA, AL, MS, AR, OK, KS, MO, TN, SC, NC, VA, WV, KY, NJ, DE, DC, MD.

Given the above conclusion, in further considering the issue of indicator we 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 some studies have reported positive associations between relatively high concentrations of particles of non-urban origin (i.e., crustal material from windblown dust in non-urban areas, see above) and mortality and morbidity, we note that the extent to which these associations would remain at the lower particle concentrations more typical of U.S. and Canadian urban study locations remains uncertain.[10] Given these considerations, and given the increased potential for coarse particles in urban areas to become contaminated by toxic components of fine particles from urban/industrial sources (US EPA, 2004), we conclude that it remains appropriate to maintain a standard that allows lower ambient thoracic coarse particle concentrations in urban areas than in non-urban areas.

Given this conclusion, we note that it would be reasonable to consider an indicator that targets control on areas with the types of ambient mixes generally present in urban areas. Such an indicator would focus control on areas with ambient mixes known with greater certainty to be associated with adverse health effects and, therefore, would provide public health benefits with the greatest degree of certainty. As noted in the last review of the PM NAAQS, a PM_{10} standard would allow lower concentrations of $PM_{10-2.5}$ in areas with higher fine particle concentrations, which tend to be urban locations, than areas with lower fine particle concentrations, which tend to be rural locations (section 3.1.1.2 above). Therefore, as in the last review, we reach the conclusion that a PM_{10} indicator would appropriately target protection to those locations where the evidence is strongest for associations between adverse health effects and exposures to thoracic coarse particles. In contrast, we note that a $PM_{10-2.5}$ indicator, for a standard set at a single unvarying level, would not achieve this targeting, given that allowable thoracic coarse particle concentrations would be the same regardless of the location or the likely sources of PM. Therefore, given the currently available evidence, one possible result of using a $PM_{10-2.5}$ indicator would be a standard that is overprotective in rural areas and/or underprotective in urban areas.

In addition, while we note that administrative feasibility is not an appropriate basis for informing decisions on the NAAQS or its elements (see above), we also note that $PM_{10-2.5}$ concentrations are not routinely measured and reported at present (US EPA, 2009a, section

[10]Other than the dust storm studies, we note that the study in Coachella Valley by Ostro et al. (2003) reported statistically significant associations in a location where thoracic coarse particles are expected to be largely due to windblown dust. Specifically, we note the CASAC conclusion in the last review that "studies from Ostro *et al.* showed significant adverse health effects, primarily involving exposures to coarse-mode particles arising from crustal sources" (Henderson, 2005b). In considering this study, we also note the relatively high PM_{10} concentrations in the study area (see Figure 3-2 above).

3.5.1.1). In the last review of the PM NAAQS, EPA required monitoring of $PM_{10-2.5}$ mass and we expect that approximately 80 stations will be reporting mass concentrations as part of the National Core (NCore) network (http://www.epa.gov/ttnamti1/ncore/index.html) (section 1.3.3 and Appendix B, section B.4). However, data from those monitors are not available for locations and time periods of existing $PM_{10-2.5}$ health studies.

In their review of the second draft PA, CASAC agreed with staff's conclusions that the available evidence supports consideration in the current review of a PM_{10} indicator for a standard that protects against exposures to thoracic coarse particles. Specifically, CASAC concluded that "[w]hile it would be preferable to use an indicator that reflects the coarse PM directly linked to health risks ($PM_{10-2.5}$), CASAC recognizes that there is not yet sufficient data to permit a change in the indicator from PM_{10} to one that directly measures thoracic coarse particles" (Samet, 2010d, p. ii). In addition, CASAC "vigorously recommends the implementation of plans for the deployment of a network of $PM_{10-2.5}$ sampling systems so that future epidemiological studies will be able to more thoroughly explore the use of $PM_{10-2.5}$ as a more appropriate indicator for thoracic coarse particles" (Samet, 2010d, p. 7).

Given all of the above considerations, as in the draft Policy Assessment, we conclude that the available evidence supports consideration in the current review of a PM_{10} indicator for a standard that protects against exposures to thoracic coarse particles. We further conclude that consideration of alternative indicators (e.g., $PM_{10-2.5}$) in future reviews is desirable and could be informed by additional research, as described below (section 3.5).

3.3.2 Averaging Time

Based primarily on epidemiological studies that reported positive associations between short-term (24-hour) $PM_{10-2.5}$ concentrations and mortality and morbidity, the Administrator concluded in the last review that the available evidence supported 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 (US EPA, 2004a, Chapter 9), the Administrator further concluded that an annual coarse particle standard was not warranted at that time (71 FR 61198-61199).

In the current review, we consider the extent to which the available evidence provides information relevant for decisions on averaging time 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 exposures to $PM_{10-2.5}$?**

With regard to this question, we note the conclusions from the ISA regarding the weight of evidence for short-term and long-term $PM_{10-2.5}$ exposures 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 epidemiological 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 small 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 above).

In considering these weight of evidence determinations in the ISA, we conclude that, at a minimum, they suggest the importance of maintaining a standard that protects against short-term exposures to thoracic coarse particles. Given that the majority of the evidence supporting the link between short-term $PM_{10-2.5}$ and morbidity and mortality is based on 24-hour average thoracic coarse particle concentrations, we conclude that the evidence available in this review continues to support consideration of a 24-hour averaging time for a PM_{10} standard meant to protect against effects associated with short-term exposures to $PM_{10-2.5}$. We further conclude that the available evidence does not support consideration of an annual thoracic coarse particle standard at this time. In reaching this conclusion, we also 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 some protection against any potential effects associated with long-term exposures to ambient concentrations. CASAC agreed with these conclusions (Samet, 2010c).

3.3.3 Form

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 that standard. In identifying a single statistic for the form, we note that although future air quality improvement strategies in any particular area are not defined until after a standard is promulgated, many such strategies are likely to affect a broad distribution of PM air quality concentrations in an area. Therefore, although the form of the standard defines a single statistic, any reductions in health risks that are

likely to result from strategies designed to meet a specific standard are likely to occur across a wide range of concentrations.

As discussed above, in the last review the Administrator retained the one-expected exceedance form of the primary 24-hour PM_{10} standard. This decision was linked to the overall conclusion that "the level of protection from coarse particles provided by the current 24-hour PM_{10} standard remains requisite to protect public health with an adequate margin of safety" (71 FR 61202). Because revising either the level or the form of the standard would have altered the protection provided, it was concluded that such changes "would not be appropriate based on the scientific evidence available at this time" (71 FR 21202). Therefore, the decision in the last review to retain the one-expected-exceedance form was part of the broader decision that the existing 24-hour standard provided requisite public health protection.

In the current review, we are also considering the form of the standard within the context of the overall decision on whether, and if so how, to revise the current 24-hour PM_{10} standard. Given the conclusions above regarding the appropriate indicator and averaging time for consideration for potential alternative standards, we consider potential alternative forms for a 24-hour PM_{10} standard. To frame our consideration of this issue, we pose the following question:

- **To what extent does available evidence and information support consideration of an alternative form for a 24-hour PM_{10} standard?**

Although the selection of a specific form must be made within the context of decisions on the other elements of the standard, EPA generally favors concentration-based forms for short-term standards. In 1997 EPA established a 98^{th} percentile form for the 24-hour $PM_{2.5}$ standard and in 2010 EPA established a 98^{th} percentile form for the 1-hour NO_2 standard (62 FR 38671; 75 FR 6474) and a 99^{th} percentile form for the 1-hour SO_2 standard (75 FR 35541). In making these decisions, EPA noted that, compared to an exceedance-based form, a concentration-based form is more reflective of the health risks posed by elevated pollutant concentrations because such a form 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 level of the standard. In addition, when averaged over three years, these concentration-based forms were judged to provide an appropriate balance between limiting peak pollutant concentrations and providing a stable regulatory target, facilitating the development of stable implementation programs.

These considerations are also relevant in the current review of the 24-hour PM_{10} standard. Specifically, we conclude that it is appropriate to consider concentration-based forms that would provide a balance between limiting peak pollutant concentrations and providing a stable regulatory target. To accomplish this, it would be appropriate to consider forms from the upper

end of the annual distribution of 24-hour PM_{10} concentrations.[11] However, given the potential for local sources to have important impacts on monitored PM_{10} concentrations (US EPA, 2009a, section 2.1.1.2), we also note that it would be appropriate to consider forms that, when averaged over three years, would be expected to promote the stability of local implementation programs.[12] In considering these issues in the most recent review of the NO_2 primary NAAQS, we note that a 98th percentile form was adopted, rather than a 99th percentile form, due to the potential for "instability in the higher percentile concentrations" near local sources (75 FR 6493).[13]

In considering the potential appropriateness of a 98th percentile form in the current review, we note that, compared to the current PM_{10} standard, attainment status for a PM_{10} standard with a 98th percentile form would be based on a more stable air quality statistic and would be expected to be less influenced by relatively rare events that can cause elevations in PM_{10} concentrations over short-periods of time (Schmidt, 2011b). Specifically, we note that in areas that monitor PM_{10} every six days, every three days, or every day the one-expected-exceedance concentrations that are comparable to the current standard level are, respectively, the highest, 2nd highest, or 4th highest 24-hour PM_{10} concentrations measured during a three year period. In contrast, for the same monitoring frequencies, the PM_{10} concentrations that would be comparable to the level of a standard with a 98th percentile form would be the three-year average of the 2nd highest, 3rd highest, or 7th/8th highest 24-hour PM_{10} concentrations measured during a single year.

In further considering this issue we note that, compared to the current expected-exceedance form, a concentration-based form specified as a percentile of the annual distribution of PM_{10} concentrations (e.g., such as a 98th percentile form) would be expected to better compensate for missing data and less-than-daily monitoring (Davidson and Hopke, 1984). This is a particularly important consideration in the case of PM_{10} because, depending largely on ambient concentrations, the frequency of PM_{10} monitoring differs across locations (i.e., either daily, 1 in 2 days, 1 in 3 days, or 1 in 6 days) (Section 1.3.10 above and Appendix B). With a 98th percentile form, attainment status would be determined based on PM_{10} concentrations from

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[11]With regard to this conclusion, we also note that $PM_{10-2.5}$ is likely to make a larger contribution to PM_{10} mass on days with relatively high PM_{10} concentrations than on days with more typical PM_{10} concentrations (see above).

[12]Stability of implementation programs has been held to be a legitimate consideration in determining a NAAQS (American Trucking Assn's v. EPA, 283 F. 3d at 374-75).

[13]See also, ATA III, 283 F. 3d at 374-75 (upholding 98th percentile form since "otherwise States would have to design their pollution control programs around single high exposure events that may be due to unusual meteorological conditions alone, rendering the programs less stable – and hence, we assume, less effective – than programs designed to address longer-term average conditions."). In contrast, in the recently completed review of the SO_2 primary NAAQS, a 99th percentile form was adopted. However, in the case of SO_2, the standard was intended to limit 5-minute exposures and a 99th percentile form was markedly more effective at doing so than a 98th percentile form. 75 FR at 35540, 41.

the same part of the annual distribution of 24-hour PM_{10} concentrations, regardless of the frequency of PM_{10} monitoring.

In light of all of the above considerations, we conclude that, to the extent it is judged appropriate to revise the current 24-hour PM_{10} standard, it would be appropriate to consider revising the form to the 3-year average of the 98th percentile of the annual distribution of 24-hour PM_{10} concentrations.[14] CASAC agreed, noting that they "felt strongly that it is appropriate to change the statistical form of the PM_{10} standard to a 98th percentile form" (Samet, 2010d). In reaching this conclusion, CASAC noted that "[p]ublished work has shown that the percentile form has greater power to identify non-attainment and a smaller probability of misclassification relative to the expected exceedance form of the standard" (Samet, 2010d).

However, CASAC also noted that such a change in form "will lead to changes in levels of stringency across the country" and recommended that this issue be explored further. In considering this issue, we acknowledge that, given differences in PM_{10} air quality distributions across locations (US EPA, 2009a, Table 3-10), a revised standard with a 98th percentile form would likely target public health protection to some different locations than does the current standard with its one-expected-exceedance form. Given this, we note that a further consideration with regard to the appropriateness of revising the form of the current PM_{10} standard is the extent to which, when compared with the current standard, a revised standard with a 98th percentile form would be expected to target public health protection to areas where we have more confidence that ambient $PM_{10-2.5}$ is associated with adverse health effects.

In giving initial consideration to this issue, we have used recent PM_{10} air quality concentrations (i.e., from 2007-2009) to identify counties that would meet, and counties that would violate, the current PM_{10} standard as well as potential alternative standards with 98th percentile forms (Schmidt, 2011b).[15, 16] In some cases, counties that would violate the current standard do so because of a small number of "outlier" days (e.g., as few as one such day in three years) with PM_{10} concentrations well-above more typical concentrations (Schmidt, 2011b). Mean and 98th percentile PM_{10} and $PM_{10-2.5}$ concentrations were higher in counties that met the current standard, but would have violated a revised standard with a 98th percentile form,[17] than in

[14]As noted above, local sources can have important impacts on monitored PM_{10} concentrations. In the recent review of the NO_2 primary NAAQS, where this was also an important consideration, a 98th percentile form was adopted, rather than a 99th percentile form, due to the potential for "instability in the higher percentile concentrations" near local sources (75 FR 6493). A similar conclusion in the current review has led us to focus on the 98th percentile rather than the 99th percentile.

[15]Section 3.3.4 discusses potential alternative standard levels that would be appropriate to consider in conjunction with a revised standard with a 98th percentile form.

[16]The memo by Schmidt (2011b) identifies specific counties that are expected to meet, and counties that are expected to violate, the current standard as well as potential alternative standards with 98th percentile forms.

[17]This analysis considered a revised PM_{10} standard with a 98th percentile form and a level from the middle of the range discussed in section 3.3.4 (i.e., 75 $\mu g/m^3$).

counties that violated the current standard, but would have met a revised standard with a 98th percentile form (Schmidt, 2011b). This suggests that, to the extent a revised PM_{10} standard with a 98th percentile form could target public health protection to different areas than the current standard, those areas preferentially targeted by a revised standard generally have higher ambient concentrations of thoracic coarse particles. The issue of targeting public health protection is considered further in section 3.3.4, within the context of considering specific potential alternative standard levels for a 24-hour PM_{10} standard with a 98th percentile form.

3.3.4 Level

As noted above, to the extent it is judged in the current review that the 24-hour PM_{10} standard does not provide adequate public health protection against exposures to thoracic coarse particles, potential alternative standard levels could be considered. Given the conclusions described above for indicator, averaging time, and form, we conclude that it would be appropriate to consider potential alternative levels for a 24-hour PM_{10} standard with a 98th percentile form. To inform our consideration of this issue, we have considered the following question:

- **To what extent does available evidence and air quality information support consideration of alternative standard levels for a 24-hour PM_{10} standard with a 98th percentile form?**

Evidence-based Considerations

In considering the evidence as it relates to potential alternative standard levels, we first consider the relative weight to place on specific epidemiological studies, including the weight to place on the uncertainties associated with those studies. We have considered several factors in placing weight on specific epidemiological studies including the extent to which studies report statistically significant associations with $PM_{10-2.5}$ and the extent to which the reported associations are robust to co-pollutant confounding.

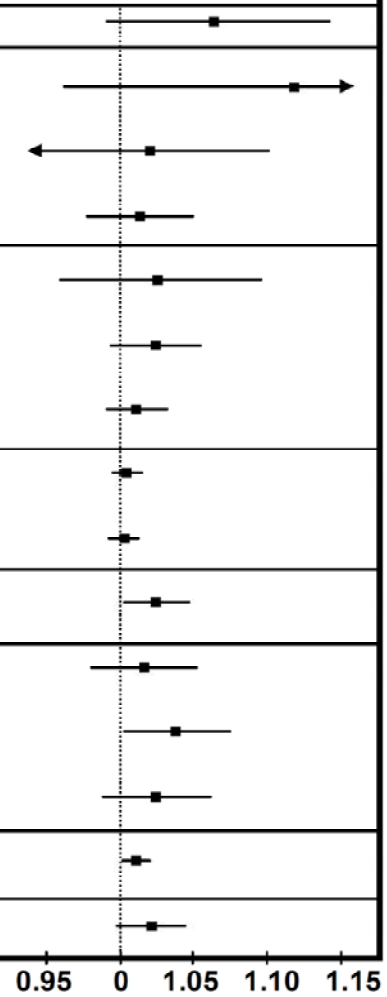
In addition, we consider the extent to which associations with $PM_{10-2.5}$ can be linked to the air quality in a specific location. With regard to this, we place greatest weight on information from single-city analyses. Although, as discussed above, multi-city studies have advantages in terms of power to detect associations and geographic coverage, the extent to which effects reported in multi-city studies are associated with the short-term air quality in any particular location is highly uncertain, especially when considering short-term concentrations at the upper end of the distribution of daily concentrations for pollutants with relatively heterogeneous spatial distributions such as PM_{10} (US EPA, 2009a, section 2.1.1.2). In contrast, single-city studies are more limited in terms of power and geographic coverage but the link between reported health effects and the air quality in a given city is more straightforward to establish (US EPA, 2009a,

section 2.1.1.2). Given this, in considering PM_{10} concentrations in locations of epidemiological studies, we place the most weight on single-city studies (Figures 3-2 and 3-3) and single-city analyses of the locations evaluated in the multi-city study by Zanobetti and Schwartz (US EPA, 2009a, Figure 6-29).

In considering PM air quality in study locations, we also note that the available evidence does not support the existence of thresholds, or lowest-observed-effects levels, in terms of 24-hour average concentrations (US EPA, 2009a, section 2.4.3). In the absence of an apparent threshold, for purposes of identifying a range of standard levels potentially supported by the health evidence, we focus on the range of PM_{10} concentrations that have been measured in locations where U.S. epidemiological studies have reported associations with $PM_{10-2.5}$ (see U.S. EPA, 2009a, Figures 6-1 to 6-30 for studies). In characterizing PM_{10} air quality in $PM_{10-2.5}$ study locations, we have used EPA's AQS to identify the highest 98^{th} percentile 24-hour PM_{10} concentrations for each year in each study location (i.e., from the monitor in the study area recording the highest 98^{th} percentile concentration), as described in Schmidt and Jenkins (2010) and Jenkins (2011). The 98^{th} percentile concentrations from each study year were averaged together and these averages are presented below in Figure 3-5 ($PM_{10-2.5}$ mortality studies) and Figure 3-6 ($PM_{10-2.5}$ morbidity studies) for locations of single-city studies.

Figure 3-5. 98th Percentile PM_{10} Concentrations in Locations of U.S. Single-City $PM_{10-2.5}$ Mortality Studies*

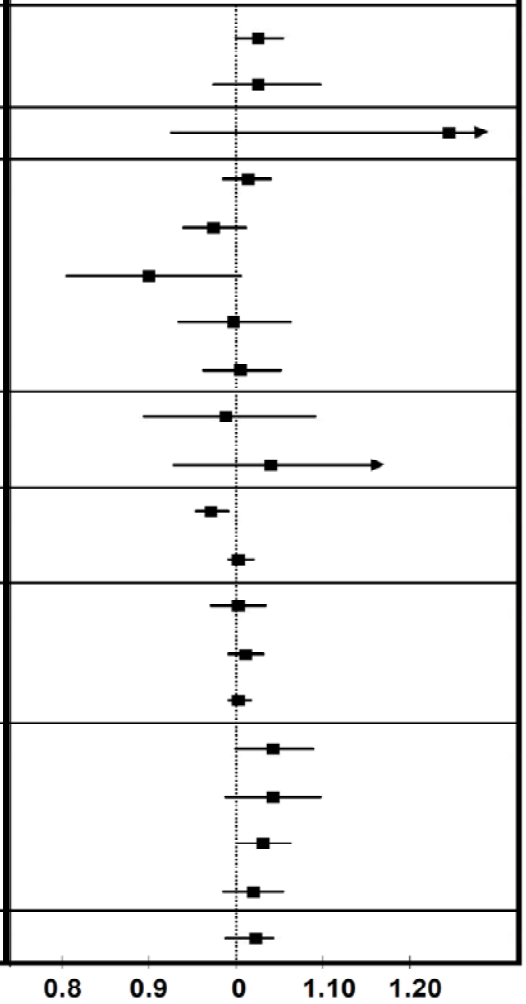
Study	Location	Mortality Endpoint	Time Period	Age	98th PM_{10} (μg/m3)	Effect Estimate (95% CI)
Klemm, 2004	Atlanta	All Cause	1998-2000	65+	74	
Fairley, 2003	Santa Clara	Respiratory	1989-1996	All	94	
		Cardiovascular				
		All Cause				
Ito, 2003	Detroit	Respiratory	1992-1994	65+	102	
		Cardiovascular				
		All Cause				
Chock, 2000	Pittsburgh	All Cause	1989-1991	75+	136	
				<75		
Mar, 2003	Phoenix	Cardiovascular	1995-1997	All	163	
Wilson, 2007	Phoenix (outer)	Cardiovascular	1995-1997	25+	163	
	(central)					
	(inner)					
Ostro, 2003	Coachella Valley	Cardiovascular	1989-1998	All	200	
Lipfert, 2000	Philadelphia	Cardiovascular	1992-1995	All	244	



*These studies are a combination of those assessed in the last review and those assessed in the ISA in the current review. Studies are ordered by increasing 98th percentile PM_{10} concentrations. See 2005 Staff Paper (US EPA, 2005, pp. 5-65 to 5-66) describing the levels from the two separate study monitors used in Ostro et al. (2003).

Figure 3-6. 98th Percentile PM_{10} Concentrations in Locations of U.S. Single-City $PM_{10-2.5}$ Morbidity Studies*

Study	Location	Morbidity Endpoint	Time Period	Age	98th PM_{10} (μg/m³)
NYS DOH, 2006	Bronx	Asthma HA	1999-2000	All	49
	Manhattan				52
Peters, 2001	Boston	MI HA	1995-1996	Mean 62	59
Peel, 2005	Atlanta	URI ED visits	1993-2000	All	67
		Pneumonia ED visits		All	
		COPD ED visits		65+	
		Asthma ED visits		All	
		RD ED visits		All	
Metzger, 2004	Atlanta	IHD ED visits	1993-2000	All	67
		CHF ED visits			
Tolbert, 2007	Atlanta	RD ED visits	1993-2004	All	71
		CVD ED visits			
Slaughter, 2005	Spokane	COPD	1995-2001	65+	81
		Asthma		All	
		RD		All	
Ito, 2003	Detroit	RI HA	1992-1994	65+	102
		COPD HA			
		IHD HA			
		CHF HA			
Sheppard, 2003	Seattle	Asthma HA	1987-1994	All	105



*These studies are a combination of those assessed in the last review and those assessed in the ISA in the current review. Studies are ordered by increasing 98th percentile PM_{10} concentrations. See 2005 Staff Paper (US EPA, 2005, pp. 5-63 to 5-66) describing measurement uncertainties associated with the reported PM_{10} levels in Ito (2003).

In addition to the single-city study locations in Figures 3-5 and 3-6, 98th percentile PM_{10} concentrations averaged across the study locations evaluated in the multi-city studies by Zanobetti and Schwartz (2009) and Peng et al. (2008) were 77 $\mu g/m^3$ (Jenkins, 2011) and 68 $\mu g/m^3$ (Schmidt and Jenkins, 2010), respectively. Multi-city effect estimates remained positive, and in some cases (i.e., Zanobetti and Schwartz for all-cause and respiratory mortality) statistically significant, in co-pollutant models that included fine particles.

Bayes-adjusted single-city effect estimates for the 47 cities evaluated by Zanobetti and Schwartz (US EPA, 2009a, Figure 6-29), which were generally positive but statistically significant in only six cities, can provide some additional insight into the PM_{10} concentrations in specific locations where associations between $PM_{10-2.5}$ and mortality have been reported. The 98th percentile PM_{10} concentrations in these 47 cities ranged from 39 $\mu g/m^3$ (Davie, FL) to 187 $\mu g/m^3$ (Phoenix, AZ), and in the 6 cities where positive and statistically significant $PM_{10-2.5}$ mortality effect estimates were reported, 98th percentile PM_{10} concentrations were as follows (Schmidt and Jenkins, 2010):

- Chicago: 91 $\mu g/m^3$
- Salt Lake City: 98 $\mu g/m^3$
- Detroit: 105 $\mu g/m^3$
- Pittsburgh: 112 $\mu g/m^3$
- Birmingham: 122 $\mu g/m^3$
- St. Louis: 138 $\mu g/m^3$

Thus, in the single-city mortality studies in Figure 3-5 above, as well as the Bayes-adjusted single-city analyses of the locations evaluated by Zanobetti and Schwartz, positive and statistically significant $PM_{10-2.5}$ effect estimates were reported in some locations with 98th percentile PM_{10} concentrations ranging from 200 $\mu g/m^3$ to 91 $\mu g/m^3$ (i.e., locations evaluated by Mar et al., 2003; Ostro et al., 2003; Wilson et al., 2007; and the cities listed above, US EPA 2009a, Figure 6-29). Among the U.S. morbidity studies, Ito (2003) reported a positive and statistically significant $PM_{10-2.5}$ effect estimate for hospital admissions for ischemic heart disease in Detroit, where the 98th percentile PM_{10} concentration (102 $\mu g/m^3$) was also within this range. $PM_{10-2.5}$ effect estimates in this study remained positive, and in some cases statistically significant, in co-pollutant models with gaseous pollutants (US EPA, 2009a, Figures 6-5 and 6-15). Other morbidity studies generally did not report statistically significant $PM_{10-2.5}$ effect estimates.

Air Quality-based Considerations

In addition to the evidence-based considerations described above, we have estimated the level of a 24-hour PM_{10} standard with a 98th percentile form that would approximate the degree of protection, on average across the country, provided by the current 24-hour PM_{10} standard with its one-expected-exceedance form. Our initial approach to estimating this "generally equivalent" 98th percentile PM_{10} concentration was to use EPA's AQS as the basis for regressing 98th percentile PM_{10} concentrations onto one-expected-exceedance concentration equivalent design values (Schmidt and Jenkins, 2010). Based on this approach, and using monitoring data from 1988 to 2008, a 98th percentile PM_{10} concentration of 87 $\mu g/m^3$ is, on average, generally equivalent to the current standard level (Figure 3-7 below and Schmidt and Jenkins, 2010). However, as indicated in Figure 3-7, the range of equivalent concentrations varies considerably across monitoring sites and over the time period evaluated (95% confidence interval ranges from 63 to 111 $\mu g/m^3$) (Schmidt and Jenkins, 2010). As a consequence, we note that in some locations a 98th percentile standard with a level of 87 $\mu g/m^3$ would likely be more protective than the current standard while in other locations it would likely be less protective than the current standard.

Regional differences in the relationship between 98th percentile PM_{10} concentrations and one-expected-exceedance concentration equivalent design values are illustrated in Figure 3-8, based on air quality data from 1988 to 2008. The 98th percentile PM_{10} concentrations that are, on average, generally equivalent to the current standard level ranged from just below 87 $\mu g/m^3$ in the southeast, southwest, upper Midwest, and outlying areas (i.e., generally equivalent 98th percentile PM_{10} concentrations ranged from 82 to 85 $\mu g/m^3$ in these regions) to just above 87 $\mu g/m^3$ in the northeast, industrial Midwest, and southern California (i.e., generally equivalent 98th percentile PM_{10} concentrations ranged from 88 to 93 $\mu g/m^3$ in these regions) (Schmidt, 2011b). However, even within these regions there is considerable variability in the "generally equivalent" 98th percentile PM_{10} concentration across monitoring sites (Figure 3-8).

Figure 3-7. Composite 3-year PM_{10} 98th Percentile 24-Hour Average concentration versus the PM_{10} Expected Exceedance Concentration-equivalent Design Value (1988-2008)

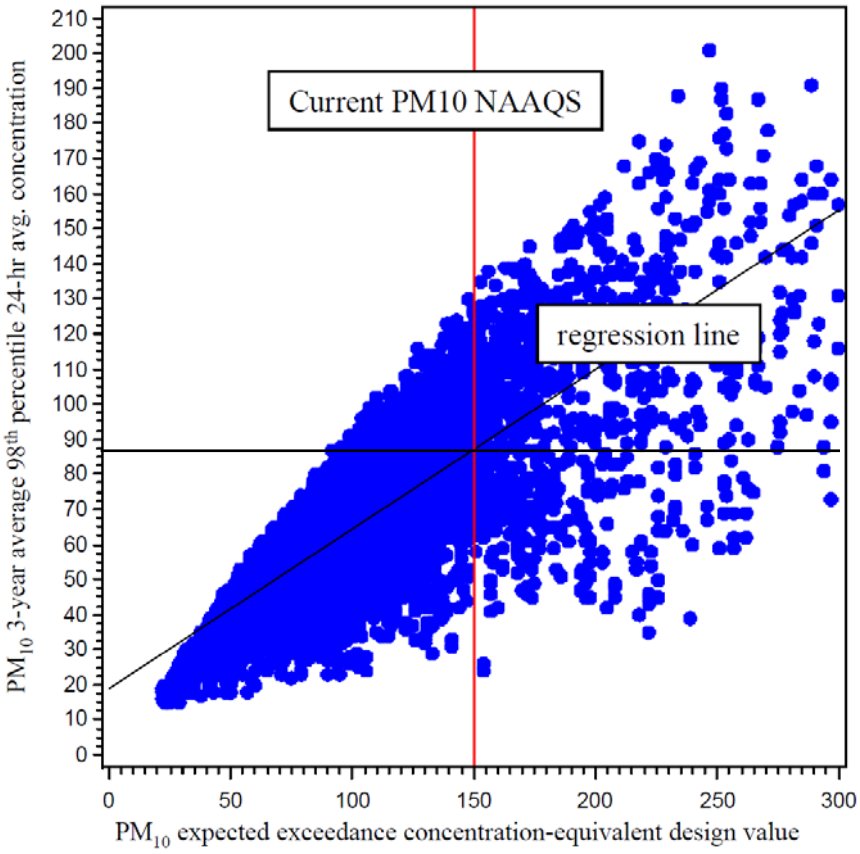
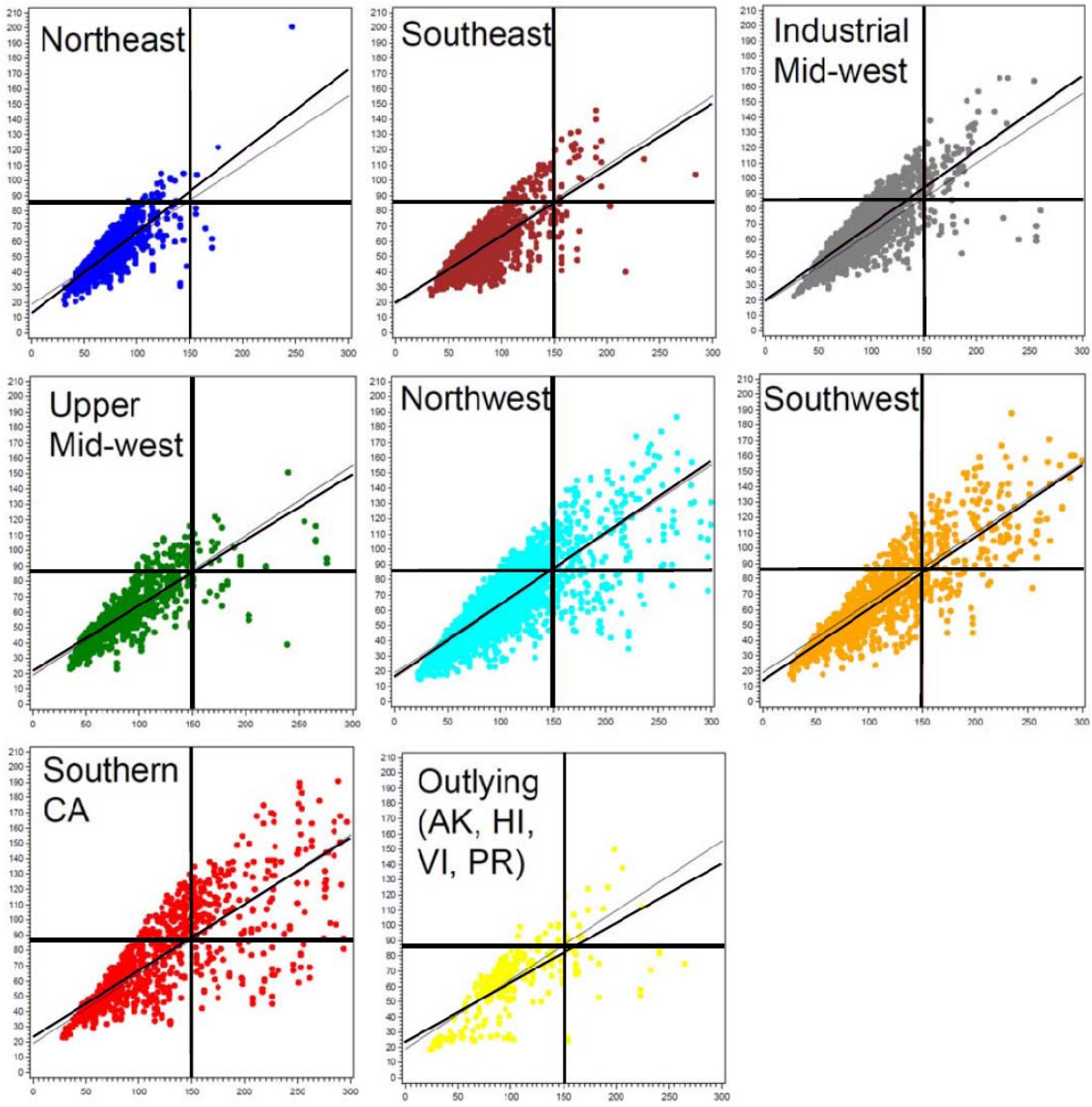


Figure 3-8. Regional 3-year PM_{10} 98th Percentile 24-Hour Average Concentrations Versus the PM_{10} Expected Exceedance Concentration-equivalent Design Values (1988-2008)*



*Bold regression lines reflect region-specific relationships between 24-hour average 98th percentile PM_{10} concentrations and PM_{10} expected exceedance concentration-equivalent design values. Non-bolded regression lines reflect the overall relationship across all regions, as illustrated above in Figure 3-7. In some areas (i.e., southeast, upper Midwest, northwest, southwest, and southern California), the two regression lines are almost indistinguishable. Vertical lines mark the level of the current standard and horizontal lines mark a 98th percentile concentration of 87 $\mu g/m^3$.

Given the spatial and temporal variability in the relationship between one-expected-exceedance concentration-equivalent design values and 98th percentile PM_{10} concentrations, no single 98th percentile PM_{10} standard level would provide public health protection equivalent to that provided by the current standard, consistently over time and across locations.[18] Therefore, to provide a broader perspective on the relationship between the current standard and potential 98th percentile standards, we have also compared the size of the populations living in counties with PM_{10} one-expected-exceedance concentration-equivalent design values greater than the current standard level to the size of the populations living in counties with 98th percentile PM_{10} concentrations above different potential alternative standard levels (based on air quality data from 2007 to 2009). Such comparisons can be considered as surrogates for comparisons of the breadth of public health protection provided by the current and potential alternative standards, as discussed below. The results are presented in Table 3-2 below.[19]

Based on comparisons of total population counts across all regions of the U.S. for the years 2007 to 2009, a 98th percentile PM_{10} standard with a level between 75 and 80 $\mu g/m^3$ would be most closely equivalent to the current standard. However, as with the regression analysis described above, there is considerable variability across locations in the "generally equivalent" 98th percentile PM_{10} concentration (see Table 3-2).

[18]The "generally equivalent" concentration also differs depending on the years of monitoring data used. For example, when this analysis was restricted to only the most recent years available (i.e., 2007 to 2009), the "generally equivalent" 98th percentile PM_{10} concentration was 78 $\mu g/m^3$. Given the temporal variability in the relationship between the current standard level and 98th percentile PM_{10} concentrations, and the potential for the "generally equivalent" 98th percentile concentration to vary year-to-year, staff concluded that it remains appropriate to consider the regression analyses that use the broader range of available monitoring years (i.e., 1998-2008), as these analyses are likely to be more robust than analyses based on a shorter period of time.

[19]Table 3-2 presents counts of counties that would not meet the current and potential alternative standards (see also Appendix D). These county counts reflect the net number of counties in each region. However, some counties that meet the current standard would violate one or more of the alternative standards while some counties that violate the current standard would meet one or more of the alternatives. Therefore, the net county counts presented in Table 3-2 do not reflect the total number of counties that could potentially change attainment status if the PM_{10} standard were to be revised. The specific counties that would violate the current standard and/or potential alternative standards with 98th percentile forms are listed in the memo by Schmidt (2011b).

Table 3-2. Predicted Counts of Counties, and Population (x 1,000) within those Counties, Not Likely to Meet the Current PM_{10} Standard and Potential Alternative PM_{10} Standards with 98th Percentile Forms (based on air quality in 2007-2009)[20]

Region >		All U.S.	Northeast	Southeast	Industrial Midwest	Upper Midwest	Southwest	Northwest	Southern California	Outlying Areas
Total # of counties >		307	37	57	50	40	25	77	18	3
Total population >		120,090	15,397	27,181	21,352	5,917	11,112	15,270	22,695	1,167
Current Standard	# counties	41	0	3	0	1	11	13	12	1
	Population (thousands)	32,835	0	4,626	0	14	5,485	1,878	20,571	260
3-year average 98th percentile > 87 µg/m^3	# counties	37	0	2	2	2	11	10	9	1
	population	20,515	0	4,063	507	552	5,924	1,789	7,421	260
3-year average 98th percentile > 85 µg/m^3	# counties	39	0	2	3	2	12	10	9	1
	population	21,887	0	4,063	1,789	552	6,014	1,789	7,421	260
3-year average 98th percentile > 80 µg/m^3	# counties	45	0	2	4	3	13	11	11	1
	population	24,535	0	4,063	3,183	599	6,131	1,833	8,467	260
3-year average 98th percentile > 75 µg/m^3	# counties	55	0	3	6	5	13	15	12	1
	population	35,703	0	4,626	3,491	637	6,131	2,570	17,986	260
3-year average 98th percentile > 70 µg/m^3	# counties	71	0	4	7	7	13	27	12	1
	population	43,823	0	4,644	8,868	881	6,131	5,052	17,986	260
3-year average 98th percentile > 65 µg/m^3	# counties	87	2	4	9	10	14	33	13	2
	population	49,394	775	4,644	10,421	1,029	7,507	5,989	18,739	290

[20]The information in Table 3-2 (and presented in more detail in Schmidt, 2011b and Appendix D) is based on monitoring data from the years 2007 to 2009. This is an update to the information presented in the memo from Schmidt and Jenkins (2010), and presented in draft versions of this Policy Assessment, which was based on the years 2006 to 2008.

One consequence of this variability, as noted above in the discussion of the form of the standard, would be that a 24-hour PM_{10} standard with a 98th percentile form and a revised level would likely target public health protection to some different locations than does the current standard. Therefore, in further considering the appropriateness of revising the form and level of the current PM_{10} standard, we have considered the following question:

- **To what extent, when compared with the current standard, would a revised PM_{10} standard be expected to target public health protection to areas where we have more confidence that $PM_{10-2.5}$ is associated with adverse health effects?**

To address this question, we considered the potential impact of revising the form and level of the PM_{10} standard in locations where health studies have reported associations with $PM_{10-2.5}$. We initially considered U.S. study locations that would likely have met the current PM_{10} standard during the study period and where positive and statistically significant associations with $PM_{10-2.5}$ were reported (PM_{10} air quality concentrations in study locations are presented above and in Schmidt and Jenkins, 2010; Jenkins, 2011). Only Birmingham, Chicago, Pittsburgh, and Detroit[21] met these criteria. As shown in Table 3-3, these areas where positive and statistically significant associations with $PM_{10-2.5}$ were reported would likely have met the current PM_{10} standard during the study periods. However, none of these areas would likely have met a 98th percentile 24-hour PM_{10} standard with a level at or below 87 $\mu g/m^3$.

Table 3-3. PM_{10} Concentrations in Locations that Met Current PM_{10} Standard and where Positive and Statistically Significant Associations with $PM_{10-2.5}$ have been Reported

Study Location	PM_{10} Concentration-Equivalent Design Value	PM_{10} 98th Percentile
Birmingham[22]	154 $\mu g/m^3$	122 $\mu g/m^3$
Chicago	113 $\mu g/m^3$	91 $\mu g/m^3$
Pittsburgh	139 $\mu g/m^3$	112 $\mu g/m^3$
Detroit	123 $\mu g/m^3$	102 $\mu g/m^3$

We next broadened our consideration of study locations to include U.S. locations where health studies have reported positive, though not necessarily statistically significant, associations between $PM_{10-2.5}$ and mortality or morbidity. Such positive associations were reported in 47

[21]Positive and statistically significant $PM_{10-2.5}$ effect estimates for Birmingham, Chicago, and Pittsburgh are reported in the ISA (U.S. EPA, 2009a, figure 6-29; from cities evaluated by Zanobetti and Schwartz, 2009). Effect estimates for Detroit are reported by Ito et al. (2003)

[22]According to rounding convention for the PM_{10} standard, a 24-hour PM_{10} concentration of 154 $\mu g/m^3$ would round to 150 $\mu g/m^3$ (71 FR 61144). Therefore, based on the PM_{10} one-expected-exceedance concentration-equivalent design value, Birmingham would have been expected to just meet the current PM_{10} standard during the study period.

locations that would likely have met the current PM_{10} standard during the study period.[23] Of these 47 locations, 13 would likely not have met a 98th percentile 24-hour PM_{10} standard with a level at 87 $\mu g/m^3$, 20 would likely not have met a 98th percentile 24-hour PM_{10} standard with a level of 75 $\mu g/m^3$, and 31 would likely not have met a 98th percentile 24-hour PM_{10} standard with a level of 65 $\mu g/m^3$ (Schmidt and Jenkins, 2010; Jenkins, 2011; Figures 3-2, 3-3, 3-5, 3-6 above).

In addition to the above analyses, we have also considered locations where health studies reported positive associations with $PM_{10-2.5}$ and where ambient PM_{10} concentrations were likely to have exceeded those allowed under the current PM_{10} standard during the study period. Nine locations met these criteria.[24] Of these locations, all would also likely have exceeded a 98th percentile PM_{10} standard with a level at or below 87 $\mu g/m^3$ (Schmidt and Jenkins, 2010; Jenkins, 2011; Figures 3-2, 3-3, 3-5, 3-6 above).

Therefore, among U.S. study locations where $PM_{10-2.5}$-associated health effects have been reported, some areas that met the current standard would likely not have met a 98th percentile PM_{10} standard with a level at or below 87 $\mu g/m^3$. In contrast, of the locations that did not meet the current standard during the study period, none would likely have met a 98th percentile PM_{10} standard with a level at or below 87 $\mu g/m^3$. Given this, we conclude that, compared to the current PM_{10} standard, a 24-hour PM_{10} standard with a 98th percentile form could potentially better target public health protection to locations where we have more confidence that ambient $PM_{10-2.5}$ concentrations are associated with mortality and/or morbidity.

Integration of evidence- and air quality-based considerations

In considering the evidence and air quality information within the context of identifying potential alternative standard levels for consideration, we first note the following:

- Linear regression analysis suggests that a 98th percentile 24-hour PM_{10} concentration as high as 87 $\mu g/m^3$ could be considered "generally equivalent" to the current PM_{10} standard, over time and across the country.

- A 98th percentile 24-hour PM_{10} standard with a level at or below 87 $\mu g/m^3$ would be expected to maintain PM_{10} and $PM_{10-2.5}$ concentrations below those present in U.S. locations where single-city studies have reported $PM_{10-2.5}$ effect estimates that are positive and statistically significant (lowest concentration in such a location was 91 $\mu g/m^3$). While some single-city studies have reported positive $PM_{10-2.5}$ effect estimates in locations with 98th percentile PM_{10} concentrations below 87 $\mu g/m^3$, these effect estimates were not statistically significant.

[23]Philadelphia (Lipfert et al., 2000), Detroit (Ito et al., 2003), Santa Clara (CA) (Fairley et al., 2003), Seattle (Sheppard et al., 2003), Atlanta (Klemm et al., 2004), Spokane (Slaughter et al., 2005), Bronx and Manhattan (NYS DOH, 2006), and 39 of the cities evaluated by Zanobetti and Schwartz (2009) (US EPA, 2009a, Figure 6-29)
[24]Pittsburgh (Chock et al., 2000), Coachella Valley (CA) (Ostro et al., 2003), Phoenix (Mar et al., 2007; Wilson et al., 2007), and 6 of the cities evaluated by Zanobetti and Schwartz (2009) (US EPA, 2009a, Figure 6-29).

- Multi-city average 98th percentile PM_{10} concentrations were below 87 $\mu g/m^3$ for U.S. multi-city studies, which have reported positive and statistically significant $PM_{10-2.5}$ effect estimates. However, the extent to which effects reported in multi-city studies are associated with the short-term air quality in any particular location is highly uncertain, especially when considering short-term concentrations at the upper end of the distribution of daily PM_{10} concentrations.

- Epidemiological studies have reported positive, and in a few instances statistically significant, associations with $PM_{10-2.5}$ in some locations likely to have met the current PM_{10} standard but not a PM_{10} standard with a 98th percentile form and a level at or below 87 $\mu g/m^3$.

To the extent the above considerations are emphasized, we note that a standard level as high as about 85 $\mu g/m^3$, for a 24-hour PM_{10} standard with a 98th percentile form, could be supported. Such a standard level would be expected to maintain PM_{10} and $PM_{10-2.5}$ concentrations below those present in U.S. locations of single-city studies where $PM_{10-2.5}$ effect estimates have been reported to be positive and statistically significant and below those present in some U.S. locations where single-city studies reported $PM_{10-2.5}$ effect estimates that were positive, but not statistically significant. These include some locations likely to have met the current PM_{10} standard during the study periods. Given this, when compared to the current standard, a 24-hour PM_{10} standard with a 98th percentile form and a level at or below 85 $\mu g/m^3$ could have the effect of focusing public health protection on locations where we have more confidence that $PM_{10-2.5}$ is associated with mortality and/or morbidity.

Given the above, we conclude that a 98th percentile standard with a level as high as 85 $\mu g/m^3$ could be considered to the extent that more weight is placed on the appropriateness of focusing public health protection in areas where positive and statistically significant associations with $PM_{10-2.5}$ have been reported, and to the extent less weight is placed on $PM_{10-2.5}$ effect estimates that are not statistically significant and/or that reflect estimates across multiple cities. It could be judged appropriate to place less weight on $PM_{10-2.5}$ effect estimates that are not statistically significant given the relatively large amount of uncertainty that is associated with the broader body of $PM_{10-2.5}$ health evidence, including uncertainty in the extent to which health effects evaluated in epidemiological studies result from exposures to $PM_{10-2.5}$ itself, rather than one or more co-occurring pollutants. This uncertainty, as well as other uncertainties discussed in section 3.2.1 above, are reflected in the ISA conclusions that the evidence is "suggestive" of a causal relationship (i.e., rather than "causal" or "likely causal") between short-term $PM_{10-2.5}$ and mortality, respiratory effects, and cardiovascular effects. In addition, it could be judged appropriate to place less weight on 98th percentile PM_{10} concentrations averaged across multiple

cities, given the uncertainty in linking multi-city effect estimates with the air quality in any particular location.

However, we also note that, overall across the U.S. based on recent air quality information (i.e., 2007-2009), fewer people live in counties with 98th percentile 24-hour PM_{10} concentrations above 85 $\mu g/m^3$ than in counties likely to exceed the current PM_{10} standard. These results could be interpreted to suggest that a 98th percentile standard with a level of 85 $\mu g/m^3$ might decrease overall public health protection compared to the current standard. Based on this analysis, a 98th percentile 24-hour PM_{10} standard with a level between 75 and 80 $\mu g/m^3$ would provide a level of public health protection that is generally equivalent, on average across the U.S., to that provided by the current standard. To the extent these population counts are emphasized in comparing the public health protection provided by the current and potential alternative standards, and to the extent it is judged appropriate to set a standard that provides at least the level of public health protection that is provided by the current standard, it would be appropriate to consider standard levels in the range of approximately 75 to 80 $\mu g/m^3$.

Alternative approaches to considering the evidence could also lead to consideration of standard levels below 75 $\mu g/m^3$. For example, a number of single-city epidemiological studies have reported positive, though not statistically significant, $PM_{10-2.5}$ effect estimates in locations with 98th percentile PM_{10} concentrations below 75 $\mu g/m^3$. Given that exposure error is particularly important for $PM_{10-2.5}$ epidemiological studies and can bias the results of these studies toward the null hypothesis, it could be judged appropriate to place more weight on positive associations reported in these epidemiological studies, even when those associations are not statistically significant. In addition, the multi-city averages of 98th percentile PM_{10} concentrations in the locations evaluated by Zanobetti and Schwartz (2009) and Peng et al. (2008) were 77 and 68 $\mu g/m^3$, respectively. Both of these multi-city studies reported positive and statistically significant $PM_{10-2.5}$ effect estimates that remained positive in co-pollutant models that included $PM_{2.5}$, though only Zanobetti and Schwartz (2009) reported $PM_{10-2.5}$ effect estimates that remained statistically significant in such co-pollutant models. Despite uncertainties in the extent to which effects reported in these multi-city studies are associated with the short-term air quality in any particular location, emphasis could be placed on these multi-city associations. We conclude that, to the extent more weight is placed on single-city studies reporting positive, but not statistically significant, $PM_{10-2.5}$ effect estimates and on multi-city studies, it could be appropriate to consider standard levels as low as 65 $\mu g/m^3$. A standard level of 65 $\mu g/m^3$ would be expected to provide a substantial margin of safety against health effects that have been associated with $PM_{10-2.5}$ and, as discussed above, could better focus (compared to

the current standard) public health protection on areas where health studies have reported associations with $PM_{10-2.5}$.

In considering potential alternative standard levels below 65 $\mu g/m^3$, we note that, as discussed above, the overall body of $PM_{10-2.5}$ health evidence is relatively uncertain, with somewhat stronger support in U.S. studies for associations with $PM_{10-2.5}$ in locations with 98th percentile PM_{10} concentrations above 85 $\mu g/m^3$ than in locations with 98th percentile PM_{10} concentrations below 65 $\mu g/m^3$. Specifically, we note the following:

- Epidemiological studies, either single-city or multi-city, have not reported positive and statistically significant $PM_{10-2.5}$ effect estimates in locations with 98th percentile PM_{10} concentrations (multi-city average 98th percentile concentrations in the case of multi-city studies) at or below 65 $\mu g/m^3$.

- Although some single-city morbidity studies have reported positive, but not statistically significant, associations with $PM_{10-2.5}$ in locations with 98th percentile PM_{10} concentrations below 65 $\mu g/m^3$, the results of U.S. morbidity studies were generally less consistent than those of mortality studies, with some $PM_{10-2.5}$ effect estimates being positive while others were negative (i.e., negative effect estimates were reported in several studies conducted in Atlanta, where the 98th percentile PM_{10} concentrations ranged from 67 $\mu g/m^3$ to 71 $\mu g/m^3$).

- Although Bayes-adjusted single-city $PM_{10-2.5}$ effect estimates were positive, but not statistically significant, in some locations with PM_{10} concentrations below 65 $\mu g/m^3$, these effect estimates were based on the difference between community-wide PM_{10} and $PM_{2.5}$ concentrations. As discussed above, it is not clear how these estimates of $PM_{10-2.5}$ concentrations compare to those more typically used in other studies to calculate $PM_{10-2.5}$ effect estimates. At present, few corroborating studies are available that use other approaches (i.e., co-located monitors, dichotomous samplers) to estimate/measure $PM_{10-2.5}$ in locations with 98th percentile PM_{10} concentrations below 65 $\mu g/m^3$.

In light of these limitations in the evidence for a relationship between $PM_{10-2.5}$ and adverse health effects in locations with relatively low PM_{10} concentrations, along with the overall uncertainties in the body of $PM_{10-2.5}$ health evidence as described above and in the ISA, we conclude that while it could be judged appropriate to consider standard levels as low as 65 $\mu g/m^3$, it is not appropriate, based on the currently available body of evidence, to consider standard levels below 65 $\mu g/m^3$.

In its review of the draft Policy Assessment, CASAC concluded that "alternative standard levels of 85 and 65 $\mu g/m^3$ (based on consideration of 98th percentile PM_{10} concentration) could be justified" (Samet, 2010d). However, in considering the evidence and uncertainties, CASAC recommended a standard level from the lower part of the range, recommending a level "somewhere in the range of 75 – 65 $\mu g/m^3$" (Samet, 2010d). In making this recommendation,

CASAC noted that the number of people living in counties with air quality not meeting the current standard is approximately equal to the number living in counties that would not meet a 98th percentile standard with a level between 75 and 80 μg/m^3. CASAC used this information as the basis for their conclusion that a 98th percentile standard between 75 and 80 μg/m^3 would be "comparable to the current standard" (Samet, 2010d).

3.4 SUMMARY OF STAFF CONCLUSIONS ON PRIMARY THORACIC COARSE PARTICLE STANDARD

In reaching conclusions on the adequacy of the current PM_{10} standard and potential alternative standards to provide requisite protection for health effects associated with short-term exposures to thoracic coarse particles, staff has considered the basic elements of the NAAQS: indicator, averaging time, form, and level (section 3.3.1 to 3.3.4 above). In considering available scientific evidence and air quality information, we reflect upon the evidence and information available in the last review integrated with evidence and information that has become available since that review as assessed and presented in the ISA (US EPA, 2009a) and summarized above in sections 3.2 and 3.3.

We recognize that selecting from among potential alternative standards will necessarily reflect consideration of the evidence as well as the uncertainties inherent in that evidence. In considering the current PM_{10} standard and identifying potential alternative primary standards 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.

Based on the currently available scientific evidence, staff reaches the following conclusions regarding the primary PM_{10} standard:

(1) It would be appropriate to consider either retaining or revising the current 24-hour PM_{10} primary standard, depending on the relative weight placed on the evidence supporting associations with $PM_{10-2.5}$, the uncertainties associated with this evidence, and the ISA conclusions that the evidence is only "suggestive" of a causal relationship (i.e., rather than "causal" or "likely causal") between short-term $PM_{10-2.5}$ and mortality, respiratory effects, and cardiovascular effects.

(2) It is appropriate to retain PM_{10} as the indicator for thoracic coarse particles. This conclusion is based on our assessment of the evidence for effects related to particles of urban and non-urban origins. We also conclude that research should be targeted so as to inform consideration of different indicators in future reviews.

(3) It is appropriate to retain a 24-hour averaging time for a PM_{10} standard meant to protect against short-term exposures to thoracic coarse particles. This conclusion reflects the body

of epidemiological studies, which are most often based on 24-hour average $PM_{10-2.5}$ concentrations.

(4) To the extent consideration is given to revising the current standard:

(a) Consideration should be given to a 98th percentile form for a 24-hour PM_{10} standard. This conclusion is based on consideration of providing a balance between limiting peak concentrations and providing a stable regulatory target, compensating for differences in monitoring frequency across locations, focusing the standard on days when $PM_{10-2.5}$ is likely to make a relatively larger contribution to PM_{10} mass, and focusing public health protection to areas where we have greater confidence that mortality and morbidity are associated with ambient $PM_{10-2.5}$.

(b) In conjunction with considering a 98th percentile form, it is appropriate to consider PM_{10} standard levels in the range of 85 $\mu g/m^3$ down to about 65 $\mu g/m^3$. This range of levels is based on consideration of 98th percentile PM_{10} concentrations in U.S. study locations where $PM_{10-2.5}$ epidemiological studies have been conducted and of the relationship between the current one-expected-exceedance form and a potential alternative 98th percentile form. Staff concludes that standard levels in the upper part of this range are supported by the strongest evidence and would reflect greater emphasis on positive and statistically significant $PM_{10-2.5}$ effect estimates reported in single-city studies. Standard levels in the lower part of this range would reflect greater emphasis on $PM_{10-2.5}$ effect estimates that are positive, though not necessarily statistically significant, and on multi-city effect estimates.

3.5 KEY UNCERTAINTIES AND AREAS FOR FUTURE RESEARCH AND DATA COLLECTION

As discussed above (see section 3.2), a number of key uncertainties and limitations in the health evidence have been considered in this review. These include uncertainties and limitations in the air quality estimates used in $PM_{10-2.5}$ epidemiological studies; in the extent to which $PM_{10-2.5}$ air quality concentrations reflect exposures to $PM_{10-2.5}$; in the extent to which $PM_{10-2.5}$ itself is responsible for health effects reported in epidemiological studies; and in the extent to which the chemical and/or biological composition of $PM_{10-2.5}$ affects particle toxicity. In this section, we highlight areas for future health-related research, model development, and data collection activities to address these uncertainties and limitations in the current body of evidence. These efforts, if undertaken, could provide important evidence for informing future PM NAAQS reviews and, in particular, consideration of possible alternative indicators, averaging times, forms, and/or levels. In some cases, research in these areas can go beyond aiding standard setting to informing the development of more efficient and effective control strategies.

As an initial matter, we note that many of the research needs identified for fine particles (see above, section 2.5) are also relevant for thoracic coarse particles. This includes research in the following areas:

- Sources and components of coarse particles, including source apportionment modeling; monitoring of components; linking specific sources/components to health outcomes; linking sources/components to intra- and inter-city differences in health effects; linking sources/components to population exposures; and evaluating different size cut-points
- Understanding the extent to which an association between thoracic coarse particles and specific health effects can be modified by co-pollutants
- Understanding associations with a broad range of cardiovascular and respiratory endpoints as well as adverse effects in the nervous system, on reproduction, and/or on development
- Understanding C-R relationships and the confidence bounds around these relationships, especially at lower ambient thoracic coarse particle concentrations
- Understanding air quality distributions in locations of epidemiological studies
- Identifying populations susceptible to $PM_{10-2.5}$-related health effects
- Modeling to estimate $PM_{10-2.5}$ mass and composition in areas with less-than-daily monitoring

These uncertainties and areas for future research are discussed above in section 2.5 and that discussion will not be repeated here. In addition to the above, there are several areas for future research that are particularly relevant for thoracic coarse particles. These include the following:

- The body of experimental inhalation studies (e.g., controlled human exposure and animal toxicology studies) is currently relatively sparse. Additional well-conducted experimental studies could play an important role in weight of evidence judgments in future ISAs. Therefore, experimental evaluation of effects (e.g., vasomotor function, airways responsiveness, pulmonary function/inflammation) of concentrated ambient $PM_{10-2.5}$ from specific sources (e.g., traffic, industrial, non-industrial) would be useful, particularly if exposure-response relationships are evaluated.
- Exposure error is of particular concern for thoracic coarse particles, given the relative lack of monitoring and its less homogeneous atmospheric distribution compared to fine particles (US EPA, 2009a, section 2.1.1.2). Therefore, short-term studies with well-characterized personal exposures to $PM_{10-2.5}$ (e.g., panel studies) would be useful. Such studies could examine indicators of cardiovascular and respiratory morbidity (e.g., arrhythmia, ischemia, vasomotor function, respiratory symptoms, pulmonary inflammation, pulmonary function, pulmonary injury) and would be particularly useful if they evaluated concentration-response relationships and/or effects of repeated peak exposures.
- Epidemiological studies currently use a variety of approaches to measure/estimate $PM_{10-2.5}$ concentrations. It is important that we better understand the relationship between results from studies that estimate $PM_{10-2.5}$ concentrations using either (1) difference method of co-located monitors, (2) difference method of county-wide averages of PM_{10} and $PM_{2.5}$, or (3) direct measurement of $PM_{10-2.5}$ using a dichotomous sampler. In addition, as described

above, $PM_{10-2.5}$ monitoring will be required at NCORE sites by 2011. It could be useful for future epidemiological studies to make use of these new $PM_{10-2.5}$ monitoring sites.

- Very little information is available to inform weight of evidence conclusions for endpoints associated with long-term $PM_{10-2.5}$ exposures. Epidemiological and animal toxicological studies of long-term exposures (i.e., months to years) to $PM_{10-2.5}$ would be helpful, though limitations in the extent to which coarse particles penetrate rodent respiratory systems could add uncertainty to the interpretation of rodent inhalation studies. Long-term studies could evaluate links with cardiovascular and respiratory morbidity, reproductive and developmental outcomes, cancer, and mortality.

3.6 REFERENCES

Abt Associates (2005). Particulate Matter Health Risk Assessment for Selected Urban Areas. Final Report. Bethesda, MD. Prepared for the Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Contract No. 68-D-03-002. EPA 452/R-05-007A. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/data/PMrisk20051220.pdf

Bell ML; Ebisu K; Peng RD; Walker J; Samet JM; Zeger SL; Dominic F (2008). Seasonal and regional short-term effects of fine particles on hospital admissions in 202 U.S. counties, 1999-2005. Am J Epidemiol, 168: 1301-1310.

Bennett CM; McKendry IG; Kelly S; Denike K; Koch T (2006). Impact of the 1998 Gobi dust event on hospital admissions in the Lower Fraser Valley, British Columbia. Sci Total Environ, 366: 918-925.

Burnett RT; Smith-Doiron M; Stieb D; Cakmak S; Brook JR. (1999). Effects of particulate and gaseous air pollution on cardiorespiratory hospitalizations. Arch Environ Occup Health, 54: 130-139.

Burnett RT; Goldberg MS. (2003). Size-fractionated particulate mass and daily mortality in eight Canadian cities. Health Effects Institute. Boston, MA

Burnett RT; Stieb D; Brook JR; Cakmak S; Dales R; Raizenne M; Vincent R; Dann T (2004). Associations between short-term changes in nitrogen dioxide and mortality in Canadian cities. Arch Environ Occup Health, 59: 228-236.

Chan CC; Chuang KJ; Chen WJ; Chang WT; Lee CT; Peng CM (2008). Increasing cardiopulmonary emergency visits by long-range transported Asian dust storms in Taiwan. Environ Res, 106: 393-400.

Chen L; Yang W; Jennison BL; Omaye ST (2000). Air particulate pollution and hospital admissions for chronic obstructive pulmonary disease in Reno, Nevada. Inhal Toxicol, 12: 281-298.

Chen Y; Yang Q; Krewski D; Shi Y; Burnett RT; McGrail K. (2004). Influence of relatively low level of particulate air pollution on hospitalization for COPD in elderly people. Inhal Toxicol, 16: 21-25.

Chen Y; Yang Q; Krewski D; Burnett RT; Shi Y; McGrail KM (2005). The effect of coarse ambient particulate matter on first, second, and overall hospital admissions for respiratory disease among the elderly. Inhal Toxicol, 17: 649-655.

Chock DP; Winkler SL; Chen C. (2000). A study of the association between daily mortality and ambient air pollutant concentrations in Pittsburgh, Pennsylvania. J Air Waste Manag Assoc, 50: 1481-1500.

Choudhury, AH; Gordian ME; Morris SS. (1997). Associations between respiratory illness and PM_{10} air pollution. Arch. Environ. Health 52: 113-117.

Davidson, JE; Hopke PK. (1984). Implications of Incomplete Sampling on a Statistical Form of the Ambient Air Quality Standard for Particulate Matter. Environ. Sci. Technol., 18: 571-580.

Edgerton, ES; Casucclo GS; Saylor RD; Lersch TL; Hartsell BE; Jansen JJ; Hansen DA. (2009). Measurements of OC and EC in coarse particulate matter in the southeastern United States. J. Air Waste Manag. Assoc., 59: 78-90.

Fairley D (2003). Mortality and air pollution for Santa Clara County, California, 1989-1996, In: Revised analyses of time-series studies of air pollution and health. Special report. Health Effects Institute. Boston, MA.http://www.healtheffects.org/Pubs/TimeSeries.pdf .

Fung KY; Khan S; Krewski D; Chen Y. (2006). Association between air pollution and multiple respiratory hospitalizations among the elderly in Vancouver, Canada. Inhal Toxicol, 18: 1005-1011.

Gong H; Linn WS; Terrell SL; Clark KW; Geller MD; Anderson KR; Cascio WE; Sioutas C. (2004). Altered heart-rate variability in asthmatic and healthy volunteers exposed to concentrated ambient coarse particles. Inhal Toxicol, 16: 335-343.

Gordian ME; Ozkaynak H; Xue J; Morris SS; Spengler JD (1996). Particulate air pollution and respiratory disease in Anchorage, Alaska. Environ Health Perspect, 104: 290-297.

Graff D; Cascio W; Rappold A; Zhou H; Huang Y; Devlin R. (2009). Exposure to concentrated coarse air pollution particles causes mild cardiopulmonary effects in healthy young adults . Environ Health Perspect, 117: 1089-1094.

Hefflin BJ; Jalaludin B; McClure E; Cobb N; Johnson CA; Jecha L; Etzel RA (1994). Surveillance for dust storms and respiratory diseases in Washington State, 1991. Arch Environ Occup Health, 49: 170-174.

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

Host S; Larrieu S; Pascal L; Blanchard M; Declercq C; Fabre P; Jusot JF; Chardon B; Le Tertre A; Wagner V; Prouvost H; Lefranc A (2007). Short-term Associations between Fine and Coarse Particles and Cardiorespiratory Hospitalizations in Six French Cities. Occup Environ Med, 18: S107-S108.

Host S; Larrieu S; Pascal L; Blanchard M; Declercq C; Fabre P; Jusot JF; Chardon B; Le Tertre A; Wagner V; Prouvost H; Lefranc A (2008). Short-term associations between fine and coarse particles and hospital admissions for cardiorespiratory diseases in six French cities. Occup Environ Med, 65: 544-551.

Ito K (2003). Associations of particulate matter components with daily mortality and morbidity in Detroit, Michigan, In: Revised analyses of time-series studies of air pollution and health. Special report. Health Effects Institute. Boston, MA. R828112. http: //www.healtheffects.org/Pubs/TimeSeries.pdf .

Jenkins S.M. (2011). Supplemental Analysis of PM_{10} Air Quality from Locations Evaluated by Zanobetti and Schwartz (2009). Memorandum to PM NAAQS review docket EPA-HQ-OAR-2007-0492.

Klemm RJ; Mason R (2003). Replication of reanalysis of Harvard Six-City mortality study. In HEI Special Report: Revised Analyses of Time-Series Studies of Air Pollution and Health, Part II (pp. 165-172). Boston, MA: Health Effects Institute.

Klemm RJ; Lipfert FW; Wyzga RE; Gust C (2004). Daily mortality and air pollution in Atlanta: two years of data from ARIES. Inhal Toxicol, 16 Suppl 1: 131-141.

Le Tertre A; Schwartz J; Touloumi G. (2005). Empirical Bayes and adjusted estimates approach to estimating the relation of mortality to eposure of PM10. Risk Anal, 25: 711-718.

Lin M; Chen Y; Burnett RT; Villeneuve PJ; Krewski D (2002). The influence of ambient coarse particulate matter on asthma hospitalization in children: case-crossover and time-series analyses. Environ Health Perspect, 110: 575-581.

Lin M; Stieb DM; Chen Y. (2005). Coarse particulate matter and hospitalization for respiratory infections in children younger than 15 years in Toronto: a case-crossover analysis. Pediatrics, 116: 235-240.

Lipfert FW; Morris SC; Wyzga RE. (2000). Daily mortality in the Philadelphia metropolitan area and size-classified particulate matter. J Air Waste Manag Assoc, 50: 1501-1513.

Lisabeth LD; Escobar JD; Dvonch JT; Sanchez BN; Majersik JJ; Brown DL; Smith MA; Morgenstern LB. (2008). Ambient air pollution and risk for ischemic stroke and transient ischemic attack. Ann Neurol, 64: 53-59.

Mar, T. F.; Norris, G. A.; Larson, T. V.; Wilson, W. E.; Koenig, J. Q. (2003). Air pollution and cardiovascular mortality in Phoenix, 1995-1997. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 177-182. Available: http://www.healtheffects.org/Pubs/TimeSeries.pdf. October 18, 2004.

Metzger KB; Tolbert PE; Klein M; Peel JL; Flanders WD; Todd KH; Mulholland JA; Ryan PB; Frumkin H (2004). Ambient air pollution and cardiovascular emergency department visits. Epidemiology, 15: 46-56.

Middleton N; Yiallouros P; Kleanthous S; Kolokotroni O; Schwartz J; Dockery DW; Demokritou P; Koutrakis P (2008). A 10-year time-series analysis of respiratory and cardiovascular morbidity in Nicosia, Cyprus: the effect of short-term changes in air pollution and dust storms. Environ Health, 7: 39.

NYS DOH. (2006). A study of ambient air contaminants and asthma in New York City, Final Report Part B: Air contaminants and emergency department visits for asthma in the Bronx and Manhattan. Prepared for: The U.S. Department of Health and Human Services, Agency for Toxic Substance and Disease Registry.

Ostro, B. D.; Broadwin, R.; Lipsett, M. J. (2003). Coarse particles and daily mortality in Coachella Valley, California. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 199-204. Available: http://www.healtheffects.org/Pubs/TimeSeries.pdf. October 18, 2004.

Peel JL; Tolbert PE; Klein M; Metzger KB; Flanders WD; Knox T; Mulholland JA; Ryan PB; Frumkin H (2005). Ambient air pollution and respiratory emergency department visits. Epidemiology, 16: 164-174.

Peng RD; Chang HH; Bell ML; McDermott A; Zeger SL; Samet JM; Dominici F. (2008). Coarse particulate matter air pollution and hospital admissions for cardiovascular and respiratory diseases among Medicare patients. JAMA, 299: 2172-2179.

Peng R; Bell M; Geyh A; McDermott A; Zeger S; Samet J; Dominici F (2009). Emergency admissions for cardiovascular and respiratory diseases and the chemical composition of fine particle air pollution. Environ Health Perspect, 117: 957-963.

Perez L; Tobias A; Querol X; Kunzli N; Pey J; Alastuey A; Viana M; Valero N; Gonzalez-Cabre M; Sunyer J. (2008). Coarse particles from Saharan dust and daily mortality. Epidemiology, 19: 800-807.

Peters A; Dockery DW; Muller JE; Mittleman MA (2001). Increased particulate air pollution and the triggering of myocardial infarction. Circulation, 103: 2810-2815.

Pope CA III (1989). Respiratory disease associated with community air pollution and a steel mill, Utah Valley. Am J Public Health, 79: 623-628.

Pope CA III; Dockery DW; Spengler JD; Raizenne ME (1991). Respiratory health and PM10 pollution: a daily time series analysis. Am J Respir Crit Care Med, 144: 668-674.

Pope, C. A., III; Schwartz, J.; Ransom, M. R. (1992). Daily mortality and PM10 pollution in Utah valley. Arch. Environ. Health 47: 211-217.

Pope, C. A., III; Hill, R. W.; Villegas, G. M. (1999). Particulate air pollution and daily mortality on Utah's Wasatch Front. Environ. Health Perspect.: 107: 567-573.

Ross, M.; Langstaff J. (2005). Updated statistical information on air quality data from epidemiologic studies. Memorandum to PM NAAQS review docket OAR-2001-0017. January 31, 2005. Available: http://www.epa.gov/ttn/naaqs/standards/pm/data/ross_langstaff_2005.pdf

Samet, J. (2010c). Letter to EPA Administrator Lisa Jackson: "CASAC Review of Policy Assessment for the Review of the PM NAAQS – First External Review Draft (March 2010)." EPA-CASAC-10-011, May 17, 2010.

Samet, J. (2010d). Letter to EPA Administrator Lisa Jackson: "CASAC Review of Policy Assessment for the Review of the PM NAAQS – Second External Review Draft (June 2010)." EPA-CASAC-10-105, September 10, 2010.

Schmidt, M. (2005). Analyses of Particulate Matter (PM) Data for the PM NAAQS Review. Memorandum to PM NAAQS review docket OAR-2001-0017. June 30, 2005.

Schmidt, M.; Jenkins S.M. (2010). Analyses of PM_{10} and $PM_{10-2.5}$ Data for the PM NAAQS Review. Memorandum to PM NAAQS review docket EPA-HQ-OAR-2007-0492.

Schmidt, M. (2011b). PM_{10} and $PM_{10-2.5}$ Air Quality Analyses. Memorandum to PM NAAQS review docket EPA-HQ-OAR-2007-0492.

Schwartz J.; Dockery, D. W.; Neas, L. M. (1996). Is daily mortality associated specifically with fine particles? J. Air Waste Manage. Assoc. 46: 927-939.

Schwartz J (1997). Air pollution and hospital admissions for cardiovascular disease in Tucson. Epidemiology, 8: 371-377.

Schwartz J; Norris G; Larson T; Sheppard L; Claiborne C; Koenig J (1999). Episodes of high coarse particle concentrations are not associated with increased mortality. Environ Health Perspect, 107: 339-342.

Sheppard L; Levy D; Norris G; Larson TV; Koenig JQ (2003). Effects of ambient air pollution and nonelderly asthma hospital admissions in Seattle, Washington, 1987-1994. Epidemiology, 10: 23-30.

Slaughter JC; Kim E; Sheppard L; Sullivan JH; Larson TV; Claiborn C. (2005). Association between particulate matter and emergency room visits, hospital admissions and mortality in Spokane, Washington. J Expo Sci Environ Epidemiol, 15: 153-159.

Stanek L, Hassett-Sipple B, Yang R. (2010). Particulate Matter Air Quality Data Requested from Epidemiologic Study Authors. Memorandum to PM NAAQS review docket EPA-HQ-OAR-2007-0492.

Tolbert PE; Klein M; Peel JL; Sarnat SE; Sarnat JA (2007). Multipollutant modeling issues in a study of ambient air quality and emergency department visits in Atlanta. J Expo Sci Environ Epidemiol, 17: S29-S35.

US EPA (1987). PM_{10} SIP Development Guideline. Office of Air Quality Planning and Standards, Office of Air and Radiation, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; report no. EPA-450/2-86-001. June 1987. Available: http://nepis.epa.gov/Exe/ZyNET.exe/P1006IKV.txt?ZyActionD=ZyDocument&Client=EPA&Index=1986%20Thru%201990&Docs=&Query=%28sampling%20interval%29%20OR%20FNAME%3D%22P1006IKV.txt%22%20AND%20FNAME%3D%22P1006IKV.txt%22&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&UseQField=&IntQFieldOp=1&ExtQFieldOp=1&XmlQuery=&File=D%3A%5CZYFILES%5CINDEX%20DATA%5C86THRU90%5CTXT%5C00000019%5CP1006IKV.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=10&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=p

%7Cf&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x

US EPA (2004). Air Quality Criteria for Particulate Matter. National Center for Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; report no. EPA/600/P-99/002aF and EPA/600/P-99/002bF. October 2004. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_cd.html

US EPA (2005). Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. Research Triangle Park, NC 27711: Office of Air Quality Planning and Standards; report no. EPA EPA-452/R-05-005a. December 2005. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_sp.html

US EPA (2008a). Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter. National Center for Environmental Assessment and Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. Report No. EPA 452/R-08-004. March 2008. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/data/2008_03_final_integrated_review_plan.pdf

US EPA (2009a). Integrated Science Assessment for Particulate Matter (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-08/139F, December 2009. Available: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=216546

US EPA. (2009b). Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment. U.S. Environmental Protection Agency, Research Triangle Park, NC, EPA-452/P-09-002. February 2009. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pd.html

US EPA (2010a). Quantitative Risk Assessment for Particulate Matter – Final. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/P-10-001. February 2010. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_index.html.

Villeneuve PJ; Burnett RT; Shi Y; Krewski D; Goldberg MS; Hertzman C; Chen Y; Brook J. (2003). A time-series study of air pollution, socioeconomic status, and mortality in Vancouver, Canada. J Expo Sci Environ Epidemiol, 13: 427-435.

Wilson WE; Mar TF; Koenig JQ. (2007). Influence of exposure error and effect modification by socioeconomic status on the association of acute cardiovascular mortality with particulate matter in Phoenix. J Expo Sci Environ Epidemiol, 17: S11-S19.

Yang C-Y; Chen Y-S; Yang C-H; Ho S-C (2004). Relationship between ambient air pollution and hospital admissions for cardiovascular diseases in Kaohsiung, Taiwan. J Toxicol Environ Health A Curr Iss, 67: 483-493.

Yang CY; Cheng MH; Chen CC (2009). Effects of Asian Dust Storm Events on Hospital Admissions for Congestive Heart Failure in Taipei, Taiwan. J Toxicol Environ Health A Curr Iss, 72: 324-328.

Zanobetti A; Schwartz J. (2009). The effect of fine and coarse particulate air pollution on mortality: A national analysis. Environ Health Perspect, 117: 898-903.

4 REVIEW OF THE SECONDARY STANDARDS FOR VISIBILITY-RELATED EFFECTS

This chapter presents staff conclusions with regard to the adequacy of the current suite of secondary $PM_{2.5}$ standards to protect against PM-related visibility impairment as well as 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 at the outset of this review in the IRP (US EPA, 2008). The answers to these questions will inform decisions on whether, and if so how, to revise the current suite of secondary $PM_{2.5}$ standards for the purpose of providing appropriate protection from PM-related visibility impairment.

In presenting staff conclusions on a range of alternative secondary standards 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 taking into consideration the range of uncertainties that are inherent in the scientific evidence and analyses. Our approach to informing these judgments is discussed more fully below.

Information on the approaches used to set the secondary $PM_{2.5}$ standards in past reviews as well as our current approach for this review are presented in section 4.1. Our conclusions regarding the adequacy of the current suite of secondary $PM_{2.5}$ standards to protect against PM-related visibility impairment are presented in section 4.2. Section 4.3 presents our conclusions with respect to alternative $PM_{2.5}$ 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 staff conclusions on the secondary $PM_{2.5}$ standards for visibility protection. This chapter concludes with an 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 suite of secondary $PM_{2.5}$ standards builds upon and broadens the approaches used in previous PM NAAQS reviews. We first present a brief summary of the approaches used to review and establish 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 secondary $PM_{2.5}$ 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 nature of the effect on public welfare from visibility impairment, from an approach focusing only on Class I area visibility impacts to a more multifaceted approach that also considers PM-related impacts on non-Class I area visibility, such as in urban areas. This evolution has occurred in conjunction with the expansion of available PM data and information from associated studies of public perception, valuation, and personal comfort and well-being.

4.1.1.1 Review Completed in 1997

In 1997, EPA revised the identical primary and secondary PM 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 being 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 $PM_{2.5}$ on visibility, EPA concluded that the determination of a single national level was complicated by regional differences. These differences included several factors that influence visibility such as background and current levels of $PM_{2.5}$, composition of $PM_{2.5}$, and average relative humidity. Variations in these factors across regions could thus result in situations where attaining an appropriately protective concentration of fine particles in one region might or might not provide adequate protection in a different region. 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 $PM_{2.5}$ 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 were attained.

The EPA also concluded that attainment of the 24-hour $PM_{2.5}$ standard in some areas would be expected to reduce, to some degree, the number and intensity of ''bad visibility'' days, resulting in improvement in 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 those effects of PM on visibility that would not be addressed through attainment of the primary $PM_{2.5}$ standards. The regional haze program would be designed to address the widespread, regionally uniform type of haze caused by a multitude of sources. 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 is more protective than a secondary NAAQS since the goal addresses any anthropogenic impairment rather than just impairment at levels determined to be adverse to public welfare. 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 for addressing regional variations in the adverse effects of $PM_{2.5}$ on visibility than would be national secondary standards for PM with levels lower 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

[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.

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 then-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 public welfare effects associated with visibility impairment. Together, the two programs and associated control strategies were expected to provide appropriate protection against PM-related visibility impairment 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 $PM_{2.5}$ standards to address visibility impairment by making them identical to the revised primary standards. The EPA's decision regarding the need to revise the secondary $PM_{2.5}$ 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) utilized photographic representations of visibility impairment and produced reasonably consistent results in terms of the visual ranges found to be generally acceptable by study participants. The EPA considered the information generated by these studies useful in characterizing the nature of particle-induced haze and for informing judgments about the acceptability of various levels of visual air quality in urban areas across the U.S. 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 and that perception of visibility impairment is most directly related to short-term, nearly instantaneous levels of visual air quality. Thus, in considering whether the current suite of secondary standards would provide the appropriate degree of protection, he concluded that it was appropriate to focus on just the 24-hour secondary $PM_{2.5}$ standard to provide requisite protection.

The Administrator then considered whether $PM_{2.5}$ remained the appropriate indicator for a secondary standard to protect visibility, primarily in urban areas. The Administrator noted that PM-related visibility impairment is principally related to fine particle levels. Hygroscopic components of fine particles, in particular sulfates and nitrates, contribute disproportionately to visibility impairment under high humidity conditions. Particles in the coarse mode generally contribute only marginally to visibility impairment in 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 (US EPA, 2005) concluded that clear correlations existed between 24-hour average $PM_{2.5}$ concentrations and calculated (i.e., reconstructed) light extinction, which is directly related to visual range. These correlations were similar in the eastern and western regions of the U.S. 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. 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 regarding the acceptability of various degrees of visibility impairment 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 had 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 that 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 had 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% 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 tentatively 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 the proposed decision, the CASAC requested that a sub-daily standard to protect visibility be favorably reconsidered (Henderson, 2006a). The CASAC noted three cautions regarding the 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 $PM_{2.5}$ 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; and (3) The analysis showing a similarity between percentages of counties not likely to meet what the CASAC Panel 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 relative protection provided by the proposed primary standards based on the above-mentioned similarities in percentages of counties meeting alternative standards, and on the limitations in the information available concerning 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 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 $PM_{2.5}$ standards.

4.1.2 Remand of Secondary $PM_{2.5}$ Standards

Several parties filed petitions for review challenging EPA's decision to set the secondary NAAQS for fine PM at the same level as the primary NAAQS. On judicial review, the D.C. Circuit remanded to EPA for reconsideration the secondary NAAQS for fine PM because the Agency's decision was unreasonable and contrary to the requirements of section 109(b)(2). *American Farm Bureau Federation v. EPA*, 559 F. 3d 512 (D.C. Cir., 2009).

The petitioners argued that EPA's decision lacked a reasoned basis. First, they asserted that EPA never determined what level of visibility was "requisite to protect the public welfare". They argued that EPA unreasonably rejected the target level of protection recommended by its staff, while failing to provide a target level of its own. The court agreed, stating that "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 decision-making of a reasoned basis." 559 F. 3d at 530.

Second, the petitioners challenged EPA's method of comparing the protection expected from potential standards. They contended 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 based on the percentages of counties exceeding alternative standards "failed on its own terms". The same table showing the percentages of counties exceeding alternative secondary standards, used for comparison to the percentages of counties exceeding alternative primary standards to show equivalency, also included six other alternative secondary standards within the recommended CASAC range that would be more "protective" under EPA's definition than the adopted primary standards. Two-thirds of the potential secondary standards within the CASAC's recommended range would be substantially more protective than the adopted primary standards. The court found that EPA failed to explain why it looked only at one of the few potential secondary standards that would be less protective and only slightly less so than the primary standards. More fundamentally, however, the court found that EPA's equivalency analysis based on percentages of counties demonstrated nothing about the relative protection offered by the different standards, and that the tables offered no valid information about the relative visibility protection provided by the standards. 559 F. 3d at 530-31.

Finally, the Staff Paper had made clear that a visibility standard using $PM_{2.5}$ mass as the indicator in conjunction with a daily averaging time would be confounded by regional differences in humidity. The court noted that EPA acknowledged this problem, yet did not address this issue in concluding that the primary standards would be sufficiently protective of visibility. 559 F. 3d at 530. Therefore, the court granted the petition for review and remanded for reconsideration the secondary $PM_{2.5}$ NAAQS.

4.1.3 General Approach Used in Current Review

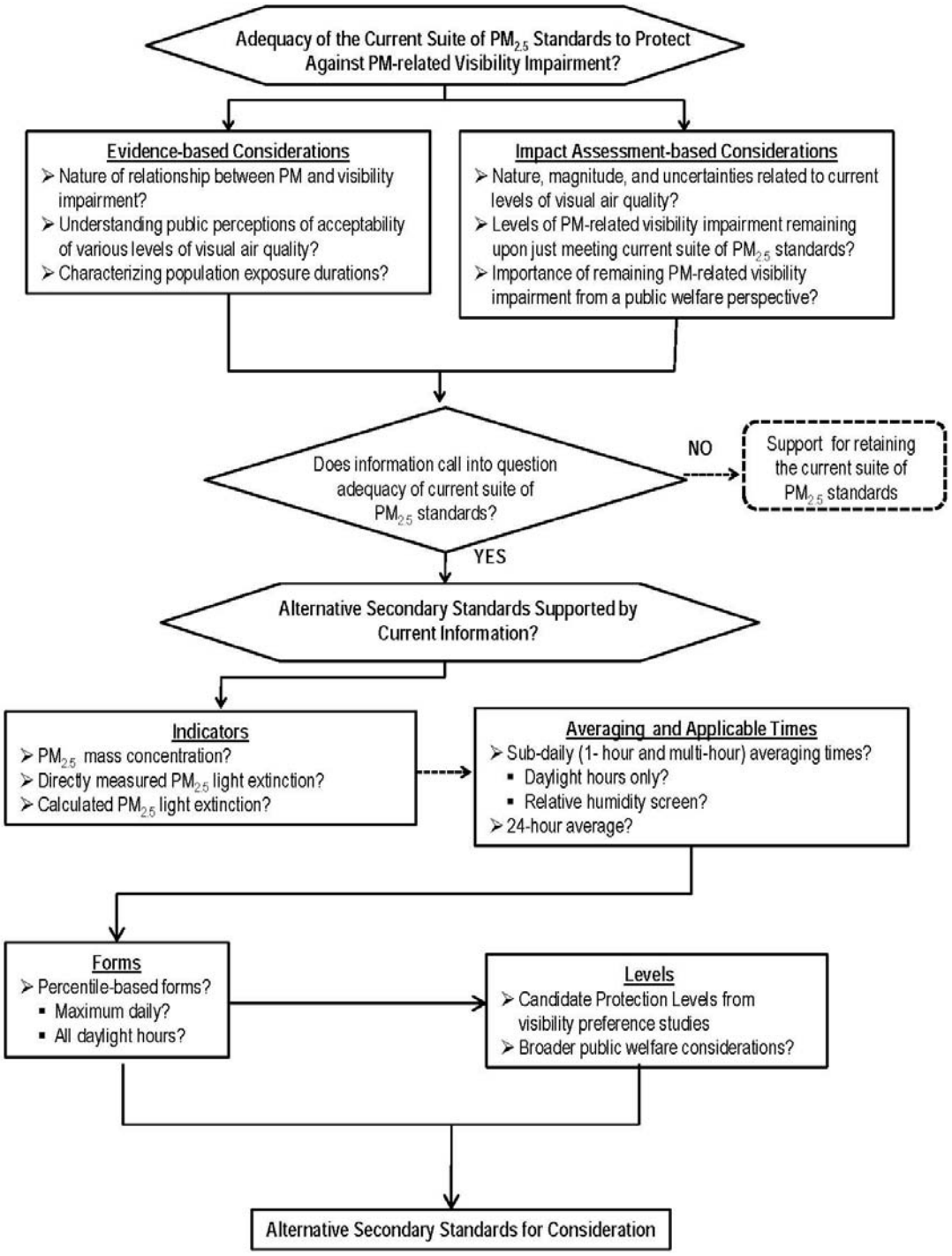
The staff's approach in this review broadens the general approaches used in the last two PM NAAQS reviews by utilizing, to the extent available, enhanced tools, methods, and data to more comprehensively characterize visibility impacts. As such, we are taking into account considerations based on both the scientific evidence ("evidence-based") and a quantitative analysis of PM-related impacts on visibility ("impact-based") to inform our conclusions related to the adequacy of the current secondary $PM_{2.5}$ standards and alternative standards that are appropriate for consideration in this review. As in past reviews, we are also considering secondary NAAQS to address PM-related visibility impairment in conjunction with the Regional Haze Program, such that the secondary NAAQS would focus on protection from visibility impairment principally in urban areas in conjunction with the Regional Haze Program that is focused on improving visibility in Class I areas. We again recognize that such an approach is the most appropriate and effective means of addressing the public welfare effects associated with visibility impairment in areas across the country. 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.

In preparing this final PA, staff has drawn from the qualitative evaluation of all studies discussed in the ISA (US EPA, 2009a). We 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 (ISA chapter 9), as well as the integration of evidence across disciplines (ISA chapter 2). 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 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, as summarized in Figure 4-1. 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: indicator, averaging time, level, and form.

Figure 4-1. Overview of Approach for Review of 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 and Impact-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, and impact-based considerations as presented in the UFVA, by considering causal inference, impacts on susceptible populations, and the nature and degree of PM-related visibility effects that would be expected to exist in urban areas when meeting the current standards.

- **To what extent do the newly available scientific evidence and other information 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 by-products of this research include new insights regarding the regional source contributions to urban visibility and better characterization of the increment in PM concentrations and visibility impairment that occur in many cities (i.e., the urban excess) relative to conditions in the surrounding rural areas (i.e., regional background). Ongoing urban $PM_{2.5}$ speciated and mass monitoring has produced new information that has allowed for updated characterization of current visibility 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. 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/(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 (US EPA, 2009a, chapter 9). However, routine monitoring rarely includes measurements of particle size and composition information with sufficient detail for such calculations. To make estimation of light extinction more practical, visibility scientists have developed a much simpler algorithm, known as the IMPROVE algorithm,[2] to estimate light extinction using routinely monitored fine particle ($PM_{2.5}$) speciation and coarse particle mass ($PM_{10-2.5}$) data. In addition, relative humidity information is needed to estimate the contribution by liquid water that is in solution with hygroscopic PM components (US EPA, 2009a, section 9.2.2.2; US EPA, 2010b, chapter 3). There is both an original and a revised version of the IMPROVE algorithm. The revised version was developed to address observed biases in the predictions using the original algorithm under very low and very high light extinction conditions.[3] These IMPROVE algorithms are routinely used to calculate light extinction levels on a 24-hour basis in Class I areas under the Regional Haze Program.

In either version of the IMPROVE algorithm, the concentration of each of the major aerosol components is multiplied by a dry extinction efficiency value and, for the hygroscopic components (i.e., ammoniated sulfate and ammonium nitrate), also multiplied by an additional factor to account for the water growth to estimate these components' contribution to light extinction. Both the dry extinction efficiency and water growth terms have been developed by a combination of empirical assessment and theoretical calculation using typical particle size distributions associated with each of the major aerosol components. They have been evaluated by comparing the algorithm estimates of light extinction with coincident optical measurements.

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[2] The algorithm is referred to as the IMPROVE algorithm because it was developed specifically to use the aerosol monitoring data generated at network sites and with equipment specifically designed to support the IMPROVE program and was evaluated using IMPROVE optical measurements at the subset of sites that make those measurements (Malm et al., 1994).

[3] These biases were detected by comparing light extinction estimates generated from the IMPROVE algorithm to direct optical measurements in a number of rural Class I areas.

Summing the contribution of each component gives the estimate of total light extinction (denoted as b_{ext}), as shown below for the original IMPROVE algorithm.

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

Light extinction (b_{ext}) is in units of Mm^{-1}, the mass concentrations of the components indicated in brackets are in units of $\mu g/m^3$, and *f(RH)* is the unitless water growth term that depends on relative humidity. The final term of 10 Mm^{-1} is known as the Rayleigh scattering term and accounts for light scattering by the natural gases in unpolluted air. The dry extinction efficiency for particulate organic mass is larger than those for particulate sulfate 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 sulfate is fully neutralized ammonium sulfate and all nitrate is assumed to be ammonium nitrate. Though often reasonable, neither assumption is always true (see US EPA, 2009a, section 9.2.3.1). In the eastern U.S. during the summer there is insufficient ammonia in the atmosphere to neutralize the sulfate 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 sulfate and nitrate compounds) to be separately approximated.

The *f(RH)* term reflects the increase in light scattering caused by particulate sulfate and nitrate under conditions of high relative humidity. 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 sulfate 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 elemental carbon (EC). Based on this algorithm, particulate sulfate 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 original IMPROVE 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.[4]

Subsequent to the development of the original IMPROVE algorithm, an alternative algorithm (variously referred to as the "revised algorithm" or the "new algorithm" in the literature) has been developed that employs a more complex split component mass extinction efficiency to correct biases believed to be related to particle size distributions, a sea salt term that can be important for remote coastal areas, a different multiplier for organic carbon for purposes of estimating organic carbonaceous material, and site-specific Rayleigh light scattering terms in place of a universal Rayleigh light scattering value. These features of the revised IMPROVE algorithm are described in section 9.2.3.1 of the ISA, which also presents a comparison of the estimates produced by the two algorithms for rural areas. Compared to the original algorithm, the revised IMPROVE algorithm can yield higher estimates of current light extinction levels in urban areas on days with relatively poor visibility (Pitchford, 2010). This difference is primarily attributable to the split component mass extinction efficiency treatment in the revised algorithm rather than to the inclusion of a sea salt term or the use of site-specific Rayleigh scattering values.

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 depends on the density of air as a function primarily of the elevation above sea level, and can be treated as a site-dependent constant. The Rayleigh scattering 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 approximately 5% of the light extinction, except where emission controls remove most of the PM prior to releasing the

[4] The IMPROVE algorithm does not explicitly separate the light-scattering and light-absorbing effects of elemental carbon.

remaining gases to the atmosphere). The remainder of this chapter focuses on the contribution of PM, which is typically much greater than that of gases, to ambient light extinction, unless otherwise specified.

In the following discussions, visual air quality is characterized both in terms of light extinction, as discussed above, and deciviews (dv). Deciview refers to an alternative scale for characterizing visibility that is defined directly in terms of light extinction (expressed in units of Mm^{-1}) by the following equation[5]:

$$\text{Deciview (dv)} = 10 \ln (b_{ext} / 10\ Mm^{-1})$$

The deciview scale is frequently used in the scientific and regulatory literature on visibility, as well as in the Regional Haze Program. In particular, the deciview scale is used in the public perception studies that were considered in the past and current reviews to inform judgments about an appropriate degree of protection to be provided by a secondary NAAQS.

- **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?**

Temporal Variations of Light Extinction

PM concentrations and light extinction in urban environments vary from hour-to-hour throughout the 24-hour day due to a combination of diurnal changes in meteorological conditions and systematic changes in emissions activity (e.g., rush hour traffic). Generally, low mixing heights at night and during the early morning hours 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 presence 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 light extinction. 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 light extinction impacts any time of day. The net effects of the systematic urban- and larger-scale variations are that peak daytime PM light extinction levels can occur any time of day, although in many areas they most often occur in early morning hours (USEPA, 2010b, sections 3.4.2 and 3.4.3; Figures 3-9, 3-10, and 3-12).

[5] As used in the Regional Haze Program, the term b_{ext} refers to light extinction due to $PM_{2.5}$, $PM_{10-2.5,}$ and "clean" atmospheric gases. In this chapter, in focusing on light extinction due to $PM_{2.5}$, the deciview values include only the effects of $PM_{2.5}$ and the gases. The "Rayleigh" term associated with clean atmospheric gases is represented by the constant value of 10 Mm^{-1}. Omission of the Rayleigh term would create the possibility of a negative deciview values when the $PM_{2.5}$ concentration is very low.

This temporal pattern in urban areas contrasts with the general lack of a strong diurnal pattern in PM concentrations and light extinction in most Class I areas, reflective of a relative lack of local sources as compared to urban areas. The use in the Regional Haze Program of 24-hour average concentrations in the IMPROVE algorithm is consistent with this general lack of a strong diurnal pattern in Class I areas.

Periods during the Day of Interest for Assessment of Visibility

Typically, we think of visibility associated with daytime periods because we are outside more during the day than at night and there are more viewable scenes at a distance during the day than at night. 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 in 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 with regard to how light extinction per se relates to visual air quality (or visibility) and public welfare. First, daytime visibility has dominated the attention of those who have studied the visibility effects of air pollution, particularly in urban areas. 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. We are not aware of urban-focused preference or valuation studies providing information on public preferences for nighttime visual air quality. 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 in urban environments 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 (US EPA, 2009a, section 9.2.2).

Given the above, we do not believe that the science is available at this time to support adequate characterization specifically of nighttime PM light extinction conditions and the related effects on public welfare. Thus, we have focused our assessments of PM visibility impacts in urban areas on daylight hours. For simplicity, and because perceptions and welfare effects from light extinction-related visual effects during the minutes of actual sunrise and sunset have not been explored, we have defined daylight hours as those hours entirely after the local sunrise time and before the local sunset time.

In so doing, we note that the 24-hour averaging time used in the Regional Haze Program includes nighttime conditions. We also note, however, that the goal of the Regional Haze Program is to address any manmade impairment of visibility without regard to distinctions between daylight and nighttime conditions. Moreover, because of the lack of strong diurnal patterns, both nighttime and daylight visibility are strongly correlated with 24-hour average visibility conditions, so a 24-hour averaging period is suitable for driving both daylight and nighttime visibility towards their natural conditions. Also, the focus on 24-hour average visibility allows the Regional Haze Program to make use of more practically obtained ambient PM measurements of adequate accuracy than if a shorter averaging period were used, an important consideration given the remoteness of many Class I area monitoring sites and given the low PM concentrations that must be measured accurately in such areas.

In addition, when natural conditions such as fog and rain cause poor visibility, it can be reasonably assumed that the light extinction properties of the air that are attributable to air pollution are not important from a public welfare perspective. Thus, it is appropriate to give special treatment to such periods when considering whether current $PM_{2.5}$ standards adequately protect public welfare from PM-related visibility impairment. In evaluating alternative sub-daily standards, we have addressed this issue by screening out hours with particularly high relative humidity. As discussed further below (section 4.3.2.1), we used a relative humidity screen of 90% on the basis that it serves as a reasonable surrogate for excluding hours affected by fog and rain.

Exposure Durations of Interest

The roles that exposure duration and variations in visual air quality within any given exposure period play in determining the acceptability or unacceptability of a given level of visual air quality has not been investigated via preference studies. In the preferences studies available for this review, subjects were simply asked to rate the acceptability or unacceptability of each image of a haze-obscured scene, without being provided any suggestion of assumed duration or of assumed conditions before or after the occurrence of the scene presented. 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 judge the acceptability or unacceptability of the viewed visual air quality conditions. Moreover, individual participants in general consistently judge the acceptability of same-scene images that differed only with respect to light extinction levels when these images were presented repeatedly for such short periods. That is, individuals generally did not say that a higher-light extinction image was acceptable while saying a lower-light extinction, same-scene image was unacceptable, even though they could not compare images side-to-side. However, we do not have information about what assumptions, if any, the participants may have made about the duration of exposure in determining the acceptability of the images. 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 the absence of such studies, we considered a variety of circumstances that are commonly expected to occur in evaluating the potential impact of visibility impairment on the public welfare based on the information we do have. 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 visual air quality at that time either enhances or diminishes the experience or view. However, the public also has many more opportunities to notice visibility conditions on a daily basis in settings associated with performing daily routines (e.g., during commutes and while working, exercising, or recreating outdoors). These scenes, whether iconic or generic, may not be consciously viewed for their scenic value and may not even be noticed for periods comparable to what would be the case during purposeful visits to scenic visits, but their visual air quality may still affect a person's sense of wellbeing. Research has demonstrated that people are emotionally affected by low visual air quality, that perception of pollution is correlated with stress, annoyance, and symptoms of depression, and that visual air quality is deeply intertwined with a "sense of place," affecting people's sense of the desirability of a neighborhood (US EPA, 2009a, 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 visual air quality, providing additional protection against short-term exposures to levels of visual air quality considered unacceptable by subjects in the context of the preference studies would be expected to provide some degree of protection against the risk of loss 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 because they spend much of their time indoors without access to windows. For such people a view of poor visual air

quality 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, conditions that may differ from hour to hour. A day with multiple hours of visibility impairment would likely be judged as having a greater impact on their wellbeing than a day with just one such hour followed by clearer conditions.

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 visual air quality 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 visual air quality based on the visibility conditions that occur during the short time period when they can see it. Since this group could be affected on the basis of observing visual air quality conditions for periods as short as one hour or less, and because during each daylight hour there are some people outdoors, commuting, or near windows, we judge that it would be appropriate to use the maximum hourly value of PM light extinction during daylight hours for each day for purposes of evaluating the adequacy of the current suite of secondary standards. This approach would recognize that at least some but not all of the population of an area will actually be exposed to this worst hour and that some that people who are exposed to this worst hour may not have an opportunity to observe clearer conditions in other hours if they were to occur. Moreover, because visibility conditions and people's daily activities on work/school days both tend to follow the same diurnal pattern day after day, those who are exposed only to the worst hour will tend to have this experience day after day.

For another group of observers, those who have access to visibility conditions often or continuously throughout the day, the impact of the day's visibility conditions on their welfare may be based on the varying visibility conditions they observe throughout the day. For this group, it might be that an hour with poor or "unacceptable" visibility can be offset by one or more other hours with clearer conditions. Based on these considerations, we judge that it would also be appropriate to use the maximum multi-hour daylight period for evaluating the adequacy of the current suite of secondary standards.

The above discussion is based on what people see, which is determined by the extinction of light along the paths between observers and various objects that are looked at. A related but separate issue is what measurement period is relevant, if (as expected) what will be measured is the light extinction property or the PM concentration of the local air at a fixed site. Light extinction conditions at a fixed site can change quickly (i.e., in less than a minute). 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., high concentration plumes) just generated in the immediate vicinity due to local sources or being transported by the wind across that point. These small-scale pockets of air causing short periods of higher light extinction at the fixed site likely do not determine the visual effect for scenes with longer sight paths. In contrast, atmospheric sight path-averaged light extinction which is pertinent to visibility impacts generally changes more slowly (i.e., tens of minutes generally), because a larger air mass must be affected by a broader set of emission sources or the air mass must be replaced by a cleaner or dirtier air mass due to the wind operating over time. 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 sight path lengths of interest in urban areas. Based on the above considerations, hourly average light extinction would generally be reasonably representative of the net visibility effect of the spatial pattern of light extinction levels, especially along site paths that generally align with the wind direction.

- **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 differences in visibility on the human observer. This has been studied in terms of the acceptability or unacceptability expressed for the visibility impact of a given level of light extinction 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.[6] Thus, a given level of light extinction may be perceived differently by observers looking at different scenes 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 visual air quality. 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

[6] By "characteristics of the scene" we mean the distance(s) between the viewer and the object(s) of interest, the shapes and colors of the objects, the contrast between objects and the sky or other background, and the inherent interest of the objects to the viewer. Distance is particularly important because at a given value of light extinction, which is a property of air at a given point(s) in space, more light is actually absorbed and scattered when light passes through more air between the object and the viewer.

demonstrated using the WinHaze model (Molenar et al., 1994) 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 for those particular scenes. While the results differed among the four urban areas, results from a rating exercise showed that within each preference study, individual survey participants consistently distinguish between photos or images representing different levels of light extinction, and that more participants rate as acceptable images representing lower levels of light extinction than do images representing higher levels.

The reanalysis of urban preference studies conducted for this review 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 one in 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 visual air quality 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 visual air quality. Given the similarities in the approaches used, 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

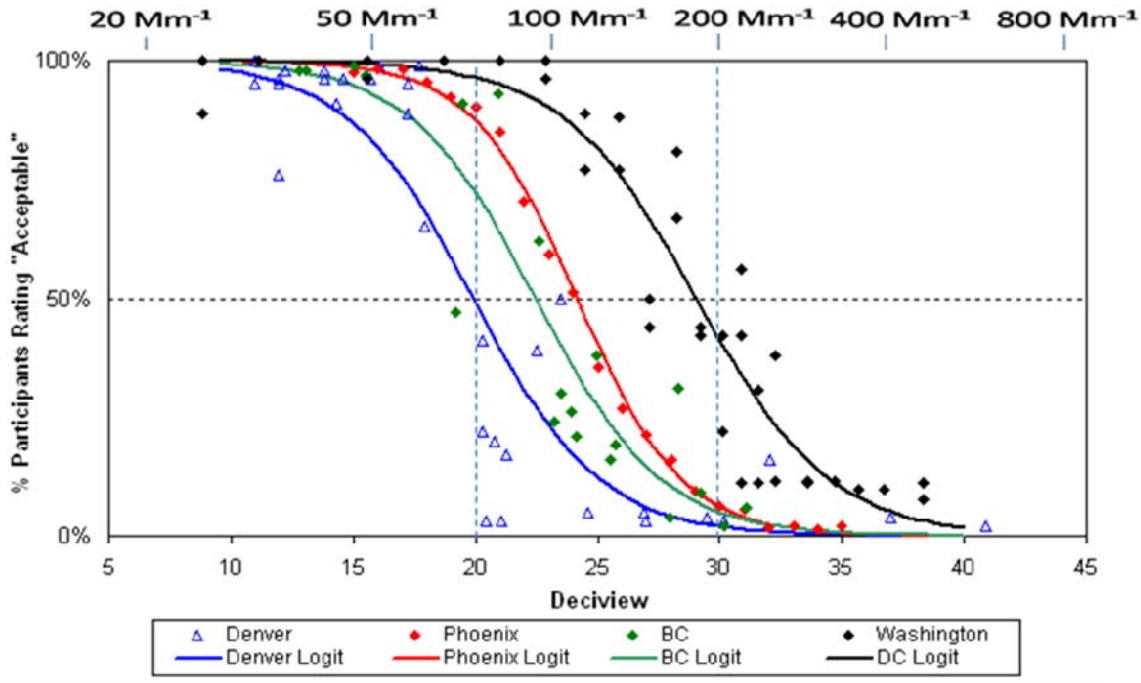
results of these comparisons. Key differences between the studies include: 1) scene characteristics; 2) image presentation methods (e.g., projected slides of actual photos, projected images generated using WinHaze (a significant technical advance in the method of presenting visual air quality conditions), or use of a computer monitor screen; 3) number of participants in each study; 4) participant representativeness of the general population of the relevant metropolitan area; and 5) 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 the visual air quality depicted in each photograph as "acceptable." Ely et al. (1991) introduced a "50% acceptability" criterion analysis of the Denver preference study results. The 50% acceptability criterion is designed to identify the visual air quality level (defined in terms of deciviews or light extinction) that best divides the photographs into two groups: those with a visual air quality rated as acceptable by the majority of the participants, and those rated not acceptable by the majority of participants. We adopted the criterion as a useful index for comparison between studies. The results of each individual analysis were then combined graphically to allow for visual comparison. Figure 4-2 (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 4-2 also contains lines at 20 dv and 30 dv that generally 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 4-2, only one photograph (or image) with a visual air quality below 20 dv was rated as acceptable by less than 50% of the participants who rated that photograph.[7] Similarly, only one image with a visual air quality above 30 dv was rated acceptable by more than 50% of the participants who viewed it.[8]

[7] Only 47% of the BC participants rated a 19.2 dv photograph as acceptable.

[8] 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, but only 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). All three points are shown in Figure 4-2.

Figure 4-2. Summary of Results of Urban Visibility Studies in Four Cities, Showing the Identified Range of the 50% Acceptance Criteria[9]



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.[10] 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 visual air quality in terms of deciview values where the estimated response functions cross the 50% acceptability level, as well as any alternative criteria levels. Selected examples of these are shown in Table 4-1 (US EPA, 2010b, Table 2-4). These results show that the logit model results also supports 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 4-2.

[9] 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.

[10] Note that the Washington, DC results (black dots) shown in Figure 4-2 include values from two separate studies individually, so there are at least two points at each haze level (x-axis). There is a third point for some haze levels because an image was sometimes presented twice. Since one of the two studies had only 9 participants, the percent of participants' acceptable ratings are limited to multiples of 1/9, so that a single participant rating can move a point by about 11%. A composite of the results from the two studies (similar to US EPA, 2010b, Figure 2-15) would show much less scatter among the points, but obscures the fact of it being data from differing studies.

Table 4-1. Logit Model-estimated Visual Air Quality Values (in deciviews) Corresponding to Various Percent Acceptability Values for the Four Cities

Acceptability Criteria	Denver	British Columbia	Phoenix	Washington, DC
90% Acceptability	14.2	16.8	19.4	23.0
75% Acceptability	17.1	19.6	21.8	26.0
50% Acceptability	**19.9**	**22.5**	**24.2**	**29.0**
25% Acceptability	22.7	25.3	26.5	32.0
10% Acceptability	25.6	28.1	28.9	35.0

Based on the composite results and the effective range of 50th percentile acceptability across the four urban preference studies shown in Figure 4-2 and Table 4-1, benchmark levels of (total) light extinction have been selected in a range from 20 dv to 30 dv (75 to 200 Mm^{-1})[11] 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 acceptable (within the range). A midpoint of 25 dv (120 Mm^{-1}) was also selected for use in the assessment. This level is also very near to the 50th percentile criterion value from the Phoenix study (i.e., 24.2 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 (total) 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 65 Mm^{-1}, 110 Mm^{-1}, and 190 Mm^{-1}. In the UFVA, these three light extinction levels were called Candidate Protection Levels

[11] These values were rounded from 74 Mm^{-1} and 201 Mm^{-1} to avoid an implication of greater precision than is warranted. Note that the middle value of 25 dv when converted to light extinction is 122 Mm^{-1} is rounded to 120 Mm^{-1} for the same reason. Assessments conducted for the UFVA and the first and second draft PAs used the unrounded values. The EPA staff considers the results of assessment using unrounded values to be sufficiently representative of what would result if the rounded values were used that it was unnecessary to redo the assessments. That is why some tables and figures in this document reflect the unrounded values.

(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 any one component of the standard but by all the components (i.e., indicator, averaging time, form, and level) being applied together. Therefore, the reader should keep in mind that the term CPL is meant only to indicate target levels of visibility within a range that we feel is appropriate for consideration that could, in conjunction with other elements of the standard, including indicator, averaging time, and form, 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 evaluate this, 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.[12] 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 is also true that each of the western scenes included objects at greater distances from the camera location than in the Washington, DC study. There is 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 seems 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 likely 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

[12] The first preference study using WinHaze images of a scenic vista from Washington, DC was conducted in 2001 using subjects who were residents of Washington, DC. More recently, Smith and Howell (2009) interviewed additional subjects using the same images and interview procedure. The additional subjects included some residents of the Washington, DC area and some residents of the Houston, TX area.

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 U.S., and possibly some areas in the western U.S. as well. 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., scenes that 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 preference study information is currently available. Based on the currently available information, we conclude that the high end of the CPL range (30 dv) is 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, could help evaluate whether the lower CPL value of 20 dv is generally 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. In 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 confidence in the selection of a low CPL value.

Based on the above considerations, and recognizing the limitations in the currently available information, staff concludes that it is reasonable to consider a range of CPL values including a high value of 30 dv, a mid-range value of 25 dv, and a low value of 20 dv. Based on its review of the second draft PA, CASAC supported this set of CPLs for consideration by the EPA in this review. CASAC noted that these CPL values were based on all available visibility preference data and that they bound the study results as represented by the 50% acceptability criteria. CASAC concluded that this range of levels is "adequately supported by the evidence presented" (Samet, 2010d, p. iii).

- **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 that such impairment would occur under ambient $PM_{2.5}$ levels that would meet the current standards?**

Current Visibility Levels

Current visibility conditions have been characterized in terms of PM light extinction levels for the 15 urban areas[13] that were selected for analysis in the UFVA. We have analyzed hourly average PM-related light extinction in terms of both PM_{10} and $PM_{2.5}$ light extinction.[14] These current visibility conditions were then compared to the CPLs identified above.

As an initial matter, as noted above, we recognize that visibility impairment occurs during periods with fog or precipitation irrespective of the presence or absence of PM. While it is a popular notion that areas with many foggy or rainy days are "dreary" places to live compared to areas with more sunny days per year, we have no basis for taking into account how the occurrence of such days might modify the effect of pollution-induced hazy days on public welfare. It is logical that periods with naturally impaired visibility due to fog or precipitation should not be treated as having PM-impaired visibility. Moreover, depending on the specific indicator, averaging time, and measurement approach used for the NAAQS, foggy conditions might result in measured or calculated indicator values that are higher than the light extinction actually caused by PM.[15] Therefore, 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 draft UFVA, we restricted our assessment of visibility conditions to daylight hours with relative humidity less than or equal to 90% when evaluating sub-daily alternative standards (US EPA, 2010b, section 3.3.5, and US EPA, 2010b, Appendix G). However, not all periods with

[13] Comments on the second draft UFVA from those familiar with the monitoring sites in St. Louis indicated that the site selected to provide continuous PM_{10} monitoring, although less than a mile from the site of the $PM_{2.5}$ data, is not representative of the urban area and resulted in unrealistically large $PM_{10-2.5}$ values. The EPA staff considers these comments credible and has set aside the St. Louis assessment results for PM_{10} light extinction. Thus, results and statements in this PA regarding PM_{10} light extinction apply to only the other 14 areas. However, results regarding $PM_{2.5}$ light extinction in most cases apply to all 15 study areas because the St. Louis estimates for $PM_{2.5}$ light extinction were not affected by the PM_{10} monitoring issue.

[14] PM-related light extinction is used here to refer to the light extinction caused by PM regardless of particle size; PM_{10} light extinction refers to the contribution by particles sampled through an inlet with a particle size 50% cutpoint of 10 μm diameter; and $PM_{2.5}$ light extinction refers to the contribution by particles sampled through an inlet with a particle size 50% cutpoint of 2.5 μm diameter.

[15] One example of an indicator and measurement approach for which indicator values could be higher than true PM light extinction as a result of fog would be a light extinction indicator measured in part by an unheated nephelometer, which is an optical instrument for measuring PM light scattering from an air sample as it flows through a measurement chamber. Rain drops would be removed by the initial size-selective inlet device, although some particles associated with fog may be small enough that they might pass through the inlet and enter the measurement chamber of the instrument. This would result in a reported scattering coefficient that does not correspond to true PM light extinction. Direct measurement of light extinction using an open-path instrument would be even more affected by both fog and precipitation.

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 not including many of the hours with meteorological causes of visibility impacts and the loss of public welfare protection of not including 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 15 urban areas included in the assessment for which meteorological data were obtained to allow an examination of the co-occurrence of high relative humidity and fog or precipitation, a 90% relative humidity cutoff criterion is effective in that on average less than 6% of the daylight hours are removed from consideration, yet those hours have on average ten times the likelihood of rain, six time the likelihood of snow/sleet, and 34 times the likelihood of fog compared with hours with 90% or lower relative humidity. Based on these findings, we conclude that it is appropriate that a sub-daily standard intended to protect against PM-related visibility impairment would be defined in such a way as to exclude hours with relative humidity greater than approximately 90%, regardless of measured values of light extinction or PM.

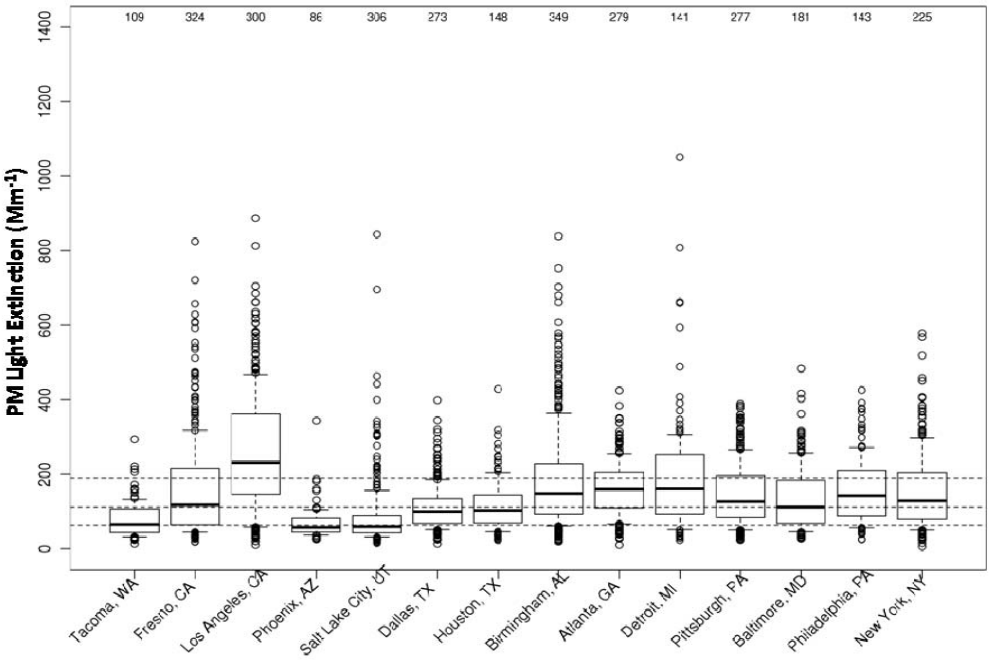
The UFVA analyses were done in terms of PM_{10} light extinction. Figure 4-3 (Figure 3-8 in UFVA) presents box-and-whisker plots to illustrate the distributions of the estimates of the daily maximum daylight 1-hour calculated PM_{10} light extinction levels in each area (excluding St. Louis) based on data from the 2005-2007 time period. The horizontal dashed lines in the plots represent the low, middle, and high CPLs for PM_{10} light extinction of 65, 110, and 190 Mm^{-1}, corresponding to the benchmark visual air quality values of 20, 25, and 30 dv, as discussed above. Table 4-2 (Table 3-7 in UFVA) provides the percentages of days (across all of 2005-2007, not seasonally weighted) in which the daily maximum daylight 1-hour PM_{10} light extinction level was greater than each of the three CPLs (excluding hours with relative humidity greater than 90%).

From these UFVA-based displays it can be seen that among these 14 urban areas, those in the East and in California tend to have a higher frequency of visibility conditions estimated to be above the high CPL compared with those in the western U.S. Both Figure 4-3 and Table 4-2 indicate that all 14 urban areas have daily maximum hourly PM_{10} light extinctions that are estimated to exceed even the highest CPL some of the days. Except for the two Texas areas and the non-California western urban areas, all of the other urban areas are estimated to exceed the high CPL from about 20% to over 60% of the days. We also note that all 14 of the urban areas are estimated to exceed the low CPL from about 40% to over 90% of the days.

Since the completion of the UFVA, EPA staff has repeated the UFVA-type modeling based on $PM_{2.5}$ light extinction and data from the 2007-2009 time period for the same 15 study areas (including St. Louis), as described in Appendix F. Figure 4-4 and Table 4-3 present the same type of information as do Figure 4-3 and Table 4-2, respectively, except for the $PM_{2.5}$ vs.

PM_{10} distinction and the use of data from a more recent time period. While the estimates of the percentage of daily maximum hourly $PM_{2.5}$ light extinction values exceeding the CPLs are somewhat lower than for PM_{10} light extinction, the patterns of these estimates across the study areas are similar. More specifically, except for the two Texas and the non-California western urban areas, all of the other urban areas are estimated to exceed the high CPL from about 10% up to about 50% of the days based on $PM_{2.5}$ light extinction, while all 15 areas are estimated to exceed the low CPL from over 10% to over 90% of the days.

Figure 4-3. Distribution of Estimated Daily Maximum Daylight 1-hour PM_{10} Light Extinction Across the 2005-2007 Period, by Study Area (excluding hours with relative humidity >90%). (Adapted from US EPA, 2010b, Figure 3-8)*

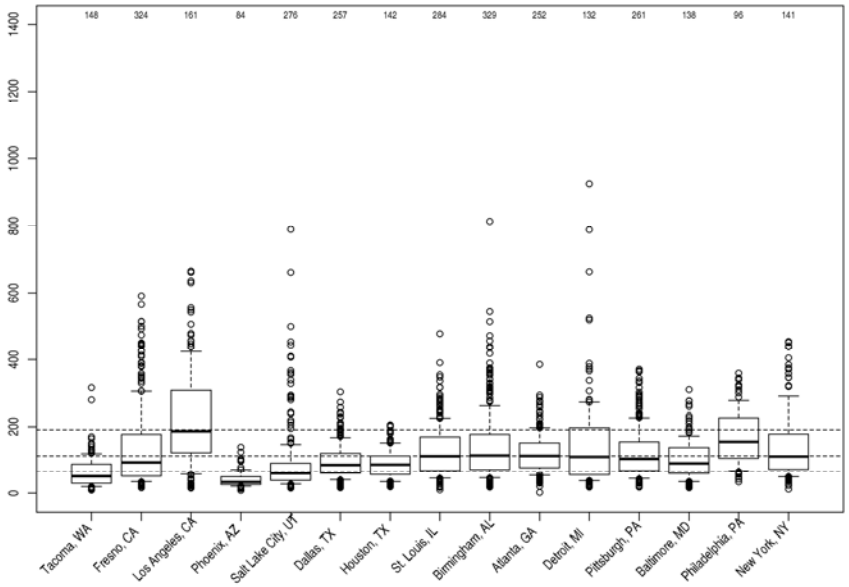


** In the box-and-whisker plot, the box represents the 25th - 75th percentile range; the whiskers represent the 10th and 90th percentiles; individual data points below the 10th percentile and above the 90th percentile are graphed as small circles. The three dashed horizontal lines represent the three CPL levels of 65, 110, and 190 Mm^{-1} (i.e., 20, 25, and 30 dv).*

Table 4-2. Percentage of 2005-2007 Daily Maximum Daylight Hourly Values of PM_{10} Light Extinction Exceeding CPLs (excluding hours with relative humidity >90%) (Adapted from Table 3-7 in UFVA)

Study Area	Number of Days with Estimates	Candidate Protection Level		
		20 dv	25 dv	30 dv
		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
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

Figure 4-4. Distribution of Estimated Daily Maximum Daylight 1-hour $PM_{2.5}$ Light Extinction Across the 2007-2009 Period, by Study Area (excluding hours with relative humidity >90%).*



** In the box-and-whisker plot, the box represents the 25th - 75th percentile range; the whiskers represent the 10th and 90th percentiles; 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 65, 110, and 190 Mm^{-1}(i.e., 20, 25, and 30 dv).*

Table 4-3. Percentage of 2007-2009 Daily Maximum Daylight Hourly Values of $PM_{2.5}$ Light Extinction Exceeding CPLs (excluding hours with relative humidity >90%)

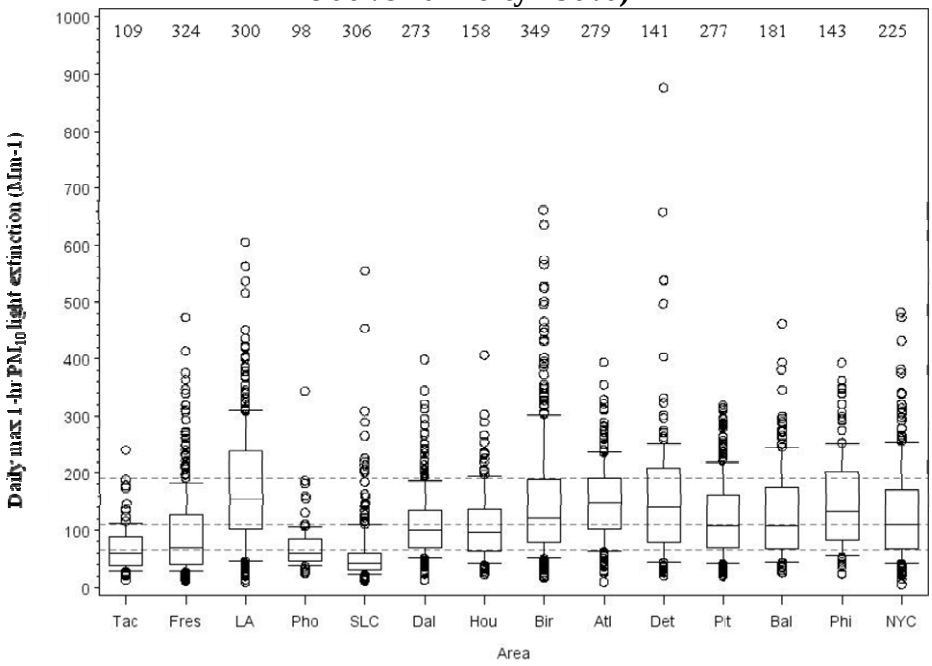
Study Area	Number of Days with Estimates	Candidate Protection Level		
		20 dv	25 dv	30 dv
		Percentage of Daily Maximum Hourly Values Exceeding CPL		
Tacoma	150	40	14	1
Fresno	325	66	43	22
Los Angeles	161	89	78	48
Phoenix	84	14	2	0
Salt Lake City	276	41	15	8
Dallas	257	72	30	5
Houston	144	70	25	2
St. Louis	287	78	49	17
Birmingham	330	79	51	21
Atlanta	258	85	49	12
Detroit	133	71	49	27
Pittsburgh	264	77	43	15
Baltimore	140	72	33	9
Philadelphia	98	92	71	34
New York	145	82	50	23

Visibility Levels That Just Meet Current Standards

We have also conducted analyses to assess the likelihood that PM-related visibility impairment would exceed CPLs for a 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. As describe in the UFVA, The steps needed to model this scenario involve explicit consideration of changes in $PM_{2.5}$ components. First, we applied proportional rollback to all the $PM_{2.5}$ monitoring sites in each study area, taking into account policy-relevant background (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 quantitative health risk assessment document (US EPA, 2010a) describes this air quality roll-back procedure in detail. The degree of rollback (i.e., the percentage reduction in non-PRB $PM_{2.5}$ mass) 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 needed 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 current $PM_{2.5}$ NAAQS 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 same percentage reduction from the first step 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 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 to calculate the PM_{10} light extinction.

In these analyses, we have estimated both PM_{10} and $PM_{2.5}$ light extinction in terms of both daily maximum 1-hour average values and multi-hour (i.e., 4-hour) average values for daylight hours. Figure 4-5 and Table 4-4 display the results of the rollback procedure as a box and whisker plot of daily maximum daylight 1-hour PM_{10} light extinction and the percentage of daily maximum hourly PM_{10} light extinction values estimated to exceed the CPLs when just meeting the current suite of $PM_{2.5}$ secondary standards (excluding hours with relative humidity greater than 90%). These displays show that the daily maximum 1-hour average values in all of the study areas other than the three western non-California areas are estimated to exceed the high CPL from 10% up to about 40% of the days and the middle CPL from 30% up to about 70% of the days, while all 14 areas are estimated to exceed the low CPL from over 20% to about 90% of the days.

Figure 4-5. Distribution of Daily Maximum Daylight 1-hour PM_{10} Light Extinction when Rolled Back to Just Meet Current $PM_{2.5}$ NAAQS, by Study Area * (excluding hours with relative humidity >90%)



** In the box-and-whisker plot, the box represents the 25th - 75th percentile range; the whiskers represent the 10th and 90th percentiles; 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 65, 110, and 190 Mm^{-1} (i.e., 20, 25, and 30 dv).*

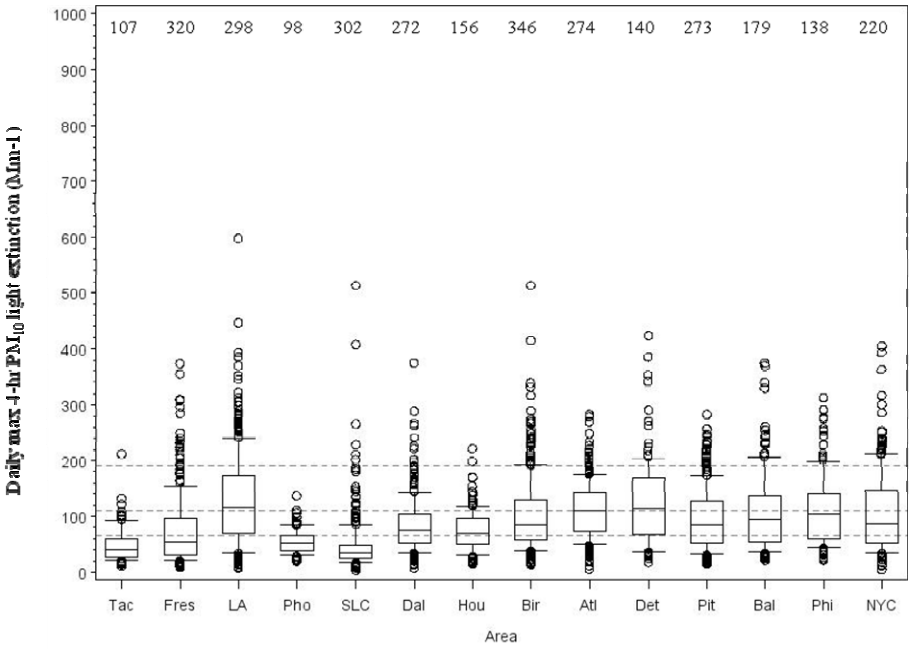
Table 4-4. Percentage of Daily Maximum Daylight Hourly Values of PM_{10} Light Extinction Exceeding CPLs When Just Meeting the Current $PM_{2.5}$ NAAQS (excluding hours with relative humidity >90%). (Adapted from Table 4-7 in UFVA)

Study Area	Number of Days with Estimates	Candidate Protection Level		
		20 dv	25 dv	30 dv
		Percentage of Daily Maximum Hourly Values Exceeding CPL		
Tacoma	109	40	12	1
Fresno	324	53	30	10
Los Angeles	300	85	70	39
Phoenix	98	44	7	1
Salt Lake City	306	23	10	4
Dallas	273	79	43	10
Houston	158	74	41	11
Birmingham	349	83	55	24
Atlanta	279	89	71	25
Detroit	141	80	61	33
Pittsburgh	277	77	49	17
Baltimore	181	76	49	20
Philadelphia	143	84	61	29
New York	225	76	49	19

Figure 4-6 and Table 4-5 show the same type of results for PM_{10} based on daily maximum 4-hour average values. While the estimates of the percentage of values exceeding the CPLs are lower than for 1-hour average light extinction, the patterns of these estimates across the study areas are similar. More specifically, the daily maximum 4-hour average values in all of the study areas other than the three western non-California areas and the two areas in Texas are estimated to exceed the high CPL from about 7% up to about 20% of the days and the middle CPL from about 20% up to over 50% of the days, while all 14 areas are estimated to exceed the low CPL from 15% to about 80% of the days.

A similar set of figures and tables have been developed in terms of $PM_{2.5}$ light extinction for all 15 areas considered in the UFVA (including St. Louis), as shown below. Figure 4-7 and Table 4-6 present results for $PM_{2.5}$ light extinction based on daily maximum 1-hour average values, and Figure 4-8 and Table 4-7 present results based on daily maximum 4-hour average values. These displays show that the daily maximum *1-hour* average $PM_{2.5}$ light extinction values in all of the study areas other than the three western non-California areas are estimated to exceed the high CPL from about 8% up to over 30% of the days and the middle CPL from about 30% up to about 70% of the days, while all areas except Phoenix are estimated to exceed the low CPL from over 15% to about 90% of the days. Further, the daily maximum *4-hour* average $PM_{2.5}$ light extinction values in all of the study areas other than the three western non-California areas and the two areas in Texas are estimated to exceed the high CPL from about 4% up to over 15% of the days and the middle CPL from about 15% up to about 45% of the days, while all areas except Phoenix are estimated to exceed the low CPL from over 10% to about 75% of the days.

Figure 4-6. Distribution of Daily Maximum Daylight 4-hour Average PM_{10} Light Extinction when Rolled Back to Just Meet Current $PM_{2.5}$ NAAQS, by Study Area* (excluding hours with relative humidity >90%)

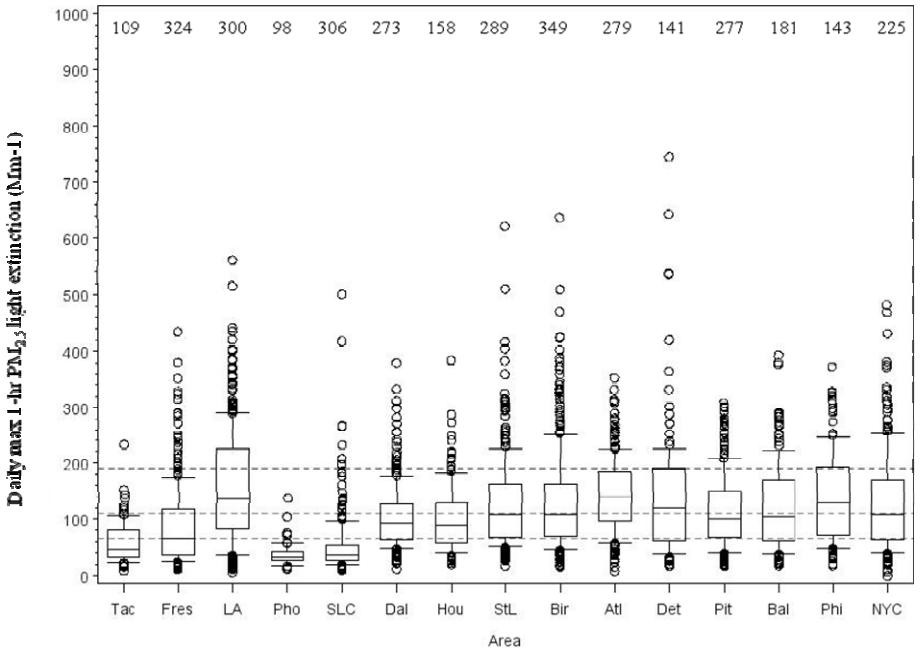


** In the box-and-whisker plot, the box represents the 25th - 75th percentile range; the whiskers represent the 10th and 90th percentiles; individual data points below the 10th percentile and above the 90th percentile are graphed as small circles. The three dashed horizontal lines represent the three CPL levels of 65, 110, and 190 Mm^{-1} (i.e., 20, 25, and 30 dv).*

Table 4-5. Percentage of Daily Maximum Daylight 4-Hour Average Values of PM_{10} Light Extinction Exceeding CPLs when Just Meeting the Current $PM_{2.5}$ NAAQS (excluding hours with relative humidity >90%)

Study Area	Number of Days with Estimates	Candidate Protection Level		
		20 dv	25 dv	30 dv
		Percentage of Daily Maximum Hourly Values Exceeding CPL		
Tacoma	107	22	3	1
Fresno	320	41	19	7
Los Angeles	298	77	53	20
Phoenix	98	30	2	0
Salt Lake City	302	15	6	2
Dallas	272	59	22	4
Houston	156	55	15	1
Birmingham	346	68	35	11
Atlanta	274	80	50	7
Detroit	140	76	51	14
Pittsburgh	273	63	34	8
Baltimore	179	67	36	13
Philadelphia	138	73	46	12
New York	220	63	35	13

Figure 4-7. Distribution of Daily Maximum Daylight 1-hour Average $PM_{2.5}$ Light Extinction when Rolled Back to Just Meet Current $PM_{2.5}$ NAAQS, by Study Area* (excluding hours with relative humidity >90%)

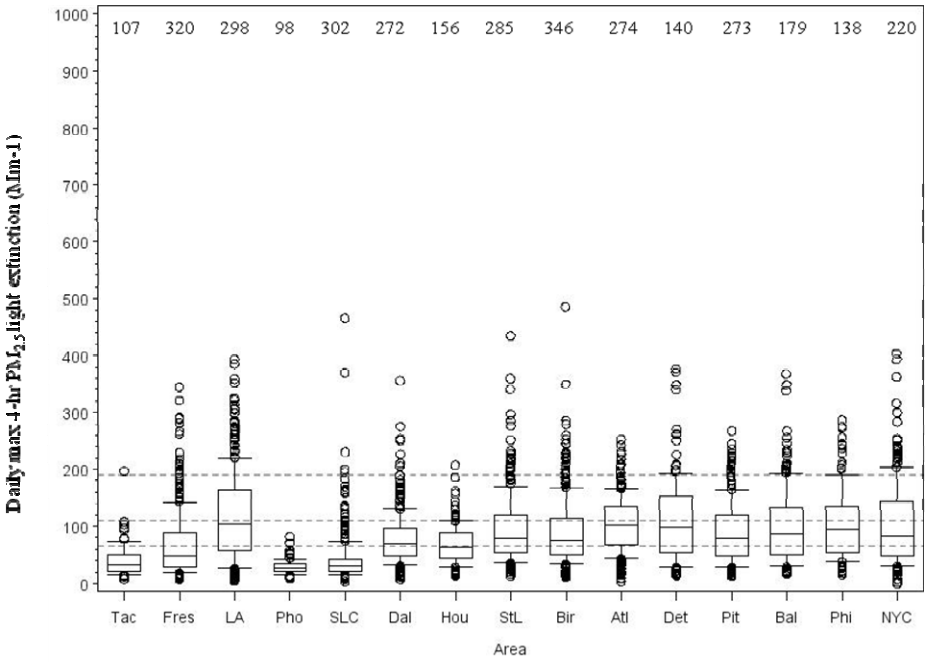


** In the box-and-whisker plot, the box represents the 25th - 75th percentile range; the whiskers represent the 10th and 90th percentiles; individual data points below the 10th percentile and above the 90th percentile are graphed as small circles. The three dashed horizontal lines represent the three CPL levels of 65, 110, and 190 Mm^{-1} (i.e., 20, 25, and 30 dv).*

Table 4-6. Percentage of Daily Maximum Daylight 1-Hour Average Values of $PM_{2.5}$ Light Extinction Exceeding CPLs when Just Meeting the Current $PM_{2.5}$ NAAQS (excluding hours with relative humidity >90%)

Study Area	Number of Days with Estimates	Candidate Protection Level		
		20 dv	25 dv	30 dv
		Percentage of Daily Maximum Hourly Values Exceeding CPL		
Tacoma	107	15	6	1
Fresno	320	37	28	9
Los Angeles	298	72	61	33
Phoenix	98	2	1	0
Salt Lake City	302	13	8	3
Dallas	272	54	38	8
Houston	156	45	35	8
St. Louis	285	61	48	17
Birmingham	346	62	48	17
Atlanta	274	76	68	20
Detroit	140	65	53	26
Pittsburgh	273	61	45	14
Baltimore	179	62	45	18
Philadelphia	138	67	57	25
New York	220	59	48	19

Figure 4-8. Distribution of Daily Maximum Daylight 4-hour Average $PM_{2.5}$ Light Extinction when Rolled Back to Just Meet Current $PM_{2.5}$ NAAQS, by Study Area* (excluding hours with relative humidity >90%)



** In the box-and-whisker plot, the box represents the 25th - 75th percentile range; the whiskers represent the 10th and 90th percentiles; 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 65, 110, and 190 Mm^{-1} (i.e., 20, 25, and 30 dv).*

Table 4-7. Percentage of Daily Maximum Daylight 4-Hour Average Values of $PM_{2.5}$ Light Extinction Exceeding CPLs when Just Meeting the Current $PM_{2.5}$ NAAQS (excluding hours with relative humidity >90%)

Study Area	Number of Days with Estimates	Candidate Protection Level		
		20 dv	25 dv	30 dv
		Percentage of Daily Maximum Hourly Values Exceeding CPL		
Tacoma	107	15	1	1
Fresno	320	37	16	6
Los Angeles	298	72	45	16
Phoenix	98	2	0	0
Salt Lake City	302	13	6	2
Dallas	272	54	18	3
Houston	156	45	8	1
St. Louis	285	61	30	7
Birmingham	346	62	28	7
Atlanta	274	76	42	4
Detroit	140	65	45	10
Pittsburgh	273	61	30	6
Baltimore	179	62	31	10
Philadelphia	138	67	39	10
New York	220	59	35	12

4.2.2 CASAC Advice

In our consideration of the adequacy of the current suite of $PM_{2.5}$ secondary standards, in addition to the evidence- and impact-based information discussed above, we have also considered the advice of CASAC, based on its review of drafts of the ISA and the UFVA, and drafts of this document, as well as comments from the public on earlier drafts of this document and the UFVA. In its comments on the second draft PA, CASAC stated agreement with EPA staff's conclusion that the "currently available information clearly calls into question the adequacy of the current standards and that consideration should be given to revising the suite of standards to provide increased public welfare protection" (Samet, 2010d, p. iii). CASAC noted that the detailed estimates of hourly PM light extinction associated with just meeting the current standards "clearly demonstrate that current standards do not protect against levels of visual air quality which have been judged to be unacceptable in all of the available urban visibility preference studies." Further, CASAC stated, with respect to the current suite of $PM_{2.5}$ secondary standards, that "[T]he levels are too high, the averaging times are too long, and the $PM_{2.5}$ mass indicator could be improved to correspond more closely to the light scattering and absorption properties of suspended particles in the ambient air" (Samet, 2010d, p. 9).

4.2.3 Staff Conclusions on Adequacy of Current Standards

Taking into account the above considerations, EPA staff concludes 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 visibility impairment, primarily in urban areas, and supports consideration of alternative standards to provide appropriate protection.

This conclusion is based in part on the large percentage of days, in many urban areas, that exceed the range of CPLs identified for consideration under simulations of conditions that would just meet the current suite of $PM_{2.5}$ secondary standards. In particular, for air quality that is simulated to just meet the current standards, for 9 of the 14 or 15 urban areas greater than 10% of the days are estimated to exceed the highest, least protective CPL of 30 dv in terms of PM_{10} and $PM_{2.5}$ light extinction, respectively, based on 1-hour average values, and would thus likely fail to meet a 90^{th} percentile-based standard at that level. For these areas, the percent of days estimated to exceed the highest CPL ranges from approximately 10% to 40%. Similarly, when the middle CPL of 25 dv is considered, for 11 of the 14 or 15 urban areas greater than 30% up to over 70% of the days are estimated to exceed that CPL in terms of PM_{10} and $PM_{2.5}$ light extinction, respectively, based on 1-hour average values. Based on a 4-hour averaging time, 5 or 6 of the areas were estimated to have at least 10% of the days exceeding the highest CPL in terms of $PM_{2.5}$ and PM_{10} light extinction, respectively, and 8 or 11 of the areas were estimated to have

greater than 30% of the days exceeding the middle CPL in terms of $PM_{2.5}$ and PM_{10} light extinction, respectively. For the lowest CPL of 20 dv, the percentages of days estimated to exceed that CPL are even higher for all cases considered. Based on all of the above, we conclude that PM light extinction estimated to be associated with just meeting the current suite of $PM_{2.5}$ secondary standards in many areas across the country exceeds levels and percentages of days that could reasonably be considered to be important from a public welfare perspective.

Further, we conclude that use of the current indicator of $PM_{2.5}$ mass, in conjunction with the current 24-hour and annual averaging times, is clearly called into question for a national standard intended to protect public welfare from PM-related visibility impairment. This is because such a standard is inherently confounded by regional differences in relative humidity and species composition of $PM_{2.5}$, which are critical factors in the relationship between the mix of fine particles in the ambient air and the associated impairment of visibility. We note that this concern was one of the important elements in the court's decision to remand the $PM_{2.5}$ secondary standards set in 2006 to the Agency, as discussed above in section 4.1.2.

Thus, beyond concluding that the available information clearly calls into question the adequacy of the protection against PM-related visibility impairment afforded by the current suite of $PM_{2.5}$ standards, we also conclude that it clearly calls into question the appropriateness of each of the current standard elements: indicator, averaging time, form, and level. Section 4.3 below discusses considerations related to each of these elements in its discussion of alternative standards for consideration.

4.3 CONSIDERATION OF ALTERNATIVE STANDARDS

Having reached the conclusion that the available information clearly calls into question the adequacy and appropriateness of the current suite of $PM_{2.5}$ standards, this section considers a second overarching question:

What alternative fine particle standards are supported by the currently available scientific evidence and impact-based information, as reflected in the ISA and UFVA?

In addressing this question, we have posed a series of more specific questions to inform decisions regarding the basic elements of the NAAQS: indicator (section 4.3.1), averaging time (section 4.3.2), form (section 4.3.3), and level (section 4.3.4). These elements are considered collectively in evaluating the welfare protection afforded by alternative standards under consideration.

4.3.1 Indicator

4.3.1.1 Evidence-based and Impact-based Considerations

- **To what extent does currently available information provide support for considering a different indicator for PM to replace the current $PM_{2.5}$ mass indicator?**

As described below, EPA staff has considered three indicators: the current $PM_{2.5}$ mass indicator and two alternative indicators, including directly measured $PM_{2.5}$ light extinction and calculated $PM_{2.5}$ light extinction.[16] Directly measured $PM_{2.5}$ light extinction is a measurement (or combination of measurements) of the light absorption and scattering caused by $PM_{2.5}$ under ambient conditions. Calculated $PM_{2.5}$ light extinction uses the IMPROVE algorithm to calculate $PM_{2.5}$ light extinction using measured $PM_{2.5}$ mass and/or measured PM components and relative humidity.[17]

We believe that consideration of the use of either directly measured $PM_{2.5}$ light extinction or calculated $PM_{2.5}$ light extinction as an indicator is justified because light extinction is a physically meaningful measure of the ambient $PM_{2.5}$ characteristic that is most relevant and directly related to PM-related visibility effects. Further, as noted in section 4.2.1 above, $PM_{2.5}$ is the component of PM responsible for most of the visibility impairment in most urban areas. In these areas, the contribution of $PM_{10–2.5}$ is a minor contributor to visibility impairment most of the time, although at some locations (see UFVA Figure 3-13 for Phoenix) $PM_{10–2.5}$ can be a major contributor to urban visibility effects. Few urban areas conduct continuous $PM_{10\text{-}2.5}$ monitoring. For example, among the 15 urban areas featured in the UFVA, only four areas had collocated continuous PM_{10} data allowing calculation of hourly $PM_{10\text{-}2.5}$ data for 2005-2007. In the absence of $PM_{10\text{-}2.5}$ air quality information from a much larger number of urban areas across the country, it is not possible at this time to know in how many urban areas $PM_{10–2.5}$ is a major contributor to urban visibility effects, though it is reasonable to assume that other urban areas in the desert southwestern region of the country may have conditions similar to the conditions shown for Phoenix. $PM_{10\text{-}2.5}$ is generally less homogenous in urban areas than $PM_{2.5}$, making it more challenging to select sites that would adequately represent urban visibility conditions. While it would be possible to include a $PM_{10–2.5}$ light extinction term in a calculated light extinction indicator, as was done in the UFVA, there is insufficient information available at this

[16] In the second draft PA, this indicator was referred to as speciated $PM_{2.5}$ mass calculated light extinction.

[17] In 2009, the D.C. Circuit remanded the secondary $PM_{2.5}$ standards to the Agency in part because EPA did not address the problem that a $PM_{2.5}$ mass-based standard using a daily averaging time would be confounded by regional differences in relative humidity, although EPA had acknowledged this problem (as discussed above in section 4.1.2). We note that both of the light extinction indicators considered in this assessment explicitly take into account differences in relative humidity in areas across the country.

time to assess the impact and effectiveness of such a refinement in providing public welfare protection in areas across the country.

The basis for considering each of these three indicators is discussed below. The discussion also addresses monitoring data requirements for directly measured $PM_{2.5}$ light extinction and for calculated $PM_{2.5}$ light extinction. The following discussion also takes into consideration different averaging times since the combination of indicator and averaging time is relevant to understanding the monitoring data requirements. Consideration of alternative averaging times is addressed more specifically in the next section (section 4.3.2) on averaging time.

$PM_{2.5}$ Mass Indicator

$PM_{2.5}$ mass monitoring methods are in widespread use, including the Federal Reference Method (FRM) involving the collection of periodic (usually 1-day-in-6 or 1-day-in-3) 24-hour filter samples. Blank and loaded filters are weighed to determine 24-hour $PM_{2.5}$ mass. Continuous $PM_{2.5}$ monitoring produces hourly average mass concentrations and is conducted at about 900 locations. About 180 of these locations employ newer model continuous instruments that have been approved by EPA as federal equivalent methods (FEM), although we note that FEM approval has been based only on 24-hour average, not hourly, $PM_{2.5}$ mass. These routine monitoring activities do not include measurement of the full water content of the ambient $PM_{2.5}$ that contributes, often significantly, to visibility impacts.[18] Further, the $PM_{2.5}$ mass concentration monitors do not provide information on the composition of the ambient $PM_{2.5}$, which plays a central role in the relationship between PM-related visibility impairment and ambient $PM_{2.5}$ mass concentrations.[19]

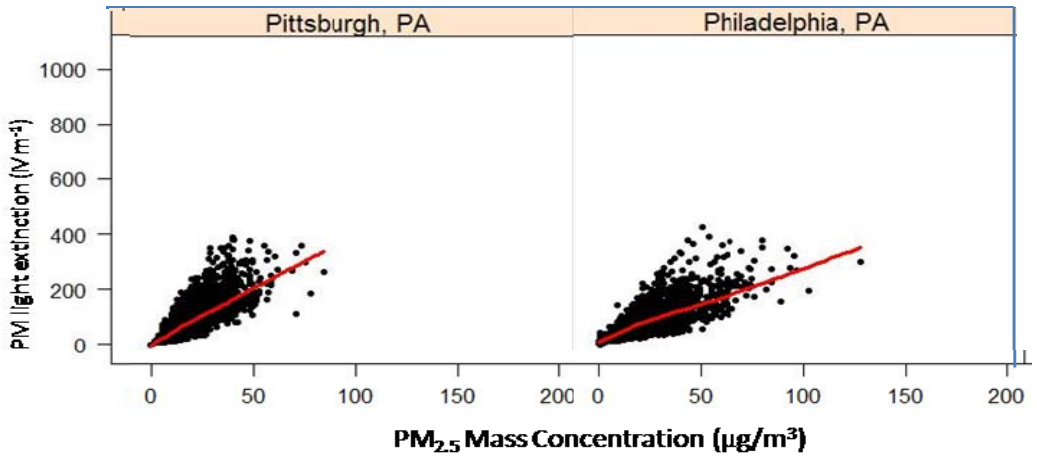
The overall performance of 1-hour average $PM_{2.5}$ mass as a predictor of PM-related visibility impairment as indicated by PM_{10} light extinction can be seen in scatter plots shown in Figure 4-9 for two illustrative urban areas, Pittsburgh and Philadelphia, PA. (Similar plots for all 14 urban areas are in Appendix D, Figure D-2 of the UFVA). These illustrative examples demonstrate the large variations in hourly PM_{10} light extinction corresponding to any specific level of hourly $PM_{2.5}$ mass concentration as well as differences in the statistical average relationships (depicted as the best fit lines) between cities. This poor correlation between hourly

[18] FRM filters are stabilized in a laboratory at fixed temperature and relative humidity levels, which alters whatever water content was present on the filter when removed from the sampler. FEM instruments are designed to meet performance criteria compared to FRM measurements, and accordingly typically manage temperature and/or humidity at the point of measurement to levels that are not the same as ambient conditions.

[19] As discussed below, 24-hour average $PM_{2.5}$ chemical component mass is measured at about 200 sites in the EPA/state/local Chemical Speciation Network.

PM_{10} light extinction and hourly $PM_{2.5}$ mass is not due to any great extent to the contribution of $PM_{10-2.5}$ to light extinction, but rather is principally due to the impact of the water content of the particles on light extinction, which depends on both the composition of the $PM_{2.5}$ and the ambient relative humidity. Both composition and especially relative humidity vary during a single day, as well as from day to day, at any site and time of year. This contributes to the noisiness of the relationship at any site and time of year. Also, there are systematic regional and seasonal differences in the distribution of ambient humidity and $PM_{2.5}$ composition conditions that make it impossible to select a $PM_{2.5}$ concentration that generally would correspond to the same PM-related light extinction levels across all areas of the nation.

Figure 4-9. Relationship between Daylight 1-hour $PM_{2.5}$ Mass Concentration vs. Same-Hour PM_{10} Calculated Light Extinction for Two Cities (from UFVA Appendix D, Figure D2)



As part of the UFVA, we conducted an assessment that estimated PM_{10} light extinction levels that may prevail if areas were simulated to just meet a range of alternative secondary standards based on hourly $PM_{2.5}$ mass as the indicator. Appendix E contains the results of this rollback-based assessment. This assessment quantifies the projected uneven protection, noted qualitatively above, that would result from the use of 1-hour average $PM_{2.5}$ mass as the indicator.

Directly Measured $PM_{2.5}$ Light Extinction Indicator

PM light extinction is the major contributor 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. The net result is that PM light extinction has a nearly

one-to-one relationship to light extinction, unlike $PM_{2.5}$ mass concentration. As explained above, $PM_{2.5}$ is the component responsible for the large majority of PM_{10} light extinction in most places and times. $PM_{2.5}$ light extinction can be directly measured. Direct measurement of $PM_{2.5}$ light extinction can be accomplished using several instrumental methods, some of which have been used for decades to routinely monitor the two components of $PM_{2.5}$ light extinction (light scattering and absorption) or to jointly measure both as total light extinction (from which Rayleigh scattering is subtracted to get $PM_{2.5}$ light extinction). There are a number of advantages to direct measurements of light extinction for use in a secondary standard relative to estimates of $PM_{2.5}$ light extinction calculated using $PM_{2.5}$ mass and speciation data, as was done to generate hourly light extinction values for the UFVA and as would be done for the calculated $PM_{2.5}$ light extinction indicator approach discussed below. These include greater accuracy of direct measurements with shorter averaging times and overall greater simplicity when compared to the need for measurements of multiple parameters to calculate PM light extinction.

As part of the UFVA, we conducted an assessment that estimated PM_{10} light extinction levels that may prevail in 14 urban study areas if the areas were simulated to just meet a secondary standard based on directly measured hourly PM_{10} light extinction as the indicator (see section 4.3 of the UFVA).[20] As would be expected, this assessment indicated that a secondary standard based on a directly measured PM_{10} light extinction indicator would provide the same percentage of days having indicator values above the level of the standard in each of the areas, with the percentage being dependent on the statistical form of the standard. We consider this assessment reasonably informative for a directly measured $PM_{2.5}$ light extinction indicator as well, because in most of the UFVA study areas PM_{10} light extinction is dominated by $PM_{2.5}$ light extinction.

In evaluating whether direct measurement of $PM_{2.5}$ or PM_{10} light extinction is appropriate to consider in the context of this PM NAAQS review, EPA produced a White Paper on Particulate Matter (PM) Light Extinction Measurements (US EPA, 2010h), and solicited comment on the White Paper from the Ambient Air Monitoring and Methods Subcommittee (AAMMS) of CASAC. In its review of the White Paper (Russell and Samet, 2010), the AAMMS made the recommendation to EPA that consideration of direct measurement should be limited to $PM_{2.5}$ light extinction as this can be accomplished by a number of commercially available instruments and because $PM_{2.5}$ is generally responsible for most of the PM visibility impairment in urban areas. The AAMMS indicated that it is technically more challenging at this time to accurately measure the $PM_{10-2.5}$ component of light extinction.

[20] This assessment was conducted prior to staff's decision to focus on $PM_{2.5}$ light extinction indicators in this PA.

The AAMMS not only endorsed the concept of direct measurement of $PM_{2.5}$ light extinction, but also commented on the capabilities of currently available instruments, and expressed optimism regarding the near-term development of even better instruments for such measurement than are now commercially available. The AAMMS advised against choosing any currently available commercial instrument, or even a general measurement approach, as a Federal Reference Method because to do so could discourage development of other potentially superior approaches. Instead, the AAMMS recommended that EPA develop performance-based approval criteria for direct measurement methods in order to put all approaches on a level playing field. Such criteria would necessarily include procedures and pass/fail requirements for demonstrating that the performance criteria have been met. For example, instruments might be required to demonstrate their performance in a wind tunnel, where the concentration of $PM_{2.5}$ components, and thus of $PM_{2.5}$ light extinction, could be controlled to known values. It might also be possible to devise approval testing procedures based on operation in ambient air, although knowing the true light extinction level (without in effect treating some particular instrument as if it were the FRM) would be more challenging. At the present time, EPA has not undertaken to develop and test such performance-base approval criteria. The EPA anticipates that if an effort were begun it would take at least several years before such criteria would be ready for regulatory use.

Calculated $PM_{2.5}$ Light Extinction Indicator

As discussed above in section 4.2.1, $PM_{2.5}$ light extinction can be calculated from $PM_{2.5}$ mass speciation data plus relative humidity data, as is presently routinely done on a 24-hour average basis under the Regional Haze Program using data from the rural IMPROVE monitoring network. This same calculation procedure, using a 24-hour average basis, could also be used for a NAAQS focused on protecting against PM-related visibility impairment primarily in urban areas using the type of data that is routinely collected from the urban CSN.[21] This calculation procedure, using the light extinction equations presented above in section 4.2.1 on a 24-hour basis, does not require $PM_{2.5}$ mass concentration measurements.

Alternatively, a conceptually similar approach could be applied in urban areas on an hourly or multi-hour basis. Applying this conceptual approach on a sub-daily basis would involve translating 24-hour speciation data into hourly estimates of species concentrations, using 24-hour average species concentrations in conjunction with hourly $PM_{2.5}$ mass concentrations.

[21] About 200 sites in the EPA/state/local CSN routinely measure 24-hour average $PM_{2.5}$ chemical components using filter-based samplers and chemical analysis in a laboratory, on either a 1-day-in-3 or 1-day-in-6 schedule, see Appendix B, section B.1.3..

This translation can be made using more or less complex alternative approaches, as discussed below.

The approach used to generate hourly PM_{10} light extinction for the UFVA was a relatively more complex method for implementing such a conceptual approach. It involved the use of the original IMPROVE algorithm[22] with estimates of hourly $PM_{2.5}$ components derived from day-specific 24-hour and hourly measurements of $PM_{2.5}$ mass, 24-hour measurements of $PM_{2.5}$ composition, and (for some but not all study sites) hourly $PM_{10-2.5}$ mass, along with hourly relative humidity information (UFVA, Section 3.3). The UFVA approach also involved the use of output from a chemical transport modeling run to provide initial estimates of diurnal profiles for $PM_{2.5}$ components at particular sites. The UFVA approach entailed numerous and complex data processing steps to generate hourly $PM_{2.5}$ composition information from these less time-resolved data, including application of a mass-closure approach, referred to as the SANDWICH approach (Frank, 2006), to adjust for nitrate retention differences between FRM and CSN filters, which is a required step for consistency with the IMPROVE algorithm and for estimating organic carbonaceous material via mass balance.[23] The EPA staff employed complex custom software to do these data processing steps. While the complexity of the approach used in the UFVA was reasonable for assessment purposes at 14 urban areas, we recognize that a relatively more simple approach would be more straightforward and have greater transparency, and thus should be considered for purposes of a national standard.[24] Therefore, we evaluated the degree to which simpler approaches would correlate with the results of the highly complex method used in the UFVA. This evaluation of two specific simpler approaches (described briefly below and in more detail in Appendix F, especially Table F-1) demonstrated that the $PM_{2.5}$ portions of the PM_{10} light extinction values developed for the UFVA can be well approximated using the same IMPROVE algorithm applied to hourly $PM_{2.5}$ composition values that were much more simply generated than with the method used in the UFVA.

The simplified approaches we examined are aimed at calculating hourly $PM_{2.5}$ light extinction using the original IMPROVE algorithm (see section 4.2.1 above) excluding the Rayleigh term for light scattering by atmospheric gases and the term for $PM_{10-2.5}$.[25] Initially, this

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[22] The original IMPROVE algorithm was selected for the described analysis in the UFVA because of its simplicity relative to the revised algorithm.

[23] Daily temperature data were also used as part of the SANDWICH method.

[24] The sheer size of the ambient air quality, meteorological, and chemical transport modeling data files involved with the UFVA approach would make it very difficult for state agencies or any interested party to consistently apply such an approach on a routine basis for the purpose of implementing a national standard defined in terms of the UFVA approach.

[25] The original IMPROVE algorithm was the basis for the approaches considered here to maintain comparability to the estimates developed in the UFVA. This allowed the effects of other simplifications relative to the UFVA approach to be better discerned.

leaves five $PM_{2.5}$ species concentration terms (i.e., sulfate, nitrate, organic carbonaceous mass, elemental carbon, and fine soil/crustal), plus relative humidity that need to be determined on an hourly basis from monitoring data. For a given time period, this algorithm with its five species concentration terms can be algebraically rearranged to a two-term algorithm (Pitchford, 2010), as shown in the equation below. The rearranged algorithm relates $PM_{2.5}$ light extinction to the product of $PM_{2.5}$ mass concentration and the sum of dry light extinction efficiency (DLEE) plus moist light extinction efficiency (MLEE). As its name suggests, DLEE accounts for light extinction (per microgram per cubic meter of air) that would occur if relative humidity were very low. MLEE accounts for the increment of light extinction associated with the water content of the $PM_{2.5}$ and thus is a function of both species composition and ambient relative humidity.

$$PM_{2.5} \text{ light extinction} \approx PM_{2.5} \times (DLEE + MLEE)$$

where DLEE is dependent only on the relative amounts of dry $PM_{2.5}$ components as measured in CSN-type sampling, and MLEE is 3 times the hygroscopic fraction (HF) of the $PM_{2.5}$ (the sulfate plus nitrate component concentrations divided by the sum of all components) times a non-linear function of relative humidity. The non-linear function of relative humidity is simply f(RH)-1, where f(RH) represents the humidity adjustment factor of the original IMPROVE algorithm.

$$MLEE = 3 \times HF \times [f(RH)-1]$$

MLEE is zero for relative humidity below 40% and increases with increasing relative humidity to be comparable to or greater than DLEE as relative humidity approaches 90%, depending on the HF.

Given this algorithm structure and the goal of estimating $PM_{2.5}$ light extinction for as many 1-hour periods as possible, we focused on two alternative approaches to determining values for DLEE and HF for 1-hour periods that are based on using hourly measured relative humidity. One approach (designated as "T" in Appendix F) is based on calculating 24-hour values of DLEE and HF for each day of speciated sampling, averaging these together within each calendar month to allow for seasonal variability, and applying the results to each daylight hour of the respective month for which hourly $PM_{2.5}$ mass data are available. A feature of this approach is that values of DLEE and HF are available for use with hourly $PM_{2.5}$ mass measurements taken on days that were not speciated sampling days. Thus, this approach would allow the full history of daylight hourly $PM_{2.5}$ mass concentrations and relatively humidity levels to be used in calculating $PM_{2.5}$-related light extinction.

A second approach (designated as "W" in Appendix F) is based on calculating 24-hour values of DLEE and HF for each day of speciated sampling and applying the results only to

daylight hours within the respective speciated sampling day. No estimates of hourly $PM_{2.5}$ light extinction would be generated on days without speciated sampling. By recognizing that DLEE and HF can vary from day to day within a month, this approach may provide somewhat more accurate estimates of hourly $PM_{2.5}$ light extinction for those hours for which estimates are made, although calculations of $PM_{2.5}$-related light extinction would be limited to air quality data gathered on only a fraction of the days in each year.

A more detailed description of the sources of the data and steps required to determine calculated $PM_{2.5}$ light extinction by approaches T and W is contained in Appendix F (see Table F-2). Also, Table F-1 of Appendix F compares/contrasts each of these approaches with the UFVA approach and with each other.

The $PM_{2.5}$ light extinction values generated by using either approach T or approach W are comparable to those developed for use in the UFVA as indicated by the regression statistics for scatter plots of the paired data (i.e., slopes of the regression equation and R^2 values are near 1 as show in Tables F-3 and F-4 in Appendix F). Because the UFVA had no way of providing estimates of $PM_{2.5}$ light extinction on days that were not CSN sampling days, we have not assessed how well approach T estimates $PM_{2.5}$ light extinction on such days. Also, Appendix F notes that approaches T and W both underestimate $PM_{2.5}$ light extinction on some days in a few study areas, which we attribute to the occurrence of very high nitrate concentrations and the failure of the FRM-correlated/adjusted FEM instrument to report the entire nitrate mass. Nevertheless, we believe that each of these simplified approaches provides reasonably good estimates of $PM_{2.5}$ light extinction and each is appropriate to consider as the indicator for a new secondary standard. In addition, there are variations of approaches T and W that may also be appropriate to consider. For example, some variations that may improve the correlation with actual ambient light extinction in certain areas of the country include the use of the split mass term approach from the revised IMPROVE algorithm,[26] the use of more refined value(s) for the organic carbon multiplier (see Appendix F), and the use of the reconstructed 24-hour $PM_{2.5}$ mass (i.e., the sum of the five $PM_{2.5}$ components from speciated monitoring) as a normalization value for the hourly measurements from the $PM_{2.5}$ instrument as a way of better reflecting ambient nitrate concentrations. Other variations may serve to simplify the calculation of $PM_{2.5}$ light extinction values, such as those suggested by CASAC for consideration, including the use of historical monthly or seasonal speciation averages as well as speciation estimates on a regional basis (Samet, 2010d, p. 11).

[26] If the revised IMPROVE algorithm were used to define the speciated $PM_{2.5}$ mass-based indicator, it would not be possible to algebraically reduce the revised algorithm to a two-factor version as described above and in Appendix F for approaches T and W. Instead, five component fractions would be determined from each day of speciated sampling, and then either applied to hourly measurements of $PM_{2.5}$ mass on the same day (as in approach W) or averaged across a month and then applied to measurements of $PM_{2.5}$ mass on each day of the month.

As mentioned above, as part of the UFVA, we conducted an assessment of PM_{10} light extinction levels that would prevail if areas met a standard based on directly measured hourly PM_{10} light extinction as the indicator. This assessment indicated that a standard based on a directly measured PM_{10} light extinction indicator would provide the same percentage of days having indicator values above the level of the standard across areas, with the percentage being dependent on the statistical form of the standard. This assessment was based on the more complex UFVA approach to estimating PM_{10} light extinction, rather than the simpler T and W approaches for estimating $PM_{2.5}$ light extinction. Nevertheless, the generally close correspondence between UFVA-consistent design values for $PM_{2.5}$ light extinction and design values based on approaches T and W (see Figure F-5 in Appendix F) suggest that the findings regarding the protection offered by alternative PM_{10} light extinction standards using a directly measured light extinction would also hold quite well for standards based on the T or W indicators.[27] Thus, we conclude that the use of a calculated $PM_{2.5}$ light extinction indicator would provide a much higher degree of uniformity in terms of the visibility levels across the country than is possible using $PM_{2.5}$ mass as the indicator. This is due to the fact that the $PM_{2.5}$ mass indicator does not account for the effects of humidity and $PM_{2.5}$ composition differences between various regions, while a calculated $PM_{2.5}$ light extinction indicator directly incorporates those effects.

The inputs that would be necessary to use either approach T or W to calculate a sub-daily $PM_{2.5}$ light extinction indicator (e.g., 1- or 4-hour averaging time) include $PM_{2.5}$ chemical speciation, relative humidity, and hourly $PM_{2.5}$ mass measurements. In defining a standard in terms of such an indicator, the criteria for allowable protocols for these inputs would need to be specified. It would be appropriate to base these criteria on the protocols utilized in the IMPROVE[28] and CSN networks, as well as sampling and analysis protocols for ambient relative humidity sensors, and approved FEM mass monitors for $PM_{2.5}$. Any approach to approving methods for use in calculating a light extinction indicator should take advantage of the existing inventory of monitoring and analysis methods.

The CSN measurements have a strong history of being reviewed by CASAC technical committees, both during their initial deployment about ten years ago,[29] and during the more

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[27] The degree of emission reduction needed to meet a standard is tightly tied to the degree to which the design value exceeds the level of the standard.

[28] Several monitoring agencies utilize IMPROVE in urban areas to meet their chemical speciation monitoring needs. These sites are known as IMPROVE-protocol stations.

[29] Notification of a Consultation on the $PM_{2.5}$ Chemical Speciation Network & Supersites Plan, EPA-SAB-CASAC-CON-99-007; Advisory on the $PM_{2.5}$ Monitoring Program, EPA-SAB-CASAC-ADV-99-002; CASAC Advisory on the $PM_{2.5}$ Monitoring Network, EPA-SAB-CASAC-ADV-00-006

recent transition to carbon sampling that is consistent with the IMPROVE protocols.[30] Because the methods for the CSN are well documented in a nationally implemented Quality Assurance Project Plan (QAPP) and accompanying SOPs, are validated through independent performance testing, and are used to meet multiple data objectives (e.g., source apportionment, trends, and as an input to health studies), consideration should be given to an approach that utilizes the existing methods as the basis for criteria for allowable sampling and analysis protocols for purposes of a calculated light extinction indicator. Such an approach of basing criteria on the current CSN and IMPROVE methods provides a nationally consistent way to provide the chemical species data used in the light extinction calculation, while preserving the opportunity for improved methods for measuring the chemical species. For relative humidity, consideration should be given to simply using criteria based on available relative humidity sensors such as already utilized by the National Oceanic and Atmospheric Administration (NOAA) at routine weather stations. These relative humidity sensors are already widely used by a number of monitoring agencies and can be easily compared to other relative humidity measurements. Finally, approaches T and W depend on having values of hourly $PM_{2.5}$ mass, as discussed below.

Since 2008, EPA has approved several $PM_{2.5}$ continuous mass monitoring methods as FEMs.[31] These methods have several advantages over filter-based FRMs, such as producing hourly data and the ability to report air quality information in near real-time. However, initial assessments of the data quality as operated by State and local monitoring agencies have mixed results. A recent assessment of continuous FEMs and collocated FRMs conducted by EPA staff (Hanley and Reff, 2011) found some sites and continuous FEM instruments to have an acceptable degree of comparability of 24-hour average $PM_{2.5}$ mass values derived from continuous FEMs and filter-based FRMs, while others had poor data quality that would not meet current data quality objectives. The EPA is working closely with the monitoring committee of the National Association of Clean Air Agencies, instrument manufacturers, and monitoring agencies to document and communicate best practices on these methods to improve quality and consistency of resulting data. It should be noted that performance testing submitted to EPA for purposes of designating the $PM_{2.5}$ continuous methods as FEMs, and the recent assessment of collocated FRMs and continuous FEMs, are both based on 24-hour sample periods. Therefore, we do not have similar performance data for continuous $PM_{2.5}$ FEMs for 1-hour or 4-hour averaging periods, nor is there an accepted practice to generate performance standards for these time periods. Until issues regarding the comparability of 24-hour $PM_{2.5}$ mass values derived

[30] EPA's Final Draft National Ambient Air Monitoring Strategy - An Advisory by the Ambient Air Monitoring and Methods Subcommittee of the EPA Clean Air Scientific Advisory Committee, EPA-SAB-CASAC-05-006

[31] EPA maintains a list of designated Reference and Equivalent Methods on the web at: http://www.epa.gov/ttn/amtic/files/ambient/criteria/reference-equivalent-methods-list.pdf

from continuous FEMs and filter-based FRMs are resolved, there is reason to be cautious about relying on a calculation procedure that uses hourly $PM_{2.5}$ mass values reported by continuous FEMs and speciated mass values from 24-hour filter-based samplers. Section 4.3.2.1 discusses another reason for such caution, based on a preliminary assessment of hourly data from continuous FEMs.

This section has addressed the types of measurements that would be necessary to support a calculated $PM_{2.5}$ light extinction indicator for either 24-hour or sub-daily (e.g., 1-hour and 4-hour) averaging periods. Considerations related specifically to each of these alternative averaging times, in conjunction with a standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator, are discussed below in section 4.3.2.

4.3.1.2 CASAC Advice on Indicator

Based on its review of the second draft PA, CASAC stated that it " overwhelmingly . . . would prefer the direct measurement of light extinction," recognizing it as the property of the atmosphere that most directly relates to visibility effects (Samet, 2010d, p. iii). CASAC noted that "[I]t has the advantage of relating directly to the demonstrated harmful welfare effect of ambient PM on human visual perception." However, based on CASAC's understanding of the time that would be required to develop an FRM for this indicator, CASAC agreed with the staff preference presented in the second draft PA for a calculated $PM_{2.5}$ light extinction indicator. CASAC noted that "[I]ts reliance on procedures that have already been implemented in the CSN and routinely collected continuous $PM_{2.5}$ data suggest that it could be implemented much sooner than a directly measured indicator" (Samet, 2010d, p. iii).

4.3.1.3 Staff Conclusions on Indicator

Taking the above considerations and CASAC's advice into account, EPA staff concludes that consideration should be given to establishing a new calculated $PM_{2.5}$ light extinction indicator. This conclusion takes into consideration the available evidence that demonstrates a strong correspondence between calculated $PM_{2.5}$ 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 $PM_{2.5}$ mass indicator. While a secondary standard that uses a $PM_{2.5}$ mass indicator could be set to provide additional protection from $PM_{2.5}$-related visibility impairment, we conclude that the advantages of using a calculated $PM_{2.5}$ light extinction indicator make it the preferred choice. In addition, We recognize that while in the future it would be appropriate to consider a direct measurement of $PM_{2.5}$ light extinction, or the sum of separate measurements of light scattering and light absorption, as the indicator for the secondary $PM_{2.5}$ standard, we conclude this is not an appropriate option in this review because a suitable specification of the

equipment and associated performance verification procedures cannot be developed in the time frame for this review.

Further, we conclude that consideration could be given to defining a calculated $PM_{2.5}$ light extinction indicator on either a 24-hour or a sub-daily basis, as discussed more fully below in section 4.3.2. In either case, it would be appropriate to base criteria for allowable monitoring and analysis protocols to obtain $PM_{2.5}$ speciation measurements on the protocols utilized in the IMPROVE and CSN networks. Further, in the case of a calculated $PM_{2.5}$ light extinction indicator defined on a sub-daily basis, it would be appropriate to consider using approaches T or W, or some variations on these approaches. In reaching this conclusion, as discussed above, we note that while it is possible to utilize data from $PM_{2.5}$ continuous FEMs on a 1-hour or multi-hour (e.g., 4-hour) basis, the mixed results of data quality assessments on a 24-hour basis, as well as the near absence of performance data for sub-daily averaging periods, increases the uncertainty of utilizing continuous methods to support 1-hour or 4-hour $PM_{2.5}$ mass measurements as an input to the light extinction calculation.

4.3.2 Averaging Time and Related Considerations

Consideration of appropriate averaging times for use in conjunction with a calculated $PM_{2.5}$ light extinction indicator was informed by information related to the nature of PM visibility effects, as discussed above in section 4.2.1, and the nature of inputs to the calculation of $PM_{2.5}$ light extinction, as discussed above in section 4.3.1. Based on this information, we have considered both sub-daily (1- and 4-hour averaging times) and 24-hour averaging times, as discussed below. In considering sub-daily averaging times, we have also addressed what diurnal periods and ambient relative humidity conditions would be appropriate to consider in conjunction with such an averaging time.

4.3.2.1 Sub-daily Averaging Times

- **To what extent does the available information provide support for alternative sub-daily averaging times in conjunction with a calculated $PM_{2.5}$ light extinction indicator?**

As an initial matter, in considering sub-daily averaging times, we took into account what we know from available studies concerning how quickly people experience and judge visibility conditions, the possibility that some fraction of the public experience infrequent or short periods of exposure to ambient visibility conditions, and the typical rate of change of the path averaged PM light extinction over urban areas. While perception of change in visibility can occur in less than a minute, meaningful changes to path-averaged light extinction occur more slowly. As discussed above in section 4.2.1, one hour is a short enough averaging period to result in indicator values that are close to the maximum one- or few-minute visibility impact that an observer could be exposed to within the hour. Further, a 1-hour averaging time could reasonably

characterize the visibility effects experienced by the segment of the population that experiences infrequent short-term exposures during peak visibility impairment periods in each area/site. Based on the above considerations, the initial analyses we conducted as part of the UFVA to support consideration of alternative standards focused on a 1-hour averaging time.

In its review of the first draft PA, CASAC agreed that a 1-hour averaging time would be appropriate to consider, noting that PM effects on visibility can vary widely and rapidly over the course of a day and such changes are almost instantaneously perceptible to human observers (Samet, 2010c, p. 19). We note that this view related specifically to a standard defined in terms of a directly measured PM light extinction indicator, in that CASAC also noted that a 1-hour averaging time is well within the instrument response times of the various currently available and developing optical monitoring methods. CASAC also advised that if a $PM_{2.5}$ mass indicator were to be used, it would be appropriate to consider "somewhat longer averaging times – 2 to 4 hours – to assure a more stable instrumental response" (Samet, 2010c, p. 19). In considering this advice, we conclude that since a calculated $PM_{2.5}$ light extinction indicator relies in part on measured $PM_{2.5}$ mass, as discussed above in section 4.3.1, it is also appropriate to consider a multi-hour averaging time in conjunction with such an indicator.

Thus, in preparing this final PA, we have also considered multi-hour averaging times, on the order of a few hours as illustrated by a 4-hour averaging time. Such averaging times might reasonably characterize the visibility effects experienced by the segment of the population who have access to visibility conditions often or continuously throughout the day. For this segment of the population, it may be that their perception of visual air quality reflects some degree of offsetting an hour with poor visual air quality with one or more hours of clearer visual conditions. Further, we recognize that a multi-hour averaging time would have the effect of averaging away peak hourly visibility impairment, which can change significantly from one hour to the next (see UFVA Figure 3-12). In considering either 1-hour or multi-hour averaging times, we recognize that no data are available with regard to how the duration and variation of time a person spends outdoors during the daytime impacts his or her judgment of the acceptability of different degrees of visibility impairment. As a consequence, it is not clear to what degree, if at all, the protection levels found to be acceptable in the public preference studies would change for a multi-hour averaging time as compared to a 1-hour averaging time. Thus, we conclude that it is appropriate to consider a 1-hour or multi-hour (e.g., 4-hour) averaging time as the basis for a sub-daily standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator.

Additionally, as part of the review of data from all continuous FEM $PM_{2.5}$ instruments operating at state/local monitoring sites, as discussed above in section 4.3.1, we have recently become aware of the occurrence of questionable outliers in 1-hour data submitted to AQS from continuous FEM $PM_{2.5}$ instruments at some of these sites (Evangelista, 2011). Some of these

outliers are questionable simply by virtue of their extreme magnitude, as high as 985 $\mu g/m^3$, whereas other values are questionable because they are isolated to single hours with much lower values before and after, a pattern that is much less plausible than if the high concentrations were more sustained.[32] The nature and frequency of questionable 1-hour FEM data collected in the past two years are being investigated by EPA. At this time, we note that any current data quality problems might be resolved in the normal course of monitoring program evolution as operators become more adept at instrument operation and maintenance and data validation or by improving the approval criteria and testing requirements for continuous instruments. Regardless, we note that multi-hour averaging of FEM data could serve to reduce the effects of such outliers relative to the use of a 1-hour averaging time.

- **What is an appropriate diurnal period to consider in conjunction with a sub-daily averaging time?**

In considering an appropriate diurnal period for use in conjunction with a sub-daily averaging time, we recognize that nighttime visibility impacts, described in the ISA (section 9.2.2) are significantly different from daytime impacts and are not sufficiently well understood to be included at this time. As a result, consistent with CASAC advice (Samet, 2010c, p. 4), we conclude that it would be appropriate to define a sub-daily standard in terms of only daylight hours at this time. 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.

- **What ambient relative humidity conditions are appropriate to consider in conjunction with a sub-daily averaging time?**

In considering the well-known interaction of PM with ambient relative humidity conditions, we recognize that PM is not generally the primary source of visibility impairment during periods with fog or precipitation. In order to reduce the probability that hours with a high degree of visibility impairment caused by fog or precipitation are unintentionally used for purposes of determining compliance with a standard, staff determined that a relative humidity screen that excludes daylight hours with average relative humidity above approximately 90% is appropriate (UFVA section 3.3.5 and UFVA Appendix G). For example, for the 15 urban

[32] Similarly questionable hourly data were not observed in the 2005-2007 continuous $PM_{2.5}$ data used in the UFVA, all of which came from early-generation continuous instruments that had not been approved as FEMs. However, only 15 sites and instruments were involved in the UFVA analyses, versus about 180 currently operating FEM instruments submitting data to AQS. Therefore, there were more opportunities for very infrequent measurement errors to be observed in the larger FEM data set. Also, the instruments providing data used in the UFVA were a mix of measurement approaches (e.g., TEOM® or beta attenuation), while the currently operating FEMs are mostly of one model (beta attenuation).

areas[33] included in the UFVA, a 90% relative humidity cutoff criterion proved effective in that on average less than 6% of the daylight hours were removed from consideration, yet those same hours had on average 10 times the likelihood of rain, 6 times the likelihood of snow/sleet, and 34 times the likelihood of fog compared with hours with 90% or lower relative humidity. However, not all periods with relative humidity above 90% have fog or precipitation. We recognize that removing those hours from consideration involves a tradeoff between the benefits of avoiding many of the hours with meteorological causes of visibility impacts and not counting some hours without fog or precipitation in which high humidity levels (> 90%) lead to the growth of hygroscopic PM to large solution droplets resulting in enhanced PM visibility impacts.

4.3.2.2 24-Hour Averaging Time

- **To what extent does the available information provide support for a 24-hour averaging time in conjunction with a calculated $PM_{2.5}$ light extinction indicator?**

As discussed in section 4.3.1 and below, there are significant reasons to consider using $PM_{2.5}$ light extinction calculated on a 24-hour basis to reduce the various data quality concerns over relying on continuous $PM_{2.5}$ monitoring data. However, we recognize that 24 hours is far longer than the hourly or multi-hour time periods that might reasonably characterize the visibility effects experienced by various segments of the population, including those who have access to visibility conditions often or continuously throughout the day, as discussed above in section 4.3.2.1. Thus, consideration of a 24-hour averaging time depends upon the extent to which PM-related light extinction calculated on a 24-hour average basis would be a reasonable and appropriate *surrogate* for PM-related light extinction calculated on a sub-daily basis, as discussed below in this section. Further, since a 24-hour averaging time combines daytime and nighttime periods, we recognize that the public preference studies do not directly provide a basis for identifying an appropriate level of protection, in terms of 24-hour average light extinction, based on judgments of acceptable daytime visual air quality obtained in those studies. Thus, consideration of a 24-hour averaging time also depends upon developing an approach to translate the candidate levels of protection derived from the public preference studies, which we have interpreted on an hourly or multi-hour basis, to a candidate level of protection defined in terms of a 24-hour average calculated light extinction, as discussed below in section 4.3.4 on level.

To determine whether $PM_{2.5}$ light extinction calculated on a 24-hour basis is a reasonable and appropriate surrogate to $PM_{2.5}$ light extinction calculated on a sub-daily basis, we have done comparative analyses of 24-hour and 4-hour averaging times in conjunction with a calculated

[33] The 90% relative humidity cap assessment was conducted as part of the UFVA on all 15 of the urban areas, including St. Louis.

$PM_{2.5}$ indicator.[34] These analyses are presented and discussed in Appendix G, section G.4. For these analyses, 4-hour average $PM_{2.5}$ light extinction was calculated based on using the UFVA approach. The 24-hour average $PM_{2.5}$ light extinction calculations used the original IMPROVE algorithm and long-term (1988 - 1997) average relative humidity conditions, to calculate monthly average values of the relative humidity term in the IMPROVE algorithm, consistent with the approach used for the Regional Haze Program. Based on these analyses, scatter plots comparing 24-hour and 4-hour calculated $PM_{2.5}$ light extinction are shown for each of the 15 cities included in the UFVA and for all 15 cities pooled together (Figures G-4 and G-5, respectively). It can be seen, as expected, that there is some scatter around the regression line for each city, because the calculated 4-hour light extinction includes day-specific and hour-specific influences that are not captured by the simpler 24-hour approach. We note that this scatter could be reduced by the use of same-day hourly relative humidity data to calculate a 24-hour average value of the relative humidity term in the IMPROVE algorithm. Scatter plots are also shown for the annual 90th percentile values, based on data from 2007 – 2009, for 4-hour and 24-hour calculated $PM_{2.5}$ light extinction across all 15 cities (Figure G-7) and for the 3-year design values across all 15 cities (Figure G-8). We judge that these analyses shown good correlation between 24-hour and 4-hour average $PM_{2.5}$ light extinction, as evidenced by reasonably high city-specific and pooled R-squared values, generally in the range of over 0.6[35] to over 0.8.

4.3.2.3 CASAC Advice on Averaging Time

As noted above, in its review of the first draft PA, CASAC agreed with the staff conclusion that PM effects on visibility can vary widely and rapidly over the course of a day and such changes are almost instantaneously perceptible to human observers (Samet, 2010c, p. 19). Based in part on this consideration, CASAC agreed that a 1-hour averaging time would be appropriate to consider in conjunction with a directly measured PM light extinction indicator, noting that a 1-hour averaging time is well within the instrument response times of the various currently available and developing optical monitoring methods. At that time, CASAC also advised that if a $PM_{2.5}$ mass indicator were to be used, it would be appropriate to consider "somewhat longer averaging times – 2 to 4 hours – to assure a more stable instrumental response" (Samet, 2010c, p. 19). Thus, CASAC's advice on averaging times that would be appropriate for consideration were predicated in part on the capabilities of monitoring methods that were available for the alternative indicators discussed in the draft PA. CASAC's views on a multi-hour averaging time would also apply to the calculated $PM_{2.5}$ light extinction indicator

[34] These analyses are also based on the use of a 90th percentile form, averaged over 3 years, as discussed below in section 4.3.3 on form.

[35] We note that the R-squared value (0.44) for Houston was notably lower than for the other cities.

since $PM_{2.5}$ mass measurements are also required for this indicator when calculated on a sub-daily basis.

In considering this advice, we first note that CASAC did not have the benefit of EPA's recent assessment of the data quality issues associated with the use of continuous FEMs as the basis for hourly $PM_{2.5}$ mass measurements. We also note that since earlier drafts of this PA did not include discussion of a calculated $PM_{2.5}$ indicator based on a 24-hour averaging time, CASAC did not have a basis to offer advice regarding a 24-hour averaging time. In addition, the 24-hour averaging time is not based on consideration of 24-hours as a relevant exposure period, but rather as a surrogate for a sub-daily period of 4 hours, which is consistent with CASAC's advice concerning an averaging time associated with the use of a $PM_{2.5}$ mass indicator.

4.3.2.4 Staff Conclusions on Averaging Time

Taking the above considerations and CASAC's advice into account, EPA staff concludes that it is appropriate to consider in this review a 24-hour averaging time, in conjunction with a calculated $PM_{2.5}$ light extinction indicator and an appropriately specified standard level. This conclusion reflects the judgment that $PM_{2.5}$ light extinction calculated on a 24-hour basis is a reasonable and appropriate surrogate for sub-daily $PM_{2.5}$ light extinction calculated on a 4-hour average basis. This conclusion is also predicated on consideration of a 24-hour average standard level, as discussed below in section 4.3.4, that is appropriately translated from the CPLs derived from the public preference studies, which we have interpreted as providing information on the acceptability of daytime visual air quality over an hourly or multi-hour exposure period.

A 24-hour average calculated $PM_{2.5}$ light extinction indicator would avoid data quality uncertainties that have recently been associated with currently available instruments for measurement of hourly $PM_{2.5}$ mass. The particular 24-hour indicator considered by staff uses the original IMPROVE algorithm and long-term relative humidity conditions to calculate $PM_{2.5}$ light extinction. By using site-specific daily data on $PM_{2.5}$ composition and site-specific long-term relative humidity conditions, this 24-hour average indicator would provide more consistent protection from $PM_{2.5}$-related visibility impairment than would a secondary $PM_{2.5}$ NAAQS based only on 24-hour or annual average $PM_{2.5}$ mass. In particular, this approach would account for the systematic difference in humidity conditions between most eastern states and most western states. Further, we have identified for consideration possible variations in the method used to calculate $PM_{2.5}$ light extinction on a 24-hour average basis that would be expected to provide somewhat more consistent protection in areas across the country, including the use of the revised IMPROVE algorithm and the use of same-day relative humidity data, either at the visibility monitoring site or another site in the same area.

Further, staff concludes that it would also be appropriate to consider a multi-hour, sub-daily averaging time, for example a period of 4 hours, in conjunction with a calculated $PM_{2.5}$ light extinction indicator and with further consideration of the data quality issues that have been raised by the recent EPA study of continuous FEMs. Such an averaging time, to the extent that data quality issues can be appropriately addressed, would be more directly related to the short-term nature of the perception of visibility impairment, short-term variability in PM-related visual air quality, and the short-term nature (hourly to multiple hours) of relevant exposure periods for segments of the viewing public. Such an averaging time would also result in an indicator that is less sensitive than a 1-hour averaging time to short-term instrument variability with respect to $PM_{2.5}$ mass measurement. In conjunction with consideration of a multi-hour, sub-daily averaging time, we conclude that consideration should be given to including daylight hours only and to applying a relative humidity screen of approximately 90% to remove hours in which fog or precipitation is much more likely to contribute to the observed visibility impairment. Recognizing that a 1-hour averaging time would be even more sensitive to data quality issues, including short-term variability in hourly data from currently available continuous monitoring methods, we conclude that it would not be appropriate to consider a 1-hour averaging time in conjunction with a calculated $PM_{2.5}$ light extinction indicator in this review.

4.3.3 Form

The "form" of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether the standard is achieved. The form of the current 24-hour $PM_{2.5}$ NAAQS is such that the level of the standard is compared to the 3-year average of the annual 98^{th} 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 unusually high pollution levels for a particular year that is otherwise typical. The use of a multi-year percentile form, among other things, makes the standard less subject to the possibility of transient violations caused by statistically unusual indicator values, thereby providing stability to the air quality management process that may enhance the practical effectiveness of efforts to implement the NAAQS. Also, a percentile form can be used to take into account the number of times an exposure might occur as part of the judgment on protectiveness in setting a NAAQS. For all of these reasons, we conclude it is appropriate to consider defining the form of a new secondary standard in terms of a 3-year average of a specified percentile air quality statistic.

- **To what extent does available information support consideration of an alternative percentile form for a secondary standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator?**

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. Given this lack of information, and recognizing that the nature of the public welfare effect is one of aesthetics and/or feelings of well-being, it is our view that it would not be appropriate to consider eliminating all exposures above the level of the standard and that allowing some number of hours/days with reduced visibility can reasonably be considered. In the UFVA, 90th, 95th, and 98th percentile forms were assessed for alternative PM light extinction standards (chapter 4, UFVA). In considering these alternative percentiles, we note that the Regional Haze Program targets the 20% most impaired days for improvements in visual air quality in Class I areas. If improvement in the 20% most impaired days were similarly judged to be appropriate for protecting visual air quality in urban areas, a percentile well above the 80th percentile would be appropriate to increase the likelihood that all days in this range would be improved by control strategies intended to attain the standard. A focus on improving the 20% most impaired days suggests to staff that the 90th percentile, which represents the median of the distribution of the 20% worst days, would be an appropriate form to consider. Strategies that are implemented so that 90% of days have visual air quality that is at or below the level of the standard would reasonably be expected to lead to improvements in visual air quality for the 20% most impaired days. Higher percentile values within the range assessed could have the effect of limiting the occurrence of days with peak PM-related light extinction in urban areas to a greater degree. In considering the limited information available from the public preference studies, we find no basis to conclude that it would be appropriate to consider limiting the occurrence of days with peak PM-related light extinction in urban areas to a greater degree.

Another aspect of the form that was considered in the UFVA for a sub-daily (i.e., 1-hour) averaging time is whether to include all daylight hours or only the maximum daily daylight hour. This consideration would also be relevant for a multi-hour (e.g., 4-hour) averaging time, although such an analysis was not included in the UFVA. The maximum daily daylight 1-hour or multi-hour form is most directly protective of the welfare of people who have limited, infrequent or intermittent exposure to visibility during the day (e.g., during commutes), but spend most of their time without an outdoor view. 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, which may be hours later or perhaps the next day. Other people have exposure to visibility conditions throughout the day. For those

people, it might be more appropriate to include every daylight hour in assessing compliance with a standard, since it is more likely that each daylight hour could affect their welfare.

We do not have information regarding the fraction of the public that has only one or a few opportunities to experience visibility during the day, nor do we have information on the role the duration of the observed visibility conditions has on wellbeing effects associated with those visibility conditions. However, it is logical to conclude 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.

In light of these considerations, the UFVA assessment included both the maximum daily hour form and the all daylight hours form. We observed a close correspondence between the level of protection afforded for all 15 urban areas in the assessment by the maximum daily daylight 1-hour approach using the 90th percentile form and the all daylight hours approach combined with the 98th percentile form (UFVA section 4.1.4). On this basis, we note that the reductions in visibility impairment required to meet either form of the standard would provide protection to both fractions of the public (i.e., those with limited opportunities and those with greater opportunities to view PM-related visibility conditions). We note that CASAC generally supported consideration of both types of forms without expressing a preference based on its review of information presented in the second draft PA (Samet, 2010d, p11).

Staff Conclusions on Form

In conjunction with a calculated $PM_{2.5}$ light extinction indicator and alternative 24-hour or sub-daily (e.g., 4-hour) averaging times, based on the above considerations, and given the lack of information on and the high degree of uncertainty over the impact on public welfare of the number of days with visibility impairment over a year, we conclude that it is appropriate to give primary consideration to a 90th percentile form, averaged over three years. Further, in the case of a multi-hour, sub-daily alternative standard, we conclude that it is appropriate to give primary consideration to a form based on the maximum daily multi-hour period in conjunction with the 90th percentile form. This sub-daily form would be expected to provide appropriate protection for various segments of the population, including those with limited opportunities during a day and those with more extended opportunities over the daylight hours to experience PM-related visual air quality.

4.3.4 Level

In considering alternative levels for a new standard that would provide requisite protection against PM-related visibility impairment primarily in urban areas, staff has taken into

account the evidence- and impact-based considerations discussed above in section 4.2.1, with a focus on the results of public perception and attitude surveys related to the acceptability of various levels of visual air quality and on the important limitations in the design and scope of such available studies. We consider this information in the context of a standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator, discussed above in section 4.3.1; with alternative averaging times of 24-hours or multi-hour, sub-daily periods (e.g., 4-hours), discussed above in section 4.3.2; and a 90^{th} percentile-based form, discussed above in section 4.3.3.

As part of our assessment of the adequacy of the current standards (section 4.2.1), we interpreted the results from the visibility preferences studies conducted in four urban areas to define a range of low, middle, and high CPLs for a sub-daily standard (e.g., 1- to 4-hour averaging time) of 20, 25, and 30 dv, which are approximately equivalent to $PM_{2,5}$ light extinction of values of 65, 110, and 190 Mm^{-1}. We note that CASAC agreed that this was an appropriate range of levels to consider for such a standard (Samet, 2010d, p. 11).[36] We also recognize that to define a range of alternative levels that would be appropriate to consider for a 24-hour calculated $PM_{2.5}$ light extinction standard, some adjustment to these CPLs is appropriate since these preference studies cannot be directly interpreted as applying to a 24-hour exposure period (as noted above in section 4.3.1). Such adjustments are more specifically discussed below.

As an initial matter, in considering alternative levels for a sub-daily standard based directly on the four preference study results, we note that the individual low and high CPLs are in fact reflective of the results from the Denver and Washington, DC studies respectively, and the middle CPL is very near to the 50^{th} percentile criteria result from the Phoenix study. As discussed above in section 4.2.1, we note that the Phoenix study was by far the best of the studies, providing somewhat more support for the middle CPL. In considering the results from these studies, we recognize that the available studies are limited in that they were conducted in only four areas, three in the U.S. and one in Canada. Further, we recognize that available studies provide no information on how the duration and variation of time a person spends outdoors during the daytime may impact their judgment of the acceptability of different degrees of visibility impairment. As such, there is a relatively high degree of uncertainty associated with using the results of these studies to inform consideration of a national standard. Nonetheless, we conclude, as did CASAC, that these studies are appropriate to use for this purpose.

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[36] In 2009, the D.C. Circuit remanded the secondary $PM_{2.5}$ standards to EPA in part because the Agency failed to identify a target level of protection, even though EPA staff and CASAC had identified a range of target levels of protection that were appropriate for consideration. The court determined that the Agency's failure to identify a target level of protection as part of its final decision was contrary to the statute and therefore unlawful, and that it deprived EPA's decision-making of a reasoned basis (as discussed above in section 4.1.2).

In identifying alternative levels for a 24-hour standard, we have explored various approaches to adjusting the CPLs derived directly from the preference studies, as presented and discussed in Appendix G, especially section G-5. These regression analyses have focused on determining adjusted CPLs for a 24-hour standard that would provide generally equivalent protection as that provided by a 4-hour standard with CPLs of 20, 25, and 30 dv. Some of these approaches focused on comparing 24-hour and 4-hour light extinction values in each of the 15 urban areas assessed in the UFVA, whereas other approaches focused on comparisons based on using aggregated data across the urban areas. Two of these approaches, which used regressions of city-specific annual 90th percentile light extinction values or 3-year light extinction design values, gave nearly identical results and were considered most appropriate to use as the basis for identifying generally equivalent 24-hour adjusted CPLs. These approaches (shown in Figures G-7 and G-8) were preferred based on the high R-squared values of the regressions and because the regressions were determined by data from days with $PM_{2.5}$ light extinction conditions in the range of 20 to 40 dv. This contrasted with the other approaches that were highly influenced by $PM_{2.5}$ light extinction conditions well below this range. Based on these analyses and staff conclusions presented in Appendix G, we have identified adjusted 24-hour CPLs of 21, 25, and 28 dv as being generally equivalent to 4-hour CPLs of 20, 25, and 30 dv.[37] To provide some perspective in considering these results (shown in Table G-6), we note that 1 deciview is about the amount that persons can distinguish when viewing scenic vistas, and that a difference of 1 deciview is equivalent to about a 10% difference in light extinction expressed in Mm^{-1}.

In more broadly considering alternative standard levels that would be appropriate for a nationally applicable secondary standard focused on protection from PM-related urban visibility impairment based on either a 24-hour or multi-hour, sub-daily (e.g., 4-hour) averaging time, we are mindful of the important limitations in the available evidence from public preference studies. We are also mindful that the scenic vistas available on a daily basis in many urban areas across the country generally do not have the inherent visual interest or the distance between viewer and object of greatest intrinsic value as in the Denver and Phoenix preference studies.

As in past reviews, we are considering a national visibility standard in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in urban, non-urban, and Class I areas across the country. We

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[37].As discussed in more detail in Appendix G, some days have higher values for 24-hour average light extinction than for daily maximum 4-hour daylight light extinction, and consequently an adjusted "equivalent" 24-hour CPL can be greater than the original 4-hour CPL. This can happen for two reasons. First, the use of monthly average historical RH data will lead to cases in which the f(RH) values used for the calculation of 24-hour average light extinction are higher than all or some of the four hourly values of f(RH) used to determine daily maximum 4-hour daylight light extinction on the same day. Second, $PM_{2.5}$ concentrations may be greater during non-daylight periods than during daylight hours.

recognize that programs implemented to meet a national standard focused primarily on the visibility problems in urban areas can be expected to improve visual air quality in surrounding non-urban areas as well, as would programs now being developed to address the requirements of the Regional Haze Program established for protection of visual air quality in Class I areas. We also believe that the development of local programs, such as those in Denver and Phoenix, can continue to be an effective and appropriate approach to provide additional protection, beyond that afforded by a national standard, for unique scenic resources in and around certain urban areas that are particularly highly valued by people living in those areas.

Staff Conclusions on Level

Based on the above considerations, we conclude that it is appropriate to give primary consideration to alternative standard levels toward the upper end of the ranges identified above for 24-hour and sub-daily standards, respectively. Thus, we conclude it is appropriate to consider the following alternative levels: a level of 28 dv or somewhat below, down to 25 dv, for a standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator, a 90^{th} percentile form, and a 24-hour averaging time; and a standard level of 30 dv or somewhat below, down to 25 dv, for a similar standard but with a 4-hour averaging time. We judge that such standards would provide appropriate protection against PM-related visibility impairment primarily in urban areas. We note that support for consideration of the upper part of the range of the CPLs derived from the public preference studies was expressed by some CASAC Panel members during the public meeting on the second draft PA. We conclude that such a standard would be appropriate in conjunction with the Regional Haze Program to achieve appropriate levels of protection against PM-related visibility impairment in areas across the country.

To provide some perspective on the implications of alternative averaging times, forms, and levels for a new secondary standard, staff assessed the percentage of counties that would not likely meet alternative 24-hour standards with a 90^{th} percentile form and a range of levels from 25 dv to 28 dv, as well as alternative 4-hour standards with a 90^{th} percentile form and a range of levels from 25 dv to 30 dv. This assessment, shown in Appendix H, Tables H-1 and H-2, was not considered as a basis for the above staff conclusions. It should be noted that the geographic coverage of this assessment was much more constrained by the availability of suitable data than the similar assessments for the primary PM standards in Appendices C and D.

4.4 SUMMARY OF STAFF CONCLUSIONS ON SECONDARY STANDARDS FOR VISIBILITY-RELATED EFFECTS

In reaching conclusions on the adequacy of the current suite of $PM_{2.5}$ secondary standards and potential alternative standards to provide requisite protection of PM-related visibility

impairment, staff has considered these standards in terms of the basic elements of the NAAQS: indicator, averaging time, form, and level (sections 4.3.1 to 4.3.4 above). In considering the scientific and technical information, we reflect on the information available in the last review integrated with information that is newly available as assessed and presented in the ISA (US EPA, 2009a) and UFVA (US EPA, 2010a) and as summarized above and in and Appendices E,F, and G. We also consider issues raised by the court in its remand of the secondary $PM_{2.5}$ standards as discussed above in section 4.1.2.

As outlined in section 4.1.3, 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 have taken 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.

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 reaching staff conclusions on alternative suites of standards and ranges of levels that are appropriate to consider, we are mindful that the CAA requires secondary standards to be set that are requisite to protect public welfare from known and anticipated adverse effects, such that the standards are to be neither more nor less stringent than necessary.

Based on the currently available information, staff reaches the following conclusions regarding the secondary $PM_{2.5}$ standards for protecting against $PM_{2.5}$-related visibility impairment:

(1) Consideration should be given to revising the current suite of $PM_{2.5}$ secondary standards to provide increased public welfare protection from $PM_{2.5}$-related visibility impairment, primarily in urban areas. This conclusion is based in part on the relatively large number of days in which PM-related light extinction is estimated to exceed levels that can reasonably be judged to be important from a public welfare perspective under simulations of conditions associated with just meeting the current suite of $PM_{2.5}$ standards. This conclusion is also based on information that indicates that the current $PM_{2.5}$ mass indicator is not appropriate for a national standard intended to protect public welfare from PM-related visibility impairment since such a standard is inherently confounded by regional differences in relative humidity and species composition of $PM_{2.5}$, which are critical factors in the relationship between the mix of fine particles in the ambient air and the associated impairment of visibility.

(2) Consideration should be given to establishing a new calculated $PM_{2.5}$ light extinction *indicator*. This conclusion takes into consideration the available evidence that demonstrates a strong correspondence between $PM_{2.5}$ light extinction as calculated based on the

IMPROVE algorithm used in the Regional Haze Program and PM-related visibility impairment, as well as the significant degree of variability in visibility protection across the U.S. allowed by a $PM_{2.5}$ mass indicator that does not take into account relative humidity and $PM_{2.5}$ species composition.

(a) While a secondary standard that uses a $PM_{2.5}$ mass indicator could be set to provide additional protection from $PM_{2.5}$-related visibility impairment, we conclude that the advantages of using a calculated $PM_{2.5}$ light extinction indicator make it the preferred choice.

(b) While in the future it may be appropriate to consider a direct measurement of PM-related light extinction, or the sum of separate measurements of light scattering and light absorption, as the indicator for the secondary $PM_{2.5}$ standard, we conclude this is not an appropriate option in this review because a suitable specification of the equipment and associated performance verification procedures, or suitable alternative to these, cannot be developed in the time frame for this review.

(3) Consideration should be given to a 24-hour *averaging time*, in conjunction with a calculated $PM_{2.5}$ light extinction indicator and an appropriately specified standard level. This conclusion reflects the judgment that $PM_{2.5}$ light extinction calculated on a 24-hour basis is a reasonable and appropriate surrogate for light extinction calculated on a sub-daily basis (e.g. 4 hours) that is more directly related to public perception of visual air quality. Such a standard would avoid data quality uncertainties that have recently been associated with currently available instruments for the measurement of hourly $PM_{2.5}$ mass.

It would also be appropriate to consider a multi-hour, sub-daily averaging period, for example a period of four hours, to the extent that data quality issues about continuous FEMs that have recently been raised can be appropriately addressed. Such a multi-hour averaging period would be more directly related to the short-term nature of the perception of visibility impairment, short-term variability in PM-related visual air quality, and the short-term nature (hourly to multiple hours) of relevant exposure periods for segments of the viewing public. It would also be less sensitive than a 1-hour averaging time to short-term variability in $PM_{2.5}$ mass measurement. In conjunction with consideration of a multi-hour, sub-daily averaging time, we conclude that consideration should be given to including daylight hours only and to applying a relative humidity screen of approximately 90% to remove hours in which fog or precipitation is much more likely to contribute to the observed visibility impairment.

(4) With regard to *form*, in conjunction with a calculated $PM_{2.5}$ light extinction indicator and alternative 24-hour or multi-hour, sub-daily (e.g., 4-hour) averaging times, primary consideration should be given to a 90^{th} percentile form, averaged over three years. This form recognizes the high degree of uncertainty over the impact on public welfare of the number of days with visibility impairment over a year. In the case of a sub-daily alternative standard, we conclude that it is appropriate to give primary consideration to a maximum daily value form.

(5) With regard to *level*, primary consideration should be given to alternative levels toward the upper end of the ranges identified above for 24-hour and multi-hour, sub-daily standards, respectively, including: a level of 28 dv or somewhat below, down to 25 dv, for a standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator, a 90^{th} percentile form, and a 24-hour averaging time; and a level of 30 dv or somewhat below, down to 25 dv, for a

similar standard but with a 4-hour averaging time. Staff concludes that such a standard would be appropriate in conjunction with the Regional Haze Program to achieve appropriate levels of protection against PM-related visibility impairment in areas across the country.

4.5 KEY UNCERTAINTIES AND AREAS FOR FUTURE RESEARCH AND DATA COLLECTION

This section will be organized into two overarching topic areas: refining current understanding of visibility preferences and characterization of ambient urban visibility conditions. The first deals principally with how the public reacts to and values visibility conditions, while the second is more concerned with determining ambient visibility conditions and the relationships between PM component concentrations and light extinction.

Visibility Preferences

- Levels: The results of the reanalysis of the four urban preference studies (UFVA Chapter 2) demonstrated well defined though significant statistical differences in visibility impairment levels that divide participant decisions on acceptable from unacceptable conditions across the study areas. A number of hypotheses concerning why the results differed for each area are discussed in chapter 2 of the UFVA, but the current state of knowledge does not support a definitive explanation for the range of results. A better understanding of the reasons for the differences in preference response among the studies of the four urban areas could influence the design of future visibility preference survey studies and the interpretation of their results ultimately leading to a better defined range of CPLs for the next PM NAAQS review.
- Averaging Times/Forms: Additional information would also be helpful in deciding among the various forms and averaging times to develop an effective visibility-based secondary PM NAAQS and to assess the overall benefits of visibility improvements. Our current understanding of urban visibility effects does not provide insights concerning:
    - relative importance of degree of visibility impairment (i.e., light extinction level) versus frequency of visibility impairment;
    - strength of preference for different distributions of visibility conditions; and
    - public exposure patterns.

Future research to address these deficiencies should include designing and conducting additional preference, valuation and exposure studies to:

- expand the number and geographic coverage of urban area preference results;
- evaluate the sensitivity of results to the differences in survey study methodology;
- apply consistent methodology at multiple urban areas to better understand reasons for preference difference among results in different urban areas;
- develop information on the strength of preference and relative importance of intensity versus frequency of visibility impairment;
- identify the types of scenic elements that are most influential for informing public visibility impact awareness; and

- provide insights concerning visibility impact exposure duration, intensity, and timing and their relationship to the degree and longevity of public welfare effects.

As part of the planning for additional preference and valuation survey studies, a literature review of recent social science literature could usefully be conducted to assess the state of knowledge of view exposure mechanisms and the psychological and behavioral effects associated with viewed stimuli.

Urban Visibility Conditions

In this review, the paucity of light extinction monitoring data for urban areas led to the use of the original IMPROVE algorithm to calculate hourly light extinction from continuous PM mass and 24-hour $PM_{2.5}$ component and relative humidity data (UFVA Chapter 3). The steps used to temporally apportion 24-hour $PM_{2.5}$ components in order to calculate hourly-averaged values used monthly-averaged diurnal $PM_{2.5}$ component variations from chemical transport air quality modeling. The mass balance method used to estimate organic carbonaceous material concentration and the loss of nitrate is reasonable but not likely to be precise. The original IMPROVE algorithm was originally developed for remote area application to estimate 24-hour light extinction and it was not verified for use in generating urban hourly estimates. The revised IMPROVE algorithm would notably increase estimates of $PM_{2.5}$ light extinction at the high end of the range of light extinction conditions. Nevertheless, the resulting hourly $PM_{2.5}$ light extinction data set is thought by EPA staff to be sufficiently representative of the hourly $PM_{2.5}$ light extinction levels in the study areas to allow an assessment of whether the current suite of secondary standards is adequately protective, although these data may be biased low at high light extinction levels, and are certainly less accurate than would be data from direct measurements.

A pilot $PM_{2.5}$ light extinction monitoring program could usefully be designed and deployed at some number of locations selected to cover a range of $PM_{2.5}$ air quality conditions with emphasis given to locations with continuous $PM_{2.5}$ mass and speciation monitoring as well as 24-hour mass and speciation sampling. Information from such a pilot monitoring program could be used to:

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

4.6 REFERENCES

Abt Associates Inc. (2001). Assessing Public Opinions on Visibility Impairment Due to Air Pollution: Summary Report.

BBC Research & Consulting. (2003). Phoenix Area Visibility Survey. Draft Report. Available: http://www.azdeq.gov/environ/air/download/vis_021903f.pdf. Accessed 9/16/2008

Edgerton, E. et al. (2006). The Southeastern Aerosol Research and Characterization Study, Part 3: Continuous Measurements of Fine Particulate Matter Mass and Composition. J. Air Waste Manage. Assoc., 56, 1325-1341.

Evangelista, M. (2011). Investigation of 1-hour $PM_{2.5}$ Mass Concentration Data from EPA-Approved Continuous Federal Equivalent Method Analyzers. Memorandum to PM NAAQS review docket EPA-HQ-OAR-2007-0492. April 5, 2011. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

Frank, N. (2006). Retained Nitrate, Hydrated Sulfates, and Carbonaceous Mass in Federal Reference Method Fine Particulate Matter for Six Eastern U.S. Cities. J. Air Waste Manage. Assoc., 56, 500-511.

Hanley, T.and Reff, A (2011). Assessment of $PM_{2.5}$ FEMs compared to collocated FRMs. Memorandum to PM NAAQS review docket EPA-HQ-OAR-2007-0492. April 7, 2011. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

Henderson, R. (2005a). Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Honorable Stephen L. Johnson, Administrator, US EPA. CASAC PM Review Panel's Peer Review of the Agency's *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information* (Second Draft PM Staff Paper, January 2005). June 6, 2005. Available at: http://www.epa.gov/sab/pdf/casac-05-007.pdf.

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

Ely DW; Leary JT; Stewart TR; Ross DM (1991). The establishment of the Denver Visibility Standard. Presented at Presented at: 84th annual meeting & exhibition of the Air & Waste Management Association; June; Vancouver, British Columbia. Pittsburgh, PA: Air & Waste Management Association; paper no. 91-48.4.

Lorang, P. (2010). Simplified Approaches for Calculation of Hourly $PM_{2.5}$ Light Extinction Values from Hourly $PM_{2.5}$ Mass and Relative Humidity Data and 24-hour $PM_{2.5}$ Composition Data. . Memorandum to PM NAAQS review docket EPA-HQ-OAR-2007-0492.November 17, 2010. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

Malm, W.C., Sisler, J.F., Huffman, D., Eldred, R.A., Cahill, T.A. (1994) Spatial and Seasonal Trends in Particle Concentration and Optical Extinction in the United States, Journal of Geophysical Research (Atmospheres) 99:1347-1370.

Molenar, J.V., Malm, W.C., Johnson, C.E. (1994) Visual air quality simulation techniques. Atmos Environ, 28(5): 1055-1063.

Pitchford , M. (2010). Assessment of the Use of Speciated $PM_{2.5}$ Mass-Calculated Light Extinction as a Secondary PM NAAQS Indicator of Visibility. . Memorandum to PM NAAQS review docket EPA-HQ-OAR-2007-0492. November 17, 2010. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

Pryor SC (1996). Assessing public perception of visibility for standard setting exercises. Atmos Environ, 30: 2705-2716.

Russell, A; Samet, J.M. (2010). Letter from the Clean Air Science Advisory Committee (CASAC) Ambient Air Monitoring and Methods Subcommittee (AAMMS) to the Honorable Lisa P, Jackson, Administrator, US EPA. Review of the White Paper on Particulate Matter (PM) Light Extinction Measurements. April 29, 2010, Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/92C9F5AA09A76A93852577150004A782/$File/EPA-CASAC-10-010-unsigned.pdf

Samet J (2010c). Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to the Honorable Lisa P. Jackson, Administrator, US EPA. CASAC Review of *Policy Assessment for the Review of the PM NAAQS – First External Revew Draft* (March 2010). May 17, 2010. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/E504EE3276D87A9E8525772700647AFB/$File/EPA-CASAC-10-011-unsigned.pdf/.

Samet J (2010d). Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to the Honorable Lisa P. Jackson, Administrator, US EPA. CASAC Review of *Policy Assessment for the Review of the PM NAAQS – Second External Revew Draft* (June 2010). September 10, 2010. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/CCF9F4C0500C500F8525779D0073C593/$File/EPA-CASAC-10-015-unsigned.pdf

Smith, A. (2009). Comments on the First External Review Draft of EPA's "Integrated Science Assessment for Particulate Matter." CRA International. Washington, DC. March 30. Prepared for the Utility Air Regulatory Group. Submitted as public comments to the public meeting of the EPA Clean Air Science Advisory Council. April 2.

Smith AE; Howell S (2009). An assessment of the robustness of visual air quality preference study results. CRA International. Washington, DC. http://yosemite.epa.gov/sab/sabproduct.nsf/B55911DF9796E5E385257592006FB737/$File/CRA+VAQ+Pref+Robustness+Study+3+30+09+final.pdf

US EPA (2005). Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. Research Triangle Park, NC 27711: Office of Air Quality Planning and Standards; report no. EPA EPA-452/R-05-005a. December 2005. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_sp.html

US EPA (2008). Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter. National Center for Environmental Assessment and Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. Report No. EPA 452/R-08-004. March 2008. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pd.html.

US EPA (2009a). Integrated Science Assessment for Particulate Matter: Final Report. National Center for Environmental Assessment-RTP Division, Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA/600/R-08/139F. December 2009. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_isa.html.

US EPA (2010 a). Quantitative Risk Assessment for Particulate Matter – Final Report. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/R-10-005. June 2010. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html

US EPA (2010b). Particulate Matter Urban-Focused Visibility Assessment – Final Report. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/R-10-004. June 2010. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

US EPA (2010c). Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards - First External Review Draft. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA 452/P-10-003. March 2010. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pa.html.

US EPA (2010f). Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards - Second External Review Draft. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA 452/P-10-007. June 2010. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pa.html.

US EPA (2010h). White Paper on PM Light Extinction Measurements. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. January 2010. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/823a6c8842610e768525764900659b22!OpenDocument

5 REVIEW OF THE SECONDARY STANDARDS FOR OTHER WELFARE EFFECTS

This chapter presents 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 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 NAAQS 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 nitrogen (N) and sulfur (S) considered in each review are detailed in this section and summarized in Table 5-1.

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).

Table 5-1. Scope of the Current Secondary PM NAAQS Review and Current NOx/SOx Secondary NAAQS 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

5.1.2.2 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 *Policy Assessment for Review of the Secondary National Ambient Air Quality Standards for Oxides of Nitrogen and Oxides of Sulfur* (US EPA, 2011) an acidification index is being considered. This index provides potential ecosystem protection from deposition related to atmospheric concentrations.

5.1.3 General Approach Used in Current Review

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

[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.

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 Standards

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, 2009a).

- **What new techniques are available to improve our understanding of climate effects of aerosols?**

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, increases the reflection of solar radiation back into space. The altitude of clouds also affects 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. is 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. In the U.S., most of the warming aerosols are emitted by biomass burning and internal engine combustion and much of the cooling aerosols are formed in the atmosphere by oxidation of SO_2 or VOC's. (US EPA, 2009a, section 3.3). Fires release large amounts of BC, CO_2, CH_4 and OC (US EPA, 2009a, section 9.3.7).

5.2.3 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, based on current estimates of aerosol radiative forcing, 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.
- Most of the warming aerosols in the U.S. are emitted by biomass burning and internal engine combustion. Much of the cooling aerosols are formed in the atmosphere by oxidation of SO2 or VOC's. The relative mix and sources of warming and cooling components will vary in areas across the U.S. and over time. Thus, a set of controls to reduce warming PM would not necessarily reduce cooling PM and vice versa.

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. 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 conclude 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 radiative forcing and climate fluctuations, significant uncertainties remain that preclude consideration of climate effects as a basis for establishing a separate NAAQS secondary standard. Further research into the effects of aerosols on climate could provide important information to reduce these uncertainties.

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). The contributions of policy-relevant background (PRB) concentrations to aerosol climate forcing are not sufficiently characterized (US EPA, 2009a, section 3.7). 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

[2] Given the reasons discussed above, this conclusion would apply for both the secondary (welfare based) and the primary (health based) standards.

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 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 is 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.

There are uncertainties associated with the potential effects of the alternative standards for visibility discussed in Chapter 4 on regional radiative forcing and climate. A secondary standard for visibility based on light extinction would result in reduced emissions that affect PM in areas where monitoring shows exceedance of the standard. The extinction budget work conducted for the UFVA (Figure 3-13, U.S. EPA, 2010b) and second draft PA (US EPA, 2010f, Appendix B) indicates that most of the current visibility impact contributions on worst days comes from light scattering particles (e.g., nitrates, sulfates) that are negative climate forcers, and a smaller portion comes from absorbing aerosols (e.g., black carbon) that are positive climate forcers. The relative proportions of scattering and absorbing particles vary by location and some major contributing emission sources contribute to both scattering and absorbing PM, so it is unclear how the ratio of scattering to absorption might change in response to a secondary standard for visibility affects. However, since the prevailing mixture of aerosol is thought to have a net cooling effect on regional climate, reducing PM and light scattering aerosols could lead to increased radiative forcing and regional climate warming while having a beneficial effect on visibility.

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, March 27, 2008; 75 FR 2938, January 19, 2010). Therefore, effects (e.g. biomass loss, foliar injury) 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 policy assessment 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: (1) to identify ecological effects associated with PM deposition that can be linked to ecosystem services and (2) to 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 Standards

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, 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 (US EPA, 2009a, 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, 2002; 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?**

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 (VOCs) 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 identified 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, 2009g) 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 difficult. 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 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.

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 concludes 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. The chemical constitution of individual particles can be strongly correlated with size, and the relationship between particle size and particle composition can 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. Nonetheless, in the absence of information that provides a basis for specific standards in terms of particle composition, observations continue to support retaining an appropriate degree of control on both fine and coarse particles to help address effects to ecosystems and ecosystem components associated with PM.

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. Further research is needed to decrease the uncertainties associated with ambient PM effects on ecosystems and ecosystem components.

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 Standards

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, 2004).

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 et al., 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 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 conclude 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. Nonetheless, 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.

5.5 REFERENCES

Audet P; Charest C (2007). Heavy metal phytoremediation from a meta-analytical perspective. Environ Pollut, 147: 231-237.

Bonazza A; Sabbioni C; Ghedini N. (2005). Quantitative data on carbon fractions in interpretation of black crusts and soiling on European built heritage. Atmos Environ, 39: 2607-2618.

Bond TC; Streets DG; Yarber KF; Nelson SM; Woo J-H; Klimont Z. (2004). A technology-based global inventory of black and organic carbon emissions from combustion. J Geophys Res, 109.

Bond TC; Sun H. (2005). Can reducing black carbon emissions counteract global warming?. Environ Sci Technol, 39: 5921-5926.

CCSP (2009). Atmospheric Aerosol Properties and Climate Impacts, A Report by the U.S. Climate Change Science Program and the Subcommittee on Global Change Research. [Mian Chin, Ralph A. Kahn, and Stephen E. Schwartz (eds.)]. National Aeronautics and Space Administration, Washington, D.C., USA.

Forster P; Ramaswamy V; Artaxo P; Betss R; Fahey DW; Haywood J; Lean J; Lowe DC; Myhre G; Nganga J; Prinn R; Raga G; Schultz M; Van Dorland R. (2007). Changes in atmospheric constituents and in radiative forcing. In Solomon, S.; Qin,D.; Manning, M.; Chen, Z.; Marquis, M.; Averyt, K. B.; Tignor, M.; Miller, H. L. (Ed.),Climate Change 2007: the physical science basis. Contribution of Working Group I to the fourth assessment report of the intergovernmental panel.

Freer-Smith PH; El-khatib A; Taylor G. (2004). Capture of particulate pollution by trees: a comparison of species typical of semi-arid areas (Ficus nitida and Eucalyptus globulus) with European and North American species. Water Air Soil Pollut,155: 173-187.

Gitay H; Brown S; Easterling W; Jallow B. (2001). Ecosystems and their goods and services. In Climate change 2001: impacts,adaptation and vulnerability. Contribution of working group II to the third assessment report of the Intergovernmental Panel on Climate Change (pp. 237-342). Cambridge, United Kingdom: Cambridge University Press.

Givati A; Rosenfeld D. (2004). Quantifying precipitation suppression due to air pollution. J Appl Meteorol, 43: 1038-1056.

Gomot-De Vaufleury A; Pihan F. (2002). Methods for toxicity assessment of contaminated soil by oral or dermal uptake in land snails: Metal bioavailability and bioaccumulation. Environ Toxicol Chem, 21: 820-827.

Grantz DA; Garner JHB; Johnson DW. (2003). Ecological effects of particulate matter. Environ Int, 29: 213-239.

Hageman KJ; Simonich SL; Campbell DH; Wilson GR; Landers DH. (2006). Atmospheric deposition of current-use and historic-use pesticides in snow at national parks in the western United States. Environ Sci Technol, 40: 3174-3180

Hassan R; Scholes R; Ash N. (2005). Ecosystems and human well-being: current state and trends, volume 1. United Kingdom: Shearwater Books.

Herrera LK; Videla HA. (2004). The importance of atmospheric effects on biodeterioration of cultural heritage constructional materials. Int Biodeterior Biodegradation, 54: 125-134.

IPCC (2007): Summary for Policymakers. In: Climate Change 2007: The Physical Science Basis. Contribution of Working Group I to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change [Solomon, S., D. Qin, M. Manning, Z. Chen, M. Marquis, K.B. Averyt, M.Tignor and H.L. Miller (eds.)]. Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA.

Jacobson MZ (2000). A physically-based treatment of elemental carbon optics: implications for global direct forcing of aerosols. Geophys Res Lett, 27: 217-220.

Jacobson MZ; Kaufman YJ (2006). Wind reduction by aerosol particles. Geophys Res Lett, 33 ARLN 24814

Kucera T; Horakova H; Sonska A (2008). Toxic metal ions in photoautotrophic organisms. Photosynthetica, 46: 481-489.

Landers DH; Simonich SL; Jaffe DA; Geiser LH; Campbell DH; Schwindt AR; Schreck CB; Kent ML; Hafner WD; Taylor HE; Hageman KJ; Usenko S; Ackerman LK; Schrlau JE; Rose NL; Blett TF; Erway MM. (2008). The Fate, Transport and Ecological Impacts of Airborne Contaminants in Western National Parks (USA). U.S. Environmental Protection Agency, Office of Research and Development, NHEERL, Western Ecology Division. Corvallis, Oregon. EPA/600/R-07/138

National Research Council (2001). Climate change science: an analysis of some key questions. National Research Council. National Academy Press. Washington, DC.

Parrish ZD; White JC; Isleyen M; Gent MPN; Iannucci-Berger W; Eitzer BD; Kelsey JW; Mattina MI. (2006). Accumulation of weathered polycyclic aromatic hydrocarbons (PAHs) by plant and earthworm species. Chemosphere, 64: 609-618.

Patra M; Bhowmik N; Bandopadhyay B; Sharma A (2004). Comparison of mercury, lead and arsenic with respect to genotoxic effects on plant systems and the development of genetic tolerance. Environ Exp Bot, 52: 199-223.

Putaud J-P; Raes F; Van Dengenen R; Bruggemann E; Facchini M-C; Decesari S; Fuzzi S; Gehrig R; Huglin C; Laj P; Lorbeer G; Maenhaut W; Mihalopoulos N; Muller K; Querol X; Rodriguez S; Schneider J; Spindler G; ten Brink H; Torseth K; Wiedensohler A. (2004). A European aerosol phenomenology--2: chemical characteristics of particulate matter at kerbside, urban, rural and background sites in Europe. Atmos Environ, 38: 2579-2595.

Regoli F; Gorbi S; Fattorini D; Tedesco S; Notti A; Machella N; Bocchetti R; Benedetti M; Piva F. (2006). Use of the land snail Helix aspersa sentinel organism for monitoring ecotoxicologic effects of urban pollution: An integrated approach. Comp Biochem Physiol A Mol Integr Physiol, 114:63-69.

Salemaa M; Derome J; Helmisaari HS; Nieminen T; Vanha-Majamaa I. (2004). Element accumulation in boreal bryophytes,lichens and vascular plants exposed to heavy metal and sulfur deposition in Finland. Sci Total Environ, 324: 141-160.

Sato M; Hansen J; Koch D; Lucis A; Ruedy R; Dubovik O; Holben B; Chin M; Novakov T. (2003). Global atmospheric black carbon inferred from AAEONET. Presented at Proceedings of the National Academy of Science.

Schilling JS; Lehman ME. (2002). Bioindication of atmospheric heavy metal deposition in the Southeastern US using the moss Thuidium delicatulum. Atmos Environ, 36: 1611-1618.

Smith WH (1990). Forest nutrient cycling: toxic ions. In Air pollution and forests: interactions between air contaminants and forest ecosystems. New York, NY: Springer-Verlag.

Strydom C; Robinson C; Pretorius E; Whitcutt JM; Marx J; Bornman MS (2006). The effect of selected metals on the central metabolic pathways in biology: A review. WaterSA, 32: 543-554.

U.S. EPA (1996). Air Quality Criteria for Particulate Matter. U.S. Environmental Protection Agency. Research Triangle Park, NC. EPA/600/P-95/001aF-cF. November 2004. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_cd.html

US EPA (2004). Air Quality Criteria for Particulate Matter. National Center for Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; report no. EPA/600/P-99/002aF and EPA/600/P-99/002bF. October 2004. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_cd.html

US EPA (2005). Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. Research Triangle Park, NC 27711: Office of Air Quality Planning and Standards; report no. EPA EPA-452/R-05-005a. December 2005. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_sp.html

U.S. EPA. (2006). Air Quality Criteria for Lead Final Report. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-05/144aF-bF, October 2006. Available at: http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_cd.html

US EPA (2008a). Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter. National Center for Environmental Assessment and Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. Report No. EPA 452/R-08-004. March 2008. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/data/2008_03_final_integrated_review_plan.pdf

US EPA (2008c). U.S. EPA. Integrated Science Assessment (ISA) for Oxides of Nitrogen and Sulfur Ecological Criteria (Final Report). U.S. Environmental Protection Agency, Washington, D.C., EPA/600/R-08/082F, December 2008. Available at: http://www.epa.gov/ttn/naaqs/standards/no2so2sec/cr_isi.html

US EPA (2009a). U.S. EPA. Integrated Science Assessment for Particulate Matter (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-08/139F, December 2009. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_isa.html

US EPA (2009h) Risk and Exposure Assessment for Review of the Secondary National Ambient Air Quality Standards for Oxides of Nitrogen and Oxides of Sulfur (Final Report). US Environmental Protection Agency, Research Triangle Park, NC, EPA-452/R-09-008a.

US EPA (2010b). Particulate Matter Urban-Focused Visibility Assessment – Final Report. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/R-10-004. June 2010. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

US EPA (2011) Policy Assessment for the Review of the Secondary National Ambient Air Quality Standards for Oxides of Nitrogen and Oxides of Sulfur. U.S. Environmental Protection Agency, Research Triangle Park, NC, EPA-452/R-11-005a,b. February 2011. Available at: http://www.epa.gov/ttn/naaqs/standards/no2so2sec/cr_pa.html

Viles HA; Gorbushina AA (2003). Soiling and microbial colonisation on urban roadside limestone: A three year study in Oxford, England. Building Environ, 38: 1217-1224.

Yogui G; Sericano J (2008). Polybrominated diphenyl ether flame retardants in lichens and mosses from King George Island, maritime Antarctica. Chemosphere, 73: 1589-1593.

APPENDICES

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APPENDIX A

Clean Air Scientific Advisory Committee (CASAC) Letter on Second Draft Policy Assessment

September 10, 2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

September 10, 2010

EPA-CASAC-10-015

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: CASAC Review of *Policy Assessment for the Review of the PM NAAQS – Second External Review Draft* (June 2010)

Dear Administrator Jackson:

The Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel met on July 26 – 27, 2010 and on August 25, 2010 in a public teleconference to review the *Policy Assessment for the Review of the PM NAAQS - Second External Review Draft* (June 2010). This letter highlights CASAC's main comments on this document, followed by consensus responses to the charge questions and comments of individual Panel members.

This review of the *Second Draft Policy Assessment* completes the first cycle through the revised suite of NAAQS review documents and thus represents a major milestone. CASAC commends EPA staff for developing an ordered and transparent basis for decision-making throughout the NAAQS review process from the *Integrated Science Assessment* (ISA) to the *Quantitative Health Risk Assessment* and *Urban Focused Visibility Assessment* and then to the *Policy Assessment*. The *Second Draft Policy Assessment* was notably responsive to CASAC's comments on the first draft. At CASAC's request, the current draft sets out the underlying decision-making algorithms, greatly enhancing the transparency and readability of the document. EPA's approach to reviewing the standard is explicitly articulated throughout the document, as are the key decision-making points and the evidence considered. CASAC's major concerns, as expressed in our letter of May 17, 2010, have been addressed. EPA staff are to be congratulated for building on CASAC's suggestions and developing an assessment that provides a scientifically sound basis for making decisions on the primary and secondary PM standards.

Primary Standards for Fine Particles

CASAC supports the EPA staff's conclusion in the *Second Draft Policy Assessment* that "currently available information clearly calls into question the adequacy of the current standards". For $PM_{2.5}$, the current 24-hour primary standard is 35 $\mu g/m^3$ and the annual standard is 15 $\mu g/m^3$. EPA staff also conclude that consideration should be given to alternative annual $PM_{2.5}$ standard levels in the range of 13 – 11 $\mu g/m^3$, in conjunction with retaining the current 24-hour $PM_{2.5}$

standard level of 35 $\mu g/m^3$, and that consideration could also be given to an alternative 24-hour $PM_{2.5}$ standard level of 30 $\mu g/m^3$ in conjunction with an annual standard level of 11$\mu g/m^3$. CASAC concludes that the levels under consideration are supported by the epidemiological and toxicological evidence, as well as by the risk and air quality information compiled in the *Integrated Science Assessment* (December 2009), *Quantitative Health Risk Assessment for Particular Matter* (June 2010) and summarized in the *Second Draft Policy Assessment.* Although there is increasing uncertainty at lower levels, there is no evidence of a threshold (i.e., a level below which there is no risk for adverse health effects). In addition, these combinations of annual/daily levels may not be adequately inclusive. It was not clear why, for example, a daily standard of 30 $\mu g/m^3$ should only be considered in combination with an annual level of 11 $\mu g/m^3$. The rationale for the 24-hour/annual combinations proposed for the Administrator's consideration (and the exclusion of other combinations within the ranges contemplated) should be more clearly explained.

Primary Standard for Thoracic Coarse Particles

CASAC recommends that the primary standard for PM_{10} should be revised downwards. While current evidence is limited, it is sufficient to call into question the level of protection afforded by the current standard (a 24-hour standard of 150 $\mu g/m^3$).

CASAC supports the EPA staff conclusion that it is appropriate to change the PM_{10} standard to a 98^{th} percentile form because of its higher rate of identifying areas in nonattainment while reducing the rate of misclassification. We do not agree that the available scientific evidence strongly supports the proposed upper bound standard level of 85 $\mu g/m^3$. The *Second Draft Policy Assessment* demonstrates that a 98^{th} percentile level of 85 $\mu g/m^3$ would be less stringent as compared to the current standard, protecting a smaller fraction of the population. In fact, on a population basis, results in the *Second Draft Policy Assessment* demonstrate that a 98^{th} percentile level between 75 and 80 $\mu g/m^3$ is comparable in the degree of protection afforded to the current PM_{10} standard. The change in form will lead to changes in levels of stringency across the country, a topic needing further exploration. While recognizing scientific uncertainties, CASAC supports a lower level to provide enhanced protection, somewhere in the range of 75 – 65 $\mu g/m^3$. We recognize that the Administrator will need to apply the Clean Air Act's requirement for a "margin of safety" in a context of uncertainty with respect to the health effects of thoracic coarse particles.

The *Second Draft Policy Assessment* concludes that PM_{10} should continue to be the indicator for thoracic coarse particles. While it would be preferable to use an indicator that reflects the coarse PM directly linked to health risks ($PM_{10-2.5}$), CASAC recognizes that there is not yet sufficient data to permit a change in the indicator from PM_{10} to one that directly measures thoracic coarse particles. To improve EPA's scientific basis for the next NAAQS review, we recommend the deployment of a network of $PM_{10-2.5}$ sampling systems so that future studies will be able to expand the evidence base on this indicator and facilitate assessment of whether $PM_{10-2.5}$ should be used as an appropriate indicator for thoracic coarse particles. In concluding this letter, we elaborate further on the urgency of research on certain aspects of PM and health.

Secondary Standard for PM-Related Visibility Impairment

CASAC supports the EPA staff conclusion that "currently available information clearly calls into question the adequacy of the current standards and that consideration should be given to revising the suite of standards to provide increased public welfare protection." The current secondary standards are identical to the current primary standards for fine and thoracic coarse particles. The detailed estimates of hourly PM light extinction under current conditions (and for assumed scenarios of meeting current standards) clearly demonstrate that current standards do not protect against levels of visual air quality which have been judged to be unacceptable in all of the available urban visibility preference studies. EPA staff's approach for translating and presenting the technical evidence and assessment results is logically conceived and clearly presented. The 20-30 deciview range of levels chosen by EPA staff as "Candidate Protection Levels" is adequately supported by the evidence presented.

While the evidence shows that the current standard does not adequately protect visibility, the choice of indicator for such protection was a subject of considerable discussion among CASAC panelists. The *Second Draft Policy Assessment* discusses three potential indicators: a $PM_{2.5}$ Mass Indicator, a Speciated $PM_{2.5}$ Mass-calculated Light Extinction Indicator, and a Directly Measured $PM_{2.5}$ Light Extinction Indicator. Overwhelmingly, CASAC would prefer the direct measurement of light extinction, the property of the atmosphere that most directly relates to visibility effects. It has the advantage of relating directly to the demonstrated harmful welfare effect of ambient PM on human visual perception. However, in discussing the Directly Measured $PM_{2.5}$ Light Extinction Indicator with EPA staff, we learned that the time required to develop an official Federal Reference Method (FRM) for this indicator would postpone its implementation for years. Given the time lag associated with implementing the Directly Measured Indicator, CASAC agrees with EPA staff's preference for a Speciated $PM_{2.5}$ Mass-calculated Light Extinction Indicator. Its reliance on procedures that have already been implemented in the Chemical Speciation Network (CSN) and routinely collected continuous $PM_{2.5}$ data suggest that it could be implemented much sooner than a directly measured indicator.

Areas for Future Research

The *Second Draft Policy Assessment* has identified scientific issues that will need to be addressed in order to improve EPA's scientific basis for promulgating PM standards in the future. As stated in our letter of May 17, 2010, CASAC urges the Agency to reinvigorate research that might lead to new indicators that may be more directly linked to the health and welfare effects associated with ambient concentrations of PM. CASAC also suggests the ongoing collection of more comprehensive PM monitoring data, including expanding the range of sizes to provide information in the ultrafine particle range, and adding measurements of numbers, chemistry, species, and related emissions characteristics of particles. CASAC strongly urges EPA to pursue research to develop a Federal Reference Method for a Directly Measured $PM_{2.5}$ Light Extinction Indicator and to develop baseline light extinction data so that it will be available for the next 5 year review cycle. CASAC is available to provide advice on priorities for PM-related research.

Thank you for the opportunity to comment on the *Second Draft Policy Assessment*. We look forward to receiving your response.

Sincerely,

/Signed/

Dr. Jonathan M. Samet, Chair
Clean Air Scientific Advisory Committee

NOTICE

This report has been written as part of the activities of the EPA's Clean Air Scientific Advisory Committee (CASAC), a federal advisory committee independently chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. CASAC provides balanced, expert assessment of scientific matters related to issues and problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies within the Executive Branch of the federal government. In addition, any mention of trade names or commercial products does not constitute a recommendation for use. CASAC reports are posted on the EPA Web site at: http://www.epa.gov/casac.

Clean Air Scientific Advisory Committee
Particulate Matter Review Panel

CHAIR
Dr. Jonathan M. Samet, Professor and Chair, Department of Preventive Medicine, University of Southern California, Los Angeles, CA

CASAC MEMBERS
Dr. Joseph Brain, Philip Drinker Professor of Environmental Physiology, Department of Environmental Health, Harvard School of Public Health, Harvard University, Boston, MA

Dr. H. Christopher Frey, Professor, Department of Civil, Construction and Environmental Engineering, College of Engineering, North Carolina State University, Raleigh, NC

Dr. Donna Kenski,[1] Data Analysis Director, Lake Michigan Air Directors Consortium, Rosemont, IL

Dr. Armistead (Ted) Russell, Professor, Department of Civil and Environmental Engineering, Georgia Institute of Technology, Atlanta, GA

Dr. Helen Suh, Associate Professor, Harvard School of Public Health, Harvard University, Boston, MA

Dr. Kathleen Weathers, Senior Scientist, Cary Institute of Ecosystem Studies, Millbrook, NY

CONSULTANTS
Dr. Lowell Ashbaugh, Associate Research Ecologist, Crocker Nuclear Lab, University of California, Davis, Davis, CA

Prof. Ed Avol, Professor, Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, CA

Dr. Wayne Cascio, Professor, Medicine, Cardiology, Brody School of Medicine at East Carolina University, Greenville, NC

Dr. David Grantz, Director, Botany and Plant Sciences and Air Pollution Research Center, Riverside Campus and Kearney Agricultural Center, University of California, Parlier, CA

Dr. Joseph Helble, Dean and Professor, Thayer School of Engineering, Dartmouth College, Hanover, NH

Dr. Rogene Henderson, Senior Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

[1] / Did not participate in this review.

Dr. Philip Hopke, Bayard D. Clarkson Distinguished Professor, Department of Chemical Engineering, Clarkson University, Potsdam, NY

Dr. Morton Lippmann, Professor, Nelson Institute of Environmental Medicine, New York University School of Medicine, Tuxedo, NY

Dr. William Malm, Research Physicist, National Park Service Air Resources Division, Cooperative Institute for Research in the Atmosphere, Colorado State University, Fort Collins, CO

Mr. Charles Thomas (Tom) Moore, Jr., Air Quality Program Manager, Western Governors' Association, Cooperative Institute for Research in the Atmosphere, Colorado State University, Fort Collins, CO

Dr. Robert F. Phalen, Professor, Department of Community & Environmental Medicine; Director, Air Pollution Health Effects Laboratory; Professor of Occupational & Environmental Health, Center for Occupation & Environment Health, College of Medicine, University of California Irvine, Irvine, CA

Dr. Kent Pinkerton, Professor, Regents of the University of California, Center for Health and the Environment, University of California, Davis, CA

Mr. Richard L. Poirot, Environmental Analyst, Air Pollution Control Division, Department of Environmental Conservation, Vermont Agency of Natural Resources, Waterbury, VT

Dr. Frank Speizer, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

Dr. Sverre Vedal, Professor, Department of Environmental and Occupational Health Sciences, School of Public Health and Community Medicine, University of Washington, Seattle, WA

SCIENCE ADVISORY BOARD STAFF

Dr. Holly Stallworth, Designated Federal Officer, EPA Science Advisory Board Staff Office

CASAC Responses to Charge Questions on the *Second Draft Policy Assessment* for the Review of the Particulate Matter NAAQS

Primary Standards for Fine Particles

1. **Current Approach (Section 2.1.3)**:
    a. **What are CASAC's views on the staff's approach to translating the available epidemiological evidence, risk information, and air quality information into the basis for reaching conclusions on the adequacy of the current standards and on alternative standards for consideration?**

CASAC agrees with the approach as described in Section 2.1.3 and appreciates the clarity with which the approach is detailed. The overview of the approach presented in Figure 2-1 is well-organized, logical, and clear. CASAC agrees that it is appropriate to return to the strategy used in 1997 that considers the annual and the short-term standards together, with the annual standard as the controlling standard, and the short-term standard supplementing the protection afforded by the annual standard. CASAC commends the expansion of the discussion on evidence of risk across life stages as well as of specific susceptibility risk factors and the use of empirical evidence and risk assessment findings together. CASAC considers it appropriate to place the greatest emphasis on health effects judged to be causal or likely causal in the analysis presented in the ISA. Finally, the statement that the data "call into question" the adequacy of the current standard could be more forcefully stated by concluding that the current standard is not protective.

    b. **Has staff appropriately applied this approach in reviewing the adequacy of the current standards (Section 2.2) and potential alternative standards (Section 2.3)?**

The staff has carefully followed this approach in reviewing the adequacy of the current standards and in considering potential alternative standards. The outline of the text of Section 2.3 follows the outline presented in the overview of the approach given in Figure 2-1.

2. **Form of the Annual Standard (Section 2.3.3.1):**
    a. **What are CASAC's views on the additional analyses conducted to characterize the potential for disproportionate impacts on susceptible populations, including low income groups and minorities associated with spatial averaging allowed by the current annual standard?**
    b. **In light of these analyses, what are CASAC's views on staff's conclusion that the form of the annual standard should be revised to eliminate spatial averaging?**

CASAC found the additional analyses provided in the 2nd draft PA to be helpful in understanding how spatial averaging differs relative to the highest average value from a single community site. This latter approach helps to ensure adequate protection of populations living in lower socioeconomic areas and contributes an additional margin of safety for other populations. Although much of the epidemiological research has been conducted using community-wide averages, several key studies reference the nearest measurement site, so that some risk estimates are not necessarily biased by the averaging process. Further, the number of such studies is likely to

expand in the future. CASAC concludes that it is reasonable for EPA to eliminate the spatial averaging in the new $PM_{2.5}$ annual average standard.

3. Alternative Levels (Section 2.3.4): What are CASAC's views on the following:

a. The insights that can be gained into potential alternative standard levels by considering:

i. Confidence bounds on concentration-response relationships?

CASAC commends the progress made in attempting to use confidence bounds in considering alternative levels of the standard, but also finds unresolved complexities. First, staff apparently made a comprehensive effort to identify relevant studies for which bounds were reported on concentration-response (C-R) relationships; this should be explicitly stated. Second, the statement made in reference to what these bounds do not indicate ("these analyses do not provide evidence of a concentration below which the confidence interval becomes notably wider and uncertainty in a C-R relationship substantially increases" [p.2-57]) is contradictory to what they, in fact, do indicate. The confidence bounds widen at lower concentrations because there are fewer data at such concentrations, as acknowledged by staff. This widening is of interest in characterizing precision of estimates as one source of uncertainty. Third, CASAC does not agree with the conclusion that these bounds cannot be used in considering alternative levels of the PM NAAQS, even with the limited C-R functions shown. EPA Staff should be encouraged to integrate the information available on relevant C-R confidence bounds with that on study concentration distributions in arriving at a range of levels for consideration.

For the future, findings of epidemiological studies might be used in several ways in considering a range of levels for a NAAQS. It would be preferable to have information on the concentrations that were most influential in generating the health effect estimates in individual studies. Less ideal, but still useful, would be information on the distribution of concentrations experienced by participants in the studies. For time-series studies, because of the similar number of events (e.g., deaths) per day, this is likely to be the same as the PM concentration distribution; the situation is more complex for cohort studies in which exposures of individuals change over time. Least preferable is using PM concentration distribution metrics, such as those used by EPA Staff in arriving at a range of levels for consideration. An attempt should be made, to the extent possible, to integrate this latter approach with aspects of the first two approaches, realizing that the reported study findings and data needed to accomplish this goal may not be readily available, and that interactions with investigators may be needed.

ii. Different statistical metrics that characterize air quality distributions from multi-city epidemiological studies?

The *Second Draft Policy Assessment* provides two alternatives, referred to as the composite monitor and the maximum monitor. On the top of page 2-61, the text appears to be stating that, for the same air quality domain, the composite monitor concentrations are less than those based on the maximum monitor approach, and an argument is made that an approach based on composite monitors has a "margin of safety" compared to the maximum monitor perspective. However, a judgment is made that data should be selected from the epidemiological studies for which the C-R relationships are "strongest," and that concentrations not more than one standard deviation below

the long-term mean concentration should be used. The judgment, while not unreasonable, is not explained.

It is not clear why the lower bound to be considered is a range from the 10^{th} to 25^{th} percentiles, as opposed to, say, the 10^{th} percentile alone. In Figure 2-7, for long-term exposure studies, in the upper panel, the 10^{th} percentile annual mean concentrations range from approximately 9 to 11 $\mu g/m^3$. The population-weighted values are 10 to 13 $\mu g/m^3$. In both cases, the upper bounds of these ranges are for the high site, and the lower bounds are for the composite monitor.

In summary, this section of the report lacks clarity and focus on the key consideration of identifying ambient concentrations at which adverse effects are observed, in anticipation of supporting a range of concentrations that take into account the statutory mandate to provide an adequate margin of safety.

b. Potential alternative annual standard levels based on composite monitor distributions versus maximum monitor distributions?

The composite monitor approach is preferable because of its stability, and for the additional margin of safety it provides. The NAAQS should provide health protection for both long-term and short-term health effects. It is not clear, for example, as to why the 24-hour level should be at least 2.5 times higher than the annual standard. Such a statement seems to be independent of consideration of health effects. A statement is made on page 2-73, lines 26-27 that "based on this consideration" consideration should be given to retaining the 35 $\mu g/m^3$ 24-hr level in conjunction with annual standards of 13 to 11 $\mu g/m^3$. Setting aside the math problem here (e.g., 11*2.5 = 27.5, not 35), the rationale for the 2.5 times factor appears arbitrary and not based on health considerations.

c. Use of risk information in informing staff conclusions on alternative annual and 24-hour standard levels, including approaches used to assess overall confidence and potential bias in the risk estimates?

The risk information provides valuable insights, and should be used in drawing conclusions. However, there is not symmetry between the evidence-based section and the risk-based section. . The "evidence-based" section reaches the conclusion that alternative levels to be considered should be 11 to 13 $\mu g/m^3$ for the annual standard and 35 ug/m^3 for the 24-hour standard, and also a combination of 11/30 $\mu g/m^3$ for the annual/24-hour levels. However, the risk-based analysis does not systematically evaluate these combinations, omitting the 11/35 $\mu g/m^3$ and 11/30 $\mu g/m^3$ combinations. Furthermore, the text implies that a 10/35 ug/m^3 case was analyzed, but no results were reported. This difference between the ranges from the two sections reflects in part the scenarios considered in the risk assessment. While the Administrator's consideration should not be limited to those combinations that were analyzed quantitatively, the final policy assessment should be systematic and emphatic about providing conclusions regarding combinations of annual and daily levels that were not analyzed quantitatively but that are recommended for consideration.

The results of the risk assessments are presented mainly in terms of percentage risk reduction compared to the current standard, in Figures 2-11 and 2-12 for long-term and short-term effects, respectively. While this is useful information, it is not directly relevant to the setting of a NAAQS,

given the goal of a NAAQS--to protect public health with an adequate margin of safety. Additionally, the information on risk reduction might be better presented as the absolute numbers of deaths avoided rather than the percentage reduction under the various scenarios. The text should be rewritten to better reflect the utility and relevance of the information on reduction of disease burden for determining the NAAQS.

This section should not only focus on the best estimate of risk, but the confidence intervals and non-quantified sources of bias, such as the role of socio-economic status (SES). See also Page 2-35, lines 10-12, which indicates that sensitivity analysis of model specification used in the risk assessment produce risk estimates that are a factor of 2 to 3 higher than the core risk estimates.

d. Staff's conclusion that alternative annual standard levels in the range of 13 to 11 µg/m^3 are most strongly supported by the available evidence and risk-based information?

The rationale for the conclusion was well developed, but could use further justification, particularly in regard to the pairing of the 24-hour and annual standards. The risk assessment did not explore all the combinations considered in the *Policy Assessment*. While CASAC agrees with the range of 13 to 11 ug/m^3, it finds less justification for the pairings proposed.

e. Staff's approach of focusing on peak-to-mean ratios to inform the level of a 24-hour standard that would provide supplemental protection to a generally controlling annual standard?

The peak-to-mean ratio merits consideration in providing insight as to whether the annual or 24-hour standard would be controlling in a particular area. It is not relevant to informing the actual level to be selected for the 24-hour standard.

f. Staff's conclusion that consideration should be given to retaining the current 24-hour standard level of 35 µg/m^3 in conjunction with annual standard levels in the range of 13 to 11 µg/m^3, and that consideration could also be given to an alternative 24-hour standard level of 30 µg/m^3 particularly in conjunction with an annual standard level of 11 µg/m^3?

The conclusions are reasonable in relation to the criteria established by the Clean Air Act (CAA), and those developed by the OAQPS Staff that have been endorsed by CASAC. The choices within these options will need to be based on the Administrator's interpretation of the CAA's requirement for an adequate margin-of-safety. In other words, in the absence of thresholds in the dose-response relationships for the health outcomes of concern, how much public health impact resulting from exposure to ambient air $PM_{2.5}$ is acceptable under the CAA.

The least protective option (35-13 µg/m^3) would provide significant additional public health benefits in most of the U.S., in comparison to the current limits (35-15 µg/m^3). The most protective option (30-11 µg/m^3) would provide significant additional public health benefits to a larger part of the U.S. population in comparison to the current limits (35-15 µg/m^3) and any of the intermediate options, but would not prevent at least some adverse health effects among the most susceptible

segments of the population, given our current understanding of dose-response relationships.

4. Key Uncertainties and Areas for Future Research and Data Collection (Section 2.5): What are CASAC's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

The key uncertainties and areas for future research and data collection are well summarized in Section 2.5. The acknowledgement (at the top of page 2-87) that "Much of this research may depend on the availability of increased monitoring data" is apt and appreciated. The opportunities for epidemiological research to effectively address the knowledge gaps on the effects, and concentration-response relationships, of PM components and source-related mixtures cannot be achieved without additional monitoring data to provide PM speciation and better temporal and spatial resolution. Only the EPA can provide the impetus and support for such an enhancement in air quality monitoring.

The research needs to address uncertainties in health outcomes, exposure durations of concern, and susceptible populations that are also very nicely outlined are well targeted, and can be effectively studied in human populations. Such studies, to be most productive, will need the enhanced monitoring data, as recognized by EPA staff.

This section, as written, has more to do with future research priorities than with uncertainties that influence impending decisions on revisions to the $PM_{2.5}$ NAAQS. The section outlines a very broad and ambitious research agenda. It would help to begin this section with a prioritized review of key uncertainties in order to help establish priorities among the suggested research topics. Obviously the key uncertainty is the range of concentrations that are causing the observed health effects in the epidemiological studies, and the degree of certainty in effects at the lower concentrations along the C-R relationship. This uncertainty has necessitated using the distributional measures of concentrations from the epidemiology studies in attempting to make the link between the epidemiological findings and consideration of alternative concentrations for the PM NAAQS. While this uncertainty is reflected in two (p.2-88 and 2-90) of the many recommendations for future research that C-R functions include confidence bounds, this uncertainty should be highlighted. We urge careful attention to priorities in relation to future revisions of the PM NAAQS, rather than a lengthy list of research topics.

CASAC finds the list to be appropriate, but also suggests consideration of the following:

- Generating time-activity data to support probabilistic scenario-based exposure models, such as additional activity diary data to incorporate into the Consolidated Human Activity Database (CHAD).
- Characterizing indoor exposures to PM of ambient origin. For example, the penetration of ambient $PM_{2.5}$ and PM_{10} into indoor microenvironments (home, work, school, restaurant, bar, vehicle) should be better characterized, particularly taking into account differences in penetration with respect to particle size and composition. Given the greater amount of time we spend in indoor vs. outdoor environments, the need for these data is compelling.

- Addressing the bidirectional linkages between climate change and concentration, size distribution and composition of PM in the PM_{10}, $PM_{2.5}$, and ultrafine particle (UFP) fractions. This would include assessing the relative effects of climate cooling due to aerosols (e.g., sulfate) vs. climate warming due to elemental carbon. Effects of increased wildfires, windblown dust and pollen seasonality are also of interest.
- Continuing support of toxicological research in terms of chemical components, sources and subfractions (to include UFP). Toxicological studies will address biological plausibility and give insights as to possible mechanisms. Although C-R relationships are a challenge to extrapolate from animal to human, animal studies do provide an effective means to conduct controlled and well-characterized exposure scenarios to examine C-R relationships.

Primary Standard for Coarse Particles

5. Current Approach (sections 3.1.4, 3.2, 3.3):

a. What are CASAC's views on the approach to translating the available evidence and air quality information into the basis for reviewing the coarse particle standard?

CASAC finds the second draft superior to the first draft reviewed earlier; it demonstrates considerable progress and responsiveness to CASAC's suggestions. The document is grounded on explicit data and clearly stated arguments. EPA staff has done its best to take the available evidence relating to exposure and health effects and to use them as the basis for reviewing the coarse particle standard.

There are inherent deficiencies which persist because of lack of data. Concentrations of the coarse particle fraction--particles between 2.5 and 10 microns—are usually estimated by subtraction and not measured directly. Moreover, given the limited data on coarse particles, much of the evidence on health effects comes from interpreting studies using PM_{10} and assessing the extent to which the health effects observed relate to the entire size range collected [including $PM_{2.5}$] or to only the coarse particle fraction.

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standard (section 3.2) and potential alternative standards (section 3.3)?

CASAC responds affirmatively to this question. The staff have noted the limitations of the data and used them in light of these limitations to address the question of whether current standards are adequate. CASAC also finds that staff has adequately discussed alternative standards and the consequences of applying them.

In toto, Chapter 3 reads well and is much improved. EPA staff has done its best to describe an evidence-based approach for applying the limited amount of health effects evidence and air quality information in different US regions as a basis for reviewing the adequacy of the current coarse particle standard.

6. Adequacy of the Current PM_{10} Standard (section 3.2): What are CASAC's views on the alternative approaches presented for considering the evidence and its uncertainties as they relate to the adequacy of the current standard?

The general consensus of CASAC is that consideration should be given to revising the current 24-hour PM_{10} standard. The rationale for this recommendation emerges from the judgment that the current data, while limited, is sufficient to call into question the level of protection afforded the American people by the current standard. The opinion hinges on the strength of associations in multi-city studies and positive trends in single city studies linking PM_{10} exposure and health endpoints, and moreover that these health effects can occur below the current standard. This approach gives significant weight to studies that have generally reported that $PM_{10-2.5}$ effect estimates remain positive when evaluated in co-pollutant models. Likewise controlled human exposure $PM_{10-2.5}$ studies showing decreases in heart rate variability and increases in markers of pulmonary inflammation are deemed adequate to support the plausibility of the associations reported in epidemiologic studies.

7. Indicator (Section 3.3.1): What are CASAC's views on the approach taken to considering standard indicator and on staff's conclusion that PM_{10} remains an appropriate indicator in this review?

The majority of CASAC determined that there was insufficient evidence currently available to support a change in the indicator from PM_{10} to $PM_{10-2.5}$. However, CASAC vigorously recommends the implementation of plans for the deployment of a network of $PM_{10-2.5}$ sampling systems so that future epidemiological studies will be able to more thoroughly explore the use of $PM_{10-2.5}$ as a more appropriate indicator for thoracic coarse particles.

If a PM_{10} indicator is retained, the Agency should consider limiting the Federal Reference Method to include only low volume PM_{10} samplers, as high volume PM_{10} samplers do not produce comparable results.

8. Form (Section 3.3.3): What are CASAC's views on the approach taken to considering the form of the standard and on staff's conclusion that revising the form to a 98^{th} percentile form would be appropriate for a 24-hour PM_{10} standard meant to protect against exposures to thoracic coarse particles?

CASAC felt strongly that it is appropriate to change the statistical form of the PM_{10} standard to a 98^{th} percentile form. Published work has shown that the percentile form has greater power to identify non-attainment and a smaller probability of misclassification relative to the expected exceedance form of the standard. This change in form will lead to changes in levels of stringency across the country, a topic needing further exploration.

9. Level (Section 3.3.4): What are CASAC's views on the following:

a. The approach taken by staff to identify potential alternative PM_{10} standard levels, in conjunction with a 98^{th} percentile form, including the weight placed on different studies?

b. Staff's conclusion that the evidence most strongly supports standard levels around 85 μg/m^3?

c. The alternative approach to considering the evidence that could support standard levels as low as 65 μg/m^3?

CASAC concurs that the approach in identifying potential alternative PM_{10} standard levels are appropriate, with the discussion regarding the weight placed on different studies clearly and cogently presented. CASAC also considered that the proposed alternative standard levels of 85 and 65 ug/m^3 (based on consideration of 98th percentile PM_{10} concentration) could be justified.

CASAC, however, does not agree that scientific evidence most strongly supports an upper bound standard level of 85 μg/m^3. As stated in the *Second Draft Policy Assessment*, scientific evidence supports the adoption of a standard at least as stringent as the current standard of 150 μg/m^3 based on one expected exceedance. Table A3 suggests that a 98th percentile level of 85μg/m^3 is less stringent as compared to the current standard, protecting a smaller fraction of the population. Results instead point to a 98th percentile level between 75 and 80 μg/m^3 as comparable to the current standard. CASAC further notes that setting new 24-hour PM_{10} standard levels should also consider the impact of corresponding changes in $PM_{2.5}$ standards, which will likely result in lower 24-hour $PM_{2.5}$ concentrations and lower measured PM_{10} values. Thus, proportionately more coarse particle mass could be airborne at the standard level. Absent corresponding reduction in the PM_{10} standard, these lower $PM_{2.5}$ concentrations would lessen the level of protection provided by the PM_{10} standard for exposure to $PM_{10-2.5}$

The *Second Draft Policy Assessment* does not adequately convey the possible rationale for selecting the lower end of the proposed range of levels. Therefore, the considerations that might lead to selecting a PM_{10} standard level more stringent than afforded by the current standard should be more clearly elaborated. These considerations focus on margin of safety, particularly as it relates to the impact and weight given to suggestive findings of causality, to findings of positive but statistically insignificant results, and to exposure measurement error and other sources of uncertainty.

10. Key Uncertainties and Areas for Future Research and Data Collection (Section 3.5): What are CASAC's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

See comments on Chapter 2.

The key distinction for this chapter is the need to seriously focus on $PM_{10-2.5}$ for both mass and composition. CASAC looks forward to the planned implementation of monitors that measure $PM_{10-2.5}$, rather than PM_{10}. There is a critical need for national monitoring data on $PM_{10-2.5}$ in order to provide a basis for epidemiological studies that focus on this size fraction. Furthermore, there is a need for speciated data to support health effects research. Spatial and temporal variability in coarse particle mass and composition need to be characterized. In addition, the national monitoring data will support a baseline for ambient air quality in order to compare with health effects data in order to assess whether there is a need for a more stringent standard.

The research areas described in the draft Section 3.5 are reasonable, but there needs to be strong emphasis on the critical need for coarse PM data, in order that the NAAQS can move beyond PM_{10} as an indicator for thoracic coarse PM in a future NAAQS revision.

Another question to be considered is regarding what size cut-points are most appropriate, and also regarding what specific components are of most interest or concern with respect to health effects.

There is a need for continuous monitoring of coarse PM (and of $PM_{2.5}$) in order to support health effects studies and to be able to assess alternative forms of possible future standards.

Other challenges for future research: (a) it may be difficult to get useful data from rodent inhalation studies since they can breathe particles only up to about 2 to 3 microns into their lung airways; (b) getting good chemical characterization of the particles will be a problem, since there are primary biological materials of potential interest in the thoracic coarse size range.

Prioritization of the research topics is needed, such as via a separate meeting or workshop.

Secondary Standard for PM-related Visibility

11. Current Approach (Section 4.1.3):

a. What are CASAC's views regarding our approach for translating technical evidence and assessment results into the basis for assessing current fine particle standards and considering alternative standards to provide protection against PM-related visibility impairment?

The translation of technical evidence and assessment results as a basis for reviewing and revising the current secondary fine particle standard is logically conceived, clearly presented, and responsive to previous CASAC recommendations. The combined evidence-based and impact-based assessments effectively contrast and integrate the various combinations of metrics for protecting urban visibility. While this approach is inherently complex, it is clearly explained in the text and concisely summarized in Figure 4-1. The various tables and graphics in Chapter 4 and its associated appendices are helpful in communicating the inherent complexity that results from the evaluation of so many possible combinations of indicators, averaging times, levels and forms.

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standard (Section 4.2) and potential alternative standards (Section 4.3)?

The detailed estimates of hourly PM light extinction under current conditions and for "what if" scenarios of just meeting current standards clearly indicate that the current $PM_{2.5}$ standards do not protect against levels of visual air quality which have been judged to be unacceptable in all of the available urban visibility preference studies. The levels are too high, the averaging times are too long, and the $PM_{2.5}$ mass indicator could be improved to correspond more closely to the light scattering and absorption properties of suspended particles in the ambient air.

While not discussed in detail in the *Second Draft Policy Assessment*, direct measurements of light extinction are the preferable indicator for an alternate standard to make an accurate assessment of the PM effect on urban visibility. These measurements would provide timely and easy-to-

understand results to address the protection of the public welfare from PM impacts, but without a Federal Reference Method (FRM) adopted or in the development process – these data are not currently available for most urban areas. Additional discussion of the timeline and process anticipated by EPA to advance direct measurement of light extinction monitoring methods to FRM status would be helpful.

Given this limitation, the detailed estimates of PM light extinction employed for 15 urban areas in the UFVA, and used to evaluate alternative new indicators including hourly $PM_{2.5}$ mass and "speciated $PM_{2.5}$ mass-calculated light extinction" in the *Second Draft Policy Assessment* are appropriate for the initial promulgation and first generation of regulatory air quality analysis and planning; similar to the process for the Regional Haze Rule. The speciated $PM_{2.5}$ mass-calculated light extinction indicator produces hourly extinction values quite similar to those resulting from more complex calculations, and it could be an appropriate indicator for a revised secondary standard, if employed on an interim basis until methods for direct light extinction measurements can be developed and deployed.

While the stated intent of the *Second Draft Policy Assessment* is "to provide as broad an array of options as is supportable by the available information", the CASAC recommends providing additional and more focused discussion of the policy implications that may be associated with selecting and implementing specific combinations of indicators, levels and forms from within this broad array of options. Some discussion should also be provided to indicate that reductions in light scattering aerosols could decrease light extinction but increase radiative forcing, while reductions in light absorbing aerosols would decrease both light extinction and radiative forcing. The contributions of anthropogenic controllable "Short-Lived-Climate-Forcers" that contribute significantly to urban visibility impairment would also be worthy of some attention in the analysis of policy implications.

12. Nature of the Indicator (Section 4.3. 1): What are CASAC's views on the following:

- **a. Staff's consideration of the three indicators identified in this section and our conclusions on the appropriateness of these indicators for consideration in this review?**
- **b. The development and evaluation of a new approach that is based on using speciated $PM_{2.5}$ mass and relative humidity to calculate $PM_{2.5}$ light extinction by means of the IMPROVE algorithm?**
- **c. The assessment approach and results comparing the PM components that contribute to the hours selected in the top percentiles for $PM_{2.5}$ mass and PM_{10} light extinction?**

As noted in past comments, CASAC strongly prefers directly measuring light extinction to using estimates based on mass measurements (e.g., the other options provided in the *Second Draft Policy Assessment*). In their recent review, the Ambient Air Monitoring and Methods Subcommittee (AAMMS) noted that there are commercial instruments available that provide light extinction measurements directly, and promising additional technologies may soon become available. The AAMMS also encouraged the EPA to begin the process of developing performance standards for PM light extinction measurements. However, a FRM for light extinction measurement does not yet

exist, and as EPA does not view it as practical to develop an FRM in time for this rule making, CASAC recognizes that alternative approaches need to be considered.

A current weakness of the *Second Draft Policy Assessment* is that it does not explicitly state the reasons that EPA does not currently recommend using a direct measurement of light extinction. It also does not provide any indication that the proposed mass-based indicators are intended for use on an interim basis, to be replaced with direct light extinction-based measurements as those methods are developed, tested and deployed. If staff consider it impractical to develop performance standards for an FRM in time for this round of rule making, this should be clearly stated and a schedule for developing such performance standards and evaluating candidate instruments should be specified well in advance of the next PM NAAQS review.

Assuming it is currently impractical to develop a FRM for direct measurements of PM light extinction in a sufficiently timely manner, CASAC agrees that for this rule making, a method to estimate extinction based on measurements from continuous $PM_{2.5}$ monitors, preferably adjusted by $PM_{2.5}$ speciation and relative humidity (RH) data, is appropriate. The "speciated $PM_{2.5}$ mass-calculated light extinction" method described in the *Second Draft Policy Assessment* appears to be a reasonable approach for estimating hourly light extinction. For purposes of "near real time" visibility tracking, CASAC recommends considering a simpler calculation in which historical, rather than concurrent, monthly or seasonal speciation averages would be used to estimate speciation for combining with real-time continuous $PM_{2.5}$ and RH data, even though the most recent speciation data would be used for developing plans for improving visibility. CASAC also recommends that the Agency consider developing the monthly or seasonal speciation estimates on a regional basis as well as on a site-specific basis, as this would allow light extinction estimates at all (>700) sites with continuous $PM_{2.5}$ data, rather than just the relatively few sites with collocated continuous $PM_{2.5}$ and speciation monitors.

13. Alternative Levels and Forms (Section 4.3.3): What are Panel views on the following:

a. The performance assessment which focused on the Candidate Protection Levels of 64, 112, 191 Mm^{-1} for $PM_{2.5}$ light extinction and speciated $PM_{2.5}$ mass-calculated light extinction, and alternative levels of 10, 20, and 30 $\mu g/m^3$ for $PM_{2.5}$ mass concentration?

These are appropriate CPL and $PM_{2.5}$ levels. The CPL values were based on all visibility preference data that are available and bound the study results as represented by the 50% acceptability criteria. However, the presentation could be improved by expanding some of the tables to include 10 and 40 dv values, in that at 10 dv, no viewer found the scene to be unacceptable, and at 40 dv, virtually all viewers found all scenes to be unacceptable. What would these dv levels correspond to in the context of $PM_{2.5}$ and the various percentile levels?

b. Use of three-year averaged 90^{th} and 95^{th} percentiles in conjunction with a 1-hour daily maximum form and use of three-year averaged 98^{th} percentile in conjunction with the all daylight hours form?

While these levels may be appropriate, they are not well justified. A cursory argument was made that the 90–95^{th} percentiles in conjunction with the 1-hour daily maximum identified similar days

and hours of non-compliance, as did the 98th percentile in conjunction with all daylight hours, and this correspondence was a sufficient basis to pick these two approaches. It would be informative to compare all, or at that least the same, percentiles for both all days and the daily hourly daily maximum. These analyses should be informative as to whether one approach is preferred. Whether different sources might be identified, depending on use of daily average or maximum values has not been adequately addressed. For example, a significantly extended episode of low visibility might be attributed to a single source, such as a large wildfire or prescribed fire, which would result in the all hour, all day approach targeting only one large emission episode that occurred for only one or a few time periods. For wintertime episodes in many cities of multi-day poor urban visibility conditions, the events can cross the end of the calendar year, tracking the highest daily hour for each day to form a full 3-year distribution of values (i.e., N = ~1,095) for which the compliance value is then compared to the percentile level selected by EPA.

c. Insights to be drawn by comparing the PM components for hours included among the 10% highest for a 1-hour daily maximum form with the hours included among the 2% highest for an all daylight hours form, for the various indicators considered (Appendix C)?

See comments above. These two approaches appear to be similar; however, it would be helpful to quantify the similarities as opposed to relying only on a qualitative discussion. A scatter plot might be useful for the 14 sites that provides the average fractional contribution of a species in relation to the time metric used. Additionally, comparisons should be shown for the specific days found in non-compliance by metric.

14. Key Uncertainties and Areas for Future Research and Data Collection (Section 4.5): What are CASAC's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

The major areas of research and data collection needed to address key uncertainties related to a visibility-based secondary standard are nicely captured in Section 4.5 of the *Second Draft Policy Assessment*. The section appropriately identifies two major areas of need, one related to visibility preference, and one related to methods of measurement.

In the first category, preference studies, the details noted by EPA all identify a strong need for additional urban visibility preference studies conducted using consistent methodology. The range of 50% acceptability values discussed as possible standards are based on just four studies (Figure 4-2), which, given the large spread in values, provide only limited confidence that the benchmark candidate protection levels cover the appropriate range of preference values. Studies using a range of urban scenes (including, but not limited to, iconic scenes – "valued scenic elements" such as those in the Washington DC study), should also be considered.

In the second category related to methods of measurement, CASAC supports the proposal to conduct studies in several cities, pairing direct monitoring of light extinction with enhanced monitoring of PM size and composition distributions (i.e., continuous PM speciation monitoring). Additional work should also be conducted to understand the contribution of $PM_{10-2.5}$ in

southwestern areas other than Phoenix, to address the lack of information for scattering associated with this fraction of PM_{10} as is noted on page 4-30.

Underlying this overall discussion is a clear need for better particle size – composition distribution information (i.e., particle composition distributions as a function of particle size). These data gaps are addressed in different ways in the discussion of future research needs elsewhere in the Second Draft Policy Assessment (Sections 2.5 and 3.5). Moreover, the development of continuous monitoring methods for specific PM components addressed in Section 2.5 is equally applicable here. Improved understanding of size-dependent PM composition would also help address the questions related to the role of scattering and absorbing aerosols in climate forcing that are raised in Section 5.2.4.

Finally, a number of research and data collection topics overlap between the secondary PM NAAQS, and the $PM_{2.5}$ and PM_{10} primary PM NAAQS. For example, the fraction of combustion-related primary carbon PM species can be an important indicator of harmful health effects, visibility impairment and climate forcing.

With these characteristics, research to jointly quantify and reduce these primary PM carbon species from combustion sources would advance the information available to the Administrator for her judgment about the necessary level of protection to be provided by the future PM NAAQS, to be assessed in the next review cycle.

CASAC suggests that EPA look for additional opportunities to align health and welfare improvement strategies simultaneously for common indicators, such that the next reviews of the PM and other NAAQS have not only the analyses of the effects of PM and other NAAQS indicators on health and welfare, but also include metrics useful for measuring progress toward attainment.

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APPENDIX B

Ambient PM Monitoring Networks

The measurement of ambient air pollution in the United States is provided through a number of ambient air monitoring networks operated almost exclusively by state, local, and tribal air monitoring programs. This section briefly describes the objectives for each of the PM monitoring networks as well as the coverage for each network across the country.

The ambient air monitoring networks are designed to meet three basic monitoring objectives. Each objective is important and must be considered individually. The objectives are:

- to support compliance with ambient air quality standards and emissions strategy development, including comparison to the NAAQS, assess ambient exposures, development of attainment and maintenance plans, evaluation of regional air quality models used in developing emission strategies, and tracking trends in air pollution abatement control measures' impact on improving air quality;
- to provide air pollution data to the general public in a timely manner such as reporting the Air Quality Index (AQI) through AIRNow (www.airnow.gov), monitoring agency web sites, conventional media outlets such as newspapers, radio and television news, and emerging outlets such as social networking sites; and
- to support air pollution research studies, including atmospheric, health, and epidemiological studies that are used to inform future reviews of the NAAQS.

The sections below briefly summarize the monitoring networks for $PM_{2.5}$, including $PM_{2.5}$ mass, $PM_{2.5}$ speciation, PM_{10} mass, $PM_{10-2.5}$ mass, and the forthcoming National Core (NCore) multi-pollutant network.

B.1 $PM_{2.5}$

The $PM_{2.5}$ design criteria require State and Local Air Monitoring Stations (SLAMS) in Metropolitan Statistical Areas (MSAs) based on a combination of population and design value (Table D-5, 40 CFR Part 58) with higher populated locations having more polluted air required to have the most stations. Background and transport sites are also required of each state with options for utilizing Interagency Monitoring of Protected Visual Environments (IMPROVE) stations and other $PM_{2.5}$ data to provide for flexibility in meeting the requirement.

In urban areas, required $PM_{2.5}$ monitoring stations are sited to represent community-wide air quality. These monitoring stations will typically be at neighborhood or urban scale; however, where a population-oriented micro- or middle-scale $PM_{2.5}$ monitoring station represents many such locations throughout a metropolitan area, these smaller scales can be approved by the

applicable EPA Regional Office to also represent community-wide air quality. The EPA's existing network design criteria for $PM_{2.5}$ states: "(1) at least one monitoring station is to be sited in a population-oriented area of expected maximum concentration and (2) for areas with more than one required SLAMS, a monitoring station is to be sited in an area of poor air quality" (40 CFR, PART 58, Appendix D, section 4.7). Since monitors sited for either of these network design criteria must represent community-wide air quality, they are also representative of population exposure. Most $PM_{2.5}$ monitoring in urban areas should be representative of a neighborhood scale.

In rural areas, the design of the network relies on IMPROVE, rural NCore stations, a limited number of smaller cities, and partner monitoring agencies to provide for regional characterization of $PM_{2.5}$. Stations in these areas are typically sited to represent regional scale air quality and are therefore located away from any local sources, should they exist.

B.1.1 $PM_{2.5}$ Federal Reference Method (FRM) Network

The network of $PM_{2.5}$ FRMs has been operational since 1999. This network includes over 900 monitoring stations throughout the country. The FRMs are primarily used to determine compliance with the NAAQS, but also serve other objectives. Since FRMs are filter-based methods requiring post-sampling laboratory analysis, which is labor intensive, monitoring programs have some flexibility in how often they must be operated. Approximately 150 FRMs operate every day, 600 every third day, and another 150 every sixth day. Sample frequencies of every third and sixth day are based on a national sample calendar provided by EPA. The number of $PM_{2.5}$ FRMs may decrease over the coming years as $PM_{2.5}$ continuous FEMs[1] are now available and can replace FRMs for purposes of comparison to the NAAQS. Figure B-1 illustrates the locations of $PM_{2.5}$ FRMs reporting to the Air Quality System (AQS).

B.1.2 $PM_{2.5}$ Continuous Monitor Network

Continuous $PM_{2.5}$ monitors are required in MSAs at one half (rounded up) the number of monitoring stations that are required to have an FRM/FEM monitor. Since most deployed $PM_{2.5}$ continuous monitors are not approved as FEMs, many of these monitors are collocated at monitoring locations with an FRM so that the availability of data from both instruments supports each of the major monitoring objectives described earlier in this section. Collocation with $PM_{2.5}$ FRMs and continuous monitors also ensures that reference data are available to validate the performance of the continuous monitor. While $PM_{2.5}$ continuous monitors primarily support forecasting and reporting the AQI, they are also used in interpreting the diurnal characterization

[1] A Federal Equivalent Method (FEM) means a method for measuring the concentration of an air pollutant in the ambient air that has been designated as an equivalent method in accordance with 40 CFR Part 53.

of $PM_{2.5}$. The network of $PM_{2.5}$ continuous monitors has grown to over 700 locations throughout the country with approximately 160 monitors in operation as continuous FEMs. Continuous FEMs are compared to the NAAQS when designated as the primary monitor at a station. A recent assessment of continuous $PM_{2.5}$ FEM data quality, as compared to collocated FRMs, indicates that some FEMs are meeting the performance criteria used to approve these methods, which are based on daily measurements, while others are not. The assessments and recommendations for addressing data quality issues are detailed in Hanley and Reff, 2011.[2] Additionally, as part of a review of 1-hour data from all continuous FEM $PM_{2.5}$ instruments operating at state/local monitoring sites, we have recently become aware of the occurrence of questionable outliers in 1-hour data submitted to AQS from continuous FEM $PM_{2.5}$ instruments at some of these sites (Evangelista, 2011).[3] Figure B-2 illustrates the locations of $PM_{2.5}$ continuous monitors reporting to AQS, including those that are now approved as FEMs.

B.1.3 $PM_{2.5}$ Speciation

As part of the $PM_{2.5}$ NAAQS review completed in 1997, EPA established a $PM_{2.5}$ Chemical Speciation Network (CSN) consisting of 54 Speciation Trends Network (STN) sites. The STN was established to conduct routine speciation monitoring in primarily urban areas to provide nationally consistent data for the assessment of trends and to provide a long-term record of the chemical composition of $PM_{2.5}$ in the United States. The initial STN monitoring began with a pilot of 13 sites in February 2000. In addition to the STN, EPA also implemented a network of about 200 supplemental speciation sites for multiple monitoring objectives including support for: the development of modeling tools and the application of source apportionment modeling for control strategy development to implement the NAAQS; health effects and exposure research studies; assessment of the effectiveness of emission reductions strategies through the characterization of air quality; and development of state implementation plans (SIPs). The STN and supplemental speciation monitoring sites together are referred to as the CSN. The CSN sampling systems do not include any FRM/FEMs; therefore, data produced from this network are not used for comparison to the NAAQS. However, FRMs are almost always collocated with the CSN since these are among the most important $PM_{2.5}$ sites in a network.

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[2] Hanley, T. and Reff, A (2011). Assessment of $PM_{2.5}$ FEMs Compared to Collocated FRMs. Memorandum to PM NAAQS Review Docket, EPA-HQ-OAR-2007-0492. April 7, 2011. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

[3] Evangelista, M. (2011). Investigation of 1-hour $PM_{2.5}$ Mass Concentration Data from EPA-Approved Continuous Federal Equivalent Method Analyzers. Memorandum to PM NAAQS Review Docket (EPA-HQ-OAR-2007-0492). April 5, 2011. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

In 2005, EPA conducted an assessment specifically focused on the $PM_{2.5}$ speciation monitoring network. In consultation with State and local monitoring agencies, EPA evaluated CSN sites to determine which ones might be shut down to provide resources for future monitoring needs. The EPA ranked the sites according to their overall information value. The ranking was based on several factors, including whether the site was in a non-attainment area and

Figure B-1. $PM_{2.5}$ FRMs Reporting to AQS

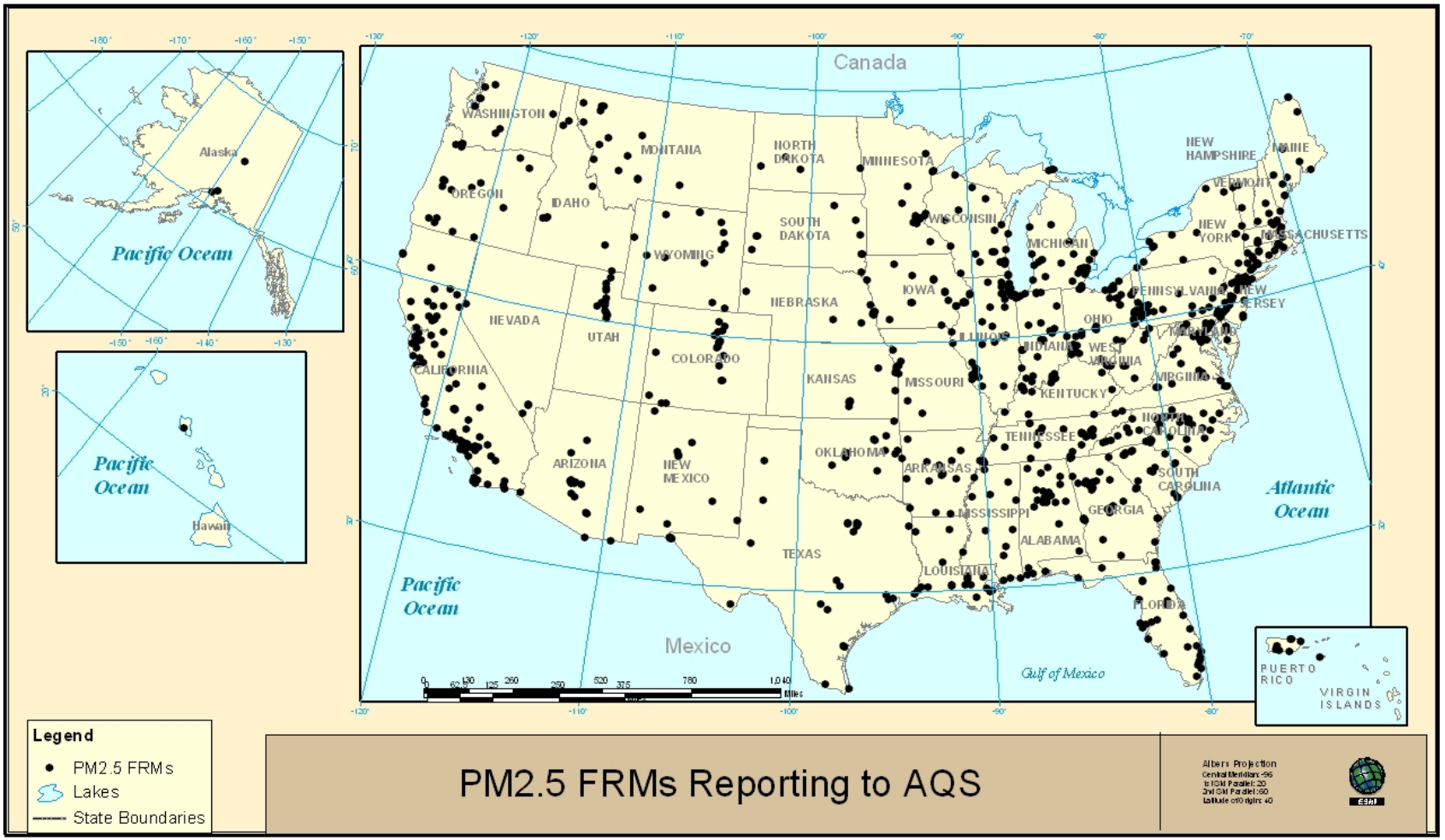
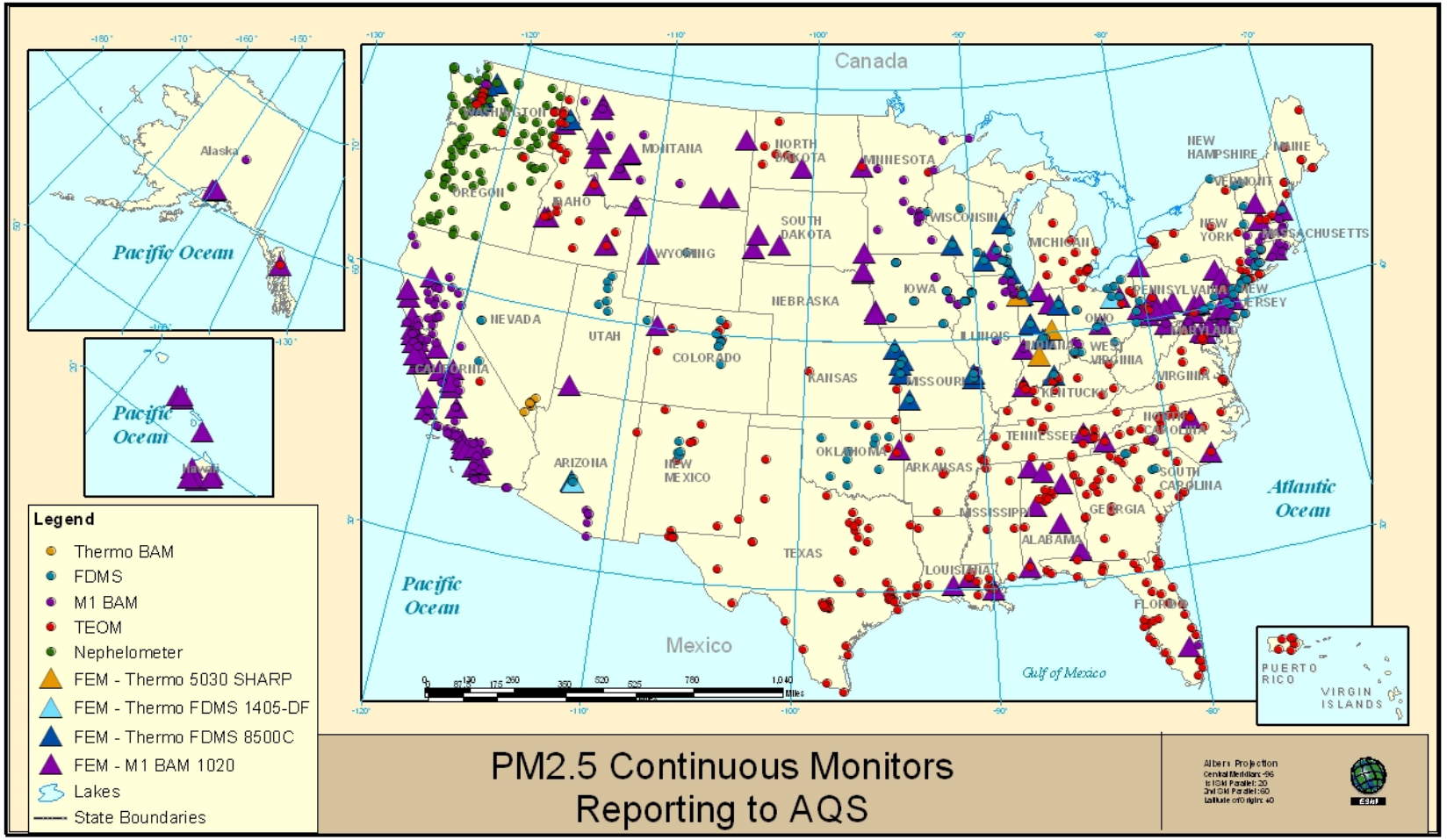


Figure B-2. $PM_{2.5}$ Continuous Monitors Reporting to AQS



whether other sites were nearby. There was general agreement that some of the sites should be shut down when FY 2005 funding ran out. Other sites were identified as high value sites, particularly with regard to the $PM_{2.5}$ NAAQS program. The EPA evaluated each of these sites when FY 2006 regional funding allocations for continued operation and maintenance were developed. In doing so, EPA balanced filter-based $PM_{2.5}$ speciation against funding for other $PM_{2.5}$ measurements, such as FRM site operations, filter analysis, and startup of additional precursor gas sites and continuous speciation sites.

As of 2010, the $PM_{2.5}$ CSN includes about 50 STN sites and about 150 SLAMS supplemental sites. All STN sites operate on a one-in-three day sample collection schedule. A majority of the SLAMS supplemental sites operate on a one-in-six day sample collection schedule. These sites collect aerosol samples over 24 hours on filters that are analyzed for $PM_{2.5}$ mass, a number of trace elements, major ions (e.g., sulfate, nitrate, and ammonium), and organic and elemental carbon.

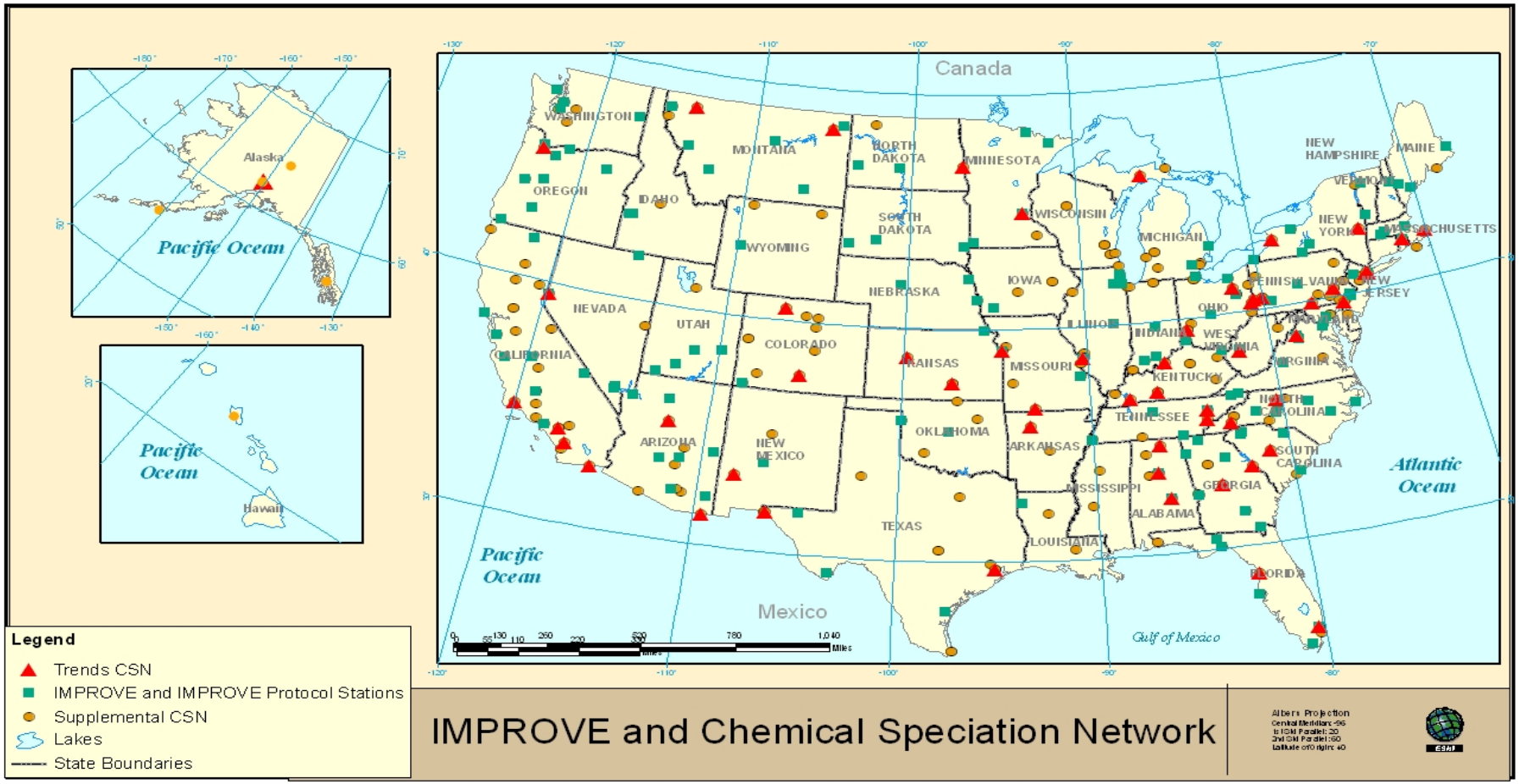
The IMPROVE program was established in 1985 to aid the creation of federal and state implementation plans for the protection of visibility in Class 1 areas (155 national parks and wilderness areas) as stipulated in the 1977 amendments to the CAA and further supported in the goals set forth in the 1999 Regional Haze Rule.[4] Similar to the CSN, the IMPROVE program provides $PM_{2.5}$ mass and speciation data for organic and elemental carbon, major ions, and trace elements; however, unlike CSN IMPROVE also samples for PM_{10} mass. The IMPROVE network is presently comprised of 110 regionally representative monitoring sites; 7 sites operated collaboratively with the Clean Air Status and Trends Network (CASTNET); 30 sites operated by State and local agencies referred to as "IMPROVE Protocol Stations"; several sites operated by Tribal air monitoring programs; and about 9 sites operated by federal land managers. IMPROVE samplers are also collocated at 5 CSN stations to assess on-going comparability of the programs. Figure B-3 provides a map of all IMPROVE and CSN stations.

From May 2007 until October 2009, the approximately 200 CSN sites transitioned to a new method of sampling and analysis for carbon measurements that is consistent with the IMPROVE network methodology. This transition occurred in three phases: 56 CSN stations began using the new method in the first phase which started May 1, 2007; 63 stations were in the second phase beginning on April 1, 2009; and 78 stations were in the third phase beginning on October 1, 2009.

While the network of approximately 200 CSN sites provide valuable data for development and tracking of control strategies, its use for supporting studies of health and welfare effects is somewhat limited. The CSN sites provide data on a one-in-three or one-in-six

[4] Additional information is available at http://www.epa.gov/visibility/actions.html

Figure B-3. IMPROVE and Chemical Speciation Network



day schedule and do not capture data every day or everywhere. 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 $PM_{2.5}$ exposures on public health/welfare in the most meaningful way. 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. These researchers expressed a strong interest in having access to $PM_{2.5}$ speciation measurements collected more frequently.[5]

B.2 PM_{10}

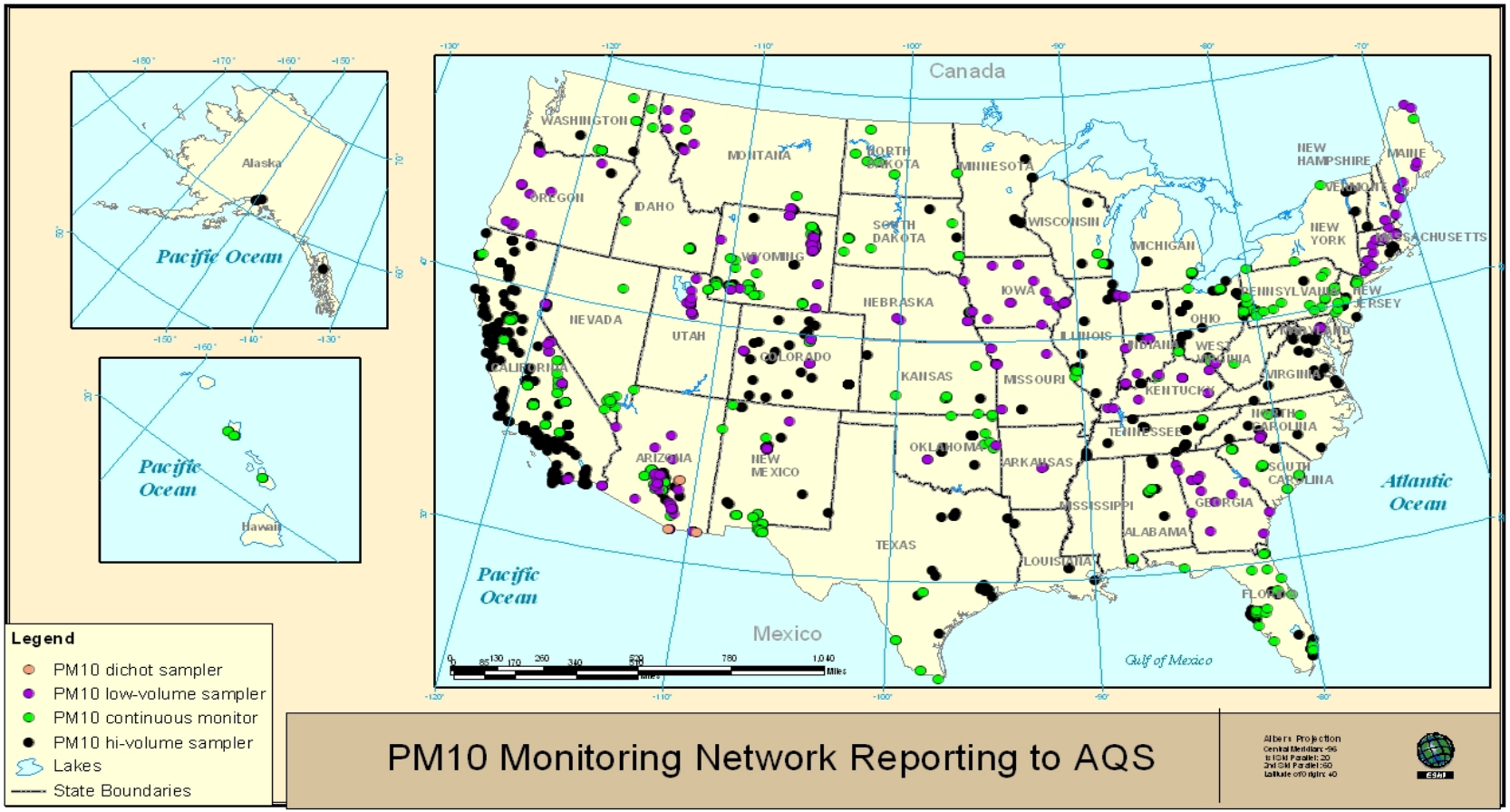
Measurements from PM_{10} monitoring stations are primarily used for comparison to the NAAQS; however, most serve multiple objectives. PM_{10} monitoring stations generally have an urban focus and are required in MSAs according to population and concentrations relative to the NAAQS. Local considerations are also a factor in determining the actual required number of monitoring sites. More stations are required in larger MSAs and MSAs with more evidence of poor air quality, while monitors are also required in clean MSAs of certain size. The number of monitors in areas where MSA populations exceed 1,000,000 must be in the range from 2 to 10 stations, while in low population urban areas no more than two stations are required (see Table D–4 of Appendix D to CFR Part 58). Because sources of air pollutants and local control efforts can vary from one part of the country to another, some flexibility is allowed in selecting the actual number of PM_{10} stations in any one locale.

The network of PM_{10} monitors has been operational since 1987. The network currently includes over 800 monitoring stations throughout the country with most metropolitan areas operating more PM_{10} monitors than required by current monitoring requirements. The PM_{10} monitoring stations operate FRMs using different sampling frequencies including: daily, one-in-two day, one-in-three day, or one-in-six day sampling. The sampling frequency is based on the relative concentration level of the site with respect to the 24-hour standard. There are also FEMs that are operated continuously. PM_{10} monitors operating across the country are almost exclusively FRMs or FEMs. Figure B-4 illustrates the locations of the PM_{10} FRMs and FEMs reporting to AQS.

The PM_{10} monitoring stations are currently required to collect and report monitoring data under standard temperature and pressure (STP) conditions. $PM_{2.5}$ and $PM_{10\text{-}2.5}$ are required to be collected and reported at local conditions. Correction of the sampled aerosol volume to "standard" conditions is typically small (e.g., less than a few percent) except in locations at

[5] A summary of the workshop including recommendations was published in December 2008 and is available at www.epa.gov/ORD/npd/pdfs/FINAL-April-2008-AQ-Health-Research-Workshop-Summary-Dec-2008.pdf.

Figure B-4. PM_{10} Monitoring Network Reporting to AQS



higher altitudes and those with large diurnal or seasonal temperature changes (US EPA, 1996, Volume I, Section 4.2.4).

B.3 $PM_{10-2.5}$

The EPA is requiring approximately 80 $PM_{10-2.5}$ monitoring stations as part of the National Core (NCore) multiple pollutant network. This network is planned to be fully operational by January 1, 2011.[6] As State and local agencies measure $PM_{10-2.5}$ mass as required through the NCore program, we anticipate the number of stations will increase. In addition to NCore, it is appropriate to calculate $PM_{10-2.5}$ concentrations from collocated $PM_{2.5}$ and PM_{10} methods of the same make and model. However, in many cases the PM_{10} data will need to be adjusted to local conditions since most PM_{10} data are reported as STP, while $PM_{2.5}$ is reported at local conditions (LC). Note: only low-volume samplers are used in calculating $PM_{10-2.5}$ as these are the only approved reference and equivalent methods for this measurement.[7]

For $PM_{10-2.5}$ speciation, we do not expect methods to be fully developed in time to meet the January 1, 2011, start date for monitoring at NCore. The EPA has been working with the CASAC Ambient Air Monitoring and Methods Subcommittee (AAMMS) on this issue and has implemented a pilot program evaluating $PM_{10-2.5}$ speciation methods at two locations in 2010.[8]

B.4 NATIONAL CORE (NCORE)

The NCore network is a multi-pollutant network that includes measurements of particles, gases, and meteorology (71 FR 61236, October 17, 2006). The network is intended to support integrated air program management needs. While measurements made at NCore stations will often be used for comparison to one or more NAAQS as well as for public reporting of air quality data, their enhanced value is in providing multi-pollutant data for validation of models, trends, and as an input to research studies to determine the relative importance of collocated pollutants. The NCore monitoring network began January 1, 2011 at approximately 80 stations. NCore stations are intended to be long-term stations useful for a variety of applications. The locations of these stations are specified to be placed away from direct emissions sources that could substantially impact the ability to detect area-wide concentrations. The NCore network is comprised of stations in both urban and rural areas. Urban NCore stations are to be generally

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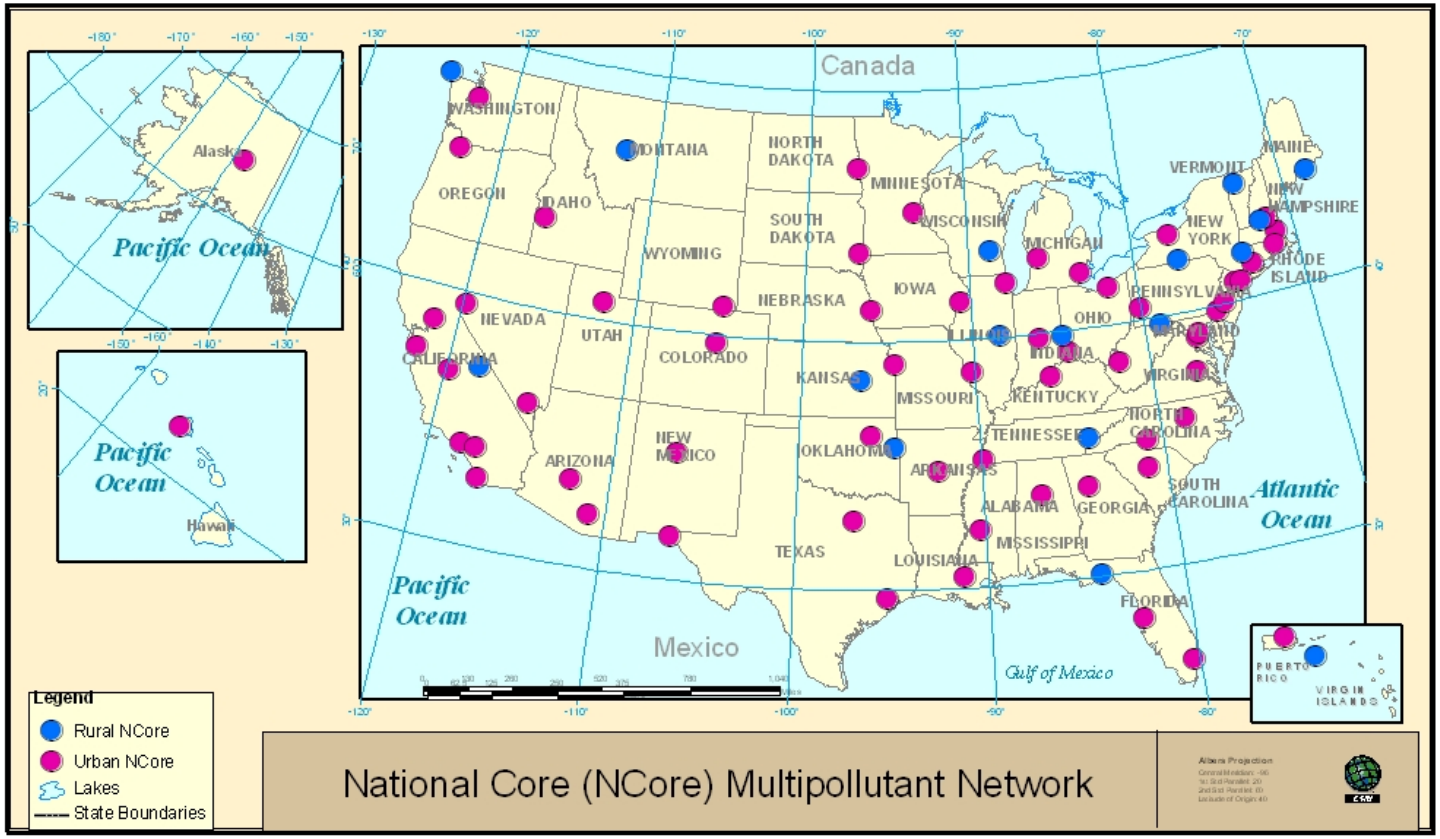
[6] Monitoring agencies are bringing their $PM_{10-2.5}$ methods online now and, as of April 2011, 21 NCore sites are already reporting data to the AQS.

[7] A list of approved FRMs and FEMs is available on EPA's web site at: http://www.epa.gov/ttn/amtic/criteria.html.

[8] A February 2009 consultation with the CASAC AAMM subcommittee discussed issues related to coarse particle speciation measures. For more information on this consultation, please see: http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/3494de4d0ccb3944852574630064d4e4!OpenDocument

located at an urban or neighborhood scale to provide representative concentrations of exposure expected throughout the metropolitan area. Rural NCore stations are to be located, to the maximum extent practicable, at a regional or larger scale away from any large local emission source, so that they represent ambient concentrations over an extensive area. States and where applicable, local monitoring agencies submitted plans for meeting the NCore requirements during the summer of 2009. The proposed NCore stations are collocated with several other well leveraged networks such as CSN, Photochemical air monitoring stations (PAMS), National Air Toxics Trends Stations (NATTS), IMPROVE, and CASTNET. The expected NCore locations are identified in Figure B-5.

Figure B-5. NCore Monitoring Network



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APPENDIX C

Table C-1. Predicted Percent of Counties with Monitors (and percent of population in counties with monitors) Not Likely to Meet Current and Alternative Annual and 24-hour $PM_{2.5}$ Standards

Region >		All U.S.	Northeast	Southeast	Industrial Midwest	Upper Midwest	Southwest	Northwest	Southern California	Outlying areas
Total # of counties >		532	93	149	135	45	17	69	17	7
Total population (x 1,000)>		184,180	44,345	40,271	37,512	7,694	8,962	20,821	22,663	1,913
Current Standards										
annual µg/m³	**24-hour µg/m³**	**Statistic**	**Numbers of counties, populations, and percentages of total**							
15	35	# counties	35	0	1	5	0	1	19	8	1
		population	28,801	0	662	3,683	0	180	6,615	17,579	83
		% # counties	7%	0%	1%	4%	0%	6%	28%	47%	14%
		% population	16%	0%	2%	10%	0%	2%	32%	78%	4%
Alternative Standards										
annual µg/m³	**24-hour µg/m³**	**Statistic**	**Numbers of counties, populations, and percentages of total**							
12	35	# counties	149	21	30	66	0	2	20	9	1
		population	76,579	14,936	10,318	23,998	0	218	6,634	20,393	83
		% # counties	28%	23%	20%	49%	0%	12%	29%	53%	14%
		% population	42%	34%	26%	64%	0%	2%	32%	90%	4%
11	35	# counties	263	39	82	102	5	3	22	9	1
		population	107,447	22,952	21,224	31,346	1,491	3,290	6,668	20,393	83
		% # counties	49%	42%	55%	76%	11%	18%	32%	53%	14%
		% population	58%	52%	53%	84%	19%	37%	32%	90%	4%
13	30	# counties	130	21	10	50	2	3	32	10	2
		population	78,286	13,688	6,152	23,692	1,627	393	12,210	20,411	114
		% # counties	24%	23%	7%	37%	4%	18%	46%	59%	29%
		% population	43%	31%	15%	63%	21%	4%	59%	90%	6%

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APPENDIX D

Table D-1. Predicted Percent of Counties with Monitors (and percent of population in counties with monitors) Not Likely to Meet Current and Alternative 24-hour PM_{10} Standards

Region>		All U.S.	Northeast	Southeast	Industrial Midwest	Upper Midwest	Southwest	Northwest	Southern California	Outlying areas
Total # of counties >		**307**	**37**	**57**	**50**	**40**	**25**	**77**	**18**	**3**
Total population (x1,000) >		**120,090**	**15,397**	**27,181**	**21,352**	**5,917**	**11,112**	**15,270**	**22,695**	**1,167**
Current Standard: 3-Year Expected Exceedance Equivalent Design Value										
µg/m^3	**Statistic**	**Numbers of counties, populations, and percentages of total**								
150	# counties	41	0	3	0	1	11	13	12	1
	population	32,835	0	4,626	0	14	5,485	1,878	20,571	260
	% # counties	13%	0%	5%	0%	3%	44%	17%	67%	33%
	% population	27%	0%	17%	0%	0%	49%	12%	91%	22%
Alternative Standards: 24-hour level (3-year average 98th percentile)										
µg/m^3	**Statistic**	**Numbers of counties, populations, and percentages of total**								
87	# counties	37	0	2	2	2	11	10	9	1
	population	20,515	0	4,063	507	552	5,924	1,789	7,421	260
	% # counties	12%	0%	4%	4%	5%	44%	13%	50%	33%
	% population	17%	0%	15%	2%	9%	53%	12%	33%	22%
85	# counties	39	0	2	3	2	12	10	9	1
	population	21,887	0	4,063	1,789	552	6,014	1,789	7,421	260
	% # counties	13%	0%	4%	6%	5%	48%	13%	50%	33%
	% population	18%	0%	15%	8%	9%	54%	12%	33%	22%
80	# counties	45	0	2	4	3	13	11	11	1
	population	24,535	0	4,063	3,183	599	6,131	1,833	8,467	260
	% # counties	15%	0%	4%	8%	8%	52%	14%	61%	33%
	% population	20%	0%	15%	15%	10%	55%	12%	37%	22%
75	# counties	55	0	3	6	5	13	15	12	1
	population	35,703	0	4,626	3,491	637	6,131	2,570	17,986	260
	% # counties	18%	0%	5%	12%	13%	52%	19%	67%	33%
	% population	30%	0%	17%	16%	11%	55%	17%	79%	22%
70	# counties	71	0	4	7	7	13	27	12	1
	population	43,823	0	4,644	8,868	881	6,131	5,052	17,986	260
	% # counties	23%	0%	7%	14%	18%	52%	35%	67%	33%
	% population	36%	0%	17%	42%	15%	55%	33%	79%	22%
65	# counties	87	2	4	9	10	14	33	13	2
	population	49,394	775	4,644	10,421	1,029	7,507	5,989	18,739	290
	% # counties	28%	5%	7%	18%	25%	56%	43%	72%	67%
	% population	41%	5%	17%	49%	17%	68%	39%	83%	25%

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APPENDIX E

Information Regarding a 1-hour $PM_{2.5}$ Mass Indicator

This Appendix presents information on 2005-2007 levels of 1-hour $PM_{2.5}$ mass concentrations in 14 urban study areas[1] and on the "what if" PM_{10} 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, US EPA, 2010b)[2], which presented similar information for 18 secondary PM NAAQS scenarios based on PM_{10} 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 $\mu g/m^3$.

In section B.1.2 of Appendix B, it was noted that recent investigations have identified issues with data quality for measurements of both 24-hour concentrations and 1-hour concentrations from continuous Federal Equivalent Methods for $PM_{2.5}$. This appendix on a 1-hour $PM_{2.5}$ mass indicator is based only on 2005-2007 data from continuous instrument models that pre-date the introduction of continuous Federal Equivalent Methods for $PM_{2.5}$. While no systematic investigation was performed on these 2005-2007 data similar to the investigations described in Hanley and Reff, 2011 and Evangelista, 2011,[3,4] no similar issues were noticed in the course of using these 2005-2007 data.

E.1 INDICATOR AND MONITORING METHOD

As in Chapter 4 of the 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

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[1] The UFVA assessed light extinction conditions in 15 study areas, one of which was St. Louis. The $PM_{10-2.5}$ values for St. Louis in the UFVA were determined by difference between two nearby monitoring sites. Based on comments received on the draft UFVA to the effect that the PM_{10} monitoring site used for St. Louis was not representative of the St. Louis urban area, EPA does not consider the $PM_{10-2.5}$ concentrations for St. Louis to be credible. The PM_{10} light extinction results for St. Louis have therefore been excluded from tables and figures in this appendix that involve PM_{10} light extinction results.

[2] *Particulate Matter Urban-Focused Visibility Assessment* Final Document, EPA 452/R-10-004, July 2010. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

[3] Hanley, T and Reff, A (2011). Assessment of $PM_{2.5}$ FEMs Compared to Collocated FRMs. Memorandum to PM NAAQS Review Docket EPA-HQ-OAR-2007-0492. April 7, 2011. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

[4] Evangelista, M. (2011). Investigation of 1-hour $PM_{2.5}$ Mass Concentration Data from EPA-Approved Continuous Federal Equivalent Method Analyzers. Memorandum to PM NAAQS Review Docket (EPA-HQ-OAR-2007-0492). April 5, 2011. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

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, and section 4.2.1 of this document at "Current Visibility Levels." 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 14 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, 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.

E.2 CURRENT CONDITIONS OF 1-HOUR $PM_{2.5}$ MASS

Figure E-1 is a box plot of 2005-2007 daily maximum daylight 1-hour $PM_{2.5}$ mass concentrations for the 14 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^{th} 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 E-1, based on the same data as Figure E-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 E-1.

Figure E-1. 2005-2007 Daily Maximum Daylight 1-hour $PM_{2.5}$ Mass Concentrations ($\mu g/m^3$) for the 14 Study Areas (excluding hours with relative humidity > 90 %)

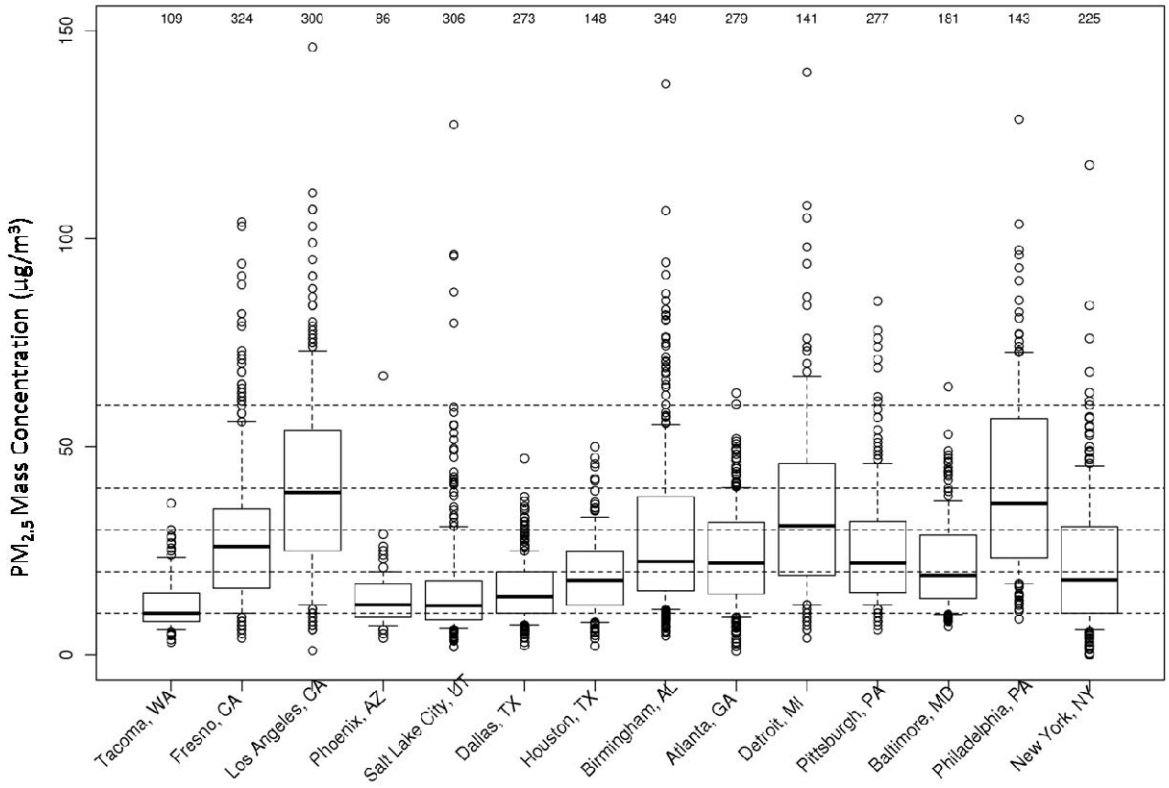


Table E-1. Percentage of Days with Daily Maximum Daylight 1-hour $PM_{2.5}$ Mass Concentration Exceeding Reference Levels in 2005-2007 (excluding hours with relative humidity > 90 %)

		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
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

E.3 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_{10} 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 90^{th} percentile value and the three-year average of the annual 95^{th} percentile value. For ease of reference, these scenarios are designated by letters from "aa" to "jj" and listed in Table E-2. Looking somewhat ahead to results presented below, the scenarios are arranged in Table E-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 E-2. Alternative NAAQS Scenarios Based on Daily Maximum Daylight 1-Hour $PM_{2.5}$ Mass, Averaged Over Three Years (excluding hours with relative humidity > 90 %)

NAAQS Scenario	Level ($\mu g/m^3$)	Statistical Form
aa	60	3-year average of 90^{th} percentile
bb	60	3-year average of 95^{th} percentile
cc	40	3-year average of 90^{th} percentile
dd	40	3-year average of 95^{th} percentile
ee	30	3-year average of 90^{th} percentile
ff	30	3-year average of 95^{th} percentile
gg	20	3-year average of 90^{th} percentile
hh	20	3-year average of 95^{th} percentile
ii	10	3-year average of 90^{th} percentile
jj	10	3-year average of 95^{th} percentile

E.4 APPROACH TO MODELING "WHAT IF" CONDITIONS OF PM_{10} 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 3-4 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 E-2 used a rollback approach that combined relevant concepts and steps from the rollback methods described in sections 4.1.4 (for PM_{10} 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 3-year average design value for that percentile form. Repeat for the 95th percentile form. These design values are presented in Table E-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 3 year average 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.

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:

$$\text{Percent reduction required} = \frac{1 - (\text{NAAQS level} - \text{PRB portion of the design value})}{\text{(non-PRB portion of the design value)}}$$

   The percentage reductions determined in step 4 are shown in Table E-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. These cases with a required percentage reduction of zero are shaded blue in Table E-4.

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, calculate PM_{10} 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_{10} light extinction (see section 3.2.3 of the UFVA for an explanation of the variables in this equation).

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_{10} 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 UFVA for NAAQS scenarios based on PM_{10} 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 sources emit both and some control methods achieve some reductions in both. However, in most of the 14 study areas, $PM_{10-2.5}$ makes a small contribution to estimated PM_{10} light extinction. For those areas for which no local data on $PM_{10-2.5}$ concentrations were available, a low contribution of $PM_{10-2.5}$ to light extinction was inevitable because of the method used to fill the $PM_{10-2.5}$ data gap. That method was to apply a long-term regional ratio of $PM_{10-2.5}$ to $PM_{2.5}$ to the local hourly $PM_{2.5}$ concentration, which by its nature cannot produce estimates of hourly $PM_{10-2.5}$ that are as high as might actually be created by shorter-term $PM_{10.2.5}$ emissions episodes

Table E-3. 2005-2007 Design Values for 1-Hour $PM_{2.5}$ Mass (µg/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
Birmingham	55	74
Atlanta	40	45
Detroit	64	79
Pittsburgh	46	51
Baltimore	37	43
Philadelphia	67	77
New York	44	55

Table E-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 (µg/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
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

E.5 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 E-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, given other uncertainties in the underlying data and in the assumptions used to estimate PM_{10} light extinction values.

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 errors, and found them to match expectations. They are not included here, for conciseness.

Table E-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	90^{th}	95^{th}	90^{th}	95^{th}	90^{th}	95^{th}	90^{th}	95^{th}	90^{th}	95^{th}
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
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

E.6 PM_{10} 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_{10} 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.

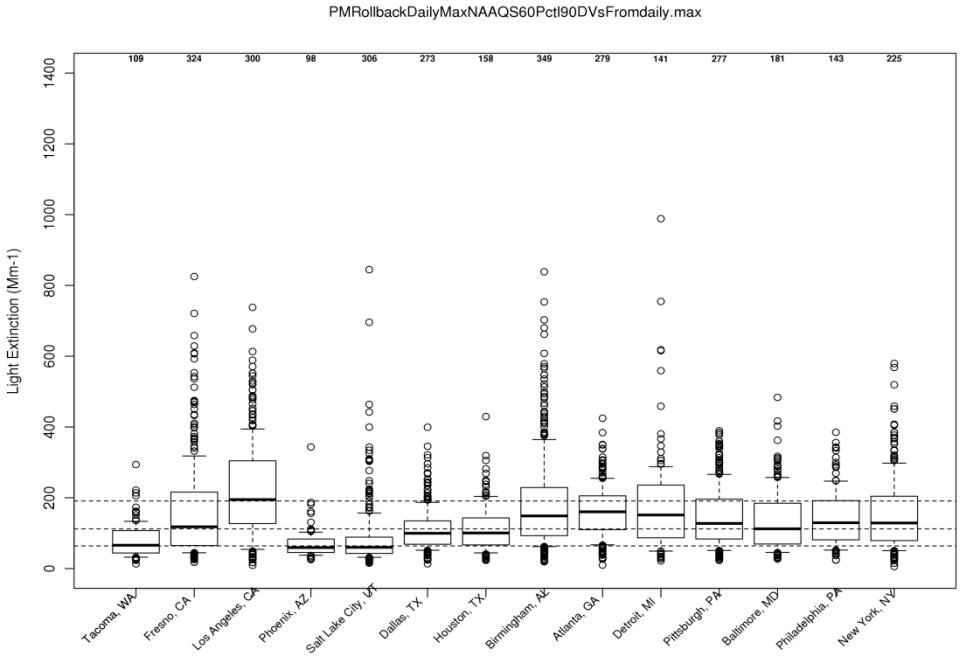
Figure E-2 presents a box plot of daily maximum daylight 1-hour PM_{10} light extinction for each NAAQS scenario based on 1-hour $PM_{2.5}$ mass. These can be compared to Figure 3-8(a) of the UFVA representing pre-rollback daily maximum PM_{10} light extinction, and to the upper panel of the figures in Appendix F of the UFVA representing the daily maximum PM_{10} light extinction levels resulting from the 20 NAAQS scenarios examined in the UFVA (18 scenarios based on PM_{10} 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 more stringent scenarios begins to require reductions in a given area).

Table E-6 presents the percentage of days in 2005-2007 on which daily maximum 1-hour PM_{10} light extinction exceeded each of the CPLs, 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_{10} 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 E-2. Distributions of Daily Maximum Daylight 1-Hour PM_{10} Light Extinction under "Just Meet" Conditions for NAAQS Scenarios Based on 1-Hour $PM_{2.5}$ Mass (excluding hours with > 90% RH)

(aa) NAAQS Scenario: 60 µg/m^3 and 90th percentile



(bb) NAAQS Scenario: 60 µg/m^3 and 95th percentile

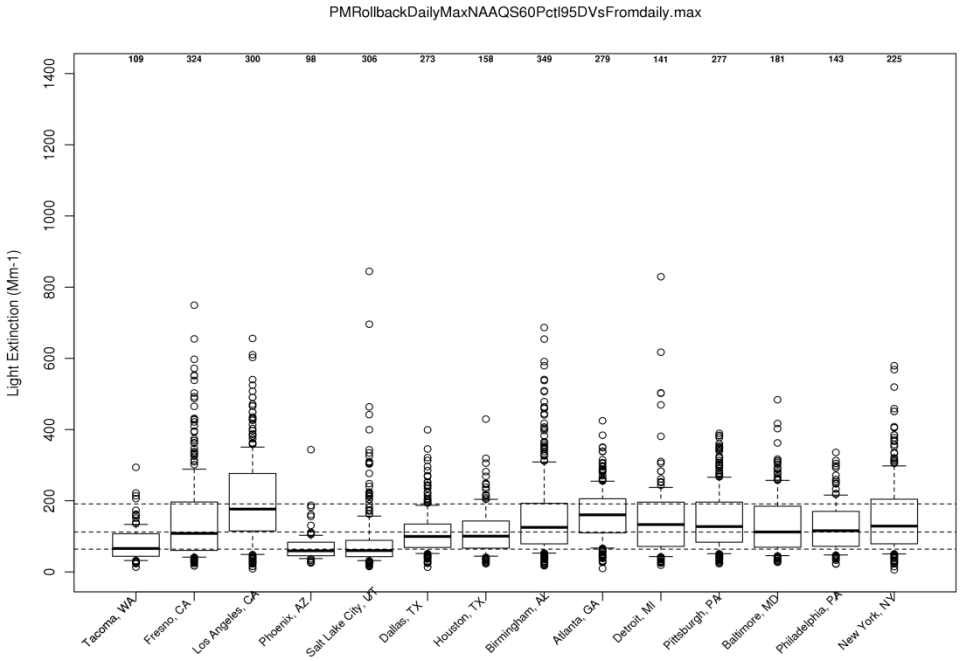
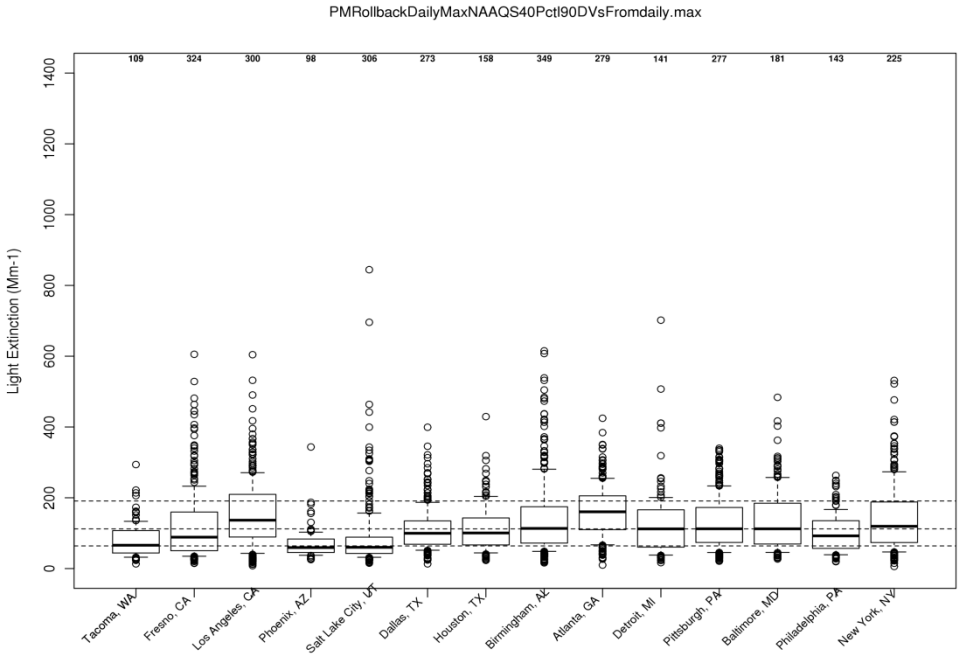


Figure E-2 (cont). Distributions of Daily Maximum Daylight 1-Hour PM_{10} Light Extinction under "Just Meet" Conditions for NAAQS Scenarios Based on 1-Hour $PM_{2.5}$ Mass (excluding hours with > 90% RH)

(cc) NAAQS Scenario: 40 µg/m^3 and 90th percentile



(dd) NAAQS Scenario: 40 µg/m^3 and 95th percentile

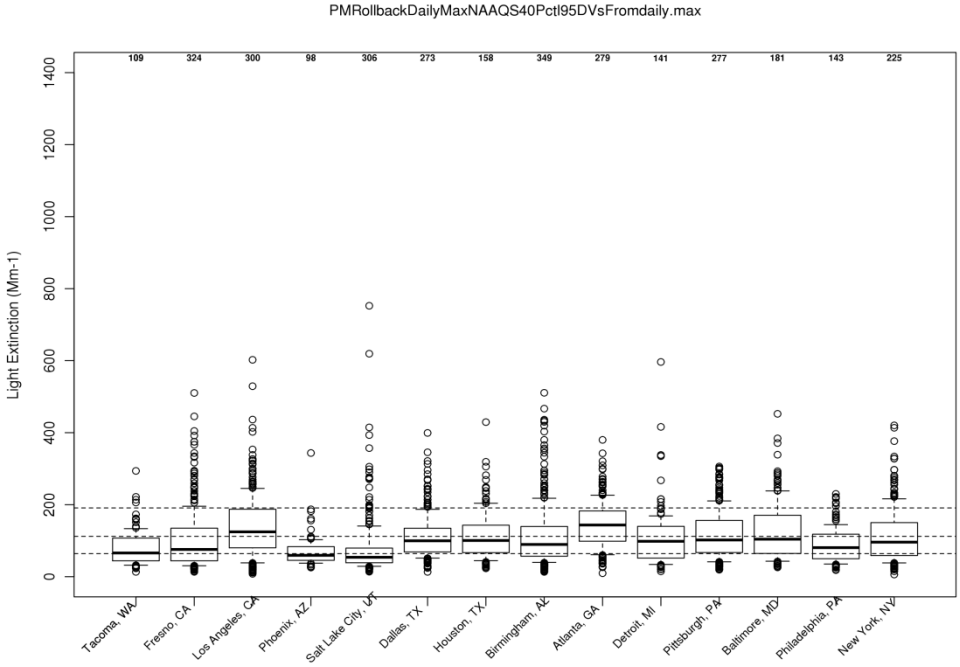
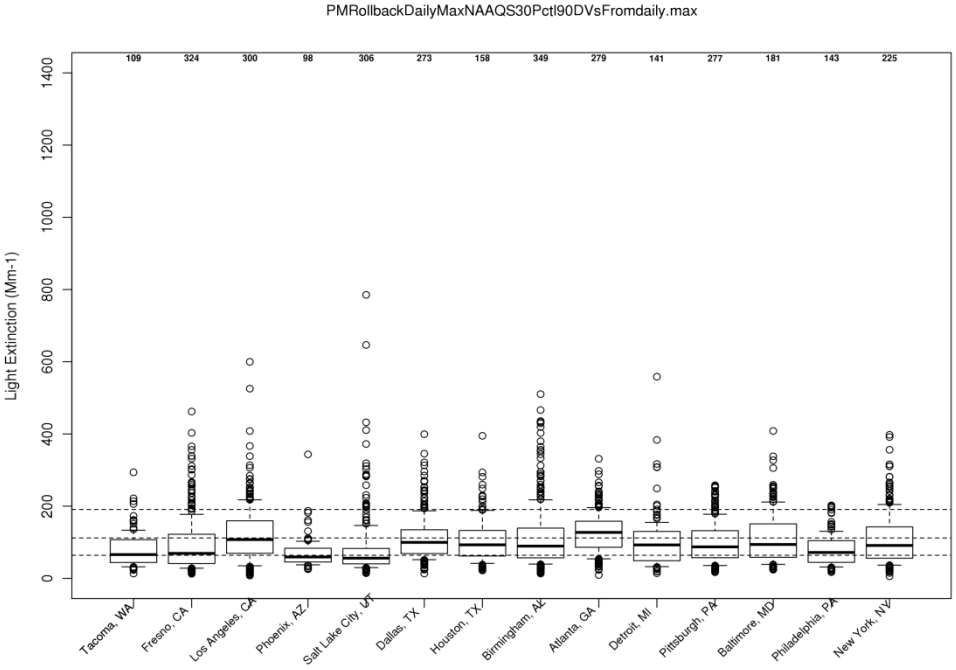


Figure E-2 (cont). Distributions of Daily Maximum Daylight 1-Hour PM_{10} Light Extinction under "Just Meet" Conditions for NAAQS Scenarios Based on 1-Hour $PM_{2.5}$ Mass (excluding hours with > 90% RH)

(ee) NAAQS Scenario: 30 µg/m^3 and 90th percentile



(ff) NAAQS Scenario: 30 µg/m^3 and 95th percentile

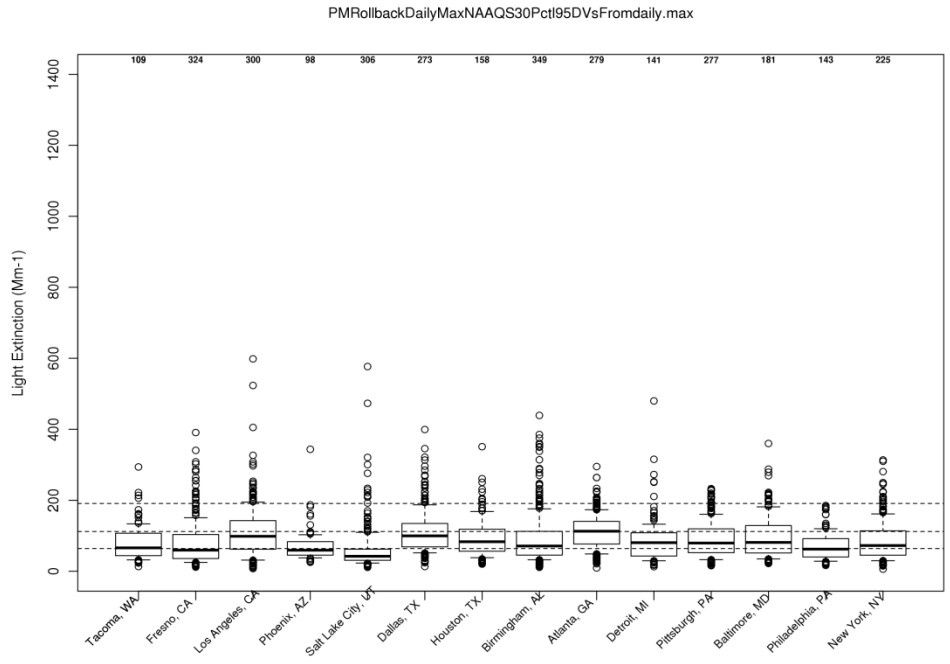
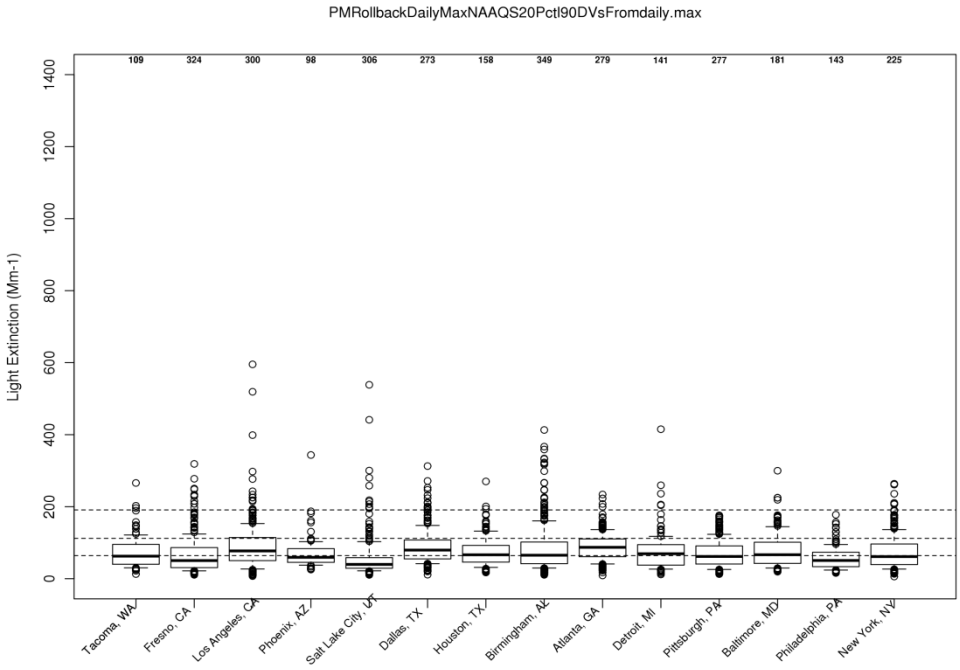


Figure E-2 (cont). Distributions of Daily Maximum Daylight 1-Hour PM_{10} Light Extinction under "Just Meet" Conditions for NAAQS Scenarios Based on 1-Hour $PM_{2.5}$ Mass (excluding hours with > 90% RH)

(gg) NAAQS Scenario: 20 µg/m^3 and 90th percentile



(hh) NAAQS Scenario: 20 µg/m^3 and 95th percentile

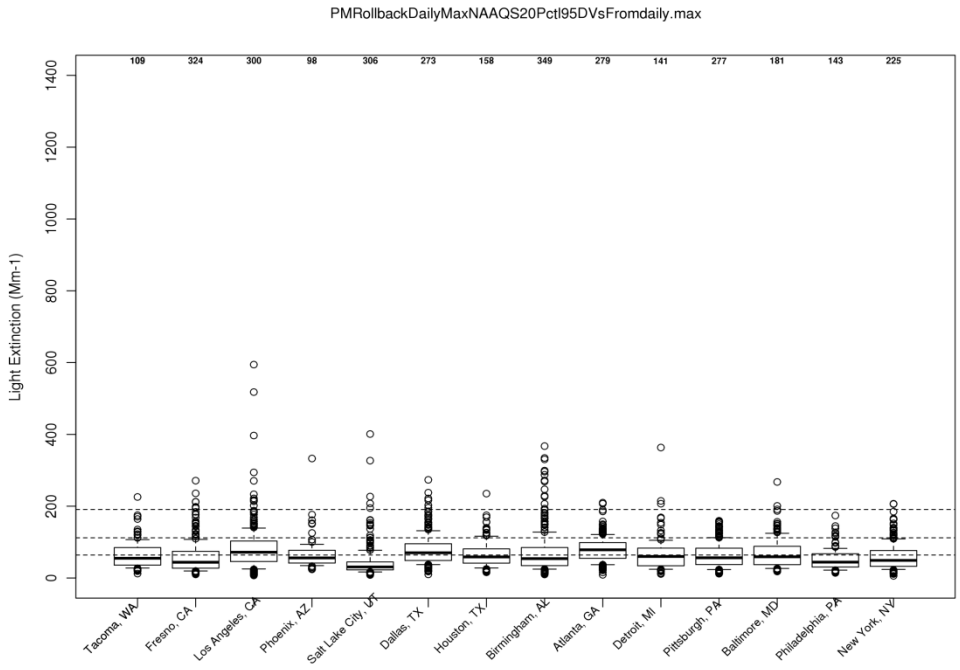
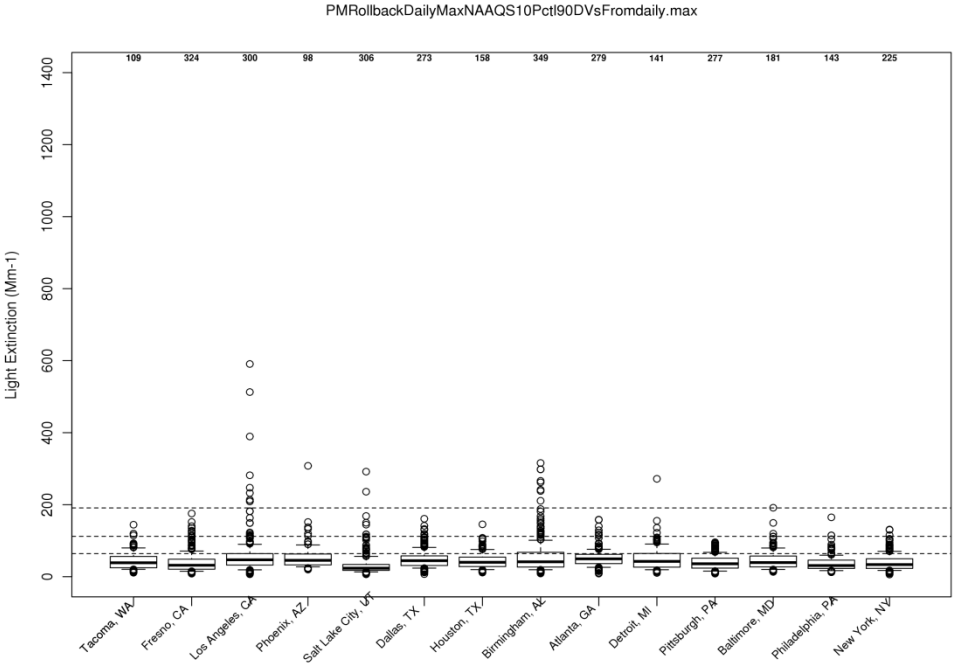


Figure E-2 (cont). Distributions of Daily Maximum Daylight 1-Hour PM_{10} Light Extinction under "Just Meet" Conditions for NAAQS Scenarios Based on 1-Hour $PM_{2.5}$ Mass (excluding hours with > 90% RH)

(ii) NAAQS Scenario: Daily Max: 10 µg/m^3 and 90th percentile



(jj) NAAQS Scenario: Daily Max: 10 µg/m^3 and 95th percentile

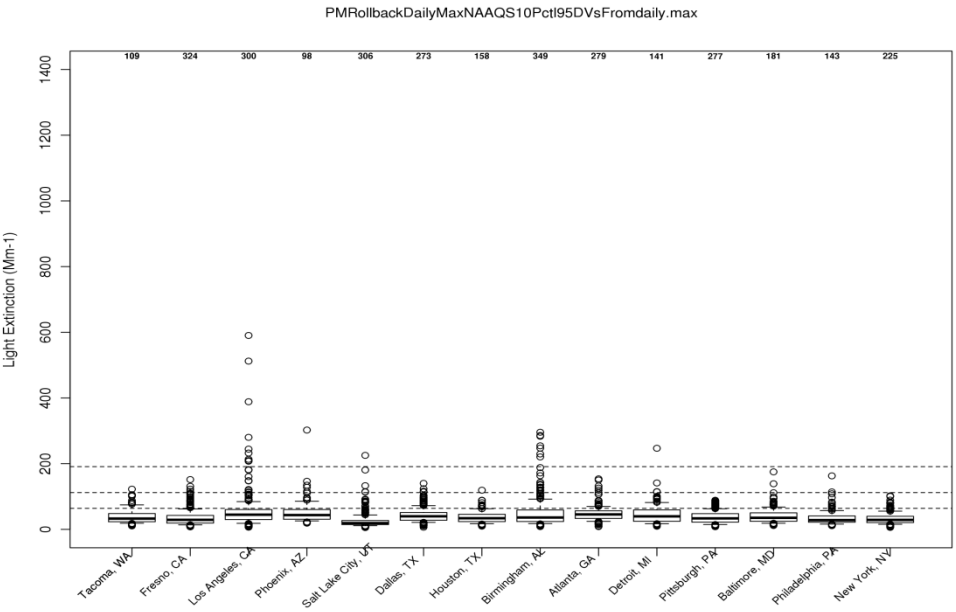


Table E-6. Percentage of Days Across Three Years (two years in the case of Phoenix and Houston) with Maximum 1-Hour Daylight PM_{10} Light Extinction Above CPLs when "Just Meeting" NAAQS Scenarios Based on 1-Hour $PM_{2.5}$ Mass (Blue shading indicates no reduction required from current conditions.)

	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 ($\mu g/m^3$)	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
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	**76**	**75**	**72**	**68**	**73**	**69**	**64**	**56**	**34**	**25**	**50**	**48**	**43**	**37**	**45**	**38**	**31**	**23**	**7**	**4**	**23**	**21**	**15**	**11**	**17**	**12**	**8**	**4**	**1**	**1**

APPENDIX F

Two Simplified Approaches to Calculate Hourly $PM_{2.5}$ Light Extinction Values from Hourly $PM_{2.5}$ Mass and Relative Humidity Data Plus 24-hour Mean $PM_{2.5}$ Composition Data

F.1 OVERVIEW

The goal of this appendix is to describe two procedures for calculating $PM_{2.5}$ light extinction that are considerably simpler than the complex method used in the original 15-city assessment (UFVA, Section 3.3).[1] The possible benefits of moving to a simpler approach include (1) more transparency in the required calculations, (2) less intensive data processing, (3) an increase in the number of monitoring sites that could meet the data requirements of the approach without adding new sampling equipment or additional laboratory analysis, and (4) an increase in the number of days per year for which the calculation of PM light extinction could be conducted.

The two simpler procedures addressed in this memo, denoted "T" and "W", are similar in many respects to approaches "D" and "F" for which a draft analysis was presented in appendix 4B of the second external review draft of the Policy Assessment Document.[2] The original UFVA and the draft analysis of approaches D and F were based on 2005-2007 data. The analysis of approaches T and W versus the UFVA approach presented here is based on 2007-2009 data. The UFVA approach has been re-executed on this more recent data set to provide a consistent point of comparison to approaches T and W.

In section B.1.2 of Appendix B, it was noted that recent investigations have identified issues with data quality for measurements of both 24-hour concentrations and 1-hour concentrations from continuous Federal Equivalent Methods for $PM_{2.5}$. This appendix on calculated $PM_{2.5}$ light extinction values is based on 2007-2009 data, most of which came from continuous instrument models that pre-date the introduction of continuous Federal Equivalent Methods for $PM_{2.5}$. Some of the 2009 data may have come from continuous FEM instruments. While no systematic investigation was performed on the 2007-2009 non-FEM data similar to the investigations described in Hanley and Reff, 2011 and Evangelista, 2011,[3,4] no similar issues

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[1] *Particulate Matter Urban-Focused Visibility Assessment* (UFVA) EPA 452/R-10-004, July 2010. The UFVA presented a method and results for PM_{10} light extinction. The assessment in this appendix focuses on $PM_{2.5}$ light extinction. The UFVA is available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

[2] The analysis of approaches D and F has been finalized in the form of a technical memo so that it is available for reference. Simplified Approaches for Calculation of Hourly $PM_{2.5}$ Light Extinction Values from Hourly $PM_{2.5}$ Mass and Relative Humidity Data and 24-hour $PM_{2.5}$ Composition Data, Phil Lorang, EPA, November 17, 2010. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

3 Hanley, T and Reff, A (2011). Assessment of $PM_{2.5}$ FEMs compared to collocated FRMs. Memorandum to PM NAAQS Review Docket EPA-HQ-OAR-2007-0492. April 7, 2011. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

[4] Evangelista, M. (2011). Investigation of 1-hour $PM_{2.5}$ Mass Concentration Data from EPA-Approved Continuous Federal Equivalent Method Analyzers. Memorandum to PM NAAQS Review Docket (EPA-HQ-OAR-2007-0492). April 5, 2011. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.htm.l

were noticed in the course of using these data. Moreover, all of the 1-hour data used in this Appendix was normalized to 24-hour concentrations measured by filter-based Federal Reference Method samplers on the same day at the same site.

F.2 COMPLEXITY OF THE UFVA APPROACH

The UFVA approach to estimation of hourly $PM_{2.5}$ light extinction has the following complex aspects:

1. The SANDWICH mass balance model is used to estimate 24-hour average $PM_{2.5}$ sulfate, nitrate, and organic carbonaceous material (OCM) mass loading on the FRM filter for each Chemical Speciation Network (CSN) sample day.[5] This requires information on daily temperature and relative humidity. The SANDWICH-estimated FRM loadings are initially used to compare with FRM mass. The sulfate and nitrate components are initially derived from the relevant CSN filters, with adjustments to represent FRM mass. FRM sulfate includes estimated particle bound water while the FRM nitrate loading may under-represent the ambient concentration of nitrate. These are re-adjusted in a subsequent step to represent ambient conditions prior to calculation of light extinction.
2. The estimates of 24-hour average $PM_{2.5}$ elemental carbon and fine soil component concentrations are determined from the analysis of the relevant CSN filter.
3. Monthly mean diurnal variations of each of the major $PM_{2.5}$ components from CMAQ air quality simulation modeling results for the location of each monitoring site are applied to sample day-specific CSN 24-hour samples to create preliminary estimates of hourly component concentrations. For the UFVA, available output from a 2004 CMAQ modeling platform was used. This step can result, for example, in preliminary estimates of concentrations of sulfate that are fairly uniform throughout a day while concentrations of nitrate may show much more variation because of temperature effects on the gas/particle partitioning of nitrate.
4. Estimates of hourly $PM_{2.5}$ mass are developed by normalizing continuous $PM_{2.5}$ measurements to the 24-hour FRM filter mass.[6]
5. The preliminary estimates of hourly components from step 3 above are scaled up or down in equal proportion to reconcile their sum to the estimate of hourly $PM_{2.5}$ mass from step 4.

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[5] Frank, N., Retained Nitrate, Hydrated Sulfates, and Carbonaceous Mass in Federal Reference Method Fine Particulate Matter for Six Eastern U.S. Cities, *J. Air Waste Manage. Assoc*., 56, 500-511, 2006.

[6] The UFVA, Appendix 4B of the second external review draft of the Policy Assessment Document, and the analysis in the technical memo referenced in footnote 2 were all based on 2005-2007 data. The continuous $PM_{2.5}$ instruments operating in this period were not EPA-approved as Federal Equivalent Methods (FEMs). The EPA-approved FEMs were first used in state networks in significant numbers in 2009. The EPA staff envisions that in any future monitoring of hourly $PM_{2.5}$ mass to implement a visibility-based secondary PM NAAQS, EPA-approved continuous FEMs will be required. For the UFVA, Appendix 4B of the second draft Policy Assessment, and the analysis in the technical memo referenced in footnote 2, therefore, hourly $PM_{2.5}$ mass values from continuous instruments were adjusted day-by-day to match the 24-hour average $PM_{2.5}$ mass reported by the collocated filter-based sampler. This was intended to make the values of hourly $PM_{2.5}$ mass more like the values that would be obtained by FEMs. The analysis in this appendix is based on 2007-2009 data from continuous instruments, but only a fraction of the data are from FEMs. Therefore, the approach of adjusting hourly $PM_{2.5}$ mass values from continuous instruments day-by-day to match the 24-hour average filter-based $PM_{2.5}$ mass was maintained in the analysis presented in this appendix.

6. The resulting hourly $PM_{2.5}$ sulfate and nitrate component concentrations are adjusted to reflect actual atmospheric concentration, which is assumed to be represented by the CSN filter sulfate and nitrate measurements. (This step in effect un-does the estimated FRM sulfate mass enhancement due to particle bound water and the FRM nitrate loss that were both introduced by the SANDWICH mass balance model.)
7. The original IMPROVE algorithm is used to estimate hourly $PM_{2.5}$ light extinction from hourly $PM_{2.5}$ component and hourly relative humidity values.

F.3 RESULTS OF THE RE-EXECUTION OF THE UFVA APPROACH FOR 2007-2009

Table F-1 shows the number of daily samples of suitable data that were available for the re-execution of the UFVA approach for each quarter and study area for the 2007-2009 period. Due to the discontinuation of CSN monitoring at AQS site 040137020 in the Phoenix area as of the end of 2006, $PM_{2.5}$ FRM and speciation data from site 040139997 (JLG SUPERSITE) were used in the re-execution of the UFVA method for 2007-2009. Continuous $PM_{2.5}$ data were taken from site 040139998. The needed combination of data was available from these two sites only for 2009, for only 84 days. Results for Phoenix should be viewed in the light of this limited set of data compared to other areas. All other study areas' monitoring sites were as documented in the UFVA.

Figure F-1 (which is also Figure 4-4 of this document) shows the box-and-whisker plots of 2007-2009 daily maximum $PM_{2.5}$ light extinction. Table F-2 shows the 90^{th} and 95^{th} percentile design values for daily maximum $PM_{2.5}$ light extinction.[7] These displays can be compared to 2005-2007 results presented in UFVA Table 3-4, the bottom panel of Figure 3-8 (also reproduced as Figure 4-3 of this document), and the top half of Table 4-2, respectively, keeping in mind that the tables and figures in the UFVA included the estimated contribution of $PM_{10-2.5}$ to PM_{10} light extinction. This comparison shows that many of the eastern areas' median and 90^{th} percentile 2007-2009 $PM_{2.5}$ light extinction levels are notably lower than the corresponding 2005-2007 PM_{10} light extinction levels, even though $PM_{10-2.5}$ in general did not contribute much to the UFVA estimates of PM_{10} light extinction in eastern areas. This is directionally consistent with the known substantial improvement in $PM_{2.5}$ air quality in the eastern U.S. over the 2005-2009 period.

[7] As in the UFVA, 2007-2009 design values have been calculated using whatever daily maximum values were available in each year. In a future regulatory program there would presumably be a data completeness requirement in order to find that an area meets or does not meet the NAAQS.

Table F-1. Number of Days per Quarter in Each Study Area

Study Area	Year	2007				2008				2009			
	Total Number of Days	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Tacoma	150	13	13	14	13	14	14	14	12	7	14	11	11
Fresno	325	26	28	30	28	29	27	30	29	15	27	28	28
Los Angeles	161	21	26	24	24	29	28	9	0	0	0	0	0
Phoenix	84	0	0	0	0	0	0	0	0	11	24	21	28
Salt Lake City	276	23	25	19	29	28	12	27	15	13	29	28	28
Dallas	257	18	23	24	21	22	25	26	20	13	23	21	21
Houston	144	15	14	9	0	15	13	12	14	7	15	15	15
St. Louis	287	29	25	22	10	24	22	27	28	14	30	29	27
Birmingham	330	30	30	27	26	31	27	30	29	13	28	28	31
Atlanta	258	25	19	26	21	22	25	24	21	12	22	21	20
Detroit-Ann Arbor	133	11	11	12	11	7	12	13	13	3	15	10	15
Pittsburgh	264	22	22	23	23	23	24	24	25	10	25	22	21
Baltimore	140	12	12	17	16	0	0	0	0	13	26	21	23
Philadelphia-Wilmington	98	13	14	12	12	9	11	14	13	0	0	0	0
New York	145	19	15	19	21	20	14	13	24	0	0	0	0

Figure F-1. Distributions of Estimated Daily Maximum Daylight 1-Hour $PM_{2.5}$ Light Extinction Across the 2007-2009 Period, by Study Area (excluding hours with relative humidity > 90%)

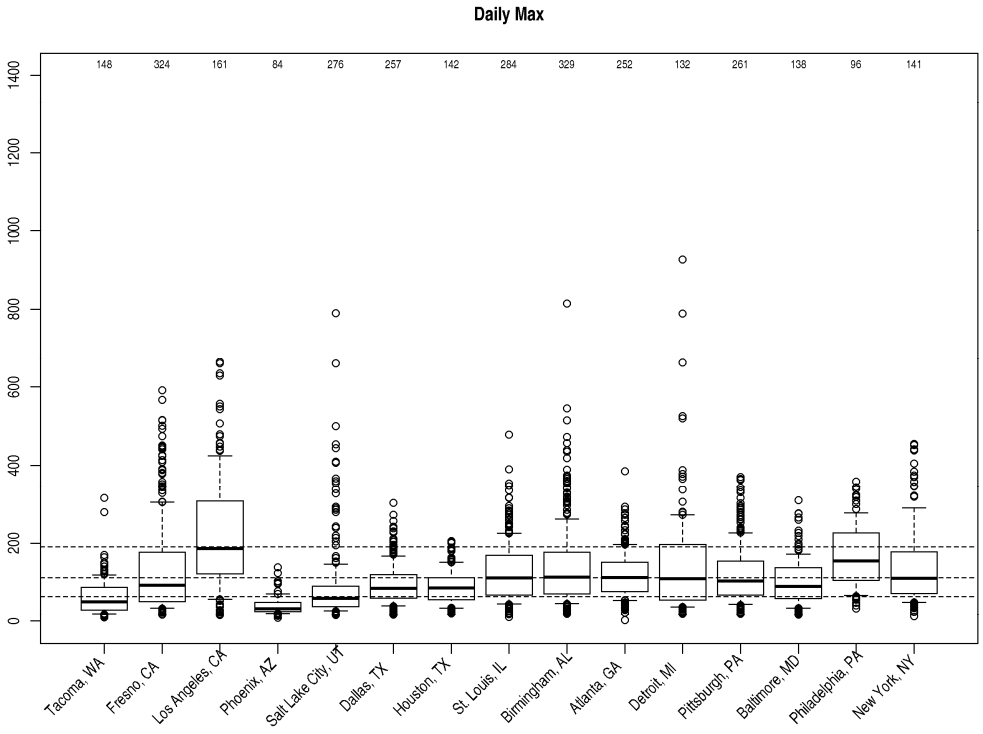


Table F-2. 2007-2009 Daily Maximum $PM_{2.5}$ Light Extinction Design Values for the Study Areas

Study Area	Design Value for 90th Percentile Form (Mm^{-1})	Design Value for 95th Percentile Form (Mm^{-1})
Tacoma	121	132
Fresno	312	394
Los Angeles	434	503
Phoenix	71	97
Salt Lake City	152	285
Dallas	162	204
Houston	145	177
St. Louis	224	267
Birmingham	269	326
Atlanta	189	212
Detroit-Ann Arbor	275	436
Pittsburgh	222	256
Baltimore	183	212
Philadelphia-Wilmington	280	320
New York	295	365

F.4 SIMPLIFIED APPROACHES T AND W

This analysis examines the difference between calculated hourly $PM_{2.5}$ light extinction values used in the UFVA and values generated using two simpler approaches. Both of the simpler approaches (designated by letters T and W) use the original IMPROVE algorithm without the Rayleigh and $PM_{10-2.5}$ contributions to total light extinction.

Approach T is similar to the previous approach F. The difference is that while approach F involved the calculation and use of monthly-averaged $PM_{2.5}$ component percentages for each of the five components, approach T uses a two-factor rearrangement of the IMPROVE algorithm and accordingly involves the calculation and use of only two monthly-averaged parameters. These parameters are the hygroscopic fraction (HF) and the dry light extinction efficiency (DLEE). A technical memo explains in more detail the definition of these parameters and their relationship to the IMPROVE algorithm.[8] Looking to a hypothetical future program based on approach T, it would be possible to develop estimates of $PM_{2.5}$ light extinction for any day for which hourly $PM_{2.5}$ mass concentrations are available from a continuous FEM instrument, including days that do not have $PM_{2.5}$ speciation data, by applying the monthly-averaged HF and DLEE values to each hourly $PM_{2.5}$ measurement.

Approach W differs from approach T in that the HF and DLEE parameters are applied day-by-day rather than averaged across a month. The inclusion of this approach in this analysis allows a close examination of the effect of the monthly-averaging step in approach T. Approach

[8] Pitchford, M (2010). Assessment of the Use of Speciated $PM_{2.5}$ Mass-Calculated Light Extinction as a Secondary PM NAAQS Indicator of Visibility. Memorandum to PM NAAQS Review Docket (EPA-HQ-OAR-2007-0492), Marc Pitchford, NOAA, November 17, 2010. Available at: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html.

W can yield estimates of $PM_{2.5}$ light extinction only for days on which $PM_{2.5}$ speciation data are available. The EPA staff notes that many $PM_{2.5}$ and PM_{10} monitoring sites currently operate on 1-day-in-3 or 1-day-in-6 schedules, and are nevertheless considered to provide sufficiently robust data for air quality management purposes.

Both approaches T and W assume that within a day, the percentage mix of $PM_{2.5}$ components is the same hour-to-hour.

Table F-3 explicitly defines the calculation steps for approaches T and W. Table F-4 compares the UFVA approach, approach T, and approach W in conceptual terms.

Table F-3. Calculation Steps for Approaches T and W

Approach T	Approach W	Comments
(i) For each CSN sampling day, subtract a sampler-dependent estimate of the OC artifact from the OC measurement, and multiply by 1.6 to estimate organic carbonaceous material (OCM). • OCM = (OC – artifact) *1.6	Same as T.	The values for the OC artifact used for 2007-2009 ranged from 0.32 to 1.53 µg/m^3, depending on CSN sampler model. The artifact adjustment for the URG 3000N sampler is of most interest prospectively, because it is the single sampler now in use for carbon sampling in CSN. The URG 3000N was used only at about one-half of the 15 study sites and only in the second half of 2007. For those sites and days, an organic carbon artifact of 0.4 µg/m^3 was assumed for the purposes of the UFVA and this document, based on early experience with this sampler. EPA staff is currently exploring whether there is a better way to adjust for organic carbon artifact based on a more recent, larger field blank and back-up filter data set. A section in the body of this appendix explains the selection of 1.6 as the multiplier for OC.
(ii) For each CSN sampling day, calculate fine soil/crustal $PM_{2.5}$ (FS) from CSN measurements of crustal elements AL, Si, Ca, Fe, and Ti, using the formula • FS = 2.20 x [Al] + 2.49 × [Si] + 1.63 × [Ca] + 2.42 × [Fe] + 1.94 × [Ti]	Same as T.	This is the same equation as used in the IMPROVE network and the Regional Haze program, and differs from the corresponding step in approaches D and F.
(iii) For each CSN sampling day, multiply CSN measurement of sulfate ion by 1.375, and multiply CSN measurement of nitrate ion by 1.29, to reflect associated ammonium under an assumption of full neutralization. • AS = Sulfate ion * 1.375 • AN = Nitrate ion * 1.29	Same as T.	
(iv) For each CSN sampling day, sum the above estimates of the 5 components of $PM_{2.5}$: • Sum = AS + AN + OCM + EC + FS	Same as T.	

Approach T	Approach W	Comments
(v) For each CSN sampling day, calculate HF and DLEE: • HF_{daily} = (AS+AN) / Sum • $DLEE_{daily}$ = [3*(AS+AN)+4*OCM+10*EC+1.0*FS] / Sum	Same as T.	
(vi) Average the values of HF_{daily} and $DLEE_{daily}$ from step (v) across the CSN sampling days of each calendar month. This results in values for • $HF_{monthly\_average}$ • $DLEE_{monthly\_average}$	This step is omitted. HF and DLEE are day-specific: • HF_{daily} • $DLEE_{daily}$	Note: An alternative approach to calculating $HF_{monthly\_average}$ would be to define it as the monthly average of the daily values of (AS + AN) divided by the monthly average of the daily values of Sum. A similar alterative definition is possible for $DLEE_{monthly\_average}$. In the analysis described in this appendix, we applied a minimum requirement of four samples per month, which is usually 80% of the samples scheduled per month at a site using one-in-six-days sampling. If there were fewer samples in a month, approach T estimates were not generated but approach W estimates were.

Approach T	Approach W	Comments
(vii) For each daylight hour of each day of a month (including days without CSN sampling), calculate $PM_{2.5}$ light extinction using the 1-hour $PM_{2.5}$ mass concentration from a continuous instrument, HF, DLEE, and 1-hour relative humidity (RH): • Hourly $PM_{2.5}$ light extinction = $PM_{2.5hourly}$ * { 3*[f(RH_{hourly})-1] * [$HF_{monthly\_average}$] + $DLEE_{monthly\_average}$ } Estimates of $PM_{2.5}$ light extinction in hours with RH greater than 90% are not valid.	(vii) For each daylight hour of each day of a month for which CSN speciation data is available, calculate $PM_{2.5}$ light extinction using the 1-hour $PM_{2.5}$ mass concentration from a continuous instrument, HF, DLEE, and 1-hour relative humidity (RH): • Hourly $PM_{2.5}$ light extinction = $PM_{2.5hourly}$ * { 3*[f(RH_{hourly})-1] * [HF_{daily}] + $DLEE_{daily}$ } Estimates of $PM_{2.5}$ light extinction in hours with RH greater than 90% are not valid.	Prospectively, this appendix assumes that only continuous instruments approved as federal equivalent methods (FEM) would be allowed for purposes of estimating hourly $PM_{2.5}$ light extinction. Accordingly, the equations to the left are based on the instrument-reported hourly $PM_{2.5}$ mass concentration. As explained in footnote 3, the available hourly $PM_{2.5}$ mass concentrations from continuous instruments for this analysis were mostly from non-FEM instruments. All the hourly $PM_{2.5}$ concentrations were therefore adjusted on a day-by-day basis to match the 24-hour concentration reported by a collocated FRM/FEM filter-based sampler, prior the step described on the left. This was intended to better simulate the future scenario of interest.

Table F-4. Detailed Comparative Description of the UFVA Approach, Approach T, and Approach W for Estimating 1-Hour $PM_{2.5}$ Light Extinction

UFVA Step[***]	Aspect of Approach	UFVA Approach	Approach T	Approach W
1	Estimation of 24-hour organic carbonaceous mass	The SANDWICH method[†††] is used to subdivide the 24-hour $PM_{2.5}$ mass reported by the FRM for each day and site into hydrated ammonium sulfate, ammonium nitrate, elemental carbon, organic carbonaceous material (OCM), fine soil, and water. This is done using information from the CSN measurements, physical models, and day-specific temperatures and relative humidity. OCM is estimated as the residual needed to reach mass closure after estimation of the other components.	Organic carbonaceous mass is assumed to equal the organic carbon value reported from CSN sampling, minus a blank filter artifact correction value that depends on PM sampler model, times 1.6.	Same as T
1, continued	Estimation of 24-hour elemental carbon mass	CSN elemental carbon concentration	Same as UFVA	Same as UFVA
1, continued	Estimation of 24-hour hydrated ammonium sulfate mass	CSN sulfate ion concentration, with day-specific SANDWICH estimates of associated ammonium and water.	Sulfate ion measurement from the CSN filter is multiplied by 1.375 to represent dry ammonium sulfate.	Same as T

[***] The numbering of steps follows that used to describe the UFVA approach in section 3.3.1 of the UFVA.

[†††] Frank NH. (2006). Retained nitrate, hydrated sulfates, and carbonaceous mass in federal reference method fine particulate matter for six eastern U.S. cities. J Air Waste Manag Assoc, 56: 500-11

UFVA Step***	Aspect of Approach	UFVA Approach	Approach T	Approach W
1, continued	Estimation of 24-hour ammonium nitrate mass	Nitrate ion on the FRM Teflon filter is estimated by SANDWICH, with day-specific estimates of associated ammonium and water.	Nitrate ion measurement from the CSN filter is multiplied by 1.29 to represent dry ammonium nitrate.	Same as T
1, continued	Estimation of 24-hour fine soil/crustal mass	Calculated from 4 CSN elements, not including Al (a difference from the IMPROVE approach)	IMPROVE approach, using 5 elements	Same as T
2	Diurnal pattern of $PM_{2.5}$ components	The CMAQ-derived monthly normalized diurnal profiles for the sulfate, nitrate, elemental carbon, organic carbonaceous material and fine soil/crustal components (each of which averages to 1.0 across 24 hours) were multiplied by the day-specific SANDWICH-based estimates of the 24-hour average concentrations of the five $PM_{2.5}$ components, to get intermediate day-specific hourly estimates of the five components (including ammonium and water associated with sulfate and nitrate ion).	No diurnal profiles are used.	Same as T

UFVA Step***	Aspect of Approach	UFVA Approach	Approach T	Approach W
3	Sum the 5 components	The hourly concentrations of these five components (including day-specific ammonium and water associated with sulfate and nitrate ion when the FRM Teflon filter is weighed) were added together, to get a sum-of-components estimate of hourly $PM_{2.5}$ mass for the day of FRM/CSN sampling.	The following approach was used instead of steps 3, 5, 7, and 8. • Calculate HF and DLEE for each day. • Average the daily values of HF and DLEE across the available CSN sampling days in the month. • Use the monthly-averaged HF and DLEE values in a two-factor version of the original IMPROVE algorithm.	The following approach was used instead of steps 3, 5, 7, and 8. • Calculate HF and DLEE for each day. • Use the day-specific HF and DLEE values in a two-factor version of the original IMPROVE algorithm.
4	Hourly $PM_{2.5}$ concentration, consistent with 24-hour FRM concentration.	The hourly data from the continuous $PM_{2.5}$ instrument on the day of the FRM sampling were normalized by their 24-hour average, to get a normalized diurnal profile. This profile was applied to the 24-hour $PM_{2.5}$ mass reported by the FRM sampler. This keeps the average of the valid 1-hour $PM_{2.5}$ values equal to the 24-hour value from the FRM sampler.	See the comment on this topic in Table F-3.	See the comment on this topic in Table F-3.

UFVA Step***	Aspect of Approach	UFVA Approach	Approach T	Approach W
5, 6	Adjust preliminary estimates of hourly $PM_{2.5}$ component concentrations (reflecting CMAQ diurnal profiles and 24-hour measurements) to be consistent with the estimate of hourly PM2.5 mass.	The two estimates of hourly $PM_{2.5}$ mass from steps 3 and 4 were compared, hour-by-hour. Within each hour, the estimates of all five components from step 3 were increased or decreased by a common percentage so that the sum of the five components after this adjustment was equal to the estimate of the hourly $PM_{2.5}$ mass from step 4. The adjustment percentage varied from hour-to-hour.	Not applicable.	Not applicable.
7	Adjust the FRM-consistent estimate of sulfate to the CSN/IMPROVE-consistent basis expected by the IMPROVE algorithm.	Each hourly estimate of sulfate concentration on the FRM filter from step 6 (which includes estimates of associated ammonium and particle bound water) was adjusted so that it excludes water and reflects full neutralization and therefore is consistent with the reporting practices of the IMPROVE program and the IMPROVE algorithm.	Not applicable.	Not applicable.

UFVA Step***	Aspect of Approach	UFVA Approach	Approach T	Approach W
8	Adjust the FRM-consistent estimate of nitrate to the CSN/IMPROVE-consistent basis expected by the IMPROVE algorithm.	A similar adjustment as in step 7 (for sulfate) was made to each hour's nitrate concentration from step 6, so that the estimate of hourly nitrate would reflect actual atmospheric conditions and be consistent with the IMPROVE algorithm. This can result in the estimate of nitrate used in the IMPROVE algorithm being higher than the FRM-consistent estimate, for days on which the SANDWICH method predicts a loss of nitrate from the FRM filter.	Not applicable. Implication: On days when the FRM filter has lost nitrate mass, the estimates of hourly $PM_{2.5}$ will be lower than actual atmospheric mass. All hourly $PM_{2.5}$ components will be biased low relative to the values that should be used in the IMPROVE algorithm, by the fraction that the lost nitrate is of total $PM_{2.5}$ mass. In the opposite direction, any water mass included in the hourly $PM_{2.5}$ mass reported by the continuous $PM_{2.5}$ instrument will in effect be allocated among the five components.	Same as T.
Not numbered in UFVA	Estimation of $PM_{2.5}$ light extinction from estimates of hourly concentrations of $PM_{2.5}$ components.	Original IMPROVE algorithm, including f (RH) determined from hourly RH. Hours with RH >90% were excluded from design values and from most graphical displays of results.	Use a two-factor re-arrangement of the original IMPROVE algorithm, per table F-3. Hours with RH >90% were excluded from design values and from all graphical displays of results.	Same as T.

F.5 COMPARATIVE PERFORMANCE OF SIMPLIFIED $PM_{2.5}$ LIGHT EXTINCTION APPROACHES T AND W

The performance assessment of simplified approaches T and W for calculated $PM_{2.5}$ light extinction was accomplished by comparing hourly values of $PM_{2.5}$ light extinction generated by each approach to their corresponding paired values generated using the original UFVA method. Data from 2007-2009 were used for the comparison. Annual box plots of the percentage differences between the paired values, as well as annual and monthly scatter plots and regression analysis of these paired data, were generated. As the results below show, approaches T and W produce hourly $PM_{2.5}$ light extinction values that in most cases are quite well correlated to the hourly $PM_{2.5}$ light extinction values generated by the original UFVA method, with a few notable exceptions discussed below. Selected graphs and summary tables of regression statistics are included and discussed below to show the degree of comparability. Note that approaches T and W can be compared to the UFVA approach only for days with CSN data. Similarly, approaches T and W can be compared to each other only for those days, as approach W does not produce estimates of $PM_{2.5}$ light extinction for other days.

The box plots of the percentage differences between calculated hourly $PM_{2.5}$ light extinction by approaches T and W versus the UFVA approach are shown in Figure F-2. In this box plot, the percentage difference is calculated as follows:

Percentage difference = 100% * [(T or W estimate) – (UFVA estimate)]/(UFVAestimate)

The patterns of percentage bias for the 15 urban areas are notably similar in both the T and W plots.[11] Fresno and Los Angeles are noticeably biased low by approaches T and W, while Houston and Philadelphia are biased high. However, these percent difference plots do not reveal the absolute level of $PM_{2.5}$ light extinction for the points corresponding to smaller or larger percent differences.

Scatter plots of calculated hourly $PM_{2.5}$ light extinction for all daylight hours comparing approaches T and W to the UFVA approach for all 15 areas are shown in Figure F-3. The same comparisons are made for daily maximum $PM_{2.5}$ light extinction in Figure F-4. Note that the vertical scale is not the same in all plots. The dashed red line is the 1:1 line, and regression statistics appear at the top of each plot. These figures give a better visual sense of how the deviations between the simpler approaches and the UFVA approach vary by area and, by implication, with the nature of $PM_{2.5}$ in each study area. For example, both simpler approaches have an obvious negative bias in Fresno, Los Angeles, and New York across a wide range of $PM_{2.5}$ light extinction values, consistent with the percentage difference box plot.

The degree of comparability for paired hourly $PM_{2.5}$ light extinction values between approach T and the UFVA approach and between approach W and the UFVA approach, by month and urban area, can also be displayed via regression statistics, as in Tables F-5 (approach T) and F-6 (approach W). Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in the scatter plots of Figures F-3 and F-4. Color shading is used to highlight cells (representing a given month across 2007-2009) in which the slope of the regression falls outside the range of 0.9 to 1.1, with deeper

[11] In the box plots, some extreme values of the percentage change are due to rounding effects when the values involved were very small.

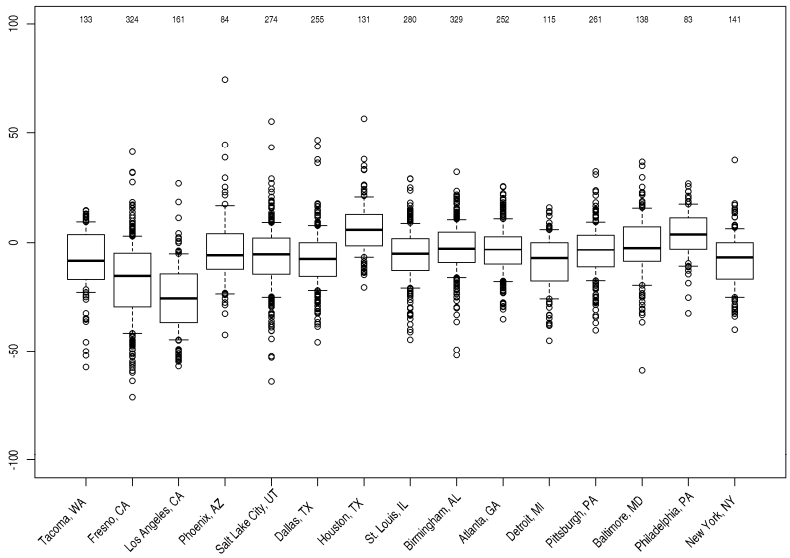
shading indicating a larger deviation from a slope of 1.0. In both tables, for most eastern urban areas and months the regression lines have slopes in the range of 0.9 to 1.1, R2 values near one, and small intercepts implying that the values are highly comparable. The western urban areas (Fresno, Houston, Los Angeles, Phoenix, Salt Lake City, and Tacoma) have intercepts, slopes, and R2 values for some months that imply a bias and/or noisier relationship than the eastern areas between values calculated by approaches T and W versus the UFVA approach. Los Angeles and Fresno, and to a lesser degree other western areas, stand out as having regression slopes that indicate that approaches T and W are biased low relative to the UFVA estimates for most of the year.

A comprehensive assessment of the reasons for the differences between approaches T and W versus the UFVA approach has not been conducted. However, some explanations are suggested by the results themselves and by the previous draft analysis of similar approaches D and E. The fact that the CMAQ-based hour-to-hour variations and the monitoring-based day-to-day variations in the dry $PM_{2.5}$ composition in the UFVA approach can in most areas be replaced by either daily-averaged or monthly-averaged values without much loss of precision in calculated hourly $PM_{2.5}$ light extinction suggests that these shorter-term variations within a single month at a single monitoring site are usually not very influential. This may imply that the differences between approaches T and W and the UFVA approach are probably not mostly due to the relative composition changes caused by use of the mass-closure SANDWICH model versus the simpler multiplier model used in approaches T and W. This suggests that the difference may be due to differences in the value of $PM_{2.5}$ mass to which the HF and DLEE factors are applied. Approaches T and W lack any step that would effectively reconcile the implicit nitrate portion of the average of the 24 hourly values of $PM_{2.5}$ mass to the CSN-measured 24-hour average nitrate concentrations, to compensate for any loss of nitrate from the continuous $PM_{2.5}$ instrument.[12] This explanation is consistent with the direction of the biases seen for sites that are known to have high ammonium nitrate (e.g., Los Angeles and Fresno). For Los Angeles and Fresno, a logical explanation is that the FRM-adjusted estimates of 1-hour $PM_{2.5}$ mass do not include the entire ambient nitrate that is present in particulate form. The UFVA approach includes an adjustment to restore this mass in the estimation of light extinction while approaches T and W do not. There are variations of approaches T and W that may improve the correlation with actual ambient light extinction in certain areas of the country, such as one that would retain some version of a mass-closure model to account for the negative artifact for ammonium nitrate, but that otherwise has the remaining simplifications of approaches T or W.

[12] FRM sampling is well known to have a negative artifact for nitrate compared to ambient concentrations under some conditions. This negative artifact presumably carries over to any continuous $PM_{2.5}$ FEM instrument that is well correlated with the FRM. A negative artifact would logically lead to an underestimate of $PM_{2.5}$ light extinction.

Figure F-2. Box and Whisker Plot of the Percent Difference in Calculated Hourly $PM_{2.5}$ Light Extinction between Approach T and the UFVA Approach (top plot) and between Approach W and the UFVA Approach (bottom plot) by Urban Study Area

Approach T



Approach W

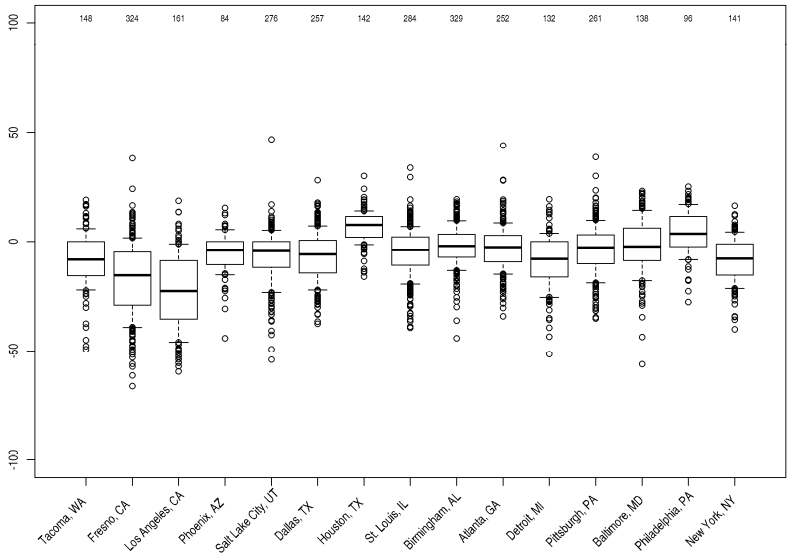


Figure F-3. Scatter Plots of Hourly $PM_{2.5}$ Light Extinction (all daylight hours) Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA Approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in this figure.

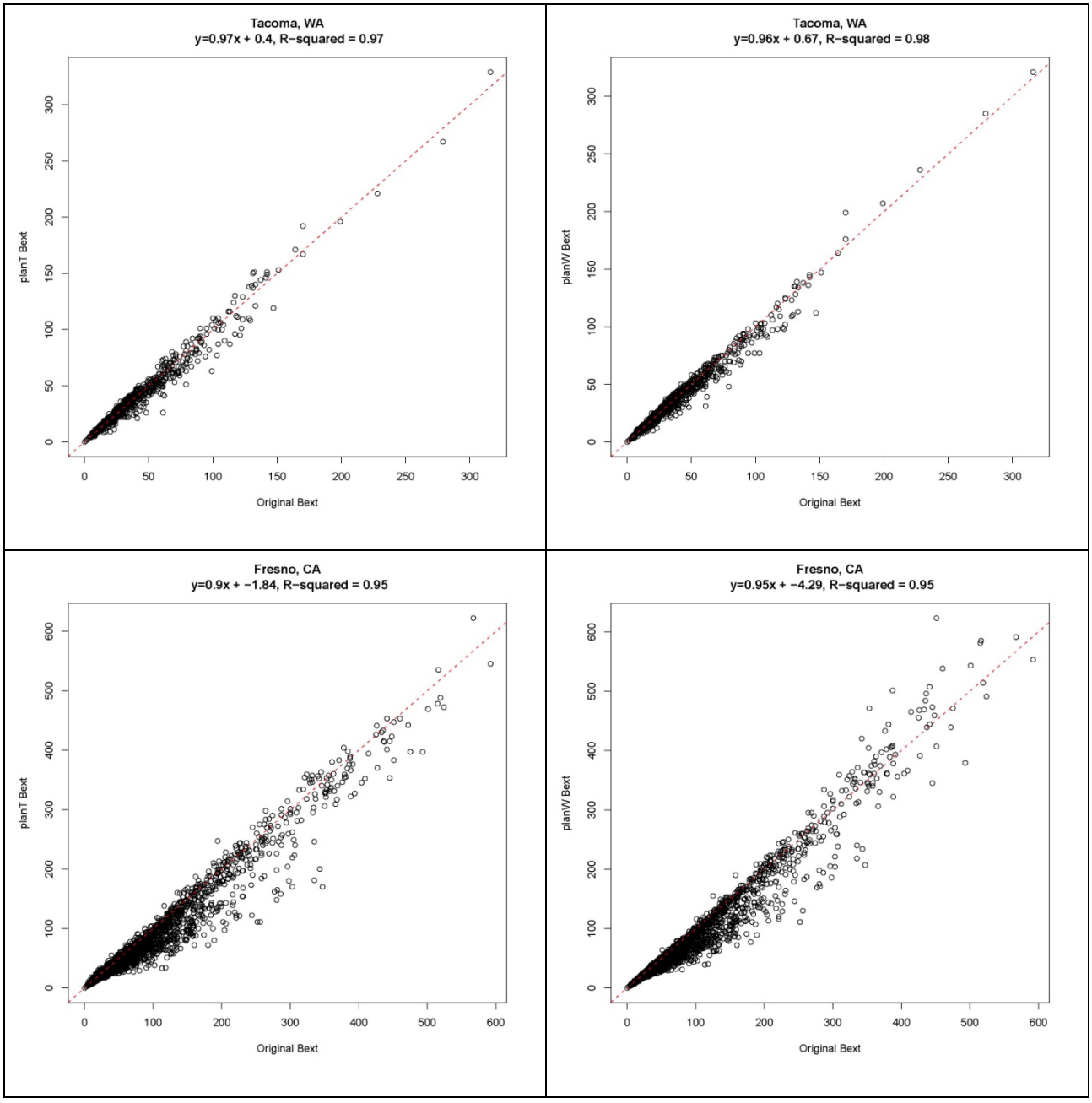


Figure F-3. Scatter Plots of Hourly $PM_{2.5}$ Light Extinction (all daylight hours) Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA Approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in this figure.

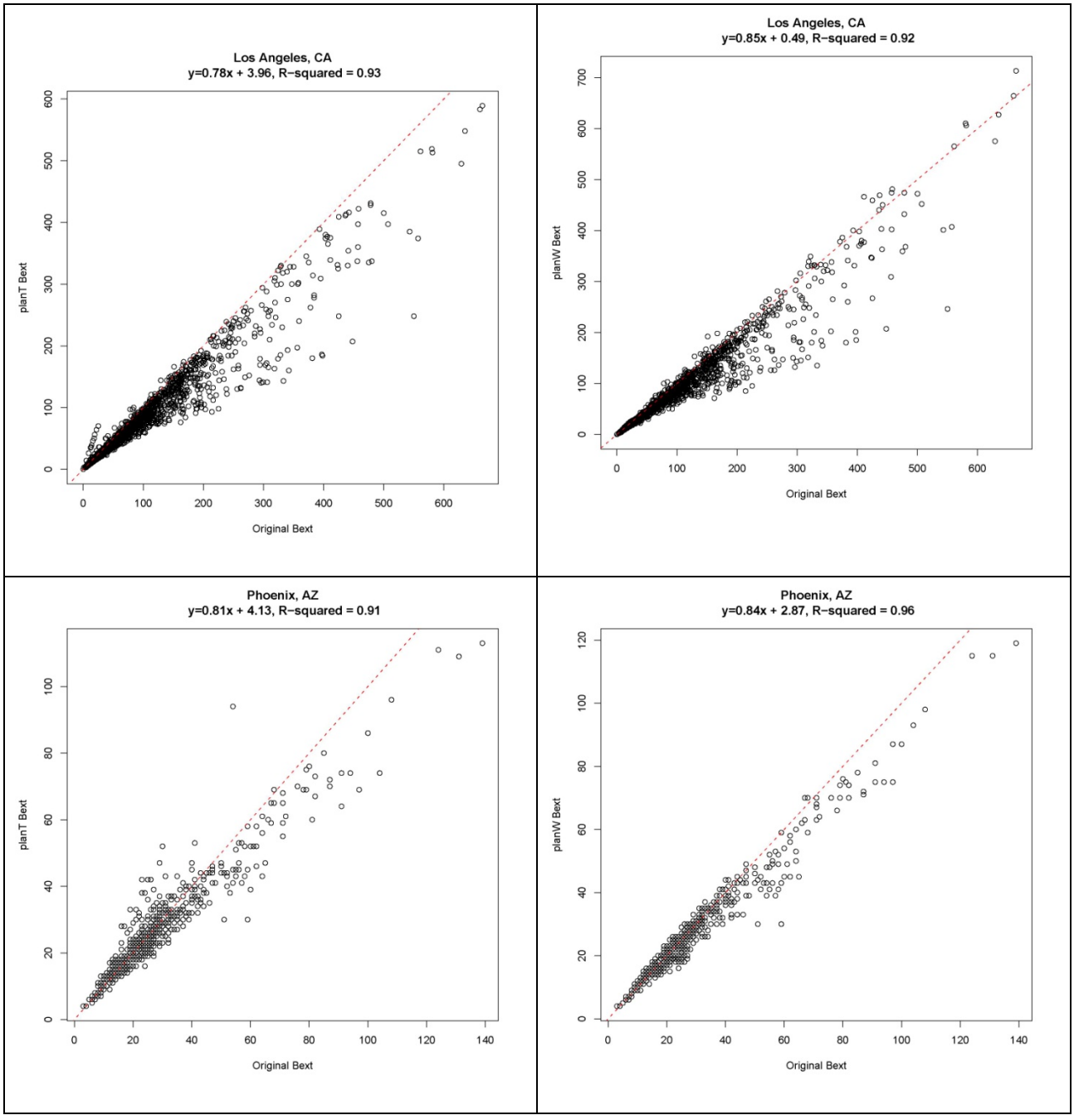


Figure F-3. Scatter Plots of Hourly $PM_{2.5}$ Light Extinction (all daylight hours) Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA Approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in this figure.

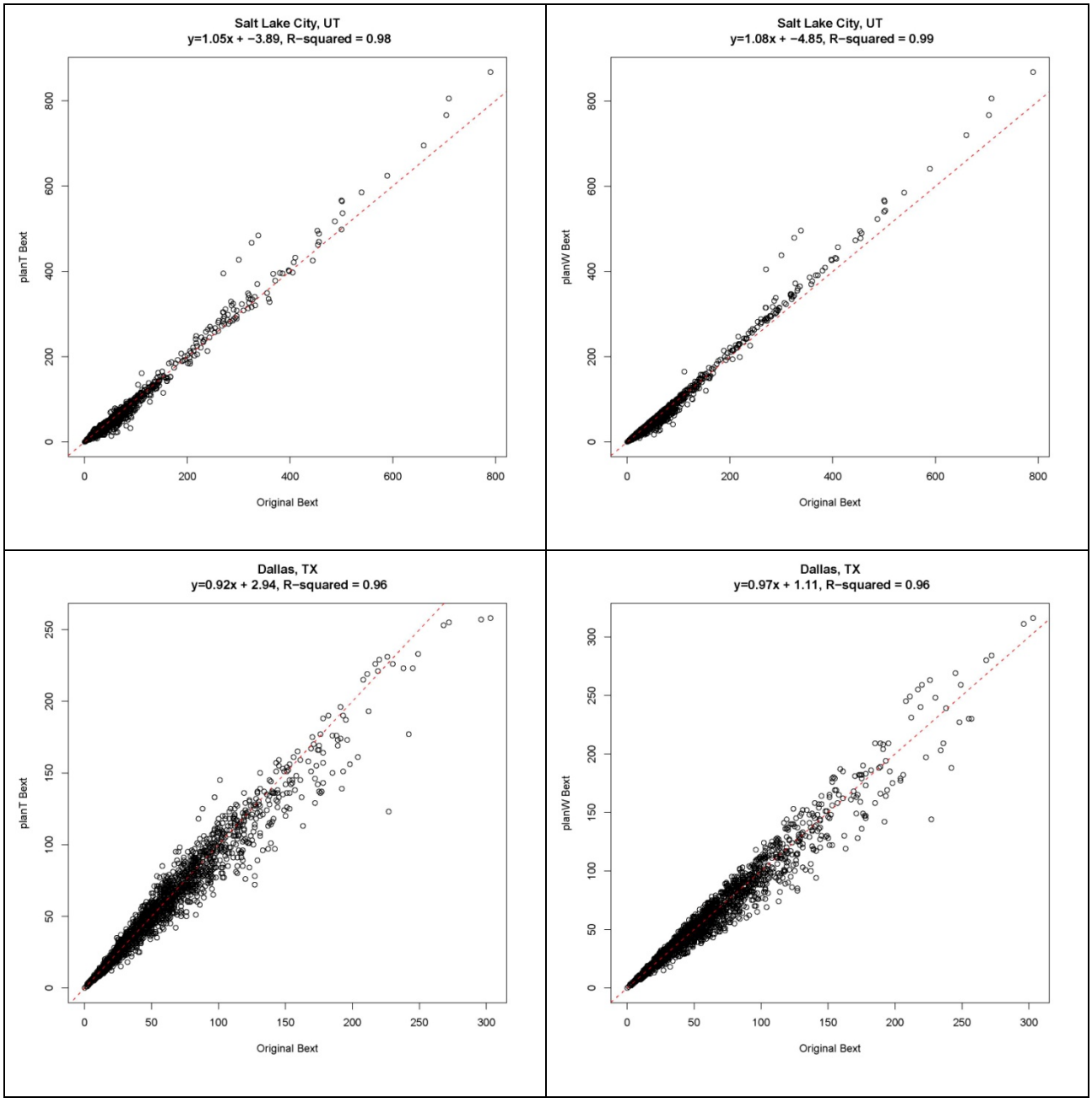


Figure F-3. Scatter Plots of Hourly $PM_{2.5}$ Light Extinction (all daylight hours) Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA Approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in this figure.

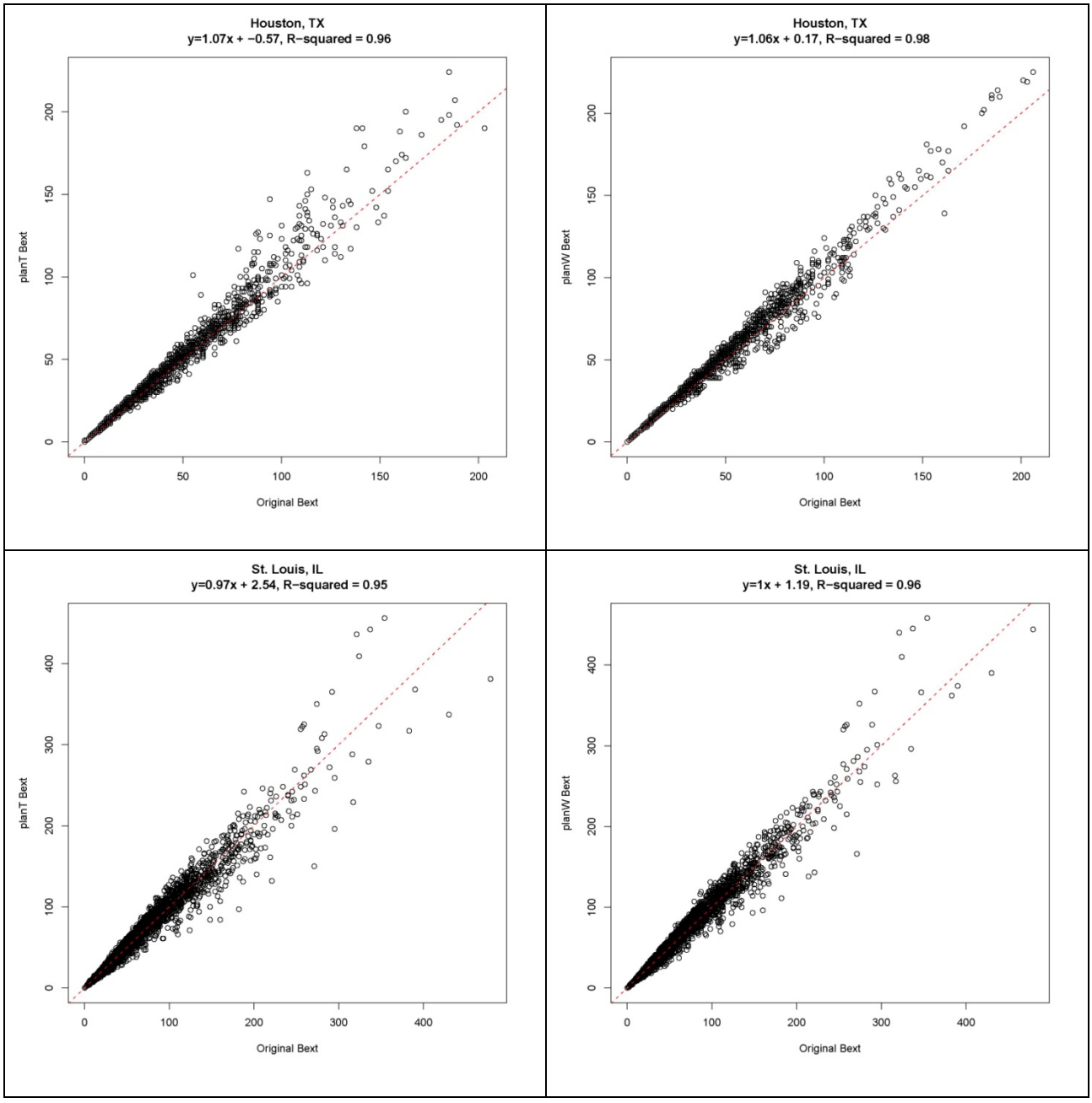


Figure F-3. Scatter Plots of Hourly $PM_{2.5}$ Light Extinction (all daylight hours) Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA Approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in this figure.

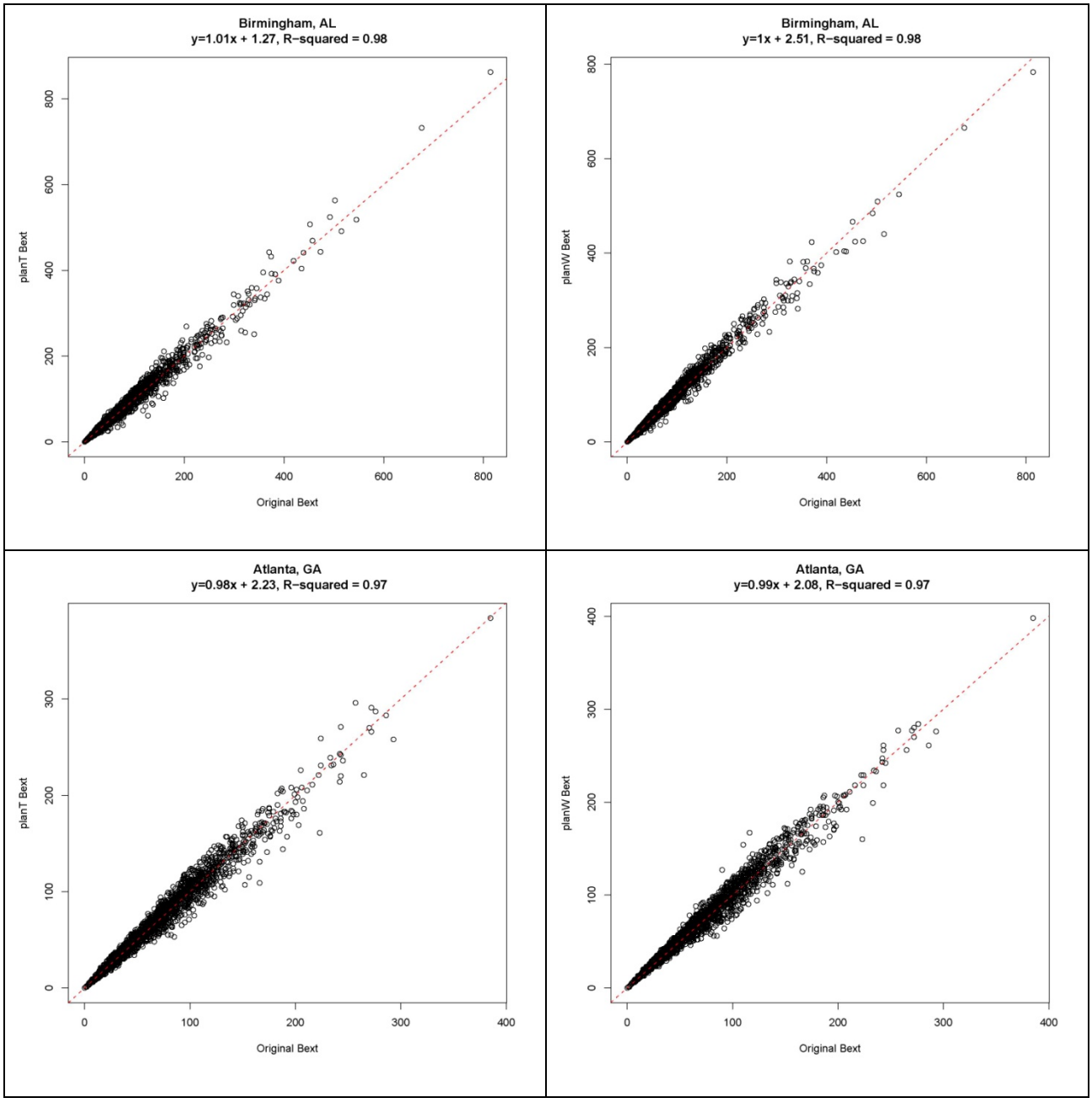


Figure F-3. Scatter Plots of Hourly $PM_{2.5}$ Light Extinction (all daylight hours) Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA Approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in this figure.

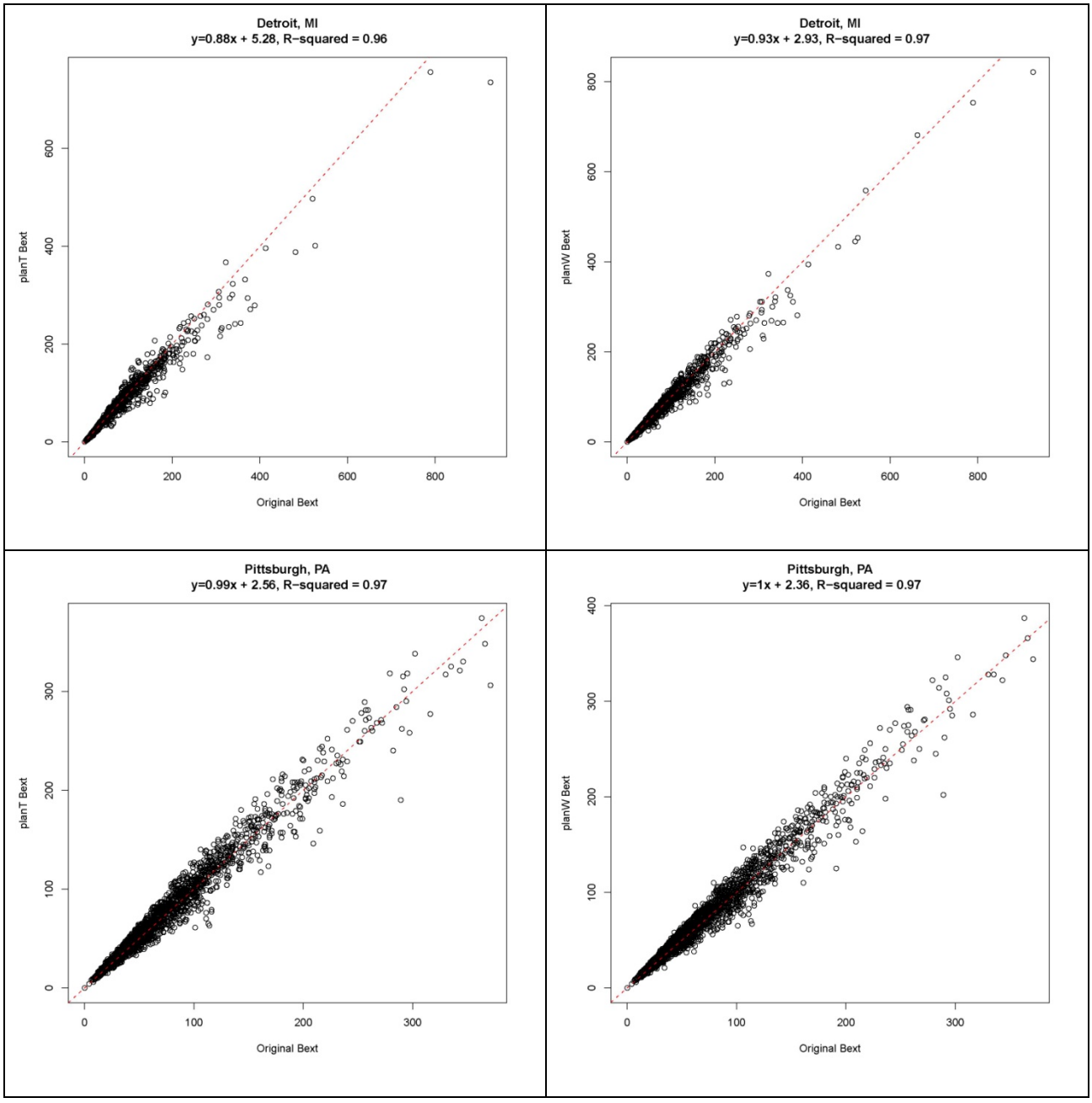


Figure F-3. Scatter Plots of Hourly $PM_{2.5}$ Light Extinction (all daylight hours) Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA Approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in this figure.

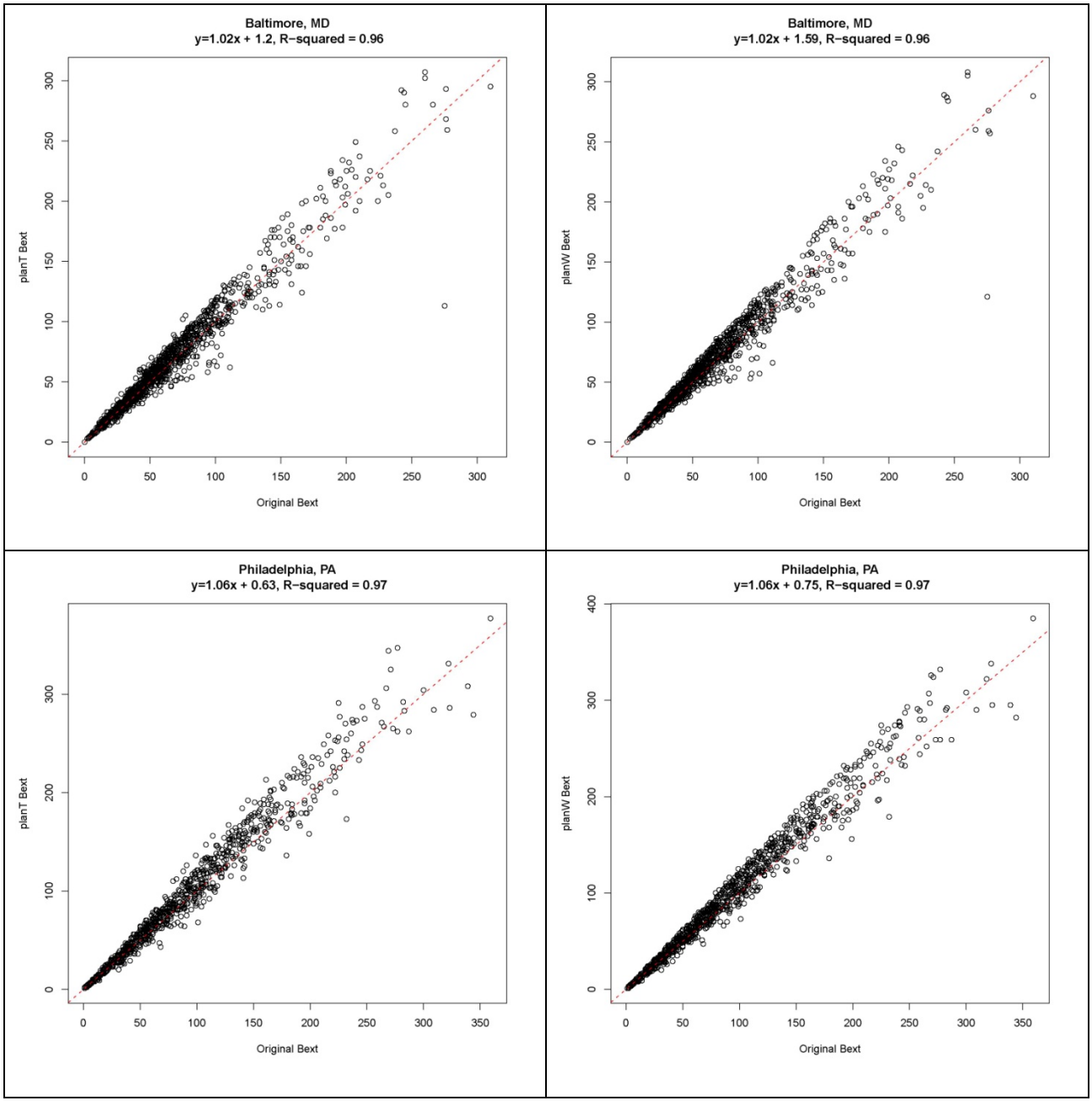


Figure F-3. Scatter Plots of Hourly $PM_{2.5}$ Light Extinction (all daylight hours) Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA Approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in this figure.

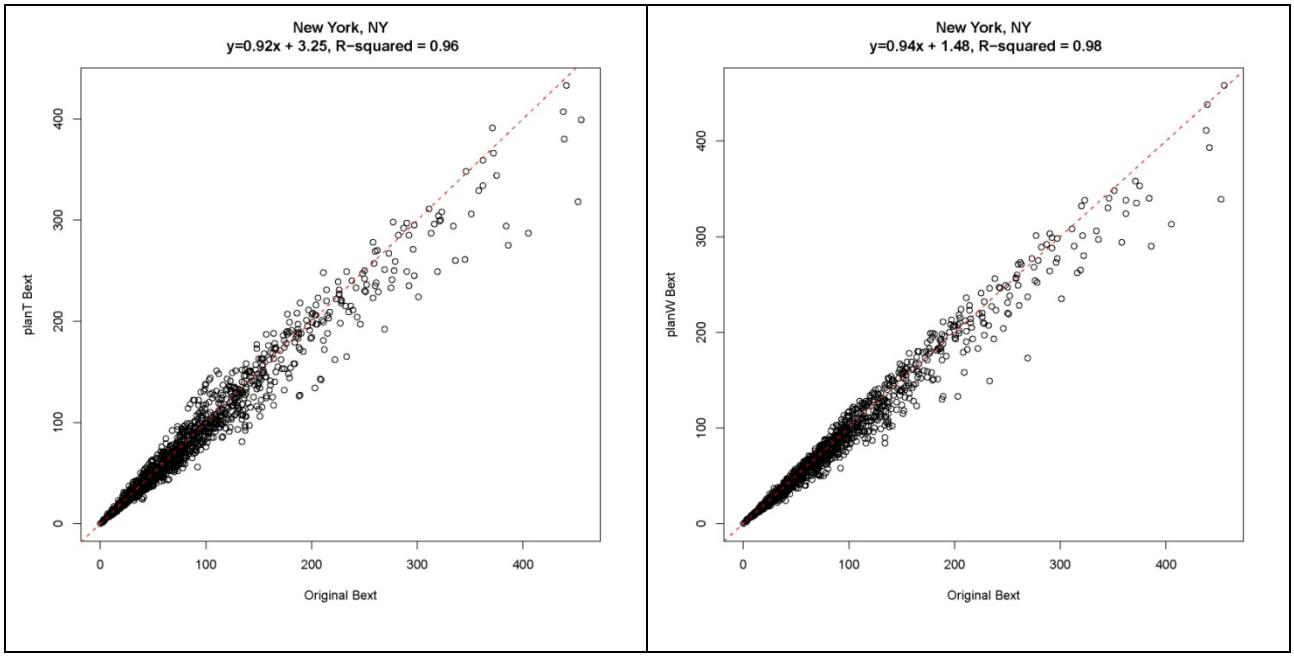


Figure F-4. Scatter Plots of Daily Maximum Daylight Hourly $PM_{2.5}$ Light Extinction Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in the scatter plots in this figure.

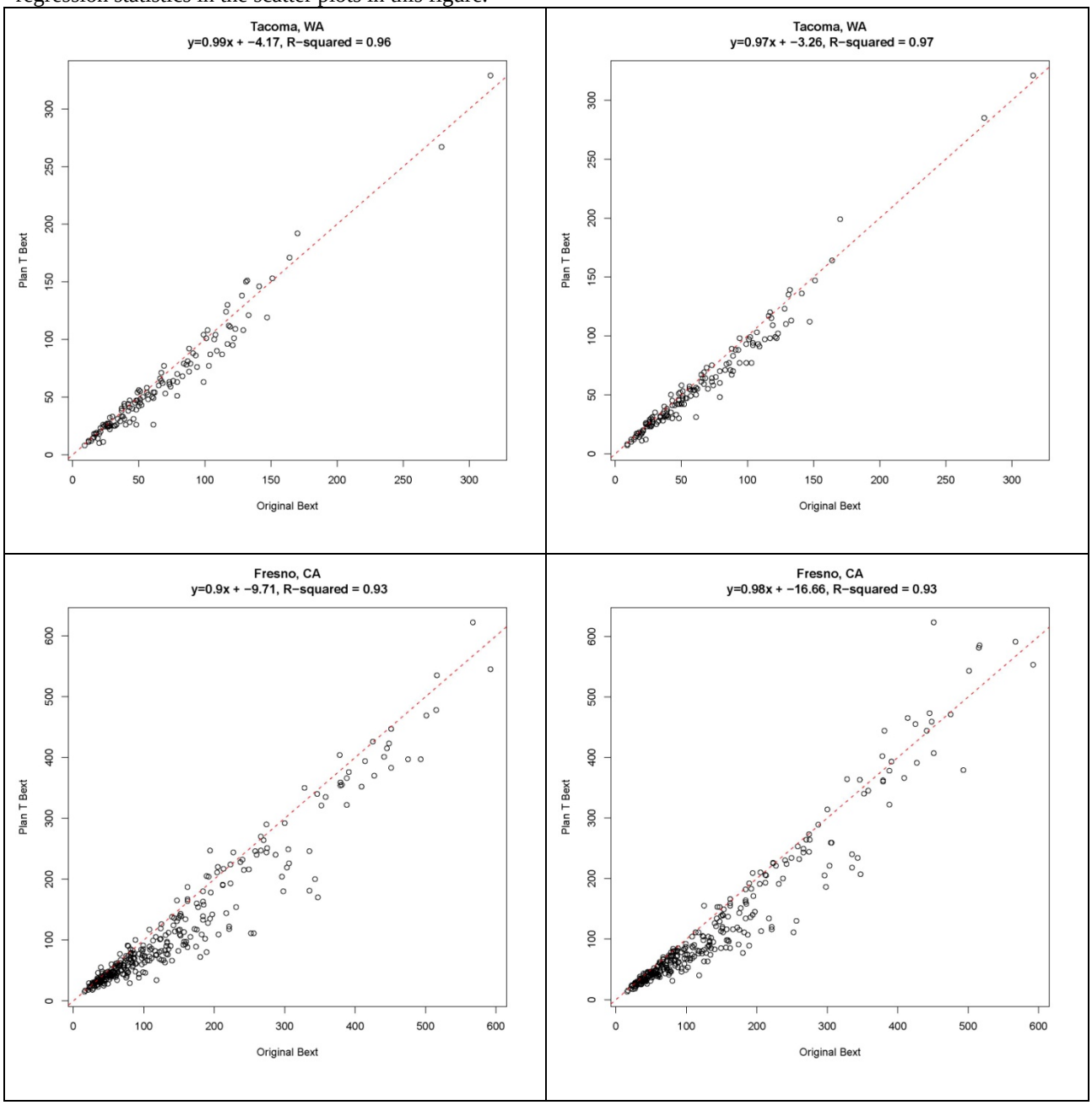


Figure F-4. Scatter Plots of Daily Maximum Daylight Hourly $PM_{2.5}$ Light Extinction Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in the scatter plots in this figure.

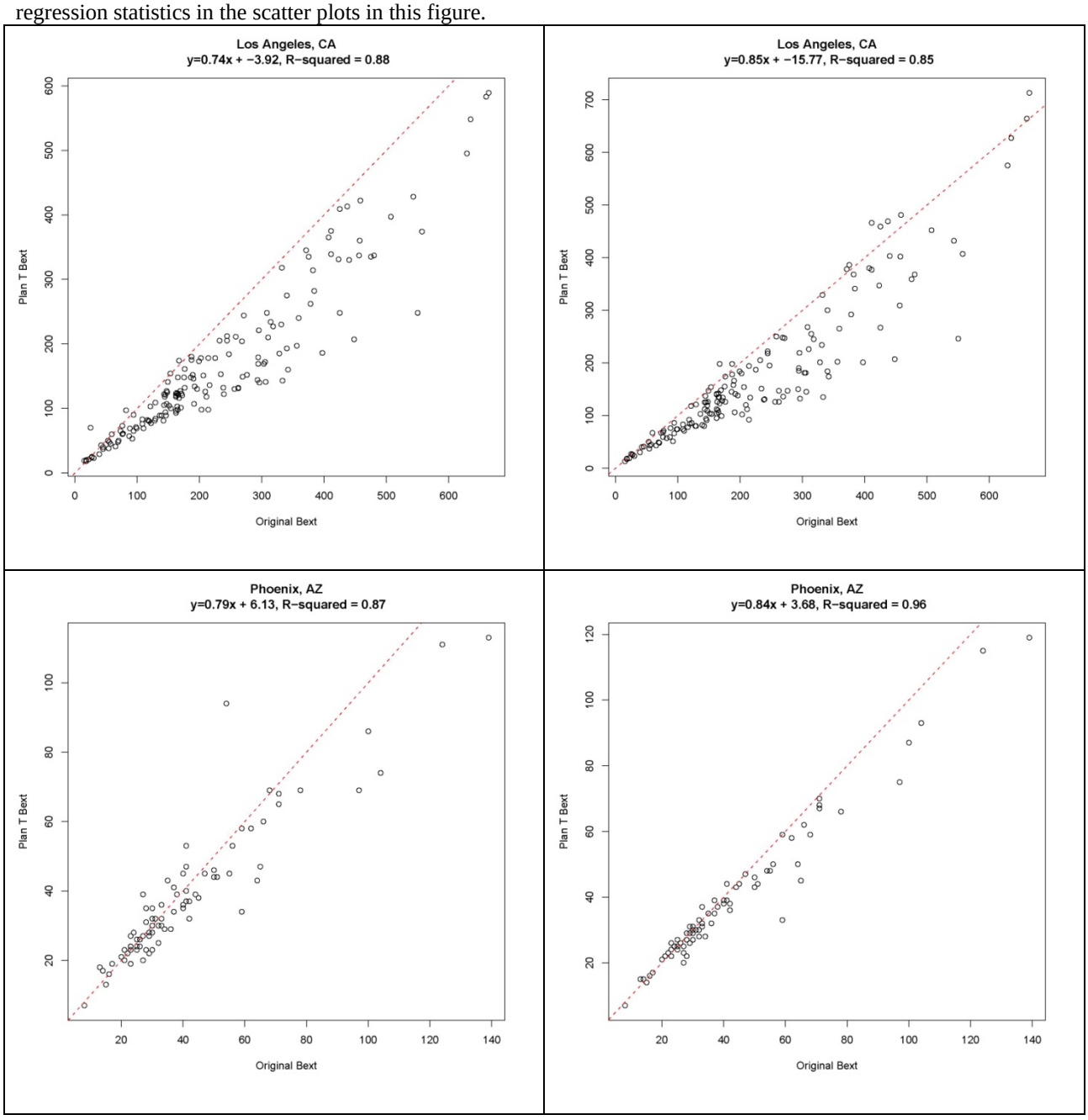


Figure F-4. Scatter Plots of Daily Maximum Daylight Hourly $PM_{2.5}$ Light Extinction Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in the scatter plots in this figure.

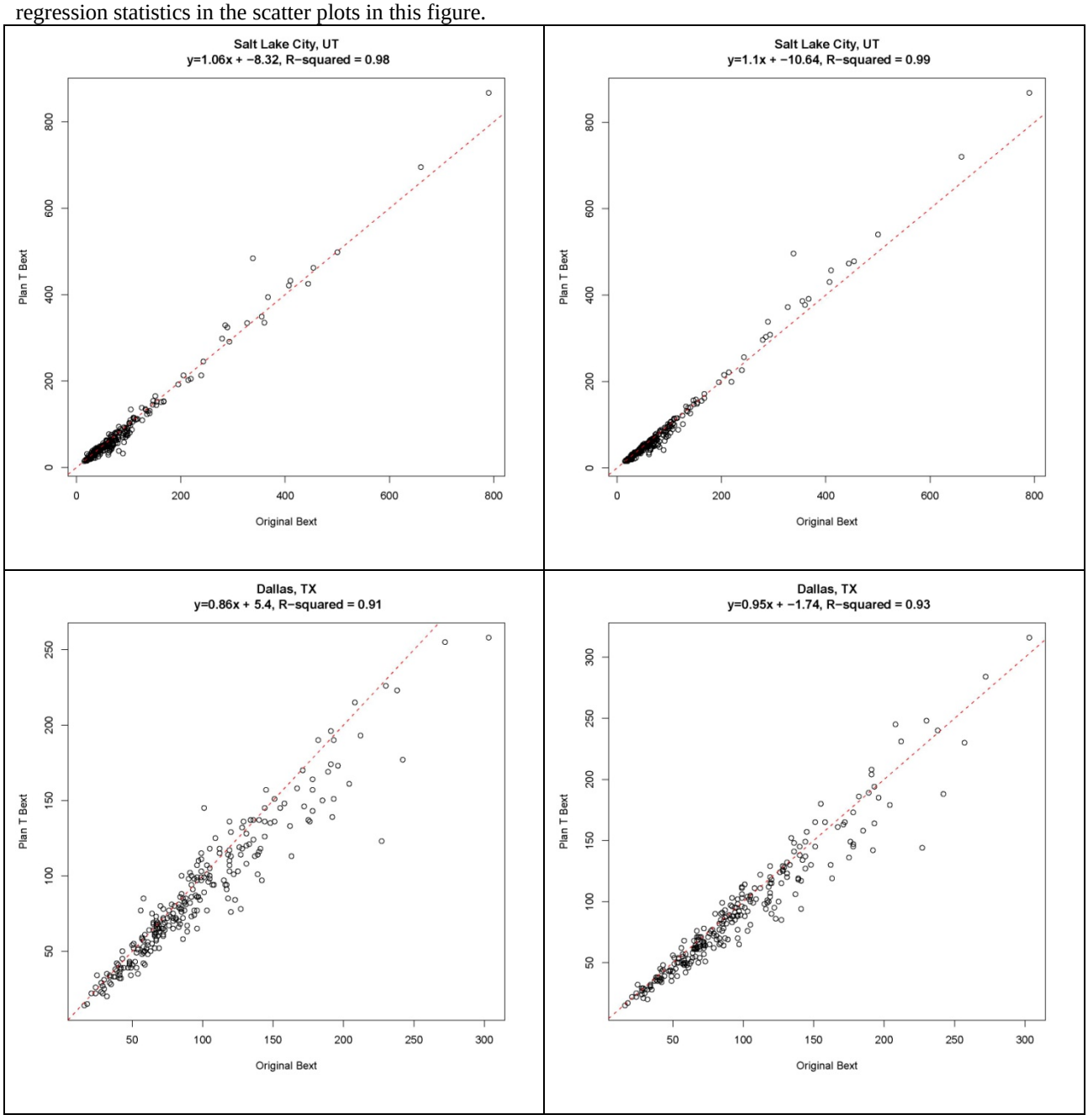


Figure F-4. Scatter Plots of Daily Maximum Daylight Hourly $PM_{2.5}$ Light Extinction Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in the scatter plots in this figure.

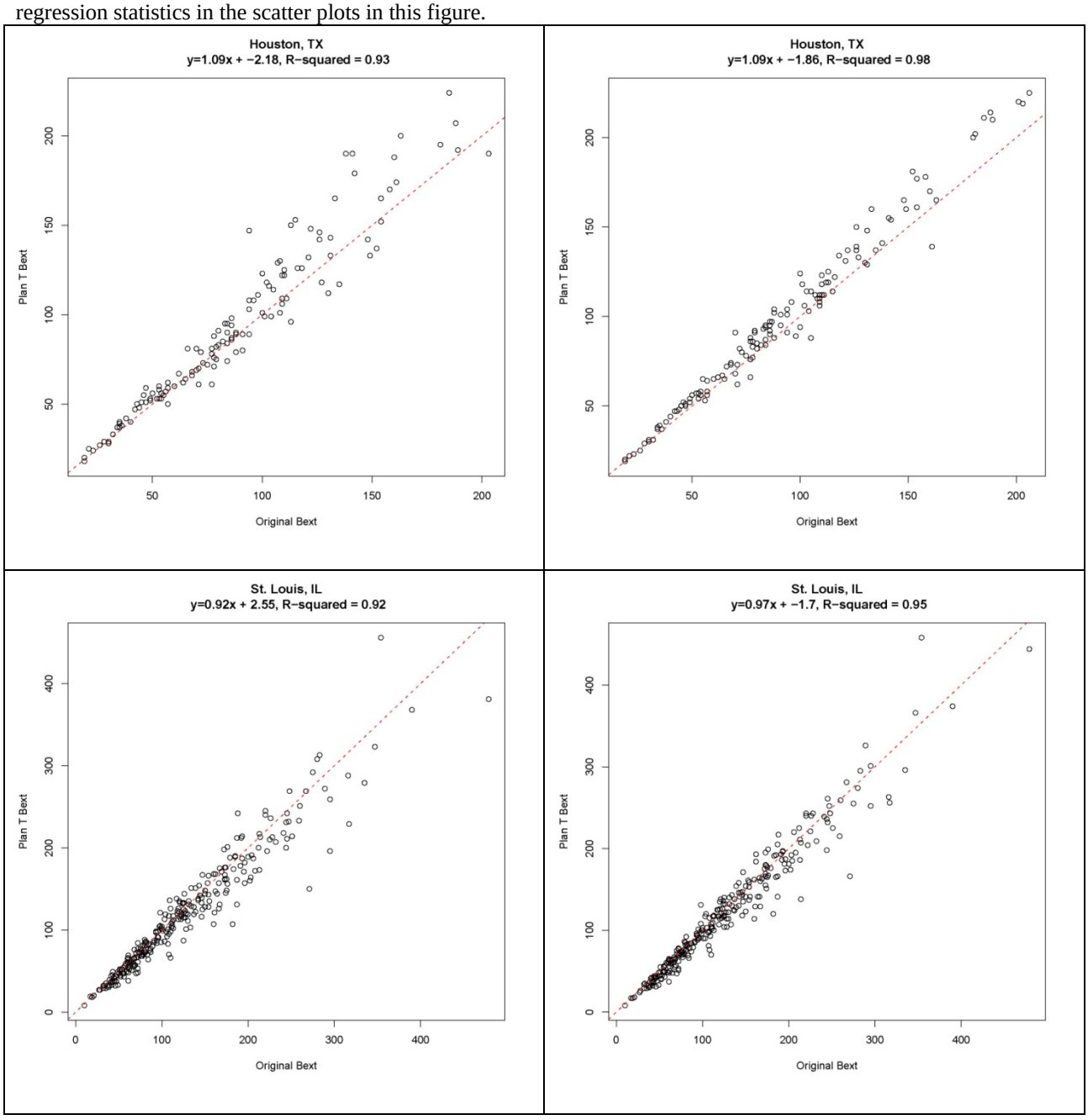


Figure F-4. Scatter Plots of Daily Maximum Daylight Hourly $PM_{2.5}$ Light Extinction Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in the scatter plots in this figure.

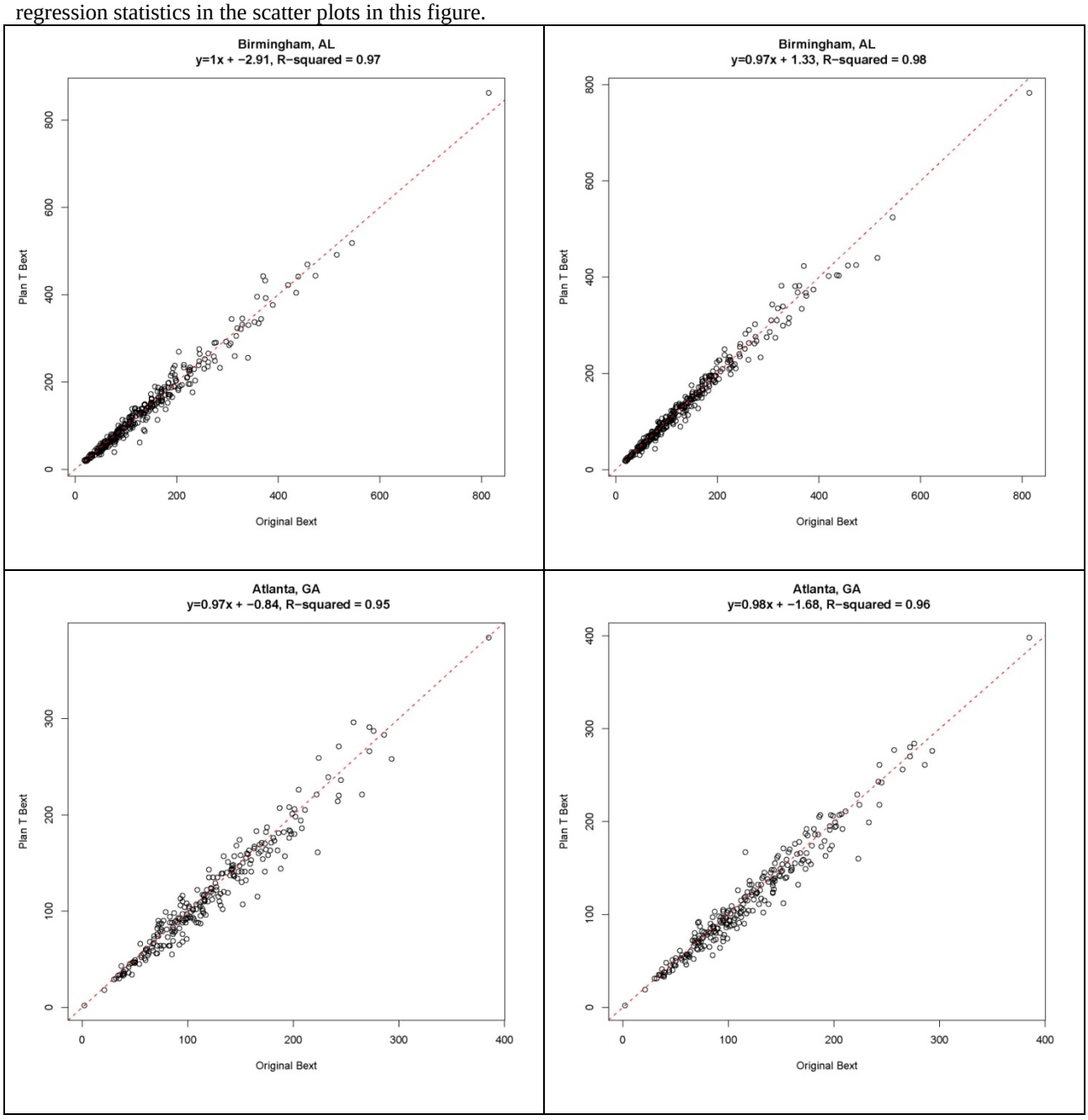


Figure F-4. Scatter Plots of Daily Maximum Daylight Hourly $PM_{2.5}$ Light Extinction Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in the scatter plots in this figure.

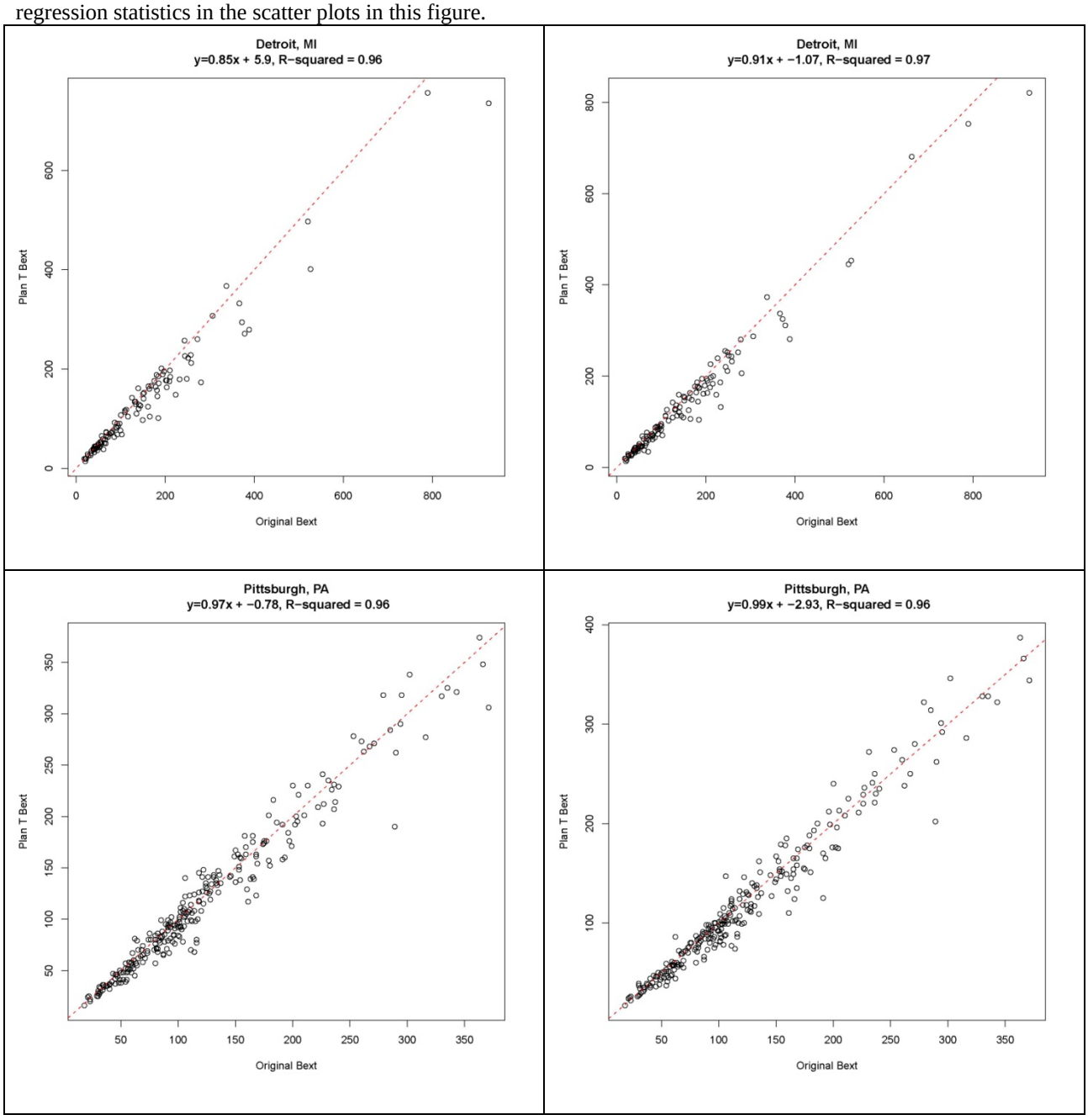


Figure F-4. Scatter Plots of Daily Maximum Daylight Hourly $PM_{2.5}$ Light Extinction Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in the scatter plots in this figure.

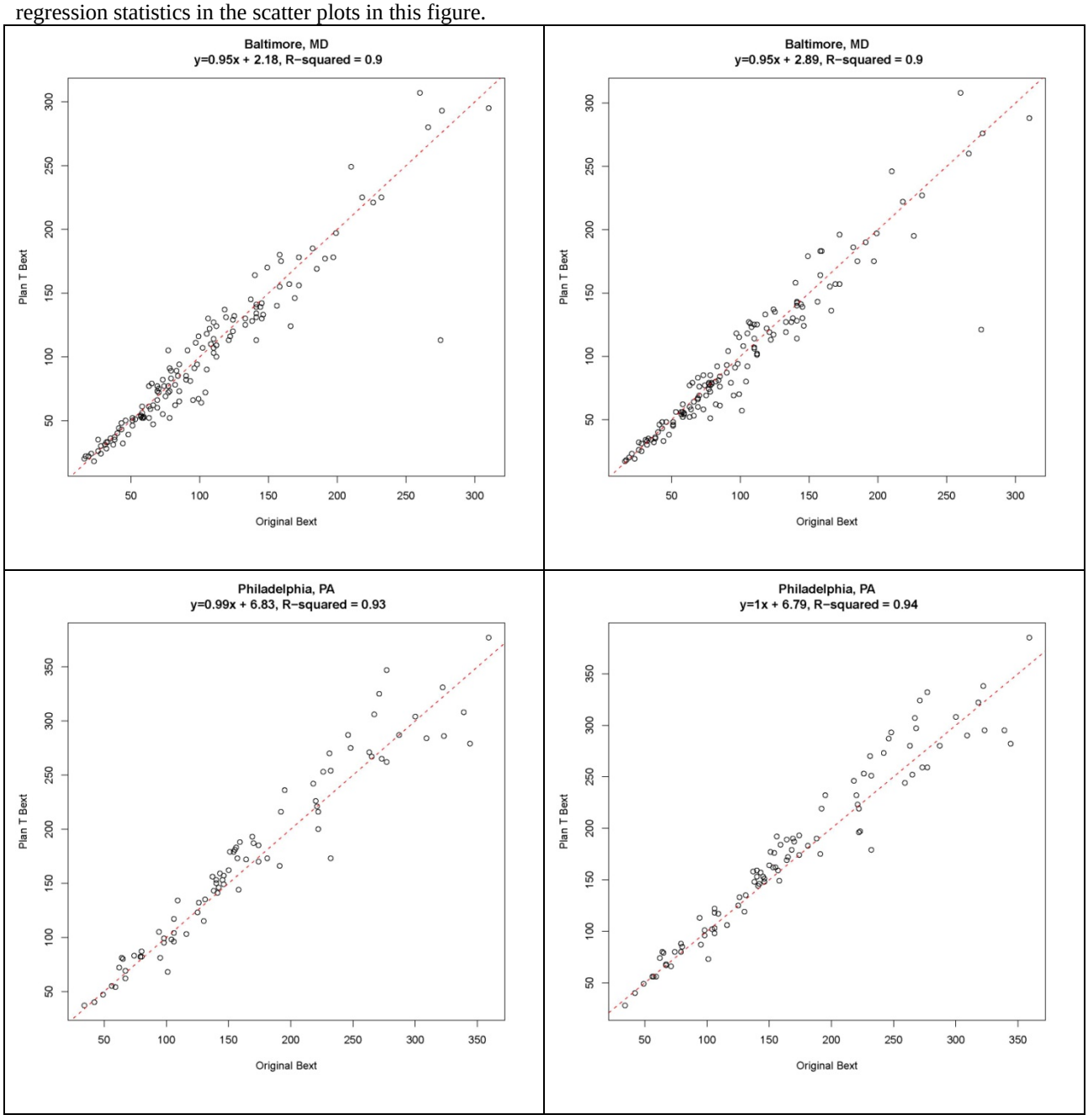


Figure F-4. Scatter Plots of Daily Maximum Daylight Hourly $PM_{2.5}$ Light Extinction Calculated by Approach T (y, left plot) and W (y, right plot) versus the UFVA approach (x)

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in the scatter plots in this figure.

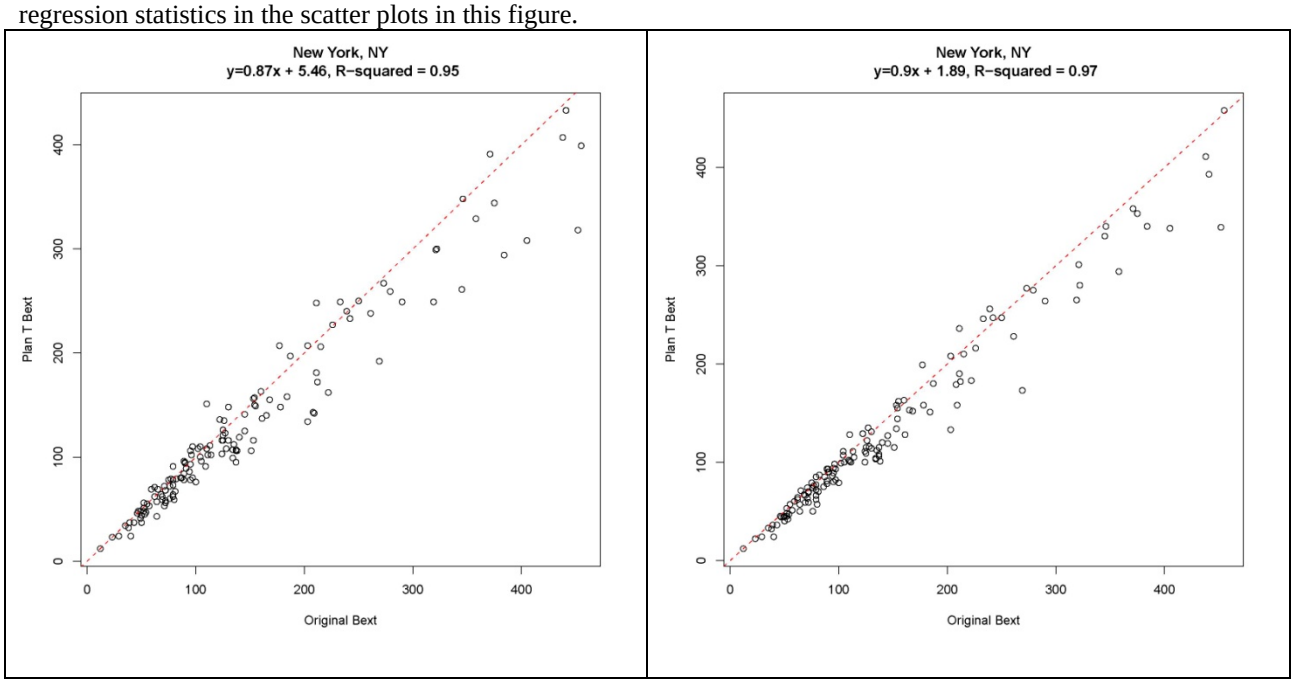


Table F-5. Linear regression equation and R^2 values (Rsq) for relating hourly $PM_{2.5}$ light extinction values (all daylight hours) calculated using approach T (x in the equation) to those using the UFVA approach (y in the equation) by month for 15 urban areas. A slope >1 indicates that approach T is biased low relative to the UFVA approach.

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in the scatter plots of Figures F-3 and F-4.

	Slope = 1.25 +	Approach T is biased low.
	Slope = 1.10 – 1.24	
	0.90 < slope < 1.10	
	Slope = 0.76 – 0.9	Approach T is biased high.
	Slope <= 0.75	

Month	1	2	3	4	5	6	7	8	9	10	11	12
Tacoma, WA	y=1.01*x +1.92; Rsq=0.99	y=0.9*x+7 .15; Rsq=0.96	y=0.96*x+ 4.53; Rsq=0.96	y=1.28*x +-4.87; Rsq=0.97	y=1.16*x +-1.53; Rsq=0.92	y=0.99*x+ 1.42; Rsq=0.96	y=0.97*x+ 2.99; Rsq=0.97	y=1.04*x +0.19; Rsq=0.96	y=1.11*x +-1.16; Rsq=0.98	y=0.93*x +7.08; Rsq=0.98	y=1.01*x+ 1.91; Rsq=0.99	y=0.93*x +5.78; Rsq=1
Fresno, CA	y=1.06*x +6.65; Rsq=0.95	y=1.15*x+ -0.69; Rsq=0.97	y=1.42*x+ 4.5; Rsq=0.89	y=1.72*x +-10.63; Rsq=0.77	y=1.08*x +4.36; Rsq=0.79	y=1.14*x+ 0; Rsq=0.95	y=1.02*x+ 2.87; Rsq=1	y=1.3*x+ -5.87; Rsq=0.94	y=1.1*x+ 6.77; Rsq=0.93	y=1.52*x +-6.34; Rsq=0.92	y=1.01*x+ 16.31; Rsq=0.97	y=0.99*x +7.29; Rsq=0.95
Los Angeles, CA	y=1.34*x +-6.07; Rsq=0.98	y=1.28*x+ -5.96; Rsq=0.99	y=1.35*x+ -6.53; Rsq=0.98	y=1.41*x +-10.4; Rsq=0.98	y=1.35*x +-7.94; Rsq=0.97	y=1.56*x+ -12.42; Rsq=0.94	y=1.74*x+ -30.53; Rsq=0.89	y=2.21*x +-74.46; Rsq=0.92	y=1.83*x +-27.22; Rsq=0.93	y=1.39*x +-3.97; Rsq=0.88	y=1.32*x+ -14.27; Rsq=0.99	y=1.15*x +6.65; Rsq=0.94
Phoenix, AZ	NA	y=1.2*x+0 .58; Rsq=0.98	y=1.36*x+ -6.26; Rsq=0.78	y=1.09*x +-1.26; Rsq=0.95	y=0.76*x +4.92; Rsq=0.72	y=1.3*x+- 4.25; Rsq=0.84	y=0.52*x+ 11.94; Rsq=0.79	y=1.12*x +-3.46; Rsq=0.94	y=1.02*x +-0.69; Rsq=0.94	y=1.38*x +-6.57; Rsq=0.97	y=1.13*x+ -2.63; Rsq=0.96	y=1.1*x+ 6.23; Rsq=0.99
Salt Lake City, UT	y=0.93*x +6.67; Rsq=0.99	y=1.02*x+ 4.81; Rsq=0.98	y=1.15*x+ 2.05; Rsq=0.96	y=1.21*x +-0.35; Rsq=0.87	y=1.05*x +1.72; Rsq=0.83	y=1.02*x+ 1.41; Rsq=0.9	y=1.07*x+ -0.69; Rsq=0.99	y=1*x+0. 81; Rsq=0.96	y=1.07*x +-0.45; Rsq=0.93	y=1.06*x +2.39; Rsq=0.92	y=1.05*x+ 2.44; Rsq=0.99	y=0.9*x+ 5.51; Rsq=0.96
Dallas, TX	y=1.14*x +1.25; Rsq=0.93	y=1.1*x+1 .86; Rsq=0.96	y=1.27*x+ -6.95; Rsq=0.96	y=1.13*x +-3.03; Rsq=0.94	y=1.05*x +-1.42; Rsq=0.95	y=0.97*x+ 1.62; Rsq=0.9	y=0.91*x+ 4.45; Rsq=0.93	y=0.98*x +0.58; Rsq=0.95	y=1*x+- 2.67; Rsq=0.98	y=1.04*x +-0.44; Rsq=0.97	y=1.12*x+ -2.81; Rsq=0.97	y=1.01*x +-0.06; Rsq=0.95
Houston, TX	y=0.9*x+ 0.54; Rsq=0.95	y=0.94*x+ 1.15; Rsq=0.95	y=0.8*x+5 .75; Rsq=0.97	y=0.96*x +1.77; Rsq=0.93	y=0.88*x +2.6; Rsq=0.96	y=0.71*x+ 13.31; Rsq=0.89	y=0.74*x+ 11.79; Rsq=0.91	y=0.9*x+ 1.86; Rsq=0.95	y=0.75*x +7.22; Rsq=0.97	y=0.97*x +-1.47; Rsq=0.98	y=0.91*x+ 3.46; Rsq=0.97	y=0.88*x +3.24; Rsq=0.94

Month	1	2	3	4	5	6	7	8	9	10	11	12
St Louis, IL	y=0.99*x +1.76; Rsq=0.98	y=0.83*x+ 13.19; Rsq=0.98	y=1.12*x+ -3.82; Rsq=0.98	y=1.08*x +0.2; Rsq=0.97	y=1.24*x +-10.62; Rsq=0.92	y=1.25*x+ -16.39; Rsq=0.9	y=1.19*x+ -17.28; Rsq=0.95	y=0.99*x +-4.12; Rsq=0.98	y=1.02*x +-3.36; Rsq=0.97	y=1.17*x +-4.2; Rsq=0.91	y=1*x+4.4 9; Rsq=0.97	y=1.01*x +0.69; Rsq=0.98
Birmingham AL	y=0.92*x +7.51; Rsq=0.97	y=0.98*x+ 3.84; Rsq=0.96	y=0.95*x+ 4.16; Rsq=0.97	y=1.06*x +-2.25; Rsq=0.97	y=0.92*x +4.45; Rsq=0.98	y=0.98*x+ -2.15; Rsq=0.99	y=0.95*x+ -0.84; Rsq=0.97	y=0.96*x +-0.66; Rsq=0.96	y=0.91*x +1.63; Rsq=0.95	y=0.96*x +2.56; Rsq=0.97	y=0.96*x+ 5.23; Rsq=0.97	y=0.9*x+ 7.7; Rsq=0.95
Atlanta, GA	y=0.97*x +5.24; Rsq=0.94	y=1*x+1.5 9; Rsq=0.98	y=0.81*x+ 13.95; Rsq=0.94	y=1.01*x +-2.51; Rsq=0.92	y=0.9*x+ 4.55; Rsq=0.94	y=0.92*x+ 4.58; Rsq=0.96	y=0.94*x+ 0.95; Rsq=0.95	y=0.98*x +-0.29; Rsq=0.99	y=1.02*x +-4.52; Rsq=0.96	y=1.02*x +-0.64; Rsq=0.93	y=1.15*x+ -4.56; Rsq=0.94	y=1*x+1. 05; Rsq=0.98
Detroit, MI	y=1.08*x +-3.49; Rsq=0.97	NA‡‡‡‡	y=1.05*x+ 0.45; Rsq=0.98	y=1.17*x +-3.64; Rsq=0.97	y=1.23*x +-5.53; Rsq=0.95	y=1.07*x+ -1.23; Rsq=0.97	y=1.12*x+ -7.1; Rsq=0.97	y=1.01*x +0.72; Rsq=0.92	y=1.13*x +-3.04; Rsq=0.93	y=1.29*x +-7.99; Rsq=0.97	y=1.1*x+0 .33; Rsq=0.98	y=1.05*x +-2.05; Rsq=0.98
Pittsburgh, PA	y=0.94*x +7.2; Rsq=0.9	y=0.97*x+ 3.64; Rsq=0.98	y=0.95*x+ 3.97; Rsq=0.98	y=1.02*x +1.71; Rsq=0.94	y=1.06*x +-3.12; Rsq=0.91	y=1.06*x+ -2.33; Rsq=0.91	y=1.09*x+ -9.79; Rsq=0.97	y=1.08*x +-11.34; Rsq=0.98	y=1.06*x +-5.84; Rsq=0.97	y=1.04*x +-0.78; Rsq=0.95	y=1.03*x+ 1.25; Rsq=0.99	y=0.94*x +6.27; Rsq=0.98
Baltimore, MD	y=0.98*x +2.1; Rsq=0.98	y=0.84*x+ 8.13; Rsq=0.98	y=0.99*x+ 2.51; Rsq=0.99	y=1.12*x +-1.54; Rsq=0.94	y=1.06*x +-0.39; Rsq=0.93	y=1.07*x+ -2.87; Rsq=0.83	y=1.19*x+ -13.9; Rsq=0.92	y=1*x+- 7.75; Rsq=0.94	y=1.09*x +-6.14; Rsq=0.97	y=1.14*x +-6.88; Rsq=0.94	y=0.97*x+ 3.86; Rsq=1	y=1.1*x+ -0.93; Rsq=0.97
Philadelphia PA	y=0.95*x +3.19; Rsq=0.99	NA‡‡‡	y=1.05*x+ -0.06; Rsq=0.98	y=1*x+1. 67; Rsq=0.93	y=1.03*x +-2.46; Rsq=0.97	y=1.06*x+ -6.29; Rsq=0.91	y=0.89*x+ -0.11; Rsq=0.98	y=0.86*x +3.68; Rsq=0.97	y=0.89*x +2.27; Rsq=0.98	y=1.07*x +-0.74; Rsq=0.97	y=1.04*x+ -1.94; Rsq=1	y=1.23*x +-7.68; Rsq=0.98
New York, NY	y=1.08*x +1.14; Rsq=0.96	y=0.99*x+ -1.41; Rsq=0.99	y=0.92*x+ 10.01; Rsq=0.98	y=1.15*x +-5.37; Rsq=0.98	y=1.2*x+ -5.67; Rsq=0.96	y=1.02*x+ -0.08; Rsq=0.95	y=1.17*x+ -19.48; Rsq=0.93	y=1.05*x +-4.46; Rsq=0.97	y=1.28*x +-2.87; Rsq=0.89	y=1.3*x+ -8.98; Rsq=0.97	y=1.12*x+ -0.2; Rsq=0.98	y=0.92*x +7.36; Rsq=0.98

‡‡‡‡ Because approach T requires a minimum of four CSN samples in a calendar month to calculate valid values of HF and DLEE, estimates for February in Detroit and Philadelphia are not available from approach T so no regression results are shown. These months do have regression results for approach W in Table F-6.

Table F-6. Linear regression equation and R^2 values (Rsq) for relating hourly $PM_{2.5}$ light extinction values (all daylight hours) calculated using approach W (x in the equation) to those using the UFVA approach (y in the equation) by month for 15 urban areas. A positive intercept indicates that approach W is biased low relative to the UFVA approach.

Note that the independent and dependent variables in Tables F-5 and F-6 are reversed from the order used to provide regression statistics in the scatter plots of Figures F-3 and F-4.

	Slope = 1.25 +	Approach W is biased low.
	Slope = 1.10 – 1.24	
	0.90 < slope < 1.10	
	Slope = 0.76 – 0.9	Approach W is biased high.
	Slope <= 0.75	

Month	1	2	3	4	5	6	7	8	9	10	11	12
Tacoma, WA	y=1.07*x +0.02; Rsq=0.99	y=1.06*x+ 1.07; Rsq=0.99	y=1.15*x+ -1.13; Rsq=0.99	y=1.23*x +-4.3; Rsq=0.96	y=1.26*x +-4.68; Rsq=0.95	y=1.01*x +1.04; Rsq=0.96	y=0.96*x +3.1; Rsq=0.96	y=1.1*x+ -1.77; Rsq=0.97	y=1.18*x +-3.19; Rsq=0.98	y=1.03*x +1.15; Rsq=0.98	y=1.02*x+ 0.72; Rsq=1	y=0.98*x+ 3.2; Rsq=1
Fresno, CA	y=1.03*x +6.82; Rsq=0.97	y=1.06*x+ 7.93; Rsq=0.98	y=1.32*x+ 8.06; Rsq=0.89	y=1.75*x +-12.08; Rsq=0.8	y=0.94*x +9.16; Rsq=0.78	y=1.07*x +1.79; Rsq=0.95	y=0.98*x +4.51; Rsq=1	y=1.2*x+ -3.17; Rsq=0.94	y=1.17*x +2.83; Rsq=0.96	y=1.25*x +4.14; Rsq=0.94	y=0.83*x+ 47.17; Rsq=0.93	y=0.91*x+ 14.37; Rsq=0.98
Los Angeles, CA	y=1.04*x +8.5; Rsq=0.99	y=1.02*x+ 7.16; Rsq=0.99	y=1.05*x+ 15.49; Rsq=0.98	y=1.17*x +4.22; Rsq=0.98	y=1.13*x +8.45; Rsq=0.97	y=1.36*x +5.73; Rsq=0.92	y=1.56*x +-15.11; Rsq=0.91	y=1.94*x +-56.56; Rsq=0.93	y=1.56*x +-12.84; Rsq=0.95	y=1.25*x +1.07; Rsq=0.94	y=1.03*x+ 13.84; Rsq=0.99	y=1.06*x+ 6.99; Rsq=0.98
Phoenix, AZ	NA	y=1.25*x+ 0.12; Rsq=0.98	y=1.31*x+ -4.86; Rsq=0.95	y=1.07*x +-0.71; Rsq=0.98	y=0.93*x +1.96; Rsq=0.89	y=1.2*x+ -2.49; Rsq=0.83	y=1.09*x +-1.41; Rsq=0.98	y=1.11*x +-2.87; Rsq=0.97	y=1.04*x +-1.29; Rsq=0.97	y=1.1*x+ -1.01; Rsq=1	y=1.08*x+ -0.91; Rsq=0.98	y=1.06*x+ 8.02; Rsq=0.99
Salt Lake City, UT	y=0.91*x +6.4; Rsq=1	y=0.94*x+ 8.75; Rsq=0.98	y=1.07*x+ 3.8; Rsq=0.96	y=1.17*x +-0.09; Rsq=0.92	y=1.17*x +-0.77; Rsq=0.87	y=1.02*x +1.15; Rsq=0.94	y=1.06*x +-0.55; Rsq=1	y=1.01*x +0.56; Rsq=0.98	y=1.04*x +0.16; Rsq=0.98	y=1.11*x +1.19; Rsq=0.96	y=0.93*x+ 8.49; Rsq=0.98	y=0.84*x+ 10.5; Rsq=0.97

Month	1	2	3	4	5	6	7	8	9	10	11	12
Dallas, TX	y=1.12*x +0.63; Rsq=0.95	y=1.09*x+ 2.57; Rsq=0.97	y=1.18*x+ -4.36; Rsq=0.96	y=1.01*x +1.32; Rsq=0.94	y=0.93*x +3.16; Rsq=0.96	y=1*x+0. 88; Rsq=0.95	y=0.96*x +3.17; Rsq=0.93	y=0.96*x +2.08; Rsq=0.97	y=0.93*x +0.44; Rsq=0.98	y=0.98*x +0.71; Rsq=0.97	y=1.09*x+ -2.7; Rsq=0.97	y=0.9*x+4 .72; Rsq=0.97
Houston, TX	y=0.88*x +1.47; Rsq=0.97	y=0.86*x+ 2.75; Rsq=0.99	y=0.86*x+ 2.15; Rsq=0.99	y=0.94*x +0.32; Rsq=0.99	y=0.85*x +2.96; Rsq=0.99	y=0.92*x +2.05; Rsq=0.96	y=0.92*x +3.75; Rsq=0.95	y=0.89*x +3.22; Rsq=0.98	y=0.89*x +0.03; Rsq=0.99	y=0.91*x +0.18; Rsq=1	y=0.98*x+ -5.56; Rsq=0.99	y=0.86*x+ 2.2; Rsq=0.98
St Louis, IL	y=0.95*x +3.53; Rsq=0.98	y=0.85*x+ 10.08; Rsq=0.97	y=1.08*x+ -1.58; Rsq=0.99	y=1.04*x +1.61; Rsq=0.98	y=1.09*x +-2.77; Rsq=0.95	y=1.16*x +-12.62; Rsq=0.93	y=1.05*x +-7.34; Rsq=0.98	y=0.95*x +-1.47; Rsq=0.99	y=1*x+- 2.58; Rsq=0.98	y=1.16*x +-4.78; Rsq=0.96	y=1.01*x+ 2.76; Rsq=0.98	y=0.97*x+ 2.83; Rsq=0.99
Birmingham AL	y=1*x+1. 7; Rsq=0.99	y=1.03*x+ 0.47; Rsq=0.99	y=1.01*x+ -1.58; Rsq=0.99	y=1.03*x +-1.5; Rsq=0.99	y=0.96*x +-0.53; Rsq=0.99	y=0.98*x +-1.93; Rsq=0.99	y=0.92*x +2.04; Rsq=0.99	y=0.91*x +3.61; Rsq=0.98	y=0.94*x +-0.87; Rsq=0.99	y=1.01*x +-0.64; Rsq=0.98	y=1.01*x+ 0.23; Rsq=0.98	y=0.97*x+ 2.37; Rsq=0.98
Atlanta, GA	y=0.97*x +4.46; Rsq=0.96	y=0.97*x+ 1.55; Rsq=0.96	y=0.9*x+7 .22; Rsq=0.97	y=1*x+- 2.29; Rsq=0.95	y=1*x+- 3.22; Rsq=0.98	y=0.94*x +2.64; Rsq=0.98	y=0.88*x +7.28; Rsq=0.96	y=0.96*x +1.44; Rsq=0.99	y=0.98*x +-1.52; Rsq=0.97	y=0.95*x +4.24; Rsq=0.98	y=1.03*x+ 4.43; Rsq=0.93	y=1.01*x+ -0.82; Rsq=0.99
Detroit, MI	y=1.03*x +1.64; Rsq=0.97	y=0.97*x+ 1.05; Rsq=1	y=0.98*x+ 5.45; Rsq=0.98	y=1.17*x +-3.56; Rsq=0.99	y=1.02*x +3.5; Rsq=0.95	y=1.02*x +0.66; Rsq=0.98	y=1.09*x +-5.24; Rsq=0.98	y=1.04*x +-0.25; Rsq=0.93	y=1.09*x +-2.11; Rsq=0.96	y=1.15*x +-2.29; Rsq=0.99	y=1.07*x+ 1.83; Rsq=0.99	y=1.03*x+ -1.05; Rsq=1
Pittsburgh, PA	y=0.92*x +8.37; Rsq=0.92	y=1.03*x+ 0.13; Rsq=0.97	y=1.06*x+ -3.39; Rsq=0.98	y=1.07*x +-1.33; Rsq=0.93	y=1.05*x +-3.5; Rsq=0.93	y=1.01*x +-1.36; Rsq=0.95	y=1.03*x +-6.36; Rsq=0.98	y=0.97*x +-1.25; Rsq=0.99	y=1.04*x +-4.35; Rsq=0.98	y=1.04*x +-1.42; Rsq=0.97	y=1.02*x+ 2.42; Rsq=0.99	y=1.02*x+ 1.75; Rsq=0.97
Baltimore, MD	y=1.06*x +-2.44; Rsq=0.99	y=0.93*x+ 3.3; Rsq=0.99	y=0.96*x+ 3.44; Rsq=0.99	y=1.1*x+ -1.37; Rsq=0.95	y=0.98*x +4.15; Rsq=0.95	y=1.08*x +-4.61; Rsq=0.85	y=1.14*x +-11.71; Rsq=0.94	y=0.97*x +-5.3; Rsq=0.97	y=1.07*x +-5.52; Rsq=0.96	y=1.1*x+ -4.68; Rsq=0.96	y=1*x+2.3 3; Rsq=1	y=1.09*x+ -1.26; Rsq=0.99
Philadelphia, PA	y=1.01*x +-0.42; Rsq=1	y=1.03*x+ -3.16; Rsq=0.99	y=0.99*x+ 2.14; Rsq=0.99	y=0.98*x +1.53; Rsq=0.97	y=1.02*x +-2.14; Rsq=0.97	y=1.05*x +-6.57; Rsq=0.92	y=0.94*x +-3.14; Rsq=0.98	y=0.89*x +2.37; Rsq=0.98	y=0.89*x +2.41; Rsq=0.99	y=1.05*x +-0.49; Rsq=0.97	y=0.99*x+ -0.3; Rsq=1	y=0.98*x+ 2.66; Rsq=0.98

Month	1	2	3	4	5	6	7	8	9	10	11	12
New York, NY	y=1.07*x +1.42; Rsq=0.99	y=1.06*x+ -3.48; Rsq=0.99	y=1.01*x+ 5.6; Rsq=0.99	y=0.99*x +0.63; Rsq=0.98	y=1.01*x +2.12; Rsq=0.98	y=1.04*x +-2.02; Rsq=0.98	y=1.09*x +-10.86; Rsq=0.97	y=1*x+0. 3; Rsq=0.99	y=1.25*x +-1.39; Rsq=0.89	y=1.17*x +-2.29; Rsq=0.98	y=1.1*x+1 .54; Rsq=0.96	y=0.98*x+ 4.74; Rsq=0.98

Figure F-5 compares the three-year, daily maximum design values for $PM_{2.5}$ light extinction developed using approaches T and W versus the UFVA approach, for both the 90^{th} and 95^{th} percentile forms. In many cases, all three methods yield similar design values, suggesting that the stringency of emission controls required to meet a given level standard may be about the same regardless of which approach is used to estimate $PM_{2.5}$ light extinction. The exceptions are for the highest levels of light extinction, which occur in Los Angeles, Fresno, and Detroit. Table F-7 provides the same information as Figure F-5 in tabular form.

Figure F-6 compares the 1-hour $PM_{2.5}$ light extinction estimates generated by approaches T and W to each other in scatter plot format, for both all daylight hours and daily maximum daylight hours. The dashed red line is the 1:1 line, and regression statistics are shown with each scatter plot. The agreement between the two approaches is very close in most cases. In Fresno, Los Angeles and to some degree also Dallas, there is a tendency for approach T to be biased low relative to approach W for the points at the high end of the range of $PM_{2.5}$ light extinction. This is consistent with the expected tendency of the monthly averaging of HF and DLEE that is part of approach T to mute the extreme daily values of HF and DLEE, extreme values that are directly used for their respective days under approach W.

Figure F-7 compares the 2007-2009 90th and 95th percentile $PM_{2.5}$ light extinction design values calculated based on approach T versus approach W. Despite some scatter between the approaches in Figure F-6, the design values from the two approaches are nearly identical. This is not surprising, since using monthly average values of HF and DLEE instead of day-specific values will sometimes result in an overestimate and sometimes in an underestimate of $PM_{2.5}$ light extinction. Also, the bias in approach T for Los Angeles, Fresno, and Dallas noted in the previous paragraph mostly affects value above the 90^{th} and 95^{th} percentile points. This suggests that approach T's ability to produce estimates of light extinction on every day, thereby allowing the full history of hourly $PM_{2.5}$ concentrations to be taken into account, may make it the preferable approach because using all days' $PM_{2.5}$ concentration provides more stability to the 90^{th} or 95^{th} percentile value than using only one-day-in-three or one-day-in six data.

It is interesting to note that in the "all hours" panels of Figure F-6, there are instances of several points falling on a straight line somewhat offset from the main data cloud, which itself seems less organized. These data points can be interpreted as days on which the day-specific values of HF and/or DLEE were markedly different from their monthly-averaged values, while relative humidity was stable for several hours. When RH is stable within part of a day, approach T (and W) results in estimates of hourly light extinction that are directly proportional to hourly $PM_{2.5}$ concentration, with the proportionality constant dependent on HF and DLEE for the day. The HF and DLEE for the day are always different between approaches T and W. The scatter plot for Phoenix appears to have three such groups of points, for example. Houston appears to have two groups.

Figure F-5. Comparison of 2007-2009 $PM_{2.5}$ light extinction design values based on approaches T and W vs. the UFVA approach

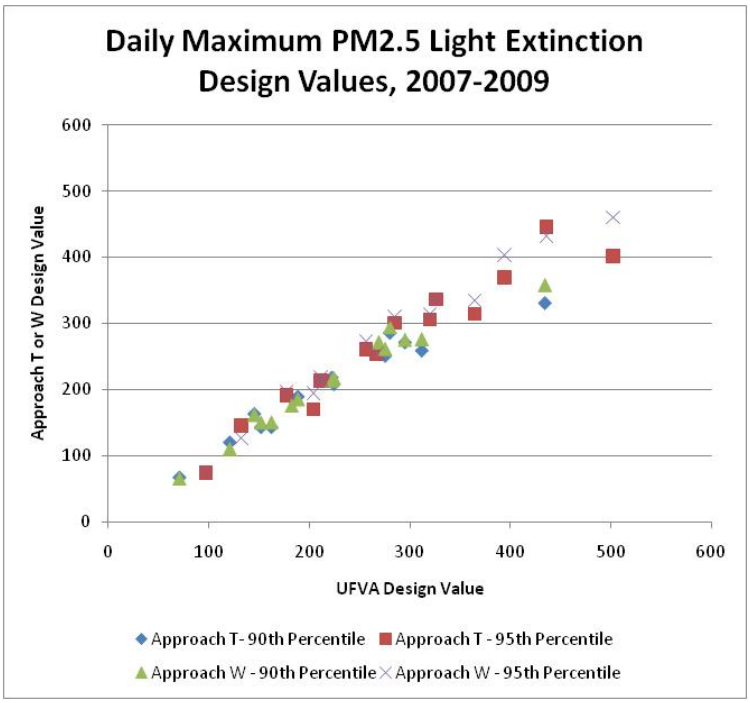


Table F-7. Comparison of 2007-2009 $PM_{2.5}$ light extinction design values based on approaches T and W vs. the UFVA approach

	90th Percentile Daily Maximum $PM_{2.5}$ Light Extinction (Mm^{-1})			95th Percentile Daily Maximum $PM_{2.5}$ Light Extinction (Mm^{-1})		
	UFVA	T	W	UFVA	T	W
Tacoma, WA	121	121	111	132	145	127
Fresno, CA	312	260	276	394	370	403
Los Angeles, CA	434	332	358	503	402	461
Phoenix, AZ	71	68	66	97	74	75
Salt Lake City, UT	152	144	150	285	301	310
Dallas, TX	162	144	151	204	170	194
Houston, TX	145	164	162	177	192	197
St Louis, IL	224	209	217	267	254	254
Birmingham, AL	269	257	271	326	336	337
Atlanta, GA	189	190	186	212	212	213
Detroit, MI	275	252	261	436	446	433
Pittsburgh, PA	222	219	214	256	261	273
Baltimore, MD	183	188	176	212	213	218
Philadelphia, PA	280	287	294	320	306	315
New York, NY	295	272	275	365	315	335

Figure F-6. Scatter plots of daily maximum daylight hourly $PM_{2.5}$ light extinction calculated by approach T (x) versus approach W (y).

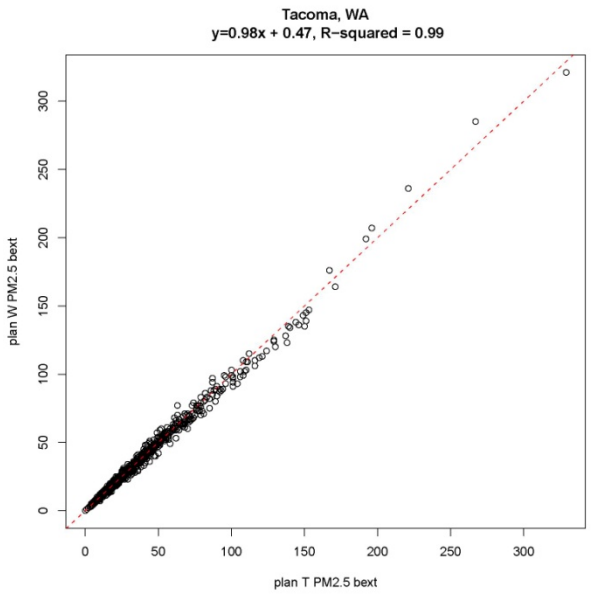
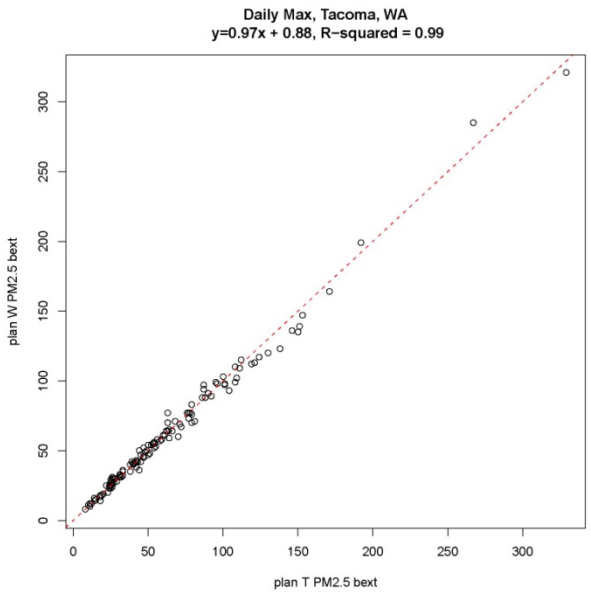
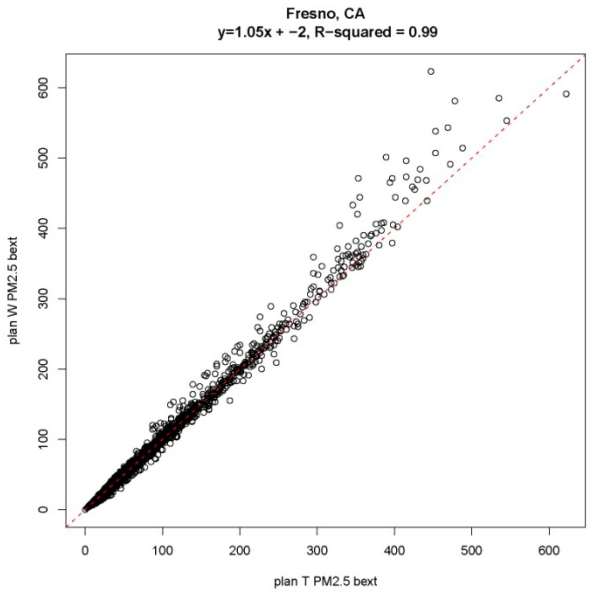
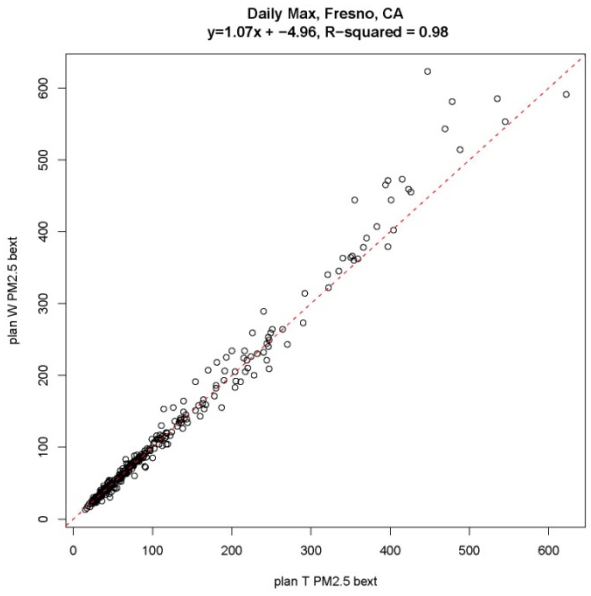
All Daylight Hours	Daily Maximum Daylight Hour
	
	

Figure F-6. Scatter plots of daily maximum daylight hourly $PM_{2.5}$ light extinction calculated by approach T (x) versus approach W (y).

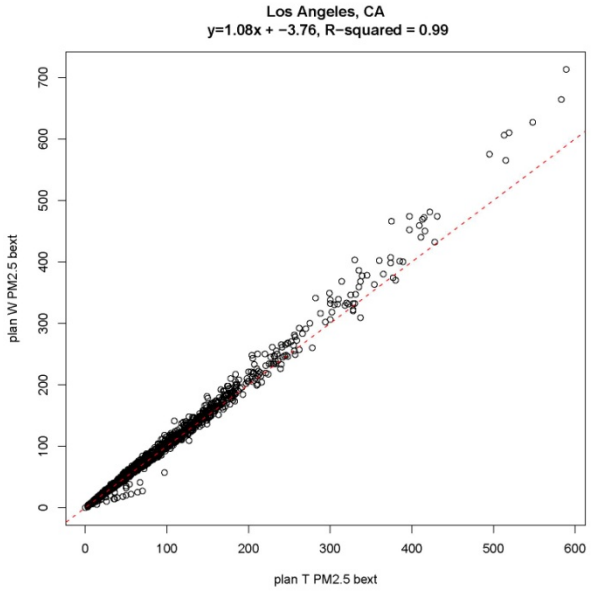
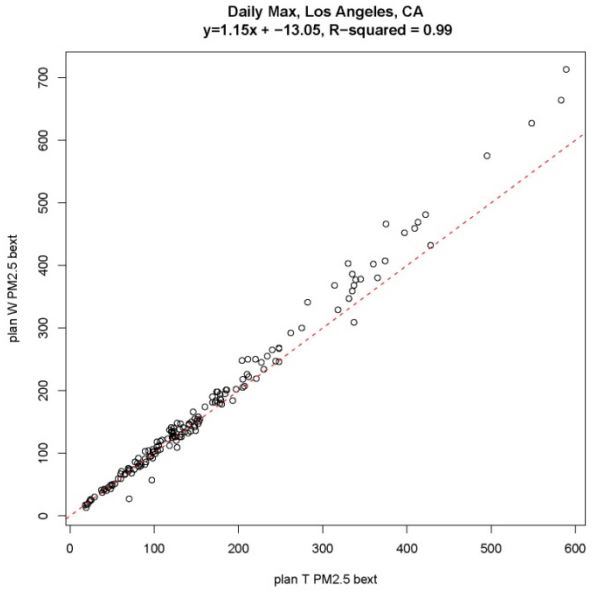
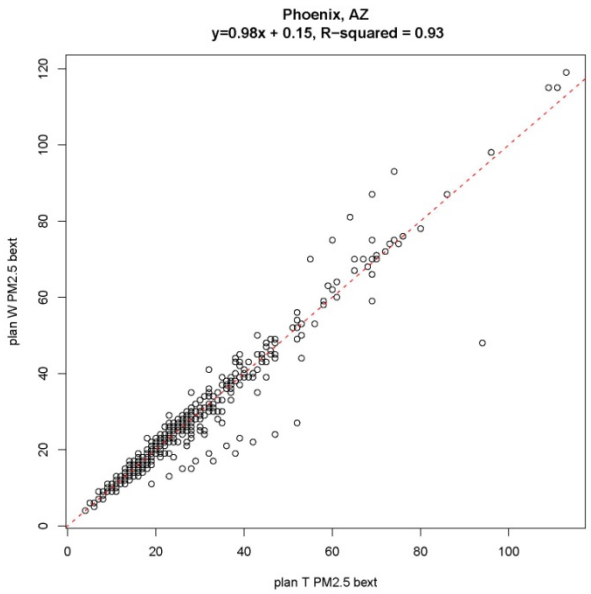
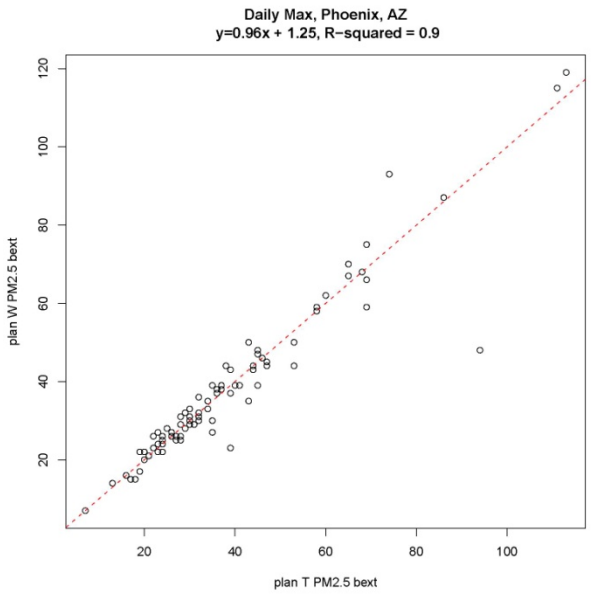
All Daylight Hours	Daily Maximum Daylight Hour
	
	

Figure F-6. Scatter plots of daily maximum daylight hourly $PM_{2.5}$ light extinction calculated by approach T (x) versus approach W (y).

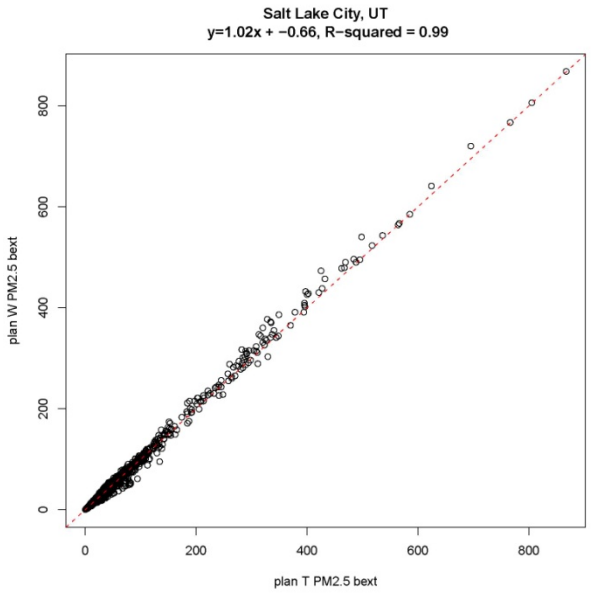
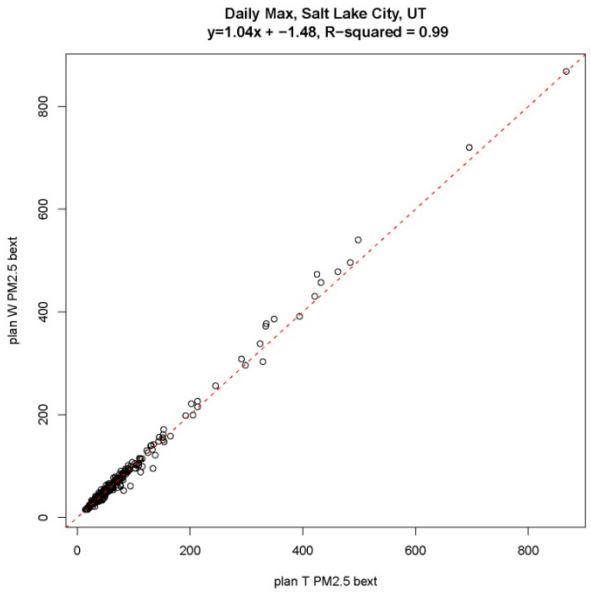
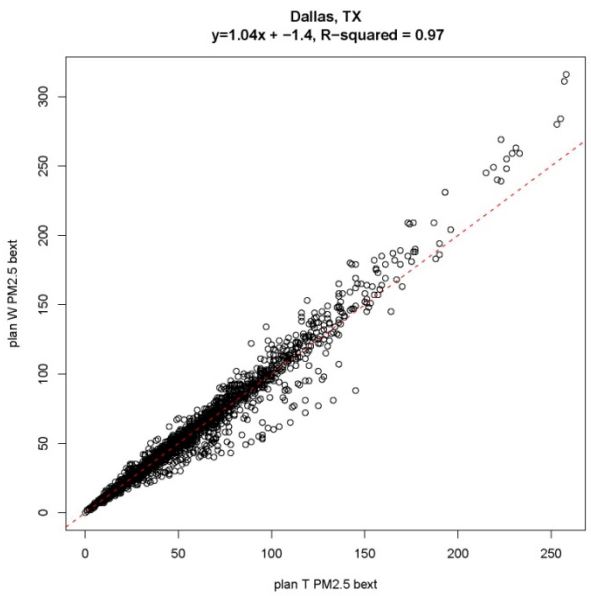
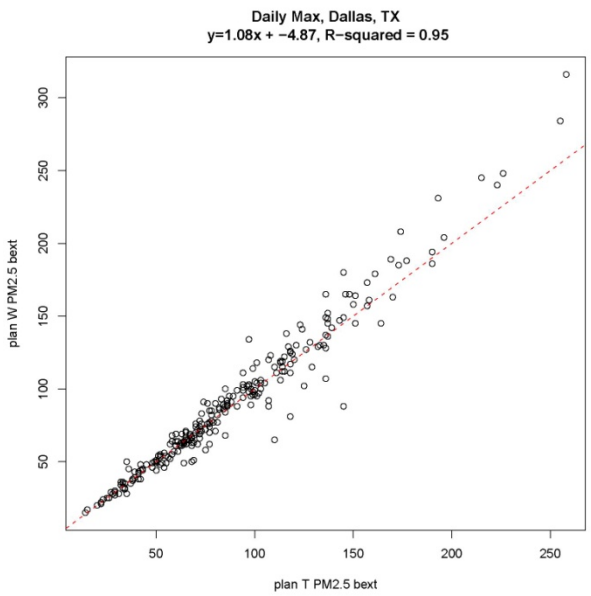
All Daylight Hours	Daily Maximum Daylight Hour
	
	

Figure F-6. Scatter plots of daily maximum daylight hourly $PM_{2.5}$ light extinction calculated by approach T (x) versus approach W (y).

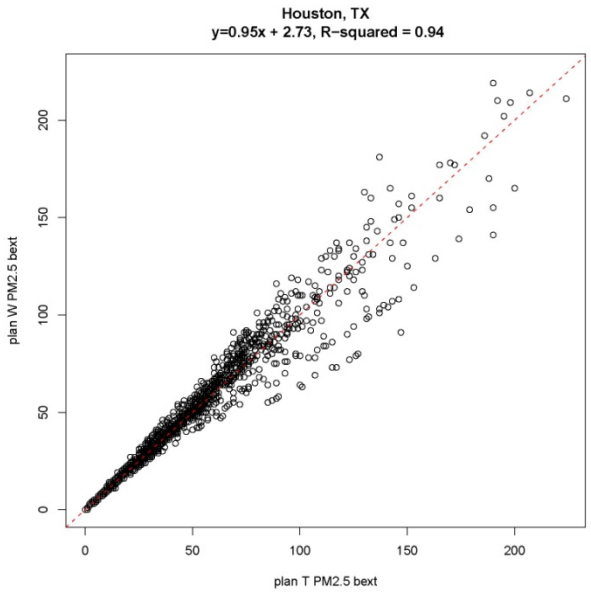
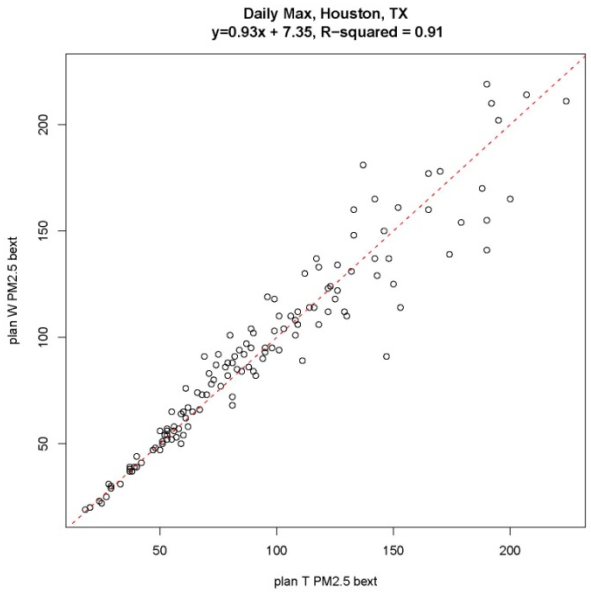
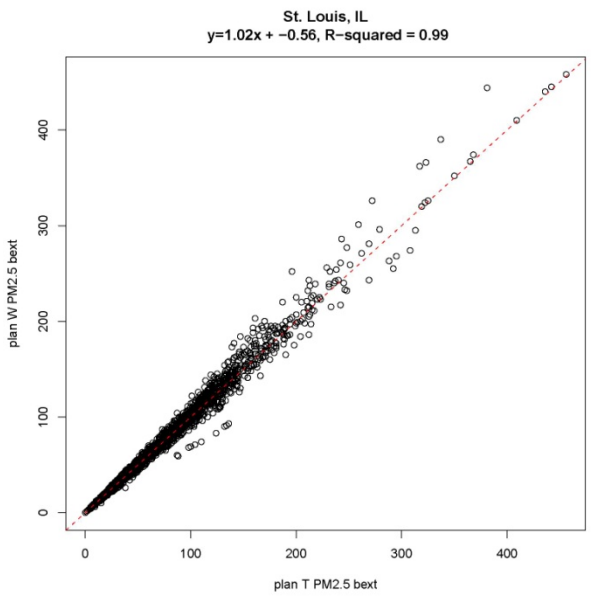
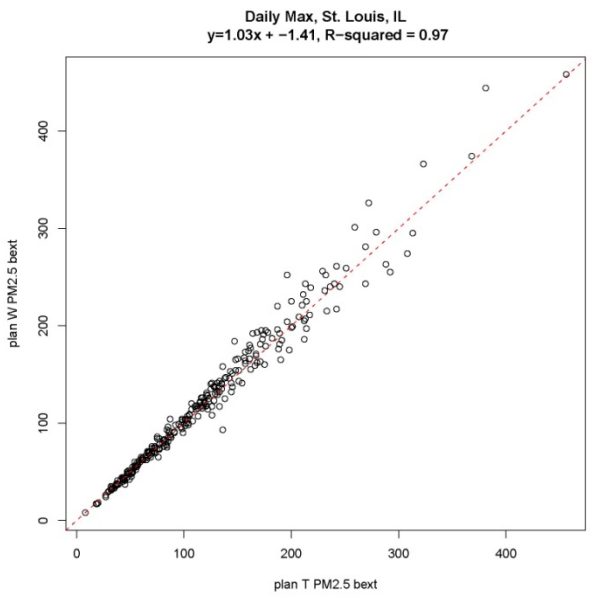
All Daylight Hours	Daily Maximum Daylight Hour
	
	

Figure F-6. Scatter plots of daily maximum daylight hourly $PM_{2.5}$ light extinction calculated by approach T (x) versus approach W (y).

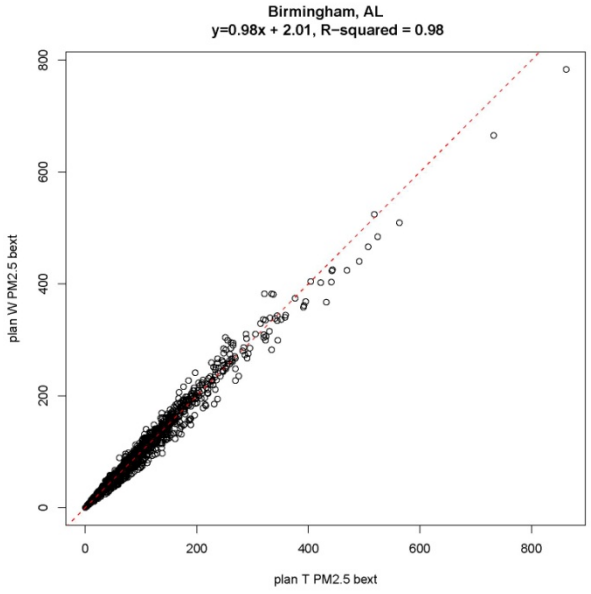
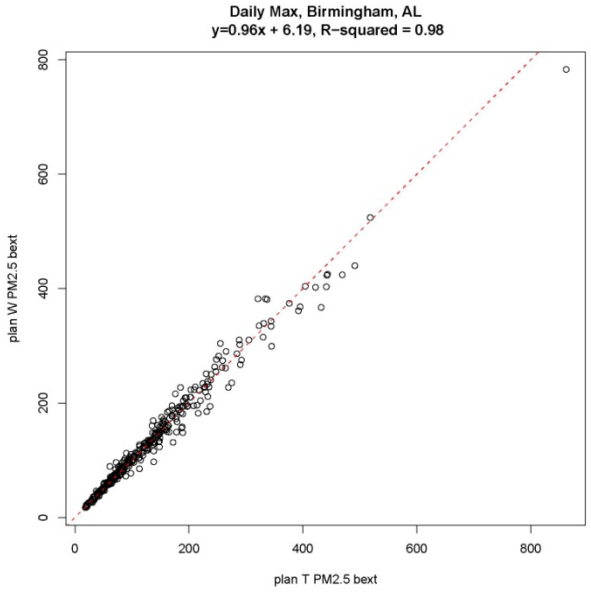
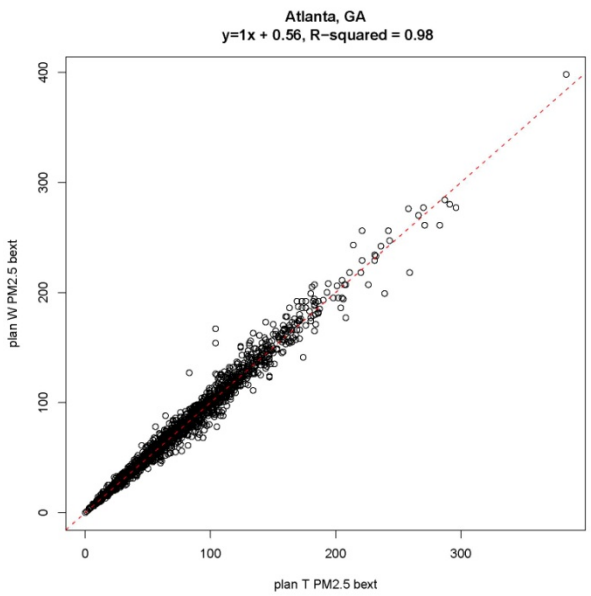
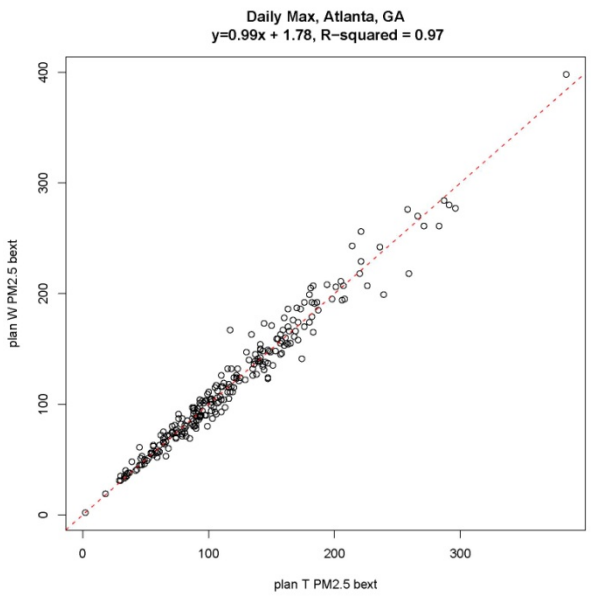
All Daylight Hours	Daily Maximum Daylight Hour
	
	

Figure F-6. Scatter plots of daily maximum daylight hourly $PM_{2.5}$ light extinction calculated by approach T (x) versus approach W (y).

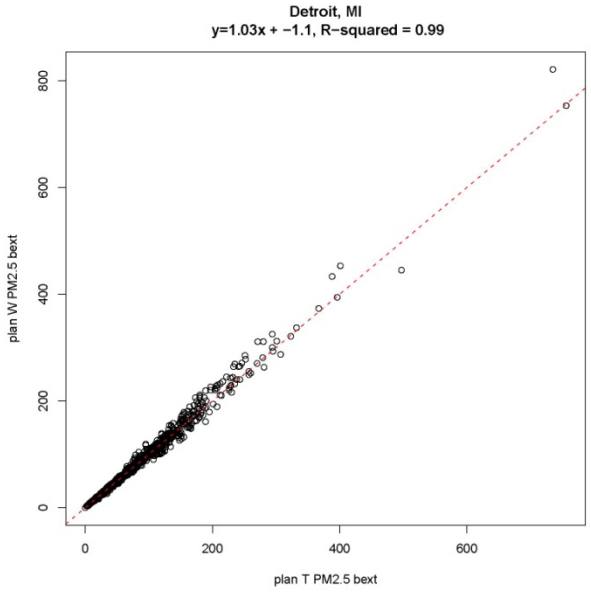
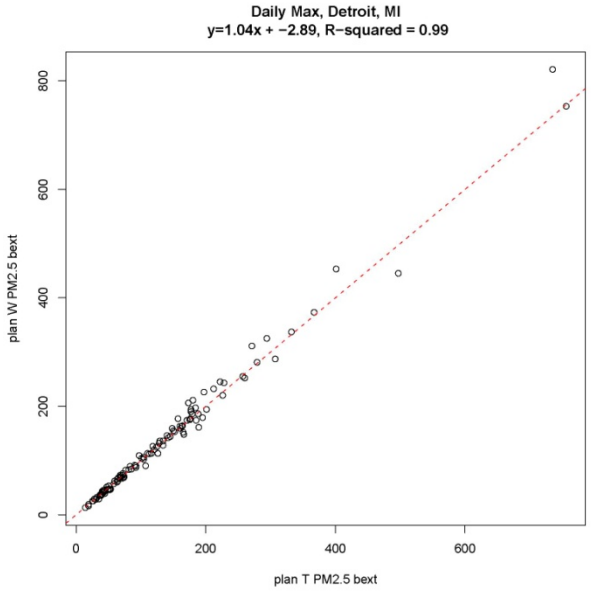
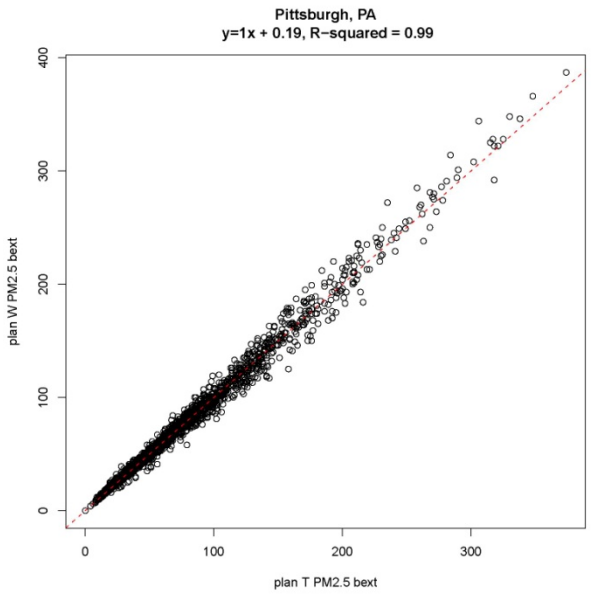
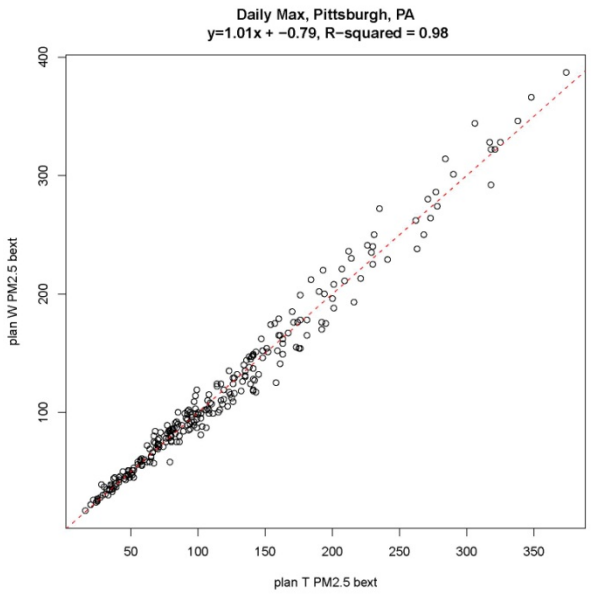
All Daylight Hours	Daily Maximum Daylight Hour
	
	

Figure F-6. Scatter plots of daily maximum daylight hourly $PM_{2.5}$ light extinction calculated by approach T (x) versus approach W (y).

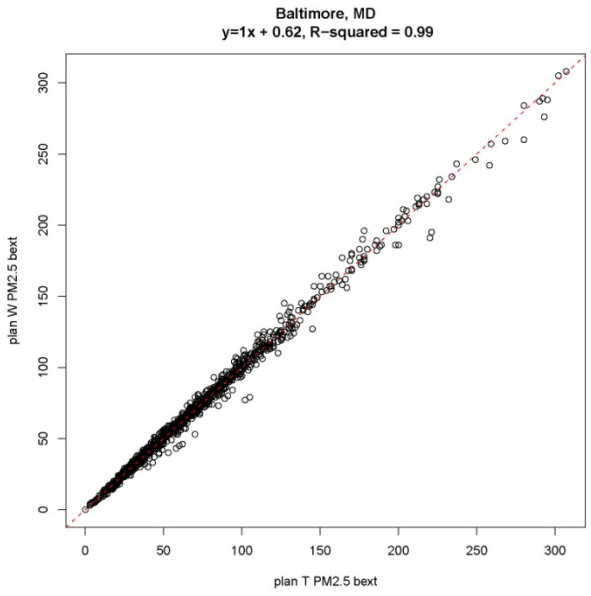
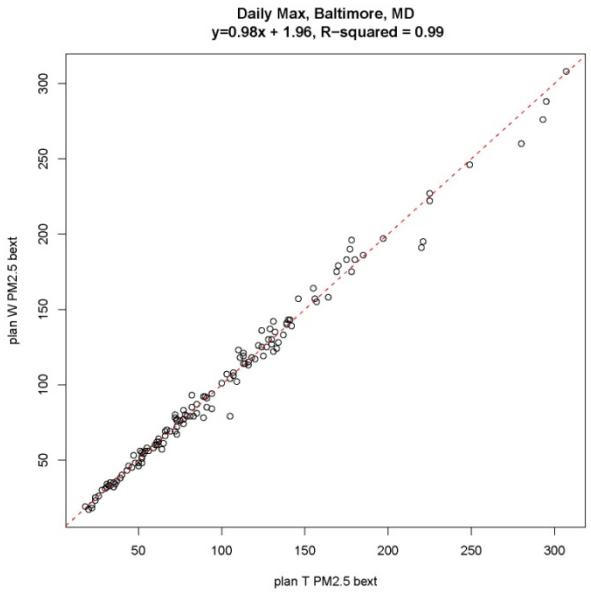
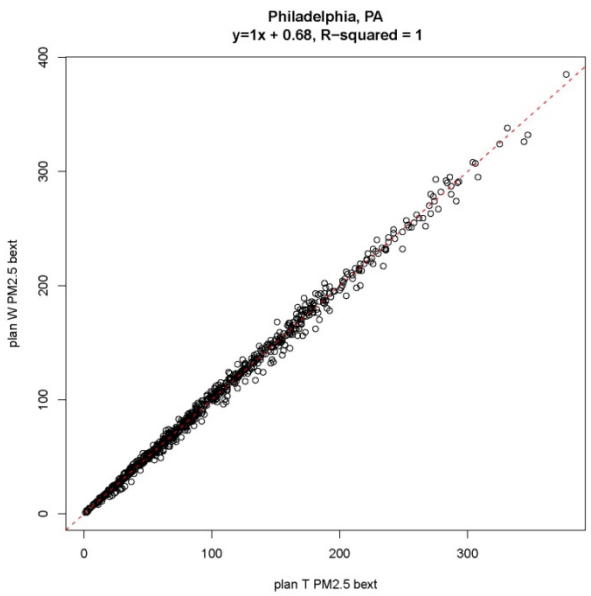
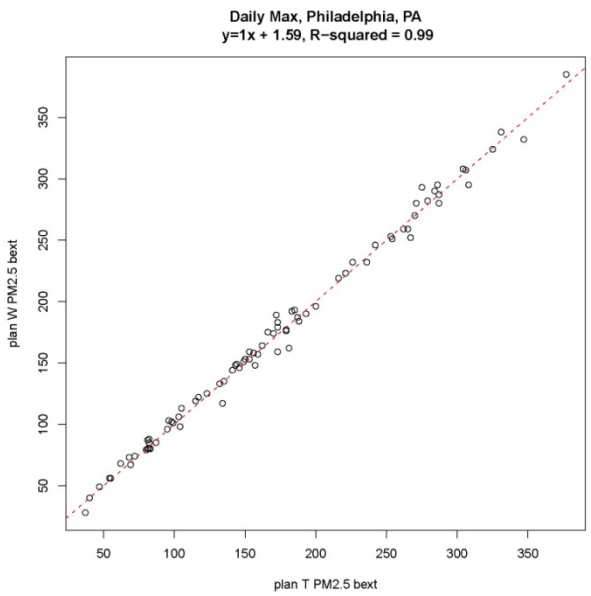
All Daylight Hours	Daily Maximum Daylight Hour
	
	

Figure F-6. Scatter plots of daily maximum daylight hourly $PM_{2.5}$ light extinction calculated by approach T (x) versus approach W (y).

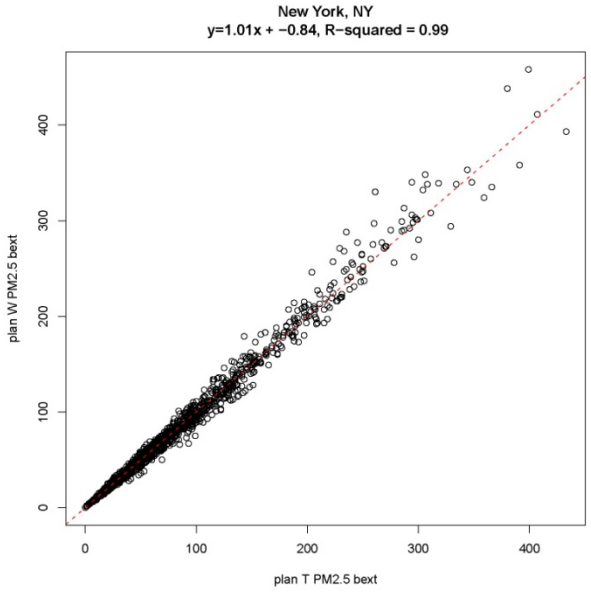
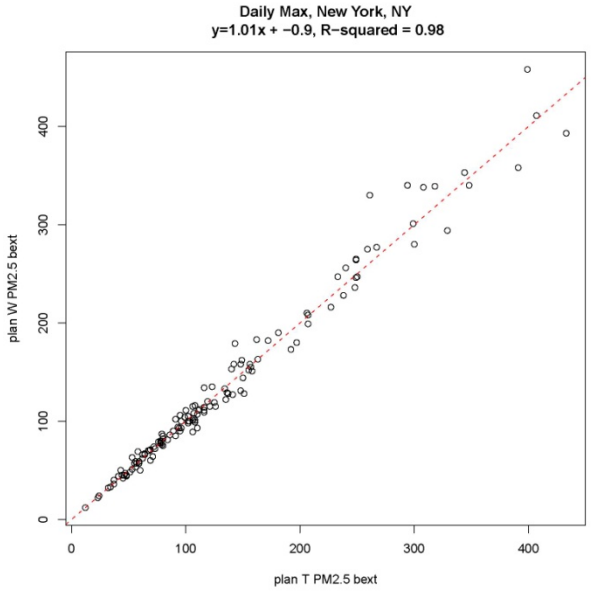
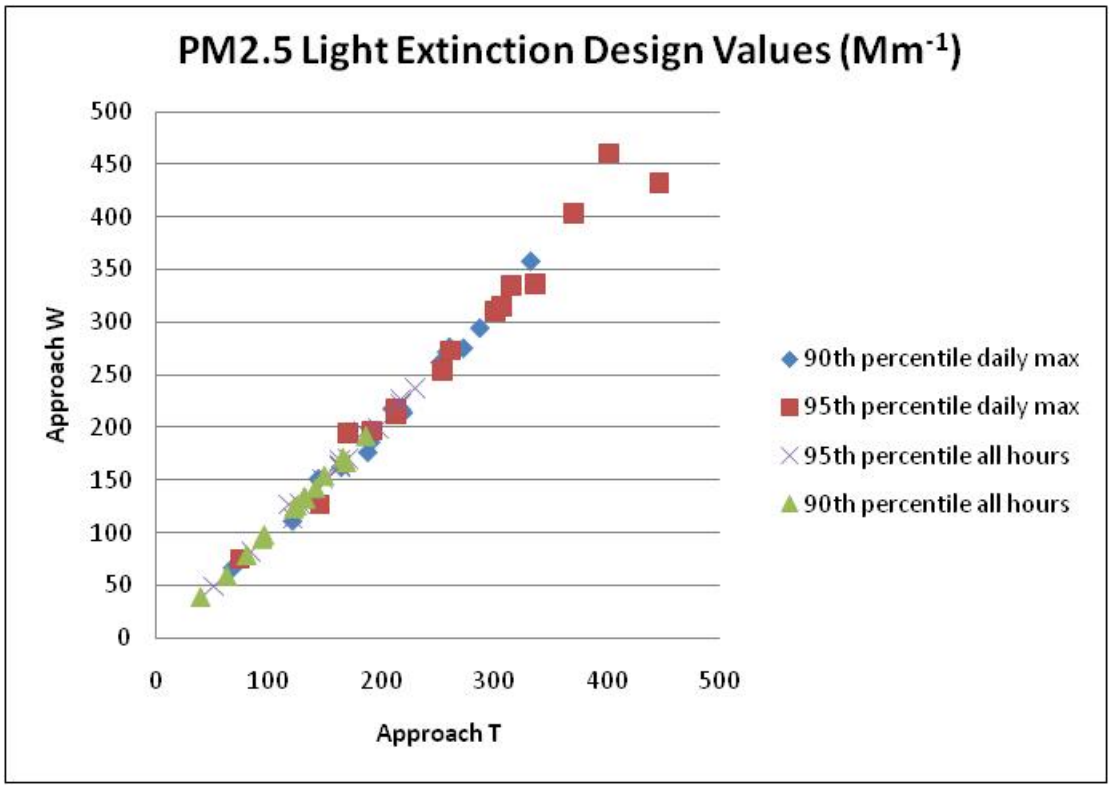
All Daylight Hours	Daily Maximum Daylight Hour
	

Figure F-7. Comparison of 2007-2009 $PM_{2.5}$ light extinction design values based on approach T vs. approach W.



F.6 EXPLANATION OF THE SELECTION OF 1.6 AS THE MULTIPLIER FOR OCM

The original IMPROVE algorithm uses a multiplier of 1.4 to estimate organic carbonaceous material (OCM) from the measurement of organic carbon (OC), after subtraction of an estimate of the organic carbon blank filter artifact. This value has been extensively questioned and investigated since its initial selection, and it is clear from the literature that the actual ratio of OCM to OC varies by site, season, PM sampler characteristics, the approach used the artifact correction, and the OC quantification method. Various researchers and organizations have suggested that other, generally higher, values be used instead of 1.4. The revised IMPROVE algorithm, for example, is based on a factor of 1.8. For simplified approaches T and W, the issue of an appropriate single value for this multiplier was re-investigated. This investigation focused on data only from samples taken in 2007-2009 from sites and months where the URG 3000N sampler was in use. The investigation considered all such CSN sites, of which there were 171 sites with an average of 77 sample days each. Because of the phased introduction of the URG 3000N sampler, there was a wide range in the number of sample days across sites, and not all sites were seasonally balanced. These samples were all analyzed for OC by Desert Research Institute using the current IMPROVE TOR method.

At each site, the SANDWICH estimate of OCM was used as the dependent (y) variable in a linear regression with the OC measurement (minus an assumed artifact of 0.4 $\mu g/m^3$) as the independent (x) variable. The slope of the regression line is an estimate of the OC-to-OCM

multiplier for that site, across the seasons represented in the monitoring data. In addition, the data from all sites were pooled and a single regression was performed for the pooled data. The following results were observed.

- The average value for R-squared from the 171 regressions was 0.68, with a wide range from site-to-site.
- The slopes of the 171 regression lines ranged from 0.57 to 3.05 (not including one negative value from a site with only nine samples), with a median of 1.73 and an average of 1.72.
- The sample size-based median slope was 1.68 and the sample size-weighted average slope was 1.65.
- The slope of the pooled regression was 1.6.

The value of 1.6 from the pooled regression was selected for use as the carbon multiplier in approaches T and W. Note that this is midway between the factor of 1.4 used in the original IMPROVE algorithm and the factor of 1.8 used in the revised IMPROVE algorithm.

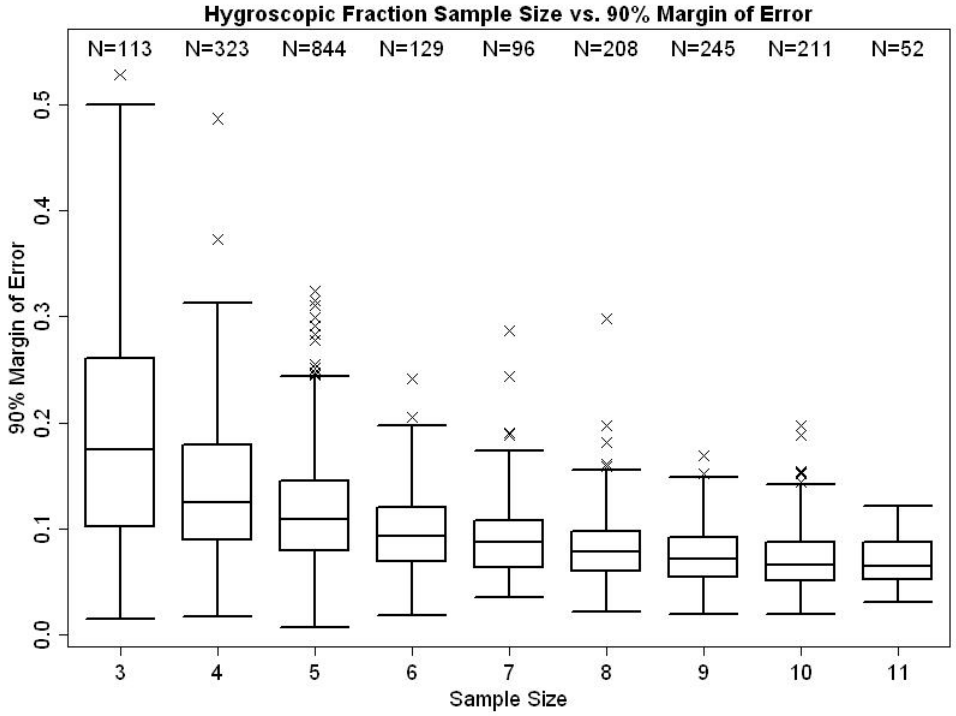
F.7 VARIABILITY IN ESTIMATES OF MONTHLY-AVERAGED HF AND DLEE AND SELECTION OF A MINIMUM SAMPLE SIZE

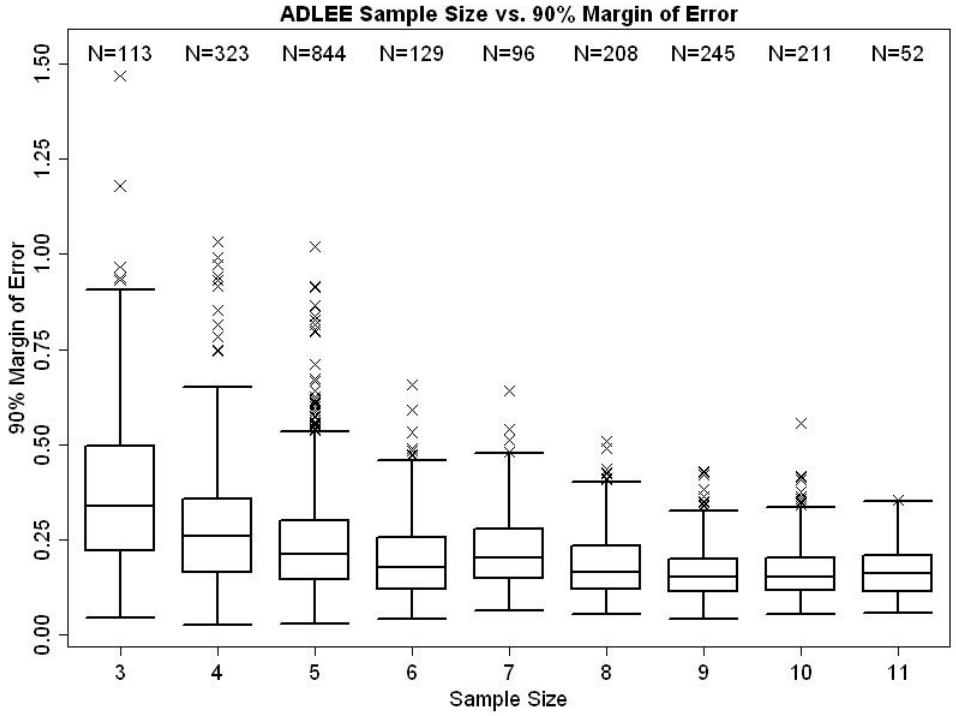
As part of the analysis of simplified methods for this appendix, EPA staff investigated the issue of the variability of monthly-averaged values of HF and DLEE, in light of the one-day-in-six sampling schedule at many CSN sites. A one-day-in-six CSN site will typically attempt to collect five samples in a month, versus 10 or 11 at a one-day-in-three site.

The margin of error (MOE) for the 90 percent confidence range for monthly-average HF and DLEE was calculated for each site-month of data from CSN sites for 2007-2009 (including many site-months prior to conversion to the URG 3000N sampler). The MOE is effectively the half-width of the confidence range. The MOE reflects both the similarity of the parameter of interest from day-to-day and the sample size.[14] Site-months were then binned according to the number of samples in the month. Figure F-7 shows the box plots of the MOEs for HF and DLEE (referred to as ADLEE in the plot), versus the number of samples available. The "N" along the top of each box plot indicates the number of CSN site-months that had the indicated number of sample days. Based on these box plots, EPA staff decided to incorporate a minimum requirement of four sample days per month for the calculation of valid monthly-average values of HF and DLEE via approach T, for the purposes of this appendix. It should be noted that based on the "N" values in the box plots, 85 percent of monthly averages for HF and DLEE were actually based on five or more samples and have a smaller margin of error than shown for the four-sample case.

[14] The formula used was MOE = (STD ERR)*t(n-1, 0.95), where STD ERR = (sample standard deviation)/sqrt(n) and t(n-1, 0.95) is the 95th percentile t-distribution with n-1 degrees of freedom (effectively removing 5% from each tail to get 90%).

Figure F-7. Margin of errors in monthly-averaged values of hygroscopic fraction (HF) and dry light extinction efficiency (ADLEE in this figure) versus the number of CSN samples in a site-month.





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APPENDIX G

Calculated 24-hour Average $PM_{2.5}$ Light Extinction and Adjusted Candidate Protection Levels

G.1 OVERVIEW

The concept of considering and adopting a relatively long averaging period for a NAAQS indicator in order to control shorter-term ambient conditions is not at all unfamiliar in the history of NAAQS reviews. This appendix investigates the possibility of using calculated 24-hour average $PM_{2.5}$ light extinction as the indicator and averaging period for a secondary $PM_{2.5}$ NAAQS that would be aimed at controlling daily maximum daylight 4-hour average light extinction conditions. This appendix assumes that the form for both standards is based on a three-year average of annual 90^{th} percentile values. A calculated 24-hour average approach would avoid data quality uncertainties that have recently been associated with currently available instruments for direct measurement of hourly $PM_{2.5}$ light extinction or for measurement of hourly $PM_{2.5}$ mass.

The calculation procedure for the 24-hour average indicator addressed in this appendix is based on the general method used by the IMPROVE monitoring program and the Regional Haze Program to characterize 24-hour light extinction levels based on 24-hour filter-based sampling for $PM_{2.5}$ composition.[1] There are several variations of this IMPROVE method, distinguished by the use of the original versus the revised IMPROVE algorithm for light extinction and by the use of same-day relative humidity (RH) at the monitoring site versus long-term (climatological) relative humidity conditions. This appendix reports the results of using the original IMPROVE algorithm, for consistency with previous results reported in the Urban Focused Visibility Assessment (UFVA)[2] and in Chapter 4 and Appendices E and F of this Policy Assessment (PA). For relative humidity, this appendix applies long-term conditions, which is the approach used in the Regional Haze Program for assessing progress towards the Program's goal of achieving natural conditions of visibility in Class I areas by 2064. By using site-specific daily data on both $PM_{2.5}$ mass and composition and site-specific long-term relative humidity conditions, it can be expected that the 24-hour average $PM_{2.5}$ light extinction indicator explored in this appendix would provide more protection of visibility than would the current secondary $PM_{2.5}$ NAAQS based only on 24-hour average and annual average $PM_{2.5}$ mass. In particular, the systematic difference in humidity conditions between the eastern states and the western states would be accounted for in large degree.[3]

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[1] The IMPROVE monitoring program and the Regional Haze Program also use filter-based data on $PM_{2.5}$ and PM_{10} mass, in order to estimate light extinction due to $PM_{10-2.5}$. $PM_{2.5}$ and PM_{10} mass values are not used in the indicator investigated in this appendix, because this indicator excludes light extinction due to $PM_{10-2.5}$.

[2] Particulate Matter Urban-Focused Visibility Assessment Final Document, EPA 452/R-10-004, July 2010. The UFVA presented a method and results for PM_{10} light extinction. The assessment in this memo focuses on $PM_{2.5}$ light extinction.

[3] The use of long-term relative humidity conditions in defining the NAAQS indicator would avoid the need for on-site relative humidity data and hence would avoid the need to establish a reference method for relative humidity, establish siting and operational requirements for the relative humidity measurements, and invest in new relative humidity instruments. On the other hand, the use of long-term relative humidity conditions can be expected to weaken to some degree the correlation between the calculated values of 24-hour average $PM_{2.5}$ light extinction and

This appendix investigates approaches for calculating adjusted Candidate Protection Levels (CPLs) for a 24-hour average $PM_{2.5}$ light extinction indicator that are generally equivalent to CPLs of 20, 25, and 30 deciviews (dv) for a daily maximum daylight 4-hour average $PM_{2.5}$ light extinction indicator, on an aggregate or "central tendency" basis. It was initially expected that the values of 24-hour average $PM_{2.5}$ light extinction and daily maximum daylight 4-hour average $PM_{2.5}$ light extinction would differ on any given day, with the shorter term peak value generally being larger. This would mean that, in concept, the level of a NAAQS based on a 24-hour average indicator should include a downward adjustment compared to the level that would be applied to a NAAQS based on a daily maximum daylight 4-hour average indicator. As discussed in section G.5, this initial expectation was verified for the 30 dv level but not for the other two levels (25, 20 dv).

In developing adjusted CPLs, comparisons are made between values of 24-hour average $PM_{2.5}$ light extinction calculated as described in section G.2 and values of daily maximum daylight 4-hour average $PM_{2.5}$ light extinction calculated from the hourly results of the UFVA approach for modeling hourly $PM_{2.5}$ light extinction, for the original 15 study areas using 2007-2009 data. The UFVA approach and the results of re-executing it for 2007-2009 data are described in Appendix F. Table G-1 shows the size and temporal distribution of the available 2007-2009 data base for the 15 study areas. Because 24-hour average $PM_{2.5}$ light extinction can be calculated with fewer required measurements as input, it is possible to calculate it for more days than shown in Table G-1. However, comparisons of 24-hour and 4-hour values for the purpose of developing adjusted CPLs can only be made for these days.

Table G-1. Number of Days per Quarter in Each Study Area

Study Area	Total Number of Days	2007				2008				2009			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Tacoma	150	13	13	14	13	14	14	14	12	7	14	11	11
Fresno	325	26	28	30	28	29	27	30	29	15	27	28	28
Los Angeles	161	21	26	24	24	29	28	9	0	0	0	0	0
Phoenix	84	0	0	0	0	0	0	0	0	11	24	21	28
Salt Lake City	276	23	25	19	29	28	12	27	15	13	29	28	28
Dallas	257	18	23	24	21	22	25	26	20	13	23	21	21
Houston	144	15	14	9	0	15	13	12	14	7	15	15	15
St. Louis	287	29	25	22	10	24	22	27	28	14	30	29	27
Birmingham	330	30	30	27	26	31	27	30	29	13	28	28	31
Atlanta	258	25	19	26	21	22	25	24	21	12	22	21	20
Detroit	133	11	11	12	11	7	12	13	13	3	15	10	15
Pittsburgh	264	22	22	23	23	23	24	24	25	10	25	22	21
Baltimore	140	12	12	17	16	0	0	0	0	13	26	21	23
Philadelphia	98	13	14	12	12	9	11	14	13	0	0	0	0
New York	145	19	15	19	21	20	14	13	24	0	0	0	0

actual daily maximum daylight 4-hour $PM_{2.5}$ light extinction, since the latter depends on actual relative humidity conditions along the sight path in the specific 4-hour period. It can be expected that the variability illustrated in this appendix would be somewhat less if the 24-hour indicator were based on same-day measurements of relative humidity either at the $PM_{2.5}$ site or another site in the same area.

G.2 CALCULATED 24-HOUR $PM_{2.5}$ LIGHT EXTINCTION

This section describes and implements an approach for calculating 24-hour average $PM_{2.5}$ light extinction using on-site 24-hour average $PM_{2.5}$ chemical speciation data but no other same-day data. The $PM_{2.5}$ light extinction values calculated by the method described here are based on the original IMPROVE algorithm and on long-term relative humidity conditions. Possible variations, not further analyzed here, include the use of the revised IMPROVE algorithm and the use of same-day relative humidity data. When converting $PM_{2.5}$ light extinction values in Mm^{-1} to deciviews, the Rayleigh term must be included to avoid the possibility of negative values.

Table G-2 explicitly defines the calculation steps for the 24-hour average indicator approach. The 24-hour average $PM_{2.5}$ component concentrations needed for the calculation are derived from 24-hour filter measurements, including a blank correction for organic carbon artifacts, a multiplier to estimate organic carbonaceous material from the blank-corrected organic carbon measurement, and the IMPROVE formula for estimating fine soil from concentrations of five crustal elements. Instead of using same-day on-site relative humidity data, climatological data are used for the humidity adjustment factor, f(RH). A spatial interpolation analysis of 1988-1997 relative humidity data completed in 2001 for the Regional Haze program provided monthly-average f(RH) values across the United States. [4] For this analysis, the monthly values from the grid point nearest to a given Chemical Speciation Network (CSN) monitoring site were used in the calculation of daily 24-hour $PM_{2.5}$ light extinction values for 2007-2009.

Figure G-1 presents monthly-average relative humidity values graphically. Table G-3 contains the month-specific 24-hour average values of $f(RH)_{hourly}$ for each of the 15 cities. The values in Figure G-1 and Table G-3, as expected, show that the more eastern of the 15 cities have higher values of f(RH) with the notable and expected exception of Tacoma which has the most humid conditions of all the areas. For those areas with strong seasonal patterns of relative humidity, the seasonal patterns of the values in Figure G-1 and Table G-3 are also as expected. Note that while some individual hours in 1988-1997 had relative humidity above 90%, no monthly average relative humidity exceeds 90%. The highest value of monthly average f(RH) is 5.05 for December in Tacoma, when the average relative humidity value is 89%. The average f(RH) value of 5.05 for this month is higher than the value of f(89%) = 3.93 because of the non-linear nature of the f(RH) function. The single hour value of relative humidity corresponding to an f(RH) value of 5.05 would be between 92% and 93%.

Figure G-2 presents the results of applying the 24-hour average approach in the form of a box-and-whisker plot of the daily 24-hour $PM_{2.5}$ light extinction values for 2007-2009. For ease of comparison to similar figures in this document that present estimates of other metrics for $PM_{2.5}$ light extinction, for example Figure F-1, horizontal lines are drawn to represent 65, 100, and 190 Mm^{-1}, although we emphasize that these are unadjusted values meant to be compared to short-term averages of light extinction rather than to 24-hour averages. As expected, the estimated values for 24-hour $PM_{2.5}$ light extinction generally are lower than for daily maximum daylight 1-hour $PM_{2.5}$ light extinction (Figure F-1), but the comparisons across cities are generally the same.

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[4] Interpolating Relative Humidity Weighting Factors to Calculate Visibility Impairment and the Effects of IMPROVE Monitor Outliers, Report by Science Applications International Corporation to EPA, August 30, 2001. http://vista.cira.colostate.edu/improve/publications/guidancedocs/DraftReportSept20.pdf. Note that this reference describes a procedure in which hourly f(RH) values were capped at f(98%). Subsequently, the IMPROVE Steering Committee decided to cap f(RH) values at f(95%). The f(RH) values used in here are based on the 95% cap.

Table G-2. Calculation Steps for the 24-hour Average $PM_{2.5}$ Light Extinction

24-hour Average Approach	Comments
(i) Using historical data, determine a representative long-term monthly average of hourly f(RH) at the monitoring site, for each month of the year. There will be 12 such values for any monitoring site.	A spatial interpolation analysis of 1988-1997 relative humidity completed in 2001 for the Regional Haze program provided monthly-average f(RH) values for 15,000 ¼-degree grid points of latitude/longitude across the United States. For this analysis, the monthly values from the grid point nearest to a given $PM_{2.5}$ (CSN) monitoring site were used in the calculation of daily 24-hour $PM_{2.5}$ light extinction values for 2007-2009. If a 24-hour average indicator were to be adopted as part of a secondary PM NAAQS, these same gridded data could be specified, or EPA could develop updated tables of gridded monthly average f(RH) values and a procedure for determining the values to be applied to any visibility monitoring site. Alternatively, the NAAQS could specify the use of same-day site-specific relative humidity data, or data from another monitoring site in the same area, for example the nearest National Weather Service site.
(ii) For each CSN sampling day, subtract a sampler-dependent estimate of the OC artifact from the OC measurement, and multiply by 1.4 to estimate organic carbonaceous material (OCM). OCM = (OC – artifact) *1.4	The IMPROVE blank filter correction values are not representative of conditions in urban areas, and cannot be used in this approach. The values for the OC artifact used for this analysis ranged from 0.32 to 1.53 µg/m^3, depending on CSN sampler model. The artifact adjustment for the URG 3000N sampler is of most interest prospectively, because it is the single sampler now in use for carbon sampling in CSN. For those sites and days, an organic carbon artifact of 0.4 µg/m^3 was assumed for the purposes of the UFVA and this document, based on early experience with this sampler. EPA staff is currently exploring whether there is a better way to adjust for organic carbon artifact based on a more recent, larger field blank and back-up filter data set. 1.4 is used for the multiplier to maintain consistency with the original IMPROVE algorithm.
(iii) For each CSN sampling day, calculate fine soil/crustal $PM_{2.5}$ (FS) from CSN measurements of crustal elements AL, Si, Ca, Fe, and Ti, using the formula • FS = 2.20 x [Al] + 2.49 × [Si] + 1.63 × [Ca] + 2.42 × [Fe] + 1.94 × [Ti]	This is the same equation as used in the IMPROVE network and the Regional Haze program.
(iv) For each CSN sampling day, multiply CSN measurement of sulfate ion by 1.375, and multiply CSN measurement of nitrate ion by 1.29, to reflect associated ammonium under an assumption of full neutralization. • AS = Sulfate ion * 1.375 • AN = Nitrate ion * 1.29	
(v) Apply the original IMPROVE algorithm to calculate 24-hour average $PM_{2.5}$ light extinction. $PM_{2.5}$ bext (Mm^{-1}) = 3[AS]f(RH) + 3[AN]f(RH) + 4[OCM] + 1[FS] + 10[EC] Where f(RH) is the monthly-averaged value from step (i) for the particular month.	

Figure G-1. Month-specific 24-Hour Average Values of Relative Humidity from 1988-1997

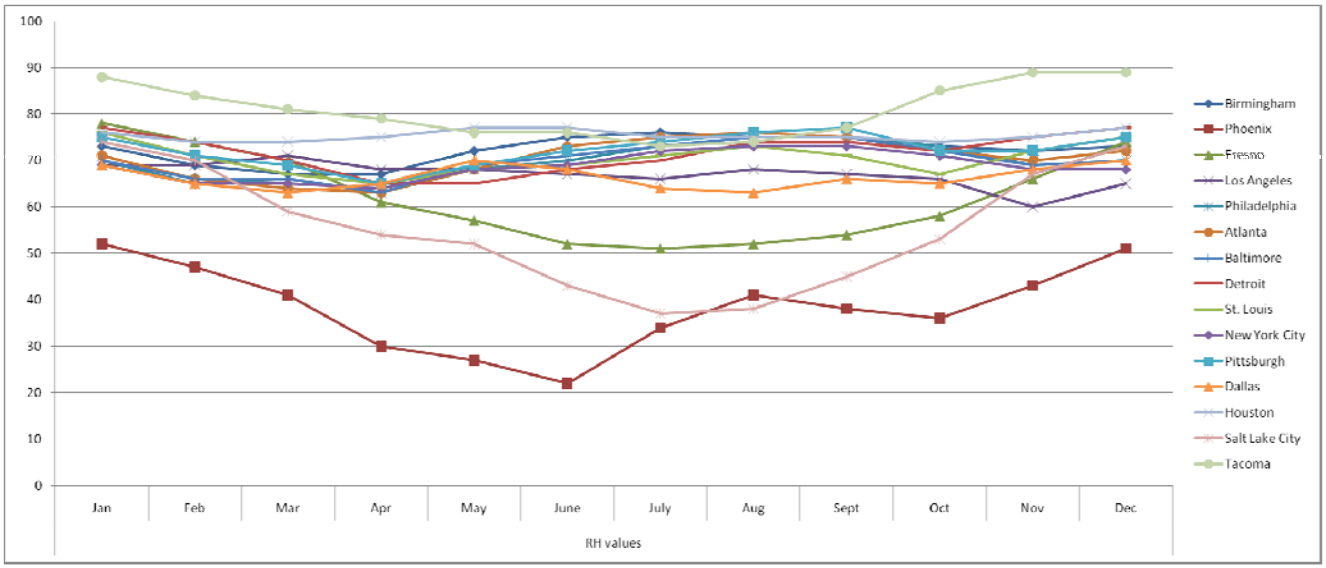
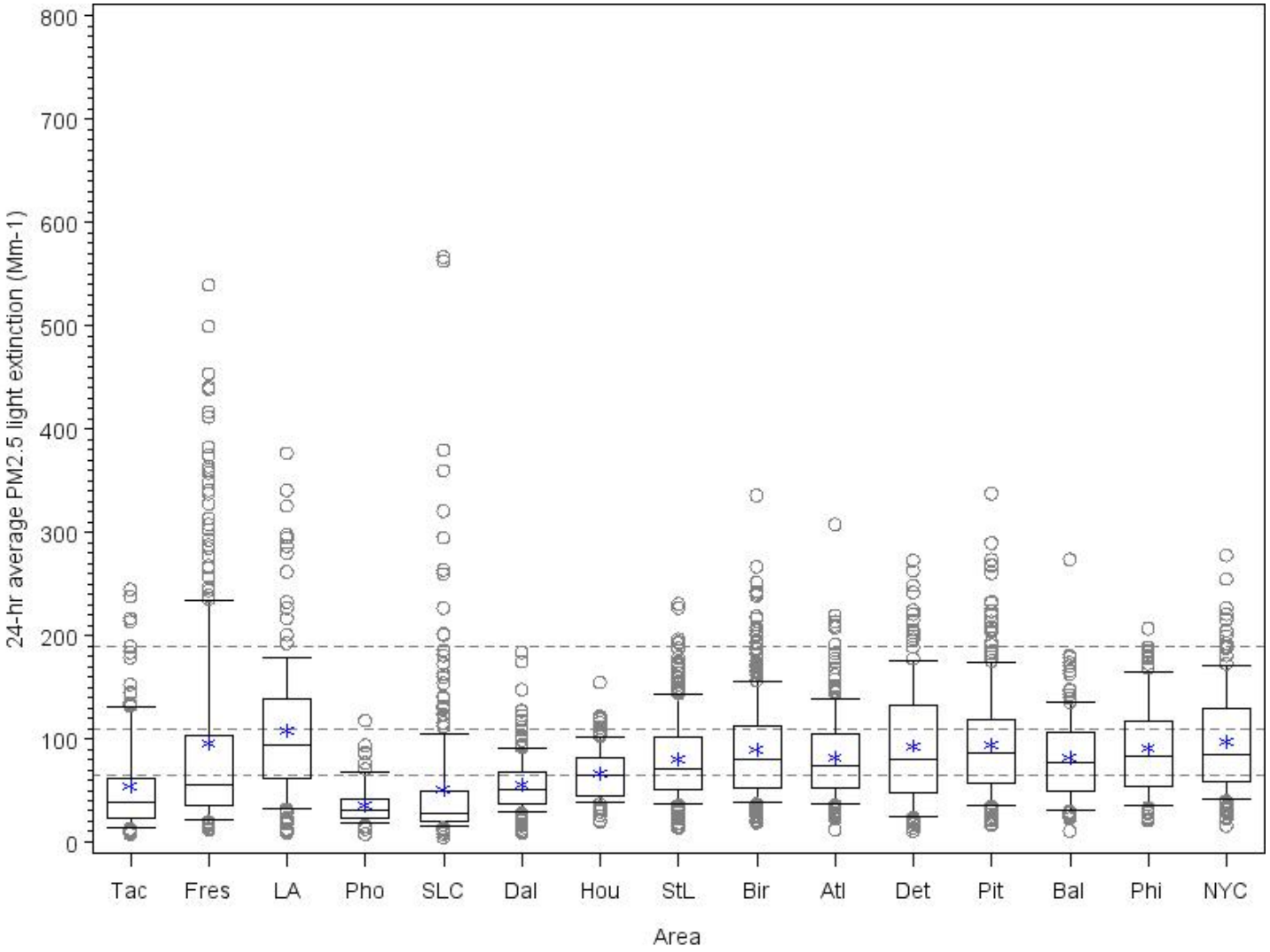


Table G-3. Month-specific 24-Hour Average Values of f(RH) from 1988-1997

Month	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
Tacoma, WA	4.85	4.35	3.98	3.81	3.49	3.26	3.02	3.17	3.68	4.56	5.04	5.05
Fresno, CA	3.47	2.97	2.65	2.09	1.88	1.67	1.62	1.66	1.77	1.97	2.53	3.26
Los Angeles, CA	2.48	2.40	2.39	2.16	2.16	2.10	2.11	2.17	2.20	2.18	2.08	2.23
Phoenix, AZ	1.86	1.67	1.50	1.21	1.13	1.06	1.25	1.41	1.33	1.30	1.49	1.85
Salt Lake City, UT	3.07	2.77	2.09	1.96	1.89	1.55	1.29	1.32	1.53	1.85	2.56	2.88
Dallas, TX	2.81	2.59	2.42	2.42	2.70	2.52	2.25	2.25	2.42	2.50	2.60	2.82
Houston, TX	3.56	3.38	3.31	3.28	3.45	3.43	3.27	3.30	3.32	3.33	3.41	3.60
St Louis, IL	3.26	2.93	2.66	2.52	2.73	2.73	2.87	3.05	2.98	2.73	2.93	3.20
Birmingham, AL	3.30	3.03	2.80	2.76	3.09	3.33	3.47	3.38	3.43	3.28	3.13	3.29
Atlanta, GA	3.26	2.95	2.68	2.54	2.81	3.13	3.31	3.40	3.31	3.16	3.08	3.26
Detroit, MI	3.06	2.81	2.71	2.47	2.44	2.62	2.71	3.04	3.07	2.88	2.93	3.13
Pittsburgh, PA	3.07	2.86	2.83	2.55	2.92	3.02	3.16	3.36	3.50	3.11	2.94	3.16
Baltimore, MD	2.85	2.60	2.68	2.47	2.84	2.89	3.04	3.20	3.27	3.11	2.77	2.88
Philadelphia, PA	2.87	2.59	2.70	2.49	2.84	2.83	3.03	3.16	3.24	3.16	2.78	2.84
New York, NY	2.71	2.49	2.58	2.51	2.76	2.72	2.85	2.96	2.99	2.93	2.65	2.68

Figure G-2. Distributions of Estimated 24-Hour Average $PM_{2.5}$ Light Extinction Across the 2007-2009 Period, by Study Area using the 24-Hour Average Approach

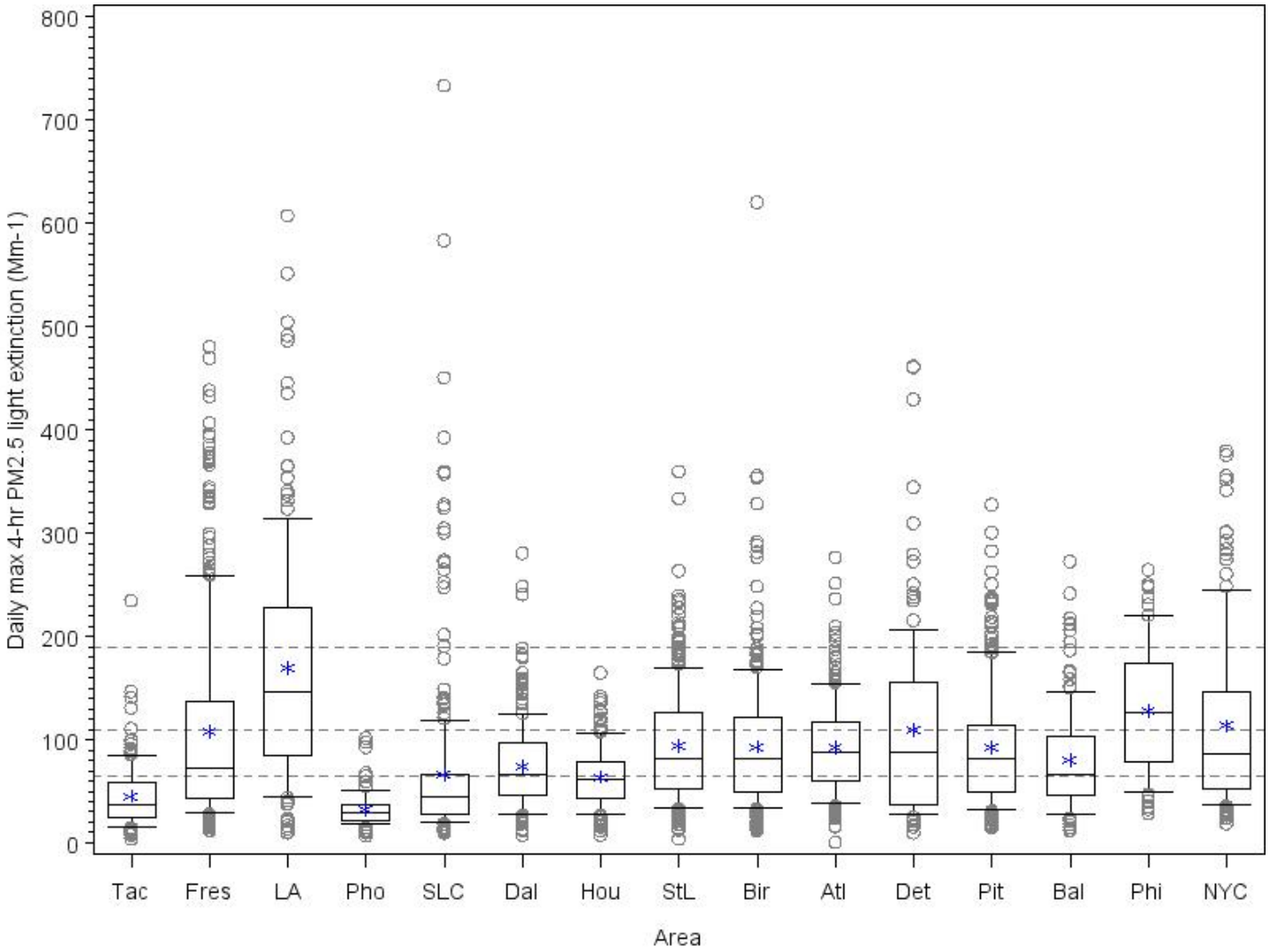


G.3 CALCULATED DAILY MAXIMUM DAYLIGHT 4-HOUR $PM_{2.5}$ LIGHT EXTINCTION

Values for the daily maximum daylight 4-hour average $PM_{2.5}$ light extinction in the 15 study cities were calculated using the results of the re-execution of the UFVA approach for 2007-2009, described in Appendix F. The UFVA-approach modeling results (rather than the modeling results using simplified approach T reported in Appendix F) are used because these results are based on modeling assumptions believed to give the best available representation of actual hourly light extinction, in that they incorporate the SANDWICH method for estimating organic carbonaceous material (rather than a simple multiplier as in approach T) and on information on site-specific diurnal concentration patterns from a run of a 2004 CMAQ modeling platform. Note that these 4-hour estimates are based on same-day hourly relative humidity data from the nearest site able to provide such data, not on gridded long-term data as are the 24-hour $PM_{2.5}$ light extinction values to which they are compared.

The daily maximum daylight 4-hour average $PM_{2.5}$ light extinction values were calculated from hourly UFVA-approach results by applying a moving 4-hour window to average the hourly light extinction estimates. Only 4-hour periods that were entirely within the daylight window were considered. At least three of four hours were required to have a valid 1-hour light extinction estimate, meaning that necessary hourly $PM_{2.5}$ mass and relative humidity data were available to calculate light extinction for the hour and the relative humidity was not greater than 90%. As such, the resulting estimates represent indicator values that could be considered comparable to a NAAQS with a 4-hour averaging period with the same restrictions for indicator value validity. The requirement for at least 3 out of 4 hourly $PM_{2.5}$ light extinction values resulted in the elimination of 39 of the 3052 site-days shown in Table G-1, because those days had no 4-hour daylight periods with at least 3 hours that had hourly $PM_{2.5}$ data and had relative humidity of 90% or less. Figure G-3 presents the results of this screening and calculation procedure in the form of a box and whisker plot of the daily maximum daylight 4-hour average $PM_{2.5}$ light extinction values for 2007-2009. As expected, the comparisons across cities are generally the same as for daily maximum daylight 1-hr $PM_{2.5}$ light extinction (Figure F-1).

Figure G-3. Distributions of Estimated Daily Maximum Daylight 4-Hour Average $PM_{2.5}$ Light Extinction Across the 2007-2009 Period, by Study Area, Based on the UFVA Modeling Approach



G.4 COMPARISON OF CALCULATED DAILY MAXIMUM DAYLIGHT 4-HOUR $PM_{2.5}$ LIGHT EXTINCTION AND CALCULATED 24-HOUR $PM_{2.5}$ LIGHT EXTINCTION

The daily values of the 24-hour average $PM_{2.5}$ light extinction from section G.2 and the values of the daily maximum daylight 4-hour average $PM_{2.5}$ light extinction from section G.3 are compared here across days within each city, to gain a sense of how they compare and as a quality control check for reasonableness. Before doing so, both sets of daily $PM_{2.5}$ light extinction values were converted to deciview units, using the following equation for the deciview metric. Note that the Rayleigh term of 10 Mm^{-1} is included in order avoid the possibility of negative deciview values, but no term is included for light extinction due to $PM_{10-2.5}$.

$$\text{Deciview (dv)} = 10 \ln ((PM_{2.5}\ b_{ext} \text{ in } Mm^{-1} + 10)/10)$$

Figures G-4 and G-5 compare the magnitudes of the daily values of the 24-hour and daily maximum daylight 4-hour average $PM_{2.5}$ light extinction estimates expressed in deciviews. Figure G-4 shows a scatter plot for each of the 15 cities including the best-fit linear regression line for each city, with the 4-hour light extinction value treated as the independent (x-axis) variable in the regression. It can be seen that there is scatter around the regression line for each city, because the estimate of 4-hour light extinction includes day-specific and hour-specific influences that are not captured by the simpler 24-hour approach. Figure G-5 shows a scatter plot for the pooled data points from all 15 cities. In both figures, the linear regression line is solid and the 1:1 line is dashed. In both figures, there are some data points – each representing a site-day – for which the value of 24-hour average $PM_{2.5}$ light extinction is higher than the value of daily maximum daylight 4-hour $PM_{2.5}$ light extinction. Directionally, the focus on the daily maximum 4-hour average should tend to make the 4-hour average number higher than the 24-hour average number because $PM_{2.5}$ concentrations in urban areas generally peak during the day rather than at night. The directionally opposite comparison seen for some data points can result due to the use of 1988-1997 humidity values that in some cases may be higher than the actual same-day conditions used to calculate the 4-hour light extinction values. Approximately one-half of all site days can be expected to have same-day conditions that are more humid than the long-term average conditions, if there is no average bias between the gridded 1988-1997 relative humidity data and 2007-2009 site conditions. The use of same-day hourly relative humidity data to calculate daily 24-hour average f(RH) would avoid this, and in theory result in data points that lie closer to the regression line. It is also quite possible for 24-hour average values of f(RH) to be higher than for hours during the daylight. A higher value for 24-hour $PM_{2.5}$ light extinction can also in theory result from the invalidation of one or more 4-hour $PM_{2.5}$ light extinction values on a day due to the screen for hourly relative humidity above 90% (resulting in a time period with lower light extinction providing the valid daily daylight 4-hour maximum), or from a diurnal pattern in which 4-hour average $PM_{2.5}$ mass peaks during the night rather than during daylight.

Table G-3 presents the city-specific regression coefficients for the scatter plots in Figure G-4, the unweighted average of these coefficients across cities, and the regression coefficients for the pooled 15-city data shown in Figure G-5. While in broad terms most of the individual scatter plots seem to have similar variability about the regression line, some values of R-squared are notably lower. Closer examination shows that the lower values of R-squared are for the cities with the smaller range of light extinction conditions.

Figure G-6 and Table G-4 describe the distributions of the daily ratio of the 24-hour and daily maximum daylight 4-hour values of $PM_{2.5}$ light extinction. For each day, the 4-hour value was divided by the 24-hour value. The distribution of these ratios across 2007-2009 is shown in Figure G-6 in box-and-whisker plot format. Table G-4 presents the minimum, 10th percentile, 25th percentile, mean, median (50th percentile), 75th percentile, 90th percentile, and maximum values from the distribution of ratios in each city.

It is also of interest to compare the annual 90th percentile values and the 3-year design values for 24-hour average and daily maximum daylight 4-hour average $PM_{2.5}$ light extinction across areas. Table G-5 presents the annual 90th percentile values and the 3-year 2007-2009 design values.[5] There are only a few cases in which the 24-hour average annual percentile or 3-year design value is notably larger than the corresponding daily maximum daylight 4-hour average value, despite the occurrence of many such points in the scatter plots of daily values. Figure G-7 is a scatter plot of the 4-hour versus the 24-hour 90th percentile values for individual years of data. Figure G-8 is a scatter plot of the 4-hour versus the 24-hour design values. The equation of the linear regression line for each scatter plot is shown below the graphic.

[5] For the purpose of this analysis, the "3-year" design values have been calculated with only 2 years of data for Los Angeles, Baltimore, Philadelphia, and New York City and one year of data for Phoenix because the re-execution of the UFVA approach for 2007-2009 created estimates only for those years. See Table G-1. Also, no data completeness minimums have been applied. The smallest sample used to determine an annual 90th percentile was 37 days, for Houston in 2007.

Figure G-4. Scatter Plots of 24-Hour Light Extinction (y-axis) and Daily Maximum Daylight 4-Hour Light Extinction (x-axis) for 15 Individual Cities, in deciviews

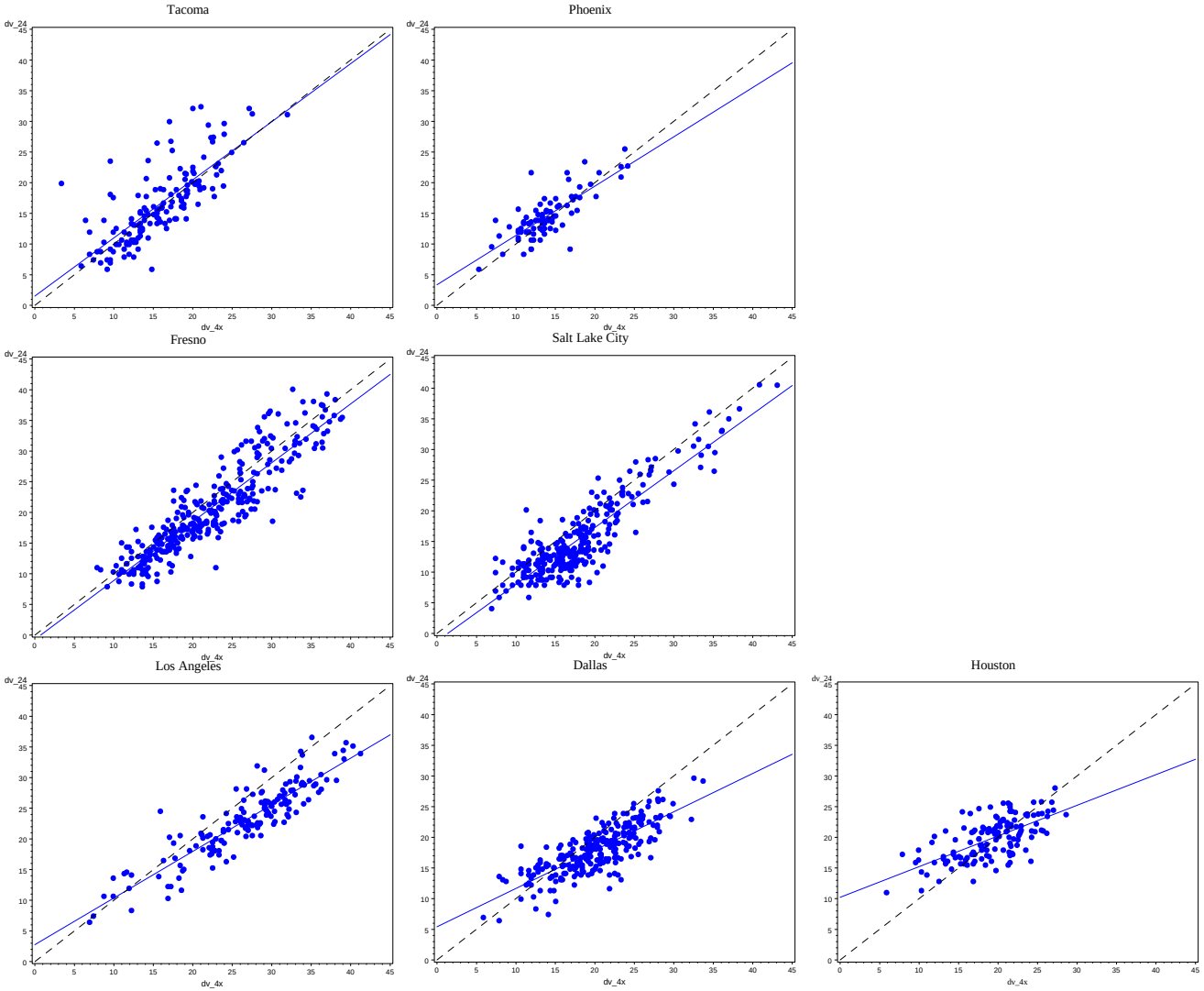


Figure G-4. Scatter Plots of 24-Hour Light Extinction (y-axis) and Daily Maximum Daylight 4-Hour Light Extinction (x-axis) for 15 Individual Cities, in deciviews (cont.)

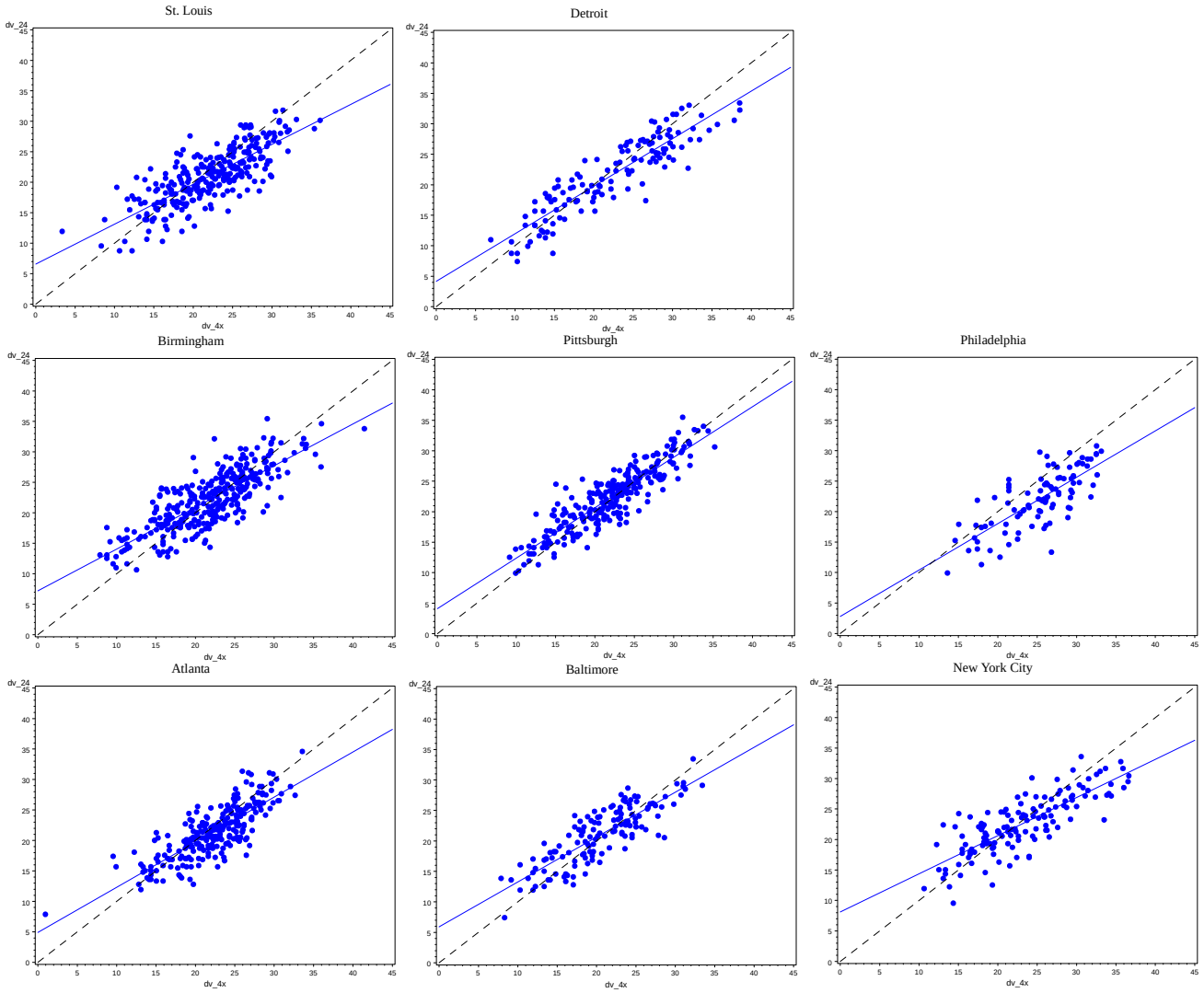


Figure G-5. Scatter Plot of 24-Hour Light Extinction (y-axis) versus Daily Maximum Daylight 4-Hour Light Extinction (x-axis) for All Cities Pooled Together, in deciviews

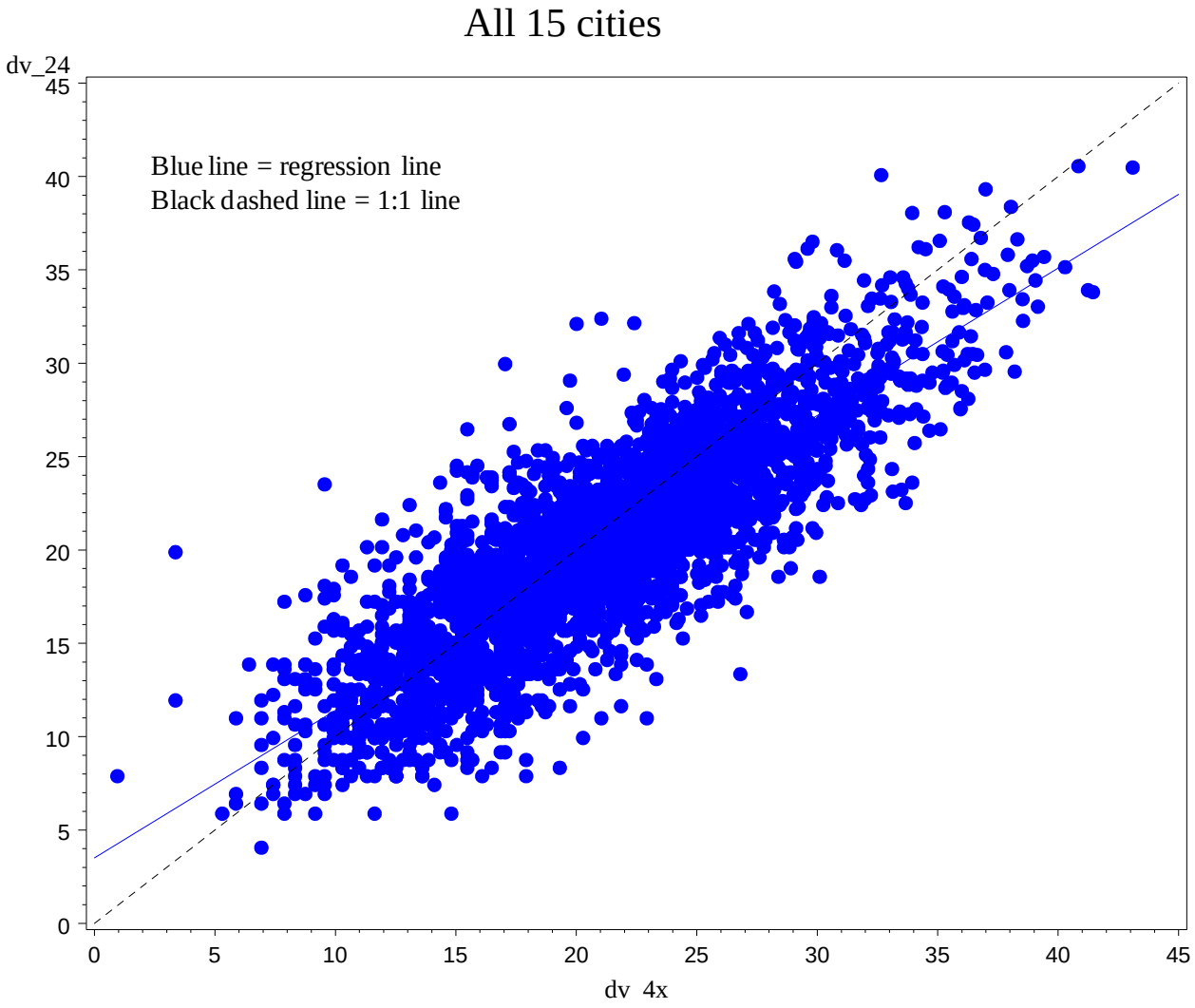
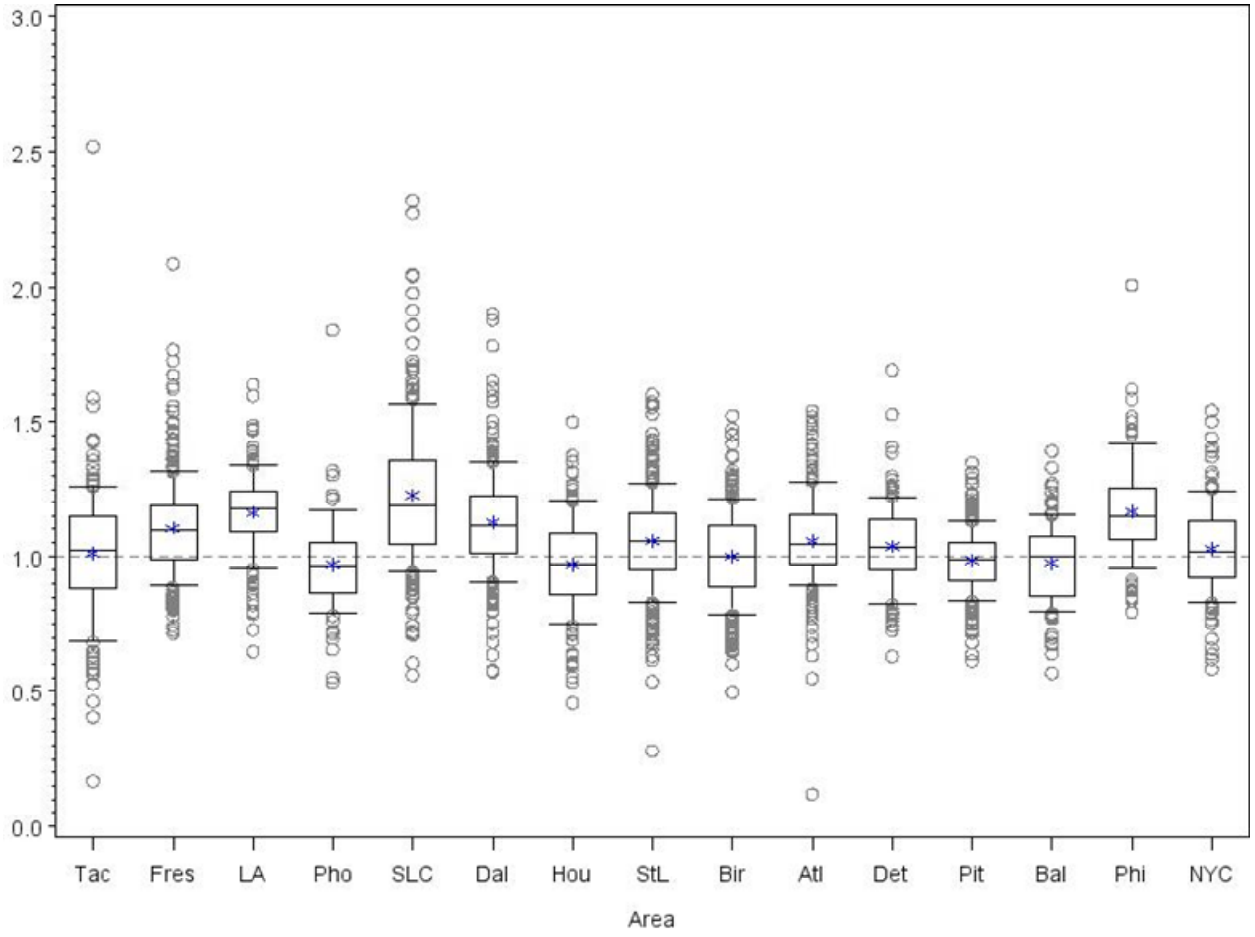


Table G-3. Regression Results for 24-Hour Light Extinction versus Daily Maximum Daylight 4-Hour Light Extinction for Individual Cities and for All Cities Pooled Together, in deciviews (4-hour light extinction is the independent variable)

Study Area	Intercept	Slope	R-squared
Tacoma, WA	1.520	0.948	0.586
Fresno, CA	-0.726	0.961	0.823
Los Angeles, CA	2.749	0.760	0.814
Phoenix, AZ	3.360	0.804	0.616
Salt Lake City, UT	-1.255	0.926	0.795
Dallas, TX	5.418	0.625	0.634
Houston, TX	10.224	0.500	0.423
St Louis, IL	6.563	0.655	0.608
Birmingham, AL	7.210	0.684	0.641
Atlanta, GA	4.912	0.740	0.641
Detroit, MI	4.163	0.780	0.816
Pittsburgh, PA	4.101	0.828	0.797
Baltimore, MD	5.925	0.736	0.701
Philadelphia, PA	2.797	0.761	0.564
New York, NY	8.109	0.626	0.645
Average Across Cities (equal weighting)	**4.338**	**0.756**	**0.674**
Regression Using Pooled Data	**3.507**	**0.790**	**0.715**

Figure G-6. Distributions of the Ratio of Daily Maximum Daylight 4-Hour Light Extinction, in deciviews (numerator), and 24-Hour Light Extinction, in deciviews (denominator)*



* Whiskers are at 10th and 90th percentiles.

Table G-4. Points on the Distributions of the Ratio of Daily Maximum Daylight 4-Hour Light Extinction (numerator) and 24-Hour Light Extinction (denominator), in deciviews

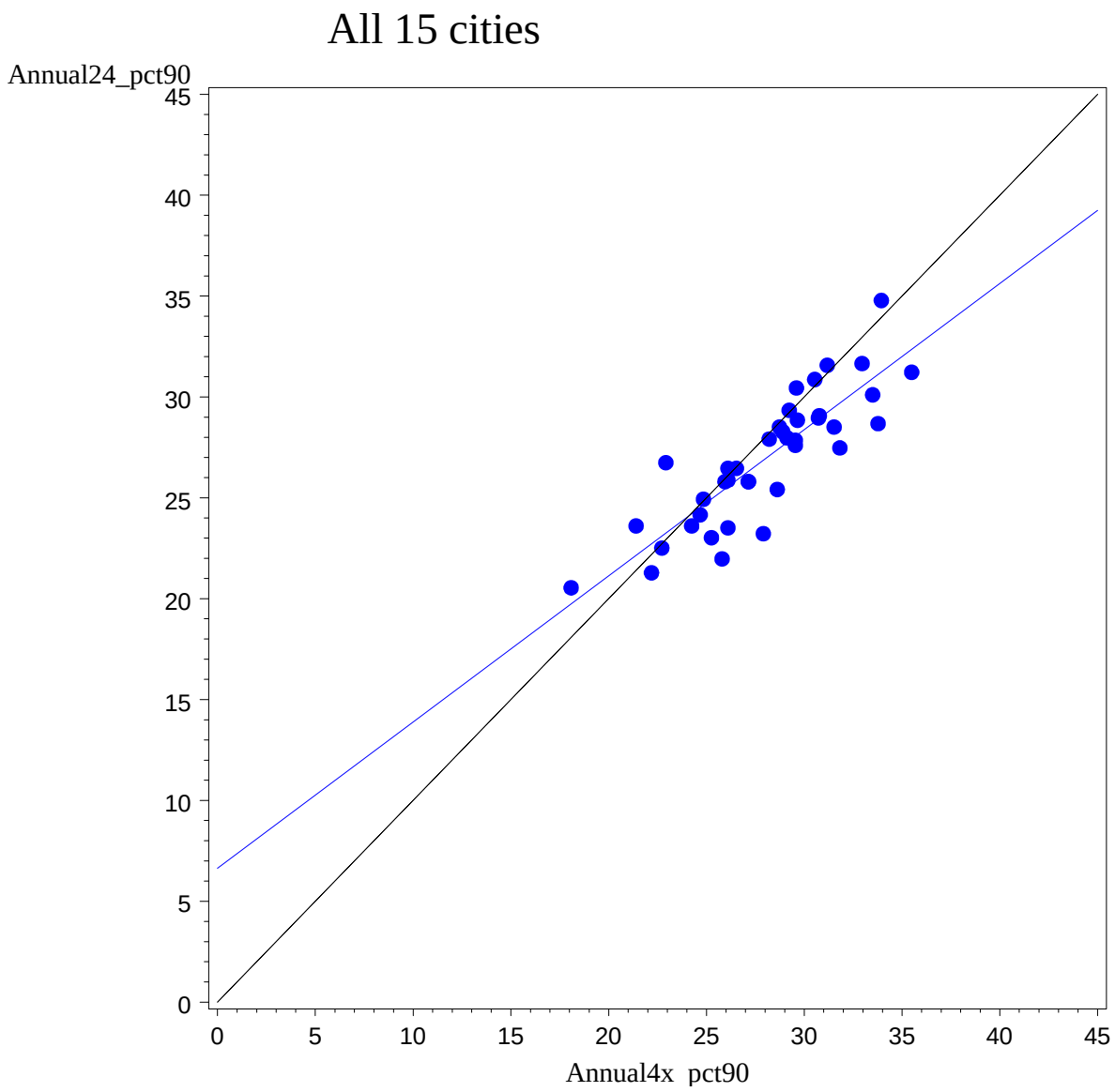
Study Area	Min	10th %-tile	25th %-tile	Mean	Median	75th %-tile	90th %-tile	Max
Tacoma, WA	0.169	0.689	0.882	1.009	1.015	1.135	1.254	2.521
Fresno, CA	0.718	0.892	0.986	1.106	1.097	1.192	1.314	2.087
Los Angeles, CA	0.648	0.960	1.089	1.163	1.172	1.246	1.340	1.638
Phoenix, AZ	0.535	0.788	0.868	0.970	0.962	1.039	1.149	1.840
Salt Lake City, UT	0.562	0.946	1.041	1.223	1.182	1.359	1.566	2.319
Dallas, TX	0.574	0.908	1.009	1.126	1.114	1.224	1.351	1.902
Houston, TX	0.458	0.751	0.862	0.970	0.972	1.084	1.205	1.501
St Louis, IL	0.282	0.831	0.953	1.056	1.057	1.163	1.268	1.600
Birmingham AL	0.498	0.775	0.879	0.987	0.986	1.095	1.191	1.523
Atlanta, GA	0.121	0.882	0.965	1.047	1.044	1.137	1.240	1.541
Detroit, MI	0.631	0.828	0.938	1.037	1.032	1.139	1.220	1.692
Pittsburgh, PA	0.614	0.839	0.913	0.986	0.987	1.052	1.132	1.348
Baltimore, MD	0.569	0.794	0.857	0.979	0.996	1.077	1.154	1.393
Philadelphia PA	0.796	0.956	1.064	1.170	1.150	1.262	1.420	2.008
New York, NY	0.584	0.829	0.922	1.028	1.018	1.133	1.241	1.542
Average Across Cities (equal weighting)				1.057	1.052			

Table G-5. Annual 90th Percentile Values and 3-year 2007-2009 90th Percentile Design Values for Daily Maximum Daylight 4-Hour $PM_{2.5}$ Light Extinction and 24-Hour $PM_{2.5}$ Light Extinction, in deciviews

Study Area	4-hour light extinction				24-hour light extinction*			
	Design Value	2007	2008	2009	Design Value	2007	2008	2009
Tacoma, WA	22.35	22.93	21.40	22.72	*24.29*	*26.74*	*23.61*	22.51
Fresno, CA	31.71	33.95	32.96	28.21	31.45	*34.78*	31.66	27.91
Los Angeles, CA	34.64	35.50	33.78		29.95	31.22	28.68	
Phoenix, AZ	18.08			18.08	*20.54*			*20.54*
Salt Lake City, UT	24.80	26.10	26.10	22.19	24.54	*26.46*	25.88	21.28
Dallas, TX	26.61	27.91	26.10	25.80	22.90	23.22	23.51	21.97
Houston, TX	24.59	24.85	24.68	24.25	24.20	*24.90*	24.20	23.60
St Louis, IL	29.03	28.90	29.55	28.62	27.10	28.27	27.60	25.42
Birmingham AL	28.23	29.60	29.12	25.95	28.07	*30.45*	27.97	25.80
Atlanta, GA	27.35	29.65	27.15	25.26	25.89	28.85	25.80	23.03
Detroit, MI	30.38	31.18	29.23	30.73	29.96	*31.57*	*29.34*	28.96
Pittsburgh, PA	28.87	30.54	29.55	26.53	28.39	*30.87*	27.85	26.46
Baltimore, MD	27.94	28.74		27.15	27.15	28.51		25.80
Philadelphia PA	31.30	30.77	31.82		28.27	29.07	27.47	
New York, NY	32.51	33.50	31.53		29.31	30.11	28.51	

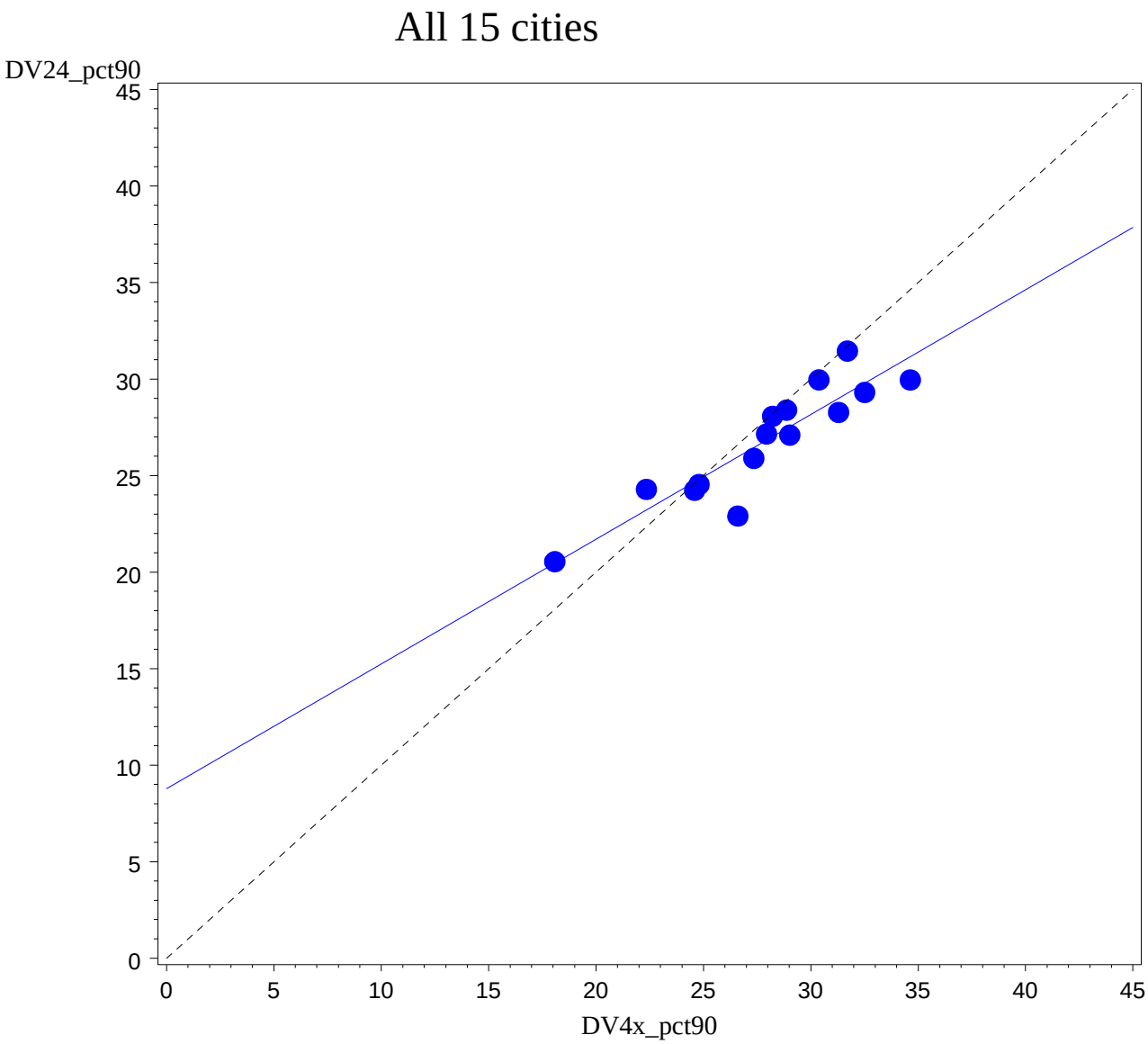
* Entries in ***italics*** indicate cases in which the 24-hour average value is larger than the corresponding 4-hour average value.

Figure G-7. Scatter Plot of 2007-2009 Annual 90th Percentile Values for Daily Maximum Daylight 4-Hour $PM_{2.5}$ Light Extinction (x-axis) and 24-Hour Average $PM_{2.5}$ Light Extinction (y-axis), in deciviews



Model: Annual24_pct90 = 6.636 + 0.725 * Annual4x_pct90 (rsquare=0.734)

Figure G-8. Scatter Plot of 90th Percentile 2007-2009 3-year Design Values for Daily Maximum Daylight 4-Hour $PM_{2.5}$ Light Extinction (x-axis) and 24-Hour Average $PM_{2.5}$ Light Extinction (y-axis), in deciviews



Model: DV24_pct90 = 8.786 + 0.646 * DV4x_pct90 (rsquare=0.820)

G.5 DEVELOPMENT OF ADJUSTED INDICATOR LEVELS APPROPRIATE FOR COMPARISON TO CALCULATED 24-HOUR $PM_{2.5}$ LIGHT EXTINCTION

This section explores several different approaches for calculating adjusted CPLs for a 24-hour average $PM_{2.5}$ light extinction indicator that may be considered to be generally equivalent on an aggregate or "central tendency" basis to CPLs of 20, 25, and 30 deciviews (dv) for a daily maximum daylight 4-hour average $PM_{2.5}$ light extinction indicator.

Several possible approaches are investigated in order to examine how robust the adjusted levels are to the choice of a specific approach. In some of the approaches explored in this section, the "equivalent" levels for individual cities are determined and then averaged across cities to get a single adjusted level. For these approaches, the range of city-specific adjusted levels is provided to give a sense of the possible variability in protection resulting from the use of the longer averaging period and long-term relative humidity data.

The following approaches were applied. The results are shown in Table G-6, rounded to the nearest whole-number value in deciviews. While some deciview results in Table G-5 were expressed with two decimal digits, EPA staff believes it would be most appropriate to set a NAAQS level in whole deciviews, given the uncertainties in the chain of analyses that may be used to determine that level.

- Approach A – The regression line based on city-specific 3-year design values displayed in Figure G-8 was used to find the 24-hour equivalents of 4-hour levels of 20, 25, and 30 dv.
- Approach B – The regression line based on city-specific annual 90^{th} percentile values displayed in Figure G-7 was used to find the 24-hour equivalents of 4-hour levels of 20, 25, and 30 dv.
- Approach C – The regression line using all days for each city (Figure G-4 and Table G-3) was used to find 24-hour equivalents of 4-hour levels of 20, 25, and 30 dv. These results were then averaged across the 15 cities. Table G-7 shows the intermediate adjusted levels for each of the cities.
- Approach D – The pooled regression line using all site-days (Figure G-5 and the last row of Table G-3) was used to find the 24-hour equivalents of 4-hour levels of 20, 25, and 30 dv.
- Approach E – In each city, the median ratio of the 24-hour $PM_{2.5}$ light extinction indicator to the 4-hour $PM_{2.5}$ light extinction indicator was applied to 20 dv (and also applied to 25 and 30 dv in turn). The median ratio was used to minimize the influence of days with extreme ratios, although Table G-4 indicates that in most cases the difference between the mean and median ratios is small. These city-specific results were averaged across the 15 cities. Table G-8 shows the intermediate adjusted levels for each of the cities.

Of these approaches, EPA staff considers Approaches A and B, which give nearly identical results, to be the most appropriate for further consideration, given the high R-squared of the regressions and the fact that the regression lines are determined by data from days with $PM_{2.5}$ light extinction conditions in the range of 20 to 40 dv. In contrast, the city-specific regression lines and the pooled data regression lines are influenced by $PM_{2.5}$ light extinction conditions well

below 20 dv because of the large amount of data in that range. Approaches A and B yield identical results except for the case of a 4-hour level of 20 dv, for which the A and B results are only 0.65 dv different before rounding but after rounding differ by 1 dv. Both A and B result in a 24-hour level that is higher than 20 dv for this case. EPA staff recommends consideration of the results from Approach B, which are adjusted CPLs of 21, 25, and 28 dv, as the 24-hour $PM_{2.5}$ light extinction indicator levels. These levels can be considered to be generally equivalent in an aggregate or central tendency sense to CPLs of 20, 25, and 30 dv applied to a daily maximum daylight 4-hour $PM_{2.5}$ light extinction indicator.

As seen above, the adjusted 24-hour CPL can be greater than an "equivalent" 4-hour level. The regression-based Approach B is sensitive to specific cases where use of the monthly average historical f(RH) values yields higher estimates of light extinction than seen when using the actual same-day RH conditions. This appears to occur more frequently at the upper end of the 24-hour distribution (i.e., design values or 90^{th} percentiles). Figure G-7 shows three data points, out of 39, in which the annual 90^{th} percentile, 24-hour average $PM_{2.5}$ light extinction value are significantly greater than their daily maximum 4-hour daylight counterpart. These data points represent Tacoma (2007), Tacoma (2008), and Phoenix (2009). The most extreme case is Tacoma (2007). Because there are 51 observations for this site-year, the sixth high value is the 90^{th} percentile value. For the daily maximum 4-hour case the sixth high occurs on 10/9/2007 (22.93 dv). The average of the four hourly RH values that went into that day's calculation of the 4-hour indicator was 78%. For the 24-hour average case, the sixth high occurs on 11/02/2007 (26.74 dv). The 24-hour average of the RH values that went into that calculation was 89% (based on the monthly average RH estimates). On this day, the 4-hour value was only 17.23 dv (24th ranked) and the average of the four hourly RH values that went into that day's calculation of the 4-hour indicator was 59%. On the five higher 24-hour light extinction days in Tacoma in 2007, the RH used for the 24-hour calculation was, on average, 15% higher than the actual used for the sub-daily maximum. As a quick sensitivity analysis, we determined that if one were to remove these three data points (i.e., Tacoma (2007 and 2008) and Phoenix (2009)) from the Approach B regression analysis, the resulting CPLs would be: 20, 24, and 28 dv. While some of these RH differences are surely due to diurnal variations and are therefore inherent and appropriate in the CPL adjustment process, some may also be due to trends in RH over the years and/or site-related differences (the climatological values were based on spatial interpolation of only NWS monitoring sites, while many of the RH values used to calculate the 4-hour indicator were obtained from non-NWS instruments at the CSN site itself). Consideration should be given to re-executing the analysis in this Appendix using same-day, same-site relative humidity data, to eliminate the possibility that differences in humidity conditions between 1988-1997 and 2007-2009 and/or differences in RH sites have substantially affected the final equivalent levels.

In considering the results shown in Table G-6, it can be kept in mind that 1 deciview is about the amount that a person can distinguish when viewing scenic vistas, and that a difference of 1 deciview is equivalent to about a 10% difference in light extinction expressed in Mm^{-1}. Examining Table G-5, there are three cases in which comparing the original CPLs of 20, 25, and 30 dv to calculated 4-hour $PM_{2.5}$ light extinction produces a different outcome than comparing the adjusted CPLs of 21, 25, and 28 dv to calculated 24-hour $PM_{2.5}$ light extinction. Dallas is estimated to fail a 4-hour CPL of 25 dv, but to pass a 24-hour CPL of 25 dv, using an appropriate rounding convention. Philadelphia is estimated to fail a 4-hour CPL of 30 dv, but to pass a 24-hour CPL of 28 dv. Detroit is estimated to pass a 4-hr CPL of 30 dv, but to fail a 24-hr CPL of 28 dv. In each case, only a small difference in design value is responsible.

Table G-6. "Equivalent" Levels for Calculated 24-Hour $PM_{2.5}$ Light Extinction Using Five Approaches

Approach	Description	24-hour level equivalent to **20 dv** for 4-hour *(range among 15 cities)*	24-hour level equivalent to **25 dv** for 4-hour *(range among 15 cities)*	24-hour level equivalent to **30 dv** for 4-hour *(range among 15 cities)*
A	3-year 90th percentile design values regression	22 dv	25 dv	28 dv
B (Preferred)	Annual 90th percentile values regression	21 dv	25 dv	28 dv
C	All-days city-specific regressions, then averaged	19 dv *(17-20)*	23 dv *(20-24)*	27 dv *(24-29)*
D	All-days pooled regression	19 dv	23 dv	27 dv
E	Median ratios, then averaged	19 dv *(16-20)*	24 dv *(20-25)*	29 dv *(26-30)*

Table G-7. Intermediate Results for Approach C

Study Area	Intercept (Table G-3)	Coefficient (Table G-3)	20 dv equiv.	25 dv equiv.	30 dv equiv.
Tacoma, WA	1.520	0.948	20.47	25.21	29.95
Fresno, CA	-0.726	0.961	18.49	23.29	28.09
Los Angeles, CA	2.749	0.760	17.96	21.76	25.56
Phoenix, AZ	3.360	0.804	19.44	23.46	27.47
Salt Lake City, UT	-1.255	0.926	17.27	21.91	26.54
Dallas, TX	5.418	0.625	17.92	21.04	24.17
Houston, TX	10.224	0.500	20.22	22.72	25.22
St Louis, IL	6.563	0.655	19.67	22.95	26.22
Birmingham AL	7.210	0.684	20.89	24.31	27.73
Atlanta, GA	4.912	0.740	19.72	23.42	27.13
Detroit, MI	4.163	0.780	19.77	23.67	27.57
Pittsburgh, PA	4.101	0.828	20.66	24.80	28.94
Baltimore, MD	5.925	0.736	20.65	24.33	28.02
Philadelphia PA	2.797	0.761	18.02	21.82	25.63
New York, NY	8.109	0.626	20.62	23.75	26.88
Average			19.45	23.23	27.01
Minimum			17.27	21.04	24.17
Maximum			20.89	25.21	29.95

Table G-8. Intermediate Results for Approach E

Study Area	Median Ratio 4-hr : 24-hour (Table G-4)	20 dv equiv.	25 dv equiv.	30 dv equiv.
Tacoma, WA	1.015	19.70	24.63	29.55
Fresno, CA	1.097	18.23	22.79	27.35
Los Angeles, CA	1.172	17.06	21.32	25.59
Phoenix, AZ	0.962	20.80	25.99	31.19
Salt Lake City, UT	1.182	16.92	21.15	25.38
Dallas, TX	1.114	17.95	22.44	26.92
Houston, TX	0.972	20.58	25.73	30.87
St Louis, IL	1.057	18.92	23.64	28.37
Birmingham AL	0.986	20.29	25.37	30.44
Atlanta, GA	1.044	19.16	23.95	28.74
Detroit, MI	1.032	19.37	24.21	29.06
Pittsburgh, PA	0.987	20.27	25.33	30.40
Baltimore, MD	0.996	20.08	25.10	30.12
Philadelphia PA	1.150	17.39	21.73	26.08
New York, NY	1.018	19.65	24.56	29.47
Average		19.09	23.86	28.64
Minimum		16.92	21.15	25.38
Maximum		20.80	25.99	31.19

G.6 SUMMARY

EPA staff has investigated the possibility of using a particular calculated 24-hour average $PM_{2.5}$ light extinction as the indicator and averaging period for a secondary $PM_{2.5}$ NAAQS that would be aimed at controlling daily maximum daylight 4-hour average light extinction conditions, focusing on a form for both standards that is based on a three-year average of annual 90^{th} percentile values. A calculated 24-hour average approach would avoid data quality uncertainties that have recently been associated with currently available instruments for direct measurement of hourly $PM_{2.5}$ light extinction or for measurement of hourly $PM_{2.5}$ mass. The particular 24-hour indicator considered by EPA staff uses the original IMPROVE algorithm and long-term (1988-1997) relative humidity conditions to calculate light extinction due to $PM_{2.5}$. By using site-specific daily data on $PM_{2.5}$ composition and long-term relative humidity conditions interpolated to each specific site, this 24-hour average indicator would provide more consistent protection of visibility than would a secondary $PM_{2.5}$ NAAQS based only on 24-hour or annual average $PM_{2.5}$ mass. In particular, this approach would account for the systematic difference in humidity conditions between most eastern states and most western states. Possible variations include the use of the revised IMPROVE algorithm and the use of same-day measurements of relative humidity either at the visibility monitoring site or another site in the same area. These variations in the method used to calculate $PM_{2.5}$ light extinction on a 24-hour

basis would be expected to provide somewhat more consistent protection in areas across the country.

In concept, in order to provide generally equivalent protection, the level of a NAAQS based on a 24-hour average indicator should include an adjustment compared to the level that would be applied to a NAAQS based on a daily maximum daylight 4-hour average indicator. Using 15 study sites, EPA staff investigated five approaches to making this adjustment, for 4-hour indicator NAAQS levels of 20, 25, and 30 dv. An approach (B) thought by EPA staff to be more appropriate for further consideration yielded adjusted NAAQS levels of 21, 25, and 28 dv as the 24-hour $PM_{2.5}$ light extinction indicator levels that are generally equivalent in an aggregate or central tendency sense to levels of 20, 25, and 30 dv applied to a daily maximum daylight 4-hour $PM_{2.5}$ light extinction indicator.

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APPENDIX H

Table H-1. Predicted Number of Counties Not Likely to Meet Current Secondary $PM_{2.5}$ Standards and Potential Alternative Secondary Standards Based on a 4-Hour Calculated $PM_{2.5}$ Light Extinction Indicator[1]

Region >			All U.S.	Northeast	Southeast	Industrial Midwest	Upper Midwest	Southwest	Northwest	Southern California	Other Areas
Total # of counties with suitable data to calculate the indicator >			114	24	28	31	8	2	15	5	1
Standard		Statistic	Number of counties and percentage of counties with suitable data[2]								
Current Standards - $PM_{2.5}$ mass indicator											
Annual	24-Hour										
15 µg/m^3	35 µg/m^3	# counties	15	0	1	3	0	0	6	4	1
		% counties	13%	0%	4%	10%	0%	0%	40%	80%	100%
Alternative Standards – Calculated $PM_{2.5}$ Light Extinction Indicator											
Form[2]	Level (Mm^{-1})										
90th	25	# counties	96	23	22	31	6	1	7	5	1
		% counties	84%	96%	79%	100%	75%	50%	47%	100%	100%
90th	26	# counties	79	20	14	29	5	1	4	5	1
		% counties	69%	83%	50%	94%	63%	50%	27%	100%	100%
90th	27	# counties	58	17	6	27	1	0	1	5	1
		% counties	51%	71%	21%	87%	13%	0%	7%	100%	100%
90th	28	# counties	47	12	3	26	1	0	1	4	0
		% counties	41%	50%	11%	84%	13%	0%	7%	80%	0%
90th	29	# counties	32	10	0	16	1	0	1	4	0
		% counties	28%	42%	0%	52%	13%	0%	7%	80%	0%
90th	30	# counties	18	6	0	7	0	0	1	4	0
		% counties	16%	25%	0%	23%	0%	0%	7%	80%	0%

[1] 3-year average of annual 90th percentile daily maximum 4-hour daylight $PM_{2.5}$ light extinction, excluding hours with relative humidity >90%.

[2] Design values for comparison with the level of the standard were calculated based on approach T, using 2007-2009 monitoring data, if at least 2500 hours of 2005-2007 data were available. (See Appendix F for the description of approach T). Actual future outcomes may differ from these estimates due to changes in instrumentation, siting, and/or the specific procedure for calculating the indicator.

Table H-2. Predicted Number of Counties Not Likely to Meet Current Secondary $PM_{2.5}$ Standards and Potential Alternative Secondary Standards Based on a 24-Hour Average Calculated $PM_{2.5}$ Light Extinction Indicator[3]

Region >			All U.S.	Northeast	Southeast	Industrial Midwest	Upper Midwest	Southwest	Northwest	Southern California	Other Areas
Total # of counties with suitable data to calculate the indicator >			187	33	47	53	10	9	26	7	2
Standard		Statistic	Number of counties and percentage of counties with suitable data[2]								
Current Standards - $PM_{2.5}$ mass indicator											
Annual	24-Hour										
15 µg/m^3	35 µg/m^3	# counties	21	0	1	3	0	0	11	5	1
		% counties	11%	0%	2%	6%	0%	0%	42%	71%	50%
Alternative Standards – Calculated $PM_{2.5}$ Light Extinction Indicator											
Form[4]	Level (Mm^{-1})										
90th	25	# counties	122	26	28	49	4	0	8	6	1
		% counties	65%	79%	60%	92%	40%	0%	31%	86%	50%
90th	26	# counties	95	22	14	48	1	0	4	5	1
		% counties	51%	67%	30%	91%	10%	0%	15%	71%	50%
90th	27	# counties	72	16	5	42	0	0	3	5	1
		% counties	39%	48%	11%	79%	0%	0%	12%	71%	50%
90th	28	# counties	44	6	2	27	0	0	3	5	1
		% counties	24%	18%	4%	51%	0%	0%	12%	71%	50%

[3] 3-year average of annual 90th percentile 24-hour average $PM_{2.5}$ light extinction.
[4] Design values for comparison with the level of the standard were calculated based on the approach specified in Table G-2 using 2007-2009 monitoring data. Actual future outcomes may differ from these estimates due to changes in instrumentation, siting, and/or the specific procedure for calculating the indicator.

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