Responses to Significant Comments on the 2012 Proposed Rule on the National Ambient Air Quality Standards for Particulate Matter (June 29, 2012; 77 FR 38890)

Docket Number EPA-HQ-OAR-2007-0492

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Table of Contents

List of Acronyms

The following acronyms have been used for the sake of brevity in this document:

AAM	Alliance of Automobile Manufacturers
AAMMS	Ambient Air Monitoring and Methods Subcommittee
AASHTO	American Association of State Highway and Transportation Officials
ACC	American Chemistry Council
ACS	American Cancer Society
AFBF	American Farm Bureau Federation
AFPM	American Fuel & Petroleum Manufacturers
AHA	American Heart Association
ALA	American Lung Association
AMC	Appalachian Mountain Club
APHEA	Air Pollution and Health: A European Approach
APHENA	Air Pollution and Health: A European and North American Approach
API	American Petroleum Institute
AQCD	Air Quality Criteria Document
AQI	Air Quality Index
AQMD	Air Quality Management District
AQS	Air Quality System
ARMs	Approved Regional Methods
ARS	Air Resource Specialists
ATS	American Thoracic Society
BC	British Columbia
CAA	Clean Air Act
CAPs	Concentrated ambient particles
CASAC	Clean Air Scientific Advisory Committee
CBD	Center for Biological Diversity
CBSA	Core Based Statistical Area
CDC	Centers for Disease Control
CF	Cystic fibrosis
CFR	Code of Federal Regulations
CHPAC	Children's Health Protection Advisory Committee
CI	Confidence intervals
CPC	Coarse Particulate Matter Coalition
CPL	Candidate Protection Level
C-R	Concentration-response
CRA	Charles River Associates
CSA	Combined Statistical Area
CSN	Chemical Speciation Network
CVD	Cardiovascular disease
DC	District of Columbia
DEC	Department of Environmental Conservation
DEQ	Department of Environmental Quality
DOH	Department of Health

DOI	U.S. Department of the Interior
DPHE	Department of Public Health and Environment
df	Degrees of freedom
dv	Deciview
DV	Design value
EC	Elemental carbon
ED	Emergency department
EPA	U.S. Environmental Protection Agency
EPRI	Electric Power Research Institute
FEM	Federal Equivalent Method
FEV_1	Forced expiratory volume in one second, volume of air exhaled in first second of exhalation
FR	Federal Register
FRM	Federal Reference Method
GMA	Georgia Mining Association
IARC	International Agency Research on Cancer
IMPROVE	Interagency Monitoring of Protected Visual Environment
IHD	Ischemic heart disease
ISA	Integrated Science Assessment
ISEE	International Society for Environmental Epidemiology
IUGR	Intrauterine growth retardation
Km	Kilometer
LML	Lowest measured level
μg	Microgram
μm	micrometer, micron
$\mu g/m^3$	microgram per cubic meter
MCAPS	Medicare Air Pollution Study
Mm^{-1}	Inverse megameters, 1/(million meters)
MSA	Metropolitan Statistical Area
NAAQS	National ambient air quality standards
NACAA	National Association of Clean Air Agencies
NAM	National Association of Manufacturers
NCBA	National Cattlemen's Beef Association
NCore	National Core Monitoring Network
NEDA/CAP	National Environmental Development Association/Clean Air Project
NESCAUM	Northeast States Coordinated Air Use Management
NMA	National Mining Association
NMMAPS	National Morbidity, Mortality, and Air Pollution Study
NO_2	Nitrogen dioxide
NPCA	National Parks Conservation Association
NSSGA	National Stone, Sand, & Gravel Association
NTAA	National Tribal Air Association
O_3	Ozone
OC	Organic carbon
OM	Organic mass
PA	Policy Assessment

PACF	Partial autocorrelation function
PM	Particulate matter
$PM_{2.5}$	In general terms, particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 µm; a measurement of fine particles
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 system
$PM_{10\text{-}2.5}$	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 particles or the coarse fraction of PM_{10}
PRB	Policy-relevant background
PSR	Physicians for Social Responsibility
QA	Quality assurance
RA	Risk Assessment
REA	Risk and Exposure Assessment
RH	Relative humidity
RR	Relative risk
RTC	Responses to Comments
SANDWICH	Sulfate, Adjusted Nitrate, Derived Water, Inferred Carbonaceous mass approacH
SD	Standard deviation
SES	Socioeconomic status
SHS	Secondhand smoke
SIP	State Implementation Plan
SLAMS	State and local air monitoring stations
SO_2	Sulfur dioxide
TCEQ	Texas Commission on Environmental Quality
TSP	Total suspended particulate
UARG	Utility Air Regulatory Group
UFPs	Ultrafine particles
UFVA	Urban Focused Visibility Assessment
VAQ	Visual air quality
WESTAR	Western States Air Resources Council
WHI	Women's Health Initiative
WHO	World Health Organization

Frequently Cited Documents

The following documents are frequently cited throughout the EPA's response to comments

Integrated Science Assessment (ISA)

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: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_isa.html.

Risk Assessment (RA)

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: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

Urban-Focused Visibility Assessment (UFVA)

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: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html.

Policy Assessment (PA)

Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA 452/R-11-003. April 2011. Available: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pa.html.

Proposal

National Ambient Air Quality Standards for Particulate Matter: Proposed Rule. 77 FR 38890, June 29, 2012

Preamble to the final rule

Preamble to the Final Rule on the Review of the National Ambient Air Quality Standards for Particulate Matter; signed December 14, 2012

I. INTRODUCTION

This document, together with the preamble to the final rule on the review of the national ambient air quality standards (NAAQS) for particulate matter (PM), presents the responses of the Environmental Protection Agency (EPA) to the more than 230,000 public comments received on the 2012 PM NAAQS proposal notice (77 FR 38890, June 29, 2012). The EPA has addressed all significant issues raised in the public comments.

Due to the large number of comments that addressed similar issues, as well as the volume of the comments received, this response-to-comments document does not generally cross-reference each response to the commenter(s) who raised the particular issue involved, although commenters are identified in some cases where they provided particularly detailed comments that were used by the EPA to frame the overall response on an issue.

The responses presented in this document are intended to augment the responses to comments that appear in the preamble to the final rule or to address comments not discussed in that preamble. Although portions of the preamble to the final rule are paraphrased in this document where useful to add clarity to responses, the preamble itself remains the definitive statement of the rationale for the revisions to the standards adopted in the final rule.

In many instances, particular responses presented in this document include cross references to responses on related issues that are located either in the preamble to the PM NAAQS final rule, or in this Response to Comments (RTC) document. All issues on which the Administrator is taking final action in the PM NAAQS final rule are addressed in the PM NAAQS rulemaking record.

Accordingly, this RTC document, together with the preamble to the PM NAAQS final rule and the information contained in the Integrated Science Assessment (ISA, U.S. EPA, 2009a), Risk and Exposure Assessments (REAs, U.S. EPA, 2010a; U.S. EPA, 2010b) and the Policy Assessment (PA, U.S. EPA, 2011a), should be considered collectively as the EPA's response to all of the significant comments submitted on the EPA's 2012 PM NAAQS proposed rule. This document incorporates directly or by reference the significant public comments addressed in the preamble to the PM NAAQS final rule as well as other significant public comments that were submitted on the proposed rule.

Consistent with the final decisions presented in the notice of final rulemaking, comments on the primary standards for fine particles and for thoracic coarse particles are addressed separately in this document in sections II and III, respectively. Comments on secondary standards for fine and coarse particles are addressed below in section IV. Comments on related monitoring and implementation issues are addressed below in sections V and VI, respectively. Section VII includes responses to legal, administrative, procedural, or misplaced comments.

In the PM NAAQS proposal, the EPA recognized that there were a number of new scientific studies on the health effects of PM that had been published recently and, therefore, were not included in the ISA (77 FR at 383899, June 29, 2012). The EPA committed to conduct a review and assessment of any significant "new" studies, including studies submitted during the public comment period. The purpose of this review was to ensure that the Administrator was fully aware of the new science before making a final decision on whether to revise the current PM NAAQS. The EPA screened and surveyed the recent literature, including studies submitted during the public comment period, and conducted a provisional assessment that places the results of those studies of potentially greatest policy relevance in the context of the findings of the ISA. This provisional assessment, entitled *Provisional Assessment of Recent Studies on Health Effects of Particulate Matter Exposure* (US EPA, 2012a), is included as

Appendix A of this document. This RTC document is part of the basis for the EPA's responses to specific public comments on the "new" science.

II. RESPONSES TO SIGNIFICANT COMMENTS ON PROPOSED PRIMARY $PM_{2.5}$ STANDARDS

A. General Comments on Proposed Primary $PM_{2.5}$ Standards

A large number of comments on the proposed primary standards for $PM_{2.5}$ were very general in nature, basically expressing one of two substantively different views: (1) support for revisions to the primary standards to be more public health-protective or (2) opposition to any revision of the current $PM_{2.5}$ standards. Many of these commenters simply expressed their views without stating any rationale, while others gave general reasons for their views but without reference to the factual evidence or rationale presented in the proposal notice as a basis for the Agency's proposed decision. The preamble to the final rule in its entirety presents the Agency's response to these very general views.

Specific public comments on a range of issues related to the proposed primary $PM_{2.5}$ standards are addressed in the preamble to the final rule and/or in this document. In particular, significant public comments related to whether or not the current $PM_{2.5}$ standards should be revised are addressed in section III.D.2 of the preamble. Sections III.E.1, III.E.2, III.E.3, and III.E.4.c of the preamble discuss significant comments addressing the four basic elements of the standard: indicator, averaging time, form, and level, respectively. Significant comments on the revised Air Quality Index (AQI) for $PM_{2.5}$ are discussed in section V of the preamble. Significant comments on the data handling conventions for $PM_{2.5}$ are discussed in section VII.A of the preamble. Below, the EPA provides more specific responses to the full range of significant issues raised in the public comments on these issues.

B. Specific Comments on Proposed Primary $PM_{2.5}$ Standards

A large number of commenters provided more detailed comments regarding the proposal to revise the level and form of the primary annual $PM_{2.5}$ standard in conjunction with retaining the current 24-hour standard. Below, the EPA provides more detailed responses to the full range of significant issues raised in these comments.

1. Need to Revise Current Standards

This section responds to more detailed comments that either support or oppose any revision to the current $PM_{2.5}$ primary standards. The responses to these comments are generally discussed in section III.D.2 of the preamble to the final rule and discussed more fully below. Significant comments on specific long- and short-term exposure studies that relate to consideration of the appropriate level of the annual and 24-hour $PM_{2.5}$ standards are addressed in sections III.E.4.c.i and III.E.4.c.ii in the preamble to the final rule and discussed more fully below in sections II.B.5.a and II.B.5.b, respectively. Incorporating responses contained in sections III.E.4.c of the preamble to the final rule, the EPA provides the following responses to specific issues related to the need to revise the fine particle standards.

a. Support for Revising the Current Standards

Many public commenters asserted that the current $PM_{2.5}$ standards are insufficient to protect public health with an adequate margin of safety and that revisions to the standards are therefore appropriate within the meaning of section 109 (d) of the Act, indeed necessitated. Among those calling for revisions to the current standards were the Children's Health Protection Advisory Committee (CHPAC); major medical and public health groups including the American Heart Association (AHA), American Lung Association (ALA), American Public Health Association (APHA), American Thoracic Society (ATS); the Physicians for Social Responsibility (PSR); the International Society for Environmental Epidemiology (ISEE); major environmental groups such as the Clean Air Council, Clean Air Task Force, Earthjustice, Environmental Defense Fund (EDF), National Resources Defense Council (NRDC), and Sierra Club; many environmental justice organizations as well as medical doctors, academic researchers, health professionals, and many private citizens.

All of these medical and public health commenters stated that the current $PM_{2.5}$ standards need to be revised, and that even more protective standards than those proposed by the EPA are needed to adequately protect public health, particularly for at-risk populations. Many environmental justice organizations and individual commenters also expressed such views.

The National Association of Clean Air Agencies (NACAA), the Northeast States for Coordinated Air Use Management (NESCAUM), and many state and local air agencies and health departments who commented on the $PM_{2.5}$ standards supported revision of the suite of current $PM_{2.5}$ standards, as did five state attorneys general (Schneiderman et al., 2012) and the National Tribal Air Association (NTAA).

(1) *Comment:* In general, all of these commenters agreed on the importance of results from the large body of scientific studies and technical analyses presented and discussed in the Integrated Science Assessment (ISA), the Risk Assessment (RA), and the Policy Assessment (PA) and on the need to revise the $PM_{2.5}$ standards as articulated in section III.D of the preamble to the proposal. Many of these commenters, however, generally expressed views differing from the EPA's proposed judgments about the extent to which the standards should be revised based on this evidence, specifically for providing protection for at-risk populations. These commenters generally concluded that the body of evidence assessed in the ISA was stronger and more compelling than in the last review. In addition, these commenters generally placed much weight on the Clean Air Scientific Advisory Committee's (CASAC) interpretation of the body of available evidence and CASAC's recommendation to revise the $PM_{2.5}$ standards to provide increased public health protection. In arguing for more health protective standards, these commenters expressed the following specific views:

- Multiple, multi-city studies show clear evidence of premature mortality, cardiovascular and respiratory harm, as well as reproductive and developmental effects at ambient concentrations "far below the level of the current standard" (ALA, et al., 2012, p. 39). Specific studies cited by commenters included:
    - Extended analyses of seminal long-term exposure studies - the American Cancer Society (ACS) (Krewski et al., 2009a), Harvard Six Cities (Laden et al., 2006), and Southern California Children's Health (Gauderman et al., 2004) studies.

- Additional long-term exposure studies available in this review, specifically a study of premature mortality in older adults (Eftim et al., 2008) and the Women's Health Initiative (WHI) study of cardiovascular morbidity and mortality effects in women (Miller et al., 2007) providing stronger evidence of mortality and morbidity effects associated with long-term $PM_{2.5}$ exposures at lower concentrations than had previously been observed, including studies of effects in at-risk populations.

- A number of short-term $PM_{2.5}$ exposure studies providing evidence of mortality and morbidity effects at concentrations below the level of the current 24-hour $PM_{2.5}$ standard. Specifically, these commenters made note of multi-city studies of premature mortality (Zanobetti and Schwartz, 2009) and increased hospitalizations for cardiovascular and respiratory-related effects in older adults (Bell et al., 2008).

- Single-city short-term $PM_{2.5}$ studies "provide valuable information regarding impacts on susceptible populations and on health risk in areas with high peak to mean concentration ratios" (ALA, et al., 2012, p. 65).

- Progress has been made in reducing many of the uncertainties identified in the last review, in better understanding mechanisms by which $PM_{2.5}$ may be causing the observed health effects, and in improving our understanding of at-risk populations.

- The EPA's quantitative risk assessment concluded that the risks estimated to remain when the current standards are met are large and important from a public health perspective and warrant increased protection.

- $PM_{2.5}$-related risks are likely larger than those estimated in the RA, in part because the EPA focused on limited study areas and health endpoints. Some commenters cited to a recent study based on 2005 air quality data. In this study, the EPA staff published estimates that "peg the annual toll from $PM_{2.5}$ at 130,000 premature deaths each year"[1] (ALA et al., p. 5). Furthermore, "this analysis estimated a staggering 1.1 million life years lost among people over age 65, accounting for 7 percent of life years lost in 2005 in this population of elderly Americans. Looking at it another way, this translates into an average shortened lifespan of 8.5 months per individual affected. Further, the analysis estimated 1,800 deaths among babies and infants attributable to PM air pollution." *Id.*

- The EPA's distributional statistical analysis of population-level data (i.e., health event data and study population data) provided important information beyond a single statistical metric (e.g., mean) to consider in reaching decisions on the appropriate annual standard level.

Response: The EPA generally agrees with these commenters' conclusion regarding the need to revise the current suite of $PM_{2.5}$ standards. The scientific evidence noted by these

[1] Fann et al., 2012

commenters was generally the same as that assessed in the ISA and the PA, and the EPA agrees that this evidence provides a strong basis for concluding that the current $PM_{2.5}$ standards, taken together, are not requisite to protect public health with an adequate margin of safety, and they need to be revised to provide increased protection. For reasons discussed in section III.E.4.c of the preamble to the final rule and in section II.B.5 below, however, the EPA disagrees with aspects of these commenters' views on the level of protection that is appropriate.

In addition, with regard to progress made to better understand mechanisms by which $PM_{2.5}$ may be causing the observed health effects and to improve our understanding of at-risk populations, the EPA notes that CASAC found that the ISA clearly presented and discussed the current scientific information related to potential modes of action (Chapter 5) and at-risk populations (Chapter 8) (Samet, 2009e, pp. 7 to 8; Samet, 2009f, pp. 2 and 11 to 12).

(2) *Comment:* With regard to the scope of the literature reviewed for $PM_{2.5}$-related health effects, some commenters asserted that the EPA inappropriately narrowed the scope of the review by excluding a number of categories of relevant studies, specifically related to studies of diesel pollution and traffic-related pollution (ALA, et al., 2012, p. 17). These commenters argued that, based upon the exclusion of these types of studies, the ISA "came to the erroneous conclusion that the causal relationship between PM and cancer is merely suggestive. This conclusion does not square with the International Agency Research on Cancer (IARC) finding that diesel emissions are a known human carcinogen nor with the conclusions of the extended analyses of the [Harvard] Six Cities and ACS cohort studies that report positive and statistically significant associations between $PM_{2.5}$ and lung cancer." *Id.*

Response: The EPA disagrees with these commenters' views that diesel exhaust studies were excluded from the ISA and were not considered when making the causality determination for cancer, mutagenicity, and genotoxicity. As discussed in section 7.5 of the ISA, diesel exhaust studies were integrated within the broader body of scientific evidence that was considered in reaching the causality determination for these health endpoints. Additionally, as discussed in section 1.5.3 of the ISA, the evidence from diesel exhaust studies was also considered as part of the collective evidence evaluated when making determinations for other, noncancer health outcomes (e.g., cardiovascular and respiratory effects). Specifically, when evaluating this evidence, the ISA focused on understanding the effects of diesel exhaust particles. It is important to recognize that the ISA focused on diesel exhaust studies that evaluated exposures that were relevant to ambient concentrations, i.e., "within one or two orders of magnitude of ambient PM concentrations" (U.S. EPA, 2009a, section 1.3). The causal determination for cancer, mutagenicity, and genotoxicity presented in the ISA represents an integration of experimental and observational evidence of exposures to ambient PM concentrations. The EPA fully considered the findings of studies that assessed these and other health effects associated with exposure to diesel particles in reaching causality determinations regarding health outcomes associated with $PM_{2.5}$ exposures.

In developing the second draft ISA, the EPA reexamined the controlled human exposure and toxicological studies of fresh diesel and gasoline exhaust. This information, in addition to other considerations, supported a change in the causal determinations for ultrafine particles. Specifically, in reevaluating the causal determinations for short-term ultrafine particle exposures and cardiovascular and respiratory effects, the EPA changed the classification from “inadequate” to “suggestive” for both categories of health outcomes (Vandenberg, 2009, p. 3). CASAC agreed with the EPA’s rationale for revising these causal determinations (Samet, 2009f, pp. 2 and 10).

With regard to traffic studies, the EPA disagrees with the commenters’ views that traffic studies that focused on exposure indicators such as distance to roadways should have been included in the ISA. These studies were excluded from consideration because they did not measure ambient concentrations of specific air pollutants, including $PM_{2.5}$, but instead were studies evaluating exposure to the undifferentiated “traffic related air pollution” mixture (ALA et al., 2012, p.17) (U.S. EPA, 2009a, section 1.3). As a result, these studies do not add to the collective body of evidence on the relationship between long- or short-term exposure to ambient concentrations of $PM_{2.5}$ and health effects.

(3) *Comment*: A number of commenters argued that by making the standards more protective, the $PM_{2.5}$ NAAQS would be more consistent with other existing standards (e.g., California's annual average standard of 12 $\mu g/m^3$) (CARB, 2012; CA OEHHA, 2012). Some commenters argued that “in the intervening decade since the California standard was established, substantial new information regarding adverse health effects at lower concentrations supports setting a more protective standard (ALA et al, 2012, p. 23). Other commenters argued that revising the primary $PM_{2.5}$ standards would be more consistent with the recommendations of the World Health Organization (WHO) and/or Canada (e.g., ALA et al., 2012, pp. 22 and 62; ISEE, 2012, p. 2; MOE-Ontario, 2012, p. 1).

Response: In considering these comments, the EPA notes that the Administrator’s decision on setting an appropriate annual standard level is constrained by the provision of the CAA that requires that the primary NAAQS be requisite to protect public health with an adequate margin of safety. This requires that her judgment is to be based on an interpretation of the evidence that neither overstates nor understates the strength and limitations of the evidence, or the appropriate inferences to be drawn from the evidence. This is not the same legal framework that governs the standards set by the State of California or Canada or the guidelines established by a working group of scientists within the WHO. For example, the California statute does not refer to setting a standard that is ‘‘requisite’’ to protect, as that term is used in the CAA, and California, unlike EPA, may take economic impacts into consideration in setting air quality standards. In addition, as with the WHO guidelines, the standards appear to be more in the nature of goals as compared to binding requirements that must be met.

As discussed in section III.E.4.d of the preamble for the final rule, the Administrator has considered the epidemiological and other scientific evidence, estimates of risk reductions associated with just meeting alternative standards, air quality analyses, related limitations and uncertainties, the advice of CASAC, and the extensive public comments on the proposal in reaching her conclusions regarding final decision on the appropriate primary annual $PM_{2.5}$ standard level, consistent with the requirements of the CAA.

(4) *Comment:* Some of these commenters also identified "new" studies that were not included in the ISA as providing further support for the need to revise the $PM_{2.5}$ standards.

Response: In the proposal, the EPA recognized that there were a number of new scientific studies on the health effects of PM that had been published since the mid-2009 cutoff date for inclusion in the ISA (77 FR 38899). As discussed in section II.B.3 of the preamble to the final rule, the EPA conducted a provisional assessment of "new" science published since the close of the ISA including studies submitted to the EPA during the public comment period. The purpose of the provisional science assessment was to ensure that the Administrator was fully aware of the "new" science that has developed since 2009 before making final decisions on whether to retain or revise the current PM NAAQS.

Specifically, the EPA screened and surveyed the recent health literature, including but not limited to studies submitted during the public comment period, and conducted a provisional assessment (U.S. EPA, 2012b) that places the results of those studies of potentially greatest policy relevance in the context of the findings of the ISA (U.S. EPA, 2009a). This provisional assessment, including a summary of the key conclusions is included in Appendix A to this RTC document.

The provisional assessment found that the "new" studies expand the scientific information considered in the ISA and provide important insights on the relationship between PM exposure and health effects. The provisional assessment also found that "new" studies generally strengthen the evidence that long- and short-term exposures to fine particles are associated with a wide range of health effects (i.e. the strongest causality determination possible under the EPA framework). Although some of the "new" epidemiological studies report effects in areas with lower $PM_{2.5}$ concentrations than those in earlier studies considered in the ISA, and "new" toxicological and epidemiological studies continue to link various health effects with a range of fine particle sources and components, the provisional assessment found that the results reported in "new" studies do not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the ISA.

As further noted in section II.B.3 of the preamble to the final rule, as in prior NAAQS reviews, the EPA is basing its decision in this review on studies and related information included in the ISA, RA, and PA, which have undergone CASAC and public review. The studies assessed in the ISA, and the integration of the scientific evidence presented in that document, have undergone extensive critical review by the EPA, CASAC, and the public during the development of the ISA. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS. NAAQS decisions can have profound impacts on public health and welfare, and NAAQS decisions are based on studies that have been rigorously assessed in an integrative manner not only by the EPA but also by the statutorily-mandated independent advisory committee, CASAC, and have been subjected as well to the public review that accompanies this process. As described above, the provisional assessment did not and could not provide that kind of in-depth critical review.

This decision is consistent with the EPA's practice in prior NAAQS reviews. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria. *See* e.g., 36 FR 8186 (April 30, 1971) (the EPA based original NAAQS for six pollutants on scientific studies discussed in air quality criteria documents and limited consideration of comments to those concerning validity of scientific basis); 38 FR 25678, 25679 to 25680 (September 14, 1973) (the EPA revised air quality criteria for sulfur oxides to provide basis for reevaluation of secondary NAAQS). This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the CAA concerning CASAC review of air quality criteria. The EPA has consistently followed this approach. 52 FR 24634, 24637 (July 1, 1987) (after review by CASAC, the EPA issued a post-proposal addendum to the PM Air Quality Criteria Document (AQCD), to address certain new scientific studies not included in the 1982 AQCD); 61 FR 25566, 25568 (May 22, 1996) (after review by CASAC, the EPA issued a post-proposal supplement to the 1982 AQCD to address certain new health studies not included in the 1982AQCD or 1986 Addendum). The EPA reaffirmed this approach in its decision not to revise the ozone NAAQS in 1993, as well as in its final decision on the PM NAAQS in the 1997 and 2006 reviews. 58 FR 13008, 13013 - 13014 (March 9, 1993) (ozone review); 62 FR 38652, 38662 (July 18, 1997) and 71 FR 61141, 61148 -61149 (October 17, 2006) (PM reviews) (The EPA conducted a provisional assessment but based the final PM decisions on studies and related information included in the air quality criteria that had been reviewed by CASAC).

As discussed in the EPA's 1993 decision not to revise the NAAQS for ozone, "new" studies may sometimes be of such significance that it is appropriate to delay a decision on revision of NAAQS and to supplement the pertinent air quality criteria so the "new" studies can be taken into account (58 FR at 13013 to 13014, March 9, 1993). In this 2012 review of the PM NAAQS, the provisional assessment of recent studies concludes that, taken in context, the "new" information and findings do not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the ISA (U.S. EPA, 2012b). For this reason, reopening the air quality criteria review would not be warranted even if there were time to do so under the court order governing the schedule for this rulemaking. Accordingly, the EPA is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review. The EPA will consider the "new" published studies for purposes of decision making in the next periodic review of the PM NAAQS, which will provide the opportunity to fully assess them through a more rigorous review process involving the EPA, CASAC, and the public.

(5) *Comment:* Some commenters encouraged the EPA to consider emerging evidence for a broader range of health outcomes. For example, one commenter urged the EPA "to exercise a high level of vigilance in order to identify and act on additional peer-reviewed

studies that may strengthen a putative link between PM and diabetes and neurodegenerative diseases" (PSR, 2012, p. 7).

Response: The EPA agrees that additional research could expand our understanding of a broader range of health outcomes (e.g., central nervous system effects) and potential additional at-risk populations (e.g., diabetics). The PA highlighted a number of areas for future health-related research, model development, and data collection activities that could provide important evidence for informing future PM NAAQS reviews (U.S. EPA, 2011a, section 2.5). The EPA will consider all policy-relevant studies published in the peer-review literature, including "new" studies published since the close of the ISA in its next PM NAAQS review.

b. Support for Retaining the Current Standards

Another group of commenters opposed revising the current $PM_{2.5}$ standards. These views were most extensively presented in comments from the Utility Air Regulatory Group (UARG), representing a group of electric generating companies and organizations and several national trade associations; the American Petroleum Institute (API) representing more than 500 oil and natural gas companies; the National Association of Manufacturers (NAM), the American Chemistry Council (ACC), the American Fuel & Petroleum Manufacturers (AFPM), the Alliance of Automobile Manufacturers, and other manufacturing associations; the Electric Power Research Institute (EPRI); and the Texas Commission on Environmental Quality (Texas CEQ). These commenters generally mentioned many of the same studies that were cited by the commenters who supported revising the standards, as well as other studies, but highlighted different aspects of these studies in reaching substantially different conclusions about their strength and the extent to which progress has been made in reducing uncertainties in the evidence since the last review. Furthermore, they asserted that the evidence that has become available since the last review does not establish a more certain risk or a risk of effects that are significantly different in character to those that provided a basis for the current standards, nor does the evidence demonstrate that the risk to public health upon attainment of the current standards would be greater than was understood when the EPA established the current standards in 2006.

These commenters generally expressed the view that the current standards provide the requisite degree of public health protection. In supporting their view, these commenters generally argued that the EPA's conclusions are inconsistent with the current state of the science and questioned the underlying scientific evidence including the causal determinations reached in the ISA. More specifically, this group of commenters argued that:

- the EPA did not apply its framework for causal determination consistently across studies or health outcomes and, in the process, the EPA relied on a selective group of long- and short-term exposure studies to reach conclusions regarding causality
- toxicological and controlled human exposure studies do not provide supportive evidence that the health effects observed in epidemiological studies are biologically plausible
- uncertainties in the underlying health science are as great or greater than in the PM NAAQS review completed in2006

- there is no evidence of greater risk since the last review to justify tightening the current annual $PM_{2.5}$ standard
- "new" studies not included in the ISA continue to increase uncertainty about possible health risks associated with exposure to $PM_{2.5}$

These comments and other similar comments are addressed below.

(1) *Comment:* Multiple commenters asserted that the EPA did not apply its framework for causal determinations consistently across studies or health outcomes (API, 2012, Attachment 1, p. 30).[2] These commenters further contended that the EPA relied on a selective group of long- and short-term $PM_{2.5}$ exposure studies when making causality determinations in the ISA (ACC, 2012, Attachment A, pp. 1 to 2; API, 2012, pp. 18 to 20; API, 2012, Attachment 1, p. 30; NAM et al., 2012, pp. 22 to 25; Texas CEQ, 2012, pp 2 to 3; UARG, Attachment 1, p. 17 to 23). These allegations included: "cherry-picking studies" and ignoring a number of studies that reported no association with $PM_{2.5}$.

Response: The EPA disagrees with these commenters' assertion that the EPA did not consistently apply the causality framework. The EPA's evaluation of the scientific evidence and its application of the causal framework used in the current PM NAAQS review was the subject of exhaustive and detailed review by CASAC and the public. Prior to finalizing the ISA, two drafts were released for CASAC and public review to evaluate the scientific integrity of the documents. Evidence related to the substantive issues raised by CASAC and public commenters with regard to the content of the first and second draft ISAs were discussed at length during these public CASAC meetings and considered in developing the final ISA. CASAC supported the development of the EPA's causality framework and its use in the current PM NAAQS review and concluded:

> The five-level classification of strength of evidence for causal inference has been systematically applied; this approach has provided transparency and a clear statement of the level of confidence with regard to causation, and we recommend its continued use in future Integrated Science Assessments (Samet 2009f, p. 1).

The EPA disagrees with these commenters' views on assessing the health effects evidence and on their conclusions regarding the causality determinations reached in the ISA. The commenters' specifically focused on counting the number of epidemiological studies that reported results with statistical significance without regard to other considerations that are important in a comprehensive evaluation of the evidence. Specifically, the EPA recognizes the distinction between evaluation of the *relative scientific quality of individual study results*, and the evaluation of the *pattern of results within the broader body of scientific evidence* and considered both in reaching causality determinations and in determining the form and level of the $PM_{2.5}$ and PM_{10} standards. The more detailed characterizations of individual studies included an assessment of the

[2] The EPA notes that the same concerns about the causal determinations presented in the ISA were raised in comments to CASAC on the first and second draft ISAs (e.g., UARG, 2009; API, 2009; ACC, 2012, Appendix B). CASAC, therefore, had the opportunity to consider these comments as it reached consensus conclusions that the EPA had consistently and appropriately applied the causality framework, as well as its consensus agreement on the causality determinations themselves.

quality of the study, which was based on specific criteria as described in the ISA (U.S. EPA, 2009a, section 1.5.3).

Statistical significance is an indicator of the precision of a study's results, which is influenced by a variety of factors including, but not limited to, the size of the study, exposure and measurement error, and statistical model specifications. Statistical significance is just one of the means of evaluating the validity of the relationships determined with epidemiological studies. The EPA can reasonably look to other indicia of reliability such as the consistency and coherence of a body of studies as well as other confirming data to justify reliance on the results of a body of epidemiological studies, even if individual studies may lack statistical significance. *American Trucking Association v. EPA*, 283 F. 3d 355, 371 (D.C. Cir. 2002). As a result, in developing an integrated assessment of the health effects evidence for PM, the EPA has emphasized the importance of examining the *pattern of results* across various studies and their coherence and consistency, and has not focused solely on *statistical significance* as a criterion of study reliability.

It has been clearly articulated throughout the epidemiological and causal inference literature that it is important not to focus on results of statistical tests to the exclusion of other information. For example, Rothman (1998) stated: "Many data analysts appear to remain oblivious to the qualitative nature of significance testing [and that]… statistical significance is itself only a dichotomous indicator. As it has only two values, significant or not significant." As a result, Rothman recommended that P-values be omitted as long as point and interval estimates are available.

The concepts underlying the EPA's approach to evaluating statistical associations reported for the health effects on $PM_{2.5}$ have been discussed in numerous publications, including a report by the U.S. Surgeon General on the health consequences of smoking (Centers for Disease Control and Prevention, 2004). This report cautions against over-reliance on statistical significance in evaluating the overall evidence for an exposure-response relationship:

Hill made a point of commenting on the value, or lack thereof, of statistical testing in the determination of cause: "No formal tests of significance can answer those [causal] questions. Such tests can, and should, remind us of the effects the play of chance can create, and they will instruct us in the likely magnitude of those effects. Beyond that, they contribute nothing to the 'proof' of our hypothesis" (Hill 1965, p. 299).

Hill's warning was in some ways prescient, as the reliance on statistically significant testing as a substitute for judgment in a causal inference remains today (Savitz et al., 1994; Holman et al., 2001; Poole 2001). To understand the basis for this warning, it is critical to recognize the difference between *inductive inferences* about the truth of underlying hypotheses, and *deductive statistical calculations* that are relevant to those inferences, but that are not inductive statements themselves. The latter include p values, confidence intervals, and hypothesis tests (Greenland 1998; Goodman 1999). The dominant approach to statistical inference today, which employs those statistical measures, obscures this important distinction between deductive and inductive inferences

(Royall 1997), and has produced the mistaken view that inferences flow directly and inevitably from data. There is no mathematical formula that can transform data into a probabilistic statement about the truth of an association without introducing some formal quantification of external knowledge, such as in Bayesian approaches to inference (Goodman 1993; Howson and Urbach, 1993). Significance testing and the complementary estimation of confidence intervals remain useful for characterizing the role of chance in producing the association in hand (CDC, 2003, pp. 23 to 24).

Accordingly, the statistical significance of findings from an individual study has played an important role in the EPA's evaluation of the study's results and overall the EPA has placed greater emphasis on studies reporting statistically significant results in making determinations as to the elements of the standard. In particular, as noted in section III.E.4.b.i of the preamble to the final rule, the EPA identified long- and short-term exposure studies considered "key" multi-city studies for consideration for informing the decisions on the appropriate standard levels and included those studies observing effects for which the evidence supported a *causal* or *likely causal* association. Figure 4 in the preamble to the final rule (also Figure 4 in the proposal, 77 FR 38933) represents the subset of multi-city studies included in Figures 1 through 3 of the preamble to the final rule (also Figures 1 through 3 in the proposal, 77 FR 38929 to 38931) that provided evidence of positive and generally statistically significant effects associated in whole, or in part, with more recent air quality data, generally representing health effects associated with lower $PM_{2.5}$ concentrations than had previously been considered in the last review. The EPA notes that many of these studies evaluated multiple health endpoints, and not all of the effects evaluated provided evidence of positive and statistically significant effects. For purposes of informing the Administrator's decision on the appropriate standard levels, the Agency considers the full body of scientific evidence and focuses on those aspects of the key studies that provided evidence of positive and generally statistically significant effects..

However, in the broader evaluation of the evidence from many epidemiological studies, and subsequently during the process of forming causality determinations, the EPA has emphasized the pattern of results across epidemiological studies for drawing conclusions on the relationship between $PM_{2.5}$ and health outcomes, and whether the effects observed are coherent across the scientific disciplines. Thus, in making causality determinations, the EPA did not limit its focus or consideration to just studies that reported positive associations or where the results were statistically significant.

As discussed in section III.D.2 of the preamble to the final rule, the EPA notes that the final causality determinations presented in the ISA reflected CASAC's recommendations on the second draft ISA (Samet, 2009f, pp. 2 to 3). Specifically, CASAC supported the EPA's changes (in the second versus first draft ISA) from "likely causal" to "causal" for long-term exposure to $PM_{2.5}$ and cardiovascular effects and for cancer and $PM_{2.5}$ (from "inadequate" to "suggestive"). *Id*. Furthermore, CASAC recommended "upgrading" the causality classification for $PM_{2.5}$ and total mortality to "causal" for both the short- and long-term timeframes. *Id.* With regard to mortality, the "EPA carefully reevaluated the body of evidence, including the collective evidence for biological plausibility for mortality effects, and determined that a causal relationship exists for short- and long-term exposure to $PM_{2.5}$ and mortality, consistent with the CASAC comments" (Jackson, 2012). With respect to ultrafine particles, in developing the second draft ISA, the EPA reexamined the controlled human exposure and toxicological studies of fresh diesel and gasoline exhaust This information, in addition to other considerations, supported a change in the causal determinations for ultrafine particles. Specifically, in reevaluating the causal determinations for short-term ultrafine particle exposures and cardiovascular and respiratory effects, the EPA changed the classification from "inadequate" to "suggestive" for both categories of health outcomes (Vandenberg, 2009, p. 3). CASAC agreed with the EPA's rationale for revising these causal determinations (Samet, 2009f, p. 10).

(2) *Comment:* Some commenters asserted that the EPA inappropriately used the Hill criteria by failing to consider the limitations of studies with weak associations, thereby overstating the consistency of the observed associations (API, 2012, Attachment 1, pp. 30 to 35). Specifically, these commenters argued that risk estimates greater than 3 to 4 reflect strong associations supportive of a causal link, while smaller risk estimates (i.e., 1.5 to 3) are considered to be weak and require other lines of evidence to demonstrate causality. Additionally, these commenters believed that the EPA downplayed *null* or inconsistent findings in numerous long-term mortality studies with reported $PM_{2.5}$ concentrations above and below the level of the current annual standard (e.g., *Id.*; NAM et al., 2012, p. 9).

Response: As discussed in section 1.5.3 of the ISA, the EPA thoroughly considered the uncertainties and limitations of all studies during its evaluation of the scientific literature (U.S. EPA, 2009a, pp. 1 to 14). This collective body of evidence, including known uncertainties and limitations of the studies evaluated, were considered by the EPA (and reviewed by the CASAC) during the process of forming causality determinations as discussed in Chapters 6 and 7 of the ISA. For example, the EPA concluded that "a causal relationship exists between short-term $PM_{2.5}$ exposure and cardiovascular effects"; however, in reaching this conclusion, the Agency recognized and considered limitations of the current evidence that still requires further examination (U.S. EPA, 2009a, section 6.2.12.1). Therefore, the commenters have mischaracterized the EPA's process. The limitations of the studies, and their uncertainties, were noted and considered by the EPA.

The EPA also disagrees with the commenters' assertion that the magnitude of the association must be large to support a determination of causality. As discussed in the ISA, the strength of the observed association is an important aspect to aid in judging causality and "while large effects support causality, modest effects therefore do not preclude it" (U.S. EPA, 2009a, Table 1-2, section 1.5.4).[3] The weight of evidence approach used by the EPA encompasses a multitude of factors of which the magnitude of the association is only one component (U.S. EPA, 2009a, Table 1-3). An evaluation of the association across multiple investigators and locations supports the "reproducibility of findings [which] constitutes one of the strongest arguments for causality" (U.S. EPA, 2009a, Table 1-2). Even though the risk estimates for air pollution studies may be

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[3] For example, environmental tobacco smoke (second-hand smoke) causes lung cancer in humans, even though the magnitude of the association is small (U.S. EPA, 1992).

modest, the associations are consistent across hundreds of studies as demonstrated throughout the ISA (U.S. EPA, 2009a, Figures 2-1, 6-27, and 7-7). Furthermore, the causality determinations rely on different lines of evidence, by integrating evidence across disciplines, including animal toxicological studies and controlled human exposure studies.

The EPA recognizes that the population potentially affected by $PM_{2.5}$ is considerable, including large subgroups of the U.S. population that have been identified as at-risk populations (e.g., children, older adults, persons with underlying cardiovascular or respiratory disease). While individual effect estimates from epidemiological studies may be modest in size, the public health impact of the mortality and morbidity associations can be quite large given that exposure to airborne $PM_{2.5}$ is ubiquitous. Indeed, with the large population exposed, exposure to a pollutant causally associated at a population level with mortality and serious illness has significant public health consequences, virtually regardless of the relative risk. Taken together, this information indicates that exposure to ambient $PM_{2.5}$ concentrations has substantial public health impacts.

Additionally, the EPA disagrees with the commenter that long-term $PM_{2.5}$ exposure studies with null or inconsistent findings were not accurately presented in the ISA. For example, as discussed throughout section 7.6 and depicted in Figures 7-6 and 7-7, the EPA presented the collective evidence from all studies that examined the association between long-term $PM_{2.5}$ exposure and mortality. Overall, across these studies there was evidence of consistent positive associations in different cohorts. That evidence in combination with the biological plausibility provided by experimental studies evaluated in sections 7.1 and 7.2 of the ISA supported that a causal relationship exists between long-term $PM_{2.5}$ exposure and mortality, which is consistent with CASAC advice (Samet, 2009f, pp. 2 to 3).

(3) *Comment:* Some commenters argued that in some cases, the EPA used the same study and the same underlying database to conclude that there was a causal association between mortality and multiple criteria pollutants. These commenters contended, "[i]n doing so, the EPA attributes the cause of the mortality effects observed to whichever criteria pollutant it is reviewing at the time" (API, 2012, pp. 14 to 16).

Response: The EPA strongly disagrees that the Agency "attributes the cause of mortality effects observed to whichever criteria pollutant it is reviewing at the time." The EPA consistently recognizes that other pollutants are also associated with health outcomes, as is reflected in the fact that the EPA has established NAAQS to limit emissions of the particulate criteria pollutants as well as other gaseous criteria pollutants. Epidemiological studies often examine the association between short- and long-term exposures to multiple air pollutants and mortality within a common dataset in an attempt to identify the air pollutant(s) of the complex mixture most strongly associated with mortality. It is important to recognize that more than one pollutant can have effects on the same system; in fact, it is not reasonable to assume that effects can be attributed to only one pollutant and to exclude effects of all other pollutants.

The EPA carefully considers evidence from experimental studies providing information on mode(s) of action in evaluating the overall weight of the scientific evidence to develop causal judgments. In evaluating these studies, the EPA employs specific study selection criteria to identify those studies most relevant to the review of the NAAQS. In its assessment of the health evidence regarding $PM_{2.5}$, the EPA has carefully evaluated the potential for confounding, effect measure modification and the role of PM as a component of a complex mixture of air pollutants (U.S. EPA, 2009a, pp. 1 to 9). The EPA used a rigorous weight of evidence approach to inform its causality determinations that evaluated consistency across studies within a discipline, evidence for coherence across disciplines, and biological plausibility. Additionally, during this process, the EPA assessed the limitations of each study in the context of the collective body of evidence. It was the collective evidence, not one individual study that ultimately determined whether a causal relationship exists between $PM_{2.5}$ and specific health outcomes.

In the ISA, the combination of epidemiological, toxicological, and controlled human exposure studies formed the basis for the Agency concluding that a causal relationship exists between short- or long-term $PM_{2.5}$ exposures and total mortality (U.S. EPA, 2009a, sections 2.3.1.1 and 2.3.1.2). This was the first time that the Agency concluded that a causal relationship exists between short-or long-term exposure to a criteria pollutant and mortality.

Additionally, while the EPA has evaluated the studies used to inform the causality determination for $PM_{2.5}$ in ISAs for other criteria air pollutants, the Agency has done so in the context of examining the *collective body of evidence* for each of the respective criteria air pollutants. Therefore, the EPA disagrees with the commenter that the underlying database used in the PM ISA was also used in concluding a causal relationship exists between mortality and other criteria pollutants. As discussed in the recently-completed ISAs for nitrogen oxides, sulfur oxides and carbon monoxide, the EPA did not conclude that a causal relationship exists with mortality and these criteria pollutants due to either short- or long-term exposures (U.S. EPA, 2008e, 2008f, 2010k).

(4) *Comment:* A number of commenters questioned the underlying scientific basis used in the ISA to conclude that a causal relationship exists between long-term $PM_{2.5}$ exposure and mortality. Specifically, commenters asserted that evidence from two studies, Janes et al. (2007) and Greven et al. (2011), indicated that the association between long-term $PM_{2.5}$ exposures and mortality is subject to unmeasured confounding. The commenters further asserted that these studies therefore indicated that unmeasured confounding is inherent in all long-term exposure studies of mortality (UARG, 2012, pp. 10 to 11, Attachment A, pp. 17 to 23; API, 2012, pp. 13 to 14, Attachment 1, pp. 11 to 14, Attachment 7, pp 3 to 10; ACC, 2012, p. 18 to 21; AFPM, 2012, p. 8; TCEQ, 2012, p. 4; EPRI, 2012, p. 3). In addition, all of the authors of the Janes et al. (2007) and Greven et al. (2011) publications, (i.e., Francesca Dominici, Scott Zeger, Holly Janes, and Sonja Greven) submitted a joint comment to the public docket in order to clarify specific points regarding these two studies (Dominici et al. 2012).

Response: The EPA evaluated the study by Janes et al. (2007) in the ISA (U.S. EPA, 2009a, p. 7-88) and evaluated the study by Greven et al. (2011) (an extension of the study by Janes et al. (2007) incorporating three additional years of data) in the Provisional

Science Assessment (U.S. EPA, 2012b). In the EPA's evaluation of the relationship between long-term exposure to $PM_{2.5}$ and mortality, the Janes et al. (2007) study was included in the body of evidence that supported the determination that a causal relationship existed (U.S. EPA, 2009a, section 7.6.5.1). For the reasons discussed below, the EPA does not agree with the commenters' views that these two studies call into question the scientific merit or the consistency of the results of long-term exposure studies of mortality that contribute to this body of evidence.

Both studies used nationwide Medicare mortality data to examine the association between monthly averages of $PM_{2.5}$ over the preceding 12 months and monthly mortality rates in 113 U.S. counties and examined whether community-specific trends in monthly $PM_{2.5}$ concentrations and mortality declined at the same rate as the national rate. The investigators examined this by decomposing the association between $PM_{2.5}$ and mortality into two components: (1) "national" trends, defined as the association between the national average trend in monthly $PM_{2.5}$ concentrations averaged over the previous 12 months and the national average trend in monthly mortality rates and (2) "local" trends, defined as county-specific deviations in monthly $PM_{2.5}$ concentrations and monthly mortality rates from national trends.

The EPA does not question the results of the national trends analyses conducted by Janes et al. (2007) and Greven et al. (2011).[4] Both Janes et al. (2007) and Greven et al. (2011) observed positive and statistically significant associations between long-term exposure to $PM_{2.5}$ and mortality in their national analyses. However, Janes et al. (2007) and Greven et al. (2011) eliminated all of the spatial variation in air pollution and mortality in their data set when estimating the national effect, focusing instead on both chronic (yearly) and sub-chronic (monthly) temporal differences in the data (Dominici et al. 2012). Janes et al. (2007) (Table 1) highlighted that over 90 percent of the variance in the data set used for the analyses conducted by both Janes et al. (2007) and Greven et al. (2011) was attributable to spatial variability, which the authors chose to discard. The focus of the analyses by Janes et al. (2007) and Greven et al. (2011) was on two components: (1) a temporal or time component, i.e., the "national" trends analysis, which examined the association between the national average trend in monthly $PM_{2.5}$ concentrations averaged over the previous 12 months and the national average trend in monthly mortality rates and (2) a space-by-time component, i.e., the "local" trends analysis, which examined county-specific deviations in monthly $PM_{2.5}$ concentrations and monthly mortality rates from national trends. These two components combined comprised less than 10 percent of the variance in the data set. The authors included a focus on the space-by-time component, which represented approximately 5 percent of the variance in the data set, in an attempt to identify, absent confounding, if $PM_{2.5}$ was associated with mortality at this unique exposure window. Thus, the national effects reported in these studies are not directly comparable to other cohort studies investigating the relationship between long-term exposure to $PM_{2.5}$ and mortality, which make use of spatial variability in air

[4] In its evaluation of Janes et al. (2007) in the ISA, the EPA did not identify limitations in the statistical methods used *per se* (U.S. EPA, 2009a, p. 7-88) and included the results of the national-scale analyses in that study in the body of evidence that supported the determination that there is a causal relationship between long-term $PM_{2.5}$ exposure and mortality.

pollution and mortality data.[5] Indeed, the study authors noted expressly that "when one considers that this wealth of [spatial] information is not accounted for in that study, it is not as surprising that we see vastly different estimates of the $PM_{2.5}$/mortality relationship than in other studies that do exploit that variability" (Dominici et al. 2012, p. 2).

For the local analyses, both Janes et al. (2007) and Greven et al. (2011) observed associations between exposure to $PM_{2.5}$ and mortality that are near the null value, often negative, and not statistically significant. The fact that the authors did not observe an association in the local analyses is not surprising. As stated in Janes et al. (2007), they were estimating "associations between temporal changes in exposure and outcomes within counties relative to the national trend." However, a limitation of the analysis conducted by Janes et al. (2007) [and subsequently by Greven et al. (2011)], and recognized in a commentary by Pope and Burnett (2007), is the use of *monthly* average $PM_{2.5}$ concentrations to examine associations at the local scale. This is a limitation because such an exposure assignment approach does not provide enough exposure contrast to observe temporal changes in mortality. The ISA (U.S. EPA, 2009a, p. 7-88) recognized comments made by Pope and Burnett (2007) that pointed out that the conclusions of Janes et al (2007) "are overstated. . . their analysis tells us little or nothing about unmeasured confounding in those and related studies because the methodology of Janes et al largely excludes the sources of variability that are exploited in those other studies. By using monthly mortality counts and lagged 12-month average pollution concentrations, the authors eliminate the opportunity to exploit short-term or day-to-day variability."

Furthermore, the EPA disagrees with commenters that Janes et al. (2007) and Greven et al. (2011) provide evidence that other studies of long-term exposure to $PM_{2.5}$ and mortality are affected by unmeasured confounding. As noted above, the design of the studies conducted by Janes et al (2007) and Greven et al (2011) are fundamentally different than those used in other studies of long-term exposure to $PM_{2.5}$ and mortality, including the ACS cohort and the Harvard Six Cities study. Studies, such as the ACS and Harvard Six Cities studies, used the spatial variation between cities to measure the effect of long-term (annual) exposures to $PM_{2.5}$ on mortality risk, and did not conduct any analyses relying on the temporal variation in $PM_{2.5}$. The opposite is true of the Janes et al. (2007) and Greven et al. (2011) studies which first removed the spatial variability in $PM_{2.5}$ and then examined the temporal variation at both the national and local scale to measure the effects of temporal differences in $PM_{2.5}$ on mortality risk. Janes et al. (2007) and Greven et al. (2011) focus on changes in $PM_{2.5}$ concentrations over time and therefore control for confounders would be based on including variables that vary over time rather than over space. As a result, any evidence of potential confounding of the $PM_{2.5}$-mortality risk relationship derived from Janes et al. (2007) and Greven et al. (2011)

[5] Though not directly comparable, the effect estimates for mortality reported by Janes et al. (2007) and Greven et al. (2011) were coincidentally similar in magnitude to those previously reported in other long-term cohort studies. It is important to note that previous cohort studies focused on identifying spatial differences in $PM_{2.5}$ concentrations between cities, while Janes et al. (2007) and Greven et al. (2011) primarily focused on temporal differences in $PM_{2.5}$ concentrations. In fact, Greven et al. (2011) stated, "We do not focus here on a third type [of statistical approach] used in cohort studies, measuring the association between average $PM_{2.5}$ levels and average age-adjusted mortality rates across cities (purely spatial or cross-sectional association)."

cannot be extrapolated to draw conclusions related to potential spatial confounding in studies based on the spatial variation in $PM_{2.5}$ concentrations.

As detailed in the ISA (U.S. EPA, 2009a, section 7.6), and recognized by the authors of Janes et al. (2007) and Greven et al. (2011), the cohort studies that informed the causality determination for long-term $PM_{2.5}$ exposure and mortality “have developed approaches to adjust for measured and unmeasured confounders” (Dominici et al. 2012). These approaches were specifically designed to adjust for spatial confounding. The hypothesis that the authors of Janes et al. (2007) and Greven et al. (2011) chose to examine was that differences in the local and national effects indicate unmeasured temporal confounding in either the local or national effect estimate. This hypothesis was specific to these two studies that examined temporal variability in exposure to air pollution and did not include known potential confounders at either the national or local scale as covariates in the statistical model. The authors acknowledged that the interpretation of either the national or local estimates needs to occur with an appreciation of the potential confounding effects of national and local scale covariates that were omitted from the model (Dominici et al., 2012). It is important to recognize that because Janes et al. (2007) and Greven et al. (2011) focused on variations in $PM_{2.5}$ over time and not space, the results from these two studies do not provide any indication that other studies of long-term exposure to $PM_{2.5}$ and mortality exhibit spatial confounding, or that $PM_{2.5}$ does not cause mortality. [6] The authors of Janes et al. (2007) and Greven et al. (2011) recognized “it is entirely possible that these papers are looking for an association at a timescale for which no association truly exists” (Dominici et al. 2012, p.3).

Specific comments by UARG (UARG, 2012, Attachment A, pp. 19 to 23) stated that there are flaws in the criticisms offered by Pope and Burnett (2007) on the paper by Janes et al. (2007). First, the commenters did not agree with Pope and Burnett (2007) that data used by Janes et al. (2007) was too aggregate (i.e., using deaths and $PM_{2.5}$ concentrations averaged over months rather than days does not provide adequate temporal variability) to detect short-term variation. The commenters stated that most of the long-term cohort studies of mortality rely on even more aggregate timescales that are multi-year averages.

The EPA agrees that many of the long-term cohort studies rely on timescales that are aggregated beyond monthly averages (as was done by Janes et al., 2007) in multi-city studies where spatial variability in exposure is being examined. However, Janes et al. (2007) discounted all of the spatial variability in their analyses. Thus, the EPA agrees with the criticism by Pope and Burnett (2007) that when looking within a single city or geographic area, as Janes et al. (2007) did in their “local” analysis, there was not enough variability in exposure to aggregate exposure at the monthly level instead of the daily level.

Second, the commenters took issue with the critique by Pope and Burnett (2007) that the use of county-level fixed effects eliminated the source of long-term average spatial variability. As stated by the commenters, “To estimate the new model developed by Janes

[6] Further, the EPA notes that Janes et al. (2007) and Greven et al. (2011) provide no information relevant to examining confounding in studies of short-term exposure to $PM_{2.5}$.

et al. (2007a), they must use other sources of variation: they must use temporal and spatial-temporal variation" (UARG, 2012, Attachment A, p. 21). While this may be true, as mentioned above, the Medicare mortality dataset used by the authors does not have adequate temporal resolution to look at spatial-temporal variation in the "local" analyses conducted by Janes et al (2007) and reanalyzed by Greven et al. (2011). As noted by Janes et al. (2007) (See Table 1), and discussed by Dominci et al. (2012) only 5 percent of the variance in the data set used in these analyses is attributable to the space by time component. Therefore, although Janes et al. (2007) and Greven et al. (2011) attempt to use temporal and spatial-temporal variation in the data set to examine associations between $PM_{2.5}$ exposure and mortality as stated by the commenters, there is not enough temporal variability to identify associations using this approach.

Third, the commenters identified the critique by Pope and Burnett (2007) that the analysis by Janes et al. (2007) was limited by the scale of the study (i.e., three years), which did not allow for consideration of longer-term variability in mortality and air pollution data. The commenters stated that "[a]ll researchers are limited by the data available to them, and Janes et al. (2007a) used only three years in their analysis because that is all the data they had available" (UARG, 2012, Attachment A, p. 21). While the EPA acknowledges that the researchers may be limited by the data available to them, scientists must decide whether those limitations enable them to answer the scientific question that they are posing. Because the Medicare mortality was aggregated at the monthly level, it could take decades and decades of data to provide the appropriate exposure contrast to conduct these analyses.

There were also specific comments suggesting that the study by Greven et al. (2011) substantiated the results of Janes et al. (2007). Specifically, the commenters stated that Greven et al. (2011) used "station-level" data instead of county level data, added three additional years of data to the study period, incorporated controls for socio-economic confounders, and investigated trends at the regional level (UARG, 2012, Attachment A, p. 22). While these may be improvements upon the original study by Janes et al. (2007), Greven et al. (2011), like Janes et al. (2007), eliminated all of the spatial variation in their data set. Therefore, the results in Greven et al. (2011) similar to Janes et al. (2007), are not comparable to, nor would they invalidate, the results of cohort studies investigating the relationship between long-term exposure to $PM_{2.5}$ and mortality (Dominici et al. 2012, p. 1.).

One commenter suggested that the epidemiological results from studies of long-term exposure to $PM_{2.5}$ and mortality characterized in the ISA are inconsistent and discordant, indicating significant confounding (API, 2012, Attachment 7, pp. 2 to 10). This commenter pointed to the study by Greven et al. (2011) as an example of a study that avoids such potential confounding. The EPA disagrees with this comment. As demonstrated in the ISA, there is a large body of evidence supporting the association between long-term exposure to $PM_{2.5}$ and mortality that generally reports consistent, positive relative risks (U.S. EPA 2009a, Figures 7.6 and 7.7). The EPA does not interpret these results as being "inconsistent and discordant".

This commenter also suggested that the data used by Greven et al. (2011) were "superior or comparable to data used in other studies of $PM_{2.5}$ and mortality" ((API, 2012, Attachment 7, p. 5). For example, the commenter claimed that Greven et al. (2011) used data from more locations than other researchers. Specifically, this commenter pointed out that Greven et al. (2011) included data from 814 ZIP code areas while Pope et al. (2009) focused on 211 county units. The EPA acknowledges that Greven et al. (2011) used a more spatially resolved data set (i.e., ZIP codes instead of counties), but points out that the study by Greven et al. (2011) includes data from just 113 counties, compared to the 211 counties included in Pope et al. (2009). Furthermore, while this enhanced spatial resolution may help to reduce exposure measurement error, the focus on the study by Greven et al. (2011) was on temporal variability in exposure, and in this case does not provide additional exposure contrast. We consequently do not accept the conclusion that the data set in Greven (2011) was superior to that in other studies.

In addition, the commenter cited the use of monthly average mortality data as a strength of the study by Geven et al. (2011), when, in fact, for a study focusing on temporal variability in exposure, daily average mortality would be preferable. The EPA thus considers the use of monthly-average mortality data in the study as a limitation, not strength. Finally, the commenter acknowledged that the study by Greven et al. (2011) did not include any individual-level covariates, but had to rely on county- and month-level information for potential confounders, including smoking whereas other cohort studies have used individual-level data (e.g., the ACS cohort (Pope et al., 2002)). For these reasons, the EPA disagrees with the commenters' views that the study by Greven et al. (2011) is superior to other cohort studies of long-term exposure to $PM_{2.5}$ and mortality.

In summary, the EPA does not question the quantitative results presented by Janes et al. (2007) and Greven et al. (2011); however, the EPA disagrees that the results of these studies are comparable to the results of other cohort studies of long-term exposure to $PM_{2.5}$ and mortality, or that the results presented in these two studies invalidate either the results themselves, or the consistency of the results observed across other cohort studies of long-term exposure to $PM_{2.5}$ and mortality. Janes et al. (2007) and Greven et al. (2011) chose to eliminate the spatial variability in the air pollution and mortality data. Thus, the results of these studies cannot be directly compared to time-series studies of short-term exposure to $PM_{2.5}$ and mortality (which rely on day-to-day changes in $PM_{2.5}$ concentrations and mortality) because the authors only use temporal variability measured on a monthly scale. Nor can the results of these studies be directly compared to cohort studies of long-term exposure to $PM_{2.5}$ and mortality (which rely on the spatial variability of air pollution concentrations and mortality) because their analyses include a fixed effect for county in the regression model which eliminates spatial variability when estimating the national effect. Additionally, Janes et al. (2007) and Greven et al. (2011) use a different time scale in their analyses compared to the timescales used in other cohort studies. Janes et al. (2007) and Greven et al. (2011) examined whether an association exists at a sub-chronic (i.e., monthly) time scale. Thus, the results of the study by Janes et al. (2007) are included in the ISA and contributed to the body of evidence for an association between long-term $PM_{2.5}$ exposures and mortality, but are not directly comparable to other cohort studies that rely on a different timescale and focus on spatial variability.

As demonstrated in the ISA, there is a large body of evidence supporting the association between long-term exposure to $PM_{2.5}$ and mortality that generally reports consistent relative risks between 1.0 and 1.5 (U.S. EPA 2009a, Figures 7.6 and 7.7). Based on this large body of evidence, the EPA concluded that a causal relationship exists between long-term exposure to $PM_{2.5}$ and mortality (U.S. EPA, section 7.6.5.1). The results presented by Janes et al. (2007) and Greven et al. (2011) are not comparable to the results of these studies of long-term exposure to $PM_{2.5}$ and mortality. Therefore, the EPA concludes that these studies do not invalidate the large body of epidemiological evidence that supports the EPA's determination that a causal relationship exists between long-term $PM_{2.5}$ exposure and mortality. [7]

(5) *Comment:* Some commenters questioned the use of epidemiological studies in assessing the adequacy of the current PM NAAQS because "of the untestable assumptions on which much of air pollution epidemiology, along with EPA's proposed NAAQS revisions, are built" (ACC, 2012, pp. 20 to 21). These commenters made this claim based on a recent publication by Moore et al. (2012), which they asserted demonstrates that "most, if not all, results from epidemiologic studies of air pollution – requires reliance on untestable and possible invalid assumptions, and that the alternative analyses designed to meet such assumptions can produce different (e.g., null instead of positive) results" (ACC, 2012, p. 20).

Response: The EPA disagrees with the commenters' views that the results of the recently published Moore et al. (2012) study bring into question the epidemiological evidence used to inform whether or not the PM NAAQS should be revised. First, the Moore et al. (2012) study focused on evaluating effects associated with ozone (O_3) exposures, which brings into question its relevance in the context of considering the available scientific evidence for the PM NAAQS review. This study was not included in the ISA or considered in the Provisional Science Assessment as this study did not include consideration of measured ambient $PM_{2.5}$ concentrations. Second, Moore et al. (2012) examined heat as a potential confounder of the O_3-asthma hospital admission relationship. For PM, temperature is also a known potential confounder, but a number of studies have demonstrated that alternative approaches to controlling for the potential confounding effects of weather do not influence PM risk estimates (e.g., Welty and Zeger (2005), as discussed on p. 6-163 and 6-164, U.S. EPA, 2009a). Therefore, the study by Moore et al. (2012) does not inform the relationship between $PM_{2.5}$ exposure and health effects.

(6) *Comment:* With regard to toxicological and controlled human exposure studies, some commenters argued that the available evidence does not provide coherence or biological plausibility for health effects observed in epidemiological studies (API, 2012, pp. 21 to 22, Attachment 1, pp. 25 to 29; AAM, 2012, pp. 15 to 16; Texas CEQ, 2012, p. 3). With regard to the issue of mechanisms, these commenters noted that although the EPA recognizes that new evidence is now available on potential mechanisms and plausible biological pathways, the evidence provided by toxicological and controlled human

[7] We note that the EPA's conclusion with regard to interpretation of the results from Janes (2007) and Greven (2012) is supported by the study *authors'* conclusion that "[o]ur results do not invalidate previous epidemiologic studies" (Dominici (2012) p. 1 (emphasis original)).

exposure studies still does not resolve all questions about how $PM_{2.5}$ at ambient concentrations could produce the mortality and morbidity effects observed in epidemiological studies. More specifically, for example, some of these commenters stated that:

> A review of the Integrated Science Assessment, however, suggests that the experimental evidence is inconsistent and not coherent with findings in epidemiology studies. Specifically, the findings of mild and reversible effects in most experimental studies conducted at elevated exposures are not consistent with the more serious associations described in epidemiology studies (e.g., hospital admissions and mortality). Also, both animal studies and controlled human exposure studies have identified no effect levels for acute and chronic exposure to PM and PM constituents at concentrations considerably above ambient levels. The EPA should consider the experimental findings in light of these higher exposure levels and what the relevance may be for ambient exposures (API, 2012, Attachment 1, p. 25).

Response: The EPA notes that in the review completed in 1997, the Agency considered the lack of demonstrated biological mechanisms for the varying effects observed in epidemiological studies to be an important caution in its integrated assessment of the health evidence upon which the standards were based (71 FR 61157, October 17, 2006). In the review completed in 2006, the EPA recognized the findings from additional research that indicated that different health responses were linked with different particle characteristics and that both individual components and complex particle mixtures appeared to be responsible for many biologic responses relevant to fine particle exposures. *Id*. Since that review, there has been a great deal of research directed toward advancing our understanding of biological mechanisms. While this research has not resolved all questions, and further research is warranted (U.S. EPA, 2011a, section 2.5), it has provided important insights as discussed in section III.B.1 of the proposal (77 FR at 38906 to 38909) and discussed more fully in the ISA (U.S. EPA, 2009a, chapter 5).

As noted in the proposal, toxicological studies provide evidence to support the biological plausibility of cardiovascular and respiratory effects associated with long- and short-term $PM_{2.5}$ exposures observed in epidemiological studies (77 FR 38906) and provide supportive mechanistic evidence that the cardiovascular morbidity effects observed in long-term exposure epidemiological studies are coherent with studies of cardiovascular-related mortality (77 FR 38907). The ISA concluded that the new evidence available in this review "greatly expands" upon the evidence available in the last review "particularly in providing greater understanding of the underlying mechanisms for $PM_{2.5}$ induced cardiovascular and respiratory effects for both short- and long-term exposures" (U.S. EPA, 2009a, p. 2-17). The mechanistic evidence now available, taken together with newly available epidemiological evidence, increases the Agency's confidence that a causal relationship exists between long- and short-term exposure to $PM_{2.5}$ and cardiovascular effects and mortality. In addition, CASAC supported the ISA approach and characterization of potential mechanisms or modes of action (Samet, 2009e, pp. 7 to 8; Samet, 2009f, p. 11), as well as the findings of a causal relationship at the population level between exposure to $PM_{2.5}$ and mortality and cardiovascular effects (Samet, 2009f, pp. 2 to 3).

Additionally, the EPA disagrees with commenters that the mild and reversible effects observed in controlled human exposure studies are inconsistent with the more serious effects observed in epidemiological studies. Ethical considerations regarding the types of studies that can be performed with human subjects limit the effects that can be evaluated to those that are transient, reversible, and of limited short-term consequence. The relatively small number of subjects recruited for controlled exposure studies should also be expected to have less variability in health status and risk factors than occurring in the general population.[8] Consequently, the severity of health effects observed in controlled human exposure studies evaluating the effects of $PM_{2.5}$ should be expected to be less than observed in epidemiological studies. Nonetheless, that effects are observed in healthy individuals participating in controlled exposure studies serves as an indication that $PM_{2.5}$ is initiating adverse health responses and that more severe responses may reasonably be expected in a more diverse population, specifically, in at-risk populations. Put another way, there are serious public health risks from exposure of large populations of people including those with pre-existing illnesses, to ambient concentrations of $PM_{2.5}$, but these are not the same as the very small risks that individuals who do not have such conditions face when participating in a controlled human exposure study.

It should also be noted that there is a small body of toxicological evidence demonstrating mortality in rodents exposed to $PM_{2.5}$ (e.g., Killingsworth et al. 1997). Overall, it is not surprising that lethality is not induced in more toxicological research, as these types of studies do not readily lend themselves to this endpoint. Epidemiological studies have observed associations between $PM_{2.5}$ and mortality in communities with populations in the range of many thousands to millions of people. Clearly, it is not feasible to expose hundreds (if not thousands) of animals to $PM_{2.5}$ (potentially over many years) in a laboratory setting to induce enough lethalities to distinguish between natural deaths and those attributable to $PM_{2.5}$. Furthermore, the heterogeneous human populations sampled in epidemiological studies are comprised of individuals with different physical, genetic, health, and socioeconomic backgrounds which may impact the outcome. However, in toxicological studies, the rodent groups most frequently evaluated are typically inbred, such that inter-individual variability is minimized. Thus, if the rodent strain used is quite robust, $PM_{2.5}$-induced effects may not be observed at low exposure concentrations.

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[8] For example, the EPA excludes from its controlled human exposure studies involving exposure to $PM_{2.5}$ any individual with a significant risk factor for experiencing adverse effects from such exposure. Thus, the EPA excludes *a priori* the following categories of persons: those with a history of angina, cardiac arrhythmias, and ischemic myocardial infarction or coronary bypass surgery; those with a cardiac pacemaker; those with uncontrolled hypertension (greater than 150 systolic and 90 diastolic); those with neurogenetive diseases; those with a history of bleeding diathesis; those taking beta-blockers; those using oral anticoagulants; those who are pregnant, attempting to become pregnant, or breastfeeding; those who have experienced a respiratory infection within four weeks of exposure; those experiencing eye or abdominal surgery within six weeks of exposure; those with active allergies; those with a history of chronic illnesses such as diabetes, cancer, rheumatologic diseases, immunodeficiency state, known cardiovascular disease, or chronic respiratory diseases; smokers. The EPA "Application for Independent Review Board Approval of Human Subjects Research: Cardiopulmonary Effects of healthy Older GSTM1 Null and Sufficient individuals to Concentrated Ambient Air Particles (CAPTAIN)," Nov. 9, 2011, p. 9.

(7) *Comment:* A number of commenters disagreed with the EPA's evaluation of specific long-term $PM_{2.5}$ exposure and mortality studies (e.g., ACC, 2012, pp. 6 to 14; AAM, 2012, pp. 6 to 18) and contended that the EPA's evaluation of the scientific evidence fails to accurately reflect the latest scientific knowledge. Common points raised by these commenters were that the results from long-term exposure studies were limited because they: (a) found biologically implausible risk estimates; (b) estimated $PM_{2.5}$ concentrations for years in which data were not available; and (c) did not account for exposure misclassification.

Response: The EPA carefully evaluated "the body of evidence, including the collective evidence for biological plausibility for mortality effects, and determined that a causal relationship exists for …long-term exposure to $PM_{2.5}$ and mortality, consistent with CASAC comments" (Jackson, 2012). This evaluation of the evidence included review of the potential limitations mentioned by commenters. Furthermore, CASAC supported the EPA's evaluation of the scientific evidence and the application of the causal framework in making a causal determination for mortality attributed to long-term PM exposures (Samet, 2009f, pp. 2 to 3). Below, the EPA responds to each of the specific limitations noted by commenters:

(a) With respect to biological plausibility, some commenters argued that the estimated associations between ambient PM and mortality are stronger than those for long-term heavy cigarette smoking, thereby defying biological plausibility (ACC, 2012, pp. 6 to 7). The comparison of smoking and ambient PM-related effect estimates was not considered relevant for the PM NAAQS review and, thus, was not considered in the ISA. This issue was not raised during the CASAC and public review of the drafts of the ISA. In order to address the comments submitted, the EPA conducted a provisional review of the "new" literature published since the close of the ISA including studies cited by commenters, and identified several relevant studies that compared and evaluated effect estimates determined for relationships between specific health outcomes and ambient particulate matter and active smoking (Pope et al. 2009; Pope et al. 2011). These authors analyzed data from the ACS cohort in order to evaluate the shape of the exposure-response relationship for $PM_{2.5}$ and both lung cancer mortality (Pope et al. 2011) and cardiovascular disease (CVD) mortality (Pope et al. 2009; Pope et al. 2011). In these studies, the authors evaluated three sources of exposure to $PM_{2.5}$: active smoking, passive smoking, and ambient air pollution.

For lung cancer mortality, the authors observed "a monotonic, nearly linear exposure response relationship with fairly constant marginal increases in RR [relative risk] with increasing exposure" across the full range of observed exposures (Pope et al. 2011). When the authors evaluated CVD mortality, they observed "an exposure-response relationship that is substantially non-linear, that is, much steeper at the very low levels of exposure compared with higher levels of exposure" (Pope et al. 2011). In fact, the study authors noted that "For lung cancer mortality, the RRs steadily increase to nearly 40 at the highest increment of cigarette smoking (>42 cigarettes per day), whereas for CVD mortality, the RRs level off at approximately 2.0-2.5" (Pope et al. 2011, Figure 1).

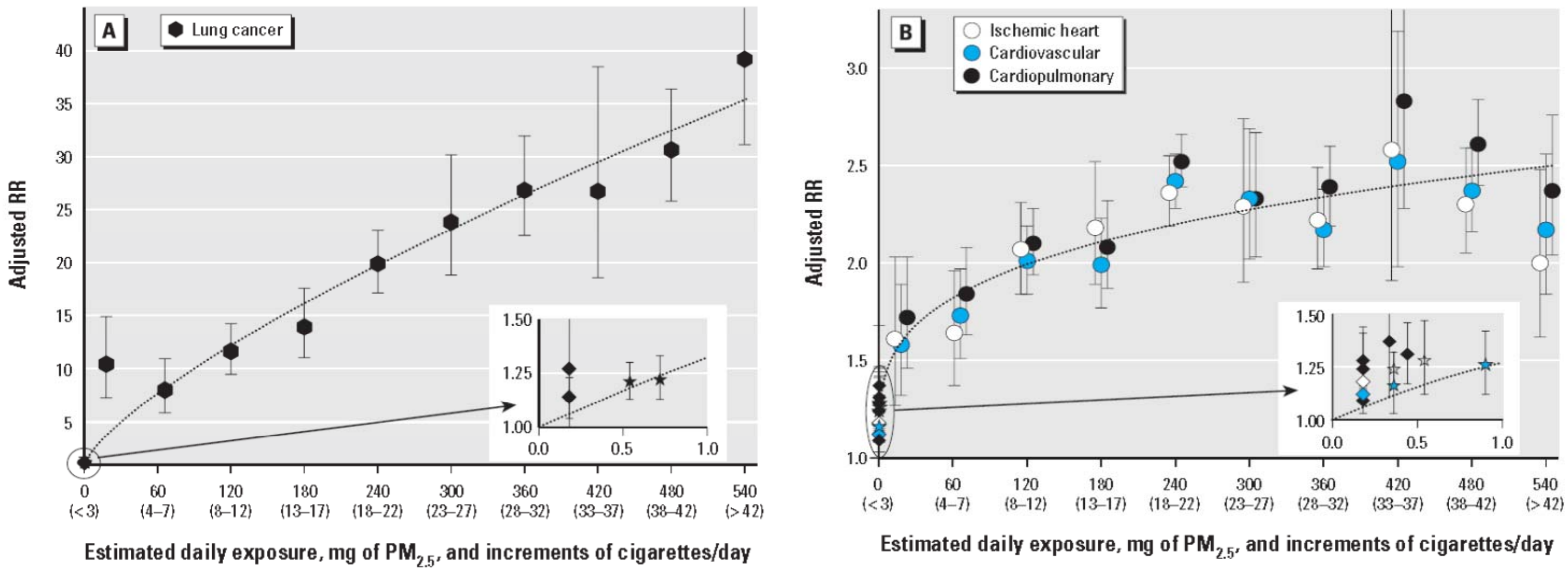


Figure 1. Adjusted RRs [with 95% confidence intervals (CIs)] of lung cancer mortality (A) and IHD, cardiovascular, and cardiopulmonary mortality (B) plotted over estimated daily exposure of $PM_{2.5}$ (milligrams) and increments of cigarette smoking relative to never smokers (cigarettes/day). Diamonds represent comparative mortality risk estimates (with 95% CIs) for $PM_{2.5}$ from air pollution from the comparative studies (Dockery et al. 1993; Laden et al. 2006; Miller et al. 2007; Pope et al. 1995, 2002, 2004). Stars represent comparable pooled RR estimates (with 95% CIs) associated with SHS exposure from comparative studies (Teo et al. 2006; U.S. Department of Health and Human Services 2006). The dotted lines represent the nonlinear power function fit through the origin and the estimates (including active smoking, SHS, ambient $PM_{2.5}$). Estimated doses from different increments of active smoking are dramatically larger than estimated doses from ambient pollution or SHS; therefore, associations at lower exposure levels (due to ambient air pollution and SHS) are shown as insets with a magnified scale. Source: Pope et al. 2011.

Because of the much steeper exposure-response relationship for long-term exposure to $PM_{2.5}$ and CVD mortality at low $PM_{2.5}$ concentrations, which flattens out at higher $PM_{2.5}$ concentrations (i.e., those associated with passive and active cigarette smoking), it is biologically plausible that the risk estimates for CVD mortality due to exposure to ambient concentrations of $PM_{2.5}$ would be similar to risk estimates for CVD mortality due to active cigarette smoking. These results are consistent with the results observed in epidemiological studies of long-term exposure to $PM_{2.5}$ and mortality, and with the conclusions drawn in the ISA. For example, Dockery et al. (1993) found essentially the same risk estimates for CVD mortality associated with both ambient $PM_{2.5}$ concentrations and active cigarette smoking in an area with relatively high levels of ambient $PM_{2.5}$ concentration. Thus, contrary to views expressed by commenters, the EPA concludes that the scientific evidence provides biologically plausibility for the mortality effects observed in epidemiological studies of ambient PM.

(b) With regard to estimating $PM_{2.5}$ exposure for periods when data are not available, as discussed in section III.E.4.c.i of the preamble to the final rule and in section II.B.5.a.i below, both in the last review and the current review, the EPA has assessed studies that used different air quality periods for estimating long-term exposure and tested associations with mortality for the different exposure periods (U.S. EPA, 2004, section 8.2.3.5; U.S. EPA 2009a, section 7.6.4). In this review, the ISA discussed studies available since the last review that have assessed the relationship between long-term exposure to $PM_{2.5}$ and mortality to explore the issue of the latency period between exposure to $PM_{2.5}$ and death (U.S. EPA, 2009a, section 7.6.4).

Notably, in a recent analysis of the extended Harvard Six Cities Study, Schwartz et al. (2008) used model averaging (i.e., multiple models were averaged and weighted by probability of accuracy) to assess exposure periods prospectively. The exposure periods were estimated across a range of unconstrained distributed lag models (i.e., same year, one year prior, two years prior to death). In comparing lags, the authors reported that the effects of changes in exposure to $PM_{2.5}$ on mortality were strongest within a two-year period prior to death (U.S. EPA, 2009a, p. 7-92, Figure 7-9). Similarly, a large multi-city study of the elderly found that the mortality risk associated with long-term exposure to PM_{10} reported cumulative effects that extended over the years that deaths were observed in the study population (i.e., the follow-up period) and for the three-year period prior to death (Zanobetti et al., 2008).

Further, in a study of two locations that experienced an abrupt decline in $PM_{2.5}$ concentrations (i.e., Utah Steel Strike, coal ban in Ireland), Röösli et al. (2005) reported that approximately 75 percent of health benefits were observed in the first 5 years (U.S. EPA, 2009a, Table 7-9). Schwartz et al. (2008) and Puett et al. (2008) found, in a comparison of exposure periods ranging from 1 month to 48 months prior to death that exposure to PM_{10} 24 months prior to death exhibited the strongest association, and the weakest association was reported for exposure in the time period of 1 month prior to death.

Collectively, the EPA notes that the available evidence for determining the window over which the mortality effects of long-term PM exposures occur, as discussed above and in section III.E.4.c.i of the preamble to the final rule and in section II.B.5.a.i below, suggests that a latency period of up to five years would account for the majority of deaths, with the strongest association observed in the two years prior to death. Further, the EPA recognizes that there is no discernible population-level threshold below which effects would not occur, such that health effects may occur over the full range of concentrations observed in the epidemiological studies, including the lower concentrations in the latter years. (U.S. EPA, 2009a, section 2.4.2.3). In light of this evidence and these considerations, the EPA concludes that it is appropriate to consider air quality concentrations that are contemporaneous with the collection of health event data (i.e., collected over the same time period) as being causally associated with at least some proportion of the deaths assessed in a long-term exposure study.

In addition, the EPA acknowledges that the appropriate exposure period for mortality effects observed in long-term exposure studies may extend up to a few years prior to the years in which health event data were collected. Such an extended exposure window would likely more fully capture the $PM_{2.5}$-related deaths in such studies. To explore how much higher the long-term mean $PM_{2.5}$ concentrations would likely have been had air quality data prior to the follow-up years of the studies been included, the EPA conducted a sensitivity analysis of long-term mean $PM_{2.5}$ concentrations (Schmidt, 2012a), particularly, considering studies that only included deaths from a relatively recent follow-up period. As examples of such studies, this analysis considered the Eftim et al. (2008) study of mortality in the ACS sites and the Harvard Six Cities sites, as well as sites in the eastern region in the Zeger et al. (2008) study. Using data from the EPA's AQS database, the analysis added the two years of air quality data just prior to the follow-up period in each study, which was 2000 to 2002 in Eftim et al. (2008) and 2000 to 2005 in Zeger et al. (2008). The analysis then calculated the extended long-term mean $PM_{2.5}$ concentration for each study. As discussed in Schmidt (2012a), in each case the long-term mean $PM_{2.5}$ concentration averaged over the extended exposure period was less than 0.4 $\mu g/m^3$ higher than the long-term mean $PM_{2.5}$ concentration averaged over the follow-up period. The EPA finds it reasonable to conclude that such a relatively small difference in long-term mean $PM_{2.5}$ concentrations would likely apply for other long-term exposure studies that used similarly recent follow-up periods as well (e.g., Goss et al., 2004; Lipfert et al., 2006a). Furthermore, the EPA finds that this sensitivity analysis illustrates that, even when considering a somewhat longer exposure window, including the years the health event data were collected plus the two previous years, health effects are occurring at concentrations below the current level of the annual standard (i.e., below 15 $\mu g/m^3$).

Moreover, as discussed in section III.E.4.c.i of the preamble to the final rule and in section II.5.a.i below, the EPA notes that the relevant exposure period for the short-term exposure studies is the period contemporaneous with the collection of health event data, and that this exposure period is not subject to the uncertainties related to the long-term exposure studies. This is one of the reasons that the EPA gave special consideration to the long-term mean concentrations evaluated in key short-term exposure studies in revising the level of the annual standard.

(c) The EPA has long recognized that exposure error is an important issue for interpretation of epidemiological studies and that assessment of air pollution exposure using community average concentrations may lead to exposure misclassification or exposure measurement error. To investigate this issue, several analyses using ACS data focused on neighborhood-to-neighborhood differences in urban air pollutants (Jerrett et al. 2005; Krewski et al. 2009a) (U.S. EPA, 2009a, section 7.6.3). These analyses used spatial interpolation and land use regression methods to assign exposure to study subjects living in Los Angeles, CA, resulting in improved exposure assessment compared to the full cohort of the ACS study. Statistically significant associations between $PM_{2.5}$ and mortality from all causes and cardiopulmonary diseases were reported with the magnitude of the relative risks being greater in the analyses with the improved exposure assessment compared to the relative risks reported for the full ACS cohort. This provides evidence that reducing exposure error can result in stronger associations between $PM_{2.5}$ and mortality than generally observed in studies having less well-characterized exposure.

(8) *Comment:* Some commenters contended that the associations observed in long-term exposure studies were due to exposures that occurred many years earlier when $PM_{2.5}$ concentrations were much higher and therefore are "misattributing those risks to more recent, lower $PM_{2.5}$ levels" (UARG, Attachment 1, pp. 14 to 15; Southern Company, 2012 p. 2; AAM, 2012, pp. 14 to 15). Additionally, these commenters asserted that mortality due to long-term exposure is the result of cumulative exposure over a lifetime, which led to the development of chronic conditions that ultimately contributed to death.

Response: As an initial matter, the EPA has recognized the challenge in distinguishing between $PM_{2.5}$-associated effects due to past and recent long-term exposures, and in identifying the relevant latency period for long-term exposure to PM and resultant health effects (U.S. EPA, 2009a; 77 FR 38941/1). While the EPA acknowledges that there remain important uncertainties related to characterizing the most relevant exposure periods in long-term exposure studies, the EPA notes that there are a number of studies that help inform the Agency's consideration of this issue.

Both in the last review and the current review, the EPA has assessed studies that used different air quality periods for estimating long-term exposure and tested associations with mortality for the different exposure periods (U.S. EPA, 2004, Section 8.2.3.5; U.S. EPA 2009a, section 7.6.4). In this review, the ISA discussed studies available since the last review that have assessed the relationship between long-term exposure to $PM_{2.5}$ and mortality in exploring the issue of the latency period between exposure to $PM_{2.5}$ and death (U.S. EPA, 2009a, Section 7.6.4).

Notably, in a recent analyses of the Harvard Six Cities Study, Schwartz et al. (2008) used model averaging (i.e., multiple models were averaged and weighted by probability of accuracy) to assess exposure periods prospectively (77 FR 38907/1-2). The exposure periods were estimated across a range of unconstrained distributed lag models (i.e., same year, one year prior, two years prior to death). In comparing lags, the authors reported the effects of changes in exposure to $PM_{2.5}$ on mortality were strongest within a two year period prior to death (U.S. EPA, 2009a, p. 7-92, Figure 7-9). Similarly, a large multi-city study of the elderly found that the mortality risk associated with long-term exposure to PM_{10} reported cumulative effects that extended over the years that deaths were observed in the study population (i.e., the follow-up period) and for the 3-year period prior to death

(Zanobetti et al., 2008).

Further, in a study of two locations that experienced an abrupt decline in $PM_{2.5}$ concentrations (i.e., Utah Steel Strike, coal ban in Ireland), Röösli et al. (2005) reported that approximately 75 percent of health benefits were observed in the first 5 years (U.S. EPA, 2009a, Table 7-9). Furthermore, Schwartz et al. (2008) and Puett et al. (2008) found, in a comparison of exposure periods ranging from 1 month to 48 months prior to death that exposure to PM_{10} 24 months prior to death exhibited the strongest association, and the weakest association was reported for exposure in the time period of 1 month prior to death.

Overall, the EPA notes that the available evidence for determining the window over which the mortality effects of long-term pollution exposures occur suggests that a latency period of up to five years would account for the majority of deaths, with the strongest association observed in the two years prior to death. Further, the EPA recognizes that there is no discernible threshold below which effects would not occur, such that health effects may occur over the full range of concentrations observed in epidemiological studies, including the lower concentrations in the latter years. In light of this evidence and these considerations, the EPA concludes that it is appropriate to consider air quality concentrations that are contemporaneous with the collection of health event data as evidence to be used in determining causality. The EPA acknowledges that exposure windows that extend up to a few years prior to the follow-up period in which health event data were collected would likely more fully capture the PM-related deaths in such studies.

To explore how much higher the long-term mean $PM_{2.5}$ concentrations would likely have been had air quality data prior to the follow-up years of the studies been included, the EPA conducted a sensitivity analysis of $PM_{2.5}$ concentrations (Schmidt, 2012), particularly, considering studies that only included deaths from a relatively recent follow-up period. As examples of such studies, this analysis considered the Eftim et al. (2008) study of mortality in both the ACS sites and the Harvard Six Cities sites, as well as sites in the eastern region in the Zeger et al. (2008) study. Using data from the EPA's AQS database, the analysis added the two years of air quality data just prior to the follow-up period in each study, which was 2000 to 2002 in Eftim et al. (2008) and 2000 to 2005 in Zeger et al. (2008). The analysis then calculated the extended long-term mean $PM_{2.5}$ concentration for each study. As discussed in Schmidt (2012), in each case the long-term mean $PM_{2.5}$ concentration averaged over the extended exposure period was no more than 0.4 $\mu g/m^3$ higher than the long-term mean $PM_{2.5}$ concentration averaged over the follow-up period. The EPA finds it reasonable to conclude that such a relatively small difference in long-term mean $PM_{2.5}$ concentrations would likely apply for other long-term exposure studies that used similarly recent follow-up periods as well (e.g., Goss et al., 2004; Lipfert et al., 2006a).

Based on the above considerations, the EPA concludes that it is appropriate to consider the available air quality information from the long-term exposure studies, while taking into account the uncertainty in the relevant long-term exposure period when weighing the information from the long-term exposure studies in the context of the broader array of epidemiological studies that inform the EPA's consideration of the level of the annual $PM_{2.5}$ standard. Furthermore, as noted in the preamble and in the response to the previous comment (Comment (7)), the relevant exposure period for the *short-term* exposure studies is the period contemporaneous with the collection of health event data, and that this exposure period is not subject to the uncertainties related to the long-term exposure studies. In this review, the EPA accordingly gave special consideration to the long-term mean concentrations evaluated in key short-term studies in revising the level of the annual standard. These comments are addressed further in section III.E.4.c.i of the preamble to the final rule and in section II.B.5.a.i below.

(9) *Comment:* Some commenters asserted there were limitations in specific long-term exposure studies of mortality. For example, one group of commenters (NAM et al., 2012, pp. 23 to 24) asserted there were serious weaknesses in the long-term exposure studies considered by the EPA (e.g., Harvard Six Cities Study, Laden et al., 2006). Specifically, NAM et al. asserted that the Harvard Six Cities Study did not account for increasing age of the cohort, and that there were discrepancies in the results of the study. Another commenter (EPRI, 2012, p. 3) asserted that the EPA mischaracterized the results of the Veterans Cohort Study (Lipfert et al., 2006).

Response: The EPA disagrees with the commenters' assertion that the increasing age of the study subjects from the Harvard Six Cities Study was not accounted for when estimating the association between decreased $PM_{2.5}$ concentrations and decreased mortality observed by Laden et al. (2006). The average age of the cohort at enrollment was 50 years (range 25 to - 74 years) and the first follow-up period consisted of the 15 years following enrollment (including 104,243 person-years of follow up and 1,364 deaths). An additional follow-up period (16 to 24 years after enrollment) included an additional 54,735 person-years of follow-up and 1,368 deaths. The overall death rate for the first follow-up period was 13.1 deaths per 1,000 years of follow-up; it was 25.0 in the second follow-up period "reflecting the aging of this cohort" (Laden et al. 2006, p. 668). To account for this, Laden et al. (2006) controlled for baseline individual risk factors and potential confounders, including age. The authors stratified study subjects "by sex and 1-yr age groups, such that each sex/age group had its own baseline hazard." *Id*. The authors found that the associations between $PM_{2.5}$ and mortality were comparable for both follow-up periods (Laden et al. 2006, p. 669). Additionally, NAM et al. asserted that there were discrepancies in results among the six cities in the study that lead to considerable uncertainty. The EPA acknowledges that there was variability in the results for the individual cities in the Harvard Six Cities Study (in fact the objective of the study was to look at the variability between cities), but disagrees that such variability contributes to uncertainty. In fact, variability in the $PM_{2.5}$ concentrations among the cities is necessary in long-term cohort studies, such as the Harvard Six Cities Study, which rely on spatial variability for exposure contrast (see also response to Comment (4), above). Laden et al. (2006) recognized that there is variability in the association between the cities, but noted that "the drop in the adjusted mortality rate was largest in the cities with the largest reductions in $PM_{2.5}$ after controlling for such a period effect."*Id.*

With regard to the Veteran's Cohort Study, the EPA acknowledges that the air quality data in Figures 1 and 4 (77 FR 38929) of the proposal were attributed to the wrong

Lipfert et al. study published in 2006. The air quality data reported in Figure 1 of the proposal incorrectly identified the long-term mean $PM_{2.5}$ concentration for Lipfert et al (2006a – labeled Lipfert et al. (2006) in Figure 1) as 14.3 $\mu g/m^3$, which was instead the long-term mean $PM_{2.5}$ concentration reported for Lipfert et al. (2006b). This mistake was also made in the Figure 2-2 of the ISA (U.S. EPA, 2009a, p. 2-15). The EPA notes that footnote a for Figure 4 of Lipfert et al. (2006a) identified that the mortality risks for $PM_{2.5}$ were based on one year of air quality data (1999), although the study did not report the long-term mean $PM_{2.5}$ concentration for that year. Rather, in Table 1 of Lipfert et al. (2006a), the study authors reported long-term mean $PM_{2.5}$ concentrations of 14.3 $\mu g/m^3$ for the years 1989 to 1996 and 14.6 $\mu g/m^3$ for the years 1997 to 2001. Based on this information, the EPA concludes that 14.3 $\mu g/m^3$ is a reasonable approximation for the long-term mean $PM_{2.5}$ concentration in Lipfert et al. (2006) even though this value was not specifically reported in that study.

The EPA disagrees that the proposal mischaracterized the results of the Lipfert et al. (2006) study. The effect estimate for Lipfert et al., (2006a) was positive and statistically significant in a single pollutant model, and remained positive (though no longer statistically significant) in a two-pollutant model that included traffic density, as well as in a three-pollutant model that included traffic density and $PM_{10-2.5}$. The EPA also acknowledges that this effect estimate represents an association for which the deaths occurred before $PM_{2.5}$ measurements were collected, but disagrees with comments that it is inappropriate to consider this study as part of the body of evidence that informed the EPA's causal determinations. Although the comments are unpersuasive that this study should be invalidated for purposes of assessing causality, the EPA notes that consideration of this study played no part in actually determining any of the elements of the revised annual $PM_{2.5}$ standard.

(10) *Comment:* Some commenters contended that $PM_{2.5}$ risk estimates are highly sensitive to the approach used to control for temporal trends (API, 2012, Attachment 1pp. 11 to 12; AAM, 2012, pp. 6 to 10). Specifically, the results of the Air Pollution and Health: A European and North American Approach (APHENA) study provided evidence of no effect of short-term PM exposure on mortality and morbidity because the "overall pattern [of effects] is not what one would expect if PM health effects associations have a real physiological basis" (AAM, 2012, pp. 6 to 10). AAM stated that this conclusion was supported by the lack of consistent statistically significant associations across all models examined. Additionally, API contended that the sensitivity of $PM_{2.5}$ risk estimates to the selection of degrees of freedom to control for temporal trends was further demonstrated in Dominici et al. (2007) and Ostro et al. (2006).

Response: The EPA disagrees with the commenters' view that the results from Katsouyanni et al. (2009), Dominici et al. (2007), and Ostro et al. (2006) demonstrate the sensitivity of $PM_{2.5}$ risk estimates to the method used to control for temporal trends and bring into question the association between short-term $PM_{2.5}$ exposures and mortality and hospital admissions. Additionally, these commenters have focused solely on the statistical significance of risk estimates and not on the pattern of associations across studies as is discussed more fully in response to Comment (1) above.

The APHENA study combined data from existing multi-city study databases from the U.S. (the National Morbidity, Mortality, and Air Pollution Study [NMMAPS]), Europe (Air Pollution and Health: A European Approach [APHEA]), and Canada to “develop more reliable estimates of the potential acute effects of air pollution on human health [and] provide a common basis for [the] comparison of risks across geographic areas” (Katsouyanni et al., 2009). In an attempt to address both of these issues the investigators conducted extensive sensitivity analyses to evaluate the robustness of the results to different model specifications (e.g., penalized splines vs. natural splines) and the extent of smoothing to control for temporal trends. In models where an appropriate number of degrees of freedom (df) to control for temporal trends were employed risk estimates were robust across the different model specifications. The trend analyses consisted of subjecting the models to varying extent of smoothing selected either a priori (i.e., 3 df/year, 8 df/year, and 12 df/year), which was selected through exploratory analyses using between 2 and 20 df, or by using the absolute sum of the residuals of the partial autocorrelation function (PACF). Although the investigators did not identify the model they deemed to be the most appropriate for comparing the results across study locations, they did specify that “overall effect estimates (i.e., estimates pooled over several cities) tended to stabilize at high degrees of freedom” (Katsouyanni et al., 2009).

The results of the APHENA study are consistent with those reported by both Dominici et al. (2007) and Ostro et al. (2006), which as part of their studies conducted sensitivity analyses to examine the influence of increasing the degrees of freedom per year to control for temporal trends on the $PM_{2.5}$-mortality association. In both cases the authors found evidence that as the degrees of freedom per year increases a point is reached where risk estimates tend to stabilize, which for both of these studies was approximately 7 degrees of freedom or more per year.

It should be noted that even the commenters acknowledged that “[i]n most cases, the results and conclusions from these updated analyses were not significantly altered, but effect estimates were lower” (API, 2012, Attachment 1, p 12). The EPA, therefore, disagrees with the commenters that the lack of consistent statistically significant results across all models supports the lack of an association between short-term PM exposure on hospital admissions and mortality. The inconsistency in the results across some of the models (i.e., for APHENA those that controlled for temporal trends using 3 df/year or PACF compared to those that employed 8 or 12 df/year, while for Dominici et al. (2007) and Ostro et al. (2006) those less than 7 df/year) is due to inadequate control for temporal trends. Additionally, the EPA disagrees with these commenters sole reliance on statistical significance when evaluating the results of these studies. As stated in the response to Comment (1) above, focusing solely on statistically significance is inappropriate when evaluating a body of studies.

(11) *Comment:* Multiple commenters (ACC, 2012, pp. 14 to 18; AAM, 2012, pp. 6 to 10) questioned the EPA’s interpretation of results from specific short-term $PM_{2.5}$ exposure studies that examined associations with morbidity and mortality outcomes. Specifically, these commenters questioned: (a) interpretation of results from copollutant models; (b) lag selection; (c) the derivation of national risk estimates from multicity studies; and (d) the ignoring of evidence indicating a reduction in PM-mortality risk over time.

Response: Overall, the EPA disagrees with each of the points raised by the commenters and provides detailed responses to each below:

(a) Interpretation of results from copollutant models

The commenters questioned the EPA's interpretation of results from the copollutants models examined in Burnett et al. (2004) as well as all studies that examined copollutants models based on Ito et al. (2007), which stated that the use of multipollutant models "are a cautionary exercise, and throw into question the now commonplace practice of using multipollutant models in health effects analysis." The EPA disagrees with the commenters' interpretation of the results from Burnett et al. (2004). The main copollutant analyses conducted over the entire study duration used $PM_{2.5}$ data that were not collected every day. As a result, when including $PM_{2.5}$ in copollutant analyses with other pollutants that are measured on a daily basis, the overall sample size is reduced, which reduces the precision of resulting effect estimates. Burnett et al. (2004) performed a sensitivity analysis that further illustrates this point. When limiting the dataset to days in which daily $PM_{2.5}$ concentrations were available, the $PM_{2.5}$ association remained robust after adjustment for NO_2, while the NO_2 association was attenuated. Overall, this result brings into question the results from copollutants analyses including $PM_{2.5}$ that is collected every third or every sixth day when other pollutants are collected more frequently.

Finally, the EPA disagrees with the commenters' interpretation of the quote from Ito et al. (2007) that they relied on to discredit the results from copollutant analyses. Ito et al. (2007) cautioned against including all pollutants in one model, which, as they demonstrated can result in "the pollutant that varies least like all the rest of the pollutants, and is least affected by concurvity in such a multi-pollutant model" being the pollutant that looks to be causing the effect. The EPA has emphasized evaluation of models including no more than two pollutants because models that included multiple pollutants are difficult to interpret due to the potential multicollinearity between pollutants. (e.g., U.S. EPA, 2004, sections 8.4.3.2 and 8.4.3.3).

(b) Lag selection

With regard to the lags selected in certain mortality studies (i.e., Franklin et al. 2007), commenters questioned the selection of lag days *a priori* and not through the use of model fit criteria (ACC, 2012, pp. 14 to 18). As demonstrated in the ISA, studies that examined the association between short-term $PM_{2.5}$ exposure and mortality "were consistently observed at lag 1 and lag 0-1, which have been confirmed through extensive analysis of PM_{10}-mortality studies" (U.S. EPA, 2009a, p. 6-200). Therefore, the lag days selected by Franklin et al. (2007) *a priori* (i.e., lag 0-1) were consistent with the large body of evidence that has demonstrated associations between short-term PM exposure and mortality.

(c) Derivation of national risk estimates from multicity studies

Some commenters questioned the derivation of national risk estimates from multi-city studies. Specifically, these commenters questioned the approach employed by study investigators to calculate a national estimate, claiming that it did not use the entirety of the community-level data (ACC, 2012, pp. 14 to 18). The EPA disagrees with these commenters understanding of the approach used to calculate national risk estimates in multicity studies. Multi-city studies, in fact, do use the entirety of the dataset to calculate national risk estimates. By calculating city-specific risk estimates and then utilizing either a meta-regression or a second stage Bayesian Hierarchical model, investigators use the city-specific estimates to calculate the national risk estimate. Investigators of multi-city studies are not excluding any community-level data, but instead are using the totality of data to provide information that is needed to calculate a national risk estimate.

(d) Ignoring evidence of a reduction in PM-mortality risk over time

Some commenters also questioned the EPA's interpretation of evidence indicating a reduction in PM-mortality risk estimates over time, and pointed to the results of Dominici et al. (2007) to support their argument (e.g., ACC, 2012, pp. 14 to 18, NAM et al., 2012, p. 9). At first glance, the results of Dominici et al. (2007) would seem to indicate that PM-mortality risk estimates have declined over time due to the observed decline in the slope for all-cause and cardiorespiratory mortality. However, this analysis was motivated by accountability research and instead of measuring the impact of a sudden change in air quality, this study attempted to measure the impact of policy interventions. As such, "a flaw in the use of the time-series study design for this type of analysis is that it adjusts for long-term trends, and, therefore, does not estimate the change in mortality in response to the gradual change in PM_{10}" (U.S. EPA, 2009a, p. 6-163). Therefore, the EPA disagrees with the commenters. Although this analysis may indicate a slight reduction in PM-mortality risk estimates over time "the analytic approach used in the study does not allow for a systematic analysis of the effect of air pollution policies on the risk of mortality" (U.S. EPA, 2009a, p. 6-163).

(12) *Comment:* In asserting that the uncertainties in the underlying health science are as great or greater than in the last review and therefore do not support revision to the standards at this time, multiple commenters (e.g., API, 2012, pp. 1, 17 to 20, and Attachment 1, pp. 9 to 24, Attachment 7, p. 9, Attachment 9; ACC, 2012, pp. 2 to 7, 14 to 18; NAM et al., 2012, pp. 9, 23; AAM, 2012, pp. 5 to 15; AFPM, 2012, p. 3; Southern Company, 2012, pp. 2 to 3; EPRI, 2012, pp. 1 to 4; Texas CEQ, 2012, pp. 1 to 4; AFPM et al., 201, p. 32) discussed a number of issues related to: (a) copollutant confounding; (b) ecological/contextual confounding; (c) heterogeneity in risk estimates, (d) exposure measurement error; (e) model specification; (f) the shape of the concentration-response (C-R) function; and (g) understanding the relative toxicity of components within the mixture of fine particles.

Response: The EPA believes that the overall uncertainty about possible health risks associated with both long- and short-term $PM_{2.5}$ exposure has diminished since the last review. The EPA disagrees with commenters' views that the remaining uncertainties in the scientific evidence are too great to support revising the current $PM_{2.5}$ NAAQS. The EPA has carefully considered the uncertainties highlighted by commenters in its evaluation of the scientific evidence as discussed in section III. D.2 of the preamble to the final rule and below:

(a) Copollutant confounding

Some commenters asserted that the EPA has not adequately interpreted the results from studies that examined the effect of copollutants on the relationship between long- and short-term $PM_{2.5}$ exposures and mortality and morbidity outcomes (e.g., NAM et al., 2012, p. 23, ACC 2012, pp. 14 to 18). These commenters contended that the EPA has inappropriately concluded that $PM_{2.5}$-related mortality and morbidity associations are generally robust to confounding. The commenters stated that statistically significant $PM_{2.5}$ associations in single-pollutant models in epidemiological studies do not remain statistically significant in copollutant models.

The EPA recognizes where $PM_{2.5}$ and other pollutants are highly correlated, it can be difficult to distinguish effects of the various pollutants in copollutant models. The loss of statistical significance or the reduction in the magnitude of the effect estimate when a copollutant model is used may be the result of factors other than confounding. These changes do not prove either the existence or absence of confounding. These impacts must be evaluated in a broader context that considers the entire body of evidence. The broader examination of this issue in the ISA included a focus on evaluating the stability of the size of the effect estimates in epidemiological studies conducted by a number of research groups using single- and co-pollutant models (U.S. EPA, 2009a, sections 6.2.10.9, 6.3.8.5, and 6.5, Figures 6-5, 6-9, and 6-15). This examination found that, for most epidemiological studies, there was little change in effect estimates based on single- and copollutant models, although the ISA recognized that in some cases, the $PM_{2.5}$ effect estimates were markedly reduced in size and lost statistical significance.

In questioning the influence of co-pollutants on associations observed in short-term PM exposure and mortality studies, commenters highlighted the lack of control for copollutants in Dominici et al. (2003, 2007) and Franklin et al. (2007). The EPA recognized that a limitation of the multi-city studies that examined the association between short-term $PM_{2.5}$ exposure and mortality evaluated in the ISA was the relative lack of copollutant analyses. This limitation was mentioned when evaluating the collective evidence and forming the causality determination for mortality. In Chapter 2 of the ISA (U.S. EPA, 2009a, p. 2-11), the EPA stated, "Although recently evaluated U.S.-based multi-city studies did not analyze potential confounding of $PM_{2.5}$ risk estimates by gaseous pollutants, evidence from the limited number of single-city studies evaluated in the 2004 PM AQCD (U.S. EPA, 2004) suggest that gaseous copollutants do not confound the $PM_{2.5}$-mortality association. This is further supported by studies that examined the PM_{10}-mortality relationship", which were discussed in section 6.5.2.1 of the ISA (U.S. EPA, 2009a).

These commenters also questioned the lack of copollutant analyses in long-term exposure and mortality studies. The EPA recognizes that a limited number of studies investigating the association between long-term exposure to $PM_{2.5}$ and mortality have included copollutant models. As discussed in the previous review, the analysis of multiple pollutants from the ACS cohort observed increases in two-pollutant models that incorporated CO, NO_2, and ozone, and were reduced only for models that incorporated SO_2 (Krewski et al. 2000). The 2004 AQCD recognized, however, that SO_2 is a precursor for fine particle sulfates, which complicates the interpretation of copollutant model results. In a follow-up study of the ACS cohort restricted to just Los Angeles, CA (Jerrett et al. 2005), the authors observed that O_3 "did not confound the relationship between particles and mortality." Similarly, analysis of the AHSMOG cohort (Chen et al. 2005) found that the association between mortality and long-term exposure to $PM_{2.5}$ became stronger when O_3 and SO_2 were included in copollutants models, and the association for $PM_{2.5}$ did not change when NO_2 was included in co-pollutants models. The results of these studies provide confidence that more recent reports with updated datasets are showing independent effects of $PM_{2.5}$.

The EPA notes that these public comments do not adequately reflect the complexities inherent in assessing the issue of copollutant confounding. As discussed in the proposal (77 FR 38907, 38909, and 38910) and more fully in the ISA (USEPA, 2009a, sections 6.2, 6.3, and 6.5), although copollutant models may be useful tools for assessing whether gaseous copollutants may be potential confounders, such models alone cannot determine whether copollutants are in fact confounders. The EPA believes that observing robust effect estimates after examination of copollutant models provides greater confidence in the observed associations between short- and long-term exposures to $PM_{2.5}$ and mortality and morbidity, while recognizing that potential confounding by copollutants remains a very challenging issue to address, even with well-designed studies. Interpretation of the results of copollutant models is complicated by correlations that often exist among air pollutants, by the fact that some pollutants play a role in the atmospheric reactions that form other pollutants such as secondary fine particles, and by the statistical power of the studies in question inherent in the study methodology. For example, as discussed in response to Comment (12)(a) above, the every-third or sixth-day sampling schedule often employed for $PM_{2.5}$ compared to daily measurements of gaseous copollutants drastically reduces the overall sample size to assess the effect of copollutants on the $PM_{2.5}$-morbidity or mortality relationship, such that the reduced sample size can lead to less precise effect estimates (e.g., wider confidence intervals, as demonstrated in Burnett et al. (2004)).

The EPA recognizes that when $PM_{2.5}$ is correlated with gaseous pollutants it can be difficult to identify the effect of individual pollutants in the ambient mixture (77 FR 38910). However, based on the available evidence, the EPA concludes epidemiological studies continue to support the conclusion that $PM_{2.5}$ associations with mortality and morbidity outcomes are robust to the inclusion of gaseous copollutants in statistical models. The EPA evaluated the potential confounding effects of gaseous copollutants and, although it is recognized that uncertainties and limitations still remain, the Agency concluded the collective body of scientific evidence is "stronger and more consistent than in previous reviews providing a strong basis for decision making in this review" (77 FR 38910/1).

(b) Ecological/contextual confounding

Some commenters contended that both short- and long-term $PM_{2.5}$ exposure studies of mortality did not appropriately control for ecological or contextual confounders (ACC, 2012, p. 3; API, 2012, Attachment 1, p. 14; NAM et al., 2012, p. 23).

In the case of short-term exposure studies, an ecological confounder would need to vary on a day-to-day basis with both air pollution and with the specific health outcome being evaluated (e.g., mortality or hospital admissions or emergency department visits). The confounders that fit these criteria for short-term exposure studies are related to weather (e.g., temperature, dew point, relative humidity). The short-term exposure studies, specifically time-series studies, evaluated in the ISA all included weather covariates in their models to account for their potential confounding effects (U.S. EPA, 2009a, Chapter 6).

With regard to long-term exposure studies, a number of multilevel cohort studies (Naess et al. 2007; Jerrett et al. 2003; Jerrett et al. 2005) have evaluated individual-level and contextual, or ecologic-level variables as potential confounders. As reported in Jerrett et al. (2005), "Contextual effects occur when individual differences in health outcomes are associated with the grouped variables that represent the social, economic, and environmental settings where the individuals live, work, or spend time (e.g., poverty or crime rate in a neighborhood). These contextual effects often operate independently from (or interactively with) the individual-level variables such as smoking." These studies found that the inclusion of contextual variables tended to attenuate the risk estimates for the association between long-term exposure to $PM_{2.5}$ and mortality, but that an independent effect of $PM_{2.5}$ on mortality remains. For example, Jerrett et al. (2005) found that for $PM_{2.5}$ (controlling for age, sex, and race), the relative risk was 1.24 (95% CI 1.11, 1.37) for a 10 $\mu g/m^3$ exposure contrast. In a parsimonious model that controlled for 44 different individual covariates and ecological confounder variables that both reduced the pollution coefficient and had associations with mortality, the relative risk was 1.11 (95% CI 0.99, 1.25) for the same exposure contrast. The EPA believes that the results of these studies provide confidence that more recent reports with updated datasets are showing independent effects of $PM_{2.5}$.

Additionally, commenters contended that non-traditional confounders have not been accounted for in epidemiological studies of short- and long-term exposure to air pollution, which could confound the associations observed (API, 2012, Attachment 1, p. 14). These confounders include physical and psychological population stress factors. The EPA disagrees with these commenters because: (1) there is very limited evidence of stress affecting the air pollution-health effect relationship upon which to base the commenters assertion; (2) in order for stress to be a true confounder it would need to vary temporally (for short-term exposure studies) and spatially (for long-term exposure studies) with both air pollution concentrations and the health effect of interest, which has not been demonstrated; and (3) rather than stress acting as a true confounder, more than likely stress is on the causal pathway to the health effects that have been observed to be associated with air pollution. The EPA acknowledges that stress may contribute bias to epidemiological studies; however, stress more than likely would influence the magnitude of individual effect estimates in a single-city or multi-city study and not the trends of positive associations observed across studies conducted in multiple locations.

(c) Heterogeneity in risk estimates

Some commenters argued that the heterogeneity in risk estimates observed in multi-city epidemiological studies and the lack of statistical significance in many regional or seasonal estimates highlights a potential bias associated with combined multi-city epidemiological study results (e.g., API, 2012, Attachment 1, pp. 15 to 19). Additionally, these commenters contended that the wide range of individual city results in these multi-city studies, specifically NMMAPS, demonstrated a biologically implausible wide range of associations (e.g, AAM, 2012, pp. 6 to 10). One commenter asserted, "there is overwhelming epidemiologic evidence, dating back to 2000, which shows clear and large geographic variation in $PM_{2.5}$ mortality risk across the United States. The $PM_{2.5}$ mortality risk is much stronger in the eastern portion of the US than in the western portion of the U.S. and there is no $PM_{2.5}$ mortality risk in California" (Enstrom, 2012, p. 1). Other commenters further argued that more refined intra-urban exposure estimates conducted for two of the largest cities included in the ACS study, Los Angeles and New York City, based on land-use regression models and/or kreiging methods (Krewski et al., 2009a) "underscore the importance of considering city-specific health estimates, which may account for heterogeneity in $PM_{2.5}$ concentrations or other differences among cities, rather than relying on pooled nationwide results from multi-city studies" (API, 2012, Attachment 1, p. 17).

With respect to understanding the nature and magnitude of $PM_{2.5}$-related risks, the EPA agrees that epidemiological studies evaluating health effects associated with long- and short-term $PM_{2.5}$ exposures have reported heterogeneity in responses between cities and effect estimates across geographic regions of the U.S. (U.S. EPA, 2009a, sections 6.2.12.1, 6.3.8.1, 6.5.2, and 7.6.1; U.S. EPA, 2011a, p. 2-25). For example, when focusing on short-term $PM_{2.5}$ exposure, the ISA found that multi-city studies that examined associations with mortality and cardiovascular and respiratory hospital admissions and emergency department visits demonstrated greater cardiovascular effects in the eastern versus the western U.S. (Dominici, et al., 2006a; Bell et al., 2008; Franklin et al. (2007, 2008)). However, the rationale that heterogeneity in risk estimates presents a potential bias as posed by the commenters is simplistic and does not account for a number of factors that have been shown to influence city-specific risk estimates in epidemiologic studies. As discussed in the ISA, the EPA recognizes that there are compositional differences in $PM_{2.5}$ across the country and that the county-level air quality data used in epidemiological studies may result in exposure error, which could in part account for variability in city-specific risk estimates (U.S. EPA, 2009a, section 2.3.2).

There are a limited number of studies that evaluated regional heterogeneity in the association between long-term exposure to $PM_{2.5}$ and mortality. Krewski et al. (2009a) conducted subset analyses of the ACS cohort in Los Angeles, CA and New York City, NY, and observed a relative risk in Los Angeles that was greater in magnitude than what was observed in the full ACS cohort, while the relative risk in New York City was less than what was observed in the full ACS cohort. These observations are likely due to the greater spatial heterogeneity in $PM_{2.5}$ concentrations observed in Los Angeles, and the overall spatial homogeneity of $PM_{2.5}$ concentrations in New York City.

In another retrospective cohort, Zeger et al. (2008) observed associations between long-term exposure to $PM_{2.5}$ and mortality for the eastern and central ZIP codes that were similar to those reported in the ACS and Harvard Six Cities studies, though no association was observed in the western region. The lack of the association in the western region is "largely because the Los Angeles basin counties (California) have higher PM levels than other West Coast urban centers, but not higher adjusted mortality rates" (Zeger et al. 2008). The ISA also evaluated studies that provided some evidence for seasonal differences in $PM_{2.5}$ risk estimates, specifically in the northeast. The ISA found evidence indicating that individuals may be at greater risk of dying from higher exposures to $PM_{2.5}$ in the warmer months, and at greater risk of $PM_{2.5}$ associated hospitalization for cardiovascular and respiratory diseases during colder months of the year. The limited influence of seasonality on PM risk estimates in other regions of the U.S. may be due to a number of factors including varying PM composition by season, exposure misclassification due to regional tendencies to spend more or less time outdoors and air conditioning usage, and the prevalence of infectious diseases during the winter months (U.S. EPA, 2009a, p. 3-182).

Overall, the EPA recognizes that uncertainties still remain regarding various factors that contribute to heterogeneity observed in epidemiological studies (77 FR 38909/3). Nonetheless, the EPA recognizes that this heterogeneity could be attributed, at least in part, to differences in $PM_{2.5}$ composition across the U.S., as well as to exposure differences that vary regionally such as personal activity patterns, microenvironmental characteristics, and the spatial variability of $PM_{2.5}$ concentrations in urban areas (U.S. EPA, 2009a, section 2.3.2; 77 FR 38910).

As recognized in the PA, the current epidemiological 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 (U.S. EPA, 2011a, p. 2-25). Furthermore, as discussed in section III.E.1 of the preamble to the final rule, the ISA concluded, "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" (U.S. EPA, 2009a, p. 2-17). CASAC thoroughly reviewed the EPA's presentation of the scientific evidence indicating heterogeneity in $PM_{2.5}$ effect estimates in epidemiological studies and concurred with the overall conclusions presented in the ISA.

(d) Exposure measurement error

Industry commenters argued that the EPA did not adequately consider exposure measurement error, which they asserted is an important source of bias in epidemiological studies that can bias effect estimates in either direction (e.g., API, 2012, Attachment 1, pp. 19 to 20).

The EPA agrees that exposure measurement error is an important source of uncertainty, and that the variability in risk estimates observed in multi-city studies could be attributed, in part, to exposure error due to measurement-related issues (77 FR 38910). However, the Agency disagrees with the commenters' assertion that exposure measurement error was not adequately considered by EPA in this review. The ISA included an extensive discussion that addresses issues of exposure measurement error (U.S. EPA, 2009a, sections 2.3.2 and 3.8.6). Exposure measurement error may lead to bias in effect estimates in epidemiological studies. A number of studies evaluated in the last review (U.S. EPA, 2004, section 8.4.5) and in the current review (U.S. EPA, 2009a, section 3.8.6) have discussed the direction and magnitude of bias resulting from specified patterns of exposure measurement error (Armstrong 1998; Thomas et al. 1993; Carroll et al. 1995) and have generally concluded "classical" (i.e., random, within-person) exposure measurement error can bias effect estimates towards the null. Therefore, consistent with conclusions reached in the last review, the ISA concluded "in most circumstances, exposure error tends to bias a health effect estimate downward" (U.S. EPA, 2009a, sections 2.3.2 and 3.8.6). Thus, the EPA has both considered and accounted for the possibility of exposure measurement error, and the possible bias would make it more difficult to detect true associations, not less difficult.

Additionally a commenter specifically questioned the influence of exposure measurement error on the results from epidemiological analyses by referencing a study conducted by Sarnat et al. (2009) (API, 2012, Attachment 1, p. 19). This commenter stated:

> Sarnat *et al*. (2009) found that personal exposures to sulfate (a major component of $PM_{2.5}$ in certain parts of the country), averaged over time, varied by individual, city and season, and this variability can lead to CRFs that do not represent the true relationship between exposure and outcome. These factors may bias the results of an epidemiology analysis in either direction and are particularly relevant for long-term studies (for which these factors likely vary over time).

The EPA disagrees with the interpretation of Sarnat et al. (2009) by the commenter. Sarnat et al. (2009) describes variability in the use of home ventilation (i.e., air conditioning) as a key factor contributing to both the bias and the variability in personal exposure. Air conditioning usage varies by individuals and between cities. Use of air conditioning results in the introduction of less outdoor air to the indoors, resulting in the central-site monitoring value overestimating exposure. In an epidemiological analysis, this condition causes the effect estimate to be biased towards the null, with some variability. Given the limiting condition that the maximum indoor concentration of ambient PM is that of the outdoors, the exposure error would not be expected to bias the effect estimate away from the null. Moreover, Sarnat et al. (2009) did not assert that the bias can go in either direction.

(e) Model specification

Commenters contended that the EPA did not account for the fact that "selecting an appropriate statistical model for epidemiologic studies of air pollution involves several choices that involve much ambiguity, scant biological evidence, and a profound impact on analytic results, given that many estimated associations are weak" (ACC, 2012, p. 5) For short-term exposure studies, the EPA recognizes, as summarized in the HEI review panel commentary that selecting a level of control to adjust for time-varying factors, such as temperature, in time-series epidemiologic studies involves a trade-off (HEI, 2003). For example, if the model does not sufficiently adjust for the relationship between the health outcome and temperature, some effects of temperature could be falsely ascribed to the pollution variable. Conversely, if an overly aggressive approach is used to control for temperature, the result would possibly underestimate the pollution-related effect and compromise the ability to detect a small but true pollution effect (U.S. EPA, 2004, p. 8-236; HEI, 2003, p. 266). The selection of approaches to address such variables depends in part on prior knowledge and judgments made by the investigators, for example, about weather patterns in the study area and expected relationships between weather and other time-varying factors and health outcomes considered in the study. As demonstrated in section 6.5 of the ISA, the EPA thoroughly considered each of these issues and the overall effect of different model specifications on the association between short-term $PM_{2.5}$ exposure and mortality. Regardless of the model employed, consistent positive associations were observed across studies that controlled for the potential confounding effects of time and weather using different approaches (e.g., U.S. EPA 2009a, Figure 6-27, with additional details found in Appendix E, section E.3, Table E-16,). The EPA also considered the influence of model specification in the examination of long-term $PM_{2.5}$ exposure studies. For example, in section 7.6, Figures 7-6 and 7-7, the ISA summarized the collective evidence that evaluated the association between long-term $PM_{2.5}$ exposure and mortality. Regardless of the model used, these studies collectively found evidence of consistent positive associations between long-term $PM_{2.5}$ exposure and mortality.

The EPA, therefore, disagrees with commenters that model specification was not considered when evaluating the epidemiologic evidence used to form causality determinations. The EPA specifically points out that the process of assessing the scientific quality and relevance of epidemiologic studies includes examining "important methodological issues (e.g., lag or time period between exposure and effects, model specifications, thresholds, mortality displacement) related to interpretation of the health evidence (U.S. EPA, 2009a, p. 1-9)." Consistent with the conclusions of the 2004 PM AQCD, the EPA recognizes that there is still no clear consensus at this time as to what constitutes appropriate control of weather and temporal trends in short-term exposure studies, and that no single statistical modeling approach is likely to be most appropriate in all cases (U.S. EPA, 2004, p. 8-238). However, the EPA believes that the available evidence interpreted in light of these remaining uncertainties does provide increased confidence relative to the last review in the reported associations between short- and long-term $PM_{2.5}$ exposures and mortality and morbidity effects, alone and in combination with other pollutants.

(f) Shape of the concentration-response relationship

With regard to the C-R relationship, commenters questioned the interpretation of the shape of the C-R relationship, specifically stating that multiple studies have demonstrated that there is a threshold in the PM-health effect relationship and that the log-linear model is not biologically plausible (API, 2012 pp. 17 to 20; API, 2012, Attachment 9; ACC, 2012, Appendix A, pp. 7 to 8). The EPA disagrees with this assertion due to the number of studies evaluated in the ISA that continue to demonstrate a no-threshold log-linear model most adequately represents the PM concentration-response relationship (U.S. EPA, 2009a, section 2.4.3). While recognizing that uncertainties remain, the EPA believes that our understanding of this issue for both long-and short-term exposure studies has advanced since the last review. As discussed in the ISA, both long- and short-term exposure studies have employed a variety of statistical approaches to examine the shape of the concentration-response function and whether a threshold exists. While the EPA recognizes that there likely are individual biologic thresholds for specific health responses, the ISA concluded the overall evidence from existing epidemiological studies does not support the existence of thresholds at the population level, for effects associated with either long- or short-term PM exposures within the ranges of air quality observed in these studies (U.S. EPA, 2009a, section 2.4.3). While epidemiological analyses have not identified a population threshold in the range of air quality concentrations evaluated in these studies, the EPA recognizes that it is possible that such thresholds exist towards the lower end of these ranges (or below these ranges). This would be a concentration far lower than the level of the revised annual standard. The ISA concluded that this evidence collectively supported the conclusion that a no-threshold, log-linear model is most appropriate (U.S. EPA, 2009a, sections 6.2.10.10, 6.5.2.7, and 7.6.4). CASAC likewise advised that "[a]lthough there is increasing uncertainty at lower levels, there is no evidence of a threshold (Samet, 2010d, p. ii).

The EPA recognizes that some short-term exposure studies have examined the PM C-R relationship in individual cities or on a city-to-city basis and observed heterogeneity in the shape of the C-R curve across cities. As discussed in (b) above, these findings are a source of uncertainty that the EPA agrees requires further investigation. Nonetheless, the ISA concluded that "the studies evaluated further support the use of a no-threshold, log-linear model, but additional issues such as the influence of heterogeneity in estimates between cities and the effects of seasonal and regional differences in PM on the concentration-response-relationship still require further investigation" (U.S. EPA, 2009a, p. 2-25).

(g) Relative toxicity of components

Some commenters highlighted uncertainties in understanding the role of individual constituents within the mix of fine particles. These commenters asserted that a mass-based standard may not be appropriate due to the growing body of evidence indicating that certain $PM_{2.5}$ components may be more closely related to specific health outcomes (e.g., elemental carbon (EC) and organic carbon (OC)) (EPRI, 2012, p. 2).

With regard to questions about the role of individual constituents within the mix of fine particles, as a general matter, the EPA recognizes that although new research directed toward this question has been conducted since the last review, important questions remain and the issue remains an important element in the Agency's ongoing research program. At the time of the last review, the Agency determined that it was appropriate to continue to control fine particles as a group, as opposed to singling out any particular component or class of fine particles (71 FR 61162 to 61164, October 17, 2006). This distinction was based largely on epidemiological evidence of health effects using various indicators of fine particles in a large number of areas that had significant contributions of differing components or sources of fine particles, together with some limited experimental studies that provided some evidence suggestive of health effects associated with high concentrations of numerous fine particle components.

In this review, as discussed in the proposal (77 FR 38922 to 38923) and in section III.E.1

preamble to the final rule, while most epidemiological studies continue to be indexed by $PM_{2.5}$ mass, several recent epidemiological studies included in the ISA have used $PM_{2.5}$ speciation data to evaluate health effects associated with fine particle exposures. In the ISA, the EPA thoroughly evaluated the scientific evidence that examined the effect of different $PM_{2.5}$ components and sources on a variety of health outcomes (U.S. EPA, 2009a, section 6.6) and observed that the available information continues to suggest that many different chemical components of fine particles and a variety of different types of source categories are all associated with, and probably contribute to, effects associated with $PM_{2.5}$. The ISA concluded that the current body of scientific evidence indicated that "many constituents of PM can be linked with differing 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" (U.S. EPA, 2009a, p. 2-26 and 6-212). Furthermore, the PA concluded that the evidence is not sufficient to support eliminating any component or group of components associated with any specific source categories from the mix of fine particles included in the $PM_{2.5}$ indicator (U.S. EPA, 2009a, p. 2-56). CASAC agreed that it was reasonable to retain $PM_{2.5}$ as an indicator for fine particles in this review as "[t]here was insufficient peer-reviewed literature to support any other indicator at this time" (Samet, 2010c, p. 12).

This information is relevant to the Agency's decision to retain $PM_{2.5}$ as the indicator for fine particles as discussed in section III.E.1 of the preamble for the final rule. The EPA also believes that it is relevant to the Agency's conclusion as to whether revision of the suite of primary $PM_{2.5}$ standards is appropriate. While there remain uncertainties about the role and relative toxicity of various components of fine PM, the current evidence continues to support the view that fine particles should be addressed as a group for purposes of public health protection and that "many constituents of PM can be linked with differencing 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" such that it is inappropriate to remove any constituent of $PM_{2.5}$ from the standard (U.S. EPA, 2009a, 2-17; U.S. EPA, 2011a, p. 2-25).

In summary, in considering the above issues related to uncertainties in the underlying health science, on balance, the EPA believes that the available evidence interpreted in light of these remaining uncertainties does provide increased confidence relative to the last review in the reported associations between long- and short- term $PM_{2.5}$ exposures and mortality and morbidity effects, alone and in combination with other pollutants, and supports stronger inferences as to the causal nature of the associations. The EPA also believes that this increased confidence, when taken in context of the entire body of available health effects evidence and in light of the evidence from epidemiological studies of associations observed in areas meeting the current primary $PM_{2.5}$ standards, specifically in areas meeting the current primary annual $PM_{2.5}$ standard, adds support to its conclusion that the current suite of $PM_{2.5}$ standards needs to be revised to provide increased public health protection from exposure to all types of $PM_{2.5}$.

(13) *Comment*: In asserting that there is no evidence of greater risk since the 2006 review to justify lowering the current annual $PM_{2.5}$ standard, some commenters argued that, "if the current primary $PM_{2.5}$ annual standard of 15 $\mu g/m^3$ was considered to be adequately

protective of public health in 2006, given relative risk estimates that EPA was using at that time, then that standard would surely still be adequately protective of the public health if relative risk estimates remain at the same level (or lower)" (UARG, 2012, Attachment 1, p. 24). These commenters compared risk coefficients used for mortality in the EPA's risk assessment done in the last review with those from the Agency's core risk assessment done as part of this review, and they concluded that "the entire range of the core relative risk for long-term mortality is lower now than it was in the prior review" (UARG, 2012, Attachment 1, p. 24). These commenters used this conclusion as the basis for a claim that there is no reason to revise the current annual $PM_{2.5}$ standard.

Response: The EPA believes that this claim is fundamentally flawed. In comparing the scientific understanding of the risk presented by exposure to $PM_{2.5}$ between the last and current reviews, one must examine not only the quantitative estimate of risk from those exposures (e.g., the numbers of premature deaths or increased hospital admissions at various concentrations), but also the degree of confidence that the Agency has that the observed health effects are causally linked to $PM_{2.5}$ exposure at those concentrations. As documented in the ISA and in the recommendations and conclusions of CASAC, the EPA recognizes significant advances in our understanding of the health effects of $PM_{2.5}$, based on evidence that is stronger than in the last review. As a result of these advances, the EPA is now more certain that fine particles, alone or in combination with other pollutants, present a significant risk to public health at concentrations allowed by the current primary $PM_{2.5}$ standards. From this more comprehensive perspective, since the risks presented by $PM_{2.5}$ are more certain, similar or even somewhat lower relative risk estimates would not be a basis to conclude that no revision to the suite of $PM_{2.5}$ standards is "requisite" to protect public health with an adequate margin of safety. The comment also ignores that the relative risk estimate is only one factor considered by the Administrator. Most obviously, it ignores that epidemiological studies since the last review indicate associations between $PM_{2.5}$ and mortality and morbidity in areas meeting the current annual standard.

In any case, the commenters' reliance on the flawed 2006 review is badly misplaced. As discussed in section III.A.2 of the preamble to the final rule, the D.C. Circuit remanded Administrator Johnson's 2006 decision to retain the primary annual $PM_{2.5}$ standard because the Agency failed to adequately explain why the annual standard provided the requisite protection from both short- and long-term exposure to fine particles including protection for at-risk populations. The EPA, in fact, knows of no legitimate explanation. The 2006 standard was also at sharp odds with CASAC advice and recommendations as to the requisite level of protection (Henderson, 2006a,b). The judgment of the then-Administrator that the 2006 primary annual $PM_{2.5}$ standard was requisite to protect public health with an adequate margin of safety is thus not precedential and is an inappropriate benchmark for the comparison drawn in the comments.

(14) *Comment:* One group of commenters who argued that a revised annual standard was not necessary to protect the public health asserted that the proposed standard was "far more stringent that the standards in other industrialized countries" (NAM et al., 2012, p.5). These commenters cited to standards set by the European Union and Japan Ministry of the Environment. *Id.*

Response: In considering these comments, as discussed in Comment (3) in section II.B.1.a above, the EPA notes that the Administrator's decision on setting an appropriate annual standard level is constrained by the provision of the CAA that requires that the primary NAAQS be requisite to protect public health with an adequate margin of safety. This requires that her judgment is to be based on an interpretation of the evidence that neither overstates nor understates the strength and limitations of the evidence, or the appropriate inferences to be drawn from the evidence. This is not the same legal framework that governs the standards set by the European Union or Japan.

As discussed in section III.E.4.d of the preamble for the final rule, the Administrator has considered the epidemiological and other scientific evidence, estimates of risk reductions associated with just meeting alternative standards, air quality analyses, related limitations and uncertainties, the advice of CASAC, and the extensive public comments on the proposal in reaching her conclusions regarding final decision on the appropriate primary $PM_{2.5}$ standard levels, consistent with the requirements of the CAA.

(15) *Comment*: Some of these commenters also identified "new" as well as older studies that had been included in prior reviews as providing additional evidence that the causality determinations presented in the ISA did not consider the totality of the scientific literature, further supporting their view that revision of the $PM_{2.5}$ NAAQS is inappropriate.

Response: As discussed in section II.B.3 of the preamble to the final rule and in section II.B.1.a above, the EPA notes that, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the PM ISA that have undergone CASAC and public review, and will consider newly published studies for purposes of decision making in the next PM NAAQS review. Nonetheless, in provisionally evaluating commenters' arguments, the EPA notes that its provisional assessment of "new" science found that such studies did not materially change the conclusions reached in the ISA (U.S. EPA, 2012b).

2. Indicator

The EPA received comparatively few public comments on issues related to the indicator for fine particles. No public comments were submitted regarding the use of a different size cut for fine particles. Public comments from all major public and private sector groups received on the proposal were generally in favor of the EPA's proposal to retain $PM_{2.5}$ as the indicator for fine particles. In addition to the responses contained in section III.E.1 of the preamble to the final rule, the EPA provides the following responses to specific issues related to the indicator for fine particles.

(1) *Comment:* Some commenters emphasized the need to conduct additional research to more fully understand the effect of specific $PM_{2.5}$ components and/or sources on public health. These commenters expressed views about the importance of evaluating health effect associations with various fine particle components and types of source categories as a basis for focusing ongoing and future research to reduce uncertainties in this area and for considering whether alternative indicator(s) may be appropriate to consider in future

PM NAAQS reviews for standards intended to protect against the array of health effects that have been associated with fine particles as indexed by $PM_{2.5}$. For example, the PSR encouraged more research and monitoring related to $PM_{2.5}$ components and noted the importance of components associated with coal combustion (PSR, 2012, pp. 5 to 6). EPRI asserted that "new" studies support focusing on elemental carbon (EC) and organic carbon (OC) and encouraged the EPA to seriously consider the mass-based approach (EPRI, 2012, p. 2). Likewise, Georgia Mining Association (GMA) supported additional monitoring and research efforts related to $PM_{2.5}$ composition and specifically encouraged the evaluation of using particle number (e.g., particle count) (GMA, 2012, pp. 2 to 3). ALA et al. argued that causal conclusions of an European expert elicitation workshop (Knol et al., 2009) are stronger than the causal determinations reached in the ISA for ultrafine particles. These commenters suggested that "action is needed to establish ambient air quality standards for ultrafines in the next review cycle" (ALA et al., 2012, p. 21). One group of commenter stated "Further delay in moving the process forward of acquiring the necessary data and beginning the long process of establishing and implementing a standard for ultrafine particles/nano particles represents an unacceptable health risk to the nation" (Sammons, et al., 2012, p. 6).

Response: The Administrator agrees with these commenters that the results of additional research and monitoring efforts will be helpful for informing future PM NAAQS reviews. Section 2.5 of the PA highlighted areas for future health-related research, model development, and data collection activities and recognized that "these efforts, if undertaken, could provide important evidence for information future PM NAAQS reviews, and, in particular, consideration of possible alternative indicators, averaging times, and/or levels" (U.S. EPA, 2011a, p. 2-106). The EPA recognizes that information from such studies could also help inform the development of strategies that emphasize control of specific types of emission sources so as to address particles of greatest concern to public health.

These views are consistent with comments offered by CASAC. In general, "CASAC urges the Agency to reinvigorate research that might lead to new indicators that my be more directly linked to the health ad 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" (Samet, 2010d, p. iii). More specifically, CASAC asserted that "$PM_{2.5}$ has been a useful surrogate index since it was adopted in the 1997 PM NAAQS promulgation, but may become an increasingly inadequate index of health risk as the mass concentration limits are reduced…While research evidence on PM and health has evolved, we urge the Agency to undertake additional efforts to leverage the gains made thus far. Now is the time 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 particulate matter (PM) and for more comprehensive PM monitoring data, including expanding the range of sizes, and adding measurements of numbers, chemistry, species, and related emissions characteristics of particles. There is an inherent feedback in the cycle from research to policy formulation whereby researchers use the monitoring data that are gathered primarily for regulatory purposes with available indicators, and, in turn, expand the scientific basis for regulation. If EPA initiates efforts with air pollution research and monitoring communities now to create a more robust monitoring platform for research, the Agency will be better positioned to make an evidence-based transition to the 'next generation' of indicators of PM-related health risks" (Samet, 2010c, p. 2).

See also response to Comment (12)(g) in section II.B.1.b above.

3. Averaging Time

The EPA received few comments on the issue of averaging time for the $PM_{2.5}$ primary standards. One specific significant comment is addressed below.

(1) *Comment:* As discussed in section III.E.2 of the preamble to the final rule, the EPA received no significant comments on the appropriateness of either the 24-hour or annual averaging times for the $PM_{2.5}$ primary standards. However, one group representing several States (i.e., NESCAUM, 2012) suggested consideration of a rolling 24-hour average, rather than a midnight-to-midnight 24-hour average, for the 24-hour $PM_{2.5}$ standard. In justifying this recommendation, NESCAUM noted that using a rolling 24-hour average, rather than the current midnight-to-midnight average, "would be particularly helpful in providing better public health protection in areas where there is the potential for seasonal overnight $PM_{2.5}$ events (e.g., from woodsmoke)."

Response: The EPA agrees with NESCAUM that it is appropriate in this review to increase public health protection against exposures to $PM_{2.5}$. As discussed in the preamble to the final rule (section III.E.4.c.ii), the Administrator has judged it appropriate to achieve such an increase in public health protection by lowering the level of the annual $PM_{2.5}$ standard and retaining the current 24-hour $PM_{2.5}$ standard. These judgments reflect in large part the Administrator's consideration of ambient $PM_{2.5}$ concentrations in the locations where long-term and short-term $PM_{2.5}$ health studies have been conducted. The $PM_{2.5}$ concentrations reported in these study locations are based on midnight-to-midnight sampling.

Altering the sampling time period for the 24-hour $PM_{2.5}$ standard, as suggested by these commenters, would alter the $PM_{2.5}$ concentrations reported and, thus, would alter the degree of health protection provided by the 24-hour standard. As discussed in section II.A of the preamble to the final rule, the CAA charges the Administrator with setting NAAQS that are "requisite" (i.e., neither more nor less stringent than necessary) to protect public health with an adequate margin of safety. In setting such standards, the Administrator must weigh the available scientific evidence and information, including associated uncertainties and limitations. In reaching her proposed decisions on the $PM_{2.5}$ standards that would provide "requisite" protection, the Administrator carefully considered the available scientific evidence and risk information, making public health policy judgments that, in her view, neither overstated nor understated the strengths and limitations of that evidence and information. Commenters have not provided new information or analyses to support the appropriateness of the changes in public health protection that could result from their recommended alterations in the sampling time period.

4. Form

The EPA received a number of public comments on the appropriate forms for the $PM_{2.5}$ standards, primarily related to the spatial averaging provisions within the form of the annual standard. Few public commenters commented specifically on the form of the 24-hour standard. None of the public commenters raised objections to continuing the use of a concentration-based form for the 24-hour standard.

Incorporating responses contained in sections III.E.3.a and III.E.3.b of the preamble to the final rule, the EPA provides the following responses to specific comments related to the form of (a) the annual $PM_{2.5}$ standard and (b) the 24-hour $PM_{2.5}$ standard.

a. Annual Standard

(1) *Comment:* Of the commenters noted in section III.D.2 of the preamble to the final rule and in section II.B.1.a above who supported a more stringent annual $PM_{2.5}$ standard, those who commented on the form of the annual $PM_{2.5}$ standard supported the EPA's proposal to eliminate the spatial averaging provisions. These commenters contended that the EPA's analyses of the potential impacts of spatial averaging, discussed in section III.E.3.a of the preamble to the final rule, demonstrated that the current form results in uneven public health protection leading to disproportionate impacts on at-risk populations. Specifically, the ALA and other environmental and public health commenters contended that "spatial averaging allows exposure of people to unhealthy levels of pollution at specific locales even within an area meeting the standard" (ALA et al., 2012, p. 23). These commenters particularly focused on the importance for low-income and minority populations of eliminating the spatial averaging provisions. They concluded that spatial averaging "is an environmental justice concern because poor people are more likely to live near roads, depots, factories, ports, and other pollution sources." *Id.* p. 24. ALA et al. further asserted that "in order for EPA to meet its Environmental Justice and Clean Air Act requirements dictating that all Americans be protected from environmental health concerns, spatial averaging must be removed" *Id*. p. 25.

Other commenters (e.g., AAM, 2012; Dow, 2012) also supported the elimination of spatial averaging in order to "avoid potential disproportionate impacts on at-risk populations" and to maximize "the benefits to public health of reducing the annual $PM_{2.5}$ standard." However, these groups expressed concern that the elimination of spatial averaging, in combination with the requirement for near road monitors (as discussed in section VIII.B.3.b.i of the proposal), would effectively and inappropriately increase the stringency of the annual $PM_{2.5}$ standard.

This concern was also shared by other commenters who disagreed with the elimination of spatial averaging. For example, the Class of '85 RRG emphasized concerns about increasing the stringency of the standard while providing few health benefits if spatial averaging is eliminated, particularly in combination with the requirement for near-road monitors. These commenters contended that "[b]ecause EPA proposes to use the readings from the highest single worst case monitor (rather than the average of all community area monitors), and since roadway monitoring locations will likely be worst case monitors, the proposed NAAQS will become more stringent without targeting the $PM_{2.5}$ species most harmful to human health" (Class of '85 RRG, 2012, p. 6). Other commenters argued that "unless the Agency adjusts the level of the NAAQS to account for the difference in concentrations at the community-based monitors used to set the standard and those at near-roach monitors, use of the latter to judge compliance with the NAAQS would be unreasonable" (API, 2012, p. 58).

Several commenters also maintained that because spatial averaging is consistent with how air quality data are considered in the underlying epidemiological studies, such averaging should not be eliminated. Specifically, commenters including NAM et al., AFPM, API, and ACC pointed out that $PM_{2.5}$ epidemiological studies use spatially averaged multi-monitor concentrations, rather than the single highest monitor, when evaluating health effects. Therefore, these commenters contended that allowing spatial averaging would make the $PM_{2.5}$ standard more consistent with the approaches used in the epidemiological studies upon which the standard is based. One commenter argued that averaging measurements across multiple monitors in an area "would almost certainly also have included monitors in areas in which minorities and low-income individuals reside. Therefore, their potentially higher exposures would have been addressed in the epidemiological studies" (API, 2012, pp. 24 to 25). Thus, this commenter asserted that elimination of spatial averaging is not warranted.

In addition, some commenters contended that the EPA failed to consider whether modifying, rather than eliminating, the constraints on spatial averaging would have been sufficient to protect public health. If so, these commenters argued that "elimination of spatial averaging would go beyond what is requisite to protect the public health" (NAM et al., 2012, p. 20).

Response: In considering the public comments on the form of the annual standard, the EPA recognizes a number of commenters agreed with the basis for the EPA's proposal to eliminate spatial averaging. While other commenters expressed disagreement or concern with the proposed decision to eliminate the spatial averaging provisions, the Agency notes that these commenters did not challenge the analyses or considerations that provided the fundamental basis for the Administrator's proposed decision. These unchallenged analyses indicate that public health would not be protected with an adequate margin of safety in all locations, as required by law, if disproportionately higher exposure concentrations in at-risk populations such as low income communities as well as minority communities were averaged together with lower concentrations measured at other sites in a large urban area. Moreover, the Agency's concern over possible disproportionate $PM_{2.5}$-related health impacts in at-risk populations extends to populations living near important sources of $PM_{2.5}$ in the ambient air, including the large populations that live near major roadways.

Rather than addressing these analyses specifically, these commenters generally raised concerns that eliminating the option for spatial averaging would increase the stringency of the standard, especially in light of additional monitoring sites in near-road environments as discussed in section VIII.B.3.b.1 of the preamble for the final rule.

The EPA does not agree with the comment that siting some monitors in near roadway environments makes the standard more stringent or impermissibly more stringent. As discussed in section VIII.B.3.b.i of the preamble to the final rule, a significant fraction of the population lives in proximity to major roads, and these exposures occur in locations that represent ambient air. Monitoring in such areas does not make the standard more stringent than warranted, but rather affords the intended protection to the exposed populations, among them at-risk populations, exposed to fine particles in these areas. Thus, in cases where monitors in near roadway environments are deemed to be representative of area-wide air quality they would be compared to the annual standard (as discussed more fully in section VIII of the preamble to the final rule). The 24-hour and annual NAAQS are designed to protect the public with an adequate margin of safety, and this siting provision is fully consistent with providing the protection the standard is designed to provide and does not make the standard more stringent or more stringent than necessary.

Monitors that are representative of area-wide air quality may be compared to the annual standard. This is consistent with the use of monitoring data in the epidemiological studies that provide the primary basis for determining the level of the annual standard. In addition, the EPA notes that the annual standard is designed to protect against both long- and short-term exposures through controlling the broad distribution of air quality across an area over time.[9] It is fully consistent with the protection the standard is designed to provide for near road monitors to be compared to the annual standard if the monitor is representative of area-wide air quality. This does not make the standard either more stringent or impermissibly more stringent.

The EPA notes that CASAC agreed that it was “reasonable” for the EPA to eliminate the spatial averaging provisions (Samet, 2010d, p. 2). Further, in CASAC’s comments on the first draft PA, it 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). In its review of the second draft PA, CASAC recognized that “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” (Samet, 2010d, pp. 1 to 2).

In considering CASAC advice and public comments, the EPA notes that the stringency or level of protection provided by each NAAQS is not based solely on the form of the standard; rather, the four elements of the standard that together serve to define each

[9] This is in contrast to the 24-hour standard which is designed to provide supplemental protection, addressing peak exposures that might not otherwise be addressed by the annual standard. Consistent with this, monitors are not required to be representative of area-wide air quality to be compared to the 24-hour standard.

standard (i.e., indicator, averaging time, form, and level) must be considered collectively in evaluating the protection afforded by each standard, including the protection afforded to at-risk populations. Therefore, the EPA considers it appropriate to discuss these comments collectively with other issues related to the appropriate level for the annual standard as discussed in section III.E.4.c-d of the preamble and in section II.B.5.c below. The EPA notes further that this issue is similar to the issue of whether to base compliance with the standard on use of a maximum monitor or composite monitors. As explained in responses addressing that parallel issue, the EPA's analysis of nationwide air quality patterns indicates that in many instances there is no difference at all, or minor difference, between maximum monitor results and those from composite monitors (Frank, 2012a.). Further, there were only a few other areas in which the maximum monitor mean concentration was appreciably higher than the composite monitor mean concentration, such as areas in which some monitors may be separately impacted by local sources. There were only 10 such areas in the country in which the maximum monitor mean concentration was between 2 to 6 $\mu g/m^3$ higher than the composite monitor concentration (Frank, 2012a, Table 4) Thus, the EPA does not agree that there is a significant difference between composite monitor mean $PM_{2.5}$ concentrations and maximum monitor mean $PM_{2.5}$ concentrations in the large majority of areas across the country such that implementation of the standard on a maximum monitor basis, or without the option of spatial averaging, provides more protection than is requisite due to some inconsistency with key underlying epidemiologic studies.

Based on the analyses done to inform consideration of the form of the standard (Schmidt, 2011, Analysis A), as well as the nationwide analysis of composite and maximum monitor values just discussed, the EPA concludes that spatial averaging (or a composite monitor approach) does not provide a margin of safety for the at-risk populations that live around the monitor measuring the highest concentration, such as in those few areas in which the maximum monitor concentration is appreciably higher than the composite monitor concentration. Thus, the comment that eliminating spatial averaging makes the standard more stringent misstates the issue. The proper question is what level of protection is *requisite* with an adequate margin of safety. If the standard needs to be made more stringent to provide such protection, then such stringency is not only permissible but required (or "appropriate" in the words of section 109 (d)). Diluting the needed protection by averaging monitoring results can demonstrably result in potentially disproportionate impacts on at-risk populations and so would fail to carry out the core statutory requirement to provide requisite protection to public health with an adequate margin of safety.[10]

(2) *Comment:* One commenter argued that the rationale to support elimination of spatial averaging to potentially avoid disproportionate impacts on at-risk populations is flawed because the "evidence for greater susceptibility from PM exposures in these populations

[10] As noted in section II.A of the preamble to the final rule, 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).

is weak" (API, 2012, Attachment 1, pp. ES-2). Furthermore, this commenter asserted that the "evidence presented in the ISA and summarized in the PA and Proposed Rule in support of increased susceptibility to PM among children, older adults, those with pre-existing heart and lung diseases, and those of lower SES is limited and inconsistent. This evidence does not add to the understanding or identification of susceptible populations, and it should not be used to support changes to the form of the annual $PM_{2.5}$ standard" (API, 2012, Attachment 1, p. 47).

Response: The EPA strongly disagrees with the commenter's conclusion regarding the evidence for populations at increased risk for PM-related health effects. Chapter 8 of the ISA discusses the available evidence regarding at-risk populations, and why children, older adults, those with pre-existing heat and lung diseases, and those of lower SES are legitimately regarded as at-risk. For example, "[o]lder adults represent a potentially susceptible population due to the higher prevalence of pre-existing cardiovascular and respiratory diseases found in this age range compared to younger age groups." (U.S. EPA, 2009 a, p. 8-3). Results of epidemiological and toxicological studies support this conclusion, and indicate as well increased susceptibility of older adults to all-cause mortality from short-term exposure, and increased susceptibility to respiratory morbidity and mortality. *Id.* at pp. 8-4 to 5. Children have generally been considered more susceptible to PM exposure due to factors such as more time spent outdoors, greater activity levels, exposures resulting in higher doses per body weight and long surface area, and the possibility of irreversible effects on the developing respiratory system. *Id.* p. 8-5.

Two drafts of the ISA drawing these conclusions with regard to at-risk populations were reviewed by CASAC and by the public, and these same comments were before CASAC as part of that public comment process. CASAC found the "organization and presentation" of the evidence for at-risk populations presented in the ISA to be "complete, clear, and well-organized" (Samet, 2009f, p. 12). Furthermore, CASAC found that the "data presented fully justifies consideration of lower socioeconomic status (SES) people as a susceptible group" (Samet, 2010c. p. 11). Indeed, as noted above, one of the reasons CASAC supported eliminating spatial averaging from the form of the annual standard was due to the "mounting evidence showing that persons with lower SES levels are a susceptible group for PM-related health risks" (Samet, 2010c, p. 13).

(3) *Comment:* Some commenters asserted that elimination of spatial averaging from the form of the annual standard "does not excuse EPA's obligation under the CAA to set standards that explicitly incorporate a margin of safety" (ALA et al., 2012, p. 25).

Response: The EPA agrees with the commenters that setting a standard that provides protection with an adequate margin of safety is not limited to considering the protection afforded by the form of the standard alone. As noted in section III.E.3.i of the preamble to the final rule, the EPA notes that the stringency or level of protection provided by each NAAQS is not based solely on the form of the standard, rather, the four elements of the of the standard that together serve to define each standard (i.e., indicator, averaging time, form, and level) must be considered collectively in evaluating the protection afforded by each standard. As discussed in section III.E.4, the EPA Administrator's conclusions on the appropriate indicator, averaging time, form, and level are considered together in reaching her final decision on the appropriate annual standard that will provide requisite public health protection with an adequate margin of safety.

b. 24-Hour Standard

(1) *Comment:* Many of the individuals and groups who supported a more stringent 24-hour $PM_{2.5}$ standard noted in section III.D.2 of the preamble to the final rule and in section II.B.1.a above, however, recommended a more restrictive concentration-based percentile form, specifically a 99th percentile form. The limited number of these commenters who provided a specific rationale for this recommendation generally expressed their concern that the 98th percentile form could allow too many days where concentrations exceeded the level of the standard, and thus fail to adequately protect public health. Other public commenters representing state and local air agencies and industry groups generally supported retaining the current 98th percentile form. In most cases, these groups expressed the overall view that the current 24-hour $PM_{2.5}$ standard, including the form of the current standard, should be retained.

Response: The EPA notes that the viewpoints represented in this review are similar to comments submitted in the last review and through various NAAQS reviews. The EPA recognizes that the selection of the appropriate form includes maintaining adequate protection against peak 24-hour values 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.[11]

As discussed in section III.E.3.b of the preamble to the final rule, the PA considered air quality data reported in 2000 to 2008 to update our understanding of the ratio between peak-to-mean $PM_{2.5}$ concentrations. This analysis provided evidence that the 98th percentile value was a more stable metric than the 99th percentile (U.S. EPA, 2011a, Figure 2-2, p. 2-62).. In retaining the 98th percentile form, the Administrator focused on the relative stability of the 98th percentile form as a basis for her decision, while recognizing that the degree of public health protection likely to be afforded by a standard is a result of the combination of the form and level of the standard.

5. Level

A large number of comments on the proposed levels for the primary $PM_{2.5}$ standards basically expressed one of two substantively different views. As explained in section III.D.2 of the preamble to the final rule and in sections II.A and II.B.1 above, one group of commenters generally opposed any change to the current primary $PM_{2.5}$ standards and more specifically disagreed with the basis for the EPA's proposal to revise the annual standard level. Another group of commenters supported revising the current suite of primary $PM_{2.5}$ standards to provide increased public health protection. Some commenters in this second group argued that both the

[11] As noted in section III.E.3.b of the preamble to the final rule, it is legitimate for the EPA to consider promotion of overall effectiveness of risk management programs designed to attain the NAAQS, including their overall stability, in setting a standard that is requisite to protect the public health. The context for the court's discussion in *ATA III* is identical to that here; whether to adopt a 98th percentile form for a 24-hour standard intended to provide supplemental protection for a generally controlling annual standard.

annual and 24-hour standard levels should be lowered while other commenters in this group agreed with the EPA's proposal to retain the level of the 24-hour standard in conjunction with revising the level of the annual standard.

Many of these commenters simply expressed their views without stating any rationale, while others gave general reasons for their views but without reference to the factual evidence or rationale presented in the proposal notice as a basis for the Agency's proposed decision regarding the levels of the primary $PM_{2.5}$ standards. A number of commenters, including many environmental and public health organizations as well as state and local air agencies and health departments and tribes, who supported the revising the standard levels generally placed great weight on the recommendations of CASAC. Sections III.D.2 and III.E.4.c of the preamble to the final rule present the Agency's response to these very general views. In addition to the discussion contained in those sections, the EPA provides the following responses to specific issues related to the levels for the primary $PM_{2.5}$ standards. This includes comments on the general approach used by the EPA to translate the available scientific information into standard levels and how specific $PM_{2.5}$ exposure studies should be considered as a basis for the standard levels.

a. Annual Standard

i. Support for Retaining the Current Level

The group of commenters opposed to any change to the current suite of primary $PM_{2.5}$ standards generally raised questions regarding the underlying scientific evidence, including the causal determinations reached in the ISA, and focused strongly on the uncertainties they saw in the scientific evidence as a basis for their conclusion that no changes to the current standard levels were warranted. In commenting on the proposed standard levels, these commenters typically relied on the arguments summarized and addressed in section III.D.2 of the preamble to the final rule and in section II.B.1.b above as to why they believed it was inappropriate for the EPA to make any revisions to the suite of primary $PM_{2.5}$ standards. That is, they asserted that the EPA's causal determinations were not adequately supported by the underlying scientific information; the biological plausibility of health effects observed in epidemiological studies has not been demonstrated in controlled human exposure and toxicological studies; uncertainties in the underlying health science are as great or greater than in 2006; there is no evidence of greater risk since the last review to justify tightening the current annual $PM_{2.5}$ standard; and "new" studies not included in the Integrated Science Assessment continue to increase uncertainty about possible health risks associated with exposure to $PM_{2.5}$.

With regard to the level of the annual standard, these commenters strongly disagreed with the Agency's proposed decision to revise the level to within a range of 12 to 13 $\mu g/m^3$ and argued that the current standard level of 15 $\mu g/m^3$ should be retained. For example, UARG, API, and other commenters in this group raised a number of issues that they asserted called into question the EPA's interpretation of the epidemiological evidence to support revising the annual standard level. These commenters raised specific questions related to the general approach used by the EPA to translate the air quality and other information from specific epidemiological studies into standard levels which are discussed in section III.E.4.c.i of the preamble to the final rule, including:

- the EPA's approach for using composite monitor air quality distributions reported in epidemiological studies to select a standard level that would be compared to measurements at the monitor recording the highest value in an area to determine compliance with the standard;
- the appropriate exposure period for effects observed in long-term exposure mortality studies; and
- the use of the EPA's analysis of distributions of underlying population-level data (i.e., health event and study population data) for those epidemiological studies for which such information was available.

These commenters also raised questions regarding the EPA's consideration of specific scientific evidence as a basis for setting a standard level, including:

- evidence of respiratory morbidity effects in long-term exposure studies and
- more limited evidence of health effects which have been categorized in the ISA as *suggestive* of a causal relationship (i.e., developmental and reproductive outcomes)

These comments and other comments are discussed below.

(1) *Comment:* Some commenters in this group argued that one reason why they believe there is no basis for setting a standard level below 15 µg/m^3 is that the air quality metric from epidemiological studies that the EPA relied on in the proposal is not the same metric that will be compared to the level of the standard to determine compliance with the standard. That is, commenters noted that the long-term mean $PM_{2.5}$ concentrations that the EPA considered, shown in Figure 4 of the preamble to the final rule, are *composite monitor* mean concentrations (i.e., concentrations averaged across multiple monitors within areas with more than one monitor), whereas the $PM_{2.5}$ concentrations that will be compared to the level of the standard are *maximum monitor* concentrations (i.e., the concentration measured by the monitor within an area reporting the highest concentration). This comment was presented most specifically in UARG's comments (UARG, 2012, Attachment 1, pp. 2 to 6), which raised two overarching issues as discussed below.

First, the commenter noted that the EPA's approach of considering composite monitor mean $PM_{2.5}$ concentrations in selecting a standard level, and then comparing the maximum monitor mean $PM_{2.5}$ concentration in each area to the standard level when the standard is implemented, was characterized in the proposal as inherently having the potential to build in a margin of safety (UARG, 2012, Attachment 1, p. 4, citing 77 FR 38905). The commenter asserted that the Administrator is ignoring this distinction between composite and maximum monitor concentrations, and that this approach creates an unwarranted case for lowering the standard level, since in the commenter's view, it would result in a margin of safety that would be arbitrary, not based on evidence, and unquantified (UARG, 2012, Attachment 1, p. 4). In support of this view, the commenter asserted that there is a significant difference between composite monitor mean $PM_{2.5}$ concentrations and maximum monitor mean $PM_{2.5}$ concentrations. The commenter asserted that the maximum monitor value will always be higher than the composite monitor value (except in areas that contain only a single monitor), such that when an area just attains the NAAQS, that area's composite monitor long-term mean $PM_{2.5}$ concentration will be lower than the level of the standard (UARG, 2012, Attachment 1, p. 3).

Second, the commenter asserted that a more "reasoned and consistent approach would be to decide on a mean composite monitor $PM_{2.5}$ level that should be achieved and then identify the maximum monitor level that would result in that composite value" (UARG, 2012, Attachment 1, p. 4). The commenter conducted an analysis of maximum monitor versus composite monitor annual mean $PM_{2.5}$ concentrations using monitoring data[12] from 2006 to 2008 and presented results averaged across areas within two groups (i.e., those with design values[13] above the current standard level and those with design values just below the current standard level) to illustrate their suggested alternative approach. The commenter interpreted this analysis as showing that the composite monitor long-term mean $PM_{2.5}$ concentrations from the subset of the epidemiological studies shown in Figure 4 (of the preamble to the final rule) that the commenter considered to be an appropriate focus for this analysis would be achieved across the U.S. if the current annual NAAQS of 15 μg/m^3 is retained and attained. The commenter considered the subset of epidemiological studies that included only long-term exposures studies of effects for which the evidence is categorized as causal or likely causal, but did not consider short-term exposure studies. On this basis, the commenter asserted that attaining the current annual $PM_{2.5}$ standard would result in composite monitor long-term mean concentrations in all areas that would be generally within or below the range of the composite monitor long-term mean concentrations from such studies and, as a result, there is no reason to lower the level of the current annual NAAQS.

Response: In considering the first issue related to the EPA's approach, the EPA notes that in proposing to revise both the form and level of the annual standard, the Administrator clearly took into account the distinction between the composite monitor long-term mean $PM_{2.5}$ concentrations from the epidemiological studies, considered as a basis for selecting an annual standard level, and maximum monitor long-term mean $PM_{2.5}$ concentrations. In deciding to focus on the composite monitor long-term mean concentrations in selecting the standard level, and on the maximum monitor concentrations in selecting the form of the standard (i.e., consistent with proposing to eliminate the option for spatial averaging across monitors within an area when implementing the standard[14]), the Administrator reasonably considered the distinction between these metrics in a manner that was consistent with advice from CASAC (Samet et al., 2010d, pp. 2 to 3).

As noted in section III.A.3 of the preamble to the final rule, the EPA recognizes that a statistical metric (e.g., the mean of a distribution) based on maximum monitor concentrations may be identical to or above the same statistical metric based on composite monitor concentrations. More specifically, many areas have only one monitor,

[12] The commenter indicated that this analysis was based on monitoring data for every core based statistical area (CBSA) in the EPA's Air Quality System (AQS) database.
[13] The design value is the air quality statistic that is compared to the level of the NAAQS to determine the attainment status of a given area.
[14] As discussed in section III.E.3.a of the preamble to the final rule and in response to comment (1) in section II.B.4.a above.

in which case the composite and maximum monitor concentrations are identical. Based on the most recent data from the EPA's AQS from 2009 to 2011 in the 331 CBSAs in which valid $PM_{2.5}$ data are available, as discussed in Frank (2012a, Table 5), there were 208 such areas (with design values ranging up to about 15 μg/m^3). Frank (2012a) also observed that other areas have multiple monitors with composite and maximum monitor mean $PM_{2.5}$ concentrations that were the same or relatively close, with 57 areas in which the maximum monitor mean concentration was no more than 0.5 μg/m^3 higher than the composite monitor mean concentration and 56 areas in which the difference was between 0.6 and 2 μg/m^3. Further, there were only a few other areas in which the maximum monitor mean concentration was appreciably higher than the composite monitor mean concentration, such as areas in which some monitors may be separately impacted by local sources. There were only 10 such areas in the country in which the maximum monitor mean concentration was between 2 to 6 μg/m^3 higher than the composite monitor concentration (Frank, 2012a, Table 4).[15] Thus, the EPA does not agree that there is a significant difference between composite monitor mean $PM_{2.5}$ concentrations and maximum monitor mean $PM_{2.5}$ concentrations in the large majority of areas across the country.

In proposing to revise the form of the annual $PM_{2.5}$ standard, as discussed in section III.E.3.a of the preamble to the final rule, the EPA noted that when an annual $PM_{2.5}$ standard was first set in 1997, the form of the standard included the option for averaging across measurements at appropriate monitoring sites within an area, generally consistent with the composite monitor approach used in epidemiological studies, with some constraints intended to ensure that spatial averaging would not result in inequities in the level of protection for communities within large metropolitan areas. In the last review the EPA tightened the constraints on spatial averaging, and in this review has eliminated the option altogether, on the basis of analyses in each review that showed that such constraints may be inadequate to avoid substantially greater exposures for people living in locations around the monitors recording the highest $PM_{2.5}$ concentrations in some areas, potentially resulting in disproportionate impacts on at-risk populations such as persons with lower SES levels. In light of these analyses, and consistent with the Administrator's decision to revise the form of the annual $PM_{2.5}$ standard by eliminating the option for spatial averaging, the EPA continues to conclude that a standard level based on consideration of long-term mean concentrations from composite monitors, and applied at each monitor within an area including the monitor measuring the highest concentration, is the appropriate approach to use in setting a standard that will protect public health, including the health of at-risk populations, with an adequate margin of safety, as required by the CAA.

The EPA acknowledges that at proposal, the Agency characterized the approach of using maximum monitor concentrations to determine compliance with the standard, while selecting the standard level based on consideration of composite monitor concentrations, as one that inherently had the potential to build in a margin of safety (77 FR 38905), and

[15] The average difference between the maximum and composite design value among the 123 CBSAs with two or more monitors is 0.8 μg/m^3 and the median difference is 0.6 μg/m^3. The 25th and 75th percentiles are 0.3 and 1.0 μg/m^3, respectively (Frank, 2012a, p. 4).

CASAC reiterated that view in supporting the EPA's approach (Samet, 2010d, p. 3). Nonetheless, in light of the analysis discussed above, the EPA more specifically recognizes that this approach does not build in any margin of safety in the large number of areas across the country with only one monitor. Further, based on the analyses done to inform consideration of the form of the standard (Schmidt, 2011, Analysis A), the EPA concludes that this approach does not provide a margin of safety for the at-risk populations that live around the monitor measuring the highest concentration, such as in those few areas in which the maximum monitor concentration is appreciably higher than the composite monitor concentration. Rather, this approach properly treats those at-risk populations the same way it does the broader populations that live in areas with only one monitor, by providing the same degree of protection for those at-risk populations that would otherwise be disproportionately impacted as it does for the broader populations in other areas. Moreover, while the EPA recognizes that this approach can result in some additional margin of safety for the subset of areas with multiple monitors in which at-risk populations may not be disproportionately represented in areas around the maximum monitor, which may be the case in areas with relatively small differences between the maximum and composite monitor concentrations, the EPA notes that this margin would be relatively small in such areas.

Based on the above considerations, the EPA does not agree that the Agency's approach of using maximum monitor concentrations to determine compliance with the standard, while selecting the standard level based on consideration of composite monitor concentrations, creates an unwarranted case for lowering the standard level based on a margin of safety that would be arbitrary, not based on evidence, or lacking quantification. The EPA recognizes that setting a standard to protect public health, including the health of at-risk populations, with an adequate margin of safety, depends upon selecting a standard level sufficiently below where the EPA has found the strongest evidence of health effects so as to provide such protection, and that the EPA's approach regarding consideration of composite and maximum monitor concentrations is intended to, and does, serve to address this requirement as part of and not separate from the selection of an appropriate standard level and form based on the health effects evidence.

In considering the second issue related to the commenter's suggested alternative approach, the EPA strongly disagrees with the commenter's view that a more "reasoned and consistent approach would be to decide on a mean composite monitor $PM_{2.5}$ level that should be achieved and then identify the maximum monitor level that would result in that composite value" (UARG, 2012, Attachment 1, p. 4). As discussed above, the EPA notes that for areas with only one monitor, or with multiple monitors that measure concentrations that are very close in magnitude, the maximum monitor level that would limit the composite monitor $PM_{2.5}$ level to be no greater than the level that should be achieved to protect public health with an adequate margin of safety, would essentially be the same as that composite monitor level. Further, as discussed above, even for areas in which the maximum monitor concentration is appreciably higher than other monitor concentrations within the same area, public health would not be protected with an adequate margin of safety if the disproportionately higher exposures of at-risk, susceptible populations around the monitor measuring the highest concentration were in essence averaged away with measurements from monitors in other locations within large urban areas. Further, the commenter's suggested approach would be based on annual average $PM_{2.5}$ concentrations that have been measured over some past time period. Such an approach would reflect the air quality that existed in the past, but it would not necessarily provide appropriate constraints on the range of concentrations that would be allowed by such a standard in the future, when relationships between maximum and composite monitor concentrations in areas across the country may be different. For these reasons, the EPA fundamentally rejects the commenter's suggested approach because it results in a standard that demonstrably would not protect public health, including providing protection for at-risk populations, with an adequate margin of safety in areas across the country.

More specifically, in further considering the commenter's analysis of design values based on maximum versus composite monitor annual mean $PM_{2.5}$ concentrations using monitoring data from 2006 to 2008 which they assert supports retaining the current standard level of 15 $\mu g/m^3$, the EPA finds flaws with the numerical results and the scope of the analysis, as well as flaws in the commenter's translation of the analysis results into the basis for selecting an annual standard level.

In considering the commenter's analysis, the EPA notes that the analysis compared maximum versus composite monitor annual mean $PM_{2.5}$ concentrations, averaged over 3 years, for two groups of areas: (1) areas with design values that exceed the current annual standard level (i.e., greater than 15.0 $\mu g/m^3$) and (2) areas with design values that are just attaining the current annual standard (i.e., between 14.5 and 15.0 $\mu g/m^3$).[16] The commenter indicated that they used the full body of $PM_{2.5}$ monitoring data from the EPA's AQS database (UARG, 2012, Attachment 1, p. 4). In attempting to reproduce the commenter's results, the EPA repeated the calculations using only valid air quality data (i.e., data that meet data completeness and monitor siting criteria) from the AQS database for the same time period (Frank, 2012a).[17] Based on this corrected analysis, the EPA finds that the composite monitor concentrations averaged across the areas within each group are somewhat higher than those calculated by the commenter, and the average differences between the maximum and composite monitor concentrations are somewhat smaller (Frank, 2012a, Table 3).[18] Notably, the difference between the maximum and composite monitor average concentrations for the second group of areas is substantially

[16] For the first group of areas (which included 33 areas), this analysis calculated an average across the areas of maximum monitor annual mean $PM_{2.5}$ concentrations, averaged over 3 years, of 17.2 $\mu g/m^3$ compared to an average of composite monitor concentrations of 14.3 $\mu g/m^3$. For the second group of areas (which included 11 areas), this analysis calculated an average across the areas of maximum monitor annual mean concentrations, averaged over 3 years, of 14.8 $\mu g/m^3$ compared to an average of composite monitor concentrations of 13.6 $\mu g/m^3$ (UARG, 2012, Attachment 1, Table 1).

[17] The EPA notes that the Frank (2012a) analysis is similar to an earlier EPA staff analysis (Hassett-Sipple et al., 2010), which used air quality data from the EPA's AQS database to compare maximum versus composite monitor long-term mean $PM_{2.5}$ concentrations across the study areas in six selected multi-city epidemiological studies.

[18] The EPA's analysis was intended to repeat the commenter's analysis, but using only valid air quality data (from 2006 to 2008). For the first group of areas (which included 21 areas with valid data), the EPA's analysis calculated an average across the areas of maximum monitor annual mean concentrations, averaged of 3 years, of 16.8 $\mu g/m^3$ compared to an average of composite monitor concentrations of 14.8 $\mu g/m^3$. For the second group of areas (which included 10 areas with valid data), the EPA's analysis calculated an average across the areas of maximum monitor annual mean concentrations, averaged over 3 years, of 14.8 $\mu g/m^3$ compared to an average of composite monitor concentrations of 14.2 $\mu g/m^3$ (Frank, 2012a, Table 3).

reduced in the corrected analysis, such that the difference (averaged across the 10 areas with valid data in the second group) is approximately 0.5 $\mu g/m^3$, not 1.2 $\mu g/m^3$ as in the commenter's analysis. In addition, the commenter's analysis compared the average of the composite monitors to the average of the maximum monitors for each subset of areas. This comparison of averages across all the areas in each subset masks the fact that the large majority of areas across the country have only one monitor, with the composite monitor and maximum monitor values the same for such areas, and many other areas have a maximum monitor value that is close to the composite monitor value. As discussed above, these circumstances have a major impact on the protection that would be achieved by the approach suggested by the commenter.

With regard to the scope of the commenter's analysis, the EPA finds that by limiting the scope to a small subset of areas with design values above or just below the current annual standard level of 15 $\mu g/m^3$, the analysis ignores the large number of areas across the country with lower design values that are relevant to consider in light of the epidemiological evidence of serious health effects at concentrations lower than 15 $\mu g/m^3$, well below the level of the current standard.

In translating its analysis results into the basis for selecting an annual standard level, the commenter's translation is premised on the view that the "natural focal point" for setting an annual $PM_{2.5}$ standard level should be somewhere within the range of the long-term mean $PM_{2.5}$ concentrations from the subset of epidemiological studies that included only long-term exposure studies of effects for which the evidence is categorized as causal or likely causal, but not for effects categorized as suggestive of causality, nor did it include short-term exposure studies (which are included in Figure 4 of the preamble to the final rule). Ignoring effects for which evidence of causality is suggestive is not consistent with setting a standard that would provide sufficient protection from the serious health effects reported even in the limited subset of studies considered by the commenter, much less protecting public health with an adequate margin of safety. Moreover, as discussed below, the EPA does not agree with the commenter's view as to the appropriate focal point for selecting the level of an annual $PM_{2.5}$ standard, or with the limited set of studies considered by the commenter as a basis for selecting the level of the annual $PM_{2.5}$ standard.

Regarding an appropriate focal point for selecting the level of the annual standard, as discussed in the proposal and as advised by CASAC, the EPA has focused on $PM_{2.5}$ concentrations somewhat *below* the lowest long-term mean concentrations from *each* of the key studies of both long- and short-term exposures of effects for which the evidence is causal or likely causal, as considered by the EPA (i.e., the first two sets of studies shown in Figure 4 of the preamble to the final rule and in the proposal, 77 FR 38933). If the level of the annual standard was set just somewhere *within* the range of the long-term mean concentrations from the various long-term exposure studies, then one or more of the studies would have a long-term mean concentration below the selected level of the standard. Absent some reason to ignore or discount these studies, which the commenter does not provide (and of which the EPA is unaware), setting such a standard would allow that level of air quality, where the evidence of health effects is strongest, and its associated risk of $PM_{2.5}$-related mortality and/or morbidity effects to continue. Selecting such a standard level could not be considered sufficient to protect the public health with an adequate margin of safety.

Further, focusing on just the long-term *mean* $PM_{2.5}$ concentrations in the key epidemiological studies – even the lowest long-term mean concentration from the set of key studies -- is not appropriate. Concentrations at and around the long-term mean concentrations represent the part of the air quality distribution where the data in any given study are most concentrated and, thus, where the confidence in the magnitude and significance of an association in such study is strongest. However, the evidence of an association with adverse health effects in the studies is not limited to the $PM_{2.5}$ concentrations just at and around the long-term mean, but rather extends more broadly to a lower part of the distribution, recognizing that no discernible population-level threshold for any such effects can be identified based on the available evidence. This broader region of the distribution of $PM_{2.5}$ concentrations should be considered to the extent relevant information is available, recognizing that the degree of confidence in the association identified in a study would become lower as one moves below concentrations at and around the long-term mean concentration in any given study. The commenter's approach ignores this fundamental consideration.

Regarding the set of studies that is appropriate to inform the selection of the level of the annual $PM_{2.5}$ standard, the EPA finds that limiting consideration only to the *long-term exposure* studies, as this commenter suggests, would be tantamount to ignoring the *short-term exposure* studies,[19] which provide some of the strongest evidence from the entire body of epidemiological studies. Thus, selecting an annual standard level using the limited set of studies suggested by the commenter would fail to provide a degree of protection that would be sufficient to protect public health with an adequate margin of safety.

For all the reasons discussed above, the EPA finds the commenter's concerns with the EPA's approach to considering composite and maximum monitor $PM_{2.5}$ concentrations in selecting the level of the annual $PM_{2.5}$ standard to be without merit. Further, the EPA finds no support in the commenter's analysis for their suggested alternative approach.

(2) *Comment:* With respect to the appropriate exposure period for mortality effects observed in long-term exposure studies, some commenters in this group generally expressed views consistent with comments from UARG that argued that these studies "are most likely detecting health risk from earlier, higher $PM_{2.5}$ levels and misattributing those risks to

[19] The commenter suggests that the EPA should not place significant reliance on the long-term mean concentrations from short-term exposure studies because "]the short-term studies did not use the annual average of $PM_{2.5}$ to develop their associations; they used the daily 24-hour averages of $PM_{2.5}$. Thus, short-term studies do not provide a natural indicator for the appropriate level of an annual standard…." (UARG, 2012, Attachment 1, p. 3). The EPA finds this argument unpersuasive. Quite simply, effects were observed in these studies with an air quality distribution that can meaningfully be characterized by these long-term mean concentrations. Indeed, in remanding the 2006 standard, the D.C. Circuit discussed at length the interrelationship of the long- and short-term standards and studies, and remanded the 2006 standard to the EPA, in part, because the EPA had either ignored these relationships or had failed to provide an adequate explanation for disregarding them. *American Farm Bureau Federation v. EPA. 559* F. 3d at 522-24.

more recent, lower $PM_{2.5}$ levels" (UARG, 2012, Attachment 1, p 7). Further, this commenter asserted that "there is no knowledge or evidence indicating whether premature deaths are the result of $PM_{2.5}$ exposures in the most recent year; or due to physical damages incurred from $PM_{2.5}$ exposures much earlier in life (with the impact on lifespan only emerging later in life); or due to total accumulated $PM_{2.5}$ exposure over many years." *Id*. In addition, the commenter asserted that the long-term exposure studies of mortality are central to the EPA's basis for proposing to set a lower annual standard level, since most of the estimated benefits associated with a lower annual $PM_{2.5}$ standard are based on reductions in mortality related to long-term exposures to $PM_{2.5}$.

Response: As an initial matter, the EPA has recognized the challenge in distinguishing between $PM_{2.5}$-associated effects due to past and recent long-term exposures, and in identifying the relevant latency period for long-term exposure to PM and resultant health effects (U.S. EPA, 2009a, section 7.6.4; 77 FR 38941/1). While the EPA has acknowledged that there remain important uncertainties related to characterizing the most relevant exposure periods in long-term exposure studies, the assertion that there is "no knowledge or evidence" that helps to inform this issue is not correct, as discussed below.

Both in the last review and in the current review, the EPA has assessed studies that used different air quality periods for estimating long-term exposure and tested associations with mortality for the different exposure periods (U.S. EPA, 2004, section 8.2.3.5; U.S. EPA 2009a, section 7.6.4). In this review, the ISA discussed studies available since the last review that have assessed the relationship between long-term exposure to $PM_{2.5}$ and mortality to explore the issue of the latency period between exposure to $PM_{2.5}$ and death (U.S. EPA, 2009a, section 7.6.4).

Notably, in a recent analysis of the extended Harvard Six Cities Study, Schwartz et al. (2008) used model averaging (i.e., multiple models were averaged and weighted by probability of accuracy) to assess exposure periods prospectively (77 FR 38907/1-2). The exposure periods were estimated across a range of unconstrained distributed lag models (i.e., same year, one year prior, two years prior to death). In comparing lags, the authors reported that the effects of changes in exposure to $PM_{2.5}$ on mortality were strongest within a 2-year period prior to death (U.S. EPA, 2009a, p. 7-92, Figure 7-9). Similarly, a large multi-city study of the elderly found that the mortality risk associated with long-term exposure to PM_{10} reported cumulative effects that extended over the years that deaths were observed in the study population (i.e., the follow-up period) and for the 3-year period prior to death (Zanobetti et al., 2008).

Further, in a study of two locations that experienced an abrupt decline in $PM_{2.5}$ concentrations (i.e., Utah Steel Strike, coal ban in Ireland), Röösli et al. (2005) reported that approximately 75 percent of health benefits were observed in the first 5 years (U.S. EPA, 2009a, Table 7-9). Schwartz et al. (2008) and Puett et al. (2008) found, in a comparison of exposure periods ranging from 1 month to 48 months prior to death, that exposure to PM_{10} 24 months prior to death exhibited the strongest association, and the weakest association was reported for exposure in the time period of 1 month prior to death.

Overall, the EPA notes that the available evidence for determining the exposure period that is causally related to the mortality effects of long-term $PM_{2.5}$ exposures, as discussed above, cannot specifically disentangle the effects observed in long-term exposure studies associated with more recent air quality measurements from effects that may have been associated with earlier, and most likely higher, $PM_{2.5}$ exposures. While the evidence suggests that a latency period of up to five years would account for the majority of deaths, it does not provide a basis for concluding that it is solely recent $PM_{2.5}$ concentrations that account for the mortality risk observed in such studies. Nonetheless, the more recent air quality data does well at explaining the relationships observed between long-term exposures to $PM_{2.5}$ and mortality, with the strongest association observed in the two years prior to death. Further, the EPA recognizes that there is no discernible population-level threshold below which effects would not occur, such that it is reasonable to consider that health effects may occur over the full range of concentrations observed in the epidemiological studies, including the lower concentrations in the latter years. In light of this evidence and these considerations, the EPA concludes that it is appropriate to consider air quality concentrations that are generally contemporaneous with the collection of health event data (i.e., collected over the same time period) as being causally associated with at least some proportion of the deaths assessed in a long-term exposure study. This would include long-term mean $PM_{2.5}$ concentrations from most of the key long-term exposure studies of effects with causal or likely causal evidence shown in Figure 4 of the preamble to the final rule, which reported long-term mean $PM_{2.5}$ concentrations ranging from 13.6 $\mu g/m^3$ to 14.3 $\mu g/m^3$. These studies include studies of mortality by Eftim et al. (2008), which separately analyzed the ACS and Harvard Six City sites, Zeger et al. (2008), and Lipfert et al. (2006a), as well as studies of morbidity endpoints by Goss et al. (2004), McConnell et al. (2003) and Gauderman et al. (2004), and Dockery et al. (1996) and Razienne et al. (1996). The EPA acknowledges that uncertainty in the relevant exposure period is most notable in two other long-term exposure studies of mortality. The Miller et al. (2007) reported a long-term mean $PM_{2.5}$ concentration for a 1-year exposure period that post-dated the follow-up period in which health event data were collected by two years. Also, the Krewski et al. (2009a) study reported a long-term mean $PM_{2.5}$ concentration for an exposure period that included only the last two years of the 18-year follow-up period. Based on these considerations, the EPA does not now consider it appropriate to put weight on the reported long-term mean concentrations from these two studies for the purpose of translating the information from the long-term mortality studies into a basis for selecting the level of the annual $PM_{2.5}$ standard.[20]

In addition, the EPA acknowledges that exposure periods that extend at least a couple years prior to the follow-up period in which health event data were collected would likely more fully capture the PM-related deaths in such studies. To explore how much higher the long-term mean $PM_{2.5}$ concentrations would likely have been had air quality data prior to the follow-up years of the studies been included, the EPA conducted a sensitivity analysis of long-term mean $PM_{2.5}$ concentrations (Schmidt, 2012a) particularly

[20] Nonetheless, the EPA notes that the Krewski et al. (2009) and Miller et al. (2007) studies provide strong evidence of mortality and cardiovascular-related effects associated with long-term $PM_{2.5}$ exposures to inform causality determinations reached in the ISA (U.S. EPA, 2009a, sections 7.2.11 and 7.6).

considering studies that only included deaths from a relatively recent follow-up period. As examples of such studies, this analysis considered the Eftim et al. (2008) study of mortality in the ACS sites and the Harvard Six Cities sites, as well as sites in the eastern region in the Zeger et al. (2008) study. Using data from the EPA's AQS database, the analysis added the two years of air quality data just prior to the follow-up period in each study, which was 2000 to 2002 in Eftim et al. (2008) and 2000 to 2005 in Zeger et al. (2008). The analysis then calculated the extended long-term mean $PM_{2.5}$ concentration for each study. As discussed in Schmidt (2012a), in each case the long-term mean $PM_{2.5}$ concentration averaged over the extended exposure period was no more than 0.4 $\mu g/m^3$ higher than the long-term mean $PM_{2.5}$ concentration averaged over the follow-up period. The EPA finds it reasonable to conclude that such a relatively small difference in long-term mean $PM_{2.5}$ concentrations would likely apply for other long-term exposure studies that used similarly recent follow-up periods as well (e.g., Goss et al., 2004; Lipfert et al., 2006).

Based on the above considerations, the EPA concludes that it is appropriate to consider the available air quality information from the long-term exposure studies, while taking into account the uncertainties in the relevant long-term exposure periods in weighing the information from these studies. The EPA recognizes that considering such information in selecting an appropriate annual standard level has the potential to build in some margin of safety. The EPA further concludes that it is appropriate to consider the air quality information from the set of long-term exposure studies discussed above in the context of the broader array of epidemiological studies that inform the EPA's consideration of the level of the annual $PM_{2.5}$ standard.

The EPA also notes that while the long-term exposure studies are an important component of the epidemiological evidence that informs the Agency's consideration of the level of the annual standard, they do not provide the only relevant information, nor are they the set of studies for which the relevant long-term mean $PM_{2.5}$ concentrations are the lowest. As discussed in the proposal, the EPA also considers the long-term mean $PM_{2.5}$ concentrations from the short-term mortality and morbidity studies as providing important information in considering the level of the annual standard. As discussed above, a large proportion of the aggregate 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 of the concentrations observed in the studies. Thus, setting the level of the annual standard based on long-term mean concentrations, as well as the distribution of concentrations below the mean, in the short-term exposure studies is the most effective and efficient way to reduce total $PM_{2.5}$-related risk from the broad array of mortality and morbidity effects associated with short-term exposures.

Further, the EPA notes that the relevant exposure period for the short-term exposure studies is the period contemporaneous with the collection of health event data, and that this exposure period is not subject to the uncertainties discussed above related to the long-term exposure studies. Recognizing that the long-term mean $PM_{2.5}$ concentrations from several of the multi-city short-term exposure studies shown in Figure 4 of the preamble to the final rule are below the long-term mean $PM_{2.5}$ concentrations from the long-term exposure studies (with the exception of Miller et al., 2007).[21] It is reasonable that in selecting the level of the annual standard primary consideration should be given to the information from this set of short-term exposure studies. There is no reasonable basis to discount the long-term mean concentrations of the short-term exposure studies for purposes of setting the level of the annual standard. Thus, the commenter is incorrect in asserting that the long-term exposure studies, not the short-term exposure studies, would be central in the Administrator's decision on the level of the annual standard. The standard is ultimately intended to protect not just against the single type of effect that contributes the most to quantitative estimates of risk to public health, but rather to the broad array of effects, including mortality and morbidity effects from long- and short-term exposures across the range of at-risk populations impacted by $PM_{2.5}$-related effects.

(3) *Comment*: With regard to the EPA's analysis of distributions of underlying population-level data (i.e., health event and study population data) and corresponding air quality data from each study area in certain key multi-city epidemiological studies (Rajan et al., 2011), some commenters in this group raised a number of issues related to this analysis (e.g., McClellan, 2012; API, 2012, Attachment 1, pp. 5 to 6). Some commenters noted the limited number of studies for which health event and study population data were available, and questioned whether these distributions would apply to other studies. Commenters expressed concerns that this analysis had not been formally reviewed by CASAC and was not published in the peer-review literature. One commenter asserted that the data sets the EPA used in the distributional analysis were "not available to other scientists for critical independent analysis and interpretation" (McClellan, 2012, p. 2). Based on such concerns, some commenters asserted that the EPA should not consider this information as a basis for selecting a standard level.

Response: As an initial matter, as discussed in section III.E.4.b of the preamble to the final rule and in previous responses in this document, the EPA agrees with CASAC's advice that it is appropriate to consider additional data beyond the mean $PM_{2.5}$ concentrations in key multi-city studies to help inform selection of the level of the annual $PM_{2.5}$ standard. As both the EPA and CASAC recognize, in the absence of a discernible threshold, health effects may occur over the full range of concentrations observed in the epidemiological studies. Nonetheless, the EPA recognizes that confidence in the magnitude and significance of an association is highest at and around the long-term mean $PM_{2.5}$ concentrations reported in the studies and the degree of confidence becomes lower at lower concentrations within any given study. Following CASAC's advice (Samet, 2010d, p.2), the EPA used additional population-level and air quality data made available by study authors to conduct an analysis of the distributions of such data, to help inform consideration of how the degree of confidence in the magnitude and significance of observed associations varies across the range of long-term mean $PM_{2.5}$ concentrations in study areas within key multi-city epidemiological studies. In the EPA's view, such consideration is important in selecting a level for an annual standard that will protect public health with an adequate margin of safety.

[21] As noted in sections III.E.4.c.i and III.E.4.d of the preamble to the final rule, the EPA is not placing weight on the reported long-term mean concentrations from the Miller et al. (2007) study for the purpose of translating the information from the long-term mortality studies into a basis for selecting the level of the annual $PM_{2.5}$ standard.

With regard to the number of multi-city studies for which an analysis of the distributions of population-level data across the study areas and the corresponding annual mean $PM_{2.5}$ concentrations was done, the EPA noted at proposal that data for such an analysis were made available from study authors for four studies, including two long-term exposure studies and two short-term exposure studies.[22] The EPA recognized that access to health event data can be restricted due to confidentiality issues, such that it is not reasonable to expect that such information could be made available from all studies. In considering the information from these four studies, the EPA has further taken into consideration uncertainties discussed in response to the above comment related to the appropriate exposure period for long-term exposure studies. Based on these considerations, as noted above, the EPA concludes that such uncertainties are an important factor in evaluating the usefulness of the air quality information from the two long-term exposure studies in this analysis (Krewski et al., 2009a; Miller et al., 2007) and that it would not be appropriate to place weight on the distributional analysis of health event and air quality data from these two studies specifically for the purpose of translating the information from the long-term mortality studies into a basis for selecting the level of the annual $PM_{2.5}$ standard. Such uncertainties are not relevant to the short-term exposure studies, and thus, the Agency focuses on the two short-term exposure studies in this analysis (Bell et al., 2008; Zanobetti and Schwartz, (2009).

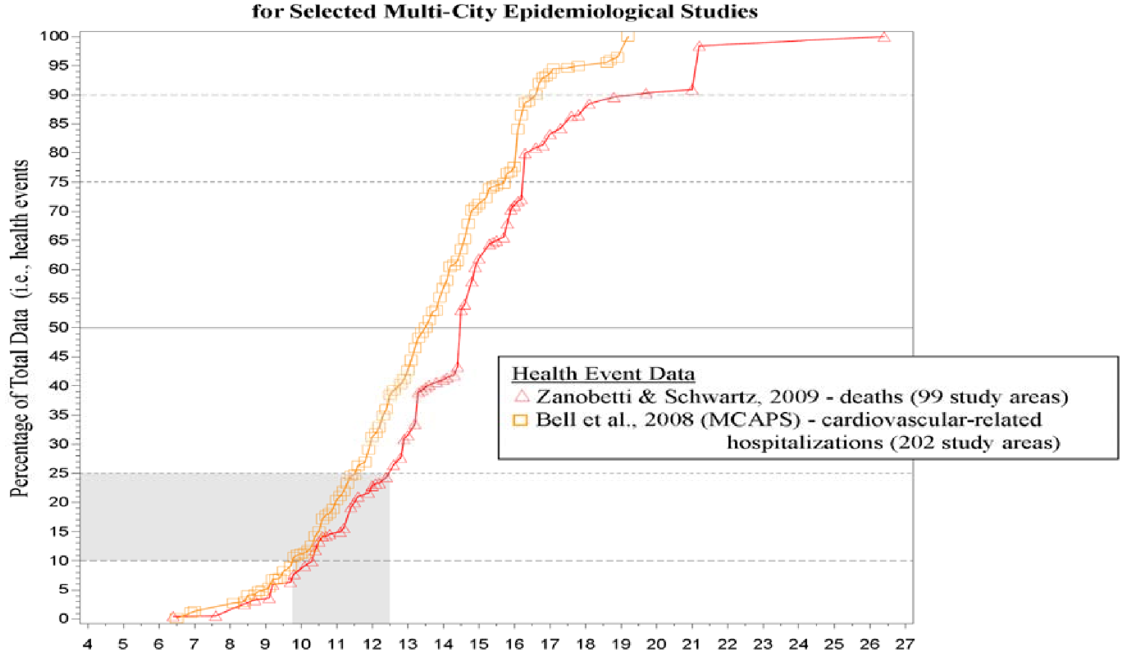
In focusing on these two short-term exposure studies, the EPA first notes that these studies are key multi-city studies that reported positive and statistically significant associations between mortality and cardiovascular-related hospital admissions across a large number of areas throughout the U.S. (112 U.S. cities in Zanobetti and Schwartz, 2009; 202 U.S. counties in Bell et al., 2008) using relatively recent air quality and health event data (i.e., 1999 through 2005 in both studies). The EPA considers these two studies to comprise a modest but important data set to use for this distributional analysis in this review to help inform consideration of how much below the long-term mean $PM_{2.5}$ concentrations in key multi-city long- and short-term exposure studies the annual $PM_{2.5}$ standard level should be set. While the EPA acknowledges that having such data available from more studies would have been useful, the Agency finds the information from this limited set of studies to be useful for consideration in selecting an annual standard level, consistent with CASAC advice to consider such information.

The results of this distributional analysis are shown in Figure 5 below (adapted from Figure 3 in Rajan et al., 2011). For each study, this figure shows the cumulative frequency of the number of health events in each study area and the corresponding long-term mean $PM_{2.5}$ concentrations in each area. Consistent with CASAC advice (Samet, 2010d, p.2), such an analysis helps to inform the EPA's understanding of the long-term mean $PM_{2.5}$ concentrations that were most influential in generating the health effect estimates in individual studies. In particular, the EPA recognizes that there is significantly greater confidence in the magnitude and significance of observed associations in that part of the air quality distribution corresponding to where the bulk of

[22] Health event data and study population data were available from two short-term exposure studies (Bell et al. 2008; Zanobetti and Schwartz, 2009) and one long-term exposure study (Krewski et al., 2009). Only study population data were available from another long-term exposure study (Miller et al., 2007).

the health events evaluated in each study have been observed. With regard to the part of the distribution in which confidence in the magnitude and significance of associations observed may become appreciably lower, the EPA considers $PM_{2.5}$ concentrations between the 25th and 10th percentiles of the distribution of health events in these studies to be a reasonable range for providing a general frame of reference for that part of the distribution in which confidence in the magnitude and significance of the association may be appreciably lower than confidence at and around the long-term mean concentration. As highlighted in Figure 5, the long-term mean $PM_{2.5}$ concentrations corresponding with study areas contributing to the 25th and 10th percentiles of the distribution of deaths and cardiovascular-related hospitalizations in the two short-term exposure studies were 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). The EPA also recognizes, however, that there is no clear dividing line or single percentile within a given distribution (including both above and below the 25th percentile) provided by the scientific evidence that is most appropriate or 'correct' to use to characterize where the degree of confidence in the associations warrants setting the annual standard level. The decision as to the appropriate standard level below the long-term mean concentrations of the key studies is largely a public health policy judgment to be made by the Administrator, taking into account all of the evidence and its related uncertainties, as discussed in section III.E.4.d of the preamble to the final rule.

Figure 5. Distribution of Health-Event Data and Corresponding $PM_{2.5}$ Concentrations for Selected Multi-City Epidemiological Studies



Source: modification of Figure 3, Rajan et al., 2011

In response to concerns that this analysis was not reviewed by CASAC nor published in the peer-reviewed literature, the EPA notes that this analysis was conducted to directly respond to advice from CASAC, as discussed in section III.E.4.b.1 of the preamble to the final rule, in conjunction with their review of the PA. The EPA notes that the same type of distributional analysis was presented in the second draft PA based on air quality data, as well as on population-weighted air quality data, rather than on health event or study population data. In considering that distributional information, CASAC urged that the EPA redo the analysis using health event or study population data, which is exactly what the EPA did and presented in the final PA. The EPA provided CASAC with the final PA and communicated how the final staff conclusions reflected consideration of its advice and that those staff conclusions were based in part on the specific distributional analysis that CASAC had urged the EPA to conduct (Wegman, 2011, Attachment p. 2). CASAC did not choose to provide any additional comments or advice after receiving the final PA. The EPA considers this distributional analysis to be the product of the peer review conducted by CASAC of the PA, and thus does not agree with commenters' characterization that the analysis lacked appropriate peer review. The EPA's final analysis was based on the comments provided by CASAC, the peer review committee established pursuant to the CAA, on the draft analysis, such that the final analysis stems directly from CASAC's advice and the EPA's response to its comments.

With regard to the availability of the underlying data sets, the EPA disagrees with the commenters' assertion that these data are not publically available. As noted in the EPA staff technical memorandum, the underlying data sets provided by study authors are available in the rulemaking docket (Rajan et al., 2011, pp. 2 to 3).

Based on the above considerations, the EPA continues to conclude that its analysis of distributions of health event and air quality data from two key multi-city epidemiological studies provides important information related to understanding the associations between health events observed in each city (e.g., deaths, hospitalizations) and the corresponding long-term mean $PM_{2.5}$ concentrations observed in the studies. While recognizing that this is a relatively modest data set, the EPA further concludes that such information can appropriately help to inform the selection of the level of an annual standard that will protect public health with an adequate margin of safety from these types of health effects which are causally related to long- and short-term exposures to $PM_{2.5}$.

(4) *Comment*: Some commenters in this group asserted there were limitations in the long-term exposure studies of morbidity, including studies evaluating respiratory effects in children. For example, one commenter (UARG, 2012, p. 12, Attachment 1, pp. 14 to 16) asserted there were serious limitations in the long-term exposure studies of respiratory morbidity in each of the studies considered by the EPA (including McConnell et al., 2003; Gauderman et al., 2004; Dockery et al., 1996; Raizenne et al., 1996; and Goss et al., 2004) and argued that this evidence provides only a "weak association" with $PM_{2.5}$ exposures. This commenter asserted that many of these long-term exposure studies evaluating respiratory effects were considered at the time the EPA reaffirmed the current annual standard level of 15 $\mu g/m^3$ in 2006, that the Administrator in the last review determined that the information they provided "was too limited to serve as the basis for setting a level of a national standard," and that they should be given little weight in setting the level of the annual standard in this review (UARG, 2012, Attachment 1, p. 14).

More specifically, this commenter asserted that the McConnell et al. (2003) and Gauderman et al. (2004) studies reported mixed results for associations with $PM_{2.5}$ and stronger associations with NO_2 (API, 2012, Attachment 1, pp. 14 to 15). Similarly, this commenter argued that the Dockery et al. (1996) and Raizenne et al. (1996) studies showed stronger associations with acidity than with fine particles (measured as $PM_{2.1}$). *Id.* pp. 15 to 16. With regard to the cystic fibrosis study, this commenter noted that the association between pulmonary exacerbations and $PM_{2.5}$ in this study was no longer statistically significant when the model adjusted for each individual's baseline lung function. The commenters referred to the data on lung function as an "important explanatory variable," and suggested that the EPA should rely on results from the model that included individual baseline lung function information. *Id.* p. 16.

Response: For the reasons discussed in section III.E.4.c.i of the preamble for the final rule, the response in section II.B.1.b above, and the further response below, the EPA disagrees with the commenters' interpretation of these studies.

As an initial matter, the EPA notes that three of these studies (McConnell et al., 2003; Dockery et al., 1996; Raizenne et al., 1996) as well as the initial studies from the Southern California Children's Health Study (Peters et al., 1999; McConnell et al., 1999' Gauderman et al., 2000, 2002; Avol et al., 2001) were discussed and considered in the 2004 Air Quality Criteria Document (U.S. EPA, 2004) and, thus, considered within the air quality criteria supporting the EPA's final decisions in the review completed in 2006. Two additional studies (Gauderman et al., 2004; Goss et al., 2004) were discussed and considered in the provisional science assessment conducted for the last review (U.S. EPA, 2006a). All of these studies were considered in the ISA that informs the current review (U.S. EPA, 2009a).

With regard to the Southern California Children's Health Study, extended analyses considered in the ISA provided evidence that clinically important deficits in lung function[23] associated with long-term exposure to $PM_{2.5}$ persist into early adulthood (U.S. EPA, 2009a, p. 7-27; Gauderman et al., 2004). These effects remained positive in copollutant models.[24] Additional analyses of the Southern California Children's Health Study cohort reported an association between long-term $PM_{2.5}$ exposure and bronchitic symptoms (U.S. EPA, 2009a, p. 7-23 to 7-24; McConnell et al., 2003, long-term mean concentration of 13.8 $\mu g/m^3$) that remained positive in co-pollutant models, with the $PM_{2.5}$ effect estimates increasing in magnitude in some models and decreasing in others, and a strong modifying effect of $PM_{2.5}$ on the association between lung function and asthma incidence (U.S. EPA, 2009a, 7-24; Islam et al., 2007). The outcomes observed in the more recent reports from the Southern California Children's Health Study, including

[23] Clinical significance was defined as an FEV_1 below 80 percent of the predicted value, a criterion commonly used in clinical settings to identify persons at increased risk for adverse respiratory conditions (U.S. EPA, 2009a, p. 7-29 to 7-30). The primary NAAQS for sulfur dioxide (SO_2) also included this interpretation for FEV_1 (75 FR 35525, June 22, 2010).

[24] Gauderman et al. (2004) clearly stated throughout their analysis that NO_2 was one component of a highly correlated mixture that contains $PM_{2.5}$. Gauderman et al. (2004) did not present the results from copollutants models but stated "two-pollutant models for any pair of pollutants did not provide a significantly better fit to the data than the corresponding single-pollutant models."

evaluation of a broader range of endpoints and longer follow-up periods, were larger in magnitude and more precise than reported in the initial version of the study. Supporting these results were new longitudinal cohort studies conducted by other researchers in varying locations using different methods (U.S. EPA, 2009a, section 7.3.9.1). The EPA, therefore, disagrees with the commenters that the studies by McConnell et al. (2003) and Gauderman et al. (2004) are flawed and should not be used in the PM NAAQS review process.

The 24-City study[25] by Dockery et al. (1996) (long-term mean concentration of 14.5 µg/m^3) was considered in the current as well as two previous reviews (U.S. EPA, 2009a; U.S. EPA, 2004; U.S. EPA, 1996). This study observed that PM, specifically "particle strong acidity" and sulfate particles (indicators of fine particles), were associated with reports of bronchitis in the previous year. Similarly, the magnitude of the associations between bronchitis and PM_{10} and $PM_{2.1}$ were similar to those for acidic aerosols and sulfate particles, though the confidence intervals for the PM_{10} and $PM_{2.1}$ associations were slightly wider and the associations were not statistically significant. Acid aerosols, sulfate, and fine particles are formed in secondary reactions of the emissions from incomplete combustion and these pollutants have similar regional and temporal distributions. As noted by the study authors, "the strong correlations of several pollutants in this study, especially particle strong acidity with sulfate (r=0.90) and $PM_{2.1}$ (r=0.82), make it difficult to distinguish the agent of interest" (Dockery et al., 1996, p. 505). Overall, Dockery et al. (1996) (and, similarly, Raizenne et al., 1996) observed similar associations between respiratory health effects and acid aerosols, sulfate, PM_{10} and $PM_{2.1}$ concentrations. The commenters noted that the associations with particle acidity were sensitive to the inclusion of the six Canadian sites. The EPA notes that none of these Canadian cities were in the "sulfate belt" where particle strong acidity was highest. Thus, the change in the effect estimate when the six Canadian cities were excluded from the analysis is likely due to the lower prevalence of bronchitis and the lower concentrations of acid aerosols in these cities, and not due to some difference in susceptibility to bronchitis between the U.S. and Canadian populations that is not due to air pollution, as suggested by the commenters (UARG, 2012, Attachment 1, p. 15). In fact, contrary to the statements made by the commenters, the authors did not observe any subgroups that appeared to be markedly more susceptible to the risk of bronchitis.

The Goss et al. (2004) study considered a U.S. cohort of cystic fibrosis patients and 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 (U.S. EPA, 2009a, p. 7-25; long-term mean concentration of 13.7 µg/m^3). The commenters noted that the association between pulmonary exacerbations and $PM_{2.5}$ in this study was no longer statistically significant when the model adjusted for each individual's baseline lung function. The commenters referred to the data on lung function as an "important explanatory variable," and suggested that the EPA should rely on results from the model that included individual baseline lung function information. The EPA

[25] The 24-City study conducted by Dockery et al. (1996) included 18 sites in the U.S. and 6 sites in Canada. The Raizenne et al. (1996) study considered 22 of these 24 study areas. Athens, OH and South Brunswick, NJ were not included in this study.

disagrees with the commenters' interpretation of this study. The Agency concludes it is unlikely that lung function is a potential confounder or an important explanatory variable in this study. In fact, the authors noted that "it is more likely that lung function decline may be intimately associated with chronic exposure to air pollutants and may be part of the causal pathway in worsening prognosis in CF [cystic fibrosis]; in support of this explanation, we found both cross-sectional and longitudinal strong inverse relationships between FEV_1 and PM levels" (Goss et al., 2004, p. 819). The EPA notes that adjusting for a variable that is on the causal pathway can lead to overadjustment bias, which is likely to attenuate the association (Schisterman et al. 2009); this is likely what was observed by the authors. Thus, the EPA continues to believe it is appropriate to focus on the results reported in Goss et al. (2004) that did not include individual baseline lung function in the model.

In addition, the EPA disagrees with commenters' reliance solely on statistical significance when interpreting the study results from individual study results and the collective evidence across studies. As discussed in section III.D.2 of the preamble to the final rule and in the response in section II.B.1.b above, statistical significance of individual study findings has played an important role in the EPA's evaluation of the study's results and the EPA has placed greater emphasis on studies reporting statistically significant results. However, in the broader evaluation of the evidence from many epidemiological studies, and subsequently during the process of forming causality determinations in the Integrated Science Assessment by integrating evidence from across epidemiological, controlled human exposure, and toxicological studies, the EPA has emphasized the *pattern of results* across epidemiological studies and whether the effects observed were *coherent* across the scientific disciplines for drawing conclusions on the relationship between $PM_{2.5}$ and different health outcomes. The EPA notes further that the D.C. Circuit has held that the EPA can look to other indicia of reliability such as the consistency and coherence of a body of studies as well as other confirming data to justify reliance on the results of a body of epidemiological studies, even if individual studies may lack statistical significance. *American Trucking Association v. EPA*, 283 F. 3d at 371 (in the context of discussing whether study results were confounded by co-pollutants).

As noted in section III.B.1.a of the proposal, with regard to respiratory effects, the Integrated Science Assessment concluded that extended analyses of studies available in the last review as well as new epidemiological studies conducted in the U.S. and abroad provided stronger evidence of respiratory-related morbidity associated with long-term $PM_{2.5}$ exposure (77 FR 38918). The strongest evidence for respiratory-related effects available in this review was from epidemiological studies that evaluated decrements in lung function growth in children and increased respiratory symptoms and disease incidence in adults (U.S. EPA, 2009a, sections 2.3.1.2, 7.3.1.1, and 7.3.2.1).

In considering the collective evidence from epidemiological, toxicological, and controlled human exposure studies, including the studies discussed above, the EPA recognizes that the Integrated Science Assessment concluded that a causal relationship is likely to exist between long-term $PM_{2.5}$ exposures and respiratory effects (U.S. EPA, 2009a, p. 2-12, pp. 7-42 to 7-43). CASAC concurred with this causality determination (Samet, 2009f, p.9).

The commenter's assertion that the EPA should adhere to its assessment of these studies as it did in the review completed in 2006 is significantly mistaken. Most obviously, the EPA's final decision in the last review was held to be deficient by the D.C. Circuit in remanding the 2006 primary annual $PM_{2.5}$ standard. As discussed in section III.A.2 of the preamble to the final rule, the D.C. Circuit specifically held that the EPA did not provide a reasonable explanation of why certain morbidity studies, including an earlier study from the Southern California Children's Health Study (Gauderman et al., 2000, long-term mean $PM_{2.5}$ concentration approximately 15 $\mu g/m^3$) and the 24-Cities Study (Raizenne et al., 1996, long-term mean concentrations approximately 14.5 $\mu g/m^3$) did not warrant a more stringent annual $PM_{2.5}$ standard when the long-term mean $PM_{2.5}$ concentrations reported in those studies were at or lower than the level of the annual standard. *American Farm Bureau Federation v. EPA*. 559 F. 3d at 525. Indeed, the court found that, viewed together, the Gauderman et al. (2000) and Raizenne et al., (1996) studies "are related and together indicate a significant public health risk…On this record, therefore, it appears the EPA too hastily discounted the Gauderman and 24-Cities studies as lacking in significance." *Id.*

In this review, the EPA recognizes a significant amount of evidence beyond these two studies that expands our understanding of respiratory effects associated with long-term $PM_{2.5}$ exposures. This body of scientific evidence includes an extended and new analyses from the Southern California Children's Health Study (Gauderman et al., 2004; Islam et al., 2007; Stanojevic et al., 2008) as well as additional studies that examined these health effects (Kim et al., 2004; Goss et al., 2004). Thus, even more so than in the last review, the evidence indicates a "significant public health risk" to children from long-term $PM_{2.5}$ exposures at concentrations below the level of the current annual standard. A standard that does not reflect appropriate consideration of this evidence would not be requisite to protect public health with an adequate margin of safety.

(5) *Comment*: With regard to the use of studies of health effects for which the EPA finds the evidence to be "suggestive" of a causal relationship, some commenters argued that such studies "do not merit any weight in the setting of the annual NAAQS" (e.g., UARG, 2012, Appendix 1, p. 3). One commenter asserted that the proposed use of evidence that is only suggestive of a causal relationship to support revision to the primary annual $PM_{2.5}$ standard is inconsistent with the EPA use of such evidence to retain the primary 24-hour PM_{10} standard and "represents a significant departure from the Agency's precedent and is not justified" (AFPM, 2012, p. 2).

Response: The EPA disagrees with the commenter's view that studies of health effects for which the evidence is suggestive of a causal relationship, rather than studies of health effects for which the evidence supports a causal or likely causal relationship, merit no weight at all in setting the NAAQS. To place no weight at all on such evidence would in essence treat such evidence as though it had been categorized as "not likely to be a causal relationship." To do so would ignore the important distinctions in the nature of the evidence supporting these different causality determinations in the ISA. It would also ignore the CAA requirement that primary standards are to be set to provide protection with an adequate margin of safety, including providing protection for at-risk populations. Thus, ignoring this information in making decisions on the appropriate standard level would not be appropriate.[26] Nonetheless, in considering studies of health effects for which the evidence is suggestive of a causal relationship, the EPA does believe that it is appropriate to place less weight on such studies than on studies of health effects for which there is evidence of a causal or likely causal relationship.

The EPA also disagrees with the commenters' assertion that the EPA's bases for final decision on the primary $PM_{2.5}$ and PM_{10} standards are inconsistent. As discussed in sections III.E.4.d and IV. G of the preamble to the final rule, in each case the EPA has considered the relevant available scientific evidence and the uncertainties and limitations associated with that evidence to reach final decisions on the appropriate primary $PM_{2.5}$ and PM_{10} standards.

(6) *Comment:* Some commenters questioned the long-term mean $PM_{2.5}$ concentration reported in the final PA and used in Figure 4 of the proposal for the Miller et al. (2007) study (e.g., API, 2012, Attachment 1, p. 8; UARG, 2012, Attachment 1, pp. 2 to 3, fn 3, p. 12).

Response: The EPA recognizes that the study authors originally reported a long-term mean $PM_{2.5}$ concentration of 13.5 $\mu g/m^3$ (Miller et al., 2007, Table 2). 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 the 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). The final PA noted that this updated long-term mean concentration matched the composite monitor approach annual mean calculated by the EPA (Hassett-Sipple et al., 2010, Attachment A, p. 6) for the year of air quality data (i.e., 2000) considered by the study investigators (U.S. EPA, 2011a, p. 2-32, fn 24). The EPA staff concluded it was most appropriate to include the updated air quality data in the final PA (*Id*.). Thus, the long-term mean $PM_{2.5}$ concentration for Miller et al. (2007) discussed in the proposal and presented in Figures 1 and 4 of the proposal was reported as 12.9 $\mu g/m^3$. The PA noted that in comparison to other long-term exposure studies, the Miller et al. (2007) study was more limited in that it was based on only one year of air quality data (U.S. EPA, 2011a, p. 2-82). The proposal further noted that the air quality data considered were extrapolated from that one single year of air quality data (2000) to the whole study, and that the air quality data post-dated the years of health events considered (i.e., 1994 to 1998) (77 FR 38918, fn 62).

For the reasons discussed in section III.E.4.c.i of the preamble to the final rule, the EPA does not now consider it appropriate to put weight on the reported long-term mean concentration from the Miller et al. (2007) study (either the original value reported in the published study nor the updated value provided by the study authors) for the purpose of

[26] As discussed in section II.A of the preamble to the final rule, 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. This certainly encompasses consideration of effects for which there is evidence suggestive of a causal relationship.

translating the epidemiological information from the long-term exposure studies into a basis for selecting the level of the annual $PM_{2.5}$ standard. Nonetheless, the EPA notes that the Miller et al. (2007) study provides strong evidence of cardiovascular-related effects associated with long-term $PM_{2.5}$ exposures to inform causality determinations reached in the ISA (U.S. EPA, 2009a, sections 7.2.11 and 7.6).

(7) *Comment:* Some commenters who supported retaining current annual standard level argued there is no basis for the EPA to select a level lower than 13 µg/m^3 (e.g., NAM et al., 2012, pp. 26 to 27; Class of '85, 2012, p. 2; Dow, 2012, pp 1 to 3).

Response: The EPA disagrees with the commenters' views that there is no basis to select a level below 13 µg/m^3. As discussed in section III.E.4.d of the preamble for the final rule, in light of the entire body of scientific evidence and technical analyses considered, the EPA Administrator judges that an annual standard level set above 12 would not be sufficient to protect public health with an adequate margin of safety from the serious health effects associated with long- and short-term $PM_{2.5}$ exposures.

(8) *Comment*: In raising objections to the requirement for near-road $PM_{2.5}$ monitoring, one industry group (AFPM, 2012) compared the consideration of PM gradients around roadways in the current review to the consideration of NO_2 gradients discussed in the most recent revision of the primary NO_2 NAAQS (75 FR 6474, February 9, 2010). Specifically, in discussing the EPA's decision to set a new 1-hour NO_2 standard at a level of 100 parts per billion, these commenters stated the following:

In taking this action, EPA noted that NO_2 concentrations could be expected to vary, and therefore, the differences between near-roadway monitors and area-wide concentrations that had been used to measure compliance with the pre-existing NO_2 annual standard could result in a variable level of the standard (*i.e.*, between 50 ppb and 75 ppb based on whether concentrations near roadways were 100% or 30% higher than at other monitors). Yet, in this proposed rule, EPA does not offer any comparable analysis with respect to the relative stringency of a $PM_{2.5}$ annual or 24-hour NAAQS as implemented through a network of new roadside monitors.

Response: As explained in section III.E.4.c.i of the preamble to the final rule and in response to Comment (1) above, it is appropriate to compare the $PM_{2.5}$ concentrations from a maximum area-wide monitor to the level of the annual $PM_{2.5}$ standard. Consequently, the approach adopted in this rulemaking for the $PM_{2.5}$ standard is consistent with the ultimate thrust of the approach in the NO_2 NAAQS: providing a level of protection in an area with a maximum monitor affords requisite protection across the entire area. However, given differences in the bodies of available scientific evidence for NO_2 and $PM_{2.5}$, it is appropriate that the EPA employed different types of analyses in the two reviews to achieve this ultimate result. In the case of NO_2, the scientific evidence that formed the basis for the final decision on the level of the revised standard included both epidemiological studies, reporting associations between respiratory endpoints and area-wide NO_2 concentrations, and controlled human exposure studies, reporting respiratory effects following short-term exposures to NO_2 concentrations at or above 100 ppb. In considering this evidence, the Administrator set a new 1-hour standard with a level of

100 ppb.

In setting this new standard, information on the NO_2 gradients around roadways was used to consider the relationships between area-wide NO_2 concentrations and potential exposure concentrations. Specifically, because the revised NO_2 standard was intended to reflect the maximum allowable NO_2 concentration in an area, the Administrator concluded that this standard would limit exposures to NO_2 concentrations reported in controlled human exposure studies to result in respiratory effects. In reaching this conclusion, the Administrator noted that the highest NO_2 exposure concentrations in urban areas could occur around major roadways. In addition, given the available evidence for NO_2 concentration gradients around roadways, she concluded that the new standard would maintain area-wide NO_2 concentrations (away from major roads) well below those in locations where key U.S. epidemiological studies had reported associations with adverse respiratory effects (75 FR 6501, February 9, 2010).

In the current review of the PM NAAQS the scientific evidence forming the basis for final decisions on the $PM_{2.5}$ standards includes epidemiological studies reporting associations between area-wide $PM_{2.5}$ concentrations and a number of adverse health outcomes (i.e., including mortality and a variety of cardiovascular and respiratory effects). While controlled human exposure studies of $PM_{2.5}$ provide coherence and biological plausibility for the effects observed in epidemiological studies, because of the exposure concentrations and durations evaluated they do not provide an appropriate basis to inform decisions on the levels of the 24-hour or annual standards. In light of this fundamental difference in the bodies of evidence available for NO_2 and $PM_{2.5}$, the approach to considering NO_2 roadway concentration gradients adopted in the most recent review of the primary NO_2 NAAQS would not similarly inform the Administrator's decisions in the current review of the PM NAAQS.[27] Therefore, the same approach would not be warranted in the two reviews.

(9) *Comment:* One group of commenters asserted that "the supplemental 24-hour standard adds to the margin of safety that protects children and other sensitive subpopulations" (NAM et al., 2012, p. 9). These commenters argued that when the 24-hour standard is "controlling" the long-term mean $PM_{2.5}$ concentrations were reduced well below the existing or proposed annual standard level. Thus, these commenters expressed the view that "the existing annual standard, when considered along-side the 24-hour standard, is not only requisite to protect the public health, but also ensures an adequate margin of safety for sensitive subpopulations" *Id.*

Response: The EPA agrees with the first point raised by the commenters; that is, the 24-hour standard provides supplemental protection beyond the protection provided by the annual standard. The EPA recognizes that the protection afforded by the two standards working together meets the CAA requirement to set primary standards that provide

[27] See also comments of UARG at 55 n. 73 drawing this same distinction ("The fact that the level of the $PM_{2.5}$ NAAQS is derived solely from epidemiological studies distinguishes it from the NO_2 NAAQS for which, as EPA notes, 77 Fed. Reg. at 39010/2-3, it recently adopted near-road monitoring requirements. That standard was based, in significant part, on controlled human exposure studies in which actual NO_2 exposures were measured that could reasonably be compared to concentrations measured near roads. 75 Fed. Reg. at 6500/1-01/2.").

requisite public health protection with an adequate margin of safety, including providing protection for at-risk populations.

With regard to the second point raised by these commenters, the EPA disagrees with the commenters' view that if the 24-hour standard is "controlling," the long-term mean $PM_{2.5}$ concentrations would be reduced well below the existing or proposed annual standard level. This comment would only be true if the 24-hour standard level was substantially lowered. As illustrated in Figure 2-10 of the PA, based on 2007 to 2009 air quality data, many counties across the country would likely meet the current 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ but not the current or alternative annual standard, i.e., the lower right quadrant of the figure characterizing counties where the annual standard would be the controlling standard (U.S. EPA, 2011a, p. 2-90).

Furthermore, the EPA recognized in the section III.A.3 of the proposal that there are various ways to combine the annual and 24-hour standards to achieve an appropriate degree of 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 (77 FR 38902), While the EPA recognized 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 98^{th} percentile) but also in lower annual mean concentrations, the EPA also noted 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. As discussed in section III.E.4.d of the preamble to the final rule, based on the evidence and quantitative risk assessment, the EPA concludes that it is appropriate to setting an annual standard that is generally controlling, which will lower the broad distribution of 24-hour average concentrations in a area as well as the annual average concentration, so as to provide protection from both long- and short-term $PM_{2.5}$ exposures, with the 24-hour standard providing supplemental protection. The EPA concludes this approach will reduce aggregate risks associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard and is the most effective and efficient way to reduce total $PM_{2.5}$-related population risk and so provide appropriate protection.

(10) *Comment:* One commenter argued that "data from the available epidemiological studies suggest that effects of chronic PM exposure are reversible and that even small reductions in PM levels decrease cardiovascular mortality within a time frame as short as a few years (Dow, 2012, pp. 2 to 3).

Response: The EPA disagrees that all effects of chronic PM exposure are reversible. The ISA concluded that there is a causal relationship between long-term $PM_{2.5}$ exposure and mortality (U.S. EPA, 2009a, sections 2.3.1 and 7.6), obviously an irreversible effect. Furthermore, with regard to morbidity effects, extended analyses of the Southern California Children's Health Study provide evidence that clinically important deficits in lung function associated with children's long-term exposure to $PM_{2.5}$ persisted into early adulthood (77 FR 38907; U.S. EPA, 2009a, p. 7-27; Gauderman et al., 2004).

The EPA agrees with the commenter's assertion that improvements in community health related to reducing $PM_{2.5}$ concentrations do not require a long latency period. As noted in the proposal (77 FR 38907), the strength of the causal relationship between long-term $PM_{2.5}$ exposure and mortality also builds 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 of approximately 5 to 9 months (U.S. 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 2 years prior to death (U.S. EPA, 2009a, p. 7–92; Figure 7–9). Looking more broadly across studies, the ISA concluded, "Generally, these results indicate a developing coherence of the air pollution mortality literature, suggesting that the health benefits form reducing air pollution do not require a long latency period and would be expected within a few years of intervention" (U.S. EPA, 2009a, p. 7-95).

(11) *Comment:* One commenter recognized the need to protect human health and supported the EPA's effort to set a primary annual $PM_{2.5}$ standard that protects human health with an adequate margin, as required by the CAA. However, this commenter asserted that the "EPA should consider the impact of using background levels in establishing the standard. If the annual PM standard is set close to or below background level, it would be impossible for nonattainment ares to attain the standard (AASHTO, 2012, p.2). This commenter recommended that "the standard be set at a level that is realistic and attainable since the standard will lose its meaning as background levels are approached." *Id.*

Response: The EPA notes that the $PM_{2.5}$ standard levels established in the final rule (i.e., an annual standard level of 12 $\mu g/m^3$ and a 24-hour standard level of 35 $\mu g/m^3$) are well above the policy-relevant background concentrations considered in the ISA (U.S. EPA, 2009a, sections 3.6, 3.7 and 3.9.1.7). Therefore, the concern raised by the commenter remains simply an academic one.

(12) *Comment:* Some of these commenters also identified "new" studies as providing additional evidence to support their views that the annual standard level does not need to be revised.

Response: As discussed in section II.B.3 of the preamble to the final rule and in section II.B.1.a above, the EPA notes that, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the PM ISA that have undergone CASAC and public review, and will consider newly published studies for purposes of decision making in the next PM NAAQS review. Nonetheless, in provisionally evaluating commenters' arguments, the EPA notes that its provisional assessment of "new" science found that such studies did not materially change the conclusions reached in the ISA (U.S. EPA, 2012b).

ii. Support for Revising the Current Level

A second group of commenters supported revising the suite of primary $PM_{2.5}$ standards to provide increased public health protection. These commenters found the available scientific information and technical analyses to be stronger and more compelling than in the last review. These commenters generally placed substantial weight on CASAC advice and on the EPA staff analyses presented in the final PA. While generally supporting the EPA's proposal to lower the level of the annual standard, many commenters in this group disagreed that a level within the EPA's proposed range (i.e., 12 to 13 $\mu g/m^3$) was adequately protective and supported a level of 11 $\mu g/m^3$ or below.

In general, these commenters expressed the view that given the strength of the available scientific evidence, the serious nature of the health effects associated with $PM_{2.5}$ exposures, the large size of the at-risk populations, the risks associated with long- and short-term $PM_{2.5}$ exposures, and the important uncertainties inherently present in the evidence, the EPA should follow a highly precautionary policy response by selecting an annual standard level that incorporates a large margin of safety.

More specifically, these commenters offered a range of comments related to the general approach used by the EPA to select standard levels, including: (1) the EPA's approach for setting a generally controlling annual standard; (2) the importance of the greatly expanded and stronger overall scientific data base; (3) consideration of the distributional statistical analysis conducted by the EPA and other approaches for translating the air quality information from specific epidemiological studies into standard levels; and (4) the significance of the $PM_{2.5}$-related public health impacts, especially potential impacts on at-risk populations, including children, in reaching judgments on setting standards that provide protection with an adequate margin of safety. These comments are discussed in turn below.

(1) *Comment:* Some of these commenters disagreed with the EPA's approach for setting a "generally controlling" annual standard in conjunction with a 24-hour standard providing supplemental protection particularly for areas with high peak-to-mean ratios. These commenters argued this approach would lead to "regional inequities" as demonstrated in the EPA's analyses contained in Appendix C of the PA (ALA et al., pp. 26 to 27). Specifically, these commenters argued:

> There is no basis in the CAA for such a determination. The CAA requires only that the NAAQS achieve public health protection with an adequate margin of safety. It is well-documented that both long- and short-term exposures to $PM_{2.5}$

> have serious and sometimes irreversible health impacts. There is no health protection reason to argue that one standard should be "controlling" as a matter of policy without regard to the health consequences of such a policy. To adopt such a policy ignores the obligation to provide equal protection under the law to all Americans because it would result in uneven protection from air pollution in different localities and regions of the country (ALA et al., 2012, p. 26).

Response: The EPA believes these commenters misunderstood the basis for the EPA's policy goal of setting a "generally controlling" annual standard. This approach relates exclusively to setting standards that will provide requisite protection against effects associated with both long- and short-term $PM_{2.5}$ exposures. It does so by lowering the overall air quality distributions across an area, recognizing that changes in $PM_{2.5}$ air quality designed to meet an annual standard would likely result not only in lower annual mean $PM_{2.5}$ concentrations but also in fewer and lower peak 24-hour $PM_{2.5}$ concentrations. As discussed in section III.A.3 in the proposal and in the preamble to the final rule, the EPA recognizes that there are various ways to combine the two primary $PM_{2.5}$ standards to achieve an appropriate degree of public health protection. Furthermore, 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.

In focusing on an approach of setting a generally controlling annual standard, the EPA's intent is in fact to avoid the potential "regional inequities" that are of concern to these commenters. The EPA judges that the most appropriate way to set standards that provide more consistent public health protection is by using the approach of setting a generally controlling annual standard. This judgment builds upon information presented in the PA as discussed in section III.A.3 of the preamble to the final rule. More specifically, the PA recognized that the short-term exposure studies primarily evaluated daily variations in health effects with monitor(s) that measured the variation in daily $PM_{2.5}$ concentrations over the course of several years. The strength of the associations observed in these epidemiological studies was demonstrably in the numerous "typical" days within the air quality distribution, not in the peak days (U.S. EPA, 2011a, p. 2-9). In addition, the quantitative risk assessments conducted for this and previous reviews demonstrated the same point: that is, much, if not most, of the aggregate risk associated with short-term $PM_{2.5}$ 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 (U.S. EPA, 2011a, section 2.2.2; U.S. EPA, 2010a, section 3.1.2.2). In addition, there was no evidence suggesting that risks associated with long-term exposures were likely to be disproportionately driven by peak 24-hour concentrations.[28] See also *American Trucking Association v. EPA*, 283 F. 3d at 373 (rejecting arguments to lower the level of the daily $PM_{2.5}$ standard when there is persuasive evidence that the main risk from exposure comes

[28] In confirmation, a number of studies have presented analyses excluding higher PM concentration days and 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).

from the entire air quality distribution rather than from peak days, and the annual standard will lower that distribution).

For these reasons, the PA concluded that strategies that focused primarily on reducing peak days were less likely to achieve reductions in the $PM_{2.5}$ concentrations that were most strongly associated with the observed health effects. Furthermore, the PA concluded that an approach that focused 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 (U.S. EPA, 2011a, p. 2-9; U.S. EPA, 2010a, section 5.2.3). This is because reductions based on control of peak days are less likely to control the bulk of the air quality distribution. As noted above, this would create the very inequity of results the commenters seek to avoid.

As a result, the EPA believes an approach that focuses on a generally controlling annual standard would likely reduce aggregate risks associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard and, therefore, would be the most effective and efficient way to reduce total $PM_{2.5}$-related population risk. The CASAC agreed with this approach and considered it was "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" (Samet, 2010d, p. 1). The EPA thus disagrees with the comments that this approach will result in the concerns raised by the commenters; rather the EPA concludes that this approach will help to address these concerns.

(2) *Comment:* Many of these commenters asserted that the currently available scientific information is greatly expanded and stronger compared to the last review. Some of these commenters highlighted the availability of multiple, multi-city long- and short-term exposure studies providing "repeated, consistent evidence of effects below the current annual standard level" (ALA et al., 2012, pp. 39 to 49) and, more specifically, "significant evidence of harm with strong confidence well below EPA's proposed annual standard range of 12-13 $\mu g/m^3$" (AHA et al., 2012, pp. 10 to 12).

Response: The EPA recognizes that in setting standards that are requisite to protect public health with an adequate margin of safety, the Administrator must weigh the various types of available scientific information in reaching public health policy judgments that neither overstate nor understate the strength and limitations of this information or the appropriate inferences to be drawn from the available science.

In general, the EPA agrees with these commenters' views that the currently available scientific evidence is stronger "because of its breadth and the substantiation of previously observed health effects" (77 FR 38906/2) and provides "greater confidence in the reported associations than in the last review" (77 FR 38940/1). The EPA also agrees with the commenters' position that it is appropriate to consider the regions within the broader air quality distributions where we have the strongest confidence in the associations reported in epidemiological studies in setting the level of the annual standard. However, as discussed in section III.E.4.d of the preamble to the final rule, in weighing the available evidence and technical analyses, as well as the associated uncertainties and limitations in that information, the EPA disagrees with the commenters' views regarding the extent to which the available scientific information provides support for considering an annual standard level below the proposed range (i.e., below 12 to 13 $\mu g/m^3$). In particular, the EPA disagrees with the degree to which these commenters place more weight on the relatively more uncertain evidence that is suggestive of a causal relationship (e.g., low birth weight). Consistent with CASAC advice (Samet, 2010d, p. 1), the Agency concludes it is appropriate and reasonable to place the greatest emphasis on health effects for which the ISA concluded there is evidence of a causal or likely causal relationship and to place less weight on the health effects that provide evidence that is only suggestive of a causal relationship.

(3) *Comment*: With regard to using the air quality information from epidemiological studies to inform decisions on standard levels, commenters in this group generally supported the EPA's efforts to explore different statistical metrics from epidemiological studies to inform the Administrator's decisions. These commenters argued that by considering different analytic measures -- either concentrations one standard deviation below the long-term means reported in the epidemiological studies or the EPA's distributional statistical analysis of population-level data that extends the approach used in previous PM NAAQS reviews to consider information beyond a single statistical metric -- "the annual standard must be significantly lower than EPA has proposed" (ALA et al., 2012, pp. 50 to 61). Furthermore, with regard to characterizing the $PM_{2.5}$ air quality at which associations have been observed, some of these commenters highlighted CASAC's recommendation that "[f]urther consideration should be given to using the 10^{th} percentile as a level for assessing various scenarios of levels for the PM NAAQS" (Samet, 2010c, p. 11) (ALA et al., 2012, p. 55). Other commenters urged that the EPA extend the distributional analysis to include additional studies. For example, CHPAC urged the EPA to also conduct distributional analysis for children's health studies to better inform standards that would protect both children and adults from adverse health outcomes (CHPAC, 2012, p. 3).

Response: The EPA agrees with these commenters' views that it is appropriate to take into account different statistical metrics from epidemiological studies to inform the decisions on standard levels that are appropriate to consider in setting a standard that will protect public health with an adequate margin of safety. In the development of the PA, the EPA staff explored various approaches for using information from epidemiological studies in setting the standards. The general approach used in the final PA, discussed in sections III.A.3 and III.E.4.a of the preamble to the final rule, reflects consideration of CASAC advice (Samet, 2010c,d) and public comments on multiple drafts of the PA.

With regard to using the distributional statistical analysis to characterize the confidence in the associations, the EPA emphasizes that there is no clear dividing line provided by the scientific evidence, and that choosing how far below the long-term mean concentrations from the epidemiological studies is appropriate to identify a standard level that will provide protection for the public health with an adequate margin of safety is largely a public health policy judgment. In this review, the EPA considers the region from approximately the 25^{th} to 10^{th} percentiles to be a reasonable range for providing a general frame of reference as to the part of the distribution over which our confidence in the magnitude and significance of the associations observed in epidemiological studies is appreciably lower. Based on these considerations, the EPA concludes that it is not appropriate to place as much confidence in the magnitude and significance of the associations over the lower percentiles of the distributions in each study as at and around the long-term mean concentrations. Thus, the EPA disagrees with the commenters' views that this analysis compels placing more emphasis on the lower part of this range in selecting a level for an annual standard that will protect public health with an adequate margin of safety. The EPA recognizes that this information comes primarily from two short-term exposure studies, a relatively modest data set. In light of the limited nature of this information, and in recognition of more general uncertainties inherent in the epidemiological evidence, the Administrator deems it reasonable not to place more emphasis on concentrations in the lower part of this range, as discussed in section III.E.4.d of the preamble to the final rule.

With regard to the scope of the distributional statistical analysis, the EPA requested additional population-level data from the study authors for a group of six multi-city studies for which previous air quality analyses had been conducted (Hassett-Sipple et al., 2010; Schmidt et al., 2010, Analysis 2). These six studies were originally selected because they considered multiple locations representing varying geographic regions across multiple years. Thus, these studies provided evidence on the influence of different particle mixtures on health effects associated with long- and short-term $PM_{2.5}$ exposures. In addition, these multi-city studies considered relatively more recent health events and air quality conditions (1999 to 2005). As discussed in section III.E.4.b.i of the preamble to the final rule, the EPA received and analyzed population-level data for four of the six studies (Rajan et al., 2011). Three of these four studies (Krewski et al., 2009a; Bell et al., 2008; Zanobetti and Schwartz, 2009) served as the basis for the C-R functions used to develop the core risk estimates (U.S. EPA, 2010a, section 3.3.3). While the EPA agrees that it would be useful to have such data from more studies, the Agency believes that the additional data that was requested and received from study authors provide useful information to help inform the Administrator's selection of the annual standard level.

(4) *Comment:* Many commenters in this group highlighted $PM_{2.5}$-related impacts on at-risk populations, including potential impacts on children, older adults, persons with pre-existing heart and lung disease, and low-income populations, to support their views that the annual standard should be revised to a level of 11 $\mu g/m^3$ or lower (e.g., CHPAC, 2012; AHA et al., 2012; ALA, 2012, pp. 29 to 38; Rom et al., 2012; Air Alliance Houston, et al., 2012, p. 1; PSR, pp. 2 and 4). These commenters urged the EPA to adopt a policy approach that placed less weight on the remaining uncertainties and limitations in the evidence and placed more emphasis on margin of safety considerations, including providing protection against effects for which there is more limited scientific evidence. For example, CHPAC urged the EPA "to place the same weight on studies examining impacts on children's health as that of adult studies. … The fact that there may be stronger evidence from adult studies does not mean that standards based on adult studies will be protective for children and consequently will meet the standard requisite to protect public health with an adequate margin of safety" (CHPAC, 2012 p. 3). Furthermore, with regard to the EPA's approach for weighing uncertainties, some of these commenters stated that "we find no justification in the preamble for an annual standard level as high as 13 $\mu g/m^3$, other than the vague assertion that uncertainties

increase at lower concentrations. Further, the final proposal completely failed to address the Policy Assessment recommendations that if 13 μg/m^3 was proposed, the 24-hour standard should be strengthened as well" (ALA et al., p. 7).

Response: The EPA has carefully evaluated and considered evidence of effects in at-risk populations. With regard to effects classified as having evidence of a causal or likely causal relationship with long- or short-term $PM_{2.5}$ exposures (i.e., premature mortality, cardiovascular effects, and respiratory effects), the Agency takes note that it considered the full range of studies evaluating these effects, including studies of at-risk populations, to inform its review of the primary $PM_{2.5}$ standards. Specific multi-city studies summarized in Figures 1, 2, and 3 in the preamble for the final rule highlight evidence of effects observed in two different lifestages – children and older adults – that have been identified as at-risk populations. Thus, the EPA places as much weight on studies that explored effects in children for which the evidence is causal or likely causal in nature as on studies of such effects in adults, including older adults. As discussed above in responses to commenters supporting the retention of the current standards, in setting the standard, the EPA has focused on considering $PM_{2.5}$ concentrations somewhat *below* the lowest long-term mean concentrations from *each* of the key studies of both long- and short-term exposures of effects for which the evidence supports a causal or likely causal relationship (i.e., the first two sets of studies shown in Figure 4 of the preamble to the final rule). The EPA has thus considered the available evidence of effects in children as well as other at-risk populations, given that those commenters urging the EPA to discount or disregard those studies provided no legitimate reason to do so. With respect to the EPA's consideration of more limited studies providing evidence suggestive of a causal relationship (e.g., developmental and reproductive effects), as noted above in responding to comments from the first group of commenters, the Agency is placing some weight on this body of evidence in setting standards that provide protection for at-risk populations,. However, the Agency does not agree that the same weight must be placed on this information as on the body of scientific information for which there is evidence of a causal or likely causal relationship. To do so here would ignore the difference in the breadth and strength of the evidence supporting the different causality determinations reached in the ISA.

With regard to weighing the uncertainties and limitations remaining in the evidence and technical analyses, as discussed in section II.A of the preamble to the final rule, the EPA recognizes that in setting a primary NAAQS that provides an adequate margin of safety, the Administrator must consider a number of factors including 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 remain. As discussed in section III.E.4.d of the preamble to the final rule, the Agency agrees with these commenters that, in weighing the available evidence and technical analyses including the uncertainties and limitations in this scientific information, there is no legitimate justification for setting a primary $PM_{2.5}$ annual standard level as high as 13 μg/m^3 (in conjunction with retaining the 24-hour standard at the current level).

(5) *Comment:* Some commenters urged the EPA "to select a standard based on science, not politics" (ALA et al., 2012, p. 6). More specficially, these commenters asserted "last

minute changes to the proposed level (following interagency review) were not accompanied by substantive changes in the text to the proposal. In fact, we find no justification in the preamble for an annual standard as high as 13 μg/m^3, other than the vague assertion that uncertainties increase at lower concentrations. Further the final proposal completely failed to address the Policy Assessment recommendations that if 13 μg/m^3 was proposed, then the 24-hour standard should be strengthened as well. The apparent last minute and unsupported insertion of a less protective annual standard to the proposal appears to be political interference, not scientific consideration" (ALA et al., 2012, p. 7).

Response: As stated in the previous response, the EPA agrees that the evidence in the record of this review does not support an annual standard at the level of 13 μg/m^3 (unless the 24-hour standard level was to be lowered substantially).

(6) *Comment:* Some commenters argued that the EPA "committed a serious procedural error in not explicitly soliciting comment on retaining the current [annual] $PM_{2.5}$ NAAQS" (API, 2012, p. 9).

Response: The commenter suggested (without providing any specific argument) that the EPA somehow prejudged the outcome of the rulemaking , or otherwise committed procedural error, by not proposing to retain the 2006 NAAQS. This is incorrect. First, the EPA provided far more process through this review than the amount required by law. Commenters had multiple opportunities to review and comment on all of the critical documents underlying the review (notably the ISA, the RA, and the PA), as well as on all of the critical scientific and policy issues, assumptions, and factual data informing the review as discussed in the proposal (77 FR 38890). Given that the basic question being addressed throughout this proceeding is whether or not it is appropriate to revise the 2006 standard (CAA section 109 (d)), that issue was necessarily before the public for comment (as evidenced by all the comments urging retention of the standard, among other indicia of proper notice). Nor does the EPA's proposal indicate a pre-judgment of the outcome of the review. Rather, the proposal reflected the EPA's consideration of the body of scientific data and analysis comprising the record for this review.

The EPA strongly disagrees that the currently available scientific evidence and technical information supports consideration for retaining the annual standard level at 15 μg/m^3. and consequently did not propose to do so. As discussed in section III.D.3. of the preamble for the final rule, having carefully considered CASAC advice and the public comments on the proposal as discussed in section III.D.2 preamble to the final rule and in section II.B.1 above, the EPA believes the fundamental scientific conclusions on the effects of $PM_{2.5}$ reached in the ISA, and discussed in the PA, are valid. The Agency believes that since the last review the overall uncertainty about the public health risks associated with both long- and short-term exposure to $PM_{2.5}$ has been diminished to an important degree. The remaining uncertainties in the available evidence do not diminish confidence in the associations between exposure to fine particles and mortality and serious morbidity effects. Based on the Agency's increased confidence in the association between exposure to $PM_{2.5}$ and serious public health effects, combined with evidence of such an association in areas that would meet the current standards , the Administrator agrees with CASAC that revision of the current suite of $PM_{2.5}$ standards to provide increased public health protection is necessary. Based on these considerations discussed in section III.D.3 of the preamble to the final rule, the Administrator concludes that the current suite of primary $PM_{2.5}$ standards is not sufficient, and thus not requisite, to protect public health with an adequate margin of safety, and that revision is needed to increase public health protection. Furthermore, as discussed in section III.E.4.e of the proposal, the Administrator provisionally concluded that the available scientific information supported consideration of an annual standard level no higher that 13 $\mu g/m^3$. In considering public comments on the proposal as discussed in sections III.E.4.c.i and III.E.4.d of the preamble for the final rule and above, the Agency concludes there is no scientific basis for considering retaining the annual standard level at 15 $\mu g/m^3$ (absent a substantially lower level of the daily standard).

(7) *Comment:* Some of these commenters also identified "new" studies as providing additional evidence to support their views that the annual standard level needs to be lowered.

Response: As discussed in section II.B.3 of the preamble to the final rule and in section II.B.1.a above, the EPA notes that, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the PM ISA that have undergone CASAC and public review, and will consider newly published studies for purposes of decision making in the next PM NAAQS review. Nonetheless, in provisionally evaluating commenters' arguments, the EPA notes that its provisional assessment of "new" science found that such studies did not materially change the conclusions reached in the ISA (U.S. EPA, 2012b).

b. 24-Hour Standard

With respect to the level of the 24-hour standard, the EPA received comments on the proposal from two distinct groups of commenters. One group that included virtually all commenters representing industry associations, businesses, and many States agreed with the Agency's proposed decision to retain the level of the 24-hour $PM_{2.5}$ standard. The other group of commenters included many medical groups, numerous physicians and academic researchers, many public health organizations, some State and local agencies, five state attorneys general, and a large number of individual commenters. These commenters disagreed with the Agency's proposed decision and argued that EPA should lower the level of the 24-hour standard to 30 or 25 $\mu g/m^3$. Comments from these groups on the level of the 24-hour $PM_{2.5}$ standard are addressed in section III.E.4.c.ii in the preamble for the final rule and below.

i. Support for Retaining the Current Level

Of the public commenters who addressed the level of the 24-hour $PM_{2.5}$ standard, all industry commenters and most State and local commenters supported the proposed decision to retain the current level of 35 $\mu g/m^3$. In many cases, these groups agreed with the rationale supporting the Administrator's proposed decision to retain the current 24-hour $PM_{2.5}$ standard, including her emphasis on the annual standard as the generally controlling standard with the 24-hour standard providing supplementary protection, and her conclusion that multi-city, short-term exposure studies provide the strongest data set for informing decisions on the appropriate 24-hour standard level. Many of these commenters agreed with the Administrator's view that the single-city, short-term studies provided a much more limited data set (e.g., limited statistical power, limited exposure data) and more equivocal results (e.g., mixed results within the same study area), making them an unsuitable basis for setting the level of the 24-hour standard.

(1) *Comment:* While these commenters agreed with the EPA's proposed decision to retain the current 24-hour $PM_{2.5}$ standard, some did not agree with the EPA's approach to considering the evidence from short-term multi-city studies. For example, a commenter representing UARG pointed out that the 98th percentile concentrations reported in the proposal for multi-city studies reflect the averages of 98th percentile concentrations across the cities included in those studies (UARG, 2012; Attachment 1; p. 25). This commenter contended that such averaged 98th percentile $PM_{2.5}$ concentrations do not provide information that can appropriately inform a decision on the adequacy of the public health protection provided by the current or alternative 24-hour standards.

Response: While the EPA agrees that there is uncertainty in linking effects reported in multi-city studies to specific air quality concentrations (U.S. EPA, 2011a, section 2.3.4.1), the EPA disagrees with this commenter's view that such uncertainty precludes the use of averaged 98th percentile $PM_{2.5}$ concentrations to inform a decision on the appropriateness of the protection provided by the 24-hour $PM_{2.5}$ standard. In particular, the EPA notes that averaged 98th percentile concentrations do provide information on the extent to which study cities contributing to reported associations would likely have met or violated the current 24-hour $PM_{2.5}$ standard during the study period. As evidence of this, the EPA notes the three multi-city studies specifically highlighted by this commenter as having averaged 98th percentile 24-hour $PM_{2.5}$ concentrations below 35 $\mu g/m^3$ (Dominici et al., 2006a; Bell et al., 2008; Zanobetti and Schwartz, 2009). Based on the 98th percentiles of 24-hour $PM_{2.5}$ concentrations in the individual cities evaluated in these studies, the EPA notes that the majority of these study cities would likely have met the current standard during the study periods (Hassett-Sipple et al., 2010). Therefore, regardless of whether the averaged 98th percentile concentrations or the 98th percentile concentrations in each city are considered, these studies provide evidence for associations between short-term $PM_{2.5}$ and mortality or morbidity across a large number of U.S. cities, the majority of which would likely have met the current 24-hour $PM_{2.5}$ standard during study periods. In their review of the PA, CASAC endorsed the conclusions drawn from analyses of averaged 98th percentile 24-hour $PM_{2.5}$ concentrations (Samet, 2010d) and the EPA continues to conclude that this type of information can appropriately inform the Administrator's decision on the current 24-hour $PM_{2.5}$ standard.[29]

(2) *Comment:* One commenter questioned whether the 24-hour standard would offer any additional protection beyond the protection provided by the annual standard. This

[29]This is not to say that the EPA's decision on whether to revise the 24-hour $PM_{2.5}$ standard should be based on or only be informed by considerations of whether studies reported associations with mortality or morbidity in areas with averaged 98th percentile $PM_{2.5}$ concentrations less than 35 mg/m^3. As discussed in section III.E.4.d of the preamble to the final rule, in reaching a decision in the final notice on the most appropriate approach to strengthen the suite of $PM_{2.5}$ standards, the Administrator considers the degree of public health protection provided by the combination of the annual and 24-hour standards together.

commenter argued that EPA has not provided any evidence that the 24-hour standard is necessary to protect public health and asserted that the EPA should better explain why the existing 24-hour standard is not more stringent than necessary (API, 2012, p. 9). More specifically, based on statements in the PA (quoting "there is no evidence suggesting that risks associated with long-term exposures are likely to be disproportionately driven by peak 24-hour concentrations" and citing to several studies that evaluated the effect on the magnitude and statistical significance of the association between $PM_{2.5}$ health impacts with and without high PM concentrations days, finding very little difference, U.S. EPA, 2011a, p. 2-9), this commenter asserted "If the annual standard is protective of effects from both short- and long-term exposures, and no additional effects are observed with peak events, this indicates that there is likely no additional benefit to having the 24-hour standard. Retaining the 24-hour standard, therefore, would be an additional level of protection, or 'margin of safety'" (API, 2012, Attachment 1, p.2).

Response: The EPA disagrees with the commenter's contention that evidence has not been provided to support the appropriateness of the retaining the current 24-hour standard in conjunction with revising the annual standard. The EPA has carefully considered the degree of public health protection provided by the annual and 24-hour $PM_{2.5}$ standards working together. As highlighted by commenters and as discussed in section III.E.4.d of the preamble to the final rule, based on the evidence and quantitative risk assessment, the EPA concludes that it is appropriate to set an annual standard with a level of 12 $\mu g/m^3$ to provide protection from both long- and short-term $PM_{2.5}$ exposures. In conjunction with the revised annual standard, the EPA concludes it is also appropriate to retain the current 24-hour standard in order to provide supplemental protection in areas with high peak-to-mean ratios of $PM_{2.5}$ concentrations, possibly associated with strong local or seasonal sources, and against $PM_{2.5}$-related effects that may be associated with shorter-than daily exposure periods.

As discussed in more detail in section III.E.4.a of the preamble to the final rule, in reaching this conclusion the EPA notes that multi-city studies provide clear evidence for positive and statistically significant associations with short-term $PM_{2.5}$ concentrations in locations with averaged (i.e., averaged across study cities) 98^{th} percentile 24-hour concentrations from 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). In many locations, the revised annual $PM_{2.5}$ standard is expected to protect against the effects reported in these studies. However, some areas of the United States, particularly in the northwest, could experience 98^{th} percentile 24-hour $PM_{2.5}$ concentrations above 35 mg/m^3 while annual $PM_{2.5}$ concentrations remain below 12 $\mu g/m^3$ (U.S. EPA, 2011, Figure 2-10). In such locations, the current 24-hour standard is necessary to provide protection against effects that have been associated with short-term $PM_{2.5}$ exposures. Without the 24-hour standard in place, short-term $PM_{2.5}$ concentrations in some locations could be allowed to exceed those that have clearly been associated with mortality and morbidity. Therefore, the EPA disagrees with commenters who call into question support for the conclusion that the 24-hour standard provides appropriate supplementary protection against effects that have been associated with fine particle exposures.

ii. Support for Revising the Current Level

Another group of commenters argued that the 24-hour standard level should be lowered. Many of these commenters supported setting the level of the 24-hour $PM_{2.5}$ standard at either 25 or 30 μg/m^3.

(1) *Comment:* In support of their position, the ALA et al., AHA et al., five state Attorneys General, and a number of additional groups pointed to 98th percentile $PM_{2.5}$ concentrations in locations of multi-city and single-city epidemiological studies. For example, the ALA and others pointed to multi-city studies by Dominici et al. (2006a), Zanobetti and Schwartz (2009), Burnett et al. (2000), and Bell et al. (2008) as providing evidence for associations with mortality and morbidity in study locations with averaged (i.e., averaged across cities) 98th percentile 24-hour $PM_{2.5}$ concentrations below 35 μg/m^3. These commenters also pointed to several single-city and panel studies reporting associations between short-term $PM_{2.5}$ and mortality or morbidity in locations with relatively low 24-hour $PM_{2.5}$ concentrations. Because some of these multi- and single-city studies have reported associations with health effects in locations with 98th percentile $PM_{2.5}$ concentrations below 35 μg/m^3, commenters maintained that the current 24-hour $PM_{2.5}$ standard (i.e., with its level of 35 μg/m^3) does not provide an appropriate degree of protection in all areas.

In further support of their position that the level of the current 24-hour standard should be lowered, these commenters pointed out the variability across the U.S. in ratios of 24-hour to annual $PM_{2.5}$ concentrations. They noted that some locations, including parts of the northwestern U.S., experience relatively low annual $PM_{2.5}$ concentrations but can experience relatively high 24-hour concentrations at certain times of the year. In order to provide protection against effects associated with short-term $PM_{2.5}$ exposures, especially in locations with high ratios of 24-hour to annual $PM_{2.5}$ concentrations, these commenters advocated setting a lower level for the 24-hour standard.

Response: The EPA agrees with these commenters that it is appropriate to maintain a 24-hour $PM_{2.5}$ standard in order to supplement the protection provided by the revised annual standard, particularly in locations with relatively high ratios of 24-hour to annual $PM_{2.5}$ concentrations. However, in highlighting 98th percentile $PM_{2.5}$ concentrations in study locations without also considering the impact of a revised annual standard on short-term concentrations, these commenters ignore the fact that many areas would be expected to experience decreasing short- and long-term $PM_{2.5}$ concentrations in response to a revised annual standard. See *American Trucking Association v. EPA*, 283 F. 3d at 373 (rejecting argument to lower the level of the 24-hour $PM_{2.5}$ standard since the argument had failed to account for the reductions in the entire air quality distribution resulting from the implementation of the annual standard).

In considering the specific multi-city studies highlighted by public commenters who advocated a more stringent 24-hour standard, the EPA notes that such studies have reported consistently positive and statistically significant associations with short-term $PM_{2.5}$ exposures in locations with averaged 98th percentile $PM_{2.5}$ concentrations ranging from 45.8 to 34.2 μg/m^3 and long-term mean $PM_{2.5}$ concentrations ranging from 13.4 to

12.8 (Burnett and Goldberg, 2003; Burnett et al., 2004; Dominici et al., 2006a; Bell et al., 2008; Franklin et al., 2008; Zanobetti and Schwartz, 2009).[30] The EPA notes that to the extent air quality distributions are reduced to meet the current 24-hour standard with its level of 35 µg/m^3 and/or the revised annual standard with its level of 12 µg/m^3, additional protection would be anticipated against the effects reported in these short-term, multi-city studies. Put another way, to attain an annual standard with a level below the long-term means in the locations of these short-term studies (as EPA is adopting in the final rule), the overall air quality distributions in the majority of study cities will necessarily be reduced, resulting in lower daily $PM_{2.5}$ ambient concentrations. We therefore expect that the revised annual standard will result in 98^{th} percentile $PM_{2.5}$ concentrations in these cities that are lower than those measured in the studies, and that the overall distributions of $PM_{2.5}$ concentrations will be lower than those reported to be associated with health effects. Thus, even for effects reported in multi-city studies with averaged 98^{th} percentile concentrations below 35 µg/m^3, additional protection from the risks associated with short-term exposures is anticipated from the revised annual standard, without revising the 24-hour standard, because long-term average $PM_{2.5}$ concentrations in multi-city study locations were above the level of the revised annual standard (i.e., 12 µg/m^3).[31] As discussed above, reducing the annual standard is the most efficient way to reduce the risks from short-term exposures identified in these studies, as the bulk of the risk comes from the large number of days across the bulk of the air quality distribution, not the relatively small number of days with peak concentrations. See *American Trucking Association*, 283 F. 3d at 372 (endorsing this reasoning).

In considering the single-city studies highlighted by public commenters who advocated a more stringent 24-hour standard, the EPA first notes that, overall, these single-city studies reported mixed results. Specifically, some studies reported positive and statistically significant associations with $PM_{2.5}$, some studies reported positive but non-significant associations, and several studies reported negative associations or a mix of positive and negative associations with $PM_{2.5}$. In light of these inconsistent results, the proposal noted that the overall body of evidence from single-city studies is mixed, particularly in locations with 98^{th} percentiles of 24-hour concentrations below 35 µg/m^3. Therefore, although some single-city studies reported effects at appreciably lower $PM_{2.5}$ concentrations than short-term multi-city studies, the uncertainties and limitations

[30]Commenters also highlighted associations with short-term $PM_{2.5}$ concentrations reported in sub-analyses restricted to days with 24-hour concentrations at or below 35 □g/m^3 (Dominici, 2006b). These sub-analyses were not included in the original publication by Dominici et al. (2006a). Authors provided results of sub-analyses for the Administrator's consideration in a letter to the docket following publication of the proposed rule in January 2006 (personal communication with Dr. Francesca Dominici, 2006b). As noted in section III.A.3 of the preamble to the final rule and to the proposal, these sub-analyses are part of the basis for the conclusion that there is no evidence suggesting that risks associated with long-term exposures are likely to be disproportionately driven by peak 24-hour concentrations. Because the sub-analyses did not present long-term average $PM_{2.5}$ concentrations, it is not clear whether they reflected $PM_{2.5}$ air quality that would have been allowed by the revised annual $PM_{2.5}$ standard being established in this notice.

[31]It is also the case that additional protection is anticipated in locations with 98^{th} percentile 24-hour $PM_{2.5}$ concentrations above 35 µg/m^3, even if long-term concentrations are below 12 µg/m^3. As noted in the proposal (77 FR 38938) and in the PA (U.S. EPA, 2011, Figure 2-10), as well as by a number of the commenters (e.g., ALA et al., 2012, p. 26), parts of the northwestern U.S. are more likely than other parts of the country to violate the 24-hour standard and meet the revised annual standard.

associated with the single-city studies were noted to be greater. In light of these greater uncertainties and limitations, the Administrator concluded in the proposal that she had less confidence in using these studies as a basis for setting the level of the standard (77 FR 38943).

Given the considerations and conclusions noted above, in the proposal the Administrator concluded that the short-term multi-city studies provide the strongest evidence to inform decisions on the level of the 24-hour standard. Further, she viewed single-city, short-term exposure studies as a much more limited data set providing mixed results, and she had less confidence in using these studies as a basis for setting the level of a 24-hour standard (77 FR 38942). In highlighting specific single-city studies, public health, environmental, and State and local commenters appear to have selectively focused on studies reporting associations with $PM_{2.5}$ and to have overlooked studies that reported more equivocal results (e.g., Ostro et al., 2003; Rabinovitch et al., 2004; Slaughter et al., 2005; Villeneuve et al., 2006) (U.S. EPA, 2011, Figure 2-9). As such, these commenters have not presented new information that causes the EPA to reconsider its decision to emphasize multi-city studies over single-city studies when identifying the appropriate level of the 24-hour $PM_{2.5}$ standard.

In further considering the single-city studies highlighted by public commenters, the EPA notes that some commenters advocating for a lower level for the 24-hour $PM_{2.5}$ standard also discussed short-term studies that have been published since the close of the ISA. These recent studies were conducted in single cities or in small panels of volunteers. As in prior NAAQS reviews and as discussed in more detail in section II.B.3 of the preamble to the final rule and in section II.B.1.a above, the EPA is basing its decisions in this review on studies and related information assessed in the ISA. The studies assessed in the ISA, and the conclusions based on those studies, have undergone extensive critical review by the EPA, CASAC, and the public. The rigor of that review makes the studies assessed in the ISA, and the conclusions based on those studies, the most reliable source of scientific information on which to base decisions on the NAAQS.

(2) *Comment:* Some public health, medical, and environmental commenters also criticized the EPA's interpretation of $PM_{2.5}$ risk results. These commenters presented risk estimates for combinations of annual and 24-hour standards using more recent air quality data than that used in the EPA's RA (U.S. EPA, 2010a). Based on these additional risk analyses, the ALA and other commenters contended that public health benefits could continue to increase as annual and 24-hour standard levels decrease below 13 $\mu g/m^3$ and 35 $\mu g/m^3$, respectively.

Response: The EPA agrees with these commenters that important public health benefits are expected as a result of revising the level of the annual standard to 12 $\mu g/m^3$, as is done in the final rule, rather than 13 $\mu g/m^3$. The Agency also acknowledges that estimated $PM_{2.5}$-associated health risks continue to decrease with annual standard levels below 12 $\mu g/m^3$ and/or with 24-hour standard levels below 35 $\mu g/m^3$. However, the EPA disagrees with the commenters' views regarding the extent to which risk estimates support setting standard levels below 12 $\mu g/m^3$ (annual standard) and 35 $\mu g/m^3$ (24-hour standard).[32]

The CAA charges the Administrator with setting NAAQS that are "requisite" (i.e., neither more nor less stringent than necessary) to protect public health with an adequate margin of safety. In setting such standards the Administrator must weigh the available scientific evidence and information, including associated uncertainties and limitations. As described above, in reaching her proposed decisions on the $PM_{2.5}$ standards that would provide "requisite" protection, the Administrator carefully considered the available scientific evidence and risk information, making public health policy judgments that, in her view, neither overstated nor understated the strengths and limitations of that evidence and information. In contrast, as discussed more fully above, public health, medical, and environmental commenters who recommended levels below 35 $\mu g/m^3$ for the 24-hour $PM_{2.5}$ standard have not provided new information or analyses to suggest that such standard levels are appropriate, given the uncertainties and limitations in the available health evidence, particularly uncertainties in studies conducted in locations with 98th percentile 24-hour $PM_{2.5}$ concentrations below 35 $\mu g/m^3$ and long-term average concentrations below 12 $\mu g/m^3$.

C. Specific Comments on the Quantitative Health Risk Assessment

This section responds to more detailed comments regarding the quantitative health risk assessment conducted for $PM_{2.5}$ (RA, US EPA, 2010a).

(1) *Comment:* Some commenters argued that the quantitative health risk assessment conducted for $PM_{2.5}$ was too limited since it "focused on only 15 urban study areas to represent the continental U.S. and only examined a fraction of the available combinations of annual and daily standards" (ALA et al., 2012, p. 73). These commenters noted that the RA indicated the quantitative risk analyses likely underestimated $PM_{2.5}$-related mortality (U.S. EPA, 2010a, p. 5-16) and argued that "the measurements of risk should be treated conservatively" (ALA, et al., 2012, p. 73). These commenters also noted that significant additional risk reduction is associated with combinations of annual and 24-hour standards lower than those considered by the EPA (ALA et al., 2012, pp. 73 to76).

Response: The RA used a case study approach wherein distinct sets of risk estimates were generated for each of 15 urban study areas. The case study approach was selected in order to make use of site-specific data in modeling $PM_{2.5}$-related risk, thereby generating risk estimates with higher overall confidence. Furthermore, the case study approach was intended to provide coverage for the range of PM-related health effects likely to be experienced by urban residents across the U. S. and was not intended to provide a comprehensive picture of total risk for the U.S. population.

With regard to the scope of the quantitative risk analysis, as stated in the proposal, "The selection of urban study areas was based on a number of criteria including: (1) consideration of urban study areas evaluated in the last PM risk assessment; (2) consideration of locations evaluated in key epidemiological studies; (3) preference for

[32] This section focuses on the 24-hour standard. Section III.E.4.c.i of the preamble to the final rule and section II.B.5.a.i above also discuss these commenters' recommendations within the context of the annual $PM_{2.5}$ standard.

locations with relatively elevated annual and/or 24-hour $PM_{2.5}$ monitored concentrations; and (4) preference for including locations from different regions across the country, reflecting potential differences in $PM_{2.5}$ sources, composition, and potentially other factors which might impact $PM_{2.5}$ -related risk" (77 FR 38912; see also U.S. EPA, 2010a, section 3.3.2). Based on the results of several analyses examining the representativeness of these 15 urban study areas in the broader national context (U.S. EPA, 2010a, section 4.4), the RA concluded that these study areas were generally representative of urban areas in the U.S. likely to experience relatively elevated levels of risk related to ambient $PM_{2.5}$ exposure with the potential for better characterization at the higher end of that distribution (U.S. EPA, 2011a, p. 2–42; U.S. EPA, 2010a, section 4.4, Figure 4–17). The CASAC's in their letter response on the 1st draft RA supported the choice of cities stating that, "The Risk Assessment understandably focuses on risk in the urban study areas, where the population is concentrated; and there appears to be an appropriate selection of cities, using defined criteria." (Samet 2010a, p. 10).

With respect to the selection of various combinations of alternative annual and 24-hour standard levels modeled in the RA, as noted in section 2.3.4.2 of the PA, 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 (U.S. EPA, 2009e) and reflected consideration for evidence related to potential $PM_{2.5}$-related health effects as presented in the second draft ISA (U.S. EPA, 2009b). The range of alternative standard levels discussed in the PA (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 $\mu g/m^3$), reflected consideration of evidence as presented in the final ISA and consequently differed somewhat from the set of alternative standard levels originally selected for modeling in the quantitative risk assessment. In addition, subsequent to the release of the second draft RA (U.S. EPA, 2010d), the Agency 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 (U.S. EPA, 2010a, Appendix J).

While the EPA agrees with the commenters that the combinations of alternative standard levels modeled in the RA were only a "fraction" of possible combinations that one might model, the EPA selection of alternative standard levels to model followed a deliberative and transparent process. Modifications in the alternative standard levels considered in the first and second draft RAs and the final RA reflected changes made in the ISA, RA, and PA based on CASAC and public comments on multiple draft assessment documents and the EPA's staff's expert judgment regarding the confidence associated with modeling different combinations of alternative standard levels. The EPA believes that the uncertainties associated with the risk estimates increase when simulating increasingly lower alternative standard levels. For example, in simulating an alternative annual standard level of 10 μg/m^3, the Agency noted increased uncertainty associated with risk estimates generated for this lower alternative standard level and for, that reason, these risk estimates were deemphasized in the final RA (U.S. EPA, 2010a, Appendix J). The EPA's decision to limit the range of alternative standard levels considered to combinations with increased confidence is consistent with advice provided by CASAC. More specifically, CASAC recommended that the "…EPA develop and apply specific criteria for determining the lower-bound exposure concentrations to be considered in the risk assessment. Mounting uncertainty at lower concentrations would be one such reasonable basis. Other relevant considerations include the range of concentrations at which the epidemiological studies have been carried out and the need for consideration of the degree of protection afforded to susceptible populations under various scenarios" (Samet 2010a, p. 2). The EPA readily acknowledges that additional risk reductions would be expected as one simulates progressively lower alternative standard levels as suggested by the commenters. However, the Agency also recognizes that the uncertainties associated with these lower alternative standard levels would also be increased resulting in more uncertain basis for informing the Agency's decisionmaking.

With regard to the comment that the RA likely underestimates risk and that for this reason, the risk estimates should be treated conservatively by the EPA when considering them in the context of the PM NAAQS review, the EPA generally agrees with the commenters' views. As noted in the proposal, the RA concluded, "it is unlikely that the estimated risks are over-stated, particularly for premature mortality related to long-term $PM_{2.5}$ exposures" (77 FR 38917/2). When model uncertainty associated with specification of the effect estimates for long-term exposure-related mortality was considered, the RA noted the potential that the risk estimates may have been under-stated (U.S. EPA, 2010a. section 4.3.2). This point is clearly made in the RA as noted above and is further reiterated when summarizing the risk estimates in the PA (U.S. EPA, 2011a, section 2.2.2, p. 2-40). In addition, the EPA recognizes that the RA estimated risks for selective health outcomes (i.e., mortality, cardiovascular- and respiratory-related hospital admissions, asthma-related emergency department visits). As summarized in section III.B of the preamble to the final rule and discussed in more detail in section III.B.1 of the proposal and section 2.2.1 of the PA, the Agency recognizes that the currently available scientific information includes evidence for a broader range of health endpoints and at-risk populations beyond those considered in the quantitative risk assessment (U.S. EPA, 2011a, p. 2-47). Thus, for the reasons discussed above, the EPA agrees with the comment that the risk estimates are most likely underestimated and should be treated conservatively.

(2) *Comment:* Some public health, medical, and environmental commenters also criticized the EPA's interpretation of the $PM_{2.5}$ risk results. These commenters summarized an expanded analysis of alternative $PM_{2.5}$ standard levels (McCubbin, 2011) that they argued documented the need for more protective standards (ALA et al., 2012, p. 73; PSR, 2012, p.5; CLF, 2012, p.3). Specifically, they asserted that the McCubbin et al. (2011) demonstrated that (a) the EPA evaluated compliance with the $PM_{2.5}$ standard for each year separately, while the McCubbin analysis used an innovative approach that

considered three years in evaluating compliance , and (b) risks can be generated using more recent air quality data than that used in the EPA's RA (U.S. EPA, 2010a) (Id.; ALA et al., 2012, pp. 73.

Response: The commenters' assertion that the EPA evaluated compliance with each simulation year separately is incorrect. In the RA, the EPA considered three years of monitoring data in constructing the design values for each monitor within an urban study area. The design values were used as the basis for establishing the magnitude of rollback to simulate both the current and alternative standards. While the rollback of each monitor (or of the composite monitor depending on the adjustment method) was completed separately for each simulation year, the design values themselves were based on three years of data (U.S. EPA, 2010a, section 3.2.3).

The commenters stated that the alternative risk assessment (McCubbin, 2011) included more recent ambient $PM_{2.5}$ data than the RA. The EPA agrees with this comment. The McCubbin (2011) analysis used air quality data from 2007 to 2009. The RA, completed in 2010 considered air quality data from 2005 to 2007. The EPA observes that the RA utilized the most recent $PM_{2.5}$ monitoring data available at the time of the analysis. It is always the case with regulatory risk assessments that they reflect the use of input data available at the time of their completion and that often, portions of that input data could be updated if the RA is repeated at a future point in time.

(3) *Comment:* One group of commenters asserted that there was no evidence for a threshold, which, in the commenters' views, argued against constraining simulation of risk to only extend down to the lowest measured level (LML) as was done in the RA (ALA et al., 2012, pp., 76 to 77).

Response: The Agency agrees that there is no evidence for a threshold for effects related to endpoints modeled in the RA, as supported by conclusions reached in the ISA (U.S. EPA, 2009a, section 2.4.3). However, application of the LML in the RA does not reflect modeling of a threshold for long-term exposure-related mortality. Rather it reflects consideration for where we have greater overall confidence in the risk estimates generated within the range of ambient $PM_{2.5}$ data reflected in the epidemiological study underlying the effect estimates used in modeling risk. Specifically, as discussed in section 5.1.6 of the RA, the EPA has relatively high confidence when we estimate risks associated with $PM_{2.5}$ concentrations within one standard deviation (SD) of the mean $PM_{2.5}$ concentrations reported in the epidemiological study underlying the effect estimates used to develop the C-R functions used in the risk assessment. However, as simulated annual average $PM_{2.5}$ concentrations extend below this range, our confidence in the risk estimates decreases, with our confidence being significantly reduced when composite monitor annual average values reach or extend below the LML associated with the epidemiological study. Consequently, application of the LML allows us to focus risk on that portion of the PM range where we have relatively higher confidence and is not meant to imply that there is no risk below the LML (U.S. EPA, 2010a, section 4.3.1.2).

(4) *Comment*: Some commenters cited to the results of an expert elicitation sponsored by the EPA providing "credence" to the EPA's use of both the Laden et al. (2006) and Krewski

et al. (2009a) studies in the RA (ALA et al., 2012, p. 20).

Response: With regard to Laden et al. (2006), the RA stated, "The Laden et al. (2006) study (which focused on the Harvard Six Cities dataset) was not selected because it used visibility data to estimate ambient $PM_{2.5}$ levels." (U.S. EPA, 2010a, p. 3-38). In addition, the EPA recognizes that the Laden et al., 2006 study utilized data from six urban study areas, only one of which (St. Louis) was reflected in the set of urban study areas modeled in the RA. By contrast, the Krewski et al. (2009a) study included a substantially larger number of urban study areas (116 including all study areas modeled in the RA). That means that the effect estimates based on Krewski et al. (2009a) are likely to be more representative of the set of urban study areas modeled in the RA than are effect estimates based on Laden et al. (2006). While the smaller number of cities reflected in Laden et al. (2006) may not compromise the study in terms of informing consideration for uncertainty related to specification of effect estimates (as reflected in the Expert Elicitation referenced by the commenter, Roman et al., 2008.), the smaller number of cities in the Laden et al., (2006) study can substantially increase uncertainty associated with using that study's effect estimates in risk assessments when those assessments focus on cities not reflected in the Laden et al., 2006 study, as noted here. The EPA did include Laden et al., (2006)-based mortality estimates as part of the national scale analysis in order to look at uncertainty related to model specification in modeling national-scale risk (U.S. EPA, 2010a, Appendix G). In that case, matching urban study areas was not as critical since a single national-level effect estimate was used to generate a national-scale estimate of risk.

(1) *Comment*: Some commenters argued that the RA is "compromised by the EPA's willingness to overlook a large amount of uncertainty in the epidemiologic studies on which it relied in the ISA and on which it based the QHRA [Quantitative Health Risk Assessment]. Because it is based on a series of critical assumptions, and the uncertainty associated with those assumptions is not fully quantified, the QHRA cannot serve the functions for which it is intended: to quantify the risk to public health remaining at the level of the current standard or at the alternative levels" considered in the proposal (API, 2012, p. 23, Attachment 1, p. 36). These commenters argued that the "RA results do not warrant being used as evidence for long-term PM health risks below current PM standards, and they should not be used to guide decisions regarding the PM standards" (API, 2012, Attachment 1, p. 36). In asserting that the uncertainties in the quantitative risk assessment have not been appropriately considered and, thus, this assessment does not support revision to the standards at this time, the commenters raised a number of detailed technical comments related to key modeling elements of the RA including: (a) the use of a no-threshold, log-linear model to support estimating risk down to LML and policy relevant background (PRB); (b) uncertainty related to model specification (selection of C-R functions), (c) failure to sufficiently consider sources of heterogeneity impacting risk estimates; (d) treatment of measurement error and potential direction of associated bias in the effect estimates; and (e) representation of the confidence associated with the risk assessment results.

Response: In presenting response to these comments, the EPA first addresses each of the detailed technical comments. Then, the EPA addresses the broader criticism made by this commenter that asserted the Agency overlooked important sources of uncertainty associated with the risk assessment, thereby compromising the ability of the risk assessment to be used to support the PM NAAQS review.

(a) Modeling risk down to LML and PRB

The commenter disagreed with the EPA's use of a no-threshold, log-linear model to support modeling risk down to either the LML or PRB, depending on the health endpoint (API, 2012, Attachment 1, p. 36).

Comments related to the shape of the C-R relationship, specifically issues related to whether there is a threshold in the $PM_{2.5}$-health effect relationship are addressed in section II. B.1.b, Comment (12)(f) above. Based on the ISA conclusion, and CASAC's consensus recommendation, that the overall evidence from existing epidemiological studies does not support the existence of thresholds at the population level for effects associated with either long- or short-term $PM_{2.5}$ exposures within the ranges of air quality observed in these studies (U.S. EPA, 2009a, section 2.4.3; Samet 2010d, p. ii), risk estimates were generated without consideration for a threshold. However, in order to focus the risk assessment on a range of PM where there is greater overall confidence (i.e., the range of ambient PM concentrations reflected in the epidemiological study(s) underlying the effect estimates used in the risk assessment), the EPA modeled risk for long-term exposure-related mortality down to the lowest measured level (LML) associated with the Krewski et al., 2009a study which provided effect estimates for this endpoint. Short-term exposure-related morbidity and mortality endpoints were modeled down to P RB since the 24-hour PM metrics reflected in those epidemiological studies typically have LML values below PRB (U.S. EPA, 2010a, section 3.1.1). The RA included a sensitivity analysis for long-term mortality comparing modeling of risk down to LML with risk modeled down to PRB. Not surprisingly, this sensitivity analysis showed that modeling risk down to PRB resulted in notably greater estimates for total risk (U.S. EPA, 2010a, section 4.3.1.1). The CASAC also supported this approach, stating that "[t]here was support [from CASAC members] for modeling risk for long-term $PM_{2.5}$ exposures to the lowest measured level (LML). For short-term risk estimates, the EPA's approach is appropriate, since as the document points out, the LMLs (which are daily) are below the PRB" (Samet, 2009c, p.2).

(b) Uncertainty related to model specification (selection of C-R functions)

One commenter argued that the EPA only considered a small fraction of overall uncertainty in the epidemiological studies and C-R functions from those studies, specifically reflected in the considering the confidence intervals (CIs) associated with the effect estimates (API, 2012, Attachment 1, p. 36). This commenter asserted that consideration of C-R function CI's does not capture significant model uncertainty. Specifically, this commenter pointed to variation in the risk estimates resulting from consideration of different C-R functions in the RA sensitivity analysis. This commenter used these arguments to support its views that the analysis results were not "robust" to model specification as stated by the EPA (API, 2012, Attachment 1, p. 39). They also asserted that the EPA communicated with the study authors associated with Krewski et al., 2009a and that, while these authors suggested that the EPA use a random effects model, the EPA elected to use the fixed-effects Cox model instead (API, 2012, Attachment 1, p. 38).

Finally, the commenter asserted that the EPA did not consider multi-pollutant models in the RA and relied only on single-pollutant models (particularly for LT mortality) (API, 2012, Attachment 1, p. 36). This commenter pointed out that an earlier study (Krewski et al., 2000) provided evidence of copollutant effects (API, 2012, Attachment 1, p. 38) and the commenter recognized that the EPA addressed the issue of copollutants in a sensitivity analysis. However, the commenter asserted that the EPA discounted its sensitivity analysis of copollutants because control for SO_2 may capture a portion of the $PM_{2.5}$ effect. The commenter agreed that this may be true for some regions of the country, but not for regions where SO_2 is not a major portion of $PM_{2.5}$. The commenter concluded by observing that single- pollutant models may over-estimate risk by including the impacts of other copollutants in the $PM_{2.5}$ signal.

The EPA disagrees that the RA did not consider the full range of uncertainty associated with the C-R functions and only considered uncertainty captured by CIs (i.e., statistical fit). As noted by the commenter, the EPA included a sensitivity analysis in the RA which specifically examined the issue of model uncertainty by considering a range of different C-R function model specifications (U.S. EPA, 2010a, section 4.3.2). The results of that sensitivity analysis suggested that, in the case of long-term exposure-related mortality, consideration of model uncertainty could result in risk estimates that are from 2-3 times *higher* than risk estimates generated for the core analysis. As discussed in section 5.1.5 of the RA, because the Krewski et al. (2009a) study does not provide coverage for lower SES individuals who were identified in the ISA as an at-risk population, there is a likely low-bias in the effect estimates associated with this study (with the results of the sensitivity analysis supporting this observation). Therefore, while the EPA agrees that model uncertainty does impact the core risk estimates, in contrast to the commenters' views, the Agency believes the direction of the bias in the Krewski et al. (2009a) models is likely downwards which means that it is unlikely that the EPA has over-estimated risk using those models. This was an important observation when discussing the overall confidence in the risk estimates within the policy context and was highlighted in the PA (U.S. EPA, 2011a, section 2.2.2).

Regarding the Krewski et al., 2009a study authors' advice to the EPA on model selection related to long-term exposure-related mortality, the EPA recognizes that in their communication, the study authors stated that they had "refrained from expressing a preference among the results for their use in quantitative risk assessment," preferring to "explore several plausible statistical models that we have fit to the available data." (Krewski, 2009b). The EPA considered this input along with the authors' recommendation that a random effects model be used. In addition, the EPA staff considered the results of an analysis presented in the study examining the importance of exposure time windows in deriving C-R functions. This analysis suggested that models developed using both exposure time windows considered in the analysis (1979-1983 and 1999-2000) were equally effective at representing the relationship between $PM_{2.5}$ exposure and long-term exposure-related mortality (U.S. EPA, 2010a, section 3.3.3) . Therefore, the EPA concluded that C-R functions used in the core analysis should include functions fitted to both exposure time windows. However, the study does not provide random effects models with ecological covariates for both exposure time windows (this form of model is only provided with a fit to the latter exposure window). Therefore, for the core analysis, the EPA reasonably decided to use the Cox proportional hazard model, since effect estimates for both exposure time windows were provided for this model. However, had random effects models been provided for the separate exposure windows, then those would have been considered for the core analysis. It is important to note that the EPA did include the random effects referenced by the Krewski et al. (2009a) authors as part of the sensitivity analysis completed for the risk assessment, and, as noted above, this sensitivity analysis suggested greater risk than estimated in the EPA's core analysis.

The issue of copollutant confounding was addressed previously in section II.B.1.b, Comment (12)(a) and points made in that response are applicable here. With specific regard to the risk assessment, the EPA also notes that the Krewsi et al. (2009a) study was selected by the EPA as the basis for the core set of risk estimates over other studies, including those using multi-pollutant models, because it has a number of advantages (e.g., extended air quality analysis which increases the power of the study and allows the study authors to examine the important issue of exposure time windows, rigorous examination of a range of model forms and effect estimates, coverage for a range of ecological variables, relatively large overall dataset with over 1.2 million individuals and 156 MSAs) (U.S. EPA, 2010a, section 3.3.3). While the Krewski et al. (2009a) analysis did not provide copollutants models, given the overall conclusion regarding the robustness of single-pollutant models (as noted in the comment-response referenced above - see section II.B.1.b, comment 13.a), The EPA concluded that these other strengths of the study design argued for the use of this study as the basis for the core set of risk estimates for long-term exposure-related mortality. In their comments on the first draft RA, CASAC supported the use of the Krewski et al. (2009a) study as the basis for modeling long-term exposure-related mortality, although they requested that the EPA provide an expanded discussion of our rationale for focusing on this study (Samet 2009c). The EPA provided that expanded discussion in the final RA (U.S. EPA, 2010a, section 3.3.3), which was also reviewed by CASAC.

(c) Failure to sufficiently consider sources of heterogeneity impacting risk estimates.

The commenter makes several points regarding heterogeneity including: (a) Bayes shrunken estimates for ST mortality are likely to mask some of the heterogeneity and can result in overly tight SDs for those effect estimates (API, 2012 Attachment 1, p. 38), (b) seasonality has been shown to impact both long-term and short-term exposure related risk and this source of heterogeneity is not captured in the RA (API, 2012, Attachment 1, p. 40, 41), (c) regional effect estimates for ST morbidity (as used by the EPA) only capture a portion of variability in the response and do not fully capture spatial and seasonal heterogeneity (API, 2012, Attachment 1, p. 40), and (d) long-term mortality risk estimates are based on nationwide CRFs that do not reflect heterogeneity across regions (API, 2012, Attachment 1, p. 42).

Regarding the use of Bayes shrunken estimates; rather than masking heterogeneity, the use of Bayes shrunken estimates has the advantage of correcting for uncertainty-induced heterogeneity. Specifically, city-specific effect estimates are shrunken towards the national effect estimates based on consideration of variance in those city-specific effect estimates. In those cases where a city-specific effect estimate has a relatively large confidence interval (reflecting uncertainty in specification of that effect estimates and not necessarily true heterogeneity), then that effect estimate will be shrunken towards the national mean, in order to incorporate information from the higher confidence national effect estimate. By using city-specific Bayes shrunken estimates, instead of a single national-level effect estimate, the EPA did reflect consideration for heterogeneity in the $PM_{2.5}$ effect across cities in modeling short-term exposure-related mortality.

The EPA addressed comments regarding potential heterogeneity in effect estimates related to seasonality in a previous comment (section II.B.1.b, comment 13c). There the EPA notes that the importance of seasonality as a factor influencing effect estimates varies regionally across the country, but does not have a systematic impact on those estimates, reflecting the complexity of this issue. The EPA also points out that for this reason heterogeneity related to seasonality is an area that could benefit from additional research.

In response to the comment regarding use of regional effect estimates in modeling ST morbidity, the EPA notes that Table 3-6 of the RA (U.S. EPA, 2010a) addresses qualitative uncertainty associated with the use of regional effect estimates in modeling this category of endpoints (specifically, use of the Bell et al. (2008) study for cardiovascular and respiratory hospital admissions). In Table 3-6, the EPA acknowledges that these regional effect estimates are in some cases non-statistically significant, but also notes that this study benefits from larger sample sizes compared to city-specific models. In addition, the EPA reiterates that a lack of statistical significance does not demonstrate a lack of causal association between exposure and response. See, e.g. section II.B.5. a. i. Comment (4).

The comment regarding regionality and the modeling of long-term exposure-related mortality has been addressed in a previous comment (see section II.B.1.b, Comment 12.c). As noted there, the PA recognizes that the current epidemiological 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 (U.S. EPA, 2011a, p. 2-25).

(d) Treatment of measurement error and potential direction of associated bias

The commenters argued that uncertainty related to variation in PM and its components (measurement error) has a greater impact on risk estimates than the EPA acknowledges. They argue that measurement error can influence results in either direction and not mainly lower as asserted by the EPA. (API, 2012, Attachment 1, p. 42).

The EPA disagrees with the commenter that measurement error has not been adequately considered in the RA. This issue was addressed in an earlier comment response (see section II.B.1.b, Comment 12.d). In that earlier response, the EPA also notes that the ISA concluded "in most circumstances, exposure error tends to bias a health effect estimate downward" (U.S. EPA, 2009a, sections 2.3.2 and 3.8.6). Thus, the EPA has both considered and accounted for the possibility of exposure measurement error, including possible bias associated with measurement error which can make it more difficult to detect true associations.

(e) Stratification of risk assessments to consider different regions of confidence

Commenters asserted that the EPA did not stratify risk estimates to consider those estimates above and below various levels of interest (e.g., LML with estimates falling below the LML having lower confidence). (API, 2012 Attachment 1, p. 42).

The EPA disagrees with the comment that the EPA did not stratify risk estimates to consider estimates above and below various levels of interest (e.g., LML, PRB etc). In Figures 2-11 and 2-12 in the PA (U.S. EPA, 2011a), the EPA presents percentile risk reductions for long-term and short-term exposure-related mortality, respectively, including stratification of those risk reductions into regions of varying confidence. In the case of long-term exposure-related mortality, these regions include differentiation based on risk estimates falling above and below the LML referenced by the commenter.

D. Specific Comments Related to Data Handling (Appendix N)

The EPA is revising the $PM_{2.5}$ NAAQS data handling rules codified in 40 CFR Part 50, appendix N. The EPA is modifying appendix N to conform to the revised $PM_{2.5}$ standards; most notably, the EPA is amending the appendix N procedures by removing the option for spatial averaging. In addition to making changes to appendix N that correspond to the changes in the annual standard form and the revised primary annual standard level, the EPA is also finalizing additional proposed revisions to the appendix in order to codify existing practices currently included in guidance documents or implemented as the EPA standard operating procedures; better align appendix N language and requirements with proposed changes in $PM_{2.5}$ ambient monitoring and reporting requirements; provide greater clarity and transparency in the provisions; and enhance consistency with data handling protocols utilized for other pollutants.

The EPA received a few substantive comments related to data handling for the primary $PM_{2.5}$ NAAQS. Most comments corresponded to specific revisions to appendix N, some addressed issues on which the EPA explicitly solicited feedback at proposal. All substantive comments are addressed below. Comments are grouped into four issue categories regarding the EPA final decision to: (1) codify proposed changes for identifying $PM_{2.5}$ data "appropriate" for NAAQS comparisons; (2) codify proposed modifications to the procedures for combining data for design value computations; (3) incorporate additional $PM_{2.5}$ data substitution tests; and (4) eliminate the special seasonal sampling 98^{th} percentile concentration identification procedure, as proposed.

1. Identifying $PM_{2.5}$ data "appropriate" for NAAQS comparisons

This topic concerns "equivalency" issues associated with measurements from certain continuous $PM_{2.5}$ Federal Equivalent Method (FEM) monitors for the calculation of $PM_{2.5}$ design values. As discussed in section VII.A.3 of the preamble to the final rule, "With regards to clarification of which monitoring data are appropriate for comparison to the $PM_{2.5}$ NAAQS, the

EPA proposal acknowledged important data quality concerns associated with the $PM_{2.5}$ measurements collected by continuous $PM_{2.5}$ FEMs and referenced a subsequent preamble proposal section that discussed the issue in more depth and put forward a solution to mitigate the data quality concerns."

(1) *Comment*: The EPA received numerous comments expressing concerns regarding the use of measurement data provided by certain continuous $PM_{2.5}$ FEMs for NAAQS comparisons.

Response: As explained in section VIII of the preamble to the final rule, the EPA is revising the monitoring regulations in conjunction with the revisions to the $PM_{2.5}$ standards to include language allowing monitoring agencies to identify $PM_{2.5}$ FEMs that are not providing data sufficiently comparable to the $PM_{2.5}$ Federal Reference Method (FRM) and, with the EPA approval, to allow such data to be excluded from comparisons with the $PM_{2.5}$ NAAQS. The EPA is modifying Sections 1 and 2 of appendix N to comport with these revisions.

2. Procedures for combining data for design value computations

This topic concerns the procedures for combining monitored data from collocated instruments into a single "combined site" data record. The EPA proposed a minor modification to these procedures for the unique situation in which a monitoring agency identifies a $PM_{2.5}$ FRM (that operates on a non-daily schedule) as the site's primary monitor instead of a collocated continuous $PM_{2.5}$ FEM instrument (that provides a measured value for every day). This minor modification, which affects few sites, and the impetus for making it are described in detail in section VII.A.3 of the proposal (77 FR 39001). No significant comments were received on the proposed minor modification noted above, and thus, for the reasons stated in the preamble to the proposed rule, it was included in the revised appendix N.

In the same section of the proposal that described the minor modification (VII.A.3), the EPA explicitly solicited comment on the more general issue of whether "non-primary" (i.e., collocated) FEM data should ever be combined with the primary data as part of the comparison to the NAAQS for $PM_{2.5}$. Numerous comments were received regarding that issue. Most substantive comments noted that due to comparability issues between certain FEMs and FRMs, it was not always prudent to combine the two data types for NAAQS comparison purposes (or even to use an FEM sited without a collocated FRM with that intention). These particular types of comments are addressed above (in the first comment response), as well as in expanded detail in section V below..

One commenter questioned a different aspect of the issue of FEM and FRM comparability and combination of the two data types. This comment, described below, questioned why the EPA had implemented different daily data completeness criteria for the two types of data.

(1) *Comment*: The EPA received a comment questioning the differences in the data handling rules for continuous and filter-based data. Specifically, the commenter questioned why continuous (FEM) data required 75 percent completeness (i.e., 18 or more hours) for a

valid daily average, while filter-based (FRM) measurements required 23 to 25 hours (95 percent to 105 percent) for a valid daily value. The commenter suggested that the EPA define consistent data handling procedures for continuous and filter-based $PM_{2.5}$ (and PM_{10} data).

Response: The EPA did not specifically propose, nor did we seek comment on this issue and we are not reopening or otherwise reconsidering the matter in this rulemaking. Nonetheless, the EPA notes that the rules for meeting a valid sample with an FRM, which have been in place since 1997, are based in part on the desire to obtain valid measurements of 24-hour periods, with some flexibility provided if a sample runs less than the minimum number of hours for a valid sample (i.e., a minimum 23 hours). The Agency also notes that continuous $PM_{2.5}$ methods, which typically report concentrations on an hourly basis and include additional diagnostic data which support data validity judgments, provide a basis for determining data completeness and validity hour by hour in a manner that is not feasible for 24-hour, filter-based methods.

3. Additional $PM_{2.5}$ data substitution tests

With regard to assessments of data completeness, the EPA proposed two additional data substitution tests[33] in appendix N for validating annual and 24-hour $PM_{2.5}$ design values otherwise deemed incomplete (via the 75 percent and 11 creditable sample minimum quarterly data completeness requirements). The EPA proposed to add these tests in order to codify existing practices currently included in guidance documents (U.S. EPA, 1999) and implemented as the EPA standard operating procedures. Further, the EPA sought to make the data handling procedures for $PM_{2.5}$ more consistent with the procedures used for other NAAQS. While the need for data substitution will lessen as more continuous $PM_{2.5}$ monitors continue to be deployed in $PM_{2.5}$ networks, the EPA believes that these substitution procedures are important to ensure that available data, if incomplete, can be confidently used to make comparisons to the NAAQS. As noted in the EPA proposal, data substitution tests are diagnostic in nature (i.e., they are only used in an illustrative manner to show that the determination of NAAQS status based on incomplete data is reasonable).

Previously, section 4.1(c) of appendix N specified only one data substitution test for validating an otherwise incomplete design value. That diagnostic test only applied to the primary and secondary annual $PM_{2.5}$ standard, and only applied in instances of a violation. This data substitution test is referred to as the “minimum quarterly value” test and is used to determine if the NAAQS is not met (i.e., is violated). The EPA proposed two additional data substitution tests to allow comparisons to the primary and secondary annual and 24-hour $PM_{2.5}$ standards to determine whether the NAAQS are met. One of these proposed tests uses collocated PM_{10} data to fill in “slightly incomplete”[34] data records, and the other uses quarter-specific maximum values to fill in “slightly incomplete” data records. These two data substitution tests are referred to as the “collocated PM_{10} test” and the “maximum quarterly value test,” respectively. Both tests are designed to confirm that the $PM_{2.5}$ design value is less than the level of the NAAQS.

[33] Data substitution tests are supplemental data completeness assessments that use estimates of 24-hour average concentrations to fill in for missing data (i.e., “data substitution”).
[34] Slightly incomplete is defined as less than 75 percent but at least 50 percent quarterly data capture.

As codified in section 4 of the revised appendix N, data are substituted for missing data to produce a “test design value” which is compared to the level of the NAAQS. If the test design value passes the diagnostic test, the “incomplete” design value (without the data substitutions) is then considered a valid design value. If an “incomplete” design value does not pass any stipulated data substitution test, then the original design value is still considered incomplete (and not valid for NAAQS comparisons).

The EPA received several comments on the proposed addition of the two data substitution tests to determine that the NAAQS were met. The majority of comments generally supported the addition of data substitution tests. However, two commenters questioned the general philosophy of all appendix N data substitution tests (i.e., the existing “over NAAQS” test and the two proposed “under NAAQS” tests) by suggesting that there were more appropriate techniques for filling in for missing data that would result in better estimates of true design value level. Another commenter questioned, and argued against, the use of collocated PM_{10} data in $PM_{2.5}$ data substitution tests.

(1) *Comment*: One commenter questioned, and argued against, the use of collocated PM_{10} data in $PM_{2.5}$ data substitution tests.

Response: At the time of proposal, the EPA believed that PM_{10} data would be appropriate for a $PM_{2.5}$ data substitution test. However, after consideration of public comments and additional air quality analyses, the EPA has decided that substitution of PM_{10} data is largely redundant with the maximum quarterly value test and, thus, as discussed in section VII.A.4 of the preamble to the final rule, the EPA decided to not include the PM_{10} substitution test in appendix N.

More specifically, the EPA analyzed the most recent three years of $PM_{2.5}$ and PM_{10} data (2009 to 2011) and assessed the separate benefit of the PM_{10} substitution routine compared to the maximum quarterly value test (Schmidt, 2012b). In this assessment of 2009 to 2011 $PM_{2.5}$ design values which did not meet the nominal data completeness requirements, the EPA found that collocated PM_{10} test was almost entirely redundant and infrequently utilized after use of the maximum quarterly value test. For the annual $PM_{2.5}$ NAAQS, the maximum quarter value test in 100 cases resulted in a test design value (TDV_{max}) less than or equal to 12.0 $\mu g/m^3$. There were only two additional cases (i.e., 2 percent) when TDV_{max} was greater than 12.0 $\mu g/m^3$ but the TDV associated with the collocated PM_{10} test was less than 12.0 $\mu g/m^3$. Similarly for the 24-hour NAAQS, the maximum quarter value test in 116 cases resulted in a test design value (TDV_{max}) less than or equal to 35 $\mu g/m^3$ and again only 2 additional sites (less than 2 percent) passed the collocated PM_{10} test but not the maximum quarterly value test. Furthermore, the maximum quarterly value tests allowed the annual and 24-hour design value to be validated approximately 5 times more often than through the use of the collocated PM_{10} test. Accordingly, the EPA has decided to not include the collocated PM_{10} data substitution tests in appendix N, and thereby further simplify the data handling procedures for making comparisons to the annual and 24-hour $PM_{2.5}$ NAAQS. Furthermore, the two tests that are now codified in the revised appendix N (the retained minimum quarterly value test and the added maximum quarterly value test) are consistent with the data substitution tests recently codified for lead, SO_2, and NO_2.

(2) *Comment*: Some commenters questioned the general philosophy of all appendix N data substitution tests (i.e., the existing “minimum quarterly value” test and the two proposed tests) and suggested that there were more appropriate techniques for filling in for missing data that would result in better estimates of true design value levels. Their suggestions included the use of collocated $PM_{2.5}$ concentrations produced by non-reference or non-equivalent monitors and use of data provided by nearby monitors.

Response: While acknowledging that other techniques to account for missing data may exist, the EPA believes that the data substitution tests provided in the finalized appendix N are all appropriate for this purpose, simple to understand and implement, and have been tested over time as the standard operating procedures for making NAAQS compliance assessments. The EPA is finalizing very conservative approaches to data substitution consistent with the intended purpose of verifying that the NAAQS standards are either met or not met. Finally, the EPA points out that the test design values derived from the data substitution tests are diagnostic in nature; that is; they are only used in an illustrative manner to show that the NAAQS status based on incomplete data is reasonable. The test design values are not used as the best estimators of the design value concentrations (i.e., not used as quantitative replacements for actual design values).[35] While the EPA does not agree with the commenter that information from nearby monitors or other sources of information would be appropriate for making comparisons with the NAAQS, the use of supplemental information can be used for other purposes, such as to assist with the implementation of the NAAQS.

4. Seasonal sampling special 98th percentile concentration identification procedure

As stated in section VII.A.4 of the preamble of the final rule, “With regard to identifying annual 98th percentile concentrations for comparison to the primary and secondary 24-hour $PM_{2.5}$ standards, the EPA suggested in the proposal to simplify the procedures used with an approved seasonal sampling schedule. Specifically, the EPA proposed to eliminate the use of a special formula for calculating annual 98th percentile concentrations with a seasonal sampling schedule and thereby proposed to use only one method for calculating annual 98th percentile concentrations for all sites (77 FR 39002).”

The proposal explained that with an approved seasonal sampling schedule, a site is typically required to sample during periods of the year when the highest concentrations are expected to occur, but less frequently during periods of the year when lower concentrations are expected to occur (77 FR 39002). This type of sampling schedule generally leads to an unbalanced data record; that is, a data record with proportionally more ambient measurements (with respect to the total number of days in the sampling period) in the “high” season and proportionally fewer ambient measurements in the “low” season.

In the proposal, the EPA noted that there were, at that time, very few $PM_{2.5}$ FRM monitors that actually operated on an approved seasonal sampling schedule (only 15 sites out of

[35] Appendix N states that when the data substitution tests are satisfied, then the NAAQS design values derived from reported $PM_{2.5}$ data which otherwise would be considered to be incomplete shall be considered valid for comparisons to the $PM_{2.5}$ NAAQS.

approximately 1,000 total sites in 2010) and that almost half of those sites had a collocated $PM_{2.5}$ FEM monitor (77 FR 39002). The proposal stated that for the 3-year period 2008 to 2010, the annual 98th percentile concentrations calculated with the special formula at those 15 sites were approximately five percent lower than if the regular procedure was used. Updating these results to 2009 to 2011, the EPA shows that among 919 sites there were only 12 (1.3 percent) that still operated on an approved seasonal sampling schedule as of the end of 2011; five of the 12 seasonal sampling sites had a collocated continuous FEM monitor; and for the 12 sites, the 2011 annual 98th percentile concentrations calculated with the seasonal sampling formula were 1.7 $\mu g/m^3$ (4.5 percent) lower on average than if the standard data handling procedures were used. The corresponding median values were 0.1 $\mu g/m^3$ (0.8 percent) lower. Both statistics show that the change in design values using the seasonal sampling formula was very small (Schmidt, 2012c).

The EPA only received a few substantive comments on the Agency's proposed elimination of the special "seasonal sampling" 98th percentile concentration identification procedure. All commenters voiced some measure of support for the elimination of the special formula. No commenter explicitly opposed the elimination of the formula, however, one commenter suggested that the EPA compare results from the special formula (for the sites that currently use it) to corresponding results from the "regular" formula to understand the extent, if any, the new method introduces bias in the $PM_{2.5}$ design value.

(1) *Comment*: The EPA should compare the seasonal formula with the simplified "regular" formula to understand the extent, if any, to which the new method introduces bias in the $PM_{2.5}$ design value at those sites that are currently using it.

Response: In section VII.A.4 of the preamble to the final rule, the EPA presents the potential bias between the 'regular approach' and the 'special formula' for use with a seasonal sampling schedule for estimating calculating annual 98th percentile concentrations for the primary 24-hour $PM_{2.5}$ standard for the 12 sites that operated an approved seasonal sampling schedule in 2011. For these locations, the annual 98th percentile concentrations in 2011 calculated with the special formula were 1.9 $\mu g/m^3$ (5.3 percent) lower on average than if the regular procedure was used; the 2009 to 2011 design values were 1.8 $\mu g/m^3$ (5.4 percent) lower on average than if the regular procedure was used. Moreover, there are no instances in the 2009 to 2011 timeframe (i.e., 0 out of 12 monitoring sites) in which the seasonal-formula 24-hour design value meets the NAAQS but the corresponding regular-formula design value does not meet the NAAQS

E. Specific Comments Related to the AQI for $PM_{2.5}$

The final rule for PM revises 40 CFR 58.50 Index Reporting, and Appendix G to 40 CFR 58.50, with respect to specifying population of a metropolitan statistical area for purposes of index reporting, and specific breakpoints for the AQI sub-index for $PM_{2.5}$. Incorporating responses contained in section V of the preamble to the final rule, the EPA provides the following responses to specific comments related to the AQI sub-index for $PM_{2.5}$.

(1) *Comment:* With respect to an AQI value of 100, which is the basis for advisories to individuals in sensitive groups, in the proposal the EPA described two general approaches that could be used to select the associated $PM_{2.5}$ level. By far the most

common approach, which has been used with all of the other sub-indices, is to set an AQI value of 100 at the same level as the short-term standard. In the proposal, the EPA recognized that some state and local air quality agencies have expressed a strong preference that the Agency set an AQI value of 100 equal to any short-term standard (77 FR 38964). These agencies typically expressed the view that this linkage is useful for the purpose of communicating with the public about the standard, as well as providing consistent messages about the health impacts associated with daily air quality. The EPA proposed to use this approach to set the AQI value of 100 at 35 μg/m^3, 24-hour average, consistent with the proposed decision to retain the current 24-hour $PM_{2.5}$ standard (*Id.*).

An alternative approach discussed in the proposal (77 FR 38964), was to directly evaluate the health effects evidence to select the level for an AQI value of 100. This was the approach used in the 1999 rulemaking to set the AQI value of 100 at a level of 40 μg/m^3, 24-hour average, when the 24-hour standard level was 65 μg/m^3. This alternative approach was used in the case of the $PM_{2.5}$ sub-index, because the annual and 24-hour $PM_{2.5}$ standards set in 1997 were designed to work together, and the intended degree of health protection against short-term risks was not defined by the 24-hour standard alone, but rather by the combination of the two standards working in concert. Indeed, at that time, the 24-hour standard was set to provide supplemental protection relative to the principal protection provided by the annual standard. In the proposal, the EPA solicited comment on this alternative approach in recognition that, as proposed, the 24-hour $PM_{2.5}$ standard is intended to continue to provide supplemental protection against effects associated with short-term exposures of $PM_{2.5}$ by working in conjunction with the annual standard to reduce 24-hour exposures to $PM_{2.5}$. The EPA recognized that in the past, some state and local air quality agencies have expressed support for this alternative approach. Using this alternative approach could have resulted in consideration of a lower level for an AQI value of 100, based on the discussion of the health information pertaining to the level of the 24-hour standard in section III.E.4 of the proposal. The EPA encouraged state and local air quality agencies to comment on both the approach and the level at which to set an AQI value of 100 together with any supporting rationale.

Of the state or local agencies, or their organizations (e.g., NACAA), that commented on the proposed changes to the AQI, only one organization, NESCAUM, expressed some support for this approach. In its comments, NESCAUM expressed support for a 24-hour standard set at 30 μg/m^3, 24 hour average. NESCAUM also expressed the view that EPA should carefully consider how to set the breakpoint for an AQI value of 100. NESCAUM expressed the view that if the EPA were to keep the 24-hour $PM_{2.5}$ standard at 35 ug/m^3, the annual standard would be controlling, and a 24-hour breakpoint at that level (35 ug/m^3) would not be very effective for the purposes of public health messaging. However, other agencies, such as the Georgia DNR and Indiana DEM, expressed the view that linkage between the short-term standard and the AQI of 100 is useful for the purpose of communicating with the public about the standard as well as providing consistent messages about the health impacts associated with the daily air quality.

A comment signed by five physicians (Sammons et al., 2012, p.2) expressed the view that based on the body of evidence of morbidity effects, if the current 24-hour standard is retained, then the calculation of the AQI should be adjusted so that AQI value of 100 occurs at a $PM_{2.5}$ concentration less than or equal to 30 µg/m^3.

Response: Based on these comments, the EPA sees no basis for deviating from the approach it proposed. Thus, as discussed in section V of the preamble to the final rule, the EPA is taking final action to set an AQI value of 100 at 35 µg/m^3, 24-hour average, consistent with the final decision on the 24-hour $PM_{2.5}$ standard level as summarized in section III.F of the preamble to the final rule.

(2) *Comment:* One set of commenters (e.g., API and UARG), expressed the view that changes to the AQI are not appropriate (API, 2012, pp. 45 to 46; UARG, 2012, pp. 42 to 43). They noted that air quality is getting better, and in fact is better than when EPA established the AQI. These commenters stated that the proposed changes to the annual standard and the AQI would mean that the public would hear less often that air quality is good, and thereby would receive apparently inconsistent or misleading messages that air quality is worse.

Response: The AQI has been revised several times in conjunction with revisions to the standards. State and local air quality agencies and organizations are proficient at communicating with the public about the reasons for changes to the AQI. Therefore, the EPA strongly disagrees with these commenters that the public will receive inconsistent or misleading messages. Recognizing the importance of the AQI as a communication tool that allows the public to take exposure reduction measures when air quality may pose health risks, the EPA agrees with state and local air quality agencies and organizations that favored revising the AQI at the same time as the primary standard. Indeed, failure to conform the AQI to the NAAQS could be a derogation of EPA's duty to utilize "a uniform air quality index" to communicate information to the public, and to "provid[e] for … reporting of air quality based upon such uniform air quality index". CAA section 319 (a)(1) and (3).

(3) *Comment*: A few state and local air quality agencies and organizations (e.g., Pennsylvania DEP, South Coast AQMD, and NACAA) recommended against using near-roadway $PM_{2.5}$ monitors for AQI reporting. In support of this comment, they expressed the following views: (1) that near-roadway monitors are source-oriented; (2) that near-roadway monitors represent micro-scale conditions; and (3) the agencies do not have experience using such monitors for AQI reporting. Additionally, one state agency, the New York DEC/DOH, commented that such reporting may be possible in the future with experience.

Response: The EPA disagrees with these comments. These monitors will be located at existing near-road stations that have been sited in locations that meet the EPA's definition of ambient air and also comply with applicable 40 CFR part 58 monitoring requirements for operating networks to meet multiple objectives including providing air quality data to the public in a timely manner. As discussed in section VIII.B.3.b.i of the preamble to the final rule, the EPA believes that these monitors will be representative of area-wide $PM_{2.5}$ concentrations indicative of many such locations throughout a metropolitan area given the ubiquitous nature of roadway emissions in major urban areas.

Although the stations may be representative of somewhat elevated concentrations, they are appropriate for characterizing exposure in typical portions of major urban areas as they provide information about $PM_{2.5}$ concentrations in areas where millions of people work, live and go to school. Accordingly, the EPA believes that such data from these near-road monitors are appropriate to use for reporting daily air quality information to the public through the AQI. The EPA is committed to helping air agencies develop appropriate ways to make use of the $PM_{2.5}$ measurements from these near-roadway monitors for AQI reporting purposes.

III. RESPONSES TO SIGNIFICANT COMMENTS ON PRIMARY PM_{10} STANDARD

Section IV.F of the preamble to the final rule discusses a number of significant public comments on the primary PM_{10} standard. This section incorporates that discussion from the preamble, as well as discussion of additional public comments on the primary PM_{10} standard.

F. Comments from Groups Supporting Retention of the Primary PM_{10} Standard

(1) *Comment:* Although industry commenters generally agreed with the Administrator's proposed decision to retain the current primary PM_{10} standard, some also contended that the current standard is "excessively precautionary" (NMA and NCBA, 2012, p. 4) and a few expressed support for a less stringent standard for coarse particles that are comprised largely of crustal material. For example, the Coarse Particulate Matter Coalition (CPMC) (2012) and several other industry commenters recommended that the final decision allow application of a 98^{th} percentile form for the current standard (i.e. with its level of 150 ug/m^3) in cases where coarse particles consist primarily of crustal material. Such an approach would allow more yearly exceedances of the existing standard level than are allowed with the current one-expected-exceedance form. These industry commenters contended that a 98^{th} percentile form applied in this way would provide appropriate regulatory relief for areas where the evidence for coarse particle-related health effects is relatively uncertain.

Response: In reaching her conclusion that the current primary PM_{10} standard is requisite to protect public health with an adequate margin of safety, the Administrator considered the degree of public health protection provided by the current standard as a whole, including all elements of that standard (i.e., indicator, averaging time, form, level). As discussed above and in the following section, this conclusion reflects the Administrator's judgments that (1) the current standard appropriately provides some measure of protection against exposures to all thoracic coarse particles, regardless of their location, source of origin, or composition and (2) the current standard appropriately allows lower ambient concentrations of $PM_{10-2.5}$ in urban areas, where the evidence is strongest that thoracic coarse particles are linked to mortality and morbidity, and higher concentrations in non-urban areas, where the public health concerns are less certain.

Because the considerations that led to these judgments, and to the conclusion that the current primary PM_{10} standard is requisite to protect public health, took into account the degree of public health protection provided by the standard as a whole, it would not be appropriate to consider revising one element of the standard (e.g., the form, as suggested by commenters in this case) without considering the extent to which the other elements of the standard should also be revised. The change in form requested by industry commenters, without also lowering the level of the standard, would markedly reduce the public health protection provided against exposures to thoracic coarse particles.[36] However, industry commenters have not presented new evidence or analyses to support their conclusion that an appropriate degree of public health protection could be achieved by allowing the use of an alternative form (i.e., 98th percentile) for some coarse particles, while retaining the other elements of the current standard. Nor have these commenters presented new evidence or analyses challenging the basis for the conclusion in the proposal that the varying amounts of coarse particles allowed in urban versus non-urban areas under the current 24-hour PM_{10} standard, based on the varying levels of $PM_{2.5}$ present, appropriately reflect the differences in the strength of evidence regarding coarse particle effects in urban and non-urban areas. In light of this, EPA does not believe that a reduction in public health protection, such as that requested by industry commenters, is warranted.

In further considering these comments, it is to be remembered that epidemiologic studies have not demonstrated that coarse particles of non-urban origin do not cause health effects, and commenters have not provided additional evidence on this point. While there are fewer studies of non-urban coarse particles than of urban coarse particles, several studies have reported positive and statistically significant associations between coarse particles of crustal, non-urban origin and mortality or morbidity (Ostro et al., 2003; Bell et al., 2008; Chan et al., 2008; Middleton et al., 2008; Perez et al., 2008). These studies formed part of the basis for the PM Integrated Science Assessment conclusion that "recent studies have suggested that PM (both $PM_{2.5}$ and $PM_{10\text{-}2.5}$) from crustal, soil or road dust sources or PM tracers linked to these sources are associated with cardiovascular effects" (U.S. EPA, 2009a, p. 2-26). Moreover, crustal coarse particles may be contaminated with toxic trace elements and other components from previously deposited fine PM from ubiquitous sources such as mobile source engine exhaust, as well as by toxic metals from smelters or other industrial activities, animal waste, or pesticides (U.S. EPA, 2004, p. 8-344). In the proposal, the Administrator acknowledged the potential for this type of contamination to increase the toxicity of coarse particles of crustal, non-urban origin (77 FR 38960; see also 71 FR 61190).

In suggesting a change in the form of the current standard, industry commenters also did not address the manifold difficulties noted above, and in the last review, associated with developing an indicator that could reliably identify ambient mixes dominated by particular types of sources of coarse particles. See above and 71 FR 61193. Yet such an

[36] Based on regression analyses presented in the PA (U.S. EPA, 2011a, Figures 3-7 and 3-8), PM_{10} one-expected-exceedance concentration-equivalent design values were between approximately 175 and 300 μg/m^3 at monitoring locations recording 3-year averages of 98th percentile 24-hour PM_{10} concentrations around 150 μg/m^3 (i.e., the level of the current standard). This suggests that, depending on the location, a 24-hour PM_{10} standard with a 98th percentile form in conjunction with the current level (i.e., as recommended by these commenters) could be "generally equivalent" to a 24-hour PM_{10} standard with a one-expected-exceedance form and a level as high as approximately 300 μg/m^3. Based on this analysis, a 24-hour PM_{10} standard with a 98th percentile form and a level of 150 μg/m^3 would be markedly less health protective than the current standard.

indicator would be a prerequisite of the type of standard these commenters request.

For all of the reasons discussed above, the EPA does not agree with industry commenters who recommended allowing the application of a 98th percentile form for the current standard in cases where coarse particles consist primarily of crustal material.

(2) *Comment:* Some industry commenters contended that the uncertainties and limitations that precluded a quantitative risk assessment also preclude revising the PM_{10} standard.

Response: Although the EPA agrees that there are important uncertainties and limitations in the extent to which the quantitative relationships between ambient $PM_{10-2.5}$ and health outcomes can be characterized in risk models, the Agency does not agree that such limitations alone preclude the option of revising a NAAQS. As noted above, the lack of a quantitative $PM_{10-2.5}$ risk assessment in the current review adds uncertainty to conclusions about the extent to which revision of the current PM_{10} standard would be expected to improve the protection of public health, beyond the protection provided by the current standard. However, the EPA does not agree that such uncertainties necessarily preclude revision of a NAAQS. Indeed, with respect to thoracic coarse particles, the D.C. Circuit noted that "[a]lthough the evidence of danger from coarse PM is, as the EPA recognizes, 'inconclusive', the agency need not wait for conclusive findings before regulating a pollutant it reasonably believes may pose a significant risk to public health." 559 F. 3d at 533. Thus, the Administrator's conclusion that the current 24-hour PM_{10} standard provides requisite protection of public health relies on her consideration of the broad body of evidence, rather than solely on the uncertainties that led to the decision not to conduct a quantitative assessment of $PM_{10-2.5}$ health risks.

(3) *Comment:* Some industry commenters argued that the EPA did not adequately consider exposure measurement error, which they asserted is an important source of bias in epidemiological studies that can bias effect estimates in either direction (e.g., NMA and NCBA, 2012).

The EPA has recognized that exposure measurement error is an important source of uncertainty, and that the variability in risk estimates observed in multi-city studies could be attributed, in part, to exposure error due to measurement-related issues (77 FR 38910). However, the Agency disagrees with the commenters' assertion that exposure measurement error was not adequately considered in this review. The Integrated Science Assessment included an extensive discussion that addresses issues of exposure measurement error (U.S. EPA, 2009a, sections 2.3.2 and 3.8.6). Exposure measurement error may lead to bias in effect estimates in epidemiological studies. A number of studies evaluated in the last review (U.S. EPA, 2004, section 8.4.5) and in the current review (U.S. EPA, 2009a, section 3.8.6) have discussed the direction and magnitude of bias resulting from specified patterns of exposure measurement error (Armstrong 1998; Thomas et al. 1993; Carroll et al. 1995) and have generally concluded "classical" (i.e., random, within-person) exposure measurement error can bias effect estimates towards the null. Therefore, consistent with conclusions reached in the last review, the Integrated Science Assessment concluded "in most circumstances, exposure error tends to bias a health effect estimate downward" (U.S. EPA, 2009a, sections 2.3.2 and 3.8.6). Thus, the

EPA has both considered and accounted for the possibility of exposure measurement error, and the possible bias would make it more difficult to detect true associations, not less difficult.

(4) *Comment:* The CPMC (2012) commented that EPA should retain the current PM_{10} standard. In support of their comments, the CPMC submitted analyses of PM_{10} air quality characterizing the potential implications of a revised PM_{10} standard. Many of these analyses were originally submitted to EPA in July 2011. The CPMC analyses were also cited by other industry commenters (e.g., NMA and NCBA, 2012) who supported the proposed decision to retain the current PM_{10} standard.

Response: As discussed above and in the preamble, the Administrator's decision to retain the current PM_{10} standard is consistent with the overall position expressed by the CPMC and by other industry groups. However, the EPA does not agree with all aspects of the analyses supporting this CPMC position. The EPA has previously responded to these analyses in a letter to the CPMC (Wayland, 2011).

G. Comments from Groups Supporting Revision of the Primary PM_{10} Standard

(1) *Comment:* Commenters representing a number of environmental groups and medical organizations disagreed with the Administrator's proposal to retain the current primary PM_{10} standard. These commenters generally requested that the EPA revise the PM_{10} standard to increase public health protection, consistent with the recommendations from CASAC.

Response: As discussed above and in the proposal, in reaching provisional conclusions in the proposal regarding the current standard, the Administrator carefully considered CASAC's advice and recommendations. She specifically noted that in making its recommendation on the current PM_{10} standard, CASAC did not discuss its approach to considering the important uncertainties and limitations in the health evidence, and did not discuss how these uncertainties and limitations were reflected in its recommendations. Such uncertainties and limitations contributed to the conclusions in the Integrated Science Assessment that the $PM_{10-2.5}$ evidence is only suggestive of a causal relationship, a conclusion that CASAC endorsed (Samet, 2009e,f). These commenters also did not address the important uncertainties in the epidemiologic studies on which their comments are based. Given the importance of these uncertainties and limitations to the interpretation of the evidence, as reflected in the weight of evidence conclusions in the Integrated Science Assessment and as discussed in the proposal, the Administrator judges that it is appropriate to consider and account for them when drawing conclusions about the implications of individual $PM_{10-2.5}$ health studies for the current standard. Commenters have not provided new information that would change the Administrator's views on the evidence and uncertainties.

(2) *Comment:* In recommending that the PM_{10} standard be revised, some commenters supported their conclusions by referencing studies that evaluated PM_{10}, rather than $PM_{10-2.5}$. These commenters contended that "[t]he most relevant studies to the setting of a PM_{10} standard are the thousands of studies that have reported adverse effects associated with PM_{10} pollution" (ALA et al., 2012).

Response: As discussed in the Policy Assessment, the proposal, and the preamble to the final rule, since the establishment of the primary $PM_{2.5}$ standards, the purpose of the primary PM_{10} standard has been to protect against health effects associated with exposures to $PM_{10-2.5}$. PM_{10} is the indicator, not the target pollutant. With regard to the appropriateness of considering PM_{10} health studies for the purpose of reaching conclusions on a standard meant to protect against exposures to $PM_{10-2.5}$, the proposal noted that PM_{10} includes both fine and coarse particles, even in locations with the highest concentrations of $PM_{10-2.5}$. Therefore, the extent to which PM_{10} effect estimates reflect associations with $PM_{10-2.5}$ versus $PM_{2.5}$ can be highly uncertain and it is often unclear how PM_{10} health studies should be interpreted when considering a standard meant to protect against exposures to $PM_{10-2.5}$. Given this uncertainty and the availability of a number of $PM_{10-2.5}$ health studies in this review, the Integrated Science Assessment considered $PM_{10-2.5}$ studies, but not PM_{10} studies, when drawing weight-of-evidence conclusions regarding the coarse fraction.[37] In light of the uncertainty in ascribing PM_{10}-related health effects to the coarse or fine fractions, indicating that the best evidence for effects associated with exposures to $PM_{10-2.5}$ comes from studies evaluating $PM_{10-2.5}$ itself, and given CASAC's support for the approach adopted in the Integrated Science Assessment, which draws weight-of-evidence conclusions for $PM_{2.5}$ and $PM_{10-2.5}$ but not for PM_{10} (Samet, 2009f), the EPA continues to conclude that it is appropriate to focus on $PM_{10-2.5}$ health studies when considering the degree of public health protection provided by the current primary PM_{10} standard, a standard intended exclusively to provide protection against exposures to $PM_{10-2.5}$.

(3) *Comment:* Two State commenters (New York DOH/DEC, 2012) expressed the view that the PM_{10} standard should be tightened if the level of the $PM_{2.5}$ standard is tightened. These commenters contended that "In order to maintain adequate protection against exposure to coarse particles in urban settings, the PM_{10} standard would need to be lowered to ensure that coarse particle levels do not rise as $PM_{2.5}$ levels decline."

Response: While it is possible that the relationships between $PM_{2.5}$ and $PM_{10-2.5}$ concentrations and/or composition will change in some locations in the future, it is not possible at this time to precisely predict the nature of such potential future changes, or to account for them in the standard. For example, changes in ambient $PM_{2.5}$ concentrations could alter not only the allowable coarse particle concentrations under the PM_{10} standard in some locations, but also the extent to which thoracic coarse particles are contaminated with specific fine particle components (section IV.G of final rule). Alterations in coarse particle composition could impact the toxicity of ambient thoracic coarse particles, potentially altering the health effects that result following coarse particle exposures and/or altering the coarse particle exposure concentrations resulting in such health

[37] Although EPA relied in the 1997 review on evidence from PM_{10} studies, EPA did so out of necessity (i.e., there were as yet no reliable studies measuring $PM_{10-2.5}$). In the 2006 review, EPA placed primary reliance on epidemiologic studies measuring or estimating $PM_{10-2.5}$, although there were comparatively few such studies. In this review, a larger body of $PM_{10-2.5}$ studies are available. EPA regards these studies as the evidence to be given principal weight in reviewing the adequacy of the PM_{10} standard.

effects. Based on the available health evidence, it is unclear the extent to which such future potential changes in PM concentrations and/or composition could support revisions to the PM NAAQS.

Future scientific studies will evaluate $PM_{10-2.5}$ health effects as fine particle concentrations and/or coarse particle composition change. The issue of whether the existing PM_{10} standard remains requisite to protect public health with an adequate margin of safety will need to be revisited in future reviews of the PM NAAQS, in light of new evidence and air quality information reflecting any future changes in particle concentrations and/or composition.

(4) *Comment:* Some environmental and public health groups disagreed with the weight-of-evidence conclusions for coarse particles. Specifically, the ALA et al. (2012) contended that "EPA should re-evaluate this conclusion and consider separately a classification of PM_{10} effects on mortality as likely causal, in light of evidence."

Response: As discussed in the preamble to the final rule (section IV.F), the EPA disagrees with these commenters regarding the extent to which it is appropriate to rely on PM_{10} studies when considering a standard meant to protect the public health against exposures to $PM_{10-2.5}$. In addition, the EPA disagrees that it is appropriate to draw separate weight-of-evidence conclusions for PM_{10}. When this issue was presented to CASAC during the development of the Integrated Science Assessment, they made the following recommendation (Samet, 2009e, p. 3):

> Revisions are needed to remove the impression that PM_{10} is a separate pollutant from $PM_{2.5}$ and $PM_{10-2.5}$. The [draft] ISA handles PM_{10}, $PM_{2.5}$, and $PM_{10-2.5}$, as if they were separate entities, even though the latter two are components of PM_{10}. The CASAC cautions against this approach and notes that PM_{10} is a mixture that contains varying proportions of particles in the smaller and larger size ranges.

In light of this advice, the final Integrated Science Assessment did not draw separate weight-of-evidence conclusions for PM_{10}. Public commenters have not presented new information that would justify going against CASAC's recommendation on this issue.

(5) *Comment:* Environmental and public health groups also commented on the appropriateness of setting standards based on evidence that has been judged to be "suggestive of a causal relationship," as is the case for $PM_{10-2.5}$. Specifically, the ALA et al. (ALA et al., 2012) stated that "EPA must set standards that protect against effects that are deemed suggestive by the evidence."

Response: The EPA agrees with these commenters that the available evidence supports the appropriateness of setting a standard to protect public health against exposures to all thoracic coarse particles. However, although the commenters are correct that EPA may establish standards to guard against threats which are uncertain, or even which research has not yet identified, it is also the case that EPA may evaluate the strength of the evidence, and a standard may legitimately be more or less stringent in order to reflect the strength of that evidence.

Therefore, in deciding whether it is appropriate to revise the PM_{10} standard, it is reasonable for EPA to account for the uncertainties inherent in the evidence, which underlie the determination that the evidence is "suggestive of a causal relationship." As discussed extensively in the preamble to the final rule (section IV.G), the Administrator concludes that the current PM_{10} standard is requisite to protect public health with an adequate margin of safety against effects associated with exposures to thoracic coarse particles.

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IV. RESPONSES TO SIGNIFICANT COMMENTS ON SECONDARY PM STANDARDS

A. General Comments on Proposed Secondary PM Standards

A number of comments on the proposed secondary standards for PM were general in nature, basically expressing one of three views: (1) support for setting a distinct secondary standard to protect from visibility impairment; (2) opposition to setting a distinct secondary standard to protect from visibility impairment; or (3) support for revising the secondary standards to be equivalent in all respects to the proposed primary standards, including the revised primary annual standard. Many of these commenters simply expressed their views without stating any rationale, while others gave general reasons for their views but without reference to the factual evidence or rationale presented in the proposal notice as a basis for the Agency's proposed decision. In general, the large majority of comments focused on the proposal to set a distinct standard to protect against visibility impairment. Relatively few commenters addressed the proposal to retain the existing secondary standards for non-visibility welfare effects.

The preamble to the final rule presents the Agency's full response to these views, expressly identifying: (1) the strengths and limitations of the scientific evidence regarding PM-related visibility impairment; (2) the need for and appropriateness of a secondary standard to protect from visibility impairment; (3) the appropriate indicator, averaging time, form and level for a standard designed to protect against PM-related visibility impairment; (4) the scientific evidence regarding non-visibility welfare effects and the appropriate standards to protect against those effects; and 5) the advice of CASAC regarding the secondary standard for PM. See sections VI.A, VI.B, and VI.C of the preamble to the final rule for a discussion of these topics.

B. Specific Comments on Proposed Secondary PM Standard to Protect Visibility

A large number of commenters provided more detailed comments regarding the proposal to set a distinct secondary standard for protection from visibility impairment. Many of these comments addressed specific elements of the proposed distinct secondary $PM_{2.5}$ standard, including indicator, averaging time, form, and level. Other comments focused on the strength of currently available evidence—particularly the visibility preference studies—as a basis for setting a distinct secondary standard. In addition, some commenters questioned whether a distinct secondary standard was needed in light of the protection already afforded by the existing secondary standards for PM, while others raised legal issues or other challenges, such as issues related to the Regional Haze Program, data handling, or monitoring. Responses to key issues raised on these topics are generally summarized in section VI.C.1 of the preamble. Below, the EPA provides more detailed responses to the full range of significant issues raised in these comments.

It is important to note that because the Administrator's final decision regarding the secondary PM standards differs from what was proposed, a number of issues raised by commenters are now moot. Specifically, since the Administrator is retaining the current suite of secondary PM standards generally, while revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard, and is not establishing a distinct secondary standard for protection from visibility impairment, concerns expressed by commenters about various aspects of the proposal, such as the overlap with the Regional Haze Program, the data handling requirements, and monitoring requirements, are no longer pertinent. Though the EPA has summarized many of these issues below, it does not respond to them in detail since they pertained to specific aspects of the proposal that were not adopted in the final rule.

1. Indicator

In the current review of the secondary $PM_{2.5}$ standards, the EPA considered what type of indicator it would be appropriate to adopt for a distinct secondary standard designed to protect from visibility impairment. While agreeing with CASAC that a directly measured PM light extinction indicator would provide the most direct link between PM in the ambient air and PM-related light extinction, the Administrator concluded this was not an appropriate option in this review due to technical limitations, and instead proposed to adopt a new calculated $PM_{2.5}$ light extinction indicator, similar to that used in the Regional Haze Program (i.e., using an IMPROVE algorithm as translated into the deciview scale). This kind of indicator, referred to as a $PM_{2.5}$ visibility index, would directly incorporate the effects of differences in $PM_{2.5}$ composition and relative humidity on visibility.

A large number of public comments on the secondary PM standards addressed the suitability of utilizing a calculated light extinction indicator for the distinct secondary standard as proposed. Some commenters supported the proposal to adopt a calculated light extinction indicator, while others advocated relying on direct measurements instead. Commenters from both groups expressed concern over specific elements of the proposed calculated $PM_{2.5}$ visibility index. In particular, commenters expressed differing views on which IMPROVE algorithm should be utilized; whether it is appropriate to exclude coarse particles from the indicator; and whether the proposed protocols for incorporating data on relative humidity and $PM_{2.5}$ species are appropriate. In addition, some commenters expressed concern about the omission of other contributors to visibility impairment from the visibility index. The EPA has addressed these comments in section VI.C.1.b of the proposal, and provides additional details in response to specific issues, below.

a. Comments Supporting Directly Measured Light Extinction Indicator

(1) *Comment:* The majority of commenters noted the uncertainties associated with relying on a calculated indicator and argued that it was inappropriate to rely on a calculated light extinction indicator rather than direct measurements. A number of these commenters advocated postponing setting a distinct secondary standard until an approach based on direct light extinction measurements can be adopted.

Response: The EPA generally agrees with commenters that an indicator based on directly measured light extinction would provide the most direct link between PM in the ambient air and PM-related light extinction. However, as noted at the time of proposal and in accordance with the advice of CASAC, the EPA has concluded that this is not an appropriate option in this review because a suitable specification of currently available equipment or performance-based verification procedures could not be developed in the time frame of this review.

In evaluating whether direct measurement of light extinction was appropriate to consider in the context of this PM review, the EPA produced a White Paper on Particulate Matter (PM) Light Extinction Measurements (U.S. EPA, 2010g) 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, 2010a), the CASAC AAMMS 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 CASAC AAMMS advised against choosing any currently available commercial instrument as the basis for an FRM, or even selecting a general measurement approach as an FRM, because to do so could discourage development of other potentially superior approaches. Instead, the CASAC 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, both in the laboratory and during field tests. At the present time of this review, the EPA has not undertaken to develop and test such performance-based 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 proposed regulatory use as an FRM.

Since the available evidence demonstrates that a strong correspondence exists between calculated $PM_{2.5}$ light extinction and PM-related visibility impairment, the EPA does not believe it would be appropriate to postpone setting a distinct secondary standard until an approach based on direct light extinction measurements could be adopted. Furthermore, the EPA notes CASAC's conclusion that the proposed calculated $PM_{2.5}$ light extinction indicator based on the original IMPROVE algorithm "appears to be a reasonable approach for estimating hourly light extinction" (Samet, 2010d, p. 11) and "its 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).

(2) *Comment:* Some commenters argued that the proposed calculated light extinction indictor is ill suited for a bright line standard because the method uses average humidity and a reconstructed visibility measurement calculated from $PM_{2.5}$ speciation filter analysis, rather than measuring what is actually observed by individuals.

Response: The available evidence demonstrates that a strong correspondence exists between calculated $PM_{2.5}$ light extinction and PM-related visibility impairment. Thus, the EPA concludes that in the absence of reliable direct measurements of visibility impairment in urban areas, it is appropriate to rely on a calculated light-extinction indicator. The EPA notes that CASAC concluded that relying on a calculated $PM_{2.5}$ light extinction indicator based on $PM_{2.5}$ chemical speciation and relative humidity data represented a reasonable approach. The inputs that are necessary include measurements that are available through existing monitoring networks and established protocols.

(3) *Comment:* Many commenters stated that relying on direct light extinction measurements would enable a standard to be based on a shorter averaging time, either 1-hour or sub-

daily (4 to 6 hours), consistent with the more instantaneous nature of perceptions of visual air quality and the advice of CASAC in this review.

Response: The EPA agrees with commenters that there would be 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. 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. However, as noted above, the EPA has concluded, in accordance with the advice of CASAC, that direct measurement is not an appropriate option in this review because a suitable specification of currently available equipment or performance-based verification procedures could not be developed in the time frame of this review. Furthermore, the available evidence demonstrates that a strong correspondence exists between calculated $PM_{2.5}$ light extinction and PM-related visibility impairment. Thus, the EPA concludes that in the absence of reliable direct measurements of visibility impairment in urban areas, it is appropriate to rely on a calculated light-extinction indicator.

(4) *Comment:* Numerous commenters supported developing a pilot study to field test and evaluate direct measurement instrumentation in several areas around the country, as recommended by CASAC AAMMS. These commenters recommended collocating pilot direct measurement instruments with other existing monitors and cameras such as CAMNET, the National Weather Service's Automated Surface Observing System monitors, and continuous $PM_{2.5}$ and filter-based $PM_{2.5}$ speciation monitors. Such a pilot field-study program using candidate instruments would allow for near real-time measurements of light extinction and would enable comparisons between existing monitors and alternative approaches.

Response: The EPA agrees with these commenters that, resources permitting, it would be useful to establish such a pilot program to inform future reviews of the PM NAAQS. However, in the current review, the Agency continues to agree with CASAC that relying on a calculated $PM_{2.5}$ light extinction indicator based on $PM_{2.5}$ chemical speciation and relative humidity data represents a reasonable approach at this time. The inputs that are necessary include measurements that are available through existing monitoring networks and established protocols.

b. Comments Supporting Calculated Light Extinction Indicator

(1) *Comment:* Recognizing the limitations on applying direct measurements at present, commenters supporting the proposal to set a distinct standard argued that relying on "calculated light extinction is a reasonable first approach" (DOI, p. 2). These commenters pointed to the advice of CASAC, which had acknowledged that it was not possible for the EPA to develop an FRM for direct measurement of light extinction within the time frame of this review and had concluded that relying on a calculated $PM_{2.5}$ light extinction indicator represented a reasonable approach that could be implemented sooner than a directly measured indicator. These commenters generally supported the proposal to adopt a calculated $PM_{2.5}$ light extinction indicator, at least as an interim approach.

Response: The EPA agrees with commenters who stated that relying on calculated $PM_{2.5}$ light extinction would be a reasonable approach at this time. The EPA notes that this conclusion is consistent with the advice of CASAC, which advised the EPA not to choose any currently available commercial instrument, or even a general measurement approach for direct light extinction measurement at this time because to do so could discourage development of other potentially superior approaches. Given the limitations in current direct measurement options, the EPA continues to conclude that it is appropriate to rely on a calculated $PM_{2.5}$ light extinction approach for purposes of a $PM_{2.5}$ visibility index at this time.

c. Comments on Specific Aspects of Calculated Light Extinction Indicator

(1) *Comment:* A number of commenters expressed concern over the proposal to use the original IMPROVE algorithm as the basis for the calculated light extinction indicator. These commenters noted that the original IMPROVE algorithm has been shown to have consistent biases at both low and high levels of light extinction. In particular, these commenters expressed concern with the algorithm's bias at higher levels of light extinction, which they pointed out were the conditions that might be encountered on hazier days in urban areas. In general, these commenters endorsed using the revised IMPROVE algorithm as a basis for a calculated light extinction indicator.

Response: The EPA agrees that the revised algorithm was developed to correct known biases in the estimated extinction in remote areas under the original IMPROVE algorithm under very low and very high light extinction conditions, with further modifications and additions to better account for differences in particle composition and aging in remote areas. However, the EPA does not believe that these same modifications and additions would necessarily be appropriate for calculating light extinction in urban areas. In general, the EPA considers the original algorithm to be suitable for purposes of calculating urban light-extinction, although the Agency believes some adjustments to this algorithm may be appropriate for urban environments, as discussed in the preamble to the final rule.

There are several reasons why the EPA considers the original IMPROVE algorithm better suited to urban environments than the revised algorithm. First, the EPA considers that the multiplier of 1.8 used to convert OC to OM in the revised IMPROVE algorithm is too high for urban environments. This is discussed further in response to specific comments on the OC multiplier, below. Second, the EPA does not believe that it would be appropriate to include a term for hygroscopic sea salt for urban light extinction. Unlike in some remote coastal locations, sea salt is not major contributor to light extinction in urban areas. Pitchford (2010) estimated that in most instances, the contribution of sea salt to $PM_{2.5}$ light extinction is well below 5% for $PM_{2.5}$ light extinction greater than 24 dv. Moreover, urban sources of salt include sanding of roads during the winter and those re-entrained particles are mostly in the coarse size range.

Third, the EPA does not consider the revised algorithm's differentiation between different size modes of sulfate, nitrate, and organic mass appropriate for urban areas. Like in remote areas, small and large size modes of sulfate, nitrate and organic mass would exist in the urban environment. However, the apportionment of the total fine particle concentration of each of the three $PM_{2.5}$ components into the concentrations of the small and large size fractions in urban areas would likely need a different approach than that used for remote areas. This is because of the closer proximity of urban sources to their emissions. This is a particular concern not only for organic mass, which as explained previously has a large contribution from nearby urban emission sources, but also for $PM_{2.5}$ nitrate whose concentrations are also higher in urban areas compared to the surrounding regions. Thus, a higher portion of the total urban concentration may be in the small mode compared to remote areas and thus a different apportionment algorithm would be needed.

Finally, the EPA does not consider it necessary to employ site-specific Rayleigh light scattering terms in place of a universal Rayleigh light scattering value for purposes of calculating light extinction in urban areas for purposes of calculating the 90th percentile values. The site-specific Rayleigh value is most important to accurately estimate extinction in remote areas, particularly for the average of the 20% best visibility days, an essential metric for the regional haze program. In most other instances, the Raleigh light scattering term has relatively little impact. For example, Pitchford (2010) estimated that the difference between the approach employed by the EPA in the UFVA and Policy Assessment to define the 20 to 30 dv range of candidate protection levels and an approach utilizing site-specific Rayleigh light scattering terms was less than 0.1 dv for light extinction around 30 dv.

For all of these reasons, the EPA considers the original IMPROVE algorithm better suited to the task of calculating urban light extinction than the revised IMPROVE algorithm. However, the EPA does consider it appropriate to make certain adjustments to the original algorithm for purposes of calculating urban light extinction. As discussed below, the EPA believes it is appropriate to use a 1.6 multiplier to convert OC to OM in urban areas, and to exclude the term for coarse particles from the IMPROVE equation.

(2) *Comment:* Some commenters supported use of the revised IMPROVE algorithm. These commenters noted that the revised equation has been through a peer review which confirmed that it is based on the best science and corrects the biases inherent in the original algorithm. Commenters also noted that this revised algorithm has been widely incorporated into Regional Haze plans, and urged the EPA to use this same equation in the visibility index for the sake of consistency: "EPA approved this approach for regional haze and does not dispute its greater accuracy. Therefore, a national secondary ambient air quality standard based on criteria that accurately reflect the latest scientific knowledge logically should not revert to the original IMPROVE algorithm" (Oklahoma DEQ, p. 2). Other states agreed, arguing that "Utilizing alternate forms of the equation will lead to inconsistency in how agencies and regulated sources evaluate visibility impacts and add an additional layer to source, SIP, and Regional Haze analysis" (Arizona DEQ, p. 3). These states urged the EPA to adopt the revised improve algorithm to maintain consistency between programs.

Response: The EPA agrees with commenters that the revised algorithm represents the best science for estimating visibility impairment from aerosol components in remote areas. The EPA does not agree that this approach is necessarily a better approach for estimating visibility impairment in urban areas. Considering the nature of urban PM composition, EPA concludes that it is appropriate to use the original IMPROVE algorithm (with the adjustments discussed in response to the previous comment, above) to relate urban PM to light extinction in urban areas.

The revised algorithm was designed to separately account for extinction and water uptake from freshly emitted versus aged aerosols and also to account for hygroscopic sea salt which was not considered in the original algorithm. The new formula includes an adjustment for the calculation of OM as 1.8*OC to account for the more aged and oxygenated organic aerosol that is found in remote areas which may also result from different emission sources.

The EPA does not believe that these same modifications and additions would necessarily be appropriate for calculating light extinction in urban areas. The composition of, and the mix of emission sources contributing to, $PM_{2.5}$ in urban areas is different than in remote areas. Thus, the urban $PM_{2.5}$ would have different light extinction properties. In particular, urban organic mass results from local and regional sources and thus has a different ratio of fresh to aged emissions and a different mass to organic carbon ratio than rural areas. The approach used by the revised algorithm to partition OM into small and large particles may not be appropriate for the urban mixture where a higher percentage of smaller particles are likely from the fresher nearby urban emissions. In addition, the 1.8 OC to OM multiplier in the revised improve algorithm is likely too high for urban OC.

The revised algorithm was developed for use in remote areas and was evaluated with concurrently available light scattering measurements at 21 remote locations. The revised algorithm is largely untested in urban areas and in fact, the $PM_{2.5}$ portion of the algorithm may overestimate urban extinction because of the contributions from organic mass. For all of these reasons, the EPA has concluded that it would not be appropriate to use the revised IMPROVE algorithm for purposes of calculating light extinction in urban areas.

(3) *Comment:* Some commenters noted that both the original and the revised IMPROVE algorithms were designed in support of the Regional Haze Program which is focused on largely rural Class I areas, and that neither algorithm is necessarily suitable for urban areas. Noting that the EPA has not thoroughly evaluated the applicability of either IMPROVE algorithm in urban areas, these commenters urged additional research to evaluate the suitability of either algorithm (or an alternative approach) in urban areas.

Response: EPA agrees with commenters that neither the original nor the revised IMPROVE algorithms have been evaluated in urban areas. Based on the advice of CASAC (Samet, 2010b), EPA concluded that it was unnecessary to develop a new urban-optimized algorithm to assess the relationship between urban PM to PM light extinction.

(4) *Comment:* Some commenters stated that they believed the 1.4 multiplier used to convert organic carbon (OC) to organic mass (OM) in the original IMPROVE algorithm was too low, and that it would be more appropriate to use a higher multiplier, such as the 1.8 multiplier that has been adopted as part of the revised IMPROVE algorithm.

Response: The EPA is aware that there has been considerable debate within the research community about the appropriate multiplier to use to best represent urban environments. In general, the EPA agrees with commenters that a multiplier of 1.4 is likely too low, and that a somewhat higher value would be appropriate. However, the EPA also believes that it would be inappropriate to use a multiplier as high as 1.8 to convert OC to OM in urban areas. As noted by commenters, the organic mass contribution to visibility impairment can be large, and generally OM is significantly larger in urban areas compared to surrounding rural areas. Because a large portion of the organic component of urban PM results from nearby emissions sources, the total OM mass is generally closer to the measured OC from which it is derived. This means it is appropriate to use a smaller multiplier to convert OC to OM in urban areas as compared to the value of 1.8 used in the revised algorithm, which is tailored to remote areas. The CASAC noted that urban OM includes fresh emissions and the EPA concluded in the Visibility Assessment that "the original version is considered more representative of urban situations when emissions are still fresh rather than aged as at remote IMPROVE sites" (U.S. EPA, 2010b, p. 3-19). Although the revised algorithm represents the best science of estimating extinction in remote areas with its aged aerosol, the commenters did not address how the EPA should modify the revised algorithm to best represent the more complex and different urban aerosol, particularly for OM.

As discussed in Appendix F of the Policy Assessment (U.S. EPA, 2011a), the EPA used the SANDWICH mass closure approach (Frank, 2006) in the Urban Focused Visibility Assessment (U.S. EPA, 2010b) for purposes of calculating maximum daylight hourly $PM_{2.5}$ light extinction and evaluated which multiplier would produce 24-hour results most similar to the SANDWICH approach using 24-hour $PM_{2.5}$ organic carbon derived from the new Chemical Speciation Network (CSN) carbon monitoring protocol established in 2007. Analyses presented in Appendix F of the Policy Assessment indicate that a multiplier of 1.6 is most appropriate for purposes of comparing the hourly $PM_{2.5}$ light extinction with calculated 24-hour extinction (see Appendix F, section F.6 for a full explanation). The EPA also considers this higher multiplier to be a better approach for urban CSN monitoring sites where the new measurements of organic carbon tend to be lower than those produced by the older NIOSH-type monitoring protocol (Malm, 2011). A multiplier of 1.6 is now used to calculate OM from OC measurements at CSN sites.

In light of all of these considerations, in particular the analyses the EPA conducted for Appendix F of the Policy Assessment and the fact that the monitoring method for organic carbon has recently changed in the CSN network, the EPA judges that a multiplier of 1.6 for urban areas would be most appropriate for purposes of calculating $PM_{2.5}$ light extinction in urban areas. The implications of this shift to a 1.6 multiplier for OC in urban areas for decisions about averaging time, level, and need for a distinct secondary standard are discussed in the preamble to the final rule in sections VI.C.1.c, VI.C.1.e, and VI.C.1.f, respectively.

(5) *Comment:* A number of commenters argued that exclusion of coarse PM from the calculated light extinction indicator was inappropriate. These commenters noted that coarse particulate matter is an important contributor to visibility impairment in many areas, particularly in the western U.S., and that the levels of "acceptable" visual air

quality derived from the visibility preference studies reflected total light extinction due to the full mix of particles (including coarse PM) in ambient air.

Response: The EPA does not agree with commenters who suggested that coarse particles should be included in the calculated light extinction indicator. As noted in the proposal, $PM_{2.5}$ is the component of PM responsible for most of the visibility impairment in most urban areas. Currently available data suggest that $PM_{10-2.5}$ is a minor contributor to visibility impairment most of the time, although at some locations (U.S. EPA, 2010b, Figure 3-13 for Phoenix) $PM_{10-2.5}$ can be a major contributor to urban visibility effects. While 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, in fact few urban areas conduct continuous $PM_{10-2.5}$ monitoring. This significantly increases the difficulty of assessing the role of coarse particles in urban visibility impairment. For example, among the 15 urban areas assessed in this review, only four areas had collocated continuous PM_{10} data allowing calculation of hourly $PM_{10-2.5}$ data for 2005 to 2007. In addition, $PM_{10-2.5}$ is generally less homogenous in urban areas than $PM_{2.5}$ in that coarse particle concentrations exhibit greater temporal variability and a steeper gradient across urban areas than fine particles (U.S. EPA, 2009a, p. 3-72). This makes it more challenging to select sites that would adequately represent urban visibility conditions. Thus, 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 Visibility Assessment, there is insufficient information available at this time to assess the impact and effectiveness of such a refinement in providing public welfare protection in areas across the country (U.S. EPA, 2011a, pp. 4-41 to 4-42).

In addition, the EPA notes CASAC's advice that it would be appropriate to focus on $PM_{2.5}$ light extinction for purposes of setting a standard to protect visibility. In its comments on the EPA's White Paper on Particulate Matter (PM) Light Extinction Measurements (U.S. EPA, 2010g), the Ambient Air Monitoring and Methods Subcommittee (AAMMS) of CASAC made the recommendation 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 CASAC AAMMS indicated that it is technically more challenging at this time to accurately measure the $PM_{10-2.5}$ component of light extinction (Russell and Samet, 2010a).

In light of the limited role of $PM_{10-2.5}$ in light extinction in most urban areas, and the greater uncertainty and variability involved in the role of coarse particle in visibility impairment, the EPA has concluded that it is not appropriate to set a standard based on a calculated light extinction indicator that includes coarse particles at this time, and that it would be appropriate to base a calculated indicator on $PM_{2.5}$ light extinction.

(6) *Comment:* Some commenters objecting to the exclusion of coarse particles from the proposed light extinction indicator argued that the EPA had not provided "compelling reasons" for not including coarse particles. For example, North Carolina DENR stated while the coarse particle fraction might contribute only a small amount toward visibility

impairment, it should still be included because "nothing presented in the proposed rule would support not including the coarse particle fraction. Where coarse particle data are not available, the EPA should develop a method to estimate the coarse particle fraction for use in the equation" (p. 4). However, other commenters, agreed with the EPA's proposal to exclude coarse particles from the calculated light extinction indicator.

Response: As noted above, in light of the limited role of $PM_{10-2.5}$ in light extinction in most urban areas, and the greater uncertainty and variability involved in the role of coarse particle in visibility impairment, the EPA continues to conclude that it is not appropriate to set a standard based on a calculated light extinction indicator that includes coarse particles at this time, and the calculated indicator should be based on $PM_{2.5}$ light extinction. The EPA notes that this conclusion was supported by the advice of CASAC.

(7) *Comment:* A few commenters noted that due to the exclusion of coarse particles, a "deciview" calculated for purposes of the proposed $PM_{2.5}$ visibility index is inconsistent with the unit as conventionally defined under the Regional Haze Program.

Response: A deciview is a unit of measure of visibility derived from calculated light extinction measurements. A one dv change is approximately a 10% change in the aerosol based extinction. As used by EPA in the $PM_{2.5}$ visibility index, however, a one dv change is approximately a 10% change in the $PM_{2.5}$ aerosol based extinction coefficient. Typically, coarse particles contribute a very small amount of the total light extinction and resulting deciviews. For example, when the $PM_{2.5}$ aerosol components result in 30 dv of light extinction, even an additional 10 $\mu g/m^3$ (the median value for the U.S., see Schmidt et al., 2010b) of coarse particles would only increase the visibility index by 0.2 dv. Thus, the EPA concludes that the exclusion of coarse particles does not have a substantial impact on visibility index values in urban areas and that it is appropriate to exclude coarse particles from the indicator for the reasons discussed above.

(8) *Comment:* Some commenters questioned why the EPA was proposing to rely on monthly average relative humidity [f(RH)] values when hourly humidity data are widely available, particularly in urban areas. One commenter argued that the EPA's proposed approach involves "guessing relative humidity" rather than relying on accurate, readily available measurements (Oklahoma DEQ, p. 1). The commenter stated that since relative humidity is highly variable and weather dependent, the proposed approach "effectively undermines the capacity of the prescribed monitoring regime to identify periods when $PM_{2.5}$ adversely affects visibility." Other commenters supported this view, noting that relative humidity can vary substantially even within a 24-hour period, and that light extinction can be very sensitive to these changes. These commenters recommended that hourly or daily humidity measurements should be utilized in place of the proposed monthly average f(RH) values.

Response: The EPA disagrees that concurrent (hourly) humidity measurements should be used. The use of longer-term averages for each monitoring site adequately captures the seasonal variability of relative humidity and its effects of visibility impairment, and this approach focuses more on the underlying aerosol contributions to visibility impairment and less on the day-to-day variations in humidity. This provides a more stable indicator for comparison to the NAAQS and one that is more directly related to the underlying emissions that contribute to visibility impairment. Moreover, the EPA disagrees with commenters that using monthly average relative humidity undermines the proposed monitoring regime, noting that the Agency's conclusion that a 24-hour averaging time would be appropriate for a visibility index standard diminishes the importance of having hourly humidity data. Longer-term average humidity data are better matched to 24-hour averaging times, which effectively smooth out the influence of peak hourly values regardless of whether hourly data are available. Therefore, the EPA continues to believe that it is appropriate to use f(RH) values for purposes of calculating a 24-hour $PM_{2.5}$ visibility index. Moreover, the EPA disagrees that this approach involves "guessing relative humidity" since the f(RH) values are based on 10 years of climatological data for each location.

(9) *Comment:* Some commenters recommended that the EPA should utilize a 90 percent relative humidity screen rather than 95 percent cap for purposes of eliminating periods in which visibility impairment is due to rain or fog. These commenters claimed that under a 95 percent cap, both the average f(RH) values and the $PM_{2.5}$ visibility index values could be inflated in locations frequently affected by fog and/or precipitation. These commenters preferred the approach of excluding hours with relative humidity above 90 percent on the grounds that this approach would eliminate foggy/rainy hours irrespective of the frequency of occurrence.

Response: The EPA believes that relying on monthly average relative humidity values based on 10 years of climatological data would appropriately reduce the effect of fog and precipitation. Although the approach of using a 95 percent humidity cap, as in the Regional Haze Program, includes some hours with relative humidity between 90-95 percent, the general approach of using a longer-term average for each monitoring site effectively eliminates the effect of very high humidity conditions on visibility at those locations. In essence, the adoption of monthly average f(RH) values mitigates (i.e., smoothes out) the peak humidity values, and capping remaining hours at 95 percent relative humidity further reduces the influence of fog or precipitation events (even if those conditions occur frequently). Therefore, the EPA disagrees with commenters that it would be more appropriate to use a 90 percent relative humidity screen.

(10) *Comment:* One commenter stated that utilizing only one sampling point for purposes of calculating the light extinction indicator would not be appropriate because it would not represent visibility across the airshed. The commenter stated that the unit of deciviews as used in the Regional Haze Program was "primarily developed for areas with a long site path to encompass a large sample size" (Clark County, Nevada, Department of Air Quality, p. 2). The commenter urged the EPA to consider requiring the use of additional sampling points for purposes of calculating light extinction in urban areas.

Response: EPA agrees that $PM_{2.5}$ is more spatially homogeneous in remote areas than in urban areas. For this reason, the visibility impairment estimated from aerosol concentrations at individual urban locations may not be representative of a nearby long urban site path. Thus urban visibility measured at the maximum concentration location in an urban area, especially at locations with a small scale of spatial representativeness for one or more PM chemical components could provide even more protection against visibility impairment than the location which is more typical of urban-wide $PM_{2.5}$ concentrations.

(11) *Comment:* A number of commenters criticized other specific aspects of the proposed visibility index, especially with regard to the inclusion, exclusion, or construction of specific terms in the IMPROVE equation. In many instances, these commenters argued that the proposed indicator was inappropriate for specific local environments due to unique or atypical conditions influencing aerosol composition or relative humidity. These commenters generally stated that it was inappropriate to adopt a single indicator for application nationwide, or that some change in the indicator was necessary to accommodate local conditions. Some commenters offered specific recommendations about ways to improve the proposed calculated $PM_{2.5}$ light extinction indicator to account for specific, local influences or to accommodate other perceived weaknesses of the proposed indicator, such as those discussed above. Other commenters urged the EPA to conduct more research on the factors influencing light extinction in specific environments, and to consider developing a revised indicator in conjunction with a pilot monitoring program. Some of these commenters stated that the proposed standard was simply too complicated, and failed to capture the full suite of necessary components.

Response: The EPA disagrees with these commenters, noting that the proposed calculated light extinction indicator is expressly designed to account for differences in humidity and $PM_{2.5}$ composition among various regions. Furthermore, the EPA notes that both the original and revised IMPROVE algorithms are routinely used to calculate PM-related light extinction on a 24-hour basis in Federal Class I areas under the Regional Haze Program, despite variability in aerosol composition and humidity among these locations. Therefore, the EPA continues to conclude that a similar approach is appropriate for a standard to protect against $PM_{2.5}$-related visibility impairment. However, as discussed in section VI.C.1.e of the preamble to the final rule and section IV.B.4, below, regarding comments on level, the EPA agrees with commenters who emphasize the high degree of variability in visibility conditions and the potential variability in visibility preferences across different parts of the country. In light of the associated uncertainty, the Administrator has judged it appropriate to establish a target level of protection at the upper end of the range of levels considered (30 dv), recognizing that no one level will be "correct" for every area in the country. The EPA considers that a standard set at this level appropriately accommodates the variability among local environments and the resulting uncertainty that concerns these commenters. In addition, the EPA notes that in light of the Agency's decision not to establish a distinct secondary standard for protection from visibility impairment at this time, these concerns are generally moot at this time.

2. Averaging Time

a. Comments Supporting 24-Hour Averaging Time

(1) *Comment:* Among commenters supporting the proposed distinct secondary standard for protection from visibility impairment, many commenters recognized the limitations on monitoring methods and currently available data that led to the EPA's proposal to adopt a

standard based on a 24-hour averaging time. Most of these commenters acknowledged that the lack of reliable hourly speciation data means that a 24-hour averaging time is the only workable approach for a standard based on calculated light extinction. Commenters advocating a distinct secondary standard therefore generally supported the proposal to adopt a 24-hour averaging time, at least as an interim approach until a directly measured light extinction indicator could be adopted in the future.

Response: As discussed in section VI.C.1.c of the preamble, the EPA agrees with these commenters that a 24-hour averaging time would be the most appropriate for purposes of a distinct secondary standard based on a calculated light extinction indicator.

(2) *Comment:* A few industry commenters argued that since a visibility index standard would be based on data from the IMPROVE and CSN monitors, which operate on a 24-hour basis with 1-in-3 (or 1-in-6) day sampling, "it is imperative that EPA retain a 24-hour averaging time if a secondary visibility standard is promulgated" (API, Attachment 3, p. 9).

Response: As discussed in section VI.C.1.c of the preamble, the EPA agrees with these commenters that a 24-hour averaging time would be the most appropriate for purposes of a standard based on a calculated light extinction indicator.

(3) *Comment:* A number of commenters supported a 24-hour averaging time due to the limitations that would be associated with using a shorter (sub-daily) averaging time. For example, New York DOH/DEC agreed with the EPA that it would not be appropriate to utilize the $PM_{2.5}$ FEM monitors for purposes of calculating a short-term light extinction value at this time. Arizona DEQ stated that it "does not support a sub-daily visibility standard with the proposed monitoring method. This approach would necessarily rely on temporal distribution estimates derived from nearby or on-site hourly PM measurements and extrapolation of 24-hour composite speciated samples. ADEQ believes this method would prove to be overly complex with seasonal variation of species and too inconsistent to utilize for a NAAQS secondary standard" (Arizona DEQ, p. 3; see also Minnesota, NY).

Response: As discussed in section VI.C.1.c of the preamble, the EPA agrees with these commenters that a 24-hour averaging time would be the most appropriate for purposes of a standard based on a calculated light extinction indicator.

b. Comments Supporting Sub-daily (1-, 4-, or 6-hour) Averaging Time

(1) *Comment:* A number of commenters expressed the view that an hourly or sub-daily averaging time would be the most appropriate approach, as supported by CASAC and the EPA's staff analyses in this review. These comments also generally stressed the desirability of adopting a directly measured light extinction indicator that could be measured on an hourly or sub-daily time scale. Some commenters noted that a standard based on a 4-6 hour averaging time would better capture peak daily light extinction while allowing stable signal quality; others urged the EPA to adopt a 1-hour averaging time in conjunction with direct measurements.

Response: In response to comments supporting a 1-hour or sub-daily (4- to 6- hour) averaging time in conjunction with a direct light extinction measurements, the EPA notes that, as discussed above in the response to comments on indicator, the Agency has concluded that a directly measured light extinction indicator is not an appropriate option in this review, independent of the decision on averaging time. Having reached the conclusion that a calculated $PM_{2.5}$ light extinction indicator would be most appropriate, the EPA next considered what averaging time would be most desirable for such an indicator. As noted in the proposal, the EPA has recognized that hourly or sub-daily (4- to 6-hour) averaging times, within daylight hours and excluding hours with high relative humidity, are more directly related than a 24-hour averaging time to the short-term nature of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. Thus, the Agency agrees with commenters' general point that, as a starting premise, a sub-daily averaging time would generally be preferable.

However, as discussed in section VI.B.1.c of the preamble to the final rule, important data quality uncertainties have recently been identified in association with currently available instruments that would be used to provide the hourly $PM_{2.5}$ mass measurements that would be needed in conjunction with an averaging time shorter than 24 hours. As a result, at this time the Agency has strong technical reservations about a secondary standard that would be defined in terms of a sub-daily averaging time. The data quality issues which have been identified, including short-term variability in hourly data from currently available continuous monitoring methods, effectively preclude adoption of a 1-hour averaging time in this review, given the sensitivity of a 1-hour averaging time to these data quality limitations. Even with regard to multi-hour averaging times, the EPA continues to conclude that the data quality concerns preclude adoption of a sub-daily averaging time.

(2) *Comment:* Commenters pointed to significant limitations associated with using a 24-hour averaging time, including the uncertainties in translating hourly or sub-daily visibility index values into 24-hour equivalent values. Some commenters criticized the analysis presented in the Policy Assessment comparing the 24-hour calculated light extinction values to the maximum daylight 4-hour calculated light extinction values. These commenters stated that the scatter plots and regressions presented in the Policy Assessment indicate there is considerable variation in the 24-hour vs. 4-hour relationship, and interpreted this to mean that 24-hour light extinction values are a poor surrogate for 4-hour values. For example, one consultant cited by several industry commenters noted that the correlation coefficient between the 24-hour and 4-hour values was as low as $r^2 = 0.42$ in Houston, and stated that the EPA was being overly "optimistic" in concluding that city-specific and pooled r^2 values in the range of 0.6 to 0.8 showed good correlation (UARG, Attachment 2, p. 27).

Response: Analyses conducted for the Policy Assessment indicate that $PM_{2.5}$ light extinction calculated on a 24-hour average basis would be a reasonable and appropriate surrogate for $PM_{2.5}$ light extinction calculated on a 4-hour basis. The scatter plots comparing 24-hour and 4-hour calculated $PM_{2.5}$ light extinction in the Policy Assessment (U.S. EPA, 2011a, Figures G-4 and G-5) do show some scatter around the regression line for each city. This was to be expected, since the calculated 4-hour light extinction includes day-specific and hour-specific influences that are not captured by the simpler 24-hour approach. Overall, however, in the EPA's view, both the city-specific and pooled 15-city 24-hour vs. 4-hour comparisons show strong correlation between the two averaging times. Moreover, the 90th percentile design values calculated for 4-hour vs. 24-hour light extinction are much more closely correlated than are the values for individual days in particular urban areas calculated using these two approaches. Thus, while the EPA agrees with commenters who pointed out the relatively low correlation between 4- and 24-hour values in cities such as Houston, the Agency points out that the correlations of 90th percentile values are much higher, particularly when one considers the average values across urban areas. In general, the 90th percentile values line up better and demonstrate closer to a one-to-one relationship.

The EPA has conducted a reanalysis (Frank et al., 2012b) of the relationships between estimated 24-hour and 4-hour visibility impairment based on the variety of metrics discussed in Appendix G of the Policy Assessment that further supports this finding. The reanalysis more appropriately considered the uncertainty of the calculated 4-hour values. It also considered the effect of changing the OC to OM multiplier used in urban areas from 1.4 to 1.6. The revised analysis shows that the 24-hour values are generally closer to the 4-hour values than originally estimated, particularly with regard to the 90^{th} percentile values or the average of the 15 city-specific values.

Since conclusions in the proposal about the relationship between 4-hour and 24-hour values were drawn not just on the basis of the city specific results but also on the more robust 90th percentile values, the EPA disagrees with commenters who state that the Agency was overly optimistic in considering 24-hour values an appropriate surrogate for 4-hour values. Also, it is appropriate to focus on the 90th percentile design value comparison since the design values would determine attainment status and the degree of improvement in air quality that could be expected in areas instituting controls to meet the standard. Therefore, the EPA does not agree with commenters who state that a 24-hour averaging time cannot serve as an appropriate surrogate for sub-daily periods of visibility impairment. On the contrary, the EPA continues to conclude, on the basis of this analysis, 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 basis.

(3) *Comment:* Some commenters emphasized the poor fit of a 24-hour averaging time with the near instantaneous judgments about visibility impairment reflected in the visibility preference studies. Some of these commenters objected to a 24-hour averaging time as unsupported by the record in this review: "Because the science the Administrator relies on for the other elements of the proposed visibility standard is tied to short-term exposures to visibility impairment, the EPA has no basis for promulgating a standard that uses a 24-hour averaging time" (API, p. 43). These commenters claimed that while the EPA may not have the information or infrastructure in place to allow the Agency to set a standard based on a 1-hour or other sub-daily averaging time, this does not justify moving to a 24-hour averaging time.

Response: The EPA has recognized that hourly or sub-daily (4- to 6-hour) averaging times, within daylight hours and excluding hours with high relative humidity, are more directly related than a 24-hour averaging time to the short-term nature of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. However, as discussed in section VI.B.1.c of the preamble to the final rule, important data quality uncertainties have recently been identified in association with currently available instruments that would be used to provide the hourly $PM_{2.5}$ mass measurements that would be needed in conjunction with an averaging time shorter than 24 hours. As a result, the EPA determined it would not be appropriate at this time to adopt a standard defined in terms of a sub-daily averaging time.

Instead, the EPA considered using $PM_{2.5}$ light extinction calculated on a 24-hour basis to reduce the various data quality concerns on relying on continuous $PM_{2.5}$ monitoring data. However, the Policy Assessment recognized 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 both those who do and do not have access to visibility conditions often or continuously throughout the day. Thus, the EPA stated in section VI.D.2.ii of the proposal that consideration of a 24-hour averaging time would depend 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. Analyses conducted for the Policy Assessment did indicate that $PM_{2.5}$ light extinction calculated on a 24-hour average basis would be a reasonable and appropriate surrogate for $PM_{2.5}$ light extinction calculated on a 4-hour basis, supporting the EPA's decision to consider this longer averaging time appropriate.

(4) *Comment:* Some commenters expressed concern over potential bias and greater uncertainty introduced by the inclusion of nighttime hours, noting that because relative humidity tends to be higher at night, inclusion of these hours could cause areas to "record NAAQS exceedances that have no corresponding visibility impairment value" (UARG, p. 36).

Response: The Policy Assessment recognized that since a 24-hour averaging time combines daytime and nighttime periods, 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. The EPA's consideration of a 24-hour averaging time therefore also depended upon developing an approach to translate the candidate levels of protection derived from the public preference studies, which the Policy Assessment interpreted on an hourly or multi-hourly basis, to a candidate level of protection defined in terms of a 24-hour average calculated light extinction. The EPA's analyses comparing 24-hour and 4-hour averaging times showed good correlation between 24-hour and 4-hour average $PM_{2.5}$ light extinction, as discussed further in section IV.2.e regarding comments on level, below, and in section VI.C.1.e of the preamble. This supported the Agency's conclusion that $PM_{2.5}$ light extinction calculated on a 24-hour average basis would be a reasonable and appropriate surrogate for $PM_{2.5}$ light extinction calculated on a 4-hour basis.

(5) *Comment:* Commenters also noted that there is greater hourly variation in PM

concentrations and resulting visibility conditions in urban areas than in Class I areas; thus, while the Regional Haze Program uses 24-hour IMPROVE data, the commenters stated that a shorter averaging time is needed for an urban-focused $PM_{2.5}$ standard to protect visibility.

Response: As discussed in section VI.B.1.c of the preamble to the final rule, the EPA has recognized that hourly or sub-daily (4- to 6-hour) averaging times, within daylight hours and excluding hours with high relative humidity, are more directly related than a 24-hour averaging time to the short-term nature of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. However, analyses of air quality in 15 urban areas conducted for the Policy Assessment indicated that $PM_{2.5}$ light extinction calculated on a 24-hour average basis would be a reasonable and appropriate surrogate for $PM_{2.5}$ light extinction calculated on a 4-hour basis. Thus, the EPA concludes that a 24-hour averaging time would be appropriate for a standard based on a calculated light extinction indicator.

(6) *Comment:* Some commenters expressed concern with the proposal to calculate the visibility index over 24-hours, noting that this would introduce additional uncertainty in the light extinction calculations: "The NCDAQ understands the Administrator's dilemma with the uncertainty that can be introduced using instrumentation that people do not have confidence in, namely some of the recently approved Federal Equivalent Methods (FEMs). At the same time the NCDAQ currently uses continuous monitors that are not Federal Reference Methods (FRMs) or FEMs to comply with meeting air quality reporting requirements. The data from these monitors are adjusted seasonally using an equation derived at each specific location so that they match the FRM data. Is the uncertainty that would occur using continuous particle monitors adjusted to match the FRM really greater than the uncertainty that occurs from using 24 hour speciation data?" (NC DENR, p. 4-5).

Response: $PM_{2.5}$ FEMs are designed and tested by manufacturers and approved by EPA according to their ability to reproduce 24-hr mass based $PM_{2.5}$ concentrations as measured by the $PM_{2.5}$ FRM. When these continuous measurements are used as part of the air quality index to publicly report $PM_{2.5}$ concentrations, they are adjusted by State and local air pollution agencies to better predict 24-hour values. Such adjustments are sometimes performed on a seasonal basis. However, the $PM_{2.5}$ FEM is not necessarily designed nor is it tested to produce precise 1-hr values. In fact, some of the potential uncertainty in 1-hour values is removed through the process of averaging multiple hours. Moreover, the composition of $PM_{2.5}$ can change from hour to hour and the estimated extinction depends on the change in composition as well as the change in hourly $PM_{2.5}$ mass concentration. However, hourly speciation and optical measurements which separately estimate the extinction contributions from scattering and absorbing $PM_{2.5}$ aerosols are not widely deployed in urban monitoring networks. Therefore, as part of the urban visibility assessment, EPA estimated the change in composition using modeling data to help estimate the change in extinction resulting from the different scattering and absorbing components of $PM_{2.5}$. For those complex calculations, the EPA also assumed that the composition did not change from day to day. Although precise measurements of hourly $PM_{2.5}$ would be helpful, EPA does not believe that they are available. Also, use of existing hourly $PM_{2.5}$ measurements in combination with all of the other stated factors introduced significant uncertainty into this analysis in the urban visibility assessment. For these reasons, EPA has more confidence in the visibility impairment derived from 24-hr speciation measurements than from the 1-hr $PM_{2.5}$ mass concentrations produced by $PM_{2.5}$ FEMs combined with assumed hour to hour changes in $PM_{2.5}$ composition.

3. Form

a. Comments on 90th Percentile

(1) *Comment:* One commenter stated that it was inappropriate to use a 90th percentile form, noting that this would result in the exclusion of a minimum of 36 days of data annually. The commenter expressed particular concern that this proposed approach, in combination with a 24-hour standard based on an unadjusted CPL, would not capture the worst visibility impairment and that this would undermine "the intent of setting a meaningful secondary visibility standard" (AMC, et al., p. 2).

Response: The EPA disagrees that a 90th percentile form would exclude too many days to offer meaningful protection against visibility impairment. The EPA notes that there is a significant lack of information on, and a high degree of uncertainty regarding, the impact on public welfare of the number of days with visibility impairment over the course of a year. For example, the visibility preference studies used to derive the range of CPLs considered in this review offered no information regarding the frequency of time that visibility levels should be below those values. Based on this limitation, the EPA concluded in the Policy Assessment that it would not be appropriate to consider eliminating all exposures above the level of the standard and that it was reasonable to consider allowing some number of days with reduced visibility. Recognizing that the Regional Haze Program focuses attention on the 20 percent worst visibility days (i.e., those at or above the 80th percentile of visibility impairment), the EPA continues to believe, as noted in the proposal, that 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 help areas attain the standard. Focusing on the 90th percentile, which represents the median of the distribution of the 20 percent worst visibility days, could be reasonably expected to lead to improvements in visual air quality on the 20 percent most impaired days. Thus, the EPA has made a reasoned judgment based on a full consideration of the upper end of the distribution of visibility impairment conditions, in light of the significant uncertainty discussed above and continues to conclude that it is appropriate to focus on the 90th percentile of visibility impairment values.

(2) *Comment:* Another commenter argued that the EPA had provided no scientific basis for why the 90th percentile form was suitable, and claimed that the Agency was making "a somewhat arbitrary judgment that people's welfare would be affected only if adverse urban visibility were to occur more than 10 percent of the time" (API, Attachment 2, p. 4).

Response: EPA notes that there is a significant lack of information on, and a high degree of uncertainty regarding, the impact on public welfare of the number of days with visibility impairment over the course of a year. For example, the visibility preference studies used to derive the range of CPLs considered in this review offered no information regarding the frequency of time that visibility levels should be below those values. Based on this limitation, the EPA concluded in the Policy Assessment that it would not be appropriate to consider eliminating all exposures above the level of the standard and that it was reasonable to consider allowing some number of days with reduced visibility. Recognizing that the Regional Haze Program focuses attention on the 20 percent worst visibility days (i.e., those at or above the 80th percentile of visibility impairment), the EPA continues to believe, as noted in the proposal, that 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 help areas attain the standard. Focusing on the 90th percentile, which represents the median of the distribution of the 20 percent worst visibility days, could be reasonably expected to lead to improvements in visual air quality on the 20 percent most impaired days. Thus, the EPA did not arbitrarily pick the 90^{th} percentile, but has made a reasoned judgment based on a full consideration of the upper end of the distribution of visibility impairment conditions, in light of the significant uncertainty as discussed above, and continues to conclude that it is appropriate to focus on the 90th percentile of visibility impairment values.

b. Comments on 3-year Average

(1) *Comment:* A few commenters argued that averaging over only 3 years would not provide a stable assessment of visual air quality in the West because this time period is insufficient to properly account for western drought and fire cycles. These commenters pointed to the approach in the Regional Haze Program of averaging visibility impairment over 5 years, and noted that even within this longer time period data can be significantly influenced by high emissions during significant fire years.

Response: The EPA disagrees that it would be appropriate to average the 90th percentile values over periods longer than 3 years. The EPA recognizes that a multi-year percentile form offers greater stability to the air quality management process by reducing the possibility that statistically unusual indicator values will lead to transient violations of the standard. Utilizing a 3-year average form provides stability from the occasional effects of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year. The Agency has adopted this approach in other NAAQS, including the current 24-hour $PM_{2.5}$ NAAQS, which has a 98th percentile form averaged over 3 years. However, adopting a multi-year averaging period longer than 3 years would increase even more the number of days with visibility impairment above the target level of protection and would therefore reduce the protectiveness of the standard. Based on this the EPA does not believe it would be appropriate to average 90th percentile values over a period as long as five years.

4. Level

The EPA received relatively few comments endorsing a specific level for a distinct secondary standard to address visibility impairment. In general, commenters who opposed setting a distinct secondary standard at this time did not address the question of what level would be appropriate if the EPA were to set a distinct secondary standard to address visibility impairment; similarly, commenters who supported adopting a distinct secondary standard at this time generally did not recommend a specific level. However, a few commenters did provide comments in support of a specific level or range of levels, with some commenters advocating standards at the upper end of the range of proposed levels (i.e., 30 dv), while others supported levels below the lower end of the proposed range (i.e., below 28 dv). These comments reflected consideration of the results of the public preference studies as well as analyses conducted in the Visibility Assessment and the Policy Assessment. Comments addressing the appropriateness of specific levels are discussed in this section. In addition, the EPA received a large number of comments addressing the information available from the public preference studies with regard to the acceptability of various levels of visual air quality. These comments, which are discussed in section IV.5, below, address the EPA's use of visibility preference studies as the basis for the selection of a range of appropriate levels for the Administrator to consider.

a. Comments Supporting a Level of 30 dv or higher

(1) *Comment:* Several industry commenters submitted an analysis which they argued indicated that the proposed level of 28 or 30 dv did not reflect the substantial difference in visibility preferences between the East and the West reflected in the preference studies (UARG, Attachment 2, p. 11), and that it did not reflect the full range of preferences (i.e., potential 50 percent acceptability levels) likely to exist nationwide (UARG, Attachment 2, p. 19). These commenters further objected to the EPA's proposal for a level of 28 or 30 dv on the grounds that the EPA had inaccurately adjusted 4-hour values into 24-hour values. Based on the analysis, the commenters concluded that "a range of adjusted values from 28 to 32 dv is needed" to account for the majority of the spread between the 4-hour vs. 24-hour equivalent values at the upper end of the distribution of values.

Response: While acknowledging the uncertainties and limitations associated with the visibility preference studies as discussed above, the EPA continues to conclude, as did CASAC, that the preference studies are appropriate to use as the basis for selecting a target level of protection from visibility impairment. However, the EPA agrees with commenters who emphasize the high degree of variability in visibility conditions and the potential variability in visibility preferences across different parts of the country. As discussed in the preamble, the information supports the view that variability in the results of the studies is likely based on variability in the content of the view at issue in the study, as compared to variability in people's preferences. In addition, the EPA has concluded that in light of the significant uncertainties, it is appropriate to place less weight on the results of western visibility preference studies and that the CPL value (30 dv) that is based on the eastern preference study results is likely to be more representative of urban areas that do not have associated mountains or other valued objects visible in the distant background. In light of the associated uncertainty, as noted in the proposal, the Administrator judged it appropriate to establish a target level of protection equivalent to the upper end of the range of Candidate Protection Levels (CPLs) identified in the Policy Assessment and generally supported by CASAC. Thus, the EPA considered the issues raised by commenters, and the EPA proposed to set a 24-hour visibility index standard that would provide protection equivalent to the protection afforded by a 4-hour standard set at a level of 30 dv. In light of the comments received on the proposal, in particular comments emphasizing the uncertainty and variability in the results of the public preference studies, the EPA continues to conclude that this approach is warranted, and that it is appropriate to set a target level of protection equivalent to the protection that would be afforded by a 4-hour, 30 dv visibility index standard.

In adjusting 4-hour values for purposes of defining an appropriate level for a 24-hour standard, the EPA noted that there were multiple approaches for estimating generally equivalent levels on a city-specific or national basis, and that both of the two preferred approaches identified in the Policy Assessment generated a range of city-specific estimates of generally equivalent 24-hour levels that encompassed the range of levels considered appropriate for 4-hour CPLs, including the CPL of 30 dv at the upper end of that range. This led to the conclusion that it would be appropriate to use an unadjusted 4-hour CPL for purposes of establishing a target level of protection for a 24-hour standard. The EPA disagrees with commenters who argued that the EPA's approach for translating 4-hour CPLs into equivalent 24-hour values was inappropriate. The EPA has conducted a reanalysis (Frank et al., 2012b) of the relationships between estimated 24-hour and 4-hour visibility impairment based on the variety of metrics discussed in Appendix G of the Policy Assessment. The reanalysis has more appropriately considered the uncertainty of the calculated 4-hour values. The revised analysis shows that, for all cases considered, the 24-hour equivalent level is even closer to the 4-hour values than originally estimated, demonstrating that the EPA's approach to translating of 4-hour CPLs into equivalent 24-hour values was appropriate.

(2) *Comment:* A number of commenters questioned whether the proposed range of levels was appropriate. One industry commenter claimed that the EPA had not explicitly justified why a standard within the proposed range was requisite, stating that "EPA makes no attempt to explain how the proposed level of the standard is neither lower nor higher than necessary to protect public welfare" (NSSGA, p. 15). Noting perceived problems with the proposed range of levels, a few commenters noted that if the EPA were to set a distinct secondary standard, the level should be set no lower than 30 dv, "to account for inconsistent value judgments, a great deal of spatial and temporal variability, and a very high level of uncertainty" (TX CEQ, p. 7).

Response: While acknowledging the uncertainties and limitations associated with the visibility preference studies as discussed above, the EPA continues to conclude, as did CASAC, that the preference studies are appropriate to use as the basis for selecting a target level of protection from visibility impairment. After considering the alternative levels proposed for a 24-hour standard, either 28 dv or 30 dv, the EPA has concluded that the current substantial degrees of variability and uncertainty inherent in the public preference studies should be reflected in a higher target protection level than would be appropriate if the underlying information were more consistent and certain. In addition, the EPA has concluded that in light of the significant uncertainties, it is appropriate to place less weight on the results of western visibility preference studies and that the CPL value (30 dv) that is based on the eastern preference study results is likely to be more representative of urban areas that do not have associated mountains or other valued objects visible in the distant background. In light of all the information available in this review, therefore, the Administrator has concluded that the protection provided by a standard defined in terms of a $PM_{2.5}$ visibility index (based on speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction), a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, set at a level of 30 dv, would be requisite to protect public welfare with regard to visual air quality.

(3) *Comment:* Many commenters also expressed concern over what they perceived to be the high degree of uncertainty associated with the proposed distinct secondary standard for visibility. For example, Nevada DEP stated "the EPA's own analysis regarding the secondary visibility standard highlights several areas of high uncertainty, which preclude a reasonable conclusion that the proposed visibility rule is sufficient, but not overly so, to protect public welfare. Therefore, it is inappropriate to pursue a fatally flawed standard" (p. 9).

Response: While acknowledging the uncertainties and limitations associated with the information available in this review, the EPA continues to conclude, as did CASAC, that this information provides a sufficient basis for selecting a target level of protection for visibility in this review. Thus the EPA disagrees with commenters who stated that the uncertainties were so great as to preclude establishing a standard at this time. Rather, the EPA has concluded that the current substantial degrees of variability and uncertainty should be reflected in a higher target protection level than would be appropriate if the underlying information were more consistent and certain. In considering the two alternative levels (28 or 30 dv) proposed for a distinct secondary standard to protect visibility, therefore, the EPA has elected to set a target level of protection at the higher of the two levels proposed (30 dv).

(4) *Comment:* The states of Arizona and Colorado submitted comments arguing that the visibility preference studies conducted in Phoenix and Denver, respectively, were designed to address a specific local problem and that the results of these studies were not an appropriate basis for selecting the level of a national standard. For example, Arizona DEQ noted:

> The cited studies were conducted considering total light extinction; including extinction resulting from particulate matter and Rayleigh scattering. Visibility impairment due to coarse particulate matter can be an important contributor in Arizona, specifically in the Phoenix area where ongoing measurements have been made. Therefore, ADEQ believes that the proposed levels of the secondary visibility standard are inconsistent with applicable urban studies. (Arizona DEQ, p. 2)

Similarly, the Colorado Department of Public Health and the Environment noted that the Denver visibility standard was designed to address "brown clouds", i.e., strong inversions that occur in the Denver metropolitan area, and that this standard "is based on a specific view of Denver" associated with particular sight paths and direct measurement methods. The commenter stated that this standard "is applicable only to this location," and that these limitations make it potentially unsuitable for application as "a national secondary standard, particularly a proposed standard that does not use a direct measurement method" (Colorado DPHE, p. 2).

Response: In the preamble to the final rule, the EPA noted several reasons for caution in interpreting the results of the Denver and Phoenix preference studies. Noting both 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, and the caution expressed by Colorado and Arizona about using the results of the Denver and Phoenix preference studies, which were aimed at addressing specific local visibility problems, to inform the choice of level for a national standard, the EPA concluded that it is appropriate, especially in light of the significant uncertainties, to place less weight on the western preference results. The EPA concluded that the high CPL value (30 dv) that is based on the eastern preference results is likely to be more representative of urban areas that do not have associated mountains or other valued objects visible in the distant background. These areas would include the middle of the country and many areas in the eastern U.S., as well as some western areas. In reaching this conclusion, the EPA recognized that no one level would be "correct" for every urban area in the country, and 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.

In regard to the commenter's concern about contributions from coarse particles and Rayleigh scattering, the EPA further notes that participants in the Phoenix and other studies were not asked to break out their preferences based on how much of the haze was caused by contributions from coarse particles, Rayleigh scattering or fine particles. Instead, Phoenix study participants were simply asked to identify levels of visual air quality that they would consider "unreasonable or objectionable," no matter what the source. Based on this information, Phoenix was able to come up with a target level of VAQ, even though pollutant mixes vary temporally and spatially, even within the Phoenix urban area. Since the goal of the secondary $PM_{2.5}$ NAAQS is to provide a uniform national level of public welfare protection from $PM_{2.5}$ related visibility impairment, the form of the EPA's proposed secondary standard was selected to allow each area to achieve that level of protection in a way that addresses its own unique mix of contributing pollutants. Therefore, the EPA disagrees with the commenter that it is inappropriate to use the results of the Phoenix study to inform a range of candidate protection levels for consideration by the Administrator in selecting a national level of visibility protection. Instead, the EPA believe the Phoenix results form an important data point that shed light on public preferences for visibility in western areas with urban scenes that include distant mountains.

b. Comments Supporting a Level below 30 dv

(1) *Comment:* Some commenters stated that the proposed range of levels from 28-30 dv was insufficiently protective based on a 24-hour averaging time, and recommended a lower level for the visibility index standard. These commenters expressed the view that the

proposed levels of 28 or 30 dv represented neither adequate surrogates for equivalent 4-hour values, as the EPA claimed, nor sufficiently protective levels based on recent air quality data. Several commenters stated that the EPA's own analyses suggested that a standard set at a level of 28 or 30 dv was insufficiently protective based on a 24-hour averaging time. One commenter emphasized that the Policy Assessment had indicated a level between 25-28 dv was appropriate for a standard calculated on a 24-hour average, and encouraged the EPA to adopt a standard level of 25 dv.

Response: The EPA disagrees with commenters who argue that the currently available evidence is sufficient to justify establishing a target level of protection at 25 dv or below. The EPA recognizes that 25 dv represents the middle of the range of 50 percent acceptability levels from the 4 cities studied, and represents the 50 percent acceptability level from the Phoenix study, which the Agency has acknowledged as the best of the four studies in terms of having the least noise in the preference study results and the most representative selection of participants. The EPA also notes the caveats discussed in the proposal regarding whether it would be appropriate to interpret results from the western studies as generally representative of a broader range of scenic vistas in urban areas across the country. The Policy Assessment noted significant differences in the characteristics of the urban scenes used in each study, with western urban visibility preference study scenes including mountains in the background and objects at greater distances, while scenes in the eastern study did not. Since objects at a greater distance have a greater sensitivity to perceived visibility changes as light extinction changes compared to otherwise similar scenes with objects at a shorter range, this likely explains part of the difference between the results of the eastern study and results of the western studies.

In the proposal, the EPA noted 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. Also, the Agency takes note of the caution expressed by Colorado and Arizona about using the results of the Denver and Phoenix preference studies, which were aimed at addressing specific local visibility problems, to inform the choice of level for a national standard. Therefore, the Agency considers it reasonable to conclude, especially in light of the significant uncertainties, that it is appropriate to place less weight on the western preference results and that the high CPL value (30 dv) that is based on the eastern preference results is likely to be more representative of urban areas that do not have associated mountains or other valued objects visible in the distant background. These areas would include the middle of the country and many areas in the eastern U.S., as well as some western areas. As a result, the EPA concludes that it is more appropriate to establish a target level of protection at the upper end of the range of 24-hour CPLs considered, recognizing that no one level will be "correct" for every urban area in the country.

(2) *Comment:* Several environmental groups provided comments stating that a 24-hour average would underestimate a 4-hour value by 13-42 percent and certain areas of the country—particularly the Northeast—would be affected disproportionately. These commenters suggested that a 24-hour $PM_{2.5}$ visibility index standard should be set at a

level of 18.6-20 dv.

Response: The EPA disagrees with these commenters that the EPA's approach for translating 4-hour CPLs into equivalent 24-hour values was inappropriate. The EPA has conducted a reanalysis (Frank et al., 2012b) of the relationships between estimated 24-hour and 4-hour visibility impairment based on the variety of metrics discussed in Appendix G of the Policy Assessment. The reanalysis has more appropriately considered the uncertainty of the calculated 24-hour and 4-hour values. The analysis in Appendix G of the Policy Assessment used the 4-hour light extinction value treated as the independent (x-axis) variable in an ordinary least squares regression. The EPA now concludes that this regression approach was not the most appropriate approach because that variable has error and in fact may be more uncertain than the calculated 24-hour extinction values. The Frank et al. (2012b) reanalysis uses an orthogonal regression instead of ordinary least squares regression and results in slopes closer to the 1:1 line for all the results, particularly for Dallas, TX. Furthermore, consistent with the EPA's conclusion that a higher multiplier for converting OC to OM would be appropriate (see section VI.C.1.b.ii above), the reanalysis substitutes a 1.6 multiplier for converting OC to OM in the calculation of 24-hour values instead of the value of 1.4 that was used in calculating 24-hour values for Appendix G. The higher multiplier is more consistent with the SANDWICH approach used to calculate the 4-hour values found in Appendix G. See Frank et al. (2012b) for a more detailed explanation.

The revised analysis shows that the 24-hour equivalent level is generally closer to the 4-hour value at the upper end of the range of CPLs than originally estimated, as can be seen in the results for Approaches B, C, and D presented in Frank et al., 2012b.[38] For example, the reanalysis indicates that Approach B (annual 90th percentile design values regression) yields an adjusted 24-hour CPL of 29 dv as generally being equivalent to a 4-hour CPL of 30 dv. In contrast, in Appendix G of the Policy Assessment, a 24-hour adjusted CPL of 28 dv was estimated to be equivalent to a 4-hour value of 30 dv under Approach B. Similarly, Approach C (all-days city-specific regression) yields a 24-hour equivalent CPL of 29 dv averaged across cities and a range of city-specific values from 25-36 dv in the reanalysis, whereas in Appendix G of the Policy Assessment, under Approach C, a 24-hour adjusted CPL of 27 dv was estimated to be equivalent to a 4-hour CPL of 30 dv when averaged across cities, and city-specific values were estimated to range from 24-30 dv. In the reanalysis, Approach D (all days pooled regression) generated results of 28 dv for the 24-hour CPL equivalent to a 4-hour value of 30 dv as compared to a value of 27 dv in the original analysis described in Appendix G.

As can be seen in the tables presented in Frank et al. (2012b), not only are the 90th percentile and pooled average values closer to the 4-hour CPL of 30 dv in the reanalysis, the range of city-specific results shows a wider spread that clearly encompasses the unadjusted 4-hour value of 30 dv near the midpoint of the city-specific range. This provides support for concluding that the EPA's approach to translating of 4-hour CPLs into equivalent 24-hour values was appropriate, and that it is appropriate to use

[38] Approach E as presented in the Policy Assessment is based on the median values for each city; these results are not affected by the regression analyses. Therefore, Approach E was not included in the reanalysis, and the results remain unchanged from those reported in the corrected Table G-6 as reported in Frank, et al., 2012b.

unadjusted 4-hour values for purposes of selecting a level for a standard based on a 24-hour averaging time.

(3) *Comment:* The Department of the Interior pointed to recent air quality data indicating that visibility on the 20% worst days in several large metropolitan areas, including Birmingham, Fresno, New York City, Phoenix, and Washington, DC was below 29 dv. While noting that these calculations were based on IMPROVE calculations which include contributions from coarse PM mass, DOI expressed the view that the proposed level of 28 to 30 dv would not provide adequate visibility protection compared to the current 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ and recommended that the standard be set at a level of 25 dv consistent with the results of the Phoenix visibility preference study.

Response: The EPA notes that the purpose of establishing NAAQS is to ensure adequate protection of public welfare from a national perspective, not to mandate continuous improvements in areas that may already be relatively clean. In fact, the evidence from the IMPROVE program cited by commenters indicating that many urban areas have total 24-hour PM-related light extinction below 29 dv on the 20 percent worst visibility days suggests that many areas have relatively good visual air quality already. Furthermore, 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.

(4) *Comment:* One group of commenters suggested that a 24-hour $PM_{2.5}$ Visibility Index standard of 28-30 dv would be equivalent to higher 4-hour values than suggested by the EPA in Appendix G of the Policy Assessment, and that individual areas such as Dallas, TX would have equivalent 4-hour values as much as 9 dv higher . They asserted that further insight into the differences in protectiveness of an unadjusted 24-hour standard could be found by examining Table G-5 in Appendix G of the Policy Assessment, which indicates that only 1 of 15 cities would exceed a 24-hour, 3-year 90th percentile standard at 30 dv . but that 5 of the cities would exceed 30 dv if light extinction were based on daily maximum daylight light extinction measured over 4 hours. (AMC, et al.)

Response: The EPA disagrees with these commenters that 24-hour light extinction in the range of 28-30 dv would be equivalent to 4-hour values as high as those presented by the commenters. The EPA has conducted a reanalysis (Frank et al., 2012b) of the relationships between estimated 24-hour and 4-hour visibility impairment based on the variety of metrics discussed in Appendix G of the Policy Assessment. The reanalysis has more appropriately considered the uncertainty of the calculated 24-hour and 4-hour values. The analysis in Appendix G of the Policy Assessment used the 4-hour light extinction value treated as the independent (x-axis) variable in an ordinary least squares regression. The EPA now concludes that this regression approach was not the most appropriate approach because that variable has error and in fact may be more uncertain than the calculated 24-hour extinction values. The Frank et al. (2012b) reanalysis uses an orthogonal regression instead of ordinary least squares regression and results in slopes closer to the 1:1 line for all the results, particularly for Dallas, TX. Furthermore, consistent with the EPA's conclusion that a higher multiplier for converting OC to OM would be appropriate (see section VI.C.1.b.ii above), the reanalysis substitutes a 1.6 multiplier for converting OC to OM in the calculation of 24-hour values instead of the value of 1.4 that was used in calculating 24-hour values for Appendix G. The higher multiplier is more consistent with the SANDWICH approach used to calculate the 4-hour values found in Appendix G. See Frank et al. (2012b) for a more detailed explanation.

Table 4 of the revised analysis shows that at the upper end of the range of levels considered (i.e., 30 dv) the 24-hour equivalent level for each city is generally closer to the 4-hour value of 30 dv. Moreover, the EPA notes that with OLS regression, the same regression equation ($Y = b_0 + b_1X$) should not be reversed—i.e. the same equation should not be used to estimate X from Y (Frank et al. 2012b). Thus the predicted 4-hour values constructed by the commenters are flawed because they used the regression equations presented by EPA in Appendix G of the Policy Assessment.

(5) *Comment:* One group of commenters suggested that, on the basis of estimated 4-hour average visibility data presented by EPA in Appendix H of the Policy Assessment, shifting to a 24-hour averaging time for a standard set a level of 28 dv would substantially reduce the protectiveness of the standard. The commenters claimed that this reduction in protection would particularly affect the Northeast, where 50% fewer counties would exceed a design value of 28 deciviews based on a 24-hour average as compared to a 4 hour daily maximum approach. According to the commenters, this indicates that a 24-hour standard in the range of 28-30 deciviews would be weaker than a 4-hour standard set at the same level and that certain areas of the country would be affected disproportionately. (AMC, et al.)

Response: The EPA notes that the illustrative 4-hour and 24-hr results presented in Tables H-1 and H-2 of the Policy Assessment were based on a two different methods. The 4-hr results were based on a method which used 2007-2009 monthly average speciation measurements in combination with hourly $PM_{2.5}$ data, used a 1.6 multiplier to estimate organic mass from $PM_{2.5}$ OC and only included counties with at least 2500 hours of $PM_{2.5}$ data. The 24-hr results were based on the method described in Appendix G which used daily speciation measurements and a 1.4 multiplier to estimate organic mass from $PM_{2.5}$ OC. A different data selection criterion was used for these 24-hr speciation measurement data. Thus the number of included counties is different, and more importantly, the presented illustrative data are not directly comparable.

Although the 24-hr results presented in Table H-2, as well as the 4-hr results presented in Table H-1, suggest that several Northeastern counties would exceed a visibility standard of 28-30 dv (even though they do not exceed the existing suite of secondary $PM_{2.5}$ standards, 15 ug/m3 annual and 35 ug/m3 24-hour), that comparison was based on 2007-2009 data. Since that time, the composition of $PM_{2.5}$ has significantly changed in the eastern U.S. due to massive reductions in SO_2 emissions and concomitant changes in $PM_{2.5}$ sulfate. As shown in Kelly 2012a and Kelly 2012b, all of the Northeastern counties would meet a 30 dv visibility index NAAQS, using 2008-10 data and using 2009-2011 data.

5. *Specific Comments on Visibility Preference Studies*

The evidence relied upon by the Administrator in determining an appropriate degree of public welfare protection from visibility impairment is predominately derived from a small number of urban-focused visibility preference studies. As a result, many comments were received on the adequacy and appropriateness of this limited dataset serving as a basis for the Administrator's judgments regarding what is requisite national protection for visibility impairment. Both CASAC and the EPA staff, as well as a few commenters, concluded that while limited, these studies did form a sufficient basis on which the Administrator could make a decision. A majority of commenters, however, expressed the view that the existing preference studies provide an insufficient basis for selection by the Administrator of an appropriate level of public welfare visibility protection for a national standard. These commenters highlighted a number of limitations and uncertainties associated with these studies as support for this view. Many of the important and fundamental comments are also discussed in the final rule, with further details provided below. As in the final rule, this section organizes and discusses the preference study comments under four broad topic areas, including: (a) limitations and uncertainties associated with the visibility preference studies; (b) preference study methods and design; (c) use of preference study results for determining adversity; (d) the appropriateness of using regionally varying preference study results to select a single level for a national standard.

a. Comments on Preference Study Limitations and Uncertainties

A large and diverse number of limitations and uncertainties associated with the visibility preference studies has been identified and discussed in the public comments. Many of these same limitations and uncertainties were also identified and discussed by the EPA in the various documents developed throughout this review such as the Integrated Science Assessment, Visibility Assessment, and Policy Assessment, as well as in the proposed rule (see section VI.b.2 beginning at 77 FR 38973, 38990) and in the final rule (section VI.C.1.e.i).

(1) *Comment:* Most commenters expressed concern over the small number of preference studies that are available in this review. In particular some note that these preference studies cover just four locations, only three of which occur in the U.S., that the two studies conducted in Washington, DC were pilot studies, not full preference studies, and/or that three of the preference studies were conducted in the West, while only one was conducted in the East, thus providing only limited geographic coverage. Typically these same commenters also noted the small number of survey participants, which totaled 852 across the four urban areas, which they assert are too few and unrepresentative nationally. These commenters thus concluded that there is insufficient information, both geographically and demographically, upon which to select a national level of a visibility index for purposes of visibility protection.

Response: The EPA notes that it is well aware of the limited nature of the information, which it has described in great detail in the Integrated Science Assessment, Visibility Assessment, and Policy Assessment, as well as in section VI.B.2 of the proposed rule (i.e., beginning at 77 FR 38973, 38990). The EPA further notes however that limited information does not preclude the Administrator from making judgments based on the best available science, taking into account the existing uncertainties and limitations associated with that available science. Thus, in reaching judgments based on the science, the Administrator appropriately weighs the associated uncertainties. The CASAC supported this view and concluded that the available information provided a sufficient basis on which the Administrator could form a judgment about requisite PM-related public welfare visibility protection. Specifically, CASAC stated "[t]he 20-30 deciview range of levels chosen by EPA staff as 'Candidate Protection Levels' is adequately supported by the evidence presented" (Samet, 2010b, p. iii). As discussed in the proposed rule (77 FR 38990), the Administrator recognized and explicitly took into account the uncertainties and limitations in the science in determining an appropriate degree of protection when she proposed a level at the upper end of the recommended range.

(2) *Comment:* Some commenters also made the point that the EPA relied on much of this same evidence to reach the conclusion in 2006 that the information was too limited to allow selection of a national standard. For example, API stated:

> [T]he bulk of the VAQ preference studies were available during the previous PM NAAQS review and were considered by the Agency in its establishment of the 2006 PM secondary NAAQS…. The Proposed Rule does not mention this fact and does not explain why many of these same studies now compel EPA to propose this new secondary NAAQS….The Proposed Rule notes in passing that, since the last review of the PM NAAQS, '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.' 77 Fed. Reg. at 38969/2. It is a serious oversight that the Proposed Rule makes no attempt to explain what that information is or how it affects the interpretation of the VAQ preference studies. This 'limited information' is an apparent reference to information provided by Dr. Anne Smith. (API, p. 37)

Response: The EPA disagrees with these commenters. First, the EPA disagrees that it failed to distinguish between studies that were available in the previous review (see discussion in section VI.A.1 of the proposal which specifically identifies the studies from Denver, Phoenix and British Columbia (77 FR 38967/2) as being considered in the last review). The EPA further disagrees with the implication that it is being circumspect about identifying the "limited information that has become available regarding the characterization of public preferences in urban areas." Beginning in section VI.A.3 of the proposed rule (77 FR 38969), the EPA was clear about what information, both preexisting and new, it relied upon in this review to inform its views and provide the basis for its proposal. In section VI.B.2 of the proposed rule, the EPA elaborates on the specific tools, methods and data which are considered in relation to the public preference studies, including the new information available since the last review.

In addition to the substantial PM urban air quality information and analyses new to this review, there are three other sources of information that have specifically "provided some new perspectives on the usefulness of" the preference studies "in informing the selection of target levels of urban visibility protection"(77 FR 38969), They include: (1) results from additional urban visibility preference study experiments conducted for Washington, DC by Smith and Howell (2009) which added to the preference data for that location, and shed light on the role of location in preference responses (77 FR 38974, 38976); (2) a review and reanalysis (Stratus Consulting, 2009) of the urban visibility public preference studies from the four urban areas, including the newly available Smith and Howell (2009) experiments which examined the similarities and differences between the studies and evaluated the potential significance of those differences on the study results (77 FR 38893, 389975-76); and (3) additional analyses, including most importantly a logit analysis (Deck and Lawson, 2010, as discussed in Chapter 2 and Appendix J of the Visibility Assessment), which was requested and reviewed by CASAC, which showed that each city's responses represented unique and statistically different curves (77 FR 38975-76).

Taken together, these sources contributed to the EPA's current knowledge and understanding of each survey study's results, the appropriateness of comparing each study's results to the others, and the key uncertainties relevant to data interpretation. In addition, in the last review the decision to not adopt a distinct secondary standard was remanded as contrary to law and failing to provide a reasoned explanation for the decision. As such it is not appropriate for purposes of comparison with the Administrator's judgment and reasoning in this review.

(3) *Comment:* Other commenters stated support for using the preference studies, concluding they provide an adequate basis, in spite of their limited nature. In particular, AMC et al. state:

> We believe that these studies provide sufficient results to inform setting a national visibility standard. While the number of studies is small, they do incorporate spatial variation and, in the case of Denver and Phoenix, varied populations…. EPA should have confidence, rather than uncertainty, in the fact that these studies used different methods and respondents and yield a range of 20 – 24 dv, with one outlier of 29. (pp. 6-7)

Response: The EPA agrees that these studies provide a sufficient basis to inform the Administrator's judgments regarding an appropriate level of protection from PM-related visibility impairment but she recognized that these studies, which are the only studies before her, are a limited source of information (see also response to (1) above). However, the EPA does not agree that the Washington, D.C. results represent an outlier, and thus the EPA believes these results are appropriately included in the range identified for the Administrator to consider.

(4) *Comment:* A number of other technical features of the studies were identified by commenters which they assert limit the usefulness of these studies in representing real world urban views and in eliciting appropriate preferences for urban visibility. For example, some commenters state that the assumption of light extinction at 550 nm is unsupported, technically flawed and invalid for a number of reasons, including that it does not account for the mix of pollutants, which varies substantially within and between urban areas, or how changes in that mix affect light extinction at different wavelengths of light, and it misses the role of sky discoloration from NO_2 and carbonaceous particles

(i.e., Brown Cloud phenomenon) which can be significant in urban areas and influence human perception of urban visibility impairment. Other commenters note that pollutant concentrations in urban areas are not uniform in all directions over the length of a line of sight and that visibility depends upon the site-path integrated concentration of fine PM. Studies which used photographic data capture the integrated site path. They further state that momentary glances at 2-dimentional pictures cannot represent the actual way that visibility is perceived outdoors.

Response: First, the EPA disagrees that its choice of measuring light extinction at 550 nm wavelength is 'unsupported, technically flawed and invalid'. The EPA's Integrated Science Assessment makes clear that 550 nm represents the "most sensitive portion of the spectrum for human vision" and has thus traditionally "been used to characterize light extinction and its components" (U.S. EPA, 2009a, p. 9-2). The ISA further states that "the convention for visibility monitoring purposes is to make measurement at or near 550 nm, which is the wavelength of maximum eye response" (U.S. EPA, 2009a, p. 9-8). The EPA therefore concludes that it remains logical to select a wavelength of light that is most relevant to human observers when evaluating impacts to the public welfare. Regarding the comment that 550 nm misses the impacts of NO_2 on sky discoloration, the EPA notes that this PM NAAQS review is intended to only address visibility impairment caused by particles present in the ambient air. Thus, while it is true that sky discoloration from NO_2 results from its ability to absorb more light in the short wavelength blue portion of the spectrum giving a yellow or brown appearance to the pollution layer or plume, improvement in the Brown Cloud Phenomenon is not the goal of this NAAQS review and would be expected to occur only indirectly from a secondary $PM_{2.5}$ NAAQS for visibility in as much as $PM_{2.5}$ controls also reduced co-emitted NO_2. The EPA further notes, however, that not every urban or other area suffers from the Brown Cloud Phenomenon. At background concentrations NO_2 absorption is generally less than five percent of the light scattering by clean air (Rayleigh scattering), making it imperceptible" (U.S. EPA, 2009a, p. 9-5) Regarding the comment that measuring light extinction using 550 nm "does not account for the mix of pollutants, which varies substantially within and between urban areas", the EPA disagrees, noting that the IMPROVE algorithm used to calculate light extinction was designed to specifically take into account the variability in the mix of pollutants from place to place and to measure the "photopic-weighted absorption efficiency at the 550 nm wavelength" in its calculations of PM-related light extinction. Thus, given the above, the EPA believes it is still appropriate to use the 550 nm wavelength in order to measure the maximum impact of ambient PM on light extinction that is perceptible to the human observer.

Second, with respect to the other technical issues raised above, the EPA agrees that photographic and WinHaze images cannot duplicate the outdoor, three dimensional viewing environment. This limitation of the preference study design does introduce some degree of uncertainty into the results. However, the EPA does not believe that this uncertainty significantly limits the usefulness of the results. People take pictures of aesthetically pleasing vistas so that they can look at them repeatedly, even though they are not exact replicas of their initial outdoor viewing experience. This shows that they appreciate the photographic view of the scene, commensurate with their appreciation with the scene itself. Thus, the EPA believes photos or digital images can be useful surrogates for the purpose of eliciting public preferences. Regarding the commenters other concern that pollutant concentrations in urban areas are not uniform in all directions over the length of a line of sight and that visibility depends upon the site-path integrated concentration of fine PM, the EPA notes that both the photos used in two of the preference study areas (Denver and British Columbia) and the WinHaze images used in two others (Phoenix and Washington, DC) depict visibility impairment over an integrated sight path. The difference between the two methods is that a photo can capture the non-uniformity across the sight path while the WinHaze views present a uniform haze integrated across the sight path. Photos of the Denver scene therefore would also have included any layered haze known as the brown cloud that was present at the time that fell within the integrated site path. Despite these variables, the ordering of the results of these studies appear to be explainable based predominantly on scene characteristics – i.e. people found impairment of the views with the most sensitive scene characteristics (Denver and Phoenix) more unacceptable at lower deciview values than those with less sensitive scenes (British Columbia and Washington, DC) regardless of the image depiction methods used. Thus, the EPA concludes that the concerns over study methods and designs identified by commenters are not substantial, and that the preference study results are still sufficiently informative to allow selection of candidate protection levels.

b. Comments on Preference Study Methods and Design

(1) *Comment:* Many commenters asserted that the methodologies used in the preference studies are fundamentally flawed. Most of these same commenters also pointed to an assessment of the preference study methodology conducted by Smith and Howell (2009) of Charles River Associates (CRA) as the basis for their views. These commenters criticized the EPA for not acknowledging that (in their view) the Smith and Howell results undermined the validity of the earlier preference studies. For example:

> Smith and Howell (2009) show that VAQ preference study outcomes are malleable and depend entirely on the design of the study. Accordingly, such studies do not identify any meaningful threshold of acceptable visibility conditions. Despite Smith and Howell's conclusions, EPA continues to assert that the VAQ preference studies can be used to identify minimally acceptable visibility conditions even though the Agency has never provided any valid scientific basis for discounting the Smith and Howell (2009) results. (API, p. 38)

> Well-controlled preference studies discussed by Anne Smith of Charles River Associates at the March 2010 CASAC meeting demonstrated that the judgment of panel members was affected by the order in which photographs were presented and tendency to identify the middle of the range of visibility degradation as a threshold of acceptability. This points to a potential flaw in these studies and that artifacts caused by these tendencies may have influenced study results. Dismissing these inherent flaws in the existing preference studies and then using these studies to set a secondary NAAQS is arbitrary and capricious. (API, attachment 14, p. 12)

> EPA also fails to acknowledge that the only study conducted since the last review

> rebuts the validity of the VAQ preference studies previously conducted. (UARG, Attachment 2. p. 28)

Response: As noted above, the EPA is aware of the issues raised regarding the uncertainties and limitations associated with the preference studies, including those associated with study methods and design and specifically solicited comment on how these uncertainties and limitations should be considered (see 77 FR 38990). However, as is explained in the following discussion, the EPA disagrees that the analysis by Smith and Howell (2009) supports the commenters' conclusion that the preference study methodologies and design were fundamentally flawed, however the EPA notes that their experiments do identify areas where additional research would be useful to further inform our limited understanding of public preferences in urban areas. Though still limited, the EPA views the Smith and Howell (2009) experiments as increasing the EPA's knowledge and understanding of the findings of the 2001 Washington, DC focus group pilot study (Abt, 2001) in several important ways. Smith and Howell (2009) conducted a series of three sets of experiments based on the 2001 Washington, DC, focus group pilot study. The first set of experiments (Test 1) was designed to replicate the 2001 focus group to explore whether the 2001 study findings could be reproduced. Tests 2 and 3 varied the range and distribution of visibility conditions to examine whether such changes would affect the results. As explained below, the EPA asserts that some aspects of the approach used by Smith and Howell (2009) in Tests 2 and 3 are flawed.

It is important to note as an initial matter, that while Smith and Howell (2009) claims to have replicated the Abt 2001 protocol, there were three distinct differences in the methods used by Smith and Howell (2009) and the methods used in the Washington, DC 2001 pilot study. First, the images of alternative levels of visibility degradation in Washington, DC were prepared and presented differently. While both studies used the same original photograph of Washington, DC, the 2001 images showing different levels of visibility degredation were prepared by John Molenar of Air Resource Specialists, Inc. (ARS) using the mainframe computer version of WinHaze available at that time. The 2009 Smith and Howell experiments, on the other hand, used images prepared in a more simple manner using the MS-Windows©-based version of WinHaze (Ver. 2.9.0) available by that time from ARS.

Second, the 2001 pilot study used high quality photographic transparencies ("color slides") prepared by ARS, which were presented on a large format, high quality projection screen. The entire group of participants was seated at the viewing angle and distance from the projection screen in a darkened room to provide the optimal viewing conditions recommended by John Molenar. The 2009 study used images presented to individuals on a large desktop computer monitor.

Third, the method used to recruit participants differed between the 2001 and 2009 studies. While a group of only 9 people can never be a statistically valid representative set of any population, the 2001 focus group participants were recruited by a professional focus group facilitation firm to reflect aspects of the demographic distribution of the Washington, DC metropolitan area adult population. The recruitment screening method was designed to obtain 9 adults resembling major aspects of the demographic gender, age, residence and income distribution of the Washington, DC area. At least two of the 2001 participants were in each of the following groups: a) Income: at least two people with household incomes under $25k, two with incomes between $25k and $60k, and two with incomes above $60k; b) Age: at least two between the ages 18 and 25, two between 26 and 55, and two over 56; c) Race/Ethnicity: at least two African Americans and two Hispanics; d) Residence location: at least two living in each of Washington, DC, Maryland and Virginia. In contrast, the Smith and Howell (2009) study did not use a structured recruitments process. Due to the schedule of the Smith and Howell (2009) study, all study participants were employees of CRA, Inc. (where both Smith and Howell are also employed). One variant of Test 1 was conducted with participants who work at the CRA Washington, DC office (and who presumably live in the Washington, DC area). The other variant of Test 1 was conducted with participants from the CRA Houston office (and likely live in the Houston area). The same set of images of Washington, DC was shown to both the CRA Washington and Houston participants.

In spite of these differences in study methods, the Test 1 results (Smith and Howell, 2009, p.11) found a "…remarkable degree of replication, given the differences in the samples, and the relatively small sample size of the Abt pilot (nine people)." Furthermore, the preferences for Washington, DC visibility provided by the Houston participants were effectively the same as both the preferences of the CRA Washington office participants and the Abt 2001 participants.

The EPA identified a number of important implications from the similarity between the Test 1 (2009) and 2001 study results.

1. The change in the presentation methods (i.e., from slide projection to computer monitor, and mainframe WinHaze images versus the simpler Windows WinHaze method) shows no evidence of impacting reported preferences.

2. The replicability of the 50% acceptable criteria results supports a hypothesis that the 2001 results, although based on a small sample of 9, were consistent with the preferences from a larger sample of the general Washington, DC population.

3. The similarity of the Test 1 Houston results to both the Test 1 Washington results and the 2001 Washington study suggest that an individual's preferences for visibility in one location (i.e., Washington, DC) may not depend on whether they live in that location or in another.

As a result of the similarity between the results of these two DC studies and the above implications, the EPA concluded that the Test 1 experiment could legitimately be combined with the 2001 study to effectively more than triple the responses to the original Washington, DC urban visibility preference study, thus increasing the available information from 9 (in the 2001 study) to 31 (with the addition of both the Washington, DC and Houston CRA participants). Smith and Howell's Test 1 thus instigated a shift in the EPA's thinking regarding the usefulness of the available Washington, DC preference study data.

The Smith and Howell (2009) Tests 2 and 3 also provided important information relevant to understanding the results of visibility preference studies. In Test 2 and 3 the range and distribution of visibility conditions shown to participants were substantially different than the range and distribution shown in Test 1 and the 2001 Washington, DC study. Test 2 removed from the range of Test 1 slides those that showed the 11 worst visibility conditions (all images above 27.1 dv). Test 3 changed the visibility conditions presented in two ways: first, the number of clean or cleaner images were reduced substantially, dropping all images in the lower third of the distribution, and adding two new images of substantially worse visibility (42 and 45 dv), which were substantially above the previous worst scene shown (38.3 dv).

Smith and Howell (2009) found that changing the range of visibility images shown has a pronounced impact on the resulting 50% acceptability level. They concluded that this is an indication that preferences obtained using the general PS method are not stable, and therefore not an accurate representation of the populations pre-existing (or "true") preferences for visibility.

While the Smith and Howell (2009) results suggest such a hypothesis, the Test 2 and Test 3 results also are consistent with a very different effect in visibility preference survey results. The range of visibility conditions shown in Test 1 and the original 2001 Washington, DC study were selected by EPA to present a good representation of the distribution of visibility conditions expected to occur in Washington, DC with then-current EPA air quality regulations. In other words, the original range and distribution of visibility conditions shown to the participants were near to current conditions, and reflected the "policy relevant" range of expected conditions. This fundamental approach was used in all the existing studies (i.e. Denver, Phoenix, and British Columbia); the range of visibility conditions reflects current real world conditions. While the participants were not informed that the images they were being shown were essentially then-current conditions, the range of images would have been consistent with the participants own experiences.

When the range of images presented was substantially different, as in Tests 2 and 3, the participants would very likely recognize that the conditions did not depict the real range of conditions. This creates a disconnect between the participants' own experiences and expectations and the hypothetical scenario being presented to them through the use of the altered ranges. This creates a form of the well known "scenario rejection bias" that has been observed in many types of stated preference studies. Current methods of stated preference research on a range of environmental issues find it is very important to present as realistic and believable a description as possible of the real world conditions matching to participants' personal experience and knowledge in order to produce robust, stable and reproducible results. The effect Smith and Howell (2009) see in their Test 2 and Test 3 methods are likely to be due to just such a scenario rejection biasing influence.

Thus, on the basis of the above discussion, the EPA disagrees that the findings of Tests 2 and 3 in Smith and Howell (2009) make the case that the methodology used in the preference studies is fundamentally flawed and therefore disagrees with commenter views that the EPA's use of these studies is somehow inappropriate, scientifically unsound, or arbitrary and capricious.

(2) *Comment:* Many commenters also asserted that preference study participants were not given guidance on how to interpret the concept of "acceptable urban visibility". This lack of guidance was considered a detriment by commenters because in their view it renders the responses subjective.

Response: EPA notes that while the overall method used in all the preference studies is consistent (based on the method and elicitation protocol developed by Ely et al., 1991 in the Denver study), each study developed a specific protocol (including the specific language on both background information and the wording of the key questions) for conducting that study's survey. The Denver and Phoenix studies each gave the survey participants specific guidance on interpreting "acceptability".

The Denver study framed the question in the explicit context of setting an urban visibility standard for Denver, and instructed the participants that they were being asked to identify the VAQ that in their opinion should violate an urban visibility standard, and that "…standard violations should be VAQ that is unreasonable/objectionable, and unacceptable visually. Participants were asked to discern 'how much haze was too much', not to indicate standard violations based on whether haze was detectable unless any amount of haze was more than they could accept" (Ely et al., 2001, p. 6-7).

The Phoenix study instructions to participants defined acceptable (or unacceptable) as "Consider 'unacceptable' as visual air quality that is unreasonable or objectionable visibility. Please do not mark a slide 'unacceptable' just because you can see some haze, unless you believe that any amount of haze is more than you would tolerate."

The British Columbia study (Pryor et al., 1996) followed the survey protocol in the Denver survey closely, and gave similar guidance to the participants on the meaning of "acceptability" in a standard setting context.

The Washington, DC (2001) study was a focus group designed to investigate a series of issues involved with conducting group interview type surveys about preferences for urban visibility. A key feature of the 2001 focus group script was to deliberately not give the participants guidance on how to interpret "acceptable" or "unacceptable" before rating the series of Winhaze images. After the series questions involving rating the images, the focus group moderator lead a discussion about how the participants interpreted the term "acceptable", and what issues and information they considered in forming their responses. The 2009 series of Washington, DC urban visibility preference experiments followed a similar procedure, although apparently conducted a more abbreviated focus group follow-on discussion.

Thus, the EPA believes that study participants were given sufficient direction and context so that they could understand the nature of the questions being posed and were all on equal footing in developing subjective judgments regarding "acceptable" and "unacceptable" visual air quality. Since the goal of these studies was to elicit personal preferences, which by very nature are subjective, the EPA does not view the subjectivity of the responses as a weakness of the study design or protocols.

c. Comments on Preference Study Results and Adversity

A number of comments were received regarding the EPA's use of preference study results to make the determination that adverse $PM_{2.5}$-related visibility effects on the public welfare are occurring. Some of these commenters questioned whether the EPA had made the case that unacceptable levels of visual air quality based on preference study results alone can be equated with an adverse public welfare effect. Other commenters questioned the EPA's selection of the 50% acceptability criterion as the appropriate benchmark for determining adversity.

(1) *Comment:* Several commenters asserted that the EPA had not made a sufficient case for the occurrence of adverse public welfare effects in association with ambient levels of $PM_{2.5}$:

> Thus, EPA seemingly was building the foundation for a determination of what constitutes an adverse effect on visibility in the context of public welfare. However … EPA subsequently veered toward an oversimplified focus on public acceptance of visibility conditions…. EPA's discussion of visibility in the Policy Assessment and its proposed rule in the Federal Register focuses entirely on "acceptable" and "unacceptable" visual air quality and make no mention of an "adverse effect" in the context of visibility. EPA's reliance on only 3 urban preference studies represents a paucity of data and a wholesale abandonment of any effort to seek a scientifically measurable adverse effect. (Kennecott Utah Copper LLC, p. 26)

These commenters suggested that unless preference study information is linked to personal comfort and well-being or other associated welfare effects, it cannot form the basis of a determination of adversity.

Response: The EPA first notes that the definition of effects on welfare included in section 302(h) of the CAA identifies both visibility and the broader category of effects on personal comfort and well-being as effects on welfare. In setting a secondary standard to address visibility impairment, the EPA considers the effect on the public from impairment of visibility as a separate and distinct welfare effect in its own right. The EPA is not required to translate this into terms of personal comfort and well-being, as visibility impairment is designated explicitly by Congress as an effect on welfare. While there may be a large degree of overlap among these different welfare effects, the EPA properly focuses on evaluating all of the information before the Agency on the effect visibility impairment has on the public, whether or not this impairment would also be categorized as having an adverse effect on personal comfort and well-being. It is in the context of all of this information that the EPA makes the judgment as to the appropriate degree of protection from known and anticipated adverse effects on the public from visibility impairment. The EPA recognizes that there is uncertainty about the degree of adversity to the public welfare associated with PM-related visibility impairment. However a secondary standard is designed to provide protection from "known or anticipated" adverse effects, and a bright line determination of adversity is not required in judging the requisite degree of protection under section 109(b)(2). Furthermore, the EPA disagrees that it has abandoned its consideration of visibility-related impacts on the welfare effect of personal comfort and well-being, as is made clear in the following quote:

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 (U.S. EPA, 2009a, section 9.2.4). ***Though it is not known to what extent 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 well-being.''*** (77 FR 38973/1, emphasis added)

The approach taken to address such qualitative, but policy-relevant, information in this review is the same as in other NAAQS reviews. The review is initiated with a comprehensive assessment of all possible public health and welfare effects associated with PM in the Integrated Science Assessment. Then policy-relevant effects for which there is sufficient quantitative information to allow a determination of the change in risks associated with incremental changes in air quality are assessed (in this review, in the Visibility Assessment) and used to provide a quantitative basis to inform the selection of an appropriate range of levels for further consideration in the Policy Assessment. In the Policy Assessment, the EPA considers all important policy-relevant evidence and information, both quantitative and qualitative, in making recommendations regarding the range of policy options appropriate for the Administrator to consider. It is in the context of all of this information that the Administrator makes her final judgment as to the appropriate degree of protection from known and anticipated adverse effects on the public from visibility impairment..

(2) *Comment:* Another issue raised in the comments regarding adversity is the EPA's decision to use the 50 percent acceptability criterion from the public preference studies in determining candidate protection levels of visibility impairment for the selection of a national level of visibility protection. For example, AMC et al. recommended "a 75% acceptability criterion as a target that is in line with protecting the broader public from the negative effects of visibility impairment" (AMC, et al., p. 9).

Response: In the Visibility Assessment, the EPA noted that the use of the 50 percent acceptance level for urban visibility was first presented in Ely et al. (1991) (U.S. EPA, 2010b, p. 2-5). Ely discussed the use of the 50 percent acceptability criterion as a reasonable basis for setting a standard to protect visibility in urban areas.

> The standard was determined based on a 50% acceptability criterion, that is, the standard was set at the level of extinction that would divide the slides into two groups: those judged acceptable and those judged unacceptable by a majority of the people in the study. The criterion is politically reasonable because it defines the point where a majority of the study participants begin to judge slides as

> representing unacceptable visibility. It is also consistent with psychological scaling theory which indicates that a "true score" exceeds a standard when more than 50% of the "observed scores" exceed that standard. (Ely et al., 1991, p. 11)

As Ely described, the 50 percent acceptability criterion and the preference study conducted by Ely were used as the basis for setting the level of the Denver Visibility Standard in 1990. That same criterion was judged appropriate and selected for use in the Phoenix preference study (BBC research, 2003) and was also used as the basis for setting the level of the Phoenix Visibility Standard in 2003. Most recently, the 50 percent acceptability criterion has been recommended by the British Columbia Visibility Coordinating Committee as the basis for the visibility standard currently under consideration by British Columbia, Canada. Furthermore, CASAC supported this approach, while recognizing the uncertainty associated with this issue. Specifically, CASAC agreed that "the 50th percentile for the acceptability criteria is logical, given the noted similarities in methodologies employed in the 4 study areas. … In terms of choosing a specific percentile from the preference studies, we note that there may not be a "preferred" one, but in assessing preference studies to propose a PM secondary NAAQS, the 50th percentile is sufficient, as it is the basis for existing visibility indexes used in the Denver/Colorado Front Range and Phoenix metropolitan areas" (Samet, 2009c, pp. 8-9). Therefore, after considering the information that served as the original basis for its selection as described in Ely et al., 1991, and given its acceptance and use in existing visibility programs, the EPA continues to conclude, consistent with the advice of CASAC, that it is reasonable to use the 50 percent acceptability criterion in determining target levels of protection from visibility impairment.

d. Comments on Using Preference Studies as Basis for Nationally Uniform Standard

A number of commenters raised concerns regarding the bases for and implications of the differences observed in the preference study results, concluding that these results were due to regionally varying factors and thus could not be used to set a national standard.

(1) *Comment:* Some commenters asserted that because the confidence intervals around the four 50 percent acceptability levels do not overlap at all, and because there are variations in preference study designs and inherent differences in the visual setting among cities and panels, the four preference curves and their associated 50 percent dv values are city-specific and statistically different. The commenters concluded, therefore, that it was inappropriate to aggregate the 50th percentile dv values from multiple studies and that they should instead be evaluated individually. Similarly, other commenters expressed the related view that the preference study results cannot be used to set a national standard for visibility impairment because the results show that visibility preferences vary regionally and/or locally for a variety of reasons. For example:

> The 'one-size-fits-all' approach…is not viable because it does not account for regional and city-specific factors that have been made evident in the disparity of preference study data…. It is well known, for example, that the level of light extinction to which people in different areas of the country are accustomed, as well as the urban setting, are the primary factors that affect a person's visual

> perception of an urban vista. Thus, the degree to which extinction threshold can be related to human welfare is inevitably regionally-dependent. (API, Attachment 2, p. 4)
>
> [T]he proposed method falls short because it is not temporally or geographically representative enough to have any meaning…. The uncertainty evidenced in these studies and the non-uniformity between the western and eastern vistas makes it impossible at this time to set an acceptable light extinction value that would appropriately address visibility concerns in non-Class I areas. (New York DOH/DEC, pp. 5-6)

These commenters suggest that the basis for the differences in preference study results include regionally varying preferences for acceptable visual air quality and/or regionally varying factors, such as relative humidity and other differences between Eastern and Western areas. These commenters asserted that it would be more appropriate to develop distinct visibility standards at the state or local level, since it is not possible to select a single level for a national standard to protect visibility across the United States that provides the appropriate degree of protection in locations with distinct characteristics, including areas which lack "important visibility vistas" that might not need standards at all, since flat areas without significant terrain have a limited maximum visual range. (NEDA/CAP, p. 3)

Response: The EPA agrees that the preference curves and the 50 percent dv levels are separate and distinct data points representing four different VAQ preference curves for four unique urban scenes. However, the EPA does not consider the fact that the four curves are distinct as a weakness of the approach or a reason that the results cannot be compared. In addition, the EPA does not agree that the study results necessarily support a conclusion that preferences are regionally dependent. In particular, the EPA notes that the results of Smith and Howell (2009) which show that participants in Houston and Washington, DC did not have significantly different views on acceptable air quality in Washington, DC, provide limited support for the conclusion that people's preferences differ less because of where they live and more because of the scene they are viewing.

The existing literature indicates that people's preferences for VAQ depend in large part on the characteristics and sensitivity of the scene being viewed. The EPA also understands that there is a wide variety or range of urban scenes within the United States. These sensitive urban scenes include those with natural vistas such as the Rocky Mountains in Colorado as well as those with iconic man-made urban structures like the Washington Monument. The EPA believes that the scenes presented in the four urban areas include important types of sensitive valued urban scenes and therefore, when considered together, can inform the selection of acceptable urban VAQ at the national scale, taking into account the variation across the country evidenced in the studies.

In response to the comments that there are factors that vary regionally that are important to take into account when setting a national standard for visibility protection, the EPA agrees, and notes that it has clearly taken these into account. Section VI.A of the preamble to the final rule regarding the history of the secondary PM NAAQS review discusses the evolution of the EPA's understanding regarding the regional differences in PM concentrations, relative humidity and other factors. As a result, the current review has gone to great lengths to address these factors, leading to the EPA's proposal to use the IMPROVE algorithm to calculate light extinction in order to take into account the varying effects of relative humidity and speciated PM. While this approach does not result in a uniform level of ambient $PM_{2.5}$, it does ensure a nationally uniform level of visibility protection. The EPA refers the reader to other sections of the final rule, including sections VI.B.1.a, VI.B.1.c, VI.C.1.b and VI.C.1.f, and other sections of the Response to Comments document for a more detailed response as to how it is taking these variables into account.

(2) *Comment:* The Arizona DEQ stated that it was inappropriate to use the Phoenix study for purposes of establishing a level for a national standard:

> The proposed secondary visibility standard does not integrate our measurement method or mirror our index scale, essentially making the program incomparable with the proposed standard. Four urban visibility studies were cited in the proposed rule as a consideration in developing the level of the secondary $PM_{2.5}$ standard. The recommended level for the proposed standard, 28 or 30 deciviews, and corresponding calculation method excludes extinction by coarse particulate matter and Rayleigh scattering. The cited studies were conducted considering total light extinction; including extinction resulting from particulate matter and Rayleigh scattering. Visibility impairment due to coarse particulate matter can be an important contributor in Arizona, specifically in the Phoenix area where ongoing measurements have been made. Therefore, ADEQ believes that the proposed levels of the secondary visibility standard are inconsistent with applicable urban studies. (Arizona DEQ, p. 2)

Response: The EPA understands that each of the four preference study areas has a different mix of pollutants and that across the studies a variety of methods for measuring and linking ambient PM concentrations to images (either photos or WinHaze) of differing haze levels at a given urban scene were employed. However, as discussed above section IV.B.5.a, the EPA conducted a detailed assessment (77 FR 38893, 77 FR 38974-75) of the differences and similarities that existed between the four studies and concluded that it was still appropriate to compare them and consider their results together. The CASAC also reached the same conclusion (Samet, 2010b, iii). In regard to the commenter's concern about contributions from coarse particles and Rayleigh, the EPA further notes that participants in the Phoenix and other studies were not asked to break out their preferences based on how much of the haze was caused by contributions from coarse particles, Rayleigh scattering or fine particles. Instead, as discussed above in section IV.B.5.b, Phoenix study participants were simply asked to identify levels of visual air quality that they would consider "unreasonable or objectionable", no matter what the source. Based on this information, Phoenix was able to come up with a target level of VAQ, even though pollutant mixes vary temporally and spatially, even within the Phoenix urban area. Since the goal of the secondary $PM_{2.5}$ NAAQS is to provide a uniform national level of public welfare protection from $PM_{2.5}$ related visibility impairment, the form of the EPA's proposed secondary standard was selected to allow each area to achieve that level of protection in a way that addresses its own unique mix of contributing pollutants. Therefore, the EPA disagrees with the commenter that it is inappropriate to use the results of the Phoenix study to inform a range of candidate protection levels for consideration by the Administrator in selecting a national level of visibility protection. Instead, the EPA believe the Phoenix results form an important data point that shed light on public preferences for visibility in western areas with urban scenes that include distant mountains.

(3) *Comment:* Similar to comment (2) above, Colorado DPHE expressed concern with the EPA's use of the Denver study results in a national context. In particular the commenter states:

> The proposed secondary visibility standard relies in part on the Denver urban visibility standard as supporting justification for establishing a new secondary standard. However, the Denver visibility standard was originally developed in 1989 in response to a bipartisan directive from the legislature to meet a statutory deadline of January 1990 for a standard based solely on aesthetics. The Denver visibility standard, set at about 20 deciviews (32 miles or 0.076/km), was based on a survey of 214 Denver citizens that evaluated 25 slides of the 'Brown Cloud', a publically understood name for the strong inversions that occur in the Denver metropolitan area. These slides were specifically referenced to data obtained using a transmissometer. Thus, this standard is based on a specific view of Denver and specific transmissometer location and path and is applicable only to this location. This constitutes a limitation with its applicability to a national secondary standard, particularly a proposed standard that does not use a direct measurement method. ... Visibility from year to year is highly variable…. [A]dditional studies are necessary to establish a secondary NAAQS standard, or what might ultimately become multiple standards, across the United States" (Colorado DPHE, p. 2-3).

Response: The Colorado comment raises some of the same concerns as the Arizona comment and the EPA refers the reader to its response to comment (2) above. In addition, this commenter states that the visibility standard is "based solely on aesthetics". This is not a significant difference with the proposed secondary visibility PM NAAQS. While qualitative information was also available regarding personal comfort and well being, the proposed range of levels considered by the Administrator was derived from the quantitative information regarding public preferences for the aesthetic quality of the urban view. This commenter also points out that the slides presented to the study participants included images of the Brown Cloud that occurs under conditions of a strong inversion. The EPA notes that while this condition does not happen everywhere, there are other urban areas that experience it and therefore preference information that takes such a phenomenon into account provides useful information for the Administrator to consider. The commenter further notes that "this standard is based on a specific view of Denver and specific transmissometer location and path and is applicable only to this location." In spite of this, however, the EPA observes that Denver still went ahead and established a standard that applies to the entire metropolitan area, even though there are many other views and paths that could be evaluated. Likewise, the EPA believes it is possible to select a national level of visibility protection based on a variety of disparate data points for urban visibility preferences, because when taken together, they provide useful information regarding the range of scene and site characteristics that can influence public perception of acceptable VAQ. While the EPA agrees that additional studies would be helpful and provide more useful data points to consider, it does not agree that they are necessary to establish a secondary standard.

6. Need for a Distinct Secondary Standard

a. Comments Supporting a Distinct Secondary Standard

(1) *Comment:* Some tribal commenters who supported the proposal to set a distinct standard to protect visibility expressed concern about the urban focus of the proposed secondary standard for visibility, and urged the EPA to focus on visibility protection in rural areas as well. Specifically, they urged the EPA to conduct additional preference studies in rural areas, and to expand monitoring in Tribal regions to obtain more information on visibility impairment in rural locations.

Response: The EPA agrees with these commenters that it is important to provide protection against PM-related visibility impairment in both urban and rural areas, and that it would helpful to have additional preference study data from more locations, including rural locations. However, with regard to the commenters' assertion that the proposed secondary standard for visibility would neglect rural areas, the EPA disagrees. The EPA has considered both urban and rural areas, and has focused on urban-related visibility impairment for a reason. CAA section 109(b) requires the Agency to establish *national* standards to protect the public welfare, which means that the NAAQS are designed to protect against adverse impacts in both urban and rural areas. In the case of visibility, the EPA has also recognized that the Regional Haze Program under sections 169A and 169B of the CAA specifically targets visibility protection in Federal Class I areas, most of which are in remote (rural) areas. The goal of the Regional Haze Program is to address all man-made impairment of visibility, and the program specifically targets the widespread, regionally uniform type of haze caused by a multitude of sources. Over time, the Regional Haze Program will provide a level of protection of visual air quality in Class I areas that extends far beyond the level of protection envisioned for a secondary NAAQS under section 109(b). The EPA notes that any national ambient air quality standard for visibility would be designed to work in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in all areas of the country, including urban, non-urban, and Federal Class I areas. While the Regional Haze Program is focused on improving visibility in Federal Class I areas and a secondary visibility index NAAQS would focus on protecting visual air quality principally in urban areas, both programs could be expected to provide benefits in surrounding areas. Thus, in considering a distinct standard to protect visibility impairment under the NAAQS program, the EPA focused particular attention on areas not already covered by the Regional Haze Program. This led to a focus on urban air quality as a means of ensuring adequate protection of visibility in all locations (i.e. as a supplement to the protection already afforded by the Regional Haze Program).

b. Comments Opposing a Distinct Secondary Standard

(1) *Comment:* A number of commenters opposed setting a distinct secondary standard to protect visibility on the grounds that existing regulatory mechanisms are adequate to protect urban visibility. According to these commenters, the combination of urban-oriented PM control programs and long-term regional haze strategies will effectively protect visibility and urban visibility will improve over time without a separate visibility NAAQS. These commenters urged the EPA to wait for implementation of the Regional Haze Program to achieve visibility improvements and then re-assess whether a secondary standard for visibility is warranted.

Response: While the EPA has determined that a distinct secondary standard to protect against visibility impairment is not needed at this time, this decision was based on the degree of protection afforded by the existing secondary $PM_{2.5}$ standards, particularly the secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$. The Regional Haze Program has more ambitious goals to be implemented over a longer time period (i.e., to eliminate all man-made impairment in visibility by 2064), and is focused primarily on remote (Federal Class I) areas. Therefore, it would not be appropriate to rely solely on that program to protect visibility in all areas across the country as required by CAA section 109(b) or to wait for the Regional Haze Program to be implemented before evaluating what additional protection might be needed for non-Federal Class I areas. The EPA continues to emphasize that the secondary PM NAAQS is designed to work in concert with the Regional Haze Program to afford the requisite degree of visibility protection in all areas.

(2) *Comment:* Some commenters urged the EPA to delay setting a distinct secondary standard for visibility pending the establishment of a pilot program to gather additional data. For example, NY State Departments of Health and Environmental Conservation stated that while they support the promulgation of a secondary standard to protect visibility, they "have serious concerns with the proposed method as it fails to be temporally and geographically representative of real-world visibility. EPA should establish a pilot measurement development program to identify methods that would more accurately measure and report real-time visibility conditions to the public" (New York DOH/DEC, p. 2).

Response: While acknowledging the uncertainties and limitations associated with the information available in this review, the EPA continues to conclude, as did CASAC, that this information provides a sufficient basis for selecting a target level of protection for visibility in this review. Thus, the EPA disagrees with these commenters that the uncertainties are so significant as to preclude establishing a standard at this time.

(3) *Comment:* Numerous commenters questioned whether a distinct secondary standard for visibility is necessary in light of the EPA's own analysis as presented in Kelly et al. (2012a) which indicated that a 24-hour mass-based $PM_{2.5}$ standard of 35 $\mu g/m^3$ would protect against visibility impacts exceeding the range of levels considered in the proposal (28-30 dv). Many commenters pointed to this analysis in support of their argument that a visibility index standard in the range proposed (28-30 dv) would provide no additional protection beyond that afforded by the existing secondary 24-hour $PM_{2.5}$ NAAQS, and

therefore no distinct secondary standard to protect visibility was necessary. These commenters advocated retaining the current 24-hour $PM_{2.5}$ mass-based standard to protect against visibility effects. "Since the 24-hour $PM_{2.5}$ standard already protects the welfare the 24-hour $PM_{2.5}$ visibility standard is designed to protect, the new standard is duplicative and unnecessary" (South Dakota DENR, p. 2). Michigan DEQ agreed, stating it believed "that the visibility index is an unnecessary standard and that the 24-hour $PM_{2.5}$standard should be used as a surrogate for evaluating visibility" (Michigan DEQ, p. 2).

Response: The EPA agrees with commenters that Kelly et al. (2012a) indicates that the existing 24-hour $PM_{2.5}$ standard provides *at least* the target level of protection for visual air quality defined by a visibility index set at 30 dv, averaged over 24-hours, with a 90th percentile, 3-year average form, which the EPA judges appropriate. While the Kelly et al. (2012a) analysis was conducted in support of proposed implementation requirements for a distinct secondary standard (specifically, the modeling demonstrations that would be required under the PSD program), the second prong of the analysis suggested that the 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would be controlling relative to a standard based on a visibility index set at 30 dv. Kelly et al. (2012a) concluded that the "overall, design values based on 2008-2010 data suggest that counties that attain 24-hour $PM_{2.5}$ NAAQS level of 35 $\mu g/m^3$ would attain the proposed secondary $PM_{2.5}$ visibility index NAAQS level of 30 dv" (pp. 17-18).

Importantly, the analysis performed by Kelly et al. (2012a) provides an area-by-area comparison of the relative degree of protectiveness of the existing secondary 24-hour $PM_{2.5}$ standard and the proposed distinct standard for visibility. This analysis confirms that for each area examined, it is highly likely that a standard of 35 $\mu g/m^3$ would provide as much or greater protection than a standard based on a visibility index set at 30 dv. Based on 2008-2010 data, it appears that there are no areas that would have exceeded a 30 dv, 24-hour visibility index standard that would not also have exceeded a 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$. Stated another way, all areas that met the 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would have had visual air quality at least as good as 30 dv (24-hour average, based on 90th percentile form averaged over 3 years). The Kelly analysis also shows that for some areas, particularly in the West, areas that would have met a 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would have had visual air quality better than 30 dv for the $PM_{2.5}$ visibility index standard, and that at sites that violated both the 24-hour level and the secondary visibility index 30 dv level, the visibility index level of 30 dv would likely be attained if $PM_{2.5}$ concentrations were reduced such that the 24-hour $PM_{2.5}$ level of 35 $\mu g/m^3$ was attained.

Moreover, the EPA has conducted a reanalysis (Kelly et al., 2012b) that confirms the results of the original Kelly et al. (2012a) memo. This reanalysis updates the area-by-area analysis in Kelly et al. (2012a) in three respects. First, noting that the original Kelly et al. (2012a) analysis used a 1.4 multiplier to convert OC to OM at those monitors not using the new CSN monitoring protocol, the EPA recalculated the visibility index design values for 2008-2010 using a higher multiplier for converting OC to OM at monitors not already using the new CSN monitoring protocol SANDWICH approach, consistent with the Agency's view that it is more appropriate to use a multiplier of 1.6 at such monitors as compared to 1.4, as described in section VI.C.1.a.ii of the preamble to the final rule and discussed in response to comments on indicator in section IV.B.1, above. The recomputed visibility design index values for 2008-2010 show the same overall relationship to 24-hour $PM_{2.5}$ design values as presented in Kelly et al., 2012a.

Second, the EPA repeated the calculations comparing visibility index design values with 24-hour $PM_{2.5}$ design values using 2009-2011 data, the most recent three years of air quality information currently available. Third, the EPA modified the area-by-area evaluation to ensure consistency with the data completeness criteria of 40 CFR part 50, Appendix N, including the removal of data approved by EPA as exceptional events, for the current 24–hour $PM_{2.5}$ standard and the proposed visibility index standard.

The results of this reanalysis, as presented in Kelly et al. (2012b), show a similar pattern to that described in the original Kelly memo. Specifically, the analysis indicates that there were no areas with visibility impairment above 30 dv that did not also exceed the secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$. The updated memo concludes that the results for 2009-2011 corroborate the findings for 2008-2010.

Based on these analyses (Kelly et al., 2012a; 2012b), the EPA concluded with a high degree of confidence that having air quality that meets the 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would be sufficient to ensure areas would not exceed 30 dv.

However, the EPA also recognizes that it is important to evaluate whether such a standard would be over-protective (i.e. more stringent than necessary to protect public welfare). The analyses presented in Kelly et al. (2012a; 2012b) indicates that the 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would achieve *more than* the target level of protection of visual air quality (30 dv) in some areas. That is, when meeting a mass-based standard of 35 $\mu g/m^3$, some areas would have levels of PM-related visibility impairment far below 30 dv. Thus, when considered by itself and without consideration of the secondary standards adopted for purposes of non-visibility welfare effects, the 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would be over-protective of visibility in some areas. However, it is important to note that as long as the current secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ remains in effect, this overprotection for visibility would occur, regardless of whether a distinct secondary standard based on a visibility index set at 30 dv were adopted. These issues are discussed more fully in section VI.D of the preamble which outlines the Administrator's final conclusions on the secondary PM standards.

(4) *Comment:* A number of commenters noted that the proposed secondary standard for visibility would not offer significant additional protection beyond the primary standard and yet would place an additional burden on states charged with monitoring and complying with the standard. These commenters objected to the additional resource burden associated with implementing a standard which had, in their view, no practical effect: "If the 24-hour $PM_{2.5}$ mass standard has the same effect as the visibility standard, crafting complex regulations to implement another standard seems redundant" (South Carolina DHEC, p. 3). Other commenters agreed: "A $PM_{2.5}$-related Visibility Index appears redundant since the benefits achieved from the current primary and secondary annual and 24-hour $PM_{2.5}$ standards already provide reductions that would improve

visibility. Establishing a new $PM_{2.5}$ secondary standard for visibility would be an additional complication and burden to the states that is not warranted" (Indiana DEM, p. 5). Similarly, Florida DEP argued that "While urban visibility is indeed a welfare issue, the standard as proposed would require unwarranted resource efforts to verify, validate and calculate the visibility parameters, complete the designation process, and revise the State Implementation Plan (SIP). These efforts would be fruitless in 49 states where the standard is either currently met or will be met without additional regulation. It is inappropriate to promulgate a national standard to affect the air quality in three counties of one state (i.e., California)" (Florida DEP, p. 1).

Response: The EPA disagrees with commenters who stated that implementation concerns, in particular the additional resource burden associated with implementing a distinct secondary standard, should alter the Agency's decision making with regard to a standard to protect visibility. The EPA may not take the costs of implementation into account in setting or revising the NAAQS. The EPA's decision not to establish a distinct secondary standard to protect against PM-related visibility impairment is based entirely on the degree of protection that would be afforded by such a standard if adopted with the indicator, averaging time, form and level judged appropriate by the Administrator, as compared to the degree of protection afforded by the existing secondary 24-hour $PM_{2.5}$ standard.

7. Specific Comments on Surrogacy Analysis

(1) *Comment:* Several commenters submitted additional analyses supporting their position that a 35 $\mu g/m^3$ 24-hour $PM_{2.5}$ standard would provide at least equivalent protection to a distinct 24-hour visibility standard within the range of levels proposed (API, Attachment 2, p. 8 and Attachment 3, p. 1).

Response: The EPA agrees with commenters that Kelly et al. (2012a) indicates that the existing 24-hour $PM_{2.5}$ standard provides *at least* an equivalent measure of protection a distinct 24-hour visibility index set at 30 dv with a 90th percentile, 3-year average form, which the EPA judges appropriate. Importantly, the analysis performed by Kelly et al. (2012a) provides an area-by-area comparison of the relative degree of protectiveness of the existing secondary 24-hour $PM_{2.5}$ standard and the proposed distinct standard for visibility. The Kelly analysis also confirms that for each area examined, it is highly likely that a standard of 35 $\mu g/m^3$ would provide as much or greater protection than a standard based on a visibility index set at 30 dv. The EPA acknowledges that the conclusions from the additional analyses submitted by the commenters are supportive of the Agency's decisions to retain the current suite of secondary PM standards and to not establish a distinct secondary standard for protection from visibility impairment. However, the EPA did not rely upon these additional analyses from the commenters to inform its decisions. Rather, the agency based its conclusions on the analysis performed by Kelly et al. (2012a).

(2) *Comment:* Three environmental commenters (Appalachian Mountain Club, National Parks Conservation Association, and Earthjustice) made several comments that questioned the technical analysis of the Kelly et al. memo (2012a) that provided the

justification of the surrogacy policy, specifically the area by area evaluation where EPA compares the design values of various areas to see if areas that attain the mass-based standard are also likely to attain the distinct secondary standard to protect against visibility impairment. These commenters claimed that "the analysis actually reaffirms that the mass-based standard is not a reasonable predictor, but EPA sweeps these concerns away with generalized and conclusory claims. Figure 6 in the memo by Kelly, et al., shows again that the correlation between meeting the 24-hour mass standard and meeting the visibility standard varies significantly from region to region." The commenters also stated that "Even more important than the fact that there is no regional consistency in the correlation between the mass and visibility standards is the fact that any linear relationship does not extend to zero." (AMC, et al., p. 11)

Response: As shown in Figure 6 of Kelly, et al. (2012a), the differences in 24-hr $PM_{2.5}$ and visibility index design values across different regions of the country do not detract from the EPA's analysis as the commenters suggest. While distinct regions of the country have distinct relationships between the 24-hr $PM_{2.5}$ design value and the secondary visibility index design value, the relationship in all regions is such that an area that meets the secondary 24-hr $PM_{2.5}$ standard would also attain the proposed visibility index standard level of 30 dv, and all areas except the Industrial Midwest would attain the proposed level of 28 dv. It is also not possible to examine the relationship for design values near zero since such levels do not occur in the ambient atmosphere. However, this situation does not limit our analysis which focuses on the potential impact of sources on design values under realistic atmospheric conditions.

(3) *Comment:* These environmental commenters claim that the plot in Figure 6 of Kelly, et al. (2012a) "suggests that an area can be closer to a violation of the visibility standard even when further from a violation of the mass standard. This is demonstrated by the fact that it is more likely to find an area violating a visibility standard of 28 dv and still meeting the mass-based standard of 35 $\mu g/m^3$ than the other way around (i.e., violating the mass standard but meeting the visibility standard)." (AMC, et al., p. 11)

Response: The EPA does not believe that comparing the closeness of the site-specific design values to each standard level is a valid way to examine the relationships between design values. Instead, the trend in the data shown in Figure 6 of Kelly et al. (2012a) from the lowest design values to the highest design values should be considered for each region since that trend is the best guide to the likely relationship between ambient mass concentrations and visibility index values in these regions. Trends in Figure 6 indicate that design values in each region would follow a path where exceedance of the 30 dv visibility index level would not occur without the secondary 24-hr $PM_{2.5}$ standard level of 35 $\mu g/m^3$ also being exceeded. Moreover, the commenters are inappropriately comparing design values across different regions in the statement about areas being more likely to violate a visibility index level of 28 dv while meeting the secondary 24-hr $PM_{2.5}$ standard level of 35 $\mu g/m^3$ than the other way around.

(4) *Comment:* These commenters took issue with the EPA's suggestion that the regional differences will be minimized over time because federal control measures will reduce sulfate levels in the Midwest. The commenters argued that the EPA had made an

unreasonable claim that in a few years the correlation between attaining the two standards would get "better" so it is acceptable to allow the surrogacy approach now. The commenters further stated that the EPA does not provide details on the time horizon or magnitude of such improvement. As a result, the commenters concluded that unless and until there is a change in this correlation, there is not reasonable basis for allowing the proposed surrogacy approach.

Response: The discussion of federal control measures was not related to minimizing regional differences between 24-hr $PM_{2.5}$ design values and visibility index design values. Instead, the control measures were mentioned to indicate that the few observed cases in the Industrial Midwest where the proposed visibility index level of 28 dv is exceeded in current air quality data while the 24-hr standard level is attained would be less likely to occur in the future due to ongoing control programs. However, the results of the analysis of 2008-2010 data presented in Kelly et al. 2012a (and the results of the reanalysis using updated 2009-2011 air quality data presented in Kelly et al. 2012b) indicate that, in all regions of the U.S., an area that met the 24-hr $PM_{2.5}$ standard would also have attained the proposed visibility index standard level of 30 dv and thus support the use of the surrogacy approach.

(5) *Comment:* The commenters also added a footnote stating that "As with other EPA regulatory decisions that have relied on EPA's Cross-State Air Pollution Rule, the D.C. Circuit's recent vacature of the rule undermines EPA's argument. See EMA Homer City Generation v, EPA, 2012 WL 3570721, (D.C. Cir. Aug. 21, 2012). Unless and until the court's vacature is reversed, EPA has no basis for claiming that the rule will change the current mix of air pollutants." (AMC, et al., p. 11)

Response: The EPA's analysis and discussion as presented in Kelly et al. (2012a) does not rely on the Cross-State Air Pollution Rule, nor are the conclusions drawn by the EPA with regard to the results presented in this analysis dependent on implementation of the Cross-State Air Pollution Rule.

8. Legal Issues

Some commenters argued that the entire approach proposed by the EPA is inconsistent with the requirements of CAA section 109(b). They pointed to a number of different aspects of the proposal which in their view made it incompatible with the CAA. For example, UARG stated:

> In the past, EPA has always used a measure of PM mass as the indicator for both primary and secondary PM NAAQS. Such a standard is, as a general matter, consistent with the directive in the CAA that the NAAQS "specify a level of air quality" and targets for control the listed criteria air pollutant. CAA § 109(b)(2). The standard contained in EPA's proposed rule does neither of these things. Instead, it would (1) regulate relative humidity, which is not a criteria pollutant; (2) fail to "specify a level of air quality" as required by section 109(b)(2) of the CAA; and (3) result in a standard necessitating nationally variable PM concentrations instead of a standard establishing a nationally uniform, minimally acceptable PM concentration. (UARG, p. 22-23)

Other commenters raised similar or related issues, arguing that the EPA improperly set a visibility standard, and not a $PM_{2.5}$ standard, and that NAAQS can only be set in terms of a level or concentration of the air pollutant. Commenters also argued that an endangerment finding and air quality criteria would be needed before the EPA could set a standard based on PM components. Each of these comments is discussed below.

As a general matter, it should be noted that the EPA disagrees with the points raised by these commenters. While the EPA is not adopting the proposed secondary standard, this decision is not based on concern over the EPA's authority to adopt a secondary standard such as the one proposed.

(1) *Comment:* Some commenters argued that the proposed standard is unlawful because it is "not a $PM_{2.5}$ standard at all, but rather a visibility standard, and visibility is neither an air pollutant nor a criteria pollutant for which a NAAQS may be promulgated" (NMA/NCBA, p. 21). According to these commenters, the CAA requires that NAAQS be established as limits on the concentration of an air pollutant in ambient air, not limits on the "identifiable effects" caused by that air pollutant. These commenters claimed that reduced visibility due to light extinction is not an air pollutant but instead is an effect, noting that "the Act's definition of 'air pollutant' speaks in terms of specific substances or matter in the ambient air" (National Stone Sand and Gravel Association, p. 8). The commenters pointed to the use of the term "air pollutant" in sections 109(a)(1)(A) and (b)(2) as support for their argument, as these provisions refer to setting standards for the "air pollutant" to address the effects associated with the presence of the air pollutant in the ambient air. They likewise pointed to section 108(a)(2)'s reference to the presence of the air pollutant in the ambient air. Since reduced visibility is not an air pollutant, they argue the EPA cannot set a NAAQS that is a standard for visibility. They argue that the proposed secondary standard it is not a $PM_{2.5}$ standard as it does not limit the concentration of $PM_{2.5}$ or any other fraction of particulate matter in the ambient air and therefore is not an "ambient air quality standard" for any pollutant.

Response: The EPA disagrees with these commenters. The proposed distinct secondary standard was a standard for $PM_{2.5}$, and was not a "visibility standard." The proposed secondary standard was based on the mass concentration of $PM_{2.5}$ in the ambient air. The standard was defined in terms of calculated $PM_{2.5}$ light extinction, which is based on the measurement of the mass concentration of ambient $PM_{2.5}$ over a 24-hour period. Under the proposed approach, the measured mass concentration would be adjusted based on information on the speciated mass components of the $PM_{2.5}$ and the relative humidity, resulting in a calculated visibility index. The level of the visibility index, combined with the form of the standard and averaging time, would identify whether a level of ambient mass concentration of $PM_{2.5}$ achieved the standard or not. Given any specific mass concentration of ambient $PM_{2.5}$, combined with information on speciation and relative humidity, it could be determined whether the specific mass concentration of ambient $PM_{2.5}$ achieved the NAAQS. Hence, the proposed secondary NAAQS clearly specified acceptable levels of ambient mass concentration of $PM_{2.5}$.

The combination of indicator, averaging time, form, and level of the proposed NAAQS is designed to provide the appropriate degree of protection from visibility impairment caused by ambient levels of $PM_{2.5}$. It does this by calculating the light extinction associated with ambient concentrations of $PM_{2.5}$ and specifying the level of acceptable $PM_{2.5}$ mass concentration in terms of this calculation. However this does not change the fact that the standard is for the air pollutant $PM_{2.5}$, and defines acceptable ambient levels of this air pollutant. It does not transform the standard into a "visibility standard" and not a standard for $PM_{2.5}$.

(2) *Comment:* One commenter argued that the EPA is required to "specify a level of air quality" under section 109(b)(2), which Congress intended as an acceptable concentration level of the air pollutant in the ambient air, noting that specification of acceptable visibility conditions is not the same as an acceptable air pollution concentration level. Citing American Farm Bureau v. EPA, 559 F.3d at 516, one commenter claimed that the court had affirmed that "the NAAQS—whether primary or secondary—is a mass-based standard" (Nevada DEP, p. 5). Commenters also refer to the legislative history of the 1970 amendments, referring to NAAQS as setting the "maximum permissible ambient air level" for an air pollutant. The commenters argue that the proposed secondary standard is improper because it would not limit the concentration of $PM_{2.5}$ or any fraction of PM in ambient air, but would improperly set a limit on visibility effects.

Response: The EPA disagrees with these commenters. The text of sections 108 and 109 does not support the limited interpretation commenters suggest. Instead, these provisions provide the EPA with significant discretion in determining the metric for air quality that is appropriate to achieve the required degree of protection of public welfare. The commenters' interpretation would improperly limit this discretion, interfering with achieving the goals of section 109(b).

The term "concentration" typically means some measure of relative content, including relative measures such as mass per unit of volume or parts per million. The EPA has often used such metrics to define the NAAQS, largely because the scientific evidence of health or welfare effects supporting the NAAQS typically use such metrics in air pollution studies. For example, the current secondary standards for PM are defined in terms of the concentration of $PM_{2.5}$ and PM_{10} in the ambient air, measured as the dried mass of the particulate matter per unit of air. However section 109(b) does not require that a NAAQS be defined this way.

Sections 109(a) and (b) both use the general term "air quality" when discussing the EPA's obligation to set NAAQS. The NAAQS are clearly national ambient "air quality" standards under section 109(b), which specifies that the primary NAAQS "shall be ambient air quality standards" and the secondary NAAQS "shall specify a level of air quality." Both the primary and secondary NAAQS are to be based on the "air quality criteria," which are to accurately reflect the latest scientific knowledge on the effects on public health and welfare associated with "the presence of such air pollutant in the ambient air, in varying quantities." Section 109(b), 108(a)(2). Congress spoke in broad terms, tasking the EPA with assessing the latest scientific knowledge about the public health and welfare associated with the presence of the pollutant in the air, without limiting this to consideration of only those effects associated with one or more measures of concentration of the air pollutant. Congress referred to any and all effects associated with the presence of the pollutant in the ambient air, not just the effects associated with the concentration of the pollutant in the ambient air. Based on this knowledge, the EPA is required to set standards for the quality of the air that will provide the appropriate degree of protection from these health and welfare effects, without limitation on how to measure or define air quality. While concentration in the air has typically been an appropriate way to set a standard to achieve these requirements, the more general terms used in section 108(a) and 109(b) do not limit the EPA to using concentration as the only way to measure air quality for purposes of setting a NAAQS. The EPA is charged with setting air quality standards, and has the discretion under section 109(b) to choose the metric for defining air quality that is appropriate to address the health or welfare effect at issue.

Congress did refer to “concentration” in certain situations. In section 109(c) Congress required the EPA to set a primary NAAQS for NO_2 concentration over 3 hours. This addressed Congress’ concern over whether the then current NO_2 standard, which used concentration as a metric, provided adequate protection. Congress also called on CASAC to advise the Administrator on the relative contribution to “air pollution concentrations” of natural and anthropogenic sources, under section 109(d)(2)(C)(iii). This information is in addition to the advice CASAC is required to provide concerning appropriate revisions to the “air quality criteria” and to the NAAQS under section 109(d)(2)(B). While these provisions refer to ambient concentrations of pollutants, this reflects the EPA’s standard practice to date in setting NAAQS, and none of them change or limit the range of discretion provided under section 109(b) in setting NAAQS. They do not change the fact that the EPA is to set “air quality” standards, and is not limited to “air concentration” standards. The reference in the legislative history to a maximum permissible ambient air level for the pollutant also does not limit the EPA to a level of air pollutant concentration, as compared to a different metric for specifying the level of air quality, if that is judged to be appropriate.

(3) *Comment:* Some commenters argued that the proposed standard improperly regulates relative humidity because it is included in the calculation to determine the value of the visibility index. According to these commenters, the CAA allows the EPA to control criteria air pollutants through the NAAQS program, but not other various substances. The commenters stated that the EPA recognized this in the last review, treating humidity as a confounding factor and considering addressing it by measuring $PM_{2.5}$ mass-based concentration over the midday hours, when humidity would have the least effect. This would target the effects caused by PM, and not by humidity. Referring to American Farm Bureau v. EPA, 559 F.3d 512, 528 (D.C.Cir. 2009) and 77 Fed. Reg. at 38979 n.153. UARG contested the proposed calculated visibility index as it does not approach relative humidity as a confounding factor but instead “embraces it and treats it as if it were a PM effect” (UARG, p. 24).

Response: Contrary to the claims of these commenters, the use of calculated $PM_{2.5}$ light extinction does not regulate relative humidity. The proposed secondary standard would define acceptable levels of ambient $PM_{2.5}$, not acceptable levels of relative humidity. In addition, section 108 explicitly requires that the air quality criteria include information on the atmospheric conditions that can alter the effects of the air pollutant on public health or welfare, and relative humidity certainly has this kind of impact. Section 109(b) requires that the standard be based on the air quality criteria, indicating that this information can and should be taken into account in setting the standard. Including relative humidity as an adjustment factor in the calculation of $PM_{2.5}$ light extinction is a reasonable and straightforward way to use the scientific information in the air quality criteria in establishing a standard to provide protection from visibility impairment.

The EPA disagrees with commenters that the EPA's treatment of humidity in this review is inconsistent with its handling of this issue in the previous review. In the last review, the EPA considered a distinct $PM_{2.5}$ mass-based secondary standard. In that context, limiting the measurement of $PM_{2.5}$ mass concentration to the mid-day hours when relative humidity had the least impact would promote the correlation between measured $PM_{2.5}$ mass concentration and light extinction, which would promote achievement of a relatively consistent degree of visibility protection across the country. However in this rulemaking the proposed calculated $PM_{2.5}$ light extinction standard achieves a consistent degree of visibility protection by directly accounting for humidity, in a scientifically defensible manner. The goal has not changed – achieving the desired degree of protection across the country. What has changed is that calculated $PM_{2.5}$ light extinction is a more direct and scientifically appropriate way to achieve that result.

Finally, it should be made clear that water is not a separate compound from $PM_{2.5}$ that confounds the impact $PM_{2.5}$ has on light extinction. As described in the Integrated Science Assessment, "PM 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" (U.S. EPA, 2009a, p. 1-4). "Particles composed of water soluble inorganic salts (i.e., ammoniated sulfate, ammonium nitrate, sodium chloride, etc.) are hygroscopic in that they absorb water as a function of relative humidity to form a liquid solution droplet. Aside from the chemical consequences of this water growth, the droplets become larger when relative humidity increases, resulting in increased light scattering. Hence, the same PM dry concentration produces more haze" (U.S. EPA, 2009a, p. 9-6). Thus water is not a compound that is separate and apart from the particle that acts as an extraneous confounding factor. The effect of relative humidity occurs after the water becomes part of the particle. Certain water soluble salts absorb water and the resulting particle is larger in size and scatters more light, increasing the visibility impact of the particle. But the particle is still a $PM_{2.5}$ particle. The fact that the PM NAAQS traditionally uses a measurement of the dried mass of the particles as the metric for the standard does not change the fact that the particles in the air include liquid droplets and particles that have increased in size because of absorption of water. These ambient $PM_{2.5}$ particles are what are in the air and impacting visibility, not just the dried mass of $PM_{2.5}$ that is measured in the laboratory and is currently used as the indicator for the PM NAAQS. Thus, the commenters improperly claimed that the proposed secondary standard regulates water or relative humidity, and not $PM_{2.5}$, when in fact the proposed secondary standard accounts in a scientific manner for the fact that some $PM_{2.5}$ particles are larger in size and have a greater impact on light extinction when the relative humidity increases.

(4) *Comment:* The commenters also stated that the use of a calculated visibility index, and the failure to exclude the effects of humidity, would result in acceptable PM concentrations that vary across the nation. These commenters claimed that such a

standard is inconsistent with the requirements of the CAA because the proposed approach fails to establish a nationally uniform PM concentration standard. For example, API argued that the proposed visibility index approach is "essentially specifying levels—not a level—of air quality" (API, p. 29). UARG agreed, and stated that the Act "requires that criteria pollutant concentrations throughout the nation reach, at the least, a single, specified ambient concentration level" (UARG, p. 25, emphasis in original). The commenters argue that a $PM_{2.5}$ visibility index standard cannot provide equal protection nationwide due to geographic variation in key factors such as relative humidity that affect level of particles allowed in different areas. The commenters noted that establishing a single national level for the $PM_{2.5}$ visibility index would necessarily result in unequal acceptable $PM_{2.5}$ levels in different areas of the country, with lowest allowable $PM_{2.5}$ levels in urban areas in the Southeast and highest allowable levels in the arid West. UARG recognized that under section 108 the air quality criteria are to "address those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant," but stated that while section 108 "allows" this, it has no bearing on this issue. Instead, the commenter stated that the EPA may take such information into account in setting a permissible concentration of the pollutant that is uniform and national (UARG, p. 25).

Response: The EPA disagrees with commenters that section 109(b) requires that the NAAQS set a single, specified ambient concentration that is nationally uniform across the country. As discussed above, the text of section 109(b) does not specify this limitation of a single national acceptable concentration. Instead the secondary NAAQS is to specify a level of air quality that achieves the appropriate degree of protection. The proposed secondary standard would do just that – specify a level of air quality, defined in terms of calculated $PM_{2.5}$ light extinction, that would achieve the desired degree of protection. The fact that this results in varying allowable levels of $PM_{2.5}$ mass concentrations is not inconsistent with the Act. The D.C. Circuit recently approved such a result. In the last review of the PM_{10} primary NAAQS, the court approved the EPA's choice of an indicator that was designed to allow varying levels of acceptable coarse PM. The court stated that:

The industry petitioners next argue that the 150 $\mu g/m^3$ standard for PM_{10} will result in arbitrarily varying levels of coarse PM, and that the agency should instead have used a $PM_{10-2.5}$ indicator. The EPA does not dispute that using the PM_{10} indicator will result in coarse PM levels that vary within the limit of 150 $\mu g/m^3$. As the EPA explains: "Because the PM_{10} indicator includes both coarse PM ($PM_{10-2.5}$) and fine PM ($PM_{2.5}$), the concentration of $PM_{10-2.5}$ allowed by a PM_{10} standard set at a single level declines as the concentration of $PM_{2.5}$ increases. Thus, the level of coarse particles allowed varies depending on the level of fine particles present." Id. at 61,195.

Although the EPA acknowledges that a PM_{10} indicator will result in varying coarse PM levels, it does not agree that the variance will be arbitrary. The EPA agrees with the industry petitioners that protection from coarse particles should be targeted at urban areas, where coarse particles have been shown to pose the greatest danger. Id. at 61,194. But the agency argues that targeting of urban areas is effectively accomplished by using an indicator that permits the varying levels that the industry petitioners challenge. … Id. at 61,195-96 (citations omitted). In other words: "The varying levels of coarse particles allowed by a PM_{10} indicator will therefore target protection in urban and industrial areas where the evidence of adverse health effects associated with exposure to coarse particles is strongest." Id.

The EPA also offers a further rationale for tying the stringency of coarse PM regulation to increases in the level of $PM_{2.5}$. … EPA argues that it is "logical to allow lower levels of coarse particles when fine particle concentrations are high. . . . [I]nclusion of $PM_{2.5}$ in the PM_{10} indicator for purposes of coarse particle protection would appropriately reflect the contribution that contaminants emitted in fine particle form can make to the overall health risk posed by coarse particles." Id.

In sum, we find that the EPA has provided a reasonable explanation for its decision[ ] … to utilize a standard that allows targeted variance in coarse PM levels in an inverse relationship to the amount of fine PM in the air. American Farm Bureau v. EPA, 559 F.3d 512, 534-5 (D.C.Cir. 2009).

A similar result applies here. Under the proposed secondary standard there would be a single level of air quality specified for the NAAQS. The standard would apply across the nation; it would not be a regional standard. The proposed standard would be the same standard everywhere—the acceptable level of mass concentration of $PM_{2.5}$ would be defined the same way across the nation, using the same method of calculating the allowable concentration of $PM_{2.5}$. The same degree of protection from visibility impairment would apply across the country. While the allowable amount of $PM_{2.5}$ could vary, this would be a reasoned way to achieve the desired degree of protection from visibility impairment. The requirements of section 109(b) would be satisfied.

(5) *Comment:* Some commenters opposed to the proposed distinct secondary standard argued that in order to base a standard on measured levels of several speciated substances, the EPA must first make an endangerment finding and issue air quality criteria for each of the speciated substances included in the calculation of $PM_{2.5}$ light extinction. According to these commenters, "EPA cannot use NAAQS to indirectly regulate multiple substances which are not criteria pollutants under the guise of establishing a visibility standard" (NMA/NCBA, p. 21). Noting that air quality criteria for particulate matter were issued in 1969, NMA/NCBA argued that the 1969 Criteria Document "did not establish air quality criteria for individual constituents that occur in particle form, instead it established criteria for particulate matter as a whole" (p. 27). In light of the fact that criteria have never been issued for "individual speciated components of particulate matter," these commenters argued, "if EPA wishes to promulgate a rule such as its secondary visibility NAAQS, it first must make a finding that the speciated components listed in Appendix N endanger public health or welfare and then issue an air quality criteria document for those components" (NMA/NCBA, p. 29). According to these commenters, the approach the EPA adopted in promulgating a NAAQS for lead supports this view:

> When EPA promulgated a NAAQS for lead, an individual substance in particle form, it did not assert that an endangerment finding or criteria document for lead

> was unnecessary because lead was already covered by the PM Criteria Document. Instead, EPA complied with the Section 108 and 109 NAAQS prerequisites for lead, just as it must do for Appendix N substances if it intends to promulgate a NAAQS for those substances. … [In 1976], EPA listed lead as an air pollutant that adversely affected public health or welfare, issued an air quality criteria document for lead, and promulgated a NAAQS for lead. 43 Fed. Reg. 46246 (Oct. 5, 1976). (NMA/NCBA, p. 29)

Response: The EPA strongly disagrees with commenters the Agency would need to issue a separate endangerment finding and establish air quality criteria for each of the speciated substances included in the calculation of $PM_{2.5}$ light extinction prior to setting a distinct secondary standard based on a $PM_{2.5}$ visibility index, as proposed. The proposed standard would set an allowable limit on ambient concentrations of $PM_{2.5}$. Information on both the speciated components of $PM_{2.5}$ and the relative humidity affect how much light extinction is associated with any specific level of $PM_{2.5}$, but the standard would be for $PM_{2.5}$. The D.C. Circuit has made it clear that $PM_{2.5}$, just like PM_{10} and TSP before that, is an appropriate subset of PM for the EPA to focus on in setting the NAAQS based on the scientific evidence before the EPA. This focus of the NAAQS does not make the subset a new pollutant that requires listing and new air quality criteria under section 108 before setting a NAAQS. American Trucking Association et al. v. EPA, 175 F.3d 1027, 1055 (D.C.Cir. 1999). Commenters' interpretation would apply to $PM_{2.5}$ as well as to components of $PM_{2.5}$, and is inconsistent with the ATA decision. In addition, it is clear that the current air quality criteria do address the scientific basis for calculating $PM_{2.5}$ light extinction as the EPA proposed (U.S. EPA, 2009a, pp. 9-5 to 9-8).

(6) *Comment:* UARG argued that the EPA has in the past recognized that the secondary NAAQS is an inappropriate vehicle for regulating PM-related visibility, referring to 62 Fed. Reg. at 38680, including fn 49. UARG claimed the same situation continues, and the EPA has not provided a valid basis for changing this conclusion.

Response: UARG mischaracterized the EPA's past decision-making. In past reviews the EPA has been clear that the EPA should take into account the existence of the visibility program under section 169A, the regional haze program, when considering a secondary NAAQS and should not treat the secondary NAAQS as the sole mechanism to address visibility impairment across the country. That is the approach the EPA has taken in this and prior reviews. See 77 FR at 38990.

9. Other Issues

(1) *Comment:* A large number of commenters expressed confusion and concern over differences between the proposed visibility index standard and the Regional Haze Program. This included commenters who supported setting a distinct secondary standard to protect visibility as well as those opposed to setting such a standard. Many of these comments focused on concerns relating to implementation challenges that might be caused by overlap between the programs. These concerns included:

- Visibility impairment would be assessed differently under the two approaches due to differences in the way light extinction is calculated, including different IMPROVE equations and differences in the inclusion and weighting of specific species and components. This would mean having two different regimes for managing visibility impairment in the exact same location.

- Since data from the IMPROVE monitoring network would inform nonattainment designations, as well as an area's obligations under the Regional Haze Program, there could be considerable confusion over how to draw nonattainment boundaries and what requirements would affect large sources in rural areas.
- There would be a large resource burden associated with maintaining two different programs aimed at protecting visibility in the same geographic area.

Response: Though the EPA's decision not to establish a distinct secondary standard for protection from visibility impairment at this time renders these comments moot, the EPA disagrees with commenters in principle that implementing two programs for visibility protection simultaneously would be overly burdensome. Since the same data can be used to calculate both visibility impairment under the Regional Haze approach and the proposed visibility index, the additional calculation burden for state and local agencies would be light. Also, to the extent that there is any difference in terms of the emissions control obligations the two different programs would impose upon state and local areas, this is likely appropriate given the extent and nature of visibility impairment in those areas. The EPA notes that in general, there is likely to be substantial overlap in the control strategies a state or local area would pursue under either program.

(2) *Comment:* Noting concerns about overlap with the Regional Haze Program, some commenters argued that a visibility NAAQS should not apply to rural areas. The Department of the Interior requested that the EPA clearly define the geographic area to which the visibility index standard would be applicable, and suggested that Class I and Class II areas should generally be excluded from the standard.

Response: The EPA disagrees with these commenters that it would be appropriate to exclude some areas from coverage under a secondary NAAQS to protect visibility. CAA section 109(b) requires the Agency to establish *national* standards to protect the public welfare, and that the specific requirements laid out in the proposal for the distinct secondary standard would ensure that the protection it afforded would be appropriately targeted toward urban areas so that it could work in conjunction with—not be in conflict with—the Regional Haze Program under sections 169A and 169B of the CAA. While it is true that the Regional Haze Program under sections 169A and 169B of the CAA also targets visibility protection (focusing on Federal Class I areas), the EPA notes that areas affected by both programs would find substantial complementarities among the controls necessary to meet the requirements associated with each program.

Comment: A number of commenters questioned the need for a distinct secondary standard to protect visibility, arguing that the existing primary PM standards combined with the Regional Haze Program ensured adequate protection of visibility, even in urban areas.

Response: The EPA notes that the objectives of the Regional Haze program are distinct from the objectives of the proposed secondary standard. While the Regional Haze program is designed to eliminate man-made impairment of visibility in Federal Class I areas over the course of several decades, a distinct secondary standard for PM-related visibility impairment would be focused on providing a nationally applicable level of protection for all areas, particularly urban areas which do not receive targeted protection under the Regional Haze Program. Moreover, the metric used to assess visibility impairment differs between the two programs precisely because each program is aimed at a different aspect of the problem. Recognizing the importance of fresh emissions for urban visibility, the Visibility Assessment focused on visibility impairment as measured by the original IMPROVE equation because "the original version is considered more representative of urban situations when emissions are still fresh rather than aged as at remote IMPROVE sites" (U.S. EPA, 2010b, p. 3-19). The Regional Haze Program, on the other hand, has shifted to a revised IMPROVE algorithm more suited to remote locations. While this difference is discussed in more detail with regard to comments on indicator, above, and in section VI.C.1.b of the preamble, the result is that each program would appropriately measure those aspects of visibility impairment most closely related to the problem the program is trying to prevent.

Thus, the EPA disagrees with commenters who stated that a distinct standard to address visibility impairment as proposed would inherently conflict with the Regional Haze Program or that it would be appropriate to draw geographical distinctions that would explicitly exclude some areas (e.g., Class I areas) from the NAAQS. The EPA notes that the CAA requires that NAAQS be national in scope, and that the specific requirements laid out in the proposal for the distinct secondary standard would ensure that the protection it afforded would be appropriately targeted toward urban areas so that it could work in conjunction with—not be in conflict with—the Regional Haze Program under sections 169A and 169B of the CAA.

(3) *Comment:* The EPA received numerous comments on data handling related to the proposed secondary standard for PM-related visibility impairment, including minimum number of PM-component measurement days, treatment of missing data, rounding or truncation protocols and assignment of relative humidity weighting factors to monitored locations.

Response: In light of the Agency's decision not to establish a distinct secondary standard to address visibility impairment at this time, these concerns are moot.

(4) *Comment:* The EPA received numerous comments on monitoring related to the proposed secondary standard for PM-related visibility impairment, including the use of IMPROVE and CSN methods, the designation of these methods as Federal Reference or Federal Equivalent Methods (FRM/FEM), preference of alternative methods such as a direct measurement of light extinction, network design, data reporting, data validation, and reporting requirements for IMPROVE and CSN data.

Response: For the reasons stated in section VI of the preamble to the final rule, EPA is not establishing a distinct secondary $PM_{2.5}$ NAAQS. Consequently, the final rule does not include requirements for monitoring to support such a standard and these concerns are moot.

C. Specific Comments on Proposed Secondary PM Standards for Non-Visibility Welfare Effects

Relatively few commenters addressed the proposal to retain the existing suite of secondary PM standards to address non-visibility welfare effects. Those who did comment either raised concerns on the proposal to retain the current secondary annual standard, or raised concerns about whether the existing secondary standards offered sufficient protection against impacts on climate.

(1) *Comment:* Some commenters opposed the proposal to retain the current secondary annual $PM_{2.5}$ standard of 15 µg/m^3 in light of the proposal to revise the primary annual $PM_{2.5}$ standard to a level between 12-13 µg/m^3. Expressing concern over the implications of this decision for the air quality planning obligations of states, these commenters argued that the EPA should revise the secondary $PM_{2.5}$ standards to be equivalent in all respects to the primary $PM_{2.5}$ standards. For example, the American Association of State Highway and Transportation Officials (AASHTO) supported "retaining secondary standards that are consistent with the primary standards in order to reduce the complexity of the transportation and air quality planning processes, as well as the transportation conformity process" (AASHTO, p. 3). Thus, if the EPA were to adopt a lower level for the primary annual $PM_{2.5}$ standard, the commenters recommended that the EPA adopt this same lower level for the primary secondary $PM_{2.5}$ standard as well.

Response: As discussed in sections VI.B.2 and VI.C.2 of the preamble on non-visibility welfare effects, the EPA lacks an appropriate scientific basis for revising the level of the secondary annual $PM_{2.5}$ standard. There is an absence of information that would support any different secondary standards for PM at this time. Comments related to the implementation challenges associated with distinct primary and secondary standards are not relevant to the Administrator's final decisions regarding what standards are requisite to protect the public welfare. Therefore, the EPA continues to conclude that it would be appropriate to retain the current suite of secondary PM standards to address non-visibility welfare effects, as proposed.

(2) *Comment:* With regard to the impacts of particulate matter on climate, one commenter cited a number of recent studies that considered mobile source black carbon emissions and associated climate impacts, and urged the EPA to protect the public welfare by setting "higher standards for gasoline quality" (Urban Air Initiative, p. 4). This commenter did not advocate specific secondary NAAQS to address climate impacts of PM.

Response: The commenters concerns are not relevant to this rulemaking, which is limited to determining the secondary NAAQS for PM under section 109(b) of the Act.

(3) *Comment:* The Center for Biological Diversity urged the EPA to "set a separate limit for black carbon within the overall $PM_{2.5}$ standard" to ensure that public welfare is fully protected "from the serious climate impacts of black carbon" (Center for Biological

Diversity, p. 2). This commenter argued that "[p]recaution is required for secondary NAAQS," citing American Trucking Associations, Inc. v. EPA, 283 F.3d 355, 369 (D.C. Cir. 2002):

> [N]othing in the Clean Air Act requires EPA to wait until it has perfect information before adopting a protective secondary NAAQS. Rather, the Act mandates promulgation of secondary standards requisite to protect public welfare from any "anticipated adverse effects associated with" regulated pollutants, 42 U.S.C. § 7409(b)(2) (emphasis added), suggesting that EPA must act as soon as it has enough information (even if crude) to "anticipate[]" such effects[.]

The commenter stressed the growing scientific evidence regarding the impacts of black carbon on climate, and argued that the EPA's proposal ignores important research studies published within the last five years which provide improved estimates of the radiative forcing associated with black carbon, and the effects of black carbon on snow and ice, the Arctic climate, water availability and climate "tipping points." The commenter also noted that reductions in cooling aerosol species, particularly sulfate, due to pollution control programs are leading to an "unmasking" of the true extent of warming due to the accumulation of greenhouse gases in the atmosphere. The commenter argued that this unmasking effect can be offset by ensuring "that sufficient black carbon reductions accompany reductions in overall aerosol pollution" (Center for Biological Diversity, p. 10).

Response: The EPA agrees with the commenters' assertion that the scientific information about the impacts of aerosol species on climate is developing rapidly, and that understanding of the magnitude of aerosol effects on climate and the contribution of individual aerosol components to those effects has improved substantially over the past decade. The EPA also agrees that certain species, in particular black carbon, play a significant role in multiple aspects of climate. The Policy Assessment recognized that "Aerosols can impact glaciers, snowpack, regional water supplies, precipitation and climate patterns," and may contribute to the melting of ice and snow, a decrease in surface albedo, and climate impacts in the Arctic and other locations (U.S. EPA, 2011a, p. 5-9). The contribution of black carbon to these effects is discussed in detail in the EPA's recent Report to Congress on Black Carbon (U.S. EPA, 2012c). In particular, black carbon plays an important role in heating the lower atmosphere by absorbing incoming solar radiation and outgoing terrestrial radiation, i.e. via "direct" radiative forcing.

However, the EPA disagrees that there is sufficient information available at this time to establish a NAAQS to protect against the climate impacts associated with current ambient concentrations of black carbon or other PM constituents. While the Integrated Science Assessment concluded 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 lifetime" (U.S. EPA, 2009a, section 9.3.10), it also identified substantial remaining uncertainties with regard to the contribution of individual aerosol species to these climate effects. The contribution of individual aerosol components to total aerosol direct radiative forcing is more uncertain than the global average (U.S. EPA, 2009a, section 9.3.6.6), and the indirect effects of aerosols and aerosol components remain highly uncertain, in particular with regard to their complex interactions with clouds.

The EPA notes the substantial remaining uncertainties and gaps with regard to the climate impacts of PM components, including black carbon. These include the uncertainties associated with the spatial and temporal heterogeneity of PM components that contribute to climate forcing; the uncertainties associated with measurement of aerosol components; the inadequate consideration of aerosol impacts in climate modeling; and the currently insufficient data on local and regional microclimate variations and the heterogeneity of cloud formations. As a result, the EPA continues to conclude that it is not currently feasible to conduct a quantitative analysis for the purpose of informing revisions of the current secondary PM standards based on climate, and 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 any of its constituents.

(4) *Comment:* The Center for Biological Diversity also argued that the EPA did not consider the negative impacts of climate change on public health adequately in the proposal.

Response: Given the large remaining uncertainties about the impact of aerosols on climate, there is even greater uncertainty with regard to how aerosol-induced climate change will affect public health. At this time, it is not possible to estimate the extent to which aerosols in general, let alone particular aerosol components, contribute to the occurrence or exacerbation of adverse health outcomes due to climate change. The EPA therefore disagrees with the Center for Biological Diversity's claim that the EPA should pursue black carbon reductions for purposes of reducing the impacts of climate change on public health.

(5) *Comment:* The Center for Biological Diversity stated that the EPA had an obligation to address the impacts of black carbon in the PM NAAQS, despite the remaining uncertainties. The commenter pointed to the U.S. EPA's report to Congress on Black Carbon (U.S. EPA, 2012X), stating that the "report shows that EPA is aware of the climate science and public health information that point to the importance of addressing black carbon pollution. EPA must use this information in its relevant decisionmaking" (p. 13).

Response: As noted above, the EPA disagrees that there is sufficient information available at this time to establish a NAAQS to protect against the climate impacts associated with current ambient concentrations of black carbon or other PM constituents. While the Integrated Science Assessment concluded 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 lifetime" (U.S. EPA, 2009a, section 9.3.10), it also identified substantial remaining uncertainties with regard to the contribution of individual aerosol species to these climate effects. The contribution of individual aerosol components to total aerosol direct radiative forcing is more uncertain than the global average (U.S. EPA, 2009a, section 9.3.6.6), and the indirect effects of aerosols and aerosol components remain highly uncertain, in particular with regard to their complex interactions with clouds. The EPA's Report to Congress on Black Carbon provides an extensive discussion of these uncertainties.

(6) *Comment:* The Center for Biological Diversity challenged the uncertainties cited by EPA with regard to the climate impacts of aerosols generally, arguing that they "do not apply to the regulation of black carbon" (p. 14). Specifically, the commenter stated that "there are significant anthropogenic sources of black carbon that contribute a large proportion of total black carbon emissions"; that "there is enough information related to black carbon's impact to know that global temperatures will rise due to black carbon emissions"; that spatial and temporal heterogeneity in black carbon emissions do not matter for estimating likely climate effects; that "[b]lack carbon's negative climate impacts do not depend upon details of cloud interactions with aerosols"; and that the EPA does not need to be able to quantify the health or climate benefits precisely to know that it is appropriate to control black carbon as a specific component of PM under the CAA (Center for Biological Diversity, pp. 14-15).

Response: The EPA disagrees with the commenter's assertion that the uncertainties about the role of aerosols in climate do not apply to black carbon. The Integrated Science Assessment identified substantial remaining uncertainties with regard to the contribution of individual aerosol species to climate effects. The contribution of individual aerosol components to total aerosol direct radiative forcing is more uncertain than the global average (U.S. EPA, 2009a, section 9.3.6.6), and the indirect effects of aerosols and aerosol components remain highly uncertain, in particular with regard to their complex interactions with clouds. Thus, the uncertainty about black carbon's effects remains significant, just as for other aerosol species.

The EPA disagrees that "black carbon's negative climate impacts do not depend upon details of cloud interactions with aerosols" and that the uncertainties associated with climate impacts of aerosols generally do not apply to black carbon. In fact, the EPA has pointed to cloud interactions as the area of greatest uncertainty with regard to black carbon: recognizing that black carbon affects cloud reflectivity (albedo), lifetime, and stability as well as precipitation, the Report to Congress on Black Carbon noted that "few quantitative estimates of these effects are available, and significant uncertainty remains. Due to all of the remaining gaps in scientific knowledge, it is difficult to place quantitative bounds on the forcing attributable to [black carbon] impacts on clouds at present" (U.S. EPA, 2012c, p. 4). The Report acknowledged that "most estimates of the forcing from aerosol indirect effects are based on all aerosol species (e.g. total PM) and are not estimated for individual species (e.g., BC alone)" (U.S. EPA, 2012c, p. 40). The Report concluded that it remains unclear the extent to which black carbon contributes to the overall aerosol indirect effect, and did not assign any central estimate or even a range of possible values to the role of black carbon in the overall aerosol indirect effect. With regard to black carbon's net contribution to climate, therefore, the Report concluded:

> The direct and snow/ice albedo effects of BC are widely understood to lead to climate warming. However, the globally averaged net climate effect of BC also includes the effects associated with cloud interactions, which are not well

> quantified and may cause either warming or cooling. Therefore, though most estimates indicate that BC has a net warming influence, a net cooling effect cannot be ruled out. It is also important to note that the net radiative effect of all aerosols combined (including sulfates, nitrates, BC and OC) is widely understood to be negative (cooling) on a global average basis. (U.S. EPA, 2012c, p. 3)

The Report to Congress on Black Carbon also stressed the importance of considering co-emitted PM species, such as SO_2 and NOx, in evaluating the benefits of black carbon mitigation options. Noting that many of these co-emitted particles and gases have a cooling influence on climate, the Report noted the difficulty of estimating the net effect of various mitigation measures on net radiative forcing or other climate variables. The EPA concluded that the location and timing of emissions reductions would be critically important for achieving climate benefits, and that "more research is needed on the benefits of individual control measures in specific locations to support policy decisions made at the national level" (U.S. EPA, 2012c, p. 140). Thus, the EPA disagrees with the Center for Biological Diversity's claim that spatial and temporal heterogeneity in black carbon emissions do not matter for estimating likely climate effects, and continues to believe that being able to quantify the climate impacts of various aerosol species, alone and in combination, is essential for informing any possible revisions to the current secondary PM standards based on climate.

(7) *Comment:* The commenter noted that the United States participates in a number of international forums that have recognized the need to take action on black carbon, and argued that the U.S. has "an obligation under the Gothenburg Protocol to address black carbon pollution" (Center for Biological Diversity, p. 13).

Response: In May, new provisions pertaining to particulate matter were added to the Gothenburg Protocol under the Convention on Long-Range Transboundary Air Pollution. Amongst other things, these provisions encourage parties to develop national inventories and projections for black carbon, and to "give priority" to black carbon when implementing measures to control PM. However, the EPA notes that the U.S. has not yet ratified the PM amendments to the Gothenburg Protocol, and furthermore, these amendments do not require action specifically to reduce black carbon, but rather encourage countries to take such actions voluntarily within the context of their broader PM reduction strategies. Thus the EPA disagrees with the commenter that the U.S. has an "obligation" to reduce black carbon under the Gothenburg Protocol, or that it has "agree[d] to choose mitigation options for particulate matter that focus on black carbon reductions" under the Protocol (Center for Biological Diversity, p. 13).

(8) *Comment:* The Center for Biological Diversity concluded that the current size-based PM mass standard "is insufficient to fully protect health and welfare," and that the EPA was obligated to establish a specific limit on black carbon as a component of PM. The commenter argued that "Black carbon must be regulated separately and in addition to $PM_{2.5}$ because absent separate standards sulfates and nitrates may be more likely to be mitigated than the black carbon component of PM" (Center for Biological Diversity, p. 17). To support this point, the commenter cited the conclusion in the Policy Assessment that:

> 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. (U.S. EPA, 2011a, p. 5-11).

The commenter also noted that existing regulations on diesel engines, which are the largest source of black carbon in the United States, do not affect existing engines and vehicles, and stated that "The NAAQS program is one of the few opportunities to reduce black carbon from existing engines, industrial and biofuel sources within the United States and rapidly reduce emissions from this pollutant" (Center for Biological Diversity, p. 18).

Response: While the EPA agrees with the commenter that a large percentage of black carbon emissions come from anthropogenic sources, including diesel engines and vehicles, the EPA notes that existing regulations on mobile diesel engines are already reducing these emissions substantially. Between 1990 and 2005, new engine requirements resulted in a 32 percent reduction in black carbon emissions from mobile sources, and a further 86 percent reduction from 2005 levels is projected to occur by 2030 as vehicles and engines meeting existing regulations are phased into the fleet (U.S. EPA, 2012c, p. 175). Long-term historic data indicate that there has been a dramatic overall decline in black carbon emissions over the past century, due to changes in fuel use, more efficient combustion practices, and implementation of PM controls.

Therefore, the EPA disagrees with the Center for Biological Diversity's claim that a distinct black carbon NAAQS is necessary to achieve reductions in black carbon emissions. Clearly, U.S. emissions of black carbon are already declining substantially, suggesting that the existing mass-based PM standards, though not targeting black carbon specifically, have been effective in achieving black carbon emissions reductions in practice. As acknowledged in the Report to Congress on Black Carbon, "While [black carbon] is not the direct target of existing programs, it has been reduced through controls aimed at reducing ambient $PM_{2.5}$ concentrations and/or direct particle emissions" (U.S. EPA, 2012c, p. 161). The EPA has acknowledged the need to encourage PM mitigation strategies that focus on reducing directly emitted $PM_{2.5}$ for purposes of reducing black carbon, and this is reflected in its general support for the revised language in the Gothenburg Protocol, as discussed above.

V. RESPONSES TO SIGNIFICANT COMMENTS ON AMENDMENTS TO AMBIENT MONITORING AND REPORTING REQUIREMENTS

A. Comments on General Issues for Reference, Equivalent, or Approved Regional Methods

(1) *Comment:* One commenter supported the proposed administrative change to 40 CFR Part 53.9 – Conditions of Designation.

Response: The comment in support of the proposal is acknowledged and EPA is adopting the proposed approached in the final rule.

(2) *Comment:* One commenter stated that the approach of requiring $PM_{2.5}$ FEMs to meet the data objectives necessary for method designation for a period of at least one year will not be effective since the data objectives used in the FEM evaluation protocols do not match the required routine operating schedules for monitoring agencies. The FRMs used by monitoring agencies are operated from midnight to midnight while the vendors used mid-morning to mid-morning for the FEM evaluation protocols. This difference creates a bias because the routine midnight-to-midnight agency samples will retain a smaller portion of volatile PM than the vendor-operated FRMs. The vendors also were required to operate and average the results from triplicate FRMs and triplicate candidate FEMs. These averaged results are more stable and consistent than individual FRM and FEM data.

Response: The EPA's intention in making this administrative change to 40 CFR Part 53.9 – Conditions of Designation is to link this long-standing requirement to the appropriate performance criteria as is done for all other Federal equivalent methods. The EPA agrees that there are differences in the way the testing and routine operation of these methods are conducted. However, despite these differences, and as explained in the preamble to the final rule, a number of $PM_{2.5}$ continuous FEMs monitors are achieving acceptable data comparability. To the extent that this change encourages a closer relationship between instrument companies and monitoring agencies, especially during the first 12 months of operation, EPA believes such a relationship will lead to mutual responsibility in striving to meet the appropriate performance criteria. Also, EPA did not propose any changes to the testing criteria.

(3) *Comment:* One commenter stated that the monitoring methods proposed to support the proposed new secondary $PM_{2.5}$ visibility index NAAQS do not address an estimate of measurement accuracy.

Response: For the reasons stated in section VI of the preamble to the final rule, EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final monitoring rule does not include requirements on the use of CSN or IMPROVE measurements.

(4) *Comment:* A few commenters stated that the EPA does not adequately recognize the potential for intrusion of coarse particle mass into fine particle measurements. The commenters noted that the potential for coarse particle intrusion is significant in the arid West, where PM concentrations of crustal origin may account for an appreciable portion

of the total ambient mass concentration.

Response: The Agency has long recognized that ambient fine and coarse modes vary appreciably with regard to origin, particle size, chemical composition, and potential adverse health effects associated with their exposure. As discussed in the Air Quality Criteria for Particulate Matter (October 2004), intermodal minimums between fine and coarse particle ambient size distribution modes typically range between 1 and 3 µm. Based on recommendations by both Agency staff and the CASAC, 2.5 µm was selected as the most appropriate size indicator in this intermodal size range when setting the fine particle standard for the 1997 PM NAAQS. The decision regarding whether to maintain the 2.5 um size cut for ambient $PM_{2.5}$ samplers was also considered during the review of the 2006 PM NAAQS, and it has again been considered during this review (see discussion at Section III.E.1 in the preamble to this final rule). In each instance, selection of $PM_{2.5}$ as the most appropriate indicator of fine particle exposure has been overwhelmingly supported by subsequent Agency reviews, CASAC peer-reviews, and Integrated Science Assessments.

When selecting the most appropriate size indicator for the fine particle standard within the 1 and 3 µm size range, the Agency recognized that there is no unambiguous definition of a size cut that would provide for complete separation of overlapping fine and coarse ambient particle modes under all circumstances. While there is generally very little particle mass in the intermodal size range in most monitoring situations, the fine mode can extend up to and above 2.5 µm in situations of high ambient relative humidity. Conversely, the coarse mode can extend down to approximately 1 micrometer in situations characterized by high coarse mode concentrations in conjunction with high wind speeds. Ultimately, the selection of $PM_{2.5}$ as the most appropriate size indicator for assessing exposure to fine particles has been based on ensuring that ambient measurements completely captured the aerosol component of greatest health concern. As a result, it was deemed by the Agency and CASAC to be more important to collect fine particles more completely under all sampling conditions than to exclude coarse-mode particles which may inadvertently intrude into fine particle measurements. In addition, there is currently insufficient epidemiological and toxicological evidence to conclude that crustal particulate matter is totally benign with respect to potential adverse health effects associated with its exposure.

The EPA notes that in order to provide a distinct measurement separation between particles above and below 2.5 µm aerodynamic diameter, the FRM for the $PM_{2.5}$ NAAQS employs use of a single-stage inertial separator which provides very sharp fractionation characteristics. The FRM's development and subsequent promulgation of equivalent method specifications includes provisions to ensure that the fractionation characteristics of $PM_{2.5}$ NAAQS monitors do not appreciably degrade as a function of aerosol loading. In conjunction with the inherently very sharp fractionation characteristics of the inertial separator itself, these provisions are designed to ensure that the intrusion of ambient coarse particles into fine particle measurements does not significantly positively bias fine particle concentrations in the presence of high concentrations of ambient crustal components.

B. Comments on use of CSN and IMPROVE methods to provide speciation data used in the proposed new secondary $PM_{2.5}$ visibility index NAAQS.

(1) *Comment:* One commenter was supportive of using the IMPROVE monitors in urban areas.

Response: For the reasons stated in section VI of the preamble to the final rule, EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final monitoring rule does not include requirements on the use of CSN or IMPROVE measurements.

(2) *Comment:* Regarding the use of IMPROVE and CSN samplers for use in the visibility index, several commenters do not support the use of methods that have not been designated as FEM or FRM in comparison to the NAAQS as this is inconsistent with all other NAAQS.

Response: For the reasons stated in section VI of the preamble to the final rule, EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final monitoring rule does not include requirements on the use of CSN or IMPROVE measurements.

(3) *Comment:* Several commenters preferred a direct measurement of light extinction. For example, use of optical instrumentation such as nephelometers and aethalometers.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final monitoring rule does not include requirements on the use methods to support such a standard.

(4) *Comment:* One commenter recommended that EPA needs to begin the process of developing a Federal Reference Method that directly measures light-extinction.

Response: The EPA can consider the development of a light extinction method for an FRM as part of an overall strategy on methods development; however, even if the EPA decides to pursue such a direct measurement method as an FRM, which would have to be considered with other method development priorities, the timing of developing such a method is expected to take several years to complete the needed laboratory and field studies prior to a future proposal.

(5) *Comment:* Several commenters recommend the EPA develop a pilot urban visibility network program that would field test and evaluate the most promising methods of direct measurement under varying field conditions.

Response: The EPA can consider such a pilot program; however, since a pilot program is inherently not a national deployment, there is no need to direct any requirements for such a program in the final rule.

(6) *Comment:* One commenter stated that the EPA should establish a pilot measurement program to identify methods that would more accurately measure and report real-time visibility conditions to the public.

Response: he EPA can consider such a pilot program; however, since a pilot program is inherently not a national deployment, there is no need to direct any requirements for such a program in the final rule.

(7) *Comment:* Several commenters stated that the IMPROVE monitoring network is not suitable for supporting a visibility standard that is intended to be primarily a program for urban areas.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements for monitoring sites to support such a standard.

(8) *Comment:* One commenter asked for clarification on how total $PM_{2.5}$ mass concentrations from IMPROVE and CSN samplers might be used for comparison to the primary $PM_{2.5}$ NAAQS.

Response: It was never the EPA's intention that the $PM_{2.5}$ mass concentrations from IMPROVE and CSN samplers would be used for comparison to the primary $PM_{2.5}$ NAAQS. Had we finalized use of the IMPROVE and CSN samplers for use with the proposed $PM_{2.5}$ visibility index NAAQS, which as described in section VI of the preamble to the final rule, we are not doing, we would have clarified this issue in the preamble.

(9) *Comment:* One commenter stated that in addition to reconstructing visibility from speciated $PM_{2.5}$, states should also have the ability to use direct measurements located at airports (AWOS/ASOS), or from nephalometer, telephotometers, and/or transmissometers.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements for monitoring sites to support such a standard.

(10) *Comment:* One commenter stated that they do not believe that at this time the PM2.5 continuous FEMs can be utilized for the purpose of calculating a short-term light extinction value for comparison to a standard.

Response: The EPA would have only needed the $PM_{2.5}$ continuous FEMs for use in a short-term light extinction calculation had it finalized a secondary $PM_{2.5}$ visibility index NAAQS with a sub-daily averaging time. For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS, nor is the short-term secondary $PM_{2.5}$ visibility index NAAQS it took comment on being finalized; consequently, the final rule does not include requirements for monitoring methods to support such a standard.

C. Comments on the Terminology Changes

(1) *Comment:* One commenter supports removing of the term ‘community-oriented’ and ‘community monitoring zone’.

Response: The comment in support of the proposal is acknowledged and EPA is adopting the proposed approach in the final rule.

D. Comments on Revoking Use of Population-Oriented as a Condition for Comparability of $PM_{2.5}$ Monitoring Sites to the NAAQS

(1) *Comment:* One commenter supports revoking the term “population-oriented” so that data comparable to the $PM_{2.5}$ NAAQS are consistent with other NAAQS.

Response: The comment in support of the proposal is acknowledged and EPA is adopting the proposed approach in the final rule.

(2) *Comment:* One commenter stated that they are concerned that revoking the population-oriented requirement may result in monitoring at locations that are not appropriate for comparison with either the annual standard or the 24-hour standard.

Response: The EPA believes that for PM, as with all other criteria pollutants, all sites that meet the definition of ambient air are appropriate for comparison to the NAAQS. However, the EPA provides additional criteria described in §58.30 on those sites that may be eligible only for comparison to the annual $PM_{2.5}$ NAAQS. Although the EPA is removing from this provision the requirement that sites be “population-oriented” to be compared to the annual $PM_{2.5}$ NAAQS, all monitoring sites must still be representative of area-wide locations to make this comparison. Thus, these sites will represent locations where there is population exposure. Therefore, the EPA disagrees that revoking the requirement for sites to be population oriented may result in monitoring at locations that are not appropriate for comparison with either the annual or 24-hour standards. oreover, this amendment will not alter the current $PM_{2.5}$ monitoring network, since (based on data in the Air Quality System (AQS) database) there are no current $PM_{2.5}$ monitoring sites that have affirmatively been categorized as “non population oriented” using the current regulations.

(3) *Comment:* One commenter stated that EPA’s definition of ambient air is specified in 40 CFR 50.1—‘‘Ambient air means that portion of the atmosphere, external to buildings, to which the general public has access.’’ While this is an appropriate definition of ambient air, monitoring for compliance with any given air quality standard should be carried out at locations where there are people actually exposed for time periods that correspond approximately to the averaging time of that NAAQS. Thus, for comparison with the annual $PM_{2.5}$ standard, the population-oriented definition is appropriate since it involves locations where a substantial number of people spend a significant fraction of the day. Without a requirement to site monitors in this manner, monitoring from locations that have little or no population exposure could be used for comparison with the $PM_{2.5}$

NAAQS. For example, in the proposal the Agency indicates:

Area-wide means all monitors sited at neighborhood, urban, and regional scales, as well as those monitors sited at either micro- or middle-scale that are representative of many such locations in the same CBSA.

The key issue with this approach is that there may be many similar micro-scale locations in a metropolitan area but none of them may have actual human exposures relevant to the averaging time of the NAAQS.

The proposed rule indicated:

In reviewing the impact that this proposed change might have on the nation's $PM_{2.5}$ monitoring network, the EPA notes that there are no remaining sites operating affirmatively as ''non-population-oriented.''

While this may be true, the proposed rule also requires the addition of a substantial number of near-road monitoring sites the location of which is still to be decided. The Agency provides no examples of cases where the current definitions have resulted in any ambiguity with regard to monitoring locations. Therefore, the commenter does not support the EPA proposal to revoke the requirement that $PM_{2.5}$ monitoring sites be ''population-oriented'' for comparison to the NAAQS.

Response: The EPA believes that the location of any site meeting the definition of ambient air, which represents a location where the public is (or may be) exposed, will represent current or potential population exposure and is an acceptable location for comparison to $PM_{2.5}$ NAAQS, as is the case with all other criteria pollutants. Additionally, for comparison to the annual $PM_{2.5}$ NAAQS, monitoring sites are also to represent area-wide air quality; therefore, even if a monitor was located in a location at a small scale where no one was actually exposed on a given day, there is still the potential for someone to be exposed there and that site is intended to represent many such other locations in the same area, where the public is (or may be) exposed. For example, undeveloped or lightly utilized areas that border industrial sources or exist along roadways may at one time have little or no population exposure, however, if subsequent housing, commercial, or recreational development occurs than population exposure will occur. Basing monitoring decisions on the ambient air definition provides states with the flexibility to place monitors in these areas before as well as after such development. With regard to the comment that "….monitoring for compliance with any given air quality standard should be carried out at locations where there are people actually exposed for time periods that correspond approximately to the averaging time of that NAAQS", the EPA notes that no such requirements exist in the monitoring regulations. While the consideration of NAAQS averaging time may be one factor on which to base the siting of monitors, monitoring agencies need flexibility in designing their networks to ensure characterization of locations to which the general public has access as well as to support the specific objectives described in Appendix D of Part 58, section 1.1. Regarding the commenter's point that we have not provided any "…examples of cases where the current definitions have resulted in any ambiguity with regard to monitoring locations", the EPA points out that such cases do exist, including the use by stakeholders of dispersion modeling to support NAAQS attainment planning, associated SIP development, and the calculation of transportation conformity budgets, and that these examples typically apply as often to locations that are unmonitored as well as locations that are monitored. The EPA contends that the monitoring rules need to be clear as to the requirements to monitor and that the removal of the "population oriented" phrase that has only applied to $PM_{2.5}$ sites will provide needed clarity for monitoring agencies that plan and operate ambient networks as well as those stakeholders that base implementation strategies, in part, on $PM_{2.5}$ monitoring requirements.

(4) *Comment:* One commenter stated that the EPA proposes to revoke the Part 58 requirement that placement of $PM_{2.5}$ monitor placements be "population oriented," because the Agency argues that this requirement is "inconsistent" with the regulatory definition of "ambient air" at 40 CFR 50.1.10 *Id.* 39011. The commenter believes this change of historical practice is unreasonable, particularly since the agency has trumpeted that the value of the proposed rulemaking is for promulgation of a suite of urban $PM_{2.5}$ NAAQS. First, we submit that the EPA conflated the issue of the definition of "ambient air" with the placement of monitors. The definition of "ambient air" is relevant to placement of stationary source monitors and compliance, not to the placement of road-side monitors. Further the definition of "ambient air" is quite flexible as evidenced by 30 years of NSR determinations. Second, what the EPA seems to desire is the ability to reorient the placement of monitors from urban areas to: (1) roads where they can "piggy back" on the recently installed NO_2 NAAQS monitors; and (2) establish a new monitoring network in rural areas; and (3) to potential hotspots in rural areas caused by energy exploration. These plans, discussed at length in the proposed notice of rulemaking, certainly do not jive with the objective of this rulemaking – a suite of urban $PM_{2.5}$ NAAQS to compliment the regional haze regulations already in place. For this reason, the proposed changes to Part 58 and the change of the focus of the existing focus of the Part 58 monitoring requirements from "population centers" to rural areas is not supportable at all based on the record of decision and we oppose it on that grounds.

Response: The EPA disagrees with several of the commenter's assertions. First, EPA disagrees that revoking the requirement for monitors to be "population-oriented' is unreasonable. As explained in the preamble, the NAAQS provide protection for the public health and welfare in areas where the public can be exposed (necessarily including rural and urban areas). For all other criteria pollutants, monitoring requirements allow the comparability of monitors in any location representative of ambient air to the NAAQS without further restriction. In the case of $PM_{2.5}$ however, the historic rules contained an additional restriction requiring monitors to be in population oriented locations to be comparable to the $PM_{2.5}$ NAAQS. The term "population oriented" has lacked a quantitative definition (e.g., the interpretation of "substantial numbers" used as part of the part 58.1 definition of "Population-Oriented Monitoring"), therefore monitoring agencies and those stakeholders who based implementation strategies and decisions on monitoring regulations have been uncertain about what locations are or are not appropriate for $PM_{2.5}$ monitoring. The EPA believes that the continued use of the population oriented restriction on NAAQS comparability represents an unwise limitation on the flexibility of monitoring agencies to revise their $PM_{2.5}$ networks to account for anticipated changes in demographics or development as well as a contradiction with the inherent applicability of the NAAQS in ambient air locations where the public has access (e.g., in any location outside the perimeter of a industrial facility). Consistent with the long-standing practice of monitoring agencies in locating ambient monitors, we also note that, based on supporting data in the AQS, all currently existing $PM_{2.5}$ monitors are located in areas that are representative of population exposures. There are no $PM_{2.5}$ monitors currently operating as "non-population oriented". The EPA does not believe that removing the restriction for monitors to be population oriented will result in monitors that are not representative of population exposures. Regarding the comment that "the definition of ambient air is relevant to placement of stationary source monitors and compliance, not to the placement of road-side monitors", the EPA disagrees that "ambient air" is not relevant to road-side monitors. The EPA points out that a significant fraction of the population lives, works, plays, and goes to school near major roads and that these exposures occur in locations that represent ambient air. As noted in the preamble, one referenced study (http://www.census.gov/housing/ahs/data/ahs2009.html) identified that 45 million Americans live within 300 feet of a major roadway or other major mobile source. The survey provides an estimate of the county's numerous housing units in the U.S. that are located with 300 feet of a highway with four or more lanes, or a railroad, or an airport.

Regarding the comment "what EPA seems to desire is the ability to reorient the placement of monitors from urban areas to: (1) roads where they can "piggy back" on the recently installed NO_2 NAAQS monitors; and (2) establish a new monitoring network in rural areas; and (3) to potential hotspots in rural areas caused by energy exploration", we point out that the requirement is to site $PM_{2.5}$ near-road monitors in urban areas with populations of 1 millions persons or more; therefore, these monitoring locations are still representative of those urban areas and the populations that live, work, play, and go to school near these major roads. Regarding the comment that the EPA is to "establish a new monitoring network in rural areas" the EPA disagrees as we did not propose, nor are we finalizing any changes to monitoring requirements in rural areas. Regarding the comment to reorient the placement of monitors from urban areas to "potential hotspots in rural areas caused by energy exploration", we again note that there was no such proposal nor are we finalizing any such language. The commenter's obscure reference to Regional Haze suggests the commenter was referring to the proposed secondary standard for visibility, which the EPA is not adopting in the final rule.

(5) *Comment:* One commenter stated that removing the requirement for population oriented combined with other proposed monitoring changes creates a situation where any monitor, anywhere, measuring only very localized air quality of a small areas, could be compared to the NAAQS.

Response: As explained in the preamble, the NAAQS provide protection for the public health and welfare in areas where the public can be exposed. For all other criteria pollutants, monitoring requirements allow the comparability of monitors in any location representative of ambient air to the NAAQS without further restriction, even if such locations characterize very localized air quality. In the case of $PM_{2.5}$ however, the additional restriction of requiring monitors to be in population oriented locations to be NAAQS comparable has existed. The term "population oriented" has lacked a quantitative definition (e.g., the interpretation of "substantial numbers" used as part of the part 58.1 definition of "Population-Oriented Monitoring"), therefore monitoring agencies and those stakeholders who based implementation strategies and decisions on monitoring regulations have been uncertain about what locations are or are not appropriate for $PM_{2.5}$ monitoring for purposes of NAAQS comparability. The EPA believes that the continued use of the population oriented restriction on NAAQS comparability represents an unwise limitation on the flexibility of monitoring agencies to revise their $PM_{2.5}$ networks to account for anticipated changes in demographics or development as well as a contradiction with the inherent applicability of the NAAQS in ambient air locations where the public has access (e.g., in any location outside the perimeter of a industrial facility). Moreover, all $PM_{2.5}$ monitoring sites must still be representative of area-wide locations to make the comparison to the annual NAAQS. Thus, these sites still represent locations where there is population exposure. Consistent with the long-standing practice of monitoring agencies in locating ambient monitors, we also note that all currently existing $PM_{2.5}$ monitors are located in areas that are representative of population exposures based on supporting data in the AQS. There are no $PM_{2.5}$ monitors currently operating as "non-population oriented" and the EPA does not believe that removing the restriction for monitor to be population oriented will result in monitors that are not representative of population exposures.

(6) *Comment:* One commenter (EEI) stated that purportedly to address "ambiguity," the EPA is proposing to remove existing requirements regarding $PM_{2.5}$ NAAQS that require monitors to be "population-oriented." The EPA additionally claims it must now align a 15-year old regulatory requirement (for population-orientation) with an even older regulatory definition of ambient air. The EPA offers no analytical support or logical rationale for this proposal and the EPA should not finalize the proposed changes. The EPA states that eliminating the requirement does not change the requirements for the design of $PM_{2.5}$ networks. But this perspective ignores other changes that the EPA is proposing to make with regard to $PM_{2.5}$ monitoring. As referenced above, the EPA is proposing to allow monitors that measure air quality representative of very small areas to be compared to the NAAQS. By additionally proposing to eliminate the requirement that such monitors be population-oriented, the EPA is not conforming its monitoring requirements to the definition of "ambient air" (which includes the specification that such air be that to which the *general public* has access). Instead, removing any requirement for population orientation combined with other proposed monitoring changes results in the prospect that any monitor, anywhere, measuring any very localized air quality of any size could be comparable to the NAAQS, and possibly drive the characterization of the air quality status of a much broader geographic area. This is inconsistent both with the definition of ambient air and with the CAA's requirement that NAAQS be protective of "public health." On a fundamental level, it appears fully consistent with the primary NAAQS process contained in CAA sections 107-109 and completely logical to maintain a population-orientation as a criterion for monitors for primary, health-based NAAQS. This is certainly the perspective that EPA adopted from the very first staff paper for the $PM_{2.5}$ NAAQS in 1997. As noted at that time, "all concentration-response functions used in these analyses are based on findings from human epidemiological studies, which rely

on fixed-site, population-oriented, ambient monitors as a surrogate for actual integrated PM exposures. Measurements of daily variations of ambient PM concentrations . . . have a plausible linkage to the daily variations of exposure from ambient sources for the populations represented by ambient monitoring stations. . .” These conditions have not changed in the years since 1997 and thus support retention of the current requirement.

Response: The EPA’s disagrees with a number of the commenter’s statements. With regard to the comment that “EPA is not conforming its monitoring requirements to the definition of ambient air (which includes the specification that such air be that to which the general public has access)”, we note that the NAAQS provide protection for the public health and welfare in areas where the public can be exposed. For all other criteria pollutants, monitoring requirements allow the comparability of monitors in any location representative of ambient air to the NAAQS without further restriction. The EPA believes that the continued use of the population oriented restriction on $PM_{2.5}$ NAAQS comparability represents an unwise limitation on the flexibility of monitoring agencies to revise their $PM_{2.5}$ networks to account for anticipated changes in demographics or development as well as a clear contradiction with the inherent applicability of the NAAQS in ambient air locations where the public has access (e.g., in any location outside the perimeter of a industrial facility). Moreover, all monitoring sites must still be representative of area-wide locations to be used for comparison with the annual $PM_{2.5}$ NAAQS. Thus, these sites still represent locations where there is population exposure. This change thus, results in monitoring requirements that are completely consistent both with the definition of ambient air and with the CAA’s requirement that NAAQS be protective of “public health.” From an operational standpoint, we have noted that from a sample of over 900 operating monitoring stations in the country, and none of the currently operated monitors have been determined to not be “population-oriented” based on data in AQS, therefore the practical implications of this revision on the operating monitoring network are inconsequential.

With regard to the comment that “As noted at that time, “*all concentration-response functions used in these analyses are based on findings from human epidemiological studies, which rely on fixed-site, population-oriented, ambient monitors as a surrogate for actual integrated PM exposures. Measurements of daily variations of ambient PM concentrations . . . have a plausible linkage to the daily variations of exposure from ambient sources for the populations represented by ambient monitoring stations. . .” These conditions have not changed in the years since 1997 and thus support retention of the current requirement”. The commenter cites language from the EPA’s initial promulgation of the “population oriented” provision (40 CFR Part 58 App. D section 2.8.1.2.3 (1997)), and suggests that a “population oriented” provision is required to be consistent with the form of the annual standard and the epidemiologic information on which the standard is based. However, as explained in section III.E.4 to the preamble to the final rule, it is appropriate in this review to eliminate the spatial averaging option from the form of the annual standard, and appropriate to compare the $PM_{2.5}$ concentrations from a maximum monitor to the level of the $PM_{2.5}$ standard. Consequently, the commenter’s premise that the “population oriented” phrase is necessary to be consistent with the form and general structure of the annual $PM_{2.5}$ NAAQS is misplaced.

The requirement that a near-road monitor represent area-wide air quality (as defined) assures that the commenter's example of "any monitor, anywhere, measuring very localized air quality" being used for comparison with the annual $PM_{2.5}$ NAAQS will not occur. This is because area-wide air quality is representative of those population exposures where large numbers of people live, work, play, and go to school. Moreover, the commenter's concern that air quality measured at a micro-scale (or other small- scale) could characterize air quality in a much broader area is not appropriately raised here. Issues as to attainment or non-attainment area boundaries are determined as part of the section 107 designation process.

(7) *Comment:* Commenters (ALA et al., 2012) stated, "We especially welcome EPA's proposal to abandon and revoke regulatory language in Part 58 that effectively prevented the implementation of the $PM_{2.5}$ NAAQS to protect populations exposed to incremental concentrations near transportation facilities. These include the current prohibitions against comparison of micro- and middle-scale monitors with the annual NAAQS, and the requirement that only "population-oriented" monitors be compared with the 24-hour NAAQS. For the reasons discussed below, we believe these policies impose limitations on the applicability of the NAAQS that are inconsistent with the text, purpose and intent of the Clean Air Act, and must be revoked.

Response: As noted in the preamble and elsewhere in this RTC, we are finalizing the removal of the population-oriented language from the applicable $PM_{2.5}$ monitoring regulatory text.

(8) *Comment:* One commenter (AASHTO, 2012) stated that "CASAC strongly recommends that key population-oriented monitors be maintained, particularly those that have been used in past health-focused and accountability studies." It was also stated that "AASHTO is concerned that this proposal will deemphasize the need for area-wide and neighborhood scale $PM_{2.5}$ monitors in these areas."

Response: The EPA notes that the removal of the population oriented language from the applicable $PM_{2.5}$ regulatory text in no way affects the current or future distribution of $PM_{2.5}$ monitors in terms of the objectives of supporting population exposure. From a sample of over 900 operating monitoring stations in the country, none of the currently operated monitors have been determined to not be "population-oriented" based on data in AQS. As noted in the preamble, neighborhood scale monitoring sites remain the backbone of the $PM_{2.5}$ monitoring network and the EPA anticipates they will continue to represent over two thirds of the operating network following the deployment of the near-road monitors. Maintaining the area-wide and largely neighborhood scale design value sites is critical to the long-standing goal of using data to support a variety of monitoring objectives.

E. Comments on Applicability of Micro- and Middle Scale Monitoring Sites to the Annual $PM_{2.5}$ NAAQS

(1) *Comment:* One commenter stated that the EPA should remove the restriction that the annual $PM_{2.5}$ standard applies only at "area-wide" sites. The proposed rule requires agencies to exclude sites that are relatively unique middle scale or micro-scale from comparison to the annual NAAQS. This construction is problematic and will be difficult for agencies to implement.

Response: The requirement that monitors represent area-wide air quality to be comparable to the annual $PM_{2.5}$ NAAQS is longstanding and the EPA did not propose to eliminate it or solicit comment on that issue. While the EPA understands that there may be some challenges in determining the differences between micro-scale and middle scale sites that meet the definition of "area-wide", such challenges have always been in place since the requirements for comparability to the $PM_{2.5}$ NAAQS were first promulgated in 1997. The EPA will work with monitoring agencies through the annual network plan approval process to address such issues.

(2) *Comment:* Several commenters suggested that the EPA should revise the network design requirement to reflect the importance of area-wide representative data to meet national and state monitoring objectives and remove the presumption that micro- and middle-scale sites are representative of many such locations.

Response: The EPA fully supports, and is maintaining, the network design criteria focusing on "area-wide" representative data. Current regulatory language in section 58.30 addressed the NAAQS applicability issue that where micro- and middle-scale sites are representative of many such locations throughout an area, they likewise represent "area-wide" air quality. Similarly, regulatory language in Appendix D, section 4.7.1(b) states that (for $PM_{2.5}$), "The required monitoring stations or sites must be sited to represent area-wide air quality." The final rule provides that the air agency recommend whether the site is or is not "area-wide" in the Annual Monitoring Network Plan. Such a recommendation is still subject to approval by the Regional Administrator.

(3) *Comment:* One commenter stated that EPA should explicitly state that near-road data are considered unique unless otherwise specified by the Regional Administrator.

Response: EPA has clarified language to note that we do not presume that any near-road monitoring site will be considered unique or not unique; rather it provides that the air agency recommend the status of such sites in the Annual Monitoring Network Plan. Such a recommendation is still subject to approval by the Regional Administrator. We disagree that all near-road locations are unique, as these sites can reflect many such locations throughout a metropolitan area. In the preamble, EPA provided examples of near-road sites that could be considered unique; these included sites located in proximity to a unique source like a tunnel entrance, nearby major point source, or other relatively unique microscale hot spot. EPA expects that near-road stations placed in other representative locations will reflect area-wide air quality.

(4) *Comment:* One commenter stated that changing the scale of monitoring site locations that can provide data for use in NAAQS attainment determinations has implications that impact monitoring objectives.

Response: The EPA disagrees that changing the scale of monitoring site locations that can provide data for use in NAAQS attainment determinations is problematic or has negative implications for monitoring objectives. Locations that are at micro- and middle-scale have always been used for comparison to the 24-hour NAAQS, and where these locations represent many such locations in the same area, they have always been appropriate to be compared to the annual NAAQS. As stated in the preamble to the final rule, EPA believes that multiple objectives can be supported with the addition of the near-road monitoring stations, so while EPA agrees there are implications, on balance EPA believes the changes will result in a better network.

(5) *Comment:* One commenter stated that the alternative proposal under consideration, permitting micro- and middle-scale sites to be classified as area-wide, would diminish our ability to track future public health progress at the neighborhood scale.

Response: EPA disagrees that allowing micro- and middle-scale sites to be classified as area-wide, diminishes the ability to track future public health progress at the neighborhood scale. Individual sites will be still be labeled with a given spatial scale (e.g., neighborhood scale) allowing stakeholders to understand the nature and general representativeness of a given site. However, to ensure neighborhood scale sites remain an important part of the PM2.5 network, EPA has addressed this issue in the final rule by clarifying language in Appendix D, section 4.7.1(b)(1) to state that "At least one monitoring station is to be sited *at neighborhood or larger scale* in an area of expected maximum concentration."

(6) *Comment:* Several commenters recommend a positive determination that a $PM_{2.5}$ monitor represents area-wide air quality, and thus eligible for comparison to the $PM_{2.5}$ NAAQS, which should be proposed in Annual Network Plan submittals, with subsequent concurrence and approval by the Regional Administrator. Representation of area-wide air quality should not be "presumed" as proposed in section 58.30(a)(2).

Response: The EPA has clarified language to note that we do not presume that any site will be considered unique or not unique; rather it provides that the air agency recommend the status of such sites in the Annual Monitoring Network Plan. Such a recommendation is still subject to approval by the Regional Administrator. Sites that are approved per section 58.30 as representing area-wide conditions will be eligible for comparison to the $PM_{2.5}$ annual NAAQS.

(7) *Comment:* One commenter (AFPM) stated that contrary to the EPA's assertions in the proposed rule, the proposed changes to allow micro- and middle-scale monitors to be compared to the NAAQS and the revoking of the "population-oriented" condition for monitoring locations (discussed below) do not promote consistency with EPA's existing regulatory definition for "ambient air." As noted by EPA, the regulatory definition of

"ambient air" specifically references the portion of outside air to which the general public has access. In implementing this regulatory definition, EPA has exempted areas where a source owns or controls the property involved and where public access has been precluded. The Agency has consistently relied on documents describing the definition of ambient air with regard to not including areas "to which public access is precluded by a fence or other physical barrier." Thus, EPA has never interpreted ambient air to be "any potential location" outside of a building and proposing to allow "any" $PM_{2.5}$ monitor to be compared to the NAAQS is clearly and directly inconsistent with this long-standing regulatory interpretation. Rather than promote consistency, the change would have the opposite effect given the expansive interpretation of "any" within the CAA. Therefore, EPA should retain the current requirements restricting the use of micro- and middle-scale monitors and additionally consider revising the regulations to *remove* the ability of a Regional Administrator to determine monitor comparability. These changes would better promote the goal of national uniformity by making it clear that monitors would not be subject to highly localized conditions (perhaps measuring highly transient air quality in areas measuring no more than a few square meters) or subject to the individual (and perhaps inconsistent) preferences of different Regional Administrators

Response: With regard to the comment that the proposed change to allow micro- and middle-scale monitors to be compared to the NAAQS does not promote consistency with the EPA's existing regulatory definition for "ambient air", the EPA disagrees. Micro- and middle-scale are already comparable to the NAAQS for all other pollutants, and even for $PM_{2.5}$, all operating micro- and middle scale sites are comparable to at least the 24-hour NAAQS. The EPA believes that its long-standing definition of ambient air is well suited to provide for the consistency needed in ensuring monitors are appropriately sited for comparison to the NAAQS. The EPA disagrees that this change would lead to an expansive interpretation for "any" within the CAA, rather as we have stated, it will promote consistency across all pollutants in determining their applicability to the NAAQS. Moreover, all $PM_{2.5}$ monitoring sites must also be representative of area-wide locations to make the comparison to the annual NAAQS. Thus, these sites will represent locations where there is population exposure. Consistent with the long-standing practice of monitoring agencies in locating ambient monitors, we also note that all currently existing $PM_{2.5}$ monitors are located in areas that are representative of population exposures based on supporting data in the AQS.

The EPA does not believe it is necessary to remove the ability of Regional Administrators to determine monitor comparability. The EPA Regional Offices are the most familiar with their individual State networks and possible changes to them. We do not believe that removing the Regional Administrator from the process of approving micro- or middle-scale sites from comparison to the annual NAAQS, will promote consistency. Rather we believe that information provided by monitoring agencies in their annual monitoring network plans will be sufficient to consistently apply recommendations and support determinations by the EPA Regional Administrator as to whether micro- or middle-scale sites are to be considered" area-wide. With regard to the comment "that monitors may be established in areas subject to highly localized conditions (perhaps measuring highly transient air quality in areas measuring no more than a few square meters)", EPA believes this to be an unrealistic observation for $PM_{2.5}$ based on the secondary nature of fine particle formation that provides for a more homogenous concentration distribution as compared with pollutants dominated by primary emissions such as CO or PM_{10}.

(8) *Comment:* One commenter (EEI, 2012) stated that EPA is proposing to change the current presumption that micro- and middle-scale monitors are unique and therefore are only comparable to the annual $PM_{2.5}$ NAAQS if approved by an EPA Regional Administrator. EPA claims that its intent in amending the current regulations is solely for consistency and predictability in the interpretation of monitoring requirements. Micro scale monitors are defined as applying to "concentrations in air volumes associated with air dimensions ranging from *several* meters up to *about* 100 meters" (emphasis added). Middle scale monitors are defined as "typical of areas *up to several* city blocks in size with dimensions ranging from *about* 100 meters to 0.5 kilometers" (emphasis added). When these vague regulatory definitions are combined with EPA's proposal to allow "any" micro- or middle-scale monitor to be comparable to the NAAQS, the result is a "standardless" standard. Under the EPA's proposed rule, the placement of a monitor may literally occur anywhere and hence the regulations provide for an arbitrary and capricious designation of nonattainment areas. The EPA provides no analytical support in the record for this fundamental change in position. In place of current restrictions, the EPA states that "*any* potential location for a $PM_{2.5}$ monitoring site would be eligible for comparison to the annual NAAQS." Rather than promote consistency, the change would have the opposite effect given the expansive interpretation of "any" within the CAA. The EPA should retain the current requirement and consider revising the current regulations to remove the ability of a Regional Administrator to determine monitor comparability. These changes would better promote the goal of national uniformity by making it clear that monitors would not be subject to highly localized conditions (perhaps down to the transient air quality in an area measuring no more than a few meters wide) or subject to the preferences on an individual Regional Administrator.

Response: The EPA disagrees with the commenter for several reasons. The EPA asserts that it has always been true that the placement of a monitor may potentially occur anywhere. However, the EPA's long-standing practice does not allow a monitor to be compared to a NAAQS unless it represents ambient air. Even under current rules, when a monitor is placed in an environment that represents ambient air, regardless of the scale of representation or whether it represents area-wide air quality it is eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS. When a monitor – at any scale – represents area-wide air quality it is also eligible for comparison to the annual NAAQS. None of these criteria have changed, other than saying "area-wide" instead of "community-wide", which terms are synonymous. With regard to the comment that "Under EPA's proposed rule, the placement of a monitor may literally occur anywhere and hence the regulations provide for an arbitrary and capricious designation of nonattainment areas", the EPA notes that such issues can appropriately be handled with the designations process, when states have the opportunity to address the interpretation of ambient air data and make recommendations on the size of the nonattainment areas based on their interpretation of ambient monitoring data.

(9) *Comment:* Commenters (ALA et al., 2012) stated, "We especially welcome EPA's proposal to abandon and revoke regulatory language in Part 58 that effectively prevented the implementation of the $PM_{2.5}$ NAAQS to protect populations exposed to incremental concentrations near transportation facilities. These include the current prohibitions against comparison of micro- and middle-scale monitors with the annual NAAQS, and the requirement that only "population-oriented" monitors be compared with the 24-hour NAAQS. For the reasons discussed below, we believe these policies impose limitations on the applicability of the NAAQS that are inconsistent with the text, purpose and intent of the Clean Air Act, and must be revoked.

Response: The EPA disagrees that a prohibition has existed against the comparison of micro- and middle-scale monitors with the annual NAAQS. Current regulatory language in section 58.30 addresses the NAAQS applicability issue that where micro- and middle-scale sites are representative of many such locations throughout an area, they likewise represent "area-wide" air quality and are eligible for comparison to the annual NAAQS. This flexibility and inclusion in the annual monitoring network plan process has been a long-standing practice that is not changed in this rulemaking. The EPA also disagrees that monitors placed near transportation facilities would ever have been discounted in a manner suggested by the commenters. As long as such monitors were located in ambient air, they would have been comparable to the 24-hour NAAQS. Any such monitors that were approved as area-wide monitors would also have been comparable to the annual NAAQS.

(10) *Comment:* One commenter (CLF) stated that they support EPA's plans to allow air quality measured at micro- and middle-scale sites near roadways to be compared to the annual standard.

Response: EPA notes that current regulatory language in section 58.30 addresses the NAAQS applicability issue that where micro- and middle-scale sites are representative of many such locations throughout an area, they likewise represent "area-wide" air quality and are eligible for comparison to the annual NAAQS. This eligibility for comparison to the annual NAAQS has been a long-standing practice that is not changed in this rulemaking.

F. Comments on the addition of $PM_{2.5}$ monitors to the near-road monitoring stations.

(1) *Comment:* One commenter strenuously objected to the $PM_{2.5}$ roadway network concept. The concerns expressed included access, safety, and other logistical problems involving roadside monitoring.

Response: As stated in section VIII of the final rule, the addition of $PM_{2.5}$ monitors to the near-road environment is part of a multipollutant design at monitoring stations that are already required and being implemented as part of the required NO_2 monitoring network. The issues referenced by the commenter have already been addressed in a Technical Assistance Document that has been provided to monitoring agencies. Therefore, EPA anticipates any issues on siting of the stations will already be resolved by the time the

$PM_{2.5}$ monitors are required to be operating. To the extent that significant problems do arise with siting a near-road $PM_{2.5}$ monitor, EPA has existing authority to address such situations on a case-by-case basis, or could undertake changes to the rule as necessary.

(2) *Comment:* One commenter stated that a near-road monitor may result in it being the controlling monitor for an area, where the components of $PM_{2.5}$ have not been fully identified, and that this is a national issue where more research is needed.

Response: As stated in section VIII of the final rule, the addition of $PM_{2.5}$ monitors to the near-road environment is to support a number of monitoring objectives. Specifically on the use of data for comparison to the $PM_{2.5}$ NAAQS, the EPA points out that people spend a substantial amount of time in these environments, resulting in a significant potential for exposure to pollutants. The agency believes near-road monitoring is important to ensure that public health is protected with an adequate margin of safety. EPA agrees that more information is needed on the components of $PM_{2.5}$ near roads, and supports the use of supplemental measurements (e,g., aethalometers for black carbon) to contribute to this body of information.

(3) *Comment:* One commenter stated that they would support $PM_{2.5}$ near-roadway monitors if these monitors were used for research data collection purposes and not as a controlling monitor.

Response: As stated in section VIII of the final rule, the addition of $PM_{2.5}$ monitors to the near-road environment is to support a number of monitoring objectives. Specifically on the use of data for comparison to the $PM_{2.5}$ NAAQS, the EPA points out that these monitors will be sited at existing near-road stations. Accordingly, data from these near-road monitors will be compared to the $PM_{2.5}$ 24-hour NAAQS and where determined to be an area-wide monitoring location they will also be compared to $PM_{2.5}$ annual NAAQS. The comparison of these sites to the $PM_{2.5}$ NAAQS is appropriate as these sites will represent ambient air. The EPA also agrees that more information is needed on many aspects of $PM_{2.5}$ levels near roads, and supports the use of supplemental measurements (e,g., aethalometers for black carbon, ultrafine particles) to contribute to research on this topic.

(4) *Comment:* Several commenters stated that while the requirement for near-road $PM_{2.5}$ monitoring can be met by collocation at a near-road NO_2 station, the requirement could also be met by locating a $PM_{2.5}$ monitor at a different near-road location where $PM_{2.5}$ concentrations are expected to be high.

Response: The EPA discusses this issue in section VIII.B.3.b.i of the preamble to the final rule. The EPA concludes that there are sufficient existing authorities to address this issue on a case-by-case basis if necessary, e.g., where a near-road site is not area-wide, and that no additional regulatory language is needed.

(5) *Comment:* One commenter stated that if additional measurements at near-road monitoring stations are believed to offer increased knowledge of the near-road environment, EPA should implement a national level program to address the data need.

Response: The EPA can consider such a program in future planning. In at least one example, EPA's Office of Research and Development is partnering with a state monitoring agency to support the deployment of additional monitors at a required near-road station.

(6) *Comment:* Several commenters recommended the near-road $PM_{2.5}$ network should be smaller and more specifically designed to capture the data needed to characterize the near-source exposures and correlate them to key source variables that extrapolate to other locations.

Response: The EPA considered comments on the size of the network in finalizing the requirements for the final rule. Rationale for the size of the network is explained in section VIII.B.3.b.i of the preamble to the final rule. As noted in the previous response, the EPA continues to pursue additional information on near-road environments.

(7) *Comment:* Several commenters recommended that the expected maximum concentration $PM_{2.5}$ monitoring sites be neighborhood scale and that the maximum concentration site not be subject to relocation on a year-to-year basis.

Response: The EPA agrees with the commenters and has adjusted the requirements accordingly. See section VIII.B.3.b.i of the preamble to the final rule for a more detailed explanation of this issue. Specifically, EPA has addressed this issue in the final rule by clarifying language in Appendix D, section 4.7.1(b)(1) to state that "At least one monitoring station is to be sited *at neighborhood or larger scale* in an area of expected maximum concentration."

(8) *Comment:* Several commenters recommended that we can improve the efficiency and effectiveness of the $PM_{2.5}$ network and reduce implementation costs by a combination of phasing, timing, and focusing the scope of the near road monitoring portion of the network by: refocusing the near-road network to provide better characterization of mobile source emissions at a more limited number of sites including the correlation of emissions to key variables such as traffic, volume, fleet composition, and prevailing winds; initiate deployment of the near-road network in MSAs with populations greater than 2.5 million; and commence deployment of near-road $PM_{2.5}$ monitors one year after implementation of near road NO_2 monitors.

Response: These issues are addressed in section VIII.B.3.b.i of the preamble to the final rule.

(9) *Comment:* One commenter stated that they understand the need to develop better characterization of near-road exposures to $PM_{2.5}$.

Response: The comment in support of the proposal is acknowledged.

(10) *Comment:* One commenter stated that for those CBSAs with just one required monitor, that monitor should be at a neighborhood scale.

Response: The EPA agrees with the commenters and has adjusted the requirements accordingly. See section VIII.B.3.b.i of the preamble to the final rule for a more detailed explanation of this issue. Specifically, the EPA has addressed this issue in the final rule by clarifying language in Appendix D, section 4.7.1(b)(1) to state that "At least one monitoring station is to be sited *at neighborhood or larger scale* in an area of expected maximum concentration."

(11) *Comment:* One commenter stated the monitoring networks resources should be used to support a developed NAAQS, not to support exploratory research. Until such time the EPA can clarify the connection between near-roadway emissions concentrations and population exposure, we believe that participation in this research should be voluntary rather than mandated by code.

Response: As explained in the preamble to the final rule, the EPA points out that a significant fraction of the population lives, works, plays, and goes to school near major roads and that these exposures occur in locations that represent ambient air for which the agency has a responsibility to ensure the public is protected with an adequate margin of safety, including through the requirement for a minimum number of ambient monitors for the NAAQS. Indeed, one study identified that 45 million Americans live within 300 feet of a highway with four or more lanes, a railroad, or an airport, and given the relative ubiquity of roads, EPA anticipates that those are predominantly near-road exposures. See study of the American Housing Survey, which is available on the web at: http://www.census.gov/housing/ahs/data/ahs2009.html.

(12) *Comment:* Two commenters stated that any near-roadway monitor should be classified as representative of micro-scale conditions and thus exempt from comparison to the NAAQS.

Response: There is no exemption from comparability to the NAAQS based solely on the scale of representation. There are requirements for comparability to the annual $PM_{2.5}$ NAAQS based on whether a site is approved in an annual monitoring network plan as area-wide or not. Near road monitors will be evaluated by monitoring agencies and the EPA to determine whether they meet the criteria to be classified as "area-wide" or not. However, all sites representative of ambient air are at a minimum compared to the 24-hour $PM_{2.5}$ NAAQS. Where an existing near-road site is not classified as area-wide for $PM_{2.5}$, EPA will work with monitoring agencies to determine whether it is appropriate to locate the monitor at a different location, such as a near-road site that is area-wide for $PM_{2.5}$.

(13) *Comment:* One commenter stated that agencies need the maximum amount of time possible to comply with the new near-road monitoring requirements; however, they do

believe they can comply with the proposed requirement for $PM_{2.5}$ monitors at near-road stations by January 1, 2015.

Response: As explained in section VIII.B.3.b.i of the preamble to the final rule, the EPA is finalizing a phased in approach for deployment of the required near-road $PM_{2.5}$ monitors.

(14) *Comment:* One commenter supports the proposal to allow research at selected near-road monitoring stations, so long as this remains voluntary.

Response: The comment in support of the proposal is acknowledged and the EPA is adopting the proposed approach in the final rule.

(15) *Comment:* One commenter stated with regard to the EPA's proposal to relocate $PM_{2.5}$ monitors to meet the near-roadway environment, the EPA rarely allows a state to simply shut down a monitoring station and relocate it. Also, that the assumption that states will have extra $PM_{2.5}$ monitors to relocate to near-roadway sites is simply untenable and unrealistic.

Response: The EPA appreciates the concern regarding the challenges of relocating a site, including getting approval from EPA Regional Offices. As explained in section VIII.B.3.b.i of the preamble to the final rule, the EPA will work with monitoring agencies in the phased implementation to address which monitors will be most appropriate for relocating. Also, as explained in the preamble, the EPA is aware that every existing $PM_{2.5}$ monitor has value to someone or some data user and that relocating these sites will result in the loss of that data; however, the EPA maintains that on balance, the siting of the monitors in the near-road environment will provide for a better overall network design to address a number of monitoring objectives.

(16) *Comment:* The EPA has not provided any information showing the near-roadway data would have any meaning with respect to measurement of population exposures. The proposed near-road monitoring network is more appropriately addressed in a research venue until such time that the EPA can adequately demonstrate that near-roadway environment has a direct nexus to a population exposure.

Response: As explained in section VIII.B.3.(b) i of the preamble to the final rule and in response to Comment (11) above, people spend a substantial amount of time in proximity to major roadways and EPA believes near-road monitoring is important to ensure that public health is protected with an adequate margin of safety.

(17) *Comment:* The PM near-road monitors appear to be an EPA-mandated, state-operated research project. These monitors do not capture broadly representative ambient air, thus they are likely to provide a comparison to the NAAQS not foreseen by the Clean Air Act.

Response: As explained in, section VIII of the preamble to the final rule and this response to comments, there are large numbers of people (in the tens of millions) that live, work, play, and go to school in close in proximity to major roadways. These exposures occur in locations that represent ambient air for which the agency has a responsibility to ensure the public is protected with an adequate margin of safety. Comparison of monitoring results from such areas to the NAAQS is therefore appropriate. The EPA disagrees that the data produced from $PM_{2.5}$ near-road monitors compared to the NAAQS will result in something unforeseen by the Clean Air Act.

(18) *Comment:* One commenter disagrees with the placement of ($PM_{2.5}$) monitors used to represent long-term public exposure at near-road sites because the data are not representative enough to compare to a national standard.

Response: The EPA disagrees that the near-road $PM_{2.5}$ data are not representative enough to compare to a national standard. The purpose of a national ambient air quality standard is not to achieve an average ambient air quality, with some areas above or below the standard, but to establish a level of air quality that all areas achieve. Likewise the purpose of a monitoring network design plan, given necessarily limited resources, is generally to locate monitors in areas that pose a risk of exceeding the standard, subject to decisions about the appropriate spatial scale or, as here, area-wide monitoring. If the comment is suggesting that the data should not be comparable to the annual NAAQS even where there is an "area-wide" monitor, the EPA rejects that argument for the reasons explained elsewhere in this document and the preamble. Moreover, if the premise of the comment is that more polluted populated areas are by definition unrepresentative, the EPA rejects that premise, and further rejects the comment that siting some monitors in near roadway environments makes the standard more stringent or impermissibly more stringent. As discussed in section VIII.B.3.b.i of the preamble to the final rule, a significant fraction of the population lives in proximity to major roads, and these exposures occur in locations that represent ambient air. Monitoring in such areas does not make the standard more stringent than warranted, but rather affords the intended protection to the exposed populations, among them at-risk populations, exposed to fine particles in these areas. Thus, in cases where monitors in near roadway environments are deemed to be representative of area-wide air quality they would be compared to the annual standard. The 24-hour and annual NAAQS are designed to protect the public with an adequate margin of safety, and this siting provision is fully consistent with providing the protection the standard is designed to provide and does not make the standard more stringent or more stringent than necessary.

Monitors that are representative of area-wide air quality may be compared to the annual standard. This is consistent with the use of monitoring data in the epidemiological studies that provide the primary basis for determining the level of the annual standard. In addition, the EPA notes that the annual standard is designed to protect against both long- and short-term exposures through controlling the broad distribution of air quality across an area over time.[39] It is fully consistent with the protection the standard is designed to provide for near road monitors to be compared to the annual standard if the monitor is

[39] This is in contrast to the 24-hour standard which is designed to provide supplemental protection, addressing peak exposures that might not otherwise be addressed by the annual standard. Consistent with this, monitors are not required to be representative of area-wide air quality to be compared to the 24-hour standard.

representative of area-wide air quality. This does not make the standard either more stringent or impermissibly more stringent. Furthermore, as the agency explained in the discussion of the form of the annual standard, higher measuring monitors are often located in areas where there are higher numbers of at-risk populations. These areas require requisite protection with an adequate margin of safety, and placing monitors in such areas and comparing results from such monitors to the $PM_{2.5}$ NAAQS is part of that process of affording requisite protection with an adequate margin of safety.

(19) *Comment:* A single monitoring station near a heavily travelled roadway is not adequate to describe the gradient of PM components with increasing distance from the roadway.

Response: The EPA is not attempting to address the question of PM components in the near-road environment, other than as explained in the proposal, those monitoring agencies that voluntarily deploy additional instrumentation in the near-road environment. Additionally, the EPA is not attempting to describe the gradient with a single monitoring station. As described in the preamble to the final rule, the network design is intended to provide for representative near-road monitoring stations that are collocated with NO_2 and CO. Thus, while a gradient of the $PM_{2.5}$ concentrations from representative near-road stations to neighborhood scale stations may be possible, if such neighborhood scale monitoring sites are located in the same general vicinity, it is not the EPA's goal to have these gradients determined for every area.

(20) *Comment:* One commenter states that near-road monitoring sites should be considered micro-scale sites due to the lack of experience with these monitoring sites, data, and experimental nature of near-road monitoring. Only when we have a better understanding of their relationship to population exposure should these sites be considered for comparison to the NAAQS.

Response: The relative experience of monitoring has nothing to do with the scale of representation of a monitoring station or its applicability to the NAAQS. Rather the variability of that data at the location where it is monitored compared to the variability of that pollutant in the surrounding area is what defines its scale of representation. As explained in the section VIII of the preamble to the final rule and in earlier responses in this document, there are large numbers of people (in the tens of millions) that live, work, play, and go to school in close proximity to major roadways. These exposures occur in locations that represent ambient air and the EPA believes near road monitoring is important to ensure the public is protected with an adequate margin of safety.

(21) *Comment:* The continued collection of data from the neighborhood scale monitors is absolutely necessary because they represent typical worst-case air quality for each Core Based Statistical Area.

Response: The EPA generally agrees with the need for continued collection of neighborhood scale data. This comment is addressed in more detail in section VIII.B.3.b.i of the preamble to the final rule for a more detailed explanation of this issue. Specifically, EPA has addressed this issue in the final rule by clarifying language in

Appendix D, section 4.7.1(b)(1) to state that "At least one monitoring station is to be sited *at neighborhood or larger scale* in an area of expected maximum concentration."

(22) *Comment:* One commenter disagreed with the proposal to add a near-road component to the compliance monitoring network. The micro-scale nature of these sites precludes the data from being used for all of the monitoring objectives except source characterization.

Response: The EPA notes that near-road monitors must represent "area-wide" air quality to be comparable to the annual NAAQS, and that we have a process for determining whether sites at smaller scales (i.e., micro- or middle-scale) represent "area-wide" air quality. The EPA disagrees with the commenter that the micro-scale nature of the near-road sites precludes their use for all monitoring objectives, except source characterization. These sites in combination with the neighborhood scale sites in the same CBSA will support a number of monitoring objectives as explained in section VIII.B.3.b.i of the preamble to the final rule.

(23) *Comment:* One commenter stated that the proposal would remove the population exposure objective from sites used in NAAQS determinations and permit micro- and middle-scale sites to be classified as area-wide. Micro- and middle-scale data are not applicable for CBSA-wide exposures and can't be used for many of the monitoring objectives including health studies, pollution trends analysis, or State Implementation Plan (SIP) development and control strategy development where necessary.

Response: As explained in the preamble, the $PM_{2.5}$ monitors at near-road monitoring stations will in fact support a number of monitoring objectives, including all of the monitoring objectives, where necessary, that the commenter lists (i.e., health studies, pollution trends analysis, or State Implementation Plan (SIP) development and control strategy development where necessary) in the comment. The EPA disagrees that we are removing population exposure from sites used in NAAQS determinations. The near-road monitoring stations, when determined to be representative of many such locations throughout an area, are considered to represent "area-wide' air quality and as such are representative of those population exposures where large numbers of people live, work, play, and go to school.

(24) *Comment:* One commenter states that the inclusion of $PM_{2.5}$ measurements near roadways is consistent with CASAC's recommendations to develop the near roadway network with a multipollutant focus and to include $PM_{2.5}$ on the list of pollutants that should be measured.

Response: The comment in support of the proposal is acknowledged and the EPA is adopting the proposed approach in the final rule.

(25) *Comment:* Several comments stated that the deployment of new near-roadway monitoring should not come at the expense of existing $PM_{2.5}$ network objectives, including neighborhood scale population exposure, AQI reporting, environmental justice, transport, and background.

Response: As explained in the preamble to the final rule, the $PM_{2.5}$ monitors at near-road monitoring stations will support a number of monitoring objectives, including several of the monitoring objectives that the commenter lists in the comment. Also, as explained in the preamble, the EPA is aware that every existing $PM_{2.5}$ monitor has value to someone or some data user and that relocating these sites will result in the loss of that data; however, the EPA maintains that on balance, the siting of the monitors in the near-road environment will provide for a better overall network design to address monitoring objectives.

(26) *Comment:* One commenter stated that for CBSAs with populations greater than 1 million, the proposed rule would require that one site be collocated with a near roadway NO_2 site, which has no corresponding requirement to be an area-wide monitor.

Response: The assignment of whether a monitor represents area-wide air quality is by a combination of the pollutant and the location of the station and not just the location of the station itself. The EPA anticipates that $PM_{2.5}$ monitoring located at near-road monitoring stations will often be representative of area-wide air quality, and will consider requests for limited deviations from the requirements of Appendix D, as necessary and appropriate, where an existing near-road site is not classified as "area-wide" for $PM_{2.5}$. Also, although the EPA does not require the NO_2 near-road sites to be area wide, we do explain the in the Near-road NO_2 Monitoring Technical Assistance Document (TAD) that higher weight should be placed on sites that are most influenced by typical roadway activity rather than those that are heavily influenced by unique sources or features.

(27) *Comment:* One commenter stated that they understand and agree with the objective to maximize resources by collocating near road monitors, as well as the desire for comprehensive, multi-pollutant data a single location.

Response: The comment in support of the proposal is acknowledged and the EPA is adopting the proposed approach in the final rule.

(28) *Comment:* One commenter provided recommendations on new language for cases where a third $PM_{2.5}$ SLAMS monitor is required in a CBSA. The recommendation stated "For areas with additional required SLAMS, a monitor should be installed to provide additional information necessary for one of the following objectives: source characterization, health studies, selection of control strategies or SIP implementation".

Response: The EPA believes the existing language is sufficient to encompass the recommendations in the comment.

(29) *Comment:* One commenter stated that the proposed near-roadway monitoring to measure particulate matter from transportation sources is only warranted with a species-based standard. The commenters also states that many recognized medical experts have long believed that transportation related $PM_{2.5}$ is a major contributor to human health impacts. So from that standpoint, the EPA's proposal to add $PM_{2.5}$ ambient air monitor to roadway

locations might be a positive step , but only if the agency is proposing a speciated $PM_{2.5}$ standard.

Response: The EPA has addressed the issue of considering a species based standard in section III.E.1 of the preamble to the final rule. As stated there, the Administrator concluded, consistent with CASAC advice, that the currently available scientific information did not provide a sufficient basis for either targeting or 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. Consequently, although EPA agrees with the comment that adding $PM_{2.5}$ monitoring roadway is a positive step, and accordingly has finalized a requirement for monitoring for $PM_{2.5}$ mass at a modest number of locations, the EPA disagrees that a consequence of such a monitoring approach must be a speciated indicator for the standard.

(30) *Comment:* One commenter provided a detailed follow-up comment on the EPAs proposal to revise the form of the annual $PM_{2.5}$ standard to base the standard on the highest community-oriented monitor in an area and to eliminate spatial averaging. The commenter stated that, according to the EPA, for an area with multiple monitors, the appropriate reporting monitor with the highest design value would determine the attainment status for that area. The commenter does not support this approach as it is not consistent with monitoring results from health study analyses. Furthermore, the commenter is very skeptical of this approach given the EPA's intent to locate more monitors along roadways in major urban areas without the requisite knowledge of what the $PM_{2.5}$ readings might be from these monitors.

Response: The EPA has addressed the issue of eliminating spatial averaging in section III.E.3.a of the preamble to the final rule. Regarding the comment that this approach is not consistent with the monitoring results from health study analyses, the EPA considered this issue in the form of the standard which is also described in section III.E.3.a of the preamble to the final rule. As explained in section II.E.c.i.1 of the preamble to the final rule, it is appropriate to compare the $PM_{2.5}$ concentrations from a maximum area-wide monitor to the level of the annual $PM_{2.5}$ standard. Regarding the commenter's statement on having the requisite knowledge of what the $PM_{2.5}$ readings might be from these monitors, the EPA has considered the available information[40] and the need to protect the public health with an adequate margin of safety in deciding to move forward with this requirement.

(31) *Comment:* One commenter stated the net effect of relocating the 52 monitors (the monitors to be located in the near-road environment) will be to overestimate the ambient air concentration of $PM_{2.5}$. These roadside monitors would be measuring $PM_{2.5}$ in a worst case scenario that would not be representative of ambient air.

Response: The EPA does not believe it will overestimate ambient air concentrations of $PM_{2.5}$ in the near road environment for the following reasons. First, when monitoring is

[40] In the preamble to the final rule we cite multiple studies (Ntziachristos et al., 2007; Ross et al., 2007; Yanosky et al., 2009; Zwack et al., 2011) that are relevant to informing what the $PM_{2.5}$ readings may be.

performed, it is an actual measurement and does not constitute an estimate of conditions present at that location. Second, the EPA in almost all cases purposely requires air agencies to site ambient air monitoring in areas that represent maximum concentrations, particularly to meet objectives such as assessing NAAQS compliance. EPA does this to focus monitoring resources where they are most worthwhile to assess compliance with the NAAQS and protection of public health and welfare. For example, our monitoring requirements are typically stated to site monitors “in area of expected maximum concentration”. This is described repeatedly throughout Appendix D to Part 58. Third, EPA’s long-standing practice is to locate monitors that meet the definition of ambient air. In the final rule EPA is requiring $PM_{2.5}$ sites in near-road environments to be collocated with NO_2. EPA notes that near-road monitors that are not “area-wide” will not be eligible for comparison to the annual NAAQS, but EPA believes that monitors comparable to the NAAQS will be representative of ambient air and representative of actual exposures in the near-road environment.

(32) *Comment:* One commenter stated that the EPA needs to consider modifications to the monitoring system for $PM_{2.5}$ emissions beyond the roadside monitors before implementing any revisions to the $PM_{2.5}$ standard and making nonattainment designations. The existing $PM_{2.5}$ monitoring network is not sufficient to predict ambient air concentrations reliably for all facility locations. For example, many monitors are located in areas expected to yield the highest $PM_{2.5}$ emissions. This high sampling bias is not representative of the true ambient air concentrations and will result in an unrealistically high number of nonattainment areas. For example, the ambient air levels for one foundry located in a rural setting are determined from a $PM_{2.5}$ emissions monitor that is located in a more urban area located 60 miles away. Consequently, the foundry may be subject unnecessarily to restrictions on modernization and expansion based on a nonattainment designation from biased and unrepresentative $PM_{2.5}$ emissions monitoring data.

Response: The network design criteria for ambient air monitoring of $PM_{2.5}$ does not specifically require source oriented monitoring stations; rather the network design is primarily focusing on characterizing area-wide air quality which represent many such locations within urban areas. The EPA purposely requires monitoring sites in the area of expected maximum concentration where it also represents area-wide air quality. The EPA does not believe it is necessary to address source oriented monitoring for facilities, for which there are no specific requirements, prior to implementing $PM_{2.5}$ monitoring in near-road environments. Any such discussion would necessarily be premature, absent the specific facts and regulatory context. The EPA notes that areas are designated nonattainment based on a determination that the area either violates or contributes to a violation of the NAAQS, and States are only required to implement those control measures that will attain the NAAQS as expeditiously as practicable. Issues as to the proper extent of the nonattainment area or control strategy may be considered as those issues arise, but EPA does not believe that avoiding a determination of nonattainment is a reason to change the monitoring network design requirements.

We note further, however, that the final rule expressly provides that $PM_{2.5}$ measurement data from monitors that are not representative of area-wide air quality but rather of relatively unique micro-scale, or localized hotspot, or relatively unique middle-scale impact sites are not eligible for comparison to the annual $PM_{2.5}$ NAAQS. The rule gives the specific example of “a micro- or middle-scale $PM_{2.5}$ monitoring site … adjacent to a unique dominating local $PM_{2.5}$ source” being eligible only for comparison to the 24-hour $PM_{2.5}$ NAAQS. Additionally, the majority of the $PM_{2.5}$ monitoring network consists of monitors that represent neighborhood scale or areas up to several kilometers across. Accordingly, the EPA believes that the revised $PM_{2.5}$ network will continue to appropriately characterize concentrations in a wide variety of settings.

(33) *Comment:* Several commenters summarized a series of concerns regarding the EPA’s proposal to end spatial averaging, to establish a new requirement for roadside monitoring, allow comparison of micro- and middle-scale monitors to the $PM_{2.5}$ NAAQS and revoke the long-standing requirement that $PM_{2.5}$ monitors used for comparison to the 24-Hour $PM_{2.5}$ NAAQS be “population-oriented”. The commenters generally object to these changes and request that EPA not act to finalize any of the new requirements. One of the rationales provided was that EPA has not provided sufficient rationale in the proposed rule for the changes, and the combined effect of all the changes would be to substantially revise the stringency of either the existing PM NAAQS (if retained) or any newly revised NAAQS.

Response: These comments are addressed in section III and section VIII of the preamble to the final rule.

(34) *Comment:* One commenter stated that although the EPA indicates that the new near-road micro-scale monitoring for $PM_{2.5}$ promotes efficiency, the EPA has apparently not considered in any substantial fashion the differences between NO_2 and $PM_{2.5}$ formation in such an environment. Instead, the EPA’s roadside monitoring plan is inherently and irretrievably arbitrary: The EPA essentially admits that the only reason that $PM_{2.5}$ monitors will be placed in such locations is that the EPA previously required such a new monitoring network for an entirely different pollutant.

Response: EPA disagrees that it has not considered the differences between NO_2 and $PM_{2.5}$. As stated in section VIII.B.3.b.i of the preamble, the EPA is requiring the addition of $PM_{2.5}$ monitors at near-road stations to support a number of monitoring objectives. Therefore, we reject the comment that the only reason we are placing $PM_{2.5}$ monitors in near-road environments is that we already have a monitoring network there for another pollutant (i.e., NO_2). Regarding the comment that we have apparently not considered, in any substantial fashion, the difference between NO_2 and $PM_{2.5}$ formation in such an environment, the EPA believes that the characterization of representative maximum $PM_{2.5}$ concentrations due to on-road mobile sources and the appropriate location of such $PM_{2.5}$ monitors will be the same approximate locations that are the focus of the near-road NO_2 network. This is due to the fact that $PM_{2.5}$, like $NO_{X,}$ is disproportionately influenced by heavy duty (HD) vehicles which are predominantly diesel fueled, when compared to light duty (LD) vehicles which are primarily gasoline fueled. Specifically, for both $PM_{2.5}$ and NOx, HD vehicles emit more of these two pollutants and their precursors on a per vehicle basis than LD vehicles. The EPA recognized this fact in the near-road NO_2 network by requiring states to consider the fleet mix of candidate road segments where near-road monitoring might occur. In the design of the NO_2 near-road network where the $PM_{2.5}$ monitors will be installed, states were instructed to place a higher priority on those highly trafficked roads which have more diesel fueled vehicles using a metric called the fleet equivalent average annual daily traffic.[41] As such, the Agency believes it is appropriate that required near-road $PM_{2.5}$ monitors would be located with near-road NO_2 monitors as they are similarly influenced not only by fleet mix but also by total traffic count, congestion patterns, roadway design, terrain, and meteorology. In addition, as discussed in section VIII of the preamble, where an air agency believes a different location is a more appropriate site for a near-road $PM_{2.5}$ monitor, the EPA can use its discretion in approving a deviation from the $PM_{2.5}$ monitoring requirements under existing authority in the network design criteria. A deviation would be appropriate for consideration where, for example, a state provides quantitative evidence demonstrating that peak ambient $PM_{2.5}$ concentrations would occur in a near-road location which meets siting criteria but is not a near-road NO_2 monitoring site. Such deviations may be approved by the Regional Administrator as described in section 4.7.1 of Appendix D to part 58.

(35) *Comment:* One commenter stated that in the final rule for the NO2 NAAQS, the near road monitoring requirement was justified by the EPA explicitly on the basis of the averaging time and level of the standard (e.g., the EPA finalized a new 1-hour standard at a level of 100 parts per billion ("ppb")). In taking this action, the EPA noted that NO_2 concentrations could be expected to vary, and therefore, the differences between near-roadway monitors and area-wide concentrations that had been used to measure compliance with the pre-existing NO_2 annual standard could result in a variable level of the standard (i.e., between 50 ppb and 75 ppb based on whether concentrations near roadways were 100% or 30% higher than at other monitors). Yet, in this proposed rule, the EPA does not offer any comparable analysis with respect to the relative stringency of a $PM_{2.5}$ annual or 24-hour NAAQS as implemented through a network of new roadside monitors.

This lack of information is even more notable since the EPA is proposing that the probe and siting criteria for near-road $PM_{2.5}$ monitoring follow the same probe and siting criteria for the NO_2 near-roadway monitoring sites. These criteria require monitors "as near as practicable" to the outside nearest edge of traffic lanes, but no greater than 50 meters from the edge of a road. AFPM provided comments to the EPA in 2009 regarding the severe limitations and qualifications that are associated with such monitors. To briefly reiterate and as reflected in the NO_2 NAAQS ISA and REA, such monitors suffer from issues involving accuracy and the relationship between area-wide monitoring data and roadside emissions is highly variable. In addition, there is increased potential for errors associated with monitor placement.

[41] See the Near-road NO_2 Monitoring Technical Assistance Document at: http://www.epa.gov/ttn/amtic/files/nearroad/NearRoadTAD.pdf

Response: As explained in section III.E.c.i.1 of the preamble to the final rule, it is appropriate to compare the $PM_{2.5}$ concentrations from a maximum area-wide monitor to the level of the annual $PM_{2.5}$ standard. Consequently, the approach adopted in this rulemaking for the $PM_{2.5}$ standard is consistent with the ultimate thrust of the approach in the NO_2 NAAQS: providing a level of protection in an area with a maximum monitor affords requisite protection across the entire area. However, given differences in the bodies of available scientific evidence for NO_2 and $PM_{2.5}$, it is appropriate that EPA employed different types of analyses in the two reviews to achieve this ultimate result. In the case of NO_2 the scientific evidence that formed the basis for the final decision on the level of the revised standard included both epidemiological studies, reporting associations between respiratory endpoints and area-wide NO_2 concentrations, and controlled human exposure studies, reporting respiratory effects following short-term exposures to NO_2 concentrations at or above 100 ppb. In considering this evidence, the Administrator set a new 1-hour standard with a level of 100 ppb.

In setting this new standard, information on the NO_2 gradients around roadways was used to consider the relationships between area-wide NO_2 concentrations and potential exposure concentrations. Specifically, because the revised NO_2 standard was intended to reflect the maximum allowable NO_2 concentration in an area, the Administrator concluded that this standard would limit exposures to NO_2 concentrations reported in controlled human exposure studies to result in respiratory effects. In reaching this conclusion, the Administrator noted that the highest NO_2 exposure concentrations in urban areas could occur around major roadways. In addition, given the available evidence for NO_2 concentration gradients around roadways, she concluded that the new standard would maintain area-wide NO_2 concentrations (away from major roads) well below those in locations where key U.S. epidemiological studies had reported associations with adverse respiratory effects (75 FR 6501).

In the current review of the PM NAAQS the scientific evidence forming the basis for final decisions on the $PM_{2.5}$ standards includes epidemiological studies reporting associations between area-wide $PM_{2.5}$ concentrations and a number of adverse health outcomes (i.e., including mortality and a variety of cardiovascular and respiratory effects). While controlled human exposure studies of $PM_{2.5}$ provide coherence and biological plausibility for the effects observed in epidemiological studies, because of the exposure concentrations and durations evaluated they do not provide an appropriate basis to inform decisions on the levels of the 24-hour or annual standards. In light of this fundamental difference in the bodies of evidence available for NO_2 and $PM_{2.5}$, the approach to considering NO_2 roadway concentration gradients adopted in the most recent review of the primary NO_2 NAAQS would not similarly inform the Administrator's decisions in the current review of the PM NAAQS.[42] Therefore, the same approach would not be warranted in the two reviews.

[42] See also comments of UARG at 55 n. 73 drawing this same distinction ("The fact that the level of the $PM_{2.5}$ NAAQS is derived solely from epidemiological studies distinguishes it from the NO_2 NAAQS for which, as the EPA notes, 77 Fed. Reg. at 39010/2-3, it recently adopted near-road monitoring requirements. That standard was based, in significant part, on controlled human exposure studies in which actual NO_2 exposures were measured that

The EPA's discusses the specifics of siting within the near-road environment in section VIII.B.5.a of the preamble to the final rule.

(36) *Comment:* One commenter stated that the EPA provides little if any technical support for this proposal. Two documents are mentioned in the preamble: the "Near-road Monitoring Pilot Studies Objectives and Approach" and the "Review of the Near-Road Document – Outline." But these documents either do not specifically address near-road $PM_{2.5}$ monitors or merely mention the issues involved with identifying monitor locations. Therefore, the EPA's proposed monitoring plan is wholly unsupported in the preamble and the docket for this rulemaking.

Response: The EPA believes that the documents cited in combination with the rationale in the preamble do support the decision to add $PM_{2.5}$ near-roadway monitoring. While these documents were created prior to the proposal to add $PM_{2.5}$ monitors to near-road environments, for reasons already explained above in this response to comment section, we believe there are a number of reasons that support siting $PM_{2.5}$ and NO_2 monitors at the same near-road monitoring station, related both to technical issues such as vehicle mix as well as support for monitoring objectives.

(37) *Comment:* One commenter stated that compounding the issue of near road monitoring is EPA's proposal to change the current regulatory presumption that micro- and middle-scale monitors are not comparable to the annual $PM_{2.5}$ NAAQS (unless specifically approved for such use by an EPA Regional Administrator) and to additionally strike other existing regulatory language that limits the use of such monitors. EPA should abandon these proposals. Instead, the EPA should consider removing the current role of the Regional Administrator in order to promote national consistency in NAAQS monitoring and to specifically disallow utilization of microscale monitors except for special purpose monitoring and for the purpose of conducting research.

Under current regulations, micro scale monitors are defined as applying to "concentrations in air volumes associated with air dimensions ranging from several meters up to about 100 meters." Thus, such monitors may comply with regulatory requirements yet be placed in varying locations, including at sites which are very close to emissions which could heavily influence monitoring results. The scale of "several meters" effectively provides no restriction at all on where monitors could be placed. When combined with EPA representation that "any potential location for a $PM_{2.5}$ monitoring site . . . would be eligible for comparison to the annual NAAQS", the result is that nonattainment areas could be considered to exist literally anywhere, including extremely small areas within a urban (or rural) area and/or where public access is prohibited.

Contrary to the EPA's assertions in the proposed rule, the proposed changes to allow micro- and middle-scale monitors to be compared to the NAAQS and the revoking of the

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could reasonably be compared to concentrations measured near roads. 75 Fed. Reg. at 6500/1-01/2.").

“population-oriented” condition for monitoring locations (discussed below) do not promote consistency with the EPA’s existing regulatory definition for “ambient air.” As noted by the EPA, the regulatory definition of “ambient air” specifically references the portion of outside air to which the general public has access. In implementing this regulatory definition, the EPA has exempted areas where a source owns or controls the property involved and where public access has been precluded. The Agency has consistently relied on documents describing the definition of ambient air with regard to not including areas “to which public access is precluded by a fence or other physical barrier.” Thus, EPA has never interpreted ambient air to be “any potential location” outside of a building and proposing to allow “any” $PM_{2.5}$ monitor to be compared to the NAAQS is clearly and directly inconsistent with this long-standing regulatory interpretation. It is also contrary to original distinctions Congress made between ambient air and other air quality issues. In the 1970 Clean Air Act, Congress distinguished between ambient air issues where emissions emanated from diverse stationary and moving sources, and other pollution agents that were “generally confined, at least for detection purposes, to the area of the emission source.”

Finally, as noted above with reference to roadside monitoring, the EPA provides no documentation for this proposal in the preamble or, as of this date, the docket. Rather than promote consistency, the change would have the opposite effect given the expansive interpretation of “any” within the CAA. Therefore, the EPA should retain the current requirements restricting the use of micro- and middle-scale monitors and additionally consider revising the regulations to remove the ability of a Regional Administrator to determine monitor comparability. These changes would better promote the goal of national uniformity by making it clear that monitors would not be subject to highly localized conditions (perhaps measuring highly transient air quality in areas measuring no more than a few square meters) or subject to the individual (and perhaps inconsistent) preferences of different Regional Administrators.

Response: The EPA utilizes the Regional Administrators in the approval of annual monitoring network plans and in many other areas applicable to network design and probe and siting criteria. We believe that the annual monitoring network plans, which are described in §58.10, provide an appropriate place for monitoring agencies to describe their networks, since the public has an opportunity to provide input on plans where there are changes. The EPA Regional Offices are the most familiar with their individual State networks and possible changes to them and there is routine coordination across the EPA Regional Offices on technical and policy issues. Therefore, we do not believe that removing the Regional Administrator from the process of approving micro- or middle-scale sites from comparison to the annual NAAQS, will promote consistency.

Regarding the comment, “Thus, EPA has never interpreted ambient air to be “any potential location” outside of a building and proposing to allow “any” $PM_{2.5}$ monitor to be compared to the NAAQS is clearly and directly inconsistent with this long-standing regulatory interpretation”. The EPA disagrees that we are intending ambient air to be “any potential location outside of a building”. We will continue to use our long standing definition of “ambient air” which is specified in 40 CFR 50.1 – our definition is: –

"Ambient air means that portion of the atmosphere, external to buildings, to which the general public has access". If a monitoring station does not meet this definition, monitoring results from the station could not be compared to the $PM_{2.5}$ NAAQS. Consequently, the rule does not authorize comparison with the annual $PM_{2.5}$ NAAQS with monitoring data from sites to which the public lacks access. Moreover, the final rule provides that to be compared to the annual $PM_{2.5}$ NAAQS, measurement data must come from monitors that are representative of area-wide air quality. Section 58.1. Area-wide "means all monitors sited at neighborhood, urban, and regional scales, as well as those monitors sited at either micro- or middle-scale that are representative of many such locations in the same CBSA." Id. So in addition to representing areas in which there is public exposure, sites must be representative of many similar locations in an area for comparison with the annual $PM_{2.5}$ NAAQS.

(38) *Comment:* One commenter stated that the proposed near-roadway monitoring to measure particulate matter from transportation sources is only warranted with a species-based standard. The commenters also states that many recognized medical experts have long believed that transportation related $PM_{2.5}$ is a major contributor to human health impacts. So from that standpoint, the EPA's proposal to add $PM_{2.5}$ ambient air monitor to roadway locations might be a positive step , but only if the agency is proposing a speciated $PM_{2.5}$ standard.

Response: The EPA has addressed the issue of considering a species based standard in section 3E.1 of the preamble to the final rule.

(39) *Comment:* One commenter provide a detailed follow-up comment on the EPA's proposal to revise the form of the annual $PM_{2.5}$ standard to base the standard on the highest community-oriented monitor in an area and to eliminate spatial averaging. The commenter stated that, according to the EPA, for an area with multiple monitors, the appropriate reporting monitor with the highest design value would determine the attainment status for that area. The commenter does not support this approach as it is not consistent with monitoring results from health study analyses. Furthermore, the commenter is very skeptical of this approach given the EPA's intent to locate more monitors along roadways in major urban areas without the requisite knowledge of what the $PM_{2.5}$ readings might be from these monitors.

Response: The EPA has addressed the issue of eliminating spatial averaging in the preamble to the final rule. Regarding the commenter's statement on having the requisite knowledge of what the $PM_{2.5}$ readings might be from these monitors, EPA believes it has sufficient information to move forward with this requirement. In the preamble to the final rule we cite multiple studies (Ntziachristos et al., 2007; Ross et al., 2007; Yanosky et al., 2008; Zwack et al., 2011) that are relevant to informing what the $PM_{2.5}$ readings may be.

(40) *Comment:* One commenter stated that the EPA is proposing to remove existing requirements regarding $PM_{2.5}$ NAAQS that require monitors to be "population-oriented" but provides exceedingly thin and conflicting rationale for the proposed change. On one

hand, the EPA proposes to eliminate this requirement since it claims it will have no impact. In the same breath, however, the EPA provides a justification for the proposal based on ambiguity in "applying modeling across an area." The illogic of these two statements is apparent. If a provision has no impact, it can hardly create ambiguity.

Outside of this observation, AFPM believes that population-oriented requirements fulfill an important purpose in the implementation of NAAQS. Indeed, such requirements are aligned with the focus of primary NAAQS as standards intended to protect public health. Maintaining this current regulatory requirement is also consistent with the epidemiological data upon which the 1997 $PM_{2.5}$ NAAQS was established and on which this proposed rule still relies. Epidemiological studies, at their heart, are designed to probe relationships between human exposures and varying levels of an air pollutant. Such studies explicitly rely on existing air quality data in order to assess long-term and short-term associations, and this relationship has been noted since the initial staff review of scientific information that was used to finalize a fine particulate standard. The EPA should recognize this association and abandon its proposal to revoke this long-standing – and logical – requirement.

Response: In section VIII.B.2 of the preamble to the final rule and in this Response to Comments, the EPA explains that removing "population-oriented" does not have a practical impact on siting of monitors, but eliminates ambiguity and confusion that has arisen in other, related NAAQS-regulatory contexts, such as dispersion modeling for attainment planning and SIP development.

The EPA believes that the location of any site meeting the definition of ambient air, which represents a location where the public is (or may be) exposed, will represent current or potential population exposure and is an acceptable location for comparison to $PM_{2.5}$ NAAQS, as is the case with all other criteria pollutants. Additionally, for comparison to the annual $PM_{2.5}$ NAAQS, monitoring sites are also to represent area-wide air quality; therefore, even if a monitor was located in a location at a small scale where no one was actually exposed on a given day, and this site was determined to be an area-wide site, there is still the potential for someone to be exposed there and that site is intended to represent many such other locations in the same area, where the public is (or may be) exposed.

On the comment of maintaining this current regulatory requirement for consistency with the epidemiological data upon which the 1997 $PM_{2.5}$ NAAQS was established and on which this proposed rule still relies, as explained in section II.E.c.i.1 of the preamble to the final rule, it is appropriate to compare the $PM_{2.5}$ concentrations from a maximum area-wide monitor to the level of the annual $PM_{2.5.}$ Moreover, EPA anticipates that monitoring agencies will continue to site monitors that represent population exposure, particularly in light of the requirement to site monitors in ambient air, and the "area-wide" requirement for comparability to the annual NAAQS. EPA also points out that it is maintaining the overwhelming majority of the network at existing locations and that this data will continue to be available to support epidemiological studies for comparison to the NAAQS and other objectives. The addition of near-road PM2.5 monitoring data will add value to the ambient air network as it will provide for data in near-road environments where millions of people are exposed[43] and for which we have very little data.

(41) *Comment:* One commenter stated that they have no problem with monitoring anywhere in the near-road environment for research purposes, but they are concerned that any $PM_{2.5}$ monitoring that is to be used to compare with the annual standard for attainment purposes must be population-oriented.

Response: This comment is addressed in the preamble to the final rule. As discussed there and elsewhere in this Response to Comments, a significant fraction of the population lives in proximity to major roads, and these exposures occur in locations that represent ambient air. Monitoring in such areas does not make the standard more stringent than warranted, but rather affords the intended protection to the exposed populations, among them at-risk populations, exposed to fine particles in these areas. Thus, in cases where monitors in near roadway environments are deemed to be representative of area-wide air quality they would be compared to the annual standard. However, the EPA has limited the comparability of monitors that are not "area-wide" for purposes of comparison with the annual $PM_{2.5}$ NAAQS.

(42) *Comment:* One commenter stated several issues with the way the EPA proposes to implement the near-road requirement. The commenter is concerned that the elimination of spatial averaging and the definition of population-oriented when combined with the requirement to co-locate $PM_{2.5}$ monitors with near-road NO2 and CO monitors will result in collection of data in locations that are representative of no-one's annual average or 24-hour average $PM_{2.5}$ exposure. This could result in a major tightening of the standard, with significant unintended consequences for industry and economic development. Entire metropolitan areas could be placed in non-attainment based on measurements made where no-one is actually exposed.

The commenter is concerned that the decision to co-locate with NO_2 monitors was based on convenience and the intent of the NO_2 near-road monitoring is to find the highest micro-scale concentrations within a few meters of the most heavily travelled segments of the most heavily travelled expressways, a unique situation.

The proposed rule defends the decision to piggy-back the PM monitoring with the planned NO_2 monitoring because considerable thought and review has gone into that network design. However, the final guidelines for monitor placement do not require population exposure at the monitoring site. The final Technical Assistance Document notes "It is important to recall that the objective is to monitor in locations that are as near as practicable to roads where peak, ground-level NO2 concentrations are expected to occur." Once candidate sites are identified based on traffic counts and other factors, the potential for population exposure can be considered as noted in the TAD. However, the

[43] One study identified that 45 million Americans live within 300 feet of a major roadway or other source of mobile emissions. The commenters' information is based on the American Housing Survey, which is available on the web at: http://www.census.gov/housing/ahs/data/ahs2009.html. The survey provides an estimate of the county's housing units in the U.S. that are located with 300 feet of a highway with four or more lanes, or a railroad, or an airport.

discussion of population exposure suggests that it is near-by population rather than actual population exposure at the monitoring site that is the relevant consideration. Once a site has been selected and approved, the TAD indicates that the information for the site in the EPA's Air Quality System identify the site as "source-oriented" and include the horizontal distance from the probe to the nearest edge of the target road. The TAD also discusses the fact that the probe may be located in the right-of-way (ROW) of a limited access expressway. Thus, the location of NO_2 and any co-located $PM_{2.5}$ monitors will be source-oriented and not population-oriented. This would be a major change from prior practice and is not justified. Near-road monitor results should not be used to compare to the annual or 24-hour $PM_{2.5}$ standard unless it can be shown that it is from a population-oriented site consistent with the definition in 40 CFR 58.1. Although the EPA proposes to allow the Regional Administrator to give a waiver for "unique" micro-scale sites, the Agency should not allow consideration of source-oriented sites in the first place.

Response: The commenter raises several points to address, a number of which are discussed in the preamble to the final rule in section III.E.3.a on the form of the annual $PM_{2.5}$ NAAQS or in section VIII.B.3.b.i on the addition of a near-road component to the $PM_{2.5}$ monitoring network. For example, section III.E.c.i.1 of the preamble to the final rule explains why it is appropriate to compare the $PM_{2.5}$ concentrations from a maximum area-wide monitor to the level of the annual $PM_{2.5}$.

The comment suggests that the decision to co-locate with NO_2 monitors was based on convenience. The EPA does believe that there are some benefits to local monitoring agencies in reduced resource needs from siting the $PM_{2.5}$ monitors in the near-road environment with other measurements; however, the most important reason we are requiring these monitors be located at multi-pollutant near-road station is to support multiple monitoring objectives. As stated in section VIII.B.3.b.i of the preamble: "a number of key monitoring objectives will be supported, including collection of NAAQS comparable data in the near-road environment, support for long-term health studies investigating adverse effects on people, providing a better understanding of pollutant gradients impacting neighborhoods that parallel major roads, availability of data to validate performance of models simulating near-road dispersion, characterization of areas with potentially elevated concentrations and/or poor air quality, implementation of a multi-pollutant paradigm as stated in the NO_2 NAAQS proposed rule (74 FR 34442, July 15, 2009), and monitoring goals consistent with existing objectives noted in the specific design criteria for $PM_{2.5}$ described in appendix D, 4.7.1(b) to 40 CFR part 58".

The comment further suggests that the intent of the NO_2 near-road monitoring is to find the highest micro-scale concentrations within a few meters of the most heavily travelled segments of the most heavily travelled expressways, a unique situation, and that the monitors "will be source-oriented and not population-oriented. This would be a major change from prior practice and is not justified." The EPA notes that the substantive criteria for which monitors are eligible to be compared to the $PM_{2.5}$ NAAQS monitors are not changing-- near road monitors have always been eligible for comparison to the 24 hour standard, and will continue to be eligible for comparison to the annual standard only if they are found to be "area-wide" (i.e., to represent many such locations in the area).

The EPA disagrees that siting monitors in the area of expected maximum concentration is a unique situation. Such cases of seeking the highest concentrations of a pollutant have been a long-standing goal in the network design of every criteria pollutant as described in appendix D to Part 58 in order to provide the greatest degree of protection for public health and welfare without requiring an overly burdensome monitoring network. The EPA maintains that the near-road environments are locations where there is a significant potential for population exposure to $PM_{2.5}$ and it is important to locate monitors to measure that exposure. To the extent these sites are "unique" they would not be comparable to the annual $PM_{2.5}$ NAAQS.

Regarding the comment that the near-road monitor results should not be used to compare to the annual or 24-hour $PM_{2.5}$ standard unless it can be shown that it is from a population-oriented site consistent with the definition in 40 CFR 58.1. For the reasons explained in section VIII.B.2.a of the preamble to the final rule, the EPA will no longer be using "population-oriented" as a condition for comparability to the $PM_{2.5}$ NAAQS. The EPA disagrees that we should not allow consideration of source-oriented sites in the first place. There is no exemption from the NAAQS for violations caused by sources. Indeed, for some NAAQS, such as Pb, most of the monitoring network may be source-oriented but that does not mean that the data is not comparable to the NAAQS. Moreover, source oriented and population-oriented are not mutually exclusive. So there is no basis, even if we were keeping a requirement for population oriented (which we are not), to exclude source oriented sites. However, the EPA is requiring that all monitors must be at least "area-wide" to be compared to the annual NAAQS.

(43) *Comment:* One commenter is also concerned that EPA is overestimating the gradients in $PM_{2.5}$ near the road. The four references provided in the proposed rule do not make a sufficient case to add near-road $PM_{2.5}$ monitoring. The Zwack et al. (2011) study involves the impact in street canyons in mid-town Manhattan and concludes that $PM_{2.5}$ is elevated by from 5 to 8 % over background. Although the Zwack et al. study is useful, it does not apply to the multi-lane expressway case that is at issue in the proposed rule. The Ross et al. (2007) and Yanosky et al. (2008) references are to studies that used land-use regression to estimate $PM_{2.5}$ exposures and do not include any data on actual roadway impacts. The Ntziachristos et al. (2007) study evaluated the composition near the road with a site 1 mile downwind and did not evaluate the gradient near the roadway. In contrast to these studies, Karner et al. (2010) synthesized the results of 41 studies evaluating the shape and rate of decay curves of pollutants near roadways. The review included 16 studies with $PM_{2.5}$ measured at various distances from the roadway. Karner et al. report, in contrast with other pollutants, $PM_{2.5}$ shows little or no gradient with distance from the road. Since the Karner et al. review analyzed real-world data from a variety of roadway situations, the commenter urges the Agency to re-visit its concern over $PM_{2.5}$ gradients near roadways and the need for near-road monitoring. Karner et al. show that near-road exposures to $PM_{2.5}$ are not substantially elevated compared to community-wide exposures.

Response: The EPA has reviewed the Karner paper and believes that the results presented are consistent with the results from Zwack, which support our position that there are gradients in near-road environments. The EPA also believes the other papers cited in the preamble (Ross, Yanosky, and Ntziachristos) are useful to support its position that there are elevated levels of $PM_{2.5}$ in near-road environments. The information presented in Karner states that $PM_{2.5}$ concentration levels in near-road environments have a 22% decrease between the edge-of-road concentration and the farthest downwind measured value, which was identified at a distance of 986 meters. Therefore, the EPA disagrees with the commenters point that current information establishes there are little or no gradients with distance from road. The EPA maintains its position that these gradients exist and there is a need for near-road monitoring for the reasons explained in the section VIII.B.3.b.i of the preamble to the final rule. However, the EPA agrees that there are uncertainties over the extent of the gradient and it may be modest. To the extent there is a smaller than expected gradient, the information will still be useful to support monitoring objectives, and the fears of several commenters that near road monitoring is unrepresentative of wider air quality will be dispelled.

(44) *Comment:* One commenter stated that along with the small gradient near roadways, there is also evidence that drivers and passengers in vehicles experience lower $PM_{2.5}$ exposures due to deposition losses in the vehicle air handling system. For example, Riedeker et al., 200359 report in-vehicle $PM_{2.5}$ was 24% lower than ambient and roadside levels, in a study of the occupational exposure of North Carolina State troopers during their normal work shifts, probably due to deposition associated with the recirculating air. Similarly, Rodes et al., 199860 in a study of thirty-two, 2-hour commuting trips in Los Angeles and Sacramento, CA in the fall of 1997 reported that particle concentrations were significantly higher outside the vehicles than inside, with inside levels often less than roadside levels, presumably due to losses in the vehicles ventilation system. Thus, there is also evidence that in-vehicle exposures to $PM_{2.5}$ are not elevated compared to community-wide exposures.

Response: As stated in the section VIII.B.3.1 of the preamble to the final rule, we are requiring $PM_{2.5}$ monitors in the near-road environment to support a number of objectives. However, we did not state that we are attempting to characterize the actual on-road concentrations; rather, we are attempting to understand, among other objectives, the health impacts of near-road $PM_{2.5}$ exposures. Therefore, while the on-road exposure is still a relevant consideration, since these are locations where the public is exposed, it was not the sole basis for the proposed network design requirements for $PM_{2.5}$ monitors in near-road environments, and the possibility that there is a gradient of exposure for people inside moving cars as compared to outside, while useful to understand, is not a reason to forego near road monitoring. Therefore, we maintain our position that there are gradients in the near-road environment and that we have a responsibility to monitor the exposure of the public in these areas.

(45) *Comment:* One commenter stated that basing attainment designations on each area's single worst-case monitor, instead of using the current practice of area-wide averaging produces non-representative sampling results. Compounding this proposed approach is EPA's intent to require placement of monitors near heavily traveled roadways. These two

elements of the proposed monitoring scheme will significantly and improperly skew results in many areas.

Response: The first part of this comment has to do with EPA's decision to revoke spatial averaging and use the highest-reading area-wide monitor in each area for purposes of comparing to the annual NAAQS. This comment is addressed in the section III.E.3.a of the preamble to final rule, but EPA notes briefly that no area is currently using spatial averaging. The second part of the comment connects the requirement to place monitors near-heavily travelled roads with the commenters point on producing non-representative sampling results. The EPA disagrees with the commenters point on producing non-representative sampling results. The EPA's network design requirements for PM2.5 include a provision to locate sites at area-wide locations, thus these locations are in fact representative of many such locations throughout the same area. In addition, as discussed elsewhere, EPA believe that monitors should generally be located in areas of expected maximum concentration so that the NAAQS can be attained and provide requisite protection throughout the country.

(46) *Comment:* Several commenters stated that EPA had not demonstrated the need to add a requirement for near-road monitoring of $PM_{2.5}$. The primary purpose of these monitor appears to be research.

Response: The EPA addressed the objectives of the near-road $PM_{2.5}$ monitors in section VIII of the preamble to the final rule. The EPA believes these objectives provide sufficient rationale to add the requirement for the near-road $PM_{2.5}$ monitors. The EPA agrees that one of the purposes for these monitors is research; however, the EPA disagrees that this is the primary purpose.

(47) *Comment:* One commenter (for API) stated that placing $PM_{2.5}$ monitors near roadways rather than at population-oriented locations will likely measure locally unique concentrations of primary particulate associated directly with diesel exhaust, tire and brake wear and roadway dust. These observations will likely have limited geographical representativeness, and should be interpreted with caution. Monitors should not be moved near roadways if these measurements do not represent the broader area.

Response: The EPA notes that near road monitors will be characterized by monitoring agencies, subject to Regional Administrator approval, as to whether they are "area-wide" (i.e., whether they represent many such locations within an area). To the extent that concentrations of primary particulate are captured during the monitoring of $PM_{2.5}$ in any near-road environment that is determined to be an area-wide location, such monitoring is representative of many locations throughout the area and therefore is not unique.

(48) *Comment:* One commenter stated that they view near-road or source-oriented monitoring as failing to represent population exposures (unless people are sitting in lawn chairs by roads for extended periods of time) or visibility concerns under the proposed primary and secondary $PM_{2.5}$ NAAQS. The newly installed NO_2 monitoring network is devised to address NO_2 emission from mobile sources and address curbside health concerns since

NO_2 is radicalized quickly in the atmosphere. The height and distance of such stations from roads, seems particularly unsuited for $PM_{2.5}$ formation in urban areas, although we fully appreciate why the EPA would like to take advantage of these stations because of the cost of a new monitoring network. We think the EPA should re-examine these plans. Instead, the EPA should utilize existing monitors for these purposes, and importantly, that will require much more extensive changes to Part 58 regulations that exceed the proposed changes in this rulemaking. Among these are changes that allow for existing monitors to be relocated.

Response: Regarding the comment that views near-road or source-oriented monitoring as failing to represent population exposures, the EPA disagrees. As explained in section VIII.B.3.b.i of the preamble to the final rule and this response to comments, there are large numbers of people (in the tens of millions) that live, work, play, and go to school in close in proximity to major roadways. These exposures occur in locations that represent ambient air for which the agency has a responsibility to ensure the public is protected with an adequate margin of safety. Comparison of monitoring results from such areas to the NAAQS is therefore appropriate.

The height and distance of the $PM_{2.5}$ monitors is addressed in section VIII.B.5.a, while the rationale of why $PM_{2.5}$ is collocated with NO_2 at near-roadway station is addressed in VIII.B.3.b.i. As we explain in the preamble, we believe that the characterization of representative maximum $PM_{2.5}$ concentrations due to on-road mobile sources with $PM_{2.5}$ monitors will be at the same approximate locations that are the focus of the near-road NO_2 network. This is due to the fact that $PM_{2.5}$, like $NO_{X,}$ is disproportionately influenced by heavy duty (HD) vehicles which are predominantly diesel fueled, when compared to light duty (LD) vehicles which are primarily gasoline fueled. Specifically, for both $PM_{2.5}$ and NOx, HD vehicles emit more of these two pollutants and their precursors on a per vehicle basis than LD vehicles. The EPA recognized this fact in the near-road NO_2 network by requiring states to consider the fleet mix of candidate road segments where near-road monitoring might occur. In the design of the NO_2 near-road network where the $PM_{2.5}$ monitors will be installed, states were instructed to place a higher priority on those highly trafficked roads which have more diesel fueled vehicles using a metric called the fleet equivalent average annual daily traffic. As such, the Agency believes it is appropriate that required near-road $PM_{2.5}$ monitors would be located with near-road NO_2 monitors as they are similarly influenced not only by fleet mix but also by total traffic count, congestion patterns, roadway design, terrain, and meteorology. As discussed in section VIII of the preamble, if States can demonstrate that a different monitor location is more appropriate, e.g., through a quantitative demonstration that peak ambient $PM_{2.5}$ concentrations would occur in a near-road location which meets siting criteria but is not a near-road NO_2 monitoring site, then the EPA Regional Administrator may use its existing discretion to approve a deviation from the $PM_{2.5}$ monitoring requirements.

(49) *Comment:* One commenter (H&W) stated they believe an emphasis on near-road monitors could skew monitored $PM_{2.5}$ emissions results away from a representative dataset compatible with measuring NAAQS attainment. NAAQS have traditionally

assessed air quality health impacts across general areas. The EPA admits near-road monitors will result in an undefined "bump" in monitored $PM_{2.5}$. *See* 77 Fed Reg. at 39007. In this way, requiring near-road monitors may morph what are now area-wide air quality assessments into a hot-spot analysis predicated solely on, in EPA's terminology, "bump" $PM_{2.5}$ levels. The proposed PM Rule's near-road monitor requirements should not have the normative effect of forcing vast geographic swaths to lower emissions simply because of limited non-representative monitoring data. Instead, EPA should eschew plans that will undermine the representative quality of air quality monitoring data and require broad $PM_{2.5}$ emissions reductions in order to achieve attainment at discrete locations where no population is likely to be exposed for the averaging periods (24-hour and annual) of the NAAQS. For this reason, the commenter urges the EPA to reexamine the proposed PM Rule's near-road monitoring requirements.

Response: As discussed elsewhere, the EPA generally tries to place NAAQS monitors in areas of expected maximum concentration, in order to make the most efficient use of limited monitoring resources while protecting public health and welfare. As explained in, section VIII.B.3.b.i of the preamble to the final rule and this response to comments, there are large numbers of people (in the tens of millions) that live, work, play, and go to school in close in proximity to major roadways and the EPA believes it is important to monitor their exposure to $PM_{2.5}$ in the near-road environment. EPA notes that the criteria for which monitors are comparable to the NAAQS are not substantively changing, as monitors will still be required to be “area-wide” to be comparable to the NAAQS and EPA does not believe that removal of the “population oriented” requirement will substantively affect which monitors are comparable (particularly in light of the area-wide requirement).

To the extent the commenter is concerned about the “effect of forcing vast geographic swaths to lower emissions simply because of limited non-representative monitoring data,” the EPA notes that issues as to the proper extent of the nonattainment area or control strategy may be considered as those issues arise, but the agency does not agree that avoiding a determination of nonattainment is a reason to change the monitoring network design requirements.

(50) *Comment:* One commenter stated that the EPA proposes to determine compliance with the proposed $PM_{2.5}$ standard based solely on measurements acquired from $PM_{2.5}$ monitors that are placed in close proximity to major roads in each air quality area. Importantly, data from other existing $PM_{2.5}$ monitors will not be used to calculate the spatial average for the air quality area. This method of compliance demonstration will bias the results toward non-attainment since "near road" monitors will likely record higher $PM_{2.5}$ readings than other monitors. For example, assume that the EPA revises the $PM_{2.5}$ standard from 15 $\mu g/m^3$ to 12.8 $\mu g/m^3$ and that the concentration of $PM_{2.5}$ based on the average of existing community monitors for the air quality area is 12.5 $\mu g/m^3$. It would appear that the area is in attainment. However, if the averaged data from the existing network of community-based monitors is ignored and, instead, a single "near road" monitor - due to its location - records $PM_{2.5}$ at a level that is as little as 5 percent higher than the network monitors' spatial average, the air quality area is classified as non-

attainment with the revised (hypothetical) standard of 12.8 μg/m^3 (i.e., 12.5 μg/m^{3}x 105% = 13.1 μg/m^3). The Clean Air Act requires that $PM_{2.5}$ sources within non-attainment areas either install additional control technologies or restrict growth in order to remedy the non-attainment condition. Non-attainment designation will have a direct economic impact on the vitality if not the viability of business located in or around the non-attainment area. By instituting a technically flawed policy of using only near-road monitors to determine attainment status for an air region, the EPA is unnecessarily increasing the cost of doing business by creating an artificial air quality concern.

Response: The EPA disagrees that it will solely use near-road monitors to determine the attainment status for an area. The EPA's network design criteria include multiple requirements for $PM_{2.5}$ monitors, including a requirement to monitor in an area-wide location of expected maximum concentration. All eligible monitors in accordance with Appendix N to Part 50 and Part 58 will be used in comparison to the NAAQS. The EPA disagrees that the addition of $PM_{2.5}$ monitors will bias the results toward non-attainment since "near road" monitors will likely record higher $PM_{2.5}$ readings than other monitors. The addition of the near-road monitors will lead to an appropriate level of protection, with an adequate margin of safety, for those populations that live, work, play, and go to school near major roadways. The rationale for the appropriate level and form of the $PM_{2.5}$ NAAQS, including a discussion on eliminating spatial averaging is described in section III.E.3 and section III.E.4 of the preamble to the final rule. While the EPA does not dispute the calculations provided in the example of the comment, the EPA points out that this example fails to recognize constraints on the use of spatial averaging from the 2006 NAAQS that are intended to ensure that spatial averaging does not adversely affect disadvantaged populations. In the 2006 PM NAAQS final rule, the EPA tightened the criteria for use of spatial averaging to provide increased protection for vulnerable populations exposed to $PM_{2.5}$. This change was based in part on an analysis of the potential for disproportionate impacts on potentially at-risk 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, October 17, 2006; U.S. EPA, 2005, section 5.3.6.1). Since those changes, no area has used spatial averaging, and no other NAAQS uses spatial averaging.

(51) *Comment:* One commenter stated that EPA should not finalize the proposed changes to $PM_{2.5}$ monitoring, which would substantially increase the stringency of the $PM_{2.5}$ Primary NAAQS, even absent the proposed tightening of the level of the annual standard.

Response: As described in section III.E.3.a of the preamble to the final rule, EPA took the addition of near-road monitoring into consideration in setting the form of the NAAQS. The EPA disagrees that the proposed changes to $PM_{2.5}$ monitoring would substantially increase the stringency of the $PM_{2.5}$ Primary NAAQS. A significant fraction of the population lives in proximity to major roads. These exposures occur in locations that represent ambient air for which the agency has a responsibility to ensure the public is protected with an adequate margin of safety. Ignoring monitoring results from such areas (or not monitoring at all) would abdicate this responsibility. Put another way, monitoring in such areas does not make the standard stricter, but rather affords requisite protection to the populations, among them at-risk populations, exposed to fine particulate in these areas. Thus, the EPA has made a determination to protect all area-wide locations, including those locations with populations living near major roads that are representative of many such locations throughout an area. As discussed above, the EPA concludes that the requirement to locate monitors to represent ambient air, along with other siting requirements, will ensure that monitors represent $PM_{2.5}$ concentrations in areas of potential public exposure.

(52) *Comment:* One commenter stated that the EPA is proposing to require that 52 near-road $PM_{2.5}$ monitors be placed in locations around the country, collocated with NO_2 monitors. The EPA states that placing $PM_{2.5}$ monitors in such locations will be the "most efficient and beneficial approach" to deploying this network. Given that the EPA performed no analysis of the differences between near-road monitoring for NO_2 and $PM_{2.5}$, this requirement is arbitrary and capricious to the extent that it would form the basis for any designation of $PM_{2.5}$ nonattainment areas. While there may indeed be economies in placing such monitors at existing sites, any monitor so co-located is not rationally related to or comparable to the NAAQS. Further, as discussed later, it appears that the proposed roadside monitors would increase the stringency of the standard and lead to designation of additional nonattainment areas.

Response: The EPA disagrees that the requirement to establish and use data from $PM_{2.5}$ monitors in near-road environments for the NAAQS is arbitrary and capricious. As explained in the section VIII.B.3.b.i of the preamble to the final rule, there are gradients in near-roadway $PM_{2.5}$ that are most likely to be associated with heavily travelled roads (particularly those with significant heavy-duty diesel activity, which is also associated with increased NO_2 concentrations), and that the largest numbers of impacted populations are located in the largest CBSAs in the country (Ntziachristos et al., 2007; Ross et al., 2007; Yanosky et al., 2008; Zwack et al., 2011). There are a number of reasons identified in the preamble and this Response to Comments that support siting $PM_{2.5}$ and NO2 monitors at the same near-road monitoring station, related both to technical issues such as vehicle mix as well as support for monitoring objectives. Further, a significant fraction of the population lives in proximity to major roads[44]. These exposures occur in locations that represent ambient air for which the agency has determined is important to monitor to protect public health and welfare. As discussed elsewhere, the EPA disagrees that monitoring in these areas increases the stringency of the standard, or that the possibility of additional nonattainment areas is a reason not to monitor in these areas.

(53) *Comment:* One commenter provided comments on the EPA's use of two documents as supportive of the new near-road monitoring requirement, i.e., the "Near-road Monitoring Pilot Studies Objectives and Approach" and the "Review of the Near-Road Document – Outline." These documents are wholly inadequate to support the proposed monitoring

[44] One study identified that 45 million Americans live within 300 feet of a major roadway or other source of mobile emissions. The commenters information is based on the American Housing Survey, which is available on the web at: http://www.census.gov/housing/ahs/data/ahs2009.html. The survey provides an estimate of the county's housing units in the U.S. that are located with 300 feet of a highway with four or more lanes, or a railroad, or an airport.

requirements. The first document does not specifically address near-road $PM_{2.5}$ monitors, but is centered on newly promulgated NO_2 NAAQS; the second document is a 1-page outline which addresses *the identification* of locations and parameters for maximum concentrations of several pollutants, not the establishment of monitoring requirements themselves. Instead, the entire basis of the EPA's proposed near-road $PM_{2.5}$ monitoring network appears to be a suggestion by CASAC that such measurements might be useful. This is an insufficient informational basis and justification for rulemaking.

Response: With regard to the documents cited and their applicability to support the near-road requirement, the EPA is not exclusively relying on these documents to support its position to add $PM_{2.5}$ monitors to the near road environment, rather these documents provide useful technical information that can be gleaned as monitoring agencies consider the addition of $PM_{2.5}$ to the near-road stations. We also explain in preamble section VIII.B.3.b.i of the final rule that the characterization of representative maximum $PM_{2.5}$ concentrations due to on-road mobile sources and the appropriate location of such $PM_{2.5}$ monitors will be the same approximate locations that are the focus of the near-road NO_2 network. This is due to the fact that $PM_{2.5}$, like NO_X, is disproportionately influenced by heavy duty (HD) vehicles which are predominantly diesel fueled, when compared to light duty (LD) vehicles which are primarily gasoline fueled. Specifically, for both $PM_{2.5}$ and NOx, HD vehicles emit more of these two pollutants and their precursors on a per vehicle basis than LD vehicles. The EPA recognized this fact in the near-road NO_2 network by requiring states to consider the fleet mix of candidate road segments where near-road monitoring might occur. In the design of the NO_2 near-road network where the $PM_{2.5}$ monitors will be installed, states were instructed to place a higher priority on those highly trafficked roads which have more diesel fueled vehicles using a metric called the fleet equivalent average annual daily traffic.[45] As such, the Agency believes it is appropriate that required near-road $PM_{2.5}$ monitors would be located with near-road NO_2 monitors as they are similarly influenced not only by fleet mix but also by total traffic count, congestion patterns, roadway design, terrain, and meteorology.

The EPA disagrees with the statement that the entire basis of the EPA's proposed near-road $PM_{2.5}$ monitoring network appears to be a suggestion by CASAC that such measurements might be useful and that this is an insufficient informational basis and justification for rulemaking. While the EPA did consider CASAC's advice, it also considered a number of other factors such as explained in section VIII.B.3.b.i of the preamble to the final rule. For example, the EPA also considered the significant fraction of the population that lives in proximity to major roads. These exposures occur in locations that represent ambient air for which the agency has a responsibility to ensure the public is protected with an adequate margin of safety.

(54) *Comment:* Several commenters (AEP) stated that EPA has not demonstrated the need to add a requirement for near-road monitoring of $PM_{2.5}$.

[45] See the Near-road NO_2 Monitoring Technical Assistance Document at: http://www.epa.gov/ttn/amtic/files/nearroad/NearRoadTAD.pdf

Response: The EPA believes that for the reasons stated in section VIII of the preamble to the final rule, there are sufficient reasons to add a requirement for near-road monitoring of $PM_{2.5}$.

(55) *Comment:* One commenter (AGC) stated that they oppose EPA's addition of near-road monitoring as it would measure mobile-source emissions instead of ambient air quality.

Response: Any monitoring station sited in an area representing ambient air is by definition measuring ambient air. Since $PM_{2.5}$ monitors are to be sited at near-road monitoring stations that are in the ambient air, they are measuring ambient air quality.

(56) *Comment:* One commenter (AGC) stated monitoring sites should reflect ambient air conditions to which a significant portion of the public is exposed – not conditions specific to one location. Emissions are naturally going to be higher in some area of a county and lower in others.

Response: As explained in section VIII.B.3.b.i, a significant fraction of the population lives in proximity to major roads. These exposures occur in locations that represent ambient air which the agency has determined is important to monitor because of the potential for population exposure to pollutants at levels exceeding the NAAQS. Although it may be true that emissions will often be higher in one area than another, the EPA generally sites monitors in areas of expected maximum concentrations to protect public health and welfare. The EPA notes, however that for the reasons explained in the preamble, monitors must be at least "area-wide" to be comparable to the annual $PM_{2.5}$ NAAQS.

(57) *Comment:* One comment letter representing 48 organizations provided strong support for the addition of the near road monitors. The comment letter stated that monitors with the highest measured concentrations of fine particulate matter tend to be located in areas where the population is more likely to be lower-income, have lower education levels, and minority. Furthermore, lower socioeconomic populations may be more vulnerable to fine particulate matter because of proximity to roadways and industry, higher rates of pre-existing diseases, less access to health care, and nutritional deficiencies. At the same time, rural areas are at high risk because of significant gaps in air monitoring. Further, numerous scientific studies have now identified increased health risks in association with traffic-generated air pollution, including fine particulate matter. With more than 45 million Americans living less than 300 feet from a highway, there is growing concern about the health impacts of living near heavily traveled roads. One of the most significant aspects of the EPA proposal relates to the proposed extension of the fine particle monitoring network to the near road environment. Motor vehicle traffic is a major and undisputed source of emissions of ultrafine, fine and coarse particles. In order to protect all citizens' right to a safe and healthy air supply, as mandated by the Clean Air Act, it is imperative that our nation's air pollution air quality monitoring network require measurement of particulate concentrations near highways and other significant sources of particulate pollution. This protection is long overdue and it is critical that that these

monitored concentrations, or the modeled equivalent, be considered in the designation of nonattainment areas and the development of associated air pollution control programs.

Response: The comment in support of requiring the addition of $PM_{2.5}$ monitors to the near-road environment is acknowledged.

(58) *Comment:* One comment letter representing five organizations stated that they welcome and support EPA's proposal to monitor the concentrations of $PM_{2.5}$ that occur in near-road communities where millions of Americans are exposed to emissions from major highways, truck terminals and facilities that attract concentrations of motor vehicles. This NAAQS proposal seeks to begin for the first time the implementation of the $PM_{2.5}$ NAAQS within the zone where emissions of fine particles from existing transportation facilities that attract large concentrations of mobile sources adversely affect concentrations of $PM_{2.5}$.

Response: The comment in support of requiring the addition of $PM_{2.5}$ monitors to the near-road environment is acknowledged.

(59) *Comment:* One commenter stated they were pleased to see that the Agency plans to increase near-roadway monitoring to provide new information on population exposures to mobile sources of PM.

Response: The comment in support of requiring the addition of $PM_{2.5}$ monitors to the near-road environment is acknowledged.

(60) *Comment:* One comment letter representing 48 organizations (different than the commenters cited above) stated that they support the addition of $PM_{2.5}$ roadway monitors, *(as)* an efficient implementation process specifically for communities that are already in non-attainment and significant environmental justice considerations, as well as consider in this and future assessments the research studies that describe the disproportionate health impacts on low income, communities of color.

The letter also stated that they applaud the EPA for realizing the importance monitoring for co-pollutants, as well proposing additional $PM_{2.5}$ monitors near highways, traffic corridors, especially near residential areas. Additional monitoring will provide a better opportunity for us to understand the health impacts of exposures, especially in core based statistical areas with one million persons or greater. With approximately 45% of the urban population living near major roads, and ethnic minorities and lower-income populations being more likely to live near sources of $PM_{2.5}$, adding to the current national monitoring network will help researchers to better understand the exposure variation near roadways and other hotspots where exposure disparities exist.

The comment letter also recommends that if at all possible, adding $PM_{10-2.5}$ monitors to this network would be extremely helpful, since there are limited PM_{10} data in the near road environment. As noted by the CASAC and others, there is an obvious data gap to support future regulatory reviews and better understand how PM_{10} emissions are contributing to the existing public health burden. The comment letter states that they support the addition of $PM_{2.5}$ near-road monitors to the existing network, and, where possible, adding in $PM_{10-2.5}$ monitors.

Response: The comment in support of requiring the siting of $PM_{2.5}$ monitors in the near-road environment is acknowledged.

With regard to the recommendation to add $PM_{10-2.5}$ measurements to the roadway environment, where possible, as explained in section VIII.B.3.b.i of the preamble to the proposal, the EPA supports the measurement of other pollutants in the near-road environment. Such additional measurement are not required, but encouraged to support enhancing knowledge of exposures in the near-road environment.

(61) *Comment:* One commenter offered some support for the addition of $PM_{2.5}$ monitors to the near-road environments stating that they agree with the EPA that "…such near-road sites could provide valuable understanding of emissions "such as BC, ultrafine particles, and particle size distribution."" However, the commenter also expressed concern as they state that "Once again, the EPA unfortunately displays its misguided bias prioritizing diesel over gasoline emissions. "The EPA believes that there are gradients in near-roadway $PM_{2.5}$ that are most likely to be associated with heavily travelled roads, particularly those with significant heavy duty diesel activity." The commenter later goes on to state that they are "…confident that these monitors will provide further reinforcement for what is already known about particle-borne toxics in our largest cities."

Response: The commenter appears to be generally supportive of pursuing characterization of the near-road environment; however, they have a specific concern regarding our placement of monitors in that we incorporate diesel as a factor in the identification of the road segment to use, which is tied siting of NO_2 monitors.

We do believe that the characterization of representative maximum $PM_{2.5}$ concentrations due to on-road mobile sources and the appropriate location of such $PM_{2.5}$ monitors will be the same approximate locations that are the focus of the near-road NO_2 network. This is due to the fact that $PM_{2.5}$, like $NO_{X,}$ is disproportionately influenced by heavy duty (HD) vehicles which are predominantly diesel fueled, when compared to light duty (LD) vehicles which are primarily gasoline fueled. Specifically, for both $PM_{2.5}$ and NOx, HD vehicles emit more of these two pollutants and their precursors on a per vehicle basis than LD vehicles. The EPA recognized this fact in the near-road NO_2 network by requiring states to consider the fleet mix of candidate road segments where near-road monitoring might occur. In the design of the NO_2 near-road network where the $PM_{2.5}$ monitors will be installed, states were instructed to place a higher priority on those highly trafficked roads which have more diesel fueled vehicles using a metric called the fleet equivalent average annual daily traffic. As such, the Agency believes it is appropriate that required near-road $PM_{2.5}$ monitors would be located with near-road NO_2 monitors as they are similarly influenced not only by fleet mix but also by total traffic count, congestion patterns, roadway design, terrain, and meteorology.

G. Comments on Revoking $PM_{10-2.5}$ Speciation Requirements at NCore Sites

(1) *Comment:* Several commenters support revoking the requirements for $PM_{10-2.5}$ speciation at NCore stations.

Response: The comment in support of the proposal is acknowledged and EPA is adopting the proposed approached in the final rule.

(2) *Comment:* One commenter stated that with regard to the EPA's proposal to revoke the requirement for $PM_{10-2.5}$ speciation monitoring as part of the current suite of NCore monitoring requirements, that dropping this requirement may seem reasonable from a compliance perspective, it is problematic from the research perspective and needlessly delays improved understanding gained from the speciated data collected.

Response: This comment is addressed in section VIII.B.3.c of the preamble to the final rule.

(3) *Comment:* One comment letter representing five organizations stated that they strongly oppose EPA's proposal to rescind the speciation requirements for PM_{10} monitoring. They find no legal, practical, or scientific justification for eliminating requirements for better characterization of coarse particle concentrations.

Response: This comment is addressed in section VIII.B.3.c of the preamble to the final rule.

H. Comments on the network design for the proposed secondary $PM_{2.5}$ visibility index.

(1) *Comment:* One commenter stated that the scope of the speciation monitors should be limited to "urban areas" only and should not include IMPROVE monitoring sites, which are already evaluated as part of the Regional Haze program.

Response: For the reasons stated in section VI of the preamble to the final rule, EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements on the use of CSN or IMPROVE stations.

(2) *Comment:* One commenter recommends that the EPA clarify that $PM_{2.5}$ chemical species measurements be only required in urban areas, primarily utilizing the CSN network. Also, to the extent that an individual monitoring agency may not have appropriate CSN measurements, and wishes to use IMPROVE instead, the agency should have that flexibility.

Response: For the reasons stated in section VI of the preamble to the final rule, EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements on the use of CSN or IMPROVE stations.

(3) *Comment:* Two commenters stated that use of data from IMPROVE sites could be problematic as those sites are not always operated by state, local, or tribal air monitoring agencies. One of these commenters would prefer to only use data that they collect, analyze, quality assure, report, and certify.

Response: For the reasons stated in section VI of the preamble to the final rule, EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements on the use of CSN or IMPROVE stations.

(4) *Comment:* One commenter stated that with regard to using deciviews that this metric was primarily developed for areas with a long site path to encompass a large sample size. The approach used for the proposed visibility standard is only one sampling point, which may not be representative for estimating visibility of an entire airshed. Additional sampling points should be considered.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements for monitoring sites to support such a standard.

(5) *Comment:* One commenter stated the many of the urban speciation sites were originally located close to industrial facilities to ascertain their unique characteristics and influence upon air quality. These sites represent impacts in only a very small urban area and thus do not necessarily represent areas large enough to comprise "vistas".

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements for monitoring sites to support such a standard.

(6) *Comment:* One commenter supported the minimum network design where only certain cities over 1 million in population would be required to have CSN stations to support the proposed visibility index. The commenter stated that they agree with the EPA's approach in not having every city in the state over 1 million in population have to perform CSN measurements as their own analyses shows that their two major cities, which have long-standing CSN stations (Raleigh and Charlotte, NC), both have deciview calculations that are the same at 24 deciviews as calculated by the EPA for years 2008 – 2010.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements for monitoring sites to support such a standard.

(7) *Comment:* One commenter identified that their monitoring program had two speciation sites in urban areas that are not near the population threshold proposed for the urban visibility standard (i.e., CBSAs greater than 1,000,000 in population).

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements for monitoring sites to support such a standard. However, to clarify, the proposed network requirements for CSN (or IMPROVE) were intended as minimum network requirements and not as criteria for comparability to the NAAQS.

(8) *Comment:* One commenter stated that the EPA's proposal of the visibility standard indicates that both urban and rural monitors are subject to the visibility standard; however, the commenter believes that rural monitoring should be excluded for use in determining attainment of the visibility index NAAQS.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements for monitoring sites to support such a standard.

(9) *Comment:* One commenter stated lacking any empirical support for its intended use of the existing monitoring network, if the EPA finalizes a secondary $PM_{2.5}$ visibility NAAQS, the EPA should at minimum adopt the approach it took in 1997 when it first established a $PM_{2.5}$ standard. In specific, President Clinton directed the EPA to only address decisions regarding attainment and nonattainment areas when a well designed $PM_{2.5}$ monitoring network was in place. The 1997 NAAQS implementation strategy stated that, "[b]ecause the EPA is establishing standards for a new indicator for PM (i.e., $PM_{2.5}$) it is critical to develop the best information possible before attainment and nonattainment designation decisions are made."47 The policy directed that "unclassifiable" designations be issued until there was a robust network specifically designed to address the new PM indicator.

Response: For the reasons stated in section VI of the preamble to the final rule, EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final monitoring rule does not include requirements on the use of CSN or IMPROVE measurements.

(10) *Comment:* One commenter (NEDA/CAP) stated EPA's proposal for the secondary visibility standard is technically flawed. EPA addressed visibility at a single point measurement rather than an integrated sight path average $PM_{2.5}$ concentration.

Response: For the reasons stated in section VI of the preamble to the final rule, EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final monitoring rule does not include requirements on the use of CSN or IMPROVE measurements, or their siting to support such a standard.

I. Comments on the use of $PM_{2.5}$ Continuous FEMs at SLAMS

(1) *Comment:* Several commenters were supportive of the proposal allowing identification of $PM_{2.5}$ continuous FEMs that should not be used for comparison to the $PM_{2.5}$ NAAQS through an evaluation in the annual monitoring network plan.

Response: The comment in support of the proposal is acknowledged and the EPA is adopting the proposed approach in the final rule.

(2) *Comment:* One of the commenters supportive of the proposal allowing identification of $PM_{2.5}$ continuous FEMs that should not be used for comparison to the $PM_{2.5}$ NAAQS stated that such an approach would encourage continued use and improvements of these methods.

Response: The comment in support of the proposal is acknowledged and the EPA is adopting the proposed approached in the final rule.

(3) *Comment:* Of the many commenters that were supportive of the proposal allowing identification of $PM_{2.5}$ continuous FEMs that should not be used for comparison to the $PM_{2.5}$ NAAQS through an evaluation in the annual monitoring network plan, several of these commenters also recommended that monitoring agencies be allowed to identify and recommend exclusion of FEM continuous data both prospectively and retrospectively.

Response: The EPA has addressed this issue in section VIII.B.3.ii of the preamble of the final rule.

(4) *Comment:* One commenter did not support the proposal to allow data comparability assessments between continuous FEMs and FRM monitors that are not located at the same site.

Response: The EPA's intention in allowing the grouping of sites for purposes of allowing identification of $PM_{2.5}$ continuous FEMs that should not be used for comparison to the $PM_{2.5}$ NAAQS through an evaluation in the annual monitoring network plan is to provide for flexibility so that monitoring agencies do not have to collocate every $PM_{2.5}$ continuous FEM with an FRM to assess that FEM's suitability for NAAQS use. The EPA wishes to recognize the reality that not every continuous FEM is collocated with an FRM. However the final approach does not in any way restrict collocating sites. Each agency can decide for itself if it chooses to collocate more than the minimally required number of sites.

(5) *Comment:* One commenter stated that reasonable minimum requirements for demonstration and assessment of FEM performance must be clearly stated, not only in a preamble, and consistently applied across all regions. As described in the preamble, the determination, demonstration, and decisions involved in the assessment of non-equivalent FEM data could easily become a significant burden for monitoring organizations that have relied on the equivalency designation to design and implement a monitoring

strategy. The EPA must develop a more representative and reliable protocol to designate approved monitoring methods.

Response: In the preamble section VIII to the final rule, the EPA provides some additional information for monitoring agencies on how to address this issue. The EPA shares the concern on assessments becoming a significant burden to monitoring agencies and will work to minimize this burden wherever possible. EPA also points out that such an assessment is not required; however, the EPA has developed an automated tool to assist monitoring agencies when performing assessments. See: http://www.epa.gov/airquality/airdata/ad_rep_frmvfem.html.

(6) *Comment:* One commenter stated that the recent availability of the "$PM_{2.5}$ Continuous Monitor Comparability Assessment" web-based tool is a valuable addition, and provides States with a uniform approach to FEM data quality assessment.

Response: The comment in support of this tool is acknowledged.

(7) *Comment:* One commenter stated that due to lack of experience, data, and the experimental nature of near-roadway monitoring, $PM_{2.5}$ FEMs should not be used for determining compliance with the NAAQS.

Response: As explained in the preamble to the proposal, the EPA has conducted an assessment of the comparability of $PM_{2.5}$ FEMs and found that in many cases the data are meeting the performance criteria used to approve theses methods when compared to collocated FRMs. Since the monitoring agencies are achieving the desired comparability with these continuous FEMs – at least in some cases, the EPA is supportive of their continued use, including for comparison to the NAAQS. The EPA has provided a process for identifying data from continuous FEMS that is not suitable for comparison to the NAAQS, and will continue to consider issues related to the performance of the continuous FEMs in the future.

(8) *Comment:* One commenter does not support the use of $PM_{2.5}$ continuous FEMs for comparison to the NAAQS at near-roadway sites until problems with FEMs have been adequately addressed.

Response: As explained in the preamble to the proposal, the EPA has conducted an assessment of the comparability of $PM_{2.5}$ FEMs and found that in many cases the data are meeting the performance criteria used to approve these methods when compared to collocated FRMs. Since the monitoring agencies are achieving the desired comparability with these continuous FEMs, the EPA is supportive of their continued use, including for comparison to the NAAQS. However, as explained in the preamble, there is a process for identifying data from continuous FEMs not suitable for comparison to the NAAQS, and it remains the monitoring agencies choice to use a FRM, filter-based FEM, or continuous FEM at near-road monitoring stations or other SLAMS. So even if the commenter disagrees with the EPA's position, it can still choose the method that they are most comfortable with so long as it is an approved FEM; FRM; or ARM, if one of those methods were to become available at a later time.

(9) *Comment:* One commenter stated that the EPA should develop sample language for inclusion in individual agencies' $PM_{2.5}$ Quality Assurance Project Plans (QAPPs) regarding criteria for FEM data exclusion.

Response: The EPA intends to work with monitoring agency stakeholder groups to develop such language. The sample language may be documented in one or more locations; for example, a location such as the Quality Assurance Handbook for Air Pollution Measurement Systems – Volume II, EPA-454/B-08-003, December 2008.

(10) *Comment:* Several commenters stated that the EPA should provide an acceptable range for each instrument parameter (for the continuous FEMs) that is associated with the ambient concentration data. Over the last several years, the EPA has provided minimal guidance on how to determine when the FEM instruments are satisfactorily performing.

Response: The EPA will work with monitoring agencies and instrument companies on updating the acceptable ranges for instrument parameters so that they can be incorporated in monitoring agency SOPs and quality assurance projects plans, where applicable. The EPA has developed draft SOPs for three of the more commonly used continuous FEMs. These SOPs were developed in cooperation with several monitoring agencies and they are available on the web at: http://www.epa.gov/ttn/amtic/contmont.html. The EPA anticipates it will update these SOPs to accommodate the latest information on acceptable ranges for each instrument parameter.

(11) *Comment:* One commenter stated that $PM_{2.5}$ monitoring methods are widely believed to be suspect. The EPA should revisit the adequacy of those methodologies before reducing the $PM_{2.5}$ standard. EPA's supporting materials for the FRM for $PM_{2.5}$ monitoring set forth in Appendix L to 40 CFR Part 50 indicate that reductions in the standard could exacerbate the limitations of the method, i.e. limiting the method's effectiveness in defining meaningful differences in $PM_{2.5}$ concentrations. The commenter understands that ongoing implementation of FEM monitoring (alternative methodologies) indicates inconsistent degrees to which a given equivalent method is comparable to the FRM, varying from site-to-site. The inconsistencies may suggest that the "equivalent" methods are producing more accurate data than the FRM. Further, the EPA research as to the reliability and accuracy of the FRM for $PM_{2.5}$ is necessary before reducing the standard.

Response: As stated in the preamble to the final rule, the EPA believes that progress is being made to implement well performing $PM_{2.5}$ continuous FEMs across the nation. However, in recognition that some monitoring agencies are not achieving the expected data comparability, and as explained in section VIII of the final rule, the EPA has finalized a process by which monitoring agencies can identify and exclude $PM_{2.5}$ continuous FEM data, where comparability results are not met, from comparison to the NAAQS. The EPA believes that the combination of using the FRMs, filter-based FEMs, and well performing continuous FEMs across the network provides more than a sufficient number of monitoring options to support the revised $PM_{2.5}$ standard. As stated in the preamble, the EPA intends to continue working with monitoring agencies and instrument manufacturers to document best practices on these methods to improve the comparability and consistency of resulting data, wherever possible.

(12) *Comment:* One commenter stated that until it is demonstrated that virtually all of the continuous FEMs reliably replicate FRM $PM_{2.5}$ concentrations throughout the U.S. and all times of the year, the FEMs should not be used to provide primary data for comparison to NAAQS unless a state provides evidence of the equivalence of FEMs in comparison with the FRM for a specific area.

Response: As described in section VIII of the preamble to the final rule, the EPA finalized an approach to allow monitoring agencies to specify their intention to use or not use data from continuous $PM_{2.5}$ FEMs that are eligible for comparison to the NAAQS as part of their annual monitoring network plan due to the applicable EPA Regional Office by July 1 each year. The EPA believes this provision ensures monitoring agencies will only use $PM_{2.5}$ continuous FEM data where an appropriate level of comparability with collocated FRMs has been determined. First, despite some differences between the instrument company field testing of the continuous FEMs with collocated FRMs and the monitoring agency operation of these methods (e.g., averaging of three FRMs and three candidate continuous FEMs in the instrument company tests; operation of the FRMs from morning to morning periods, rather than midnight to midnight as is the case in routine monitoring programs) these methods were approved as they met performance criteria in each of the field locations where they were tested. These field tests included multiple locations around the country with specifications on winter and summer seasons, depending on location. Second, as stated in the preamble there are likely multiple reasons why some of the $PM_{2.5}$ continuous FEMs are not meeting the expected performance criteria. Some of these reasons such as differences in installation, operator training, and development and use of Standard Operating Procedures (SOPs) are likely to affect data comparability on an agency by agency basis. Therefore, the EPA believes this approach appropriately allows a method working in one or more monitoring programs with acceptable comparability to be used in comparison to the NAAQS.

J. Comments on Weight of Evidence Approach in the Revisions to the Quality Assurance Requirements for SLAMS, SPMs, and PSD.

(1) *Comment*: The large majority of comments were in favor of the weight of evidence approach for determining whether the quality of data is appropriate for regulatory decision-making purposes. Some that supported the approach also provided a word of caution that there needs to be a minimum set of requirements for data collection and reporting in order for data to be used for attainment/non-attainment decisions.

Response: The EPA agrees with the commenter’s point that data should be subject to a minimum set of requirements for data collection, reporting, and quality. While the EPA considers the Appendix A requirements the minimum for reporting, it is not the only data that the EPA and the monitoring organizations use to judge quality. Therefore if an Appendix A requirement for some reason is not complete it should not be the sole reason to declare the data invalid or unusable. The comment in support of the proposal is acknowledged and the EPA is adopting the proposed approached in the final rule.

(2) *Comment:* One commenter felt that the paragraph, as written, undermines the importance of the quality control/quality assurance system dictated in Part 58 and also said that while a common sense approach to the assessment of quality data is important, minimum requirements are necessary to ensure scientifically-defensible data is being used in decision making.

Response: The EPA agrees with the commenter's point that data should be subject to a minimum set of requirements for data collection, reporting, and quality. In developing the weight of evidence approach EPA is not attempting to diminish the requirements of Appendix A but rather ensuring that other elements of a quality system that monitoring organizations implement and are documented in their QAPP can also be used when judging whether data are valid for a particular monitoring objective. After considering the support for this change, EPA will adopt the proposed weight of evidence approach in the final rule.

(3) *Comment:* One commenter who felt that the approach may be appropriate suggested that the language of the proposal was vague and may weaken the ability of air monitoring agencies to validate their own data and instead allows EPA to make decisions regarding data validity.

Response: The EPA agrees that the monitoring organizations know more about their data and that these organizations are responsible for certifying the data as valid. In the majority of cases when the quality of ambient air data is called into question, the EPA Regions and monitoring organizations work together and reach consensus on data usability. However, since the EPA is responsible for making final NAAQS decisions, in rare cases it may ultimately have to make a validity decision that the monitoring organization may not agree with. After considering the support for this change, the EPA will adopt the proposed weight of evidence approach in the final rule.

(4) *Comment:* A few commenters, although supporting the weight of evidence approach, also commented that Appendix A minimum requirements should not only apply to all air quality data collected by state, local, and tribal agencies, but also to "secondary" data collected by other monitoring efforts.

Response: The EPA believes that the term secondary data is used to represent information that may have been originally intended for one monitoring objective but is now being used for a "secondary" objective. The EPA assumes this term is used to either represent the Chemical Speciation and IMPROVE Network data being used in the light extinction calculation for the proposed secondary visibility index NAAQS standard, or for criteria pollutant data collected by entities other than the state, local or tribal monitoring organizations. The EPA agrees with the comments that the Appendix A requirements must apply to the CSN and IMPROVE data and included the term "$PM_{2.5}$ CSN" to refer to both networks. Based on the assessment of the CSN and IMPROVE data against the $PM_{2.5}$ DQOs (10% precision and $\pm$ 10% bias) it appeared that the $PM_{2.5}$ DQOs were being met under the current CSN and IMPROVE quality systems (QAPPs and

SOPs). However, since the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS, the EPA will not include these QA requirements into Appendix A since the networks will not produce data related to NAAQS decisions.

K. Comments on Quality Assurance Requirements for the Chemical Speciation Network.

There were no comments on the proposed addition of collocation and flow rate requirements in Appendix A for the chemical speciation network (CSN). However, since for the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS, we will not include any $PM_{2.5}$ secondary standard QA requirements related to the Chemical Speciation Network or IMPROVE Network into Appendix A.

L. Comments on Waiver for Wider Spacing of Collocated Monitors

(1) Comment: All comments received supported the proposed requirement allowing up to 10 meter horizontal spacing for sites at a neighborhood or larger scale of representation. During stakeholder presentations of the proposal, the EPA received verbal comments that monitoring organizations were also having difficulties meeting the 1 meter vertical limit since $PM_{2.5}$ FEMs are often housed in shelters with inlets extending through shelter roofs while the collocated FRM monitors are placed outside usually on low platforms.

Response: The comments in support of the proposal are acknowledged and the EPA is adopting the proposed approach in the final rule. Based on discussion with EPA's Office of Research and Development, the agency will amend the Appendix A requirements to allow for a 1-3 meter vertical spacing which may be approved by the Regional Administrator for sites at a neighborhood or larger scale of representation. In addition, the language will be amended to allow for waiver approvals during annual network plan approval processes.

M. Additional QA Related Comments not Specifically Related to Proposed Changes to Appendix A

(1) *Comment:* The EPA received a comment that another part of the rule appeared to encourage the use of collocated FEM samplers in an official reporting capacity where they have been held back or used sparingly up to now due to concerns regarding operational confidence. The commenter was suggesting this reference was intended to allow primary FRM monitors to be collocated with FEM monitors for QA purposes which would require a regulatory change to the current QA requirements.

Response: The verbiage described by the commenter referred to allowing FEM collocated data from a site that has an FRM as the primary monitor to replace the FRM data (if a scheduled sample was invalidated or not collected) or augment data (filling in for unscheduled samples). The FRMs collocated with continuous FEMs in this context were not meant to count towards meeting the QA collocation requirements and EPA does not intend to change the current $PM_{2.5}$ QA collocation requirements.

(2) *Comment:* A commenter had concerns that the reporting of IMPROVE data for comparison to a secondary $PM_{2.5}$ visibility index standard could prove problematic as those sites are not always operated by state, local, or tribal air monitoring agencies. They felt that the regulation should outline some data quality and certification responsibilities to the appropriate state, local, or tribal air monitoring agencies.

Response: The EPA acknowledges this comment; however, since the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS, the EPA will not include any $PM_{2.5}$ secondary standard QA requirements related to the Chemical Speciation Network or IMPROVE Network into Appendix A.

(3) *Comment:* Commenters recommended that the EPA develop explicit guidance regarding the methodology and criteria for assessing validity of air quality data from secondary sources. Such data evaluations should be included as part of the five year Network Assessment.

Response: The EPA acknowledges this comment. However, since the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS, the EPA will not include any $PM_{2.5}$ secondary standard QA requirements related to the Chemical Speciation Network or IMPROVE Network into Appendix A.

(4) *Comment:* Commenter felt that EPA should clarify the use of the term "$PM_{2.5}$ CSN" in 40 CFR part 58 Appendix A. "CSN" is used several times throughout the proposal to denote a network separate from the IMPROVE network. The definition in Appendix A should clearly state if it includes IMPROVE monitors.

Response: The EPA acknowledges this comment. However, since the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS, the EPA will not include any $PM_{2.5}$ secondary standard QA requirements related to the Chemical Speciation Network or IMPROVE Network into Appendix A since the networks will not produce data related to NAAQS decisions.

N. Comments on Probe and Monitoring Path Siting Criteria

(1) *Comment:* One commenter supports making the Appendix E siting criteria for near-road $PM_{2.5}$ monitoring the same as the Appendix E siting criteria for near road monitoring of nitrogen dioxide and carbon monoxide.

Response: The comment in support of the proposal is acknowledged and the EPA is generally adopting this approach, except as explained in the preamble to the final rule, we are also including a provision for separation distances from horizontal and vertical distances that is consistent with the existing PM criteria (i.e., greater than 2 meters). For gas monitoring the separation distances from horizontal and vertical distances is greater than 1 meter.

(2) *Comment:* Two commenters support the proposal to extend the existing probe and monitoring path siting criteria described in Appendix E to 40 CFR Part 58 for PM2.5 FRMs and FEMs to the CSN and IMPROVE measurements.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements on the use of CSN or IMPROVE measurements.

(3) *Comment:* One commenter suggested allowing the same 10 meter collocation waiver provision proposed for the $PM_{2.5}$ NAAQS to also apply to CSN monitors.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements on the use of CSN or IMPROVE measurements.

(4) *Comment:* The $PM_{2.5}$ monitor should have the same height and distance from the road requirements as NO_2, but the distance to the nearest vertical wall or obstruction should be increased to match the requirements for current micro- and middle-scale installations. It is not advisable to install a $PM_{2.5}$ monitor adjacent to a wall or other obstruction that would disrupt the normal upwind-to-downwind flow across the roadway.

Response: As explained in the preamble to the final rule, the EPA did not propose to change the existing requirements regarding placement near walls or obstructions. As such, even though a $PM_{2.5}$ monitor may be collocated with an NO_2 monitor at a near-road location, the individual siting requirements regarding placement near walls or obstructions for each pollutant still apply.

(5) *Comment:* One commenter stated that the required near-road measurements of $PM_{2.5}$ must be suitably distant from traffic so as not to be influenced by traffic wake effects that make the measurements unrepresentative of ambient air. For at-grade roadways, the turbulent wakes caused by traffic and wind blowing across a busy road result in eddies that disturb the air flow and trap pollutants. This phenomenon, similar in some respects to building-wake cavity effects, causes recirculation and high concentrations can occur if emissions are trapped within this zone. Population exposure near roadways generally occurs outside of this zone. If a monitor were to be placed in this recirculation zone, it could misrepresent concentrations in ambient air by for areas not immediately close to roadways. The general rule of thumb is that this turbulent zone could extend 5 to 10 times the vehicle height from the road, which for a box trailer would correspond to about 15 to 30 m. For an elevated roadway or complex interchange with complex structures, the required offset distance could be greater.

Response: The EPA is finalizing its proposal on the siting of the $PM_{2.5}$ monitors in the near-road environment, which is the same as the NO_2 siting, which states to be as near as practicable to the road but no more than 50 meters away. While EPA is finalizing these siting criteria, it did consider the optimum distance that sites should be located at in the Near-Road NO_2 Monitoring Technical Assistance Document (TAD) EPA-454/B-12-002, June 2012. In this document, we recommend that the ideal distance is within 20 meters the road. In providing this additional guidance we cite Baldauf et al. (2009) in the TAD, which notes that a distance of 10 to20 meters should be considered for near-roadway monitoring. The referenced paper states that this is partly to avoid being in the wake zone as described by the commenter. Now that we are finalizing requirements for siting of $PM_{2.5}$ monitors in the near-road environment and we want these measurements to be collocated with the near –road NO_2 monitors, it is appropriate to use the same additional guidance from the Near-Road NO_2 Monitoring TAD when considering the optimum location of the monitor for $PM_{2.5}$. Therefore, and as stated in the TAD, the EPA strongly encourages state and local agencies to place near-road NO2 monitor probes, and now $PM_{2.5}$ inlets within 20 meters from target road segments whenever possible. To avoid being in the wake zone as described by Baldauf et al. (2009), monitoring agencies should also consider, but are not required, to site inlets at least 10 meters from the road, if possible. While the commenter's distance is a little different as its based on an example of a box trailer (15 to 30 meters), we believe this approach adequately addresses this issue, taking into consideration the need to address other issues related to monitoring objectives for near road sites.

O. Comments on the Annual Monitoring Network Plan and Periodic Assessment

(1) *Comment:* One commenter requested that the EPA clarify the requirements for assessments and identify differences between the network assessments and the network plan requirements.

Response: The requirements for annual monitoring network plans and five year assessments are detailed in §58.10. Essentially, a five year assessment is intended to be a comprehensive assessment while an annual monitoring network plan is intended to be the year to year changes that are being implemented as a result of that comprehensive assessment as well as any other changes that are needed.

(2) *Comment:* One commenter recommends that an evaluation of the requirements for the Five Year Monitoring Network Assessment should be reevaluated in light of the frequency with which NAAQS standards are revised. The commenter recommends that this evaluation be conducted by one or more of the National Association of Clean Air Agencies (NACAA)/EPA stakeholder groups.

Response: The comment in support of a reevaluation of the requirements for the Five Year Monitoring Network Assessment, conducted by one or more of the National Association of Clean Air Agencies (NACAA)/EPA stakeholder groups is noted.

(3) *Comment:* One commenter stated that the tools available (for the five year assessments) are inadequate for the objective assessment needed for urbanized areas, and assessment of inter- and intrastate scales needed by monitoring agencies. Also, that the monitoring

and supporting data does not, and typically will not, have the spatial resolution to allow adequate network assessment at the most useful scales, the urban area, or MSA.

Response: This comment is addressed in section VIII.B.6.a of the preamble to the final rule.

(4) *Comment:* One commenter stated that EPA must take the experience gained by the states and local monitoring organizations in the development of these first assessment documents to immediately start development of new and refined tools and state-specific data hinted at in the Monitoring Assessment Guidance. Many monitoring organizations could greatly benefit from accessible tools that can be used to refine and improve MSA and state scale monitoring networks.

Response: This comment is addressed in section VIII.B.6.a of the preamble to the final rule.

(5) *Comment:* One commenter strongly recommended that EPA provide guidance to States at least one year prior to the due dates for the 5-year assessments.

Response: As stated in section VIII.B.6.a of the preamble to the final rule, the EPA will work with States to support tools and guidance on the five year assessments.

(6) *Comment:* One commenter stated that any requirements for the State agencies should be met with commensurate requirements for the EPA Region to review and respond to the assessment.

Response: The **5-**year network assessments are required to be submitted along with annual monitoring network plans during the years when the assessments are due (e.g., 2010, 2015, etc.). During the initial assessment conducted in 2010, many EPA regions did include the network assessment as part of the overall dialogue with the submitting agency. The EPA will consider ways to improve the process and the text of part 58 in a possible future rule making on monitoring.

(7) *Comment:* One commenter stated that it would be more efficient to make a periodic monitoring network assessment an activity conducted by regional planning organizations (RPOs) with commensurate funding going to the RPO as LADCO did for Region V states for the 2010 assessment.

Response: The coordination of five-year assessments by or through a regional planning organization is an appropriate way to perform these required assessments.

P. Comments on Operating Schedules

(1) *Comment:* One commenter stated that they generally agree that every day sampling is appropriate for sites whose design values are within 5% of the NAAQS. However, for sites with design values greater than 5% above the NAAQS, reduced sampling frequency

should be allowed only if the sites has a collocated continuous $PM_{2.5}$ monitor that is suitable for Air Quality Index (AQI) reporting required by 40 CFR Part 58, Appendix G.

Response: The comment in support of the proposal is acknowledged and EPA is adopting the proposed approached in the final rule. Regarding the recommendation on sites with design values greater than 5% above the NAAQS, where reduced sampling frequency should be allowed only if the site has a collocated continuous $PM_{2.5}$ monitor that is suitable for AQI reporting required by 40 CFR Part 58, Appendix G, the EPA believes the existing monitoring rules are already largely supportive of operating $PM_{2.5}$ continuous methods at SLAMS. For example, at least one-half (round-up) the minimum required sites according to Table D-5 of appendix D to part 58 are to have a $PM_{2.5}$ continuous monitor operating at the sites. This requirement ensures that there is at least one $PM_{2.5}$ continuous monitor operating in each CBSA required to monitor for $PM_{2.5}$.

(2) *Comment:* One commenter supports that it is reasonable for each agency to determine the applicability of the requirement for daily sampling once a year when updating the annual monitoring network plan.

Response: The comment in support of the proposal is acknowledged and the EPA is adopting the proposed approached in the final rule.

(3) *Comment:* One commenter recommended retaining the current sample frequencies for PM measurements.

Response: The EPA believes the proposed changes will provide flexibility and predictability regarding how sample frequency changes are addressed, which will be of benefit to monitoring agencies as they operate their $PM_{2.5}$ monitoring programs. Accordingly, the EPA is finalizing the changes to the sample frequency requirements for $PM_{2.5}$ as proposed.

Q. Comments on Data Reporting and Certification for CSN and IMPROVE data

(1) *Comment:* One commenter identified that an appropriate and efficient approach for implementing the visibility standard would be to require urban areas with only IMPROVE monitors to add one CSN monitor to the urban area and align NAAQS and CSN data reporting and certification requirements to meet the May 1 data certification deadline cited in 40 CFR 58.15.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements on the use of CSN or IMPROVE measurements.

(2) *Comment:* One commenter recommended that the EPA work with the IMPROVE program to reduce the lead time for data submittal and certification in the EPA's Air

Quality System (AQS) and align the IMPROVE quality assurance protocol with the CSN and SLAMS networks.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements on the use of CSN or IMPROVE measurements.

(3) *Comment:* One commenter recommended that data from IMPROVE be submitted to AQS no more than 6 months after they are collected.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements on the use of CSN or IMPROVE measurements.

(4) *Comment:* One commenter recommended that data from IMPROVE and CSN be placed on a separate certification schedule where data for an entire year is certified by August 1 of the following year.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements on the use of CSN or IMPROVE measurements.

(5) *Comment:* One commenter stated that the proposed delay in data certification could pose problems with the states' ability to meet mandated due dates to provide technical justification for excluding data due to exceptional events.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements on the use of CSN or IMPROVE measurements or changes to the data certification of this data.

(6) *Comment:* One commenter stated the certification data should be extended to six months from the end of the quarter in which the data were collected to provide sufficient time for lead, CSN and IMPROVE data certification.

Response: For the reasons stated in section VI of the preamble to the final rule, the EPA is not adopting the proposed secondary $PM_{2.5}$ visibility index NAAQS. Consequently, the final rule does not include requirements on the use of CSN or IMPROVE measurements or changes to the data certification of this data.

R. Comments on the Requirements for Archiving Filters

(1) *Comment:* Several commenters support the proposal to extend the filter archival requirements from one to five years, with cold storage during the first year.

Response: The comments in support of the proposal are acknowledged and the EPA is adopting the proposed approached in the final rule.

(2) *Comment:* One commenter suggested that the EPA study the effectiveness of long term cold storage looking specifically at repeatability of gravimetric measurements.

Response: Such studies already exist. Also, the EPA has existing guidance on the storage of filters and may, at its discretion, update that guidance in light of the changes to filter storage requirements.

(3) *Comment:* One commenter stated that they do not have the space to store four years of samples in either cold or ambient storage and believes this proposed requirement would be burdensome even if the samples dot not need to be stored cold.

Response: This comment is addressed in section VIII of the preamble of the final rule.

(4) *Comment:* One commenter questioned the value of filter retention beyond one year if they are not refrigerated. Critical information may be lost once filters go to room temperature. Perhaps 2-year cold storage retention with a 5-year total is more appropriate.

Response: The EPA believes, that at a minimum, analyses for elements can be conducted very successfully for several years after sample collection and that these analyses can be performed with filters that have either have or have not been refrigerated. Other analyses, such as for nitrate and sulfate ions, provide better results when refrigerated and their long term usefulness is not expected to be as good compared to elemental analysis.

S. Funding and Resources Issues associated with Ambient Air Monitoring Requirements

The EPA received numerous comments on funding and resources associated with the implementation and operation of ambient air monitors that are described in the proposed amendments to the ambient monitoring requirements. We understand that monitoring agencies desire full funding when revisions to monitoring requirements require the purchase of new equipment and installation of new sites, relocation of existing monitors, and increase burdens for staff and operational budgets. The EPA understands these concerns. The EPA has historically funded part of the cost to State, local, and Tribal governments of installation and operation of monitors to meet Federal monitoring requirements. Sections 103 and 105 of the CAA allow the EPA to provide grant funding for programs for preventing and controlling air pollution and for some research and development efforts respectively. However, the CAA requirements from which this final rule derives are not contingent on the EPA providing funding to States to assist in meeting those requirements. Accordingly, the comments regarding funding are not directly relevant to the content of this final rule. Nevertheless, the EPA recognizes that resources always have been and will remain a practical consideration for establishing and operating monitoring programs. The EPA will continue to work with States in this regard, in particular as the EPA determines how to allocate enacted funding among States and among types of monitoring so as to achieve the best possible environmental outcomes.

(1) *Comment:* One commenter representing many air agencies across the country stated that the monitoring requirements must be fully funded, including staffing as well as operation and maintenance costs. New monitoring mandates must be supported by appropriate increases in federal funding. State and local agencies need additional, adequate federal funding in order to move forward with new monitoring requirements and continue to operate and maintain existing monitoring networks, which are crucial to the protection of public health and the environment. Implementing a multipollutant near roadway monitoring network requires the purchase of new equipment and installation of new sites, relocation of monitors, and additional staff, operation and maintenance costs, and must be fully funded under Clean Air Act section 103.

Response: Information on how the EPA addresses funding for monitoring is described above.

(2) *Comment:* One commenter representing a number of air agencies stated that the EPA is proposing new requirements for ambient air monitoring. The commenter believes the costs of these requirements have been significantly underestimated, in large part because of the proposed network design and underlying assumptions for the near-road monitors. The commenter offer specific comments on the proposal that they believe will both reduce the costs and enhance the effectiveness of the network; we urge the EPA to incorporate these changes. Even with the changes, however, we believe there will be substantial monitoring costs, both for installation and ongoing operation/maintenance of the stations, as well as in data handling and network review. The commenter stated that their members do not have the financial resources to absorb these new costs and they believe the EPA must provide full funding for any new monitoring requirements that are established.

Response: The EPA believes that there will be minimal cost in relocating $PM_{2.5}$ monitors required to be implemented according to the schedule described in section VIII of the preamble to the final rule. The EPA considered the commenter's suggestions on the proposal that they believe will both reduce the costs and enhance the effectiveness of the network and, as described in Section VIII.B.3.b.i of the preamble to the final rule, the EPA is providing for a phased deployment of the near-road monitors. Regarding the comment that there will be substantial monitoring costs, the EPA believes these costs should not be new costs since we are emphasizing moving monitors, rather than adding new ones.

(3) *Comment:* One commenter representing several State air agencies stated that while their States are not opposed to adding $PM_{2.5}$ monitoring to the near-road network, as the EPA proposes, there is no funding for this new network objective.

Response: As described in Section VIII.B.3.b.i of the preamble to the final rule, the EPA noted that a number of air agencies stated concerns that the near-road monitors are challenging to site and that there is additional cost in operating these monitors, the EPA maintains that the major challenges in siting would already be accomplished by implementing the required NO_2 monitoring stations in near-road environments since the EPA fully expects that the $PM_{2.5}$ monitors will be placed at the NO_2 near roadway stations and has revised the $PM_{2.5}$ monitoring requirements consistent with that expectation. The EPA also points out that the requirements for the minimum number of $PM_{2.5}$ monitors is unchanged and that in most cases the addition of near-road $PM_{2.5}$ monitors can be accomplished by relocating an existing monitor, with no net increase in monitors. Thus, while we are requiring a new component of the $PM_{2.5}$ monitoring network, the overall size of the network is expected to remain about the same, and we expect that air agencies can meet this requirement by relocating existing lower-priority monitors. Additional information on how monitoring is funded is described above.

(4) *Comment:* One commenter stated that they continue to stress that monitoring requirements must be fully funded, including staffing as well as operation and maintenance costs. New monitoring mandates must be supported by increases in federal funding necessary to establish this new or expanded network based on revisions to the federal air quality standards. State agencies need additional, adequate federal funding in order to move forward with new monitoring requirements and continue to operate and maintain existing monitoring networks, which are crucial to the protection of public health and the environment. Implementing a new, multi-pollutant near roadway monitoring network requires the purchase of new equipment and installation of new sites, and additional staff and operation and maintenance costs at a time when state agencies are already struggling with budget and staffing shortfalls. New federal funding is necessary in order to implement these new requirements, and should be provided under Section 103 of the Clean Air Act (Act), rather than Section 105 of the Act which requires a state match for federal funding.

Response: Information on how the EPA addresses funding for monitoring is described above.

(5) *Comment:* One commenter stated that the addition or relocation of monitors can increase staffing, operation and maintenance costs for states and local agencies. U.S. EPA must support new monitoring mandates by providing appropriate increases in federal funding to ensure states and local agencies can move forward with new monitoring requirements and continue to operate and maintain existing monitoring networks, which are crucial to the protection of public health and the environment.

Response: Information on how the EPA addresses funding for monitoring is described above.

(6) *Comment:* One commenter stated that it is also important to note that the relocation of existing monitors will result in additional costs to states and these costs must be fully funded. For those agencies that may not be able to relocate existing monitors – because

they are needed to provide neighborhood scale data for a CBSA, for attainment planning or model confirmation, to address specific community-based air quality concerns, or because they are part of ongoing research efforts – full funding for the purchase, installation, and operation and maintenance of an additional monitor must be provided. We believe EPA has significantly underestimated the initial cost of the proposed monitoring requirements, as well as the costs of ongoing network operation.

Response: Information on how the EPA addresses funding for monitoring is described above. The EPA disagrees we have significantly underestimated the initial cost of the proposed monitoring requirements, as well as the costs of ongoing network operation, but even if the costs were somewhat higher, the EPA would still judge the monitoring requirements as necessary and appropriate under the Clean Air Act. As explained in Section VIII.B.3.b.i of the preamble to the final rule, the EPA noted that a number of air agencies stated concerns that the near-road monitors are challenging to site and that there is additional cost in operating these monitors, the EPA maintains that the major challenges in siting would already be accomplished by implementing the required NO_2 monitoring stations in near-road environments since the EPA fully expects that the $PM_{2.5}$ monitors will be placed at the NO_2 near roadway stations and has revised the $PM_{2.5}$ monitoring requirements consistent with that expectation. The EPA also points out that the requirements for the minimum number of $PM_{2.5}$ monitors is unchanged and that in most cases the addition of near-road $PM_{2.5}$ monitors can be accomplished by relocating an existing monitor, with no net increase in monitors. Thus, while we are requiring a new component of the $PM_{2.5}$ monitoring network, the overall size of the network is expected to remain about the same, and we expect that air agencies can meet this requirement by relocating existing lower-priority monitors, which generally requires fewer resources than operating new monitors. Additional information on how monitoring is funded is described above.

(7) *Comment:* One commenter requests that the EPA provide states with additional funding necessary to implement the revised $PM_{2.5}$ standards, including additional ambient air monitoring equipment.

Response: Information on how the EPA addresses funding for monitoring is described above.

(8) *Comment:* One commenter stated that if the EPA is going to require $PM_{2.5}$ monitoring at the near-road sites, additional funding must be provided. The EPA assumes that states can relocate existing monitors and thus incur no additional costs. This typically will not be the case as the $PM_{2.5}$ monitors decommissioned probably will not be in the same locales where near-road monitoring is being conducted. Therefore, it cannot be assumed that current staffing levels are adequate for the near-road $PM_{2.5}$ monitoring. Second, if a decision is made by a monitoring agency to shift from the FRM to other particulate monitoring methodologies, such as the FEM or aethalometry as allowed in the proposed rule, additional funding for new monitors will be needed. Third, the placement of additional monitors at some near-road sites may require that more safety barriers or

mitigation measures be installed. Hence, moving monitors cannot be assumed to be a zero-sum game.

Response: Information on how the EPA addresses funding for monitoring is described above. With regard to the comment that a decommissioned monitor may not be in the same locale as where the near-road monitoring is being conducted, the EPA points out that there will already be other measurements at the near-road stations and therefore the addition of $PM_{2.5}$ to this station will result in some efficiency for the operator responsible for the near-road station. In most cases the EPA expects that the relocation of a monitor will be from within the same CBSA. If there are cases where this cannot be accomplished and there are reasons why the relocated $PM_{2.5}$ monitors cannot be supported, the EPA will work with agencies on a case by case basis to addresses such issues.

(9) *Comment:* One commenter stated that they continue to stress that all monitoring requirements must be fully funded, including staffing as well as operation and maintenance costs. Relocation of existing monitors does result in additional costs to state and local agencies, as it requires the use of additional staff time and resources. New monitoring mandates must be supported by appropriate increases in federal funding. The commenter stated they need additional funding in order to move forward with new monitoring requirements and continue to operate and maintain existing monitoring networks, which are crucial to the protection of public health and the environment. New federal funding is needed to implement these new requirements, and should be provided under Clean Air Act § 103.

Response: Information on how the EPA addresses funding for monitoring is described above. With regard to the comment that" Relocation of existing monitors does result in additional costs to state and local agencies"; the EPA believes that such costs will be minimal, or at least will be the most cost-effective means of providing necessary monitoring, and can be managed within the timeframe of the requirement to implement the near-road monitors described in section VIIIB.3.b.i of the preamble to the final rule.

(10) *Comment:* One commenter stated that they do not support an expanded network to monitor specifically for a secondary visibility standard. States do not have the resources to add additional monitors for a secondary standard**.**

Response: As described in Section VI of the preamble to the final rule, the EPA is not finalizing a secondary NAAQS using a visibility index and therefore is not finalizing the monitoring changes that would have been necessary to support it.

(11) *Comment:* One commenter stated that they support the integration of multi-pollutant monitoring at NO_2 near-road monitoring stations so long as federal funding is provided for the deployment of the monitors.

Response: Information on how the EPA addresses funding for monitoring is described above.

(12) *Comment:* One commenter stated that the U.S. EPA needs to provide funding for all new required monitors, including capital costs and operations and maintenance costs. State and local agencies are facing an extraordinary shortage of resources. The commenter also stated that they are committed to protecting air quality and public health but we must also be careful stewards of the public's money. In the current economic environment, state and local agencies are unable to develop the additional resources needed to meet the proposed new monitoring requirements. The regulation should be written so that new monitoring is not required unless the U.S. EPA has the ability to fund the initiative.

Response: Information on how the EPA addresses funding for monitoring is described above.

(13) *Comment:* One commenter stated that they do not have a $PM_{2.5}$ monitor available for relocation to a near-road site. Therefore, they will have to purchase a new FEM for this monitoring at a cost of $25,000 to $30,000. In circumstances such as this, the EPA must provide full funding for the purchase, installation, and operation and maintenance of a new $PM_{2.5}$ monitor for the required roadway location.

Response: Information on how the EPA addresses funding for monitoring is described above.

(14) *Comment:* One commenter stated that the U.S. EPA must provide supplemental funding that does not require matching to support purchasing, installing, operating, and maintaining additional fine particulate matter ($PM_{2.5}$) monitors at near-road monitoring sites as currently proposed. If an existing monitor is relocated to a near-roadway site, supplemental funding should be made available to support the breakdown, relocation, and installation of the monitor.

Response: Information on how the EPA addresses funding for monitoring is described above.

(15) *Comment:* One commenter stated that the regulation should be written so that new monitoring is not required unless the U.S. EPA has the ability to fund the initiative.

Response: Information on how the EPA addresses funding for monitoring is described above.

(16) *Comment:* In providing comments on the proposal to require near-roadway monitors, one commenter stated that most of these laudatory objectives are not directly tied to the implementation of the new or proposed $PM_{2.5}$ NAAQS, but instead involve support for research. At a time when budgets for NAAQS-compliance monitoring are seriously limited, it does not make sense to devote those limited funds to monitoring for research purposes.

Response: As stated in section VIII.B.3.b.i, the EPA believes the addition of $PM_{2.5}$ monitors to the near-road environment will support a number of objectives and is important for the protection of public health. Information on how the EPA addresses funding for monitoring is described above.

(17) *Comment:* Multiple commenters stated that the EPA has not demonstrated the need to add a requirement for near-road monitoring of $PM_{2.5}$. The primary purpose of these monitors appears to be research. At a time when state monitoring budgets are reportedly inadequate to provide monitors to ascertain compliance with the 1-hour SO_2 NAAQS that the EPA adopted in 2010, funding should not be diverted to fund new $PM_{2.5}$ monitoring sites.

Response: As stated in section VIII.B.3.b.i, the EPA believes the addition of $PM_{2.5}$ monitors to the near-road environment will support a number of objectives and is important for the protection of public health. Information on how the EPA addresses funding for monitoring is described above.

VI. RESPONSES TO SIGNIFICANT COMMENTS ON IMPLEMENTATION

The EPA received comments on a range of implementation topics discussed in section IX of the proposal, including initial area designations, section 110(a)(2) infrastructure State Implementation Plan (SIP) requirements, nonattainment area SIPs, New Source Review (NSR) and Prevention of Significant Deterioration (PSD) program requirements (including the specific proposed changes to the PSD regulations to provide a transition into meeting new requirements associated with the revised PM NAAQS), and the transportation conformity program. Our responses to specific comments relevant to this final rule are presented below. Because the EPA is not finalizing a new secondary $PM_{2.5}$ NAAQS in this rulemaking, we are not addressing comments related to implementation of a distinct new secondary $PM_{2.5}$ NAAQS.

A. Specific Comments Related to Designation of Areas

This section responds to comments supporting and opposing the proposed schedules for initial area designations, recommending classification schemes, and discussing various technical and policy aspects of the area designations process. The responses to some of these comments are also discussed in section IX.A of the preamble to the final rule. The EPA received numerous comments on these issues from states, state organizations, local air pollution control agencies, regional organizations, industry, environmental organizations, and health-related organizations.

(1) *Comment:* Most commenters expressed support for a standard 2-year schedule for initial area designations for the primary annual $PM_{2.5}$ NAAQS.

Response: Under section 107(d)(1) of the CAA, the EPA is required to designate areas no later than 2 years following promulgation of a new or revised NAAQS, or by December 2014 based on promulgating the PM NAAQS on December 14, 2012. Also under the schedule in section 107(d)(1) and confirmed in the final PM NAAQS action, state Governors and tribes, if they choose, are required to submit their initial designation recommendations for the revised primary annual $PM_{2.5}$ NAAQS to the EPA no later than 1 year following promulgation of the revised NAAQS (i.e., by December 13, 2013). If the EPA intends to make any modifications to a state’s or tribe’s recommendations, including modifications to area boundaries, the EPA is required to notify the state or tribe no later than 120 days prior to finalizing the designation; this would be no later than August 14, 2014. States and tribes will then have an opportunity to demonstrate why the EPA's intended modification is inappropriate before the EPA makes the final designation decisions by December 12, 2014.

(2) *Comment:* Several commenters encouraged the EPA either to consider additional time (up to 1 year) for initial area designations (or not to designate areas) associated with the proposed secondary PM visibility index standard due to the lag in obtaining data from speciation monitoring networks, the variability in monitored relative humidity data, and the “unique” nature of the proposed secondary standard. Another commenter suggested that, rather than waiting for data from newly established monitors, designations for the secondary standard should be made based on the existing $PM_{2.5}$ monitoring network.

Response: For the reasons stated in section VI.D.2 of the preamble to the final rule, the Administrator has decided not to establish the proposed distinct secondary standard to address visibility impairment. Therefore, the EPA will not promulgate initial area designations for a secondary PM visibility index standard.

(3) *Comment:* Several commenters asked the EPA to clarify whether data from the proposed new near-road monitors will be used, if available, for initial area designations. Others expressed concern that data from violating near-road monitors not be used when designating areas as these monitors are not representative of surrounding communities and should not drive the designations process for an entire urban area. Many of these same commenters asked the EPA to clarify how near-road data might be used in future designations processes.

Response: The EPA does not believe that data from the new near-road monitors will be available for the EPA to consider within the timeframe for initial area designations provided by the CAA. Section 107(d)(1) of the CAA requires the EPA to designate areas no later than 2 years following promulgation of a new or revised NAAQS, or by December 2014. (The CAA provides the Agency an additional third year from promulgation should there be insufficient information on which to make compliance determinations.[46]) For initial area designations for the primary annual $PM_{2.5}$ NAAQS, the EPA relies exclusively on monitoring data to identify areas to be designated nonattainment due to violations of the standards and then uses monitoring data and other information to identify areas contributing to violations in those areas. *See Catawba County v. EPA*, 571 F.3d 12-13 (D.C. Cir. 2009). As indicated in the preamble to both the proposed and final PM NAAQS, the initial set of near-road $PM_{2.5}$ monitors will be fully deployed by January 2015 with the requisite 3 years of air quality data available in 2018.[47] The EPA intends to proceed with initial area designations for the revised primary annual $PM_{2.5}$ NAAQS using 3 years of consecutive air quality data from the existing, area-wide FRM/FEM/ARM $PM_{2.5}$ monitoring sites to complete designations by December 2014.[48] Consistent with previous area designations processes used in informing boundary decisions, the EPA would then analyze a variety of area-specific

[46]While the EPA intends to make every effort to designate areas for the primary annual $PM_{2.5}$ NAAQS on a 2-year schedule, the EPA recognizes that new information may later arise that justifies the need for additional time, up to 1 additional year is available based on insufficiency of data, to complete the process. Any subsequent change to the designations schedule would be announced.

[47]The remainder of the near-road monitors in CBSAs with populations between 1 million but less than 2.5 million will be deployed by January 1, 2017.

[48]The EPA notes that once the EPA has promulgated initial designations for a new or revised NAAQS, section 107(d)(3) of the Clean Air Act provides a separate process for redesignating areas based upon subsequent air quality-related considerations. We believe that this process is the appropriate process for addressing monitoring information that was not available in sufficient time to be considered during the designation process. As noted by the Court in *Catawba v. EPA*, 571 F.3d 52, "Congress imposed deadlines on EPA and thus clearly envisioned an end to the designation process." It is important that states can rely on the completed designations and to move forward with the associated required implementation planning.

information[49] in determining which nearby areas contribute to a violation.

Although we do not anticipate that data from the new near-road monitors will be available for initial designations, the EPA would consider near-road data meeting the EPA's completeness, quality assurance, and NAAQS comparability criteria in future designations processes (e.g., a designations process associated with a future revision to the NAAQS) or in potential redesignation processes under section 107(d)(3). The EPA believes that data from all near-road sites are comparable to the primary 24-hour $PM_{2.5}$ NAAQS and that data from near-road sites approved as area-wide sites would be comparable to the annual $PM_{2.5}$ standard. As explained in sections III.E.3.a and VIII.B.3.b.i of the final rule preamble, a significant fraction of the nation's population lives near major roads. The EPA has a responsibility to protect air quality and public health in all locations that meet EPA's definition of ambient air, including those areas with populations living near major roads. As noted in the previously mentioned preamble sections, air agencies and the EPA will use the annual monitoring network plan described in 40 CFR 58.10 to identify and approve sites that are suitable and sites that are not suitable for comparison to the annual $PM_{2.5}$ NAAQS.

(4) *Comment:* One commenter suggested that the EPA conduct dispersion modeling around transportation facilities in accordance with the EPA's transportation conformity hotspot modeling guidance and use concentrations to determine attainment status for the designations process. This same commenter also supported using modeling for unmonitored areas, e.g., communities near roadways.

Response: As previously indicated, for the primary annual $PM_{2.5}$ NAAQS, the EPA relies on monitoring data to identify areas to be designated nonattainment due to violations of the standards and does not intend to conduct or use dispersion modeling around transportation facilities or in unmonitored areas to determine whether an area is violating the standard for purposes of establishing nonattainment areas, as this is not required by the statute. *See Catawba County v. EPA*, 571 F.3d 12-13 (D.C. Cir. 2009). The EPA intends to address the factor analysis and boundary setting process in the designation guidance to the states and tribes, expected to be available shortly after promulgation of the PM NAAQS.

(5) *Comment:* Several commenters emphasized the need for the EPA to provide timely guidance and technical information for area designations. Commenters similarly encouraged the EPA to consult with potentially affected areas during the area designations process.

Response: As discussed in the preamble, the EPA intends to provide designation guidance and technical information shortly after the NAAQS are promulgated. In

[49]The EPA has used area-specific information to support boundary determinations by evaluating factors such as air quality data, emissions and emissions-related data, meteorology, geography/topography, and existing jurisdictional boundaries. This may include, as appropriate, information from non-FRM/FEM/ARM monitors and air quality modeling, where available, to help define an appropriate boundary for areas contributing to FRM/FEM/ARM-based monitored violations.

addition, the EPA plans to offer assistance to states and tribes throughout the designations process on technical and policy issues.

(6) *Comment:* One commenter suggested that the EPA use the designation categories outlined in the Clean Air Act (i.e., nonattainment, attainment, or unclassifiable) as opposed to the EPA's practice of using "unclassifiable/attainment" when designating areas that meet the NAAQS. The commenter noted that the "unclassifiable/attainment" designation is unclear to the public. Another commenter presented an additional designation category approach and asked the EPA to consider using "unclassifiable" or "transitional" when designating nonattainment areas that the EPA projects could reach attainment within 5 to 10 years based on federal measures. The commenter notes that with this approach the "EPA could take the pragmatic step of avoiding the imposition of costly and unnecessary stationary source controls while assuring continued progress toward meeting the tighter standard. Such a designation would recognize the strong role of *[sic]* federal measures provide in helping areas to attain the standard and would set the precedent of avoiding unnecessary and redundant costs where feasible."

Response: As previously discussed, the EPA intends to provide designation guidance and technical information shortly after the NAAQS are promulgated. The EPA expects this guidance to include the intended designation categories for area designations for the revised primary annual $PM_{2.5}$ NAAQS.

(7) *Comment:* Several commenters supported the EPA's proposed approach to use 3 consecutive years of monitored ambient air quality data to determine violations of the standard rather than modeling for initial area designations. One commenter urged the EPA to determine and clearly define the "contribution" to nonattainment.

Response: As indicated in both the proposed and final PM NAAQS actions, the EPA intends to proceed with initial area designations for the revised primary annual $PM_{2.5}$ NAAQS using 3 years of consecutive air quality data from the existing, area-wide FRM/FEM/ARM $PM_{2.5}$ monitoring sites to complete designations by December 2014. Consistent with previous area designations processes used in informing boundary decisions, the EPA would then use area-specific factor analyses in determining which nearby areas contribute to a violation. These supporting analyses may include information from non-FRM/FEM/ARM monitors and air quality modeling, where available, to help define an appropriate boundary for areas contributing to FRM/FEM/ARM-based monitored violations. Shortly after the NAAQS are promulgated, the EPA intends to further clarify in designations guidance and technical information the use of monitoring data, factor analyses, and "contribution."

(8) *Comment:* Several commenters submitted remarks related to establishing boundaries for PM nonattainment areas. A few commenters asserted that a Metropolitan Statistical Area (MSA), either a Core-Based Statistical Area (CBSA) or Combined Statistical Area (CSA), is too large an area to use in establishing presumptive boundaries for nonattainment areas and prefer starting at the county boundary.

Response: The EPA did not address the issue of appropriate boundaries for nonattainment areas in the PM NAAQS rule. The EPA will evaluate nonattainment area boundary recommendations from states and tribes and assess appropriate area boundaries during the designations process. Under the CAA, the EPA must designate as nonattainment any area that is violating the NAAQS or that is contributing to a nearby violation.

(9) *Comment:* Multiple commenters noted that the regulatory burden associated with the EPA's process of designating nonattainment areas will cause affected areas economic harm.

Response: The EPA's Regulatory Impact Analysis (RIA) provides illustrative estimates of the potential costs and health and welfare benefits of attaining several alternative $PM_{2.5}$ standards based on one possible set of selected control strategies for reducing direct PM and PM precursor emissions.

As previously discussed, the EPA intends to provide designation guidance and technical information shortly after the NAAQS are promulgated. Additionally, the EPA will be developing a PM NAAQS implementation rule, which the EPA intends to finalize around the time the initial area designations decisions are promulgated in December 2014. This implementation rule will address the control obligations for areas designated nonattainment and strive to identify, with appropriate stakeholder input, approaches that provide flexibility and opportunity for efficiency to the extent such approaches are consistent with the CAA and will not jeopardize expeditious attainment of the public health and welfare goals of the CAA. Finally, to the extent the CAA does not mandate specific control measures, states may consider economic concerns in development of their SIPs to address air quality.

(10) *Comment:* One commenter noted that "[i]n preparing new designations, EPA must consider needed redesignations under the 24-hour standard, even if EPA decides to retain the current standard unchanged. To ignore evidence of violations of the 24-hour standard would be arbitrary and capricious and contrary to the health protection goals of the statute. Designations must be accurate to avoid irrational outcomes, for example, around the proper permitting program for new and modified sources. EPA reasonably proposes to apply the nonattainment permitting programs in areas violating either the 24-hour or annual primary standards, but this approach, if the 24-hour designations are not revisited, would not guard against the situation where an area is designated attainment for both the annual and 24-hour standard even though it is violating the 24-hour standard. This would create the untenable situation wherein new sources in the area, governed by the PSD program, would be required to show that they will not cause or contribute to a violation of a NAAQS that the area is in fact already violating. New 2009-2011 data… identify areas that don't attain current standard yet are officially in attainment."

Response: Section 107(d)(1) of the CAA requires the EPA to designate areas no later than 2 years following promulgation of a *new or revised* NAAQS. In the EPA's final rule, the EPA revised the primary annual $PM_{2.5}$ standard, strengthening it from 15 $\mu g/m^3$ to 12 $\mu g/m^3$; retained the existing 24-hour $PM_{2.5}$ standard at 35 $\mu g/m^3$; retained the existing 24-hour PM_{10} (coarse particle) standard at 150 $\mu g/m^3$; and retained the current suite of secondary PM standards. Under section 107(d)(1), the EPA is required to designate areas only for the revised primary annual $PM_{2.5}$ standard. The CAA does not require the EPA to designate areas when it retains a standard in every aspect (level, form, averaging time and indicator). Therefore, the EPA does not intend to designate areas for the retained standards when we designate areas for the revised primary annual $PM_{2.5}$ standard. Section 107(d)(3) of the CAA provides a separate process for redesignating areas and provides the EPA with discretion regarding timing for designations/redesignations under section 107(d)(3). The EPA will work with states to achieve attainment in the most effective manner, whether this is accomplished through section 107(d)(3) or other approaches.

B. Specific Comments Related to Section 110(a)(2) Infrastructure SIP Requirements

In the proposal, the EPA invited preliminary comment on all aspects of infrastructure SIPs for the Agency to consider in developing future guidance. As stated in section IX.B of the preamble to the final rule, the EPA is currently developing a guidance document on CAA section 110 infrastructure SIP requirements that will address most infrastructure SIP elements and will aim to help states develop SIP submissions for all NAAQS, including the revised $PM_{2.5}$ NAAQS, and the EPA is considering comments received as it develops this guidance. The EPA also may issue supplemental infrastructure SIP guidance specific to the revised $PM_{2.5}$ NAAQS in the future if needed.

In addition to seeking comment on all aspects of infrastructure SIPs, the EPA sought comment specifically on the timing of infrastructure SIP submittals, particularly in light of the proposed new secondary standard. The EPA received comments both recommending and opposing granting states additional time to submit SIPs for any revised secondary standard, but because the Agency is not revising the secondary NAAQS in this rule, the issue of whether or not to allow states extra time to submit infrastructure SIPs for the secondary NAAQS is now moot.

(1) *Comment:* Some commenters emphasized the need for infrastructure guidance no later than one year after promulgation of the revised standards. The commenters also stated that the EPA's infrastructure guidance should include detailed guidance on how states should address the interstate transport obligations in CAA section 110(a)(2)(D), arguing that the guidance for the 2006 PM NAAQS indicated that technical analysis would be required, but it did not specify how the analysis should be conducted or how the EPA would evaluate the analysis. The commenters noted that the issue is further complicated by the status of the Clean Air Interstate Rule (CAIR) and the Cross State Air Pollution Rule (CSAPR or the “Transport Rule”).

A few commenters argued that the EPA should not issue guidance on CAA section 110 infrastructure SIP requirements for a revised $PM_{2.5}$ NAAQS, claiming that the requirements are already stated in the CAA and that EPA guidance would be “inappropriately prescriptive.” One of these commenters felt “the EPA should not attempt to supplant the states’ and districts’ discretion in applying the basic infrastructure requirements. If the EPA determines in the future that nonattainment areas cannot attain because of emissions outside of the area in question, out of State, or outside the United States, then the EPA can employ any of its statutory powers to address the situation."

Response: The EPA believes that issuing non-binding infrastructure SIP guidance is appropriate and that it is beneficial to states by helping them to develop plans in a nationally consistent manner. The EPA also understands commenters' concerns about the need for timely guidance and intends to issue, in the very near future, a guidance document on section 110 infrastructure SIP requirements, which will aim to help states develop SIP submissions for all NAAQS, including the revised $PM_{2.5}$ NAAQS. We intend to address most infrastructure SIP requirements in this guidance including the interstate transport requirements contained in CAA sections 110(a)(2)(D)(i)(II) and 110(a)(2)(D)(ii). In addition, the EPA may issue supplemental infrastructure SIP guidance specific to the revised $PM_{2.5}$ NAAQS if needed.

The EPA does not intend to address in the upcoming infrastructure SIP guidance document the interstate transport requirements contained in CAA section 110(a)(2)(D)(i)(I) – i.e., the requirements related to emissions from one State that significantly contribute to nonattainment or interfere with maintenance of the NAAQS in another state. The U.S. Court of Appeals for the D.C. Circuit recently issued an opinion in EME Homer City Generation v. EPA, 696 F.3d 7 (D.C. Cir.) that is relevant to this provision. Among other things the court concluded that "a SIP cannot be deemed to lack a required submission or be deemed deficient for failing to implement the good neighbor obligation [its obligation under 110(a)(2)(D)i)(I)[50]] until after EPA has defined the State's good neighbor obligation." EME Homer City Generation v. EPA, 696 F.3d 7, 31 (D.C. Cir 2012). This decision is not yet final as the mandate in EME Homer has not been issued and the EPA has petitioned for rehearing *en banc* in that case. In the meantime, the EPA intends to act in accordance with the holdings in the EME Homer opinion. Unless the EME Homer decision is altered, states will not be required to submit SIP revisions addressing the requirements in CAA section 110(a)(2)(D)(i)(I) until the EPA further defines state obligations pursuant to that section.

(2) *Comment:* Some commenters stated that the EPA should allow states the full 3-year statutory time period for submitting primary NAAQS infrastructure SIPs. Another commenter argued that the submittal deadline for section 110(a)(2)(D) SIPs for interstate transport should not be governed by the 3-year submission deadline for infrastructure SIPs.

Response: As noted in section IX.B of the preamble to the final rule, while the CAA allows the EPA to set a shorter time than 3 years from the date of promulgation of a NAAQS for submission of infrastructure SIPs, the EPA does not currently intend to do so. With respect to the second comment, the EPA is without authority to alter, in this rule, the SIP submission deadline established in the statute. The EPA has historically interpreted section 110(a)(1) of the CAA as establishing the required submittal date for

[50] The Court refers to section 110(a)(2)(D)(i)(I) as the "good neighbor provision" and obligations under that provision as a state's "good neighbor obligation." EME Homer City, 696 F.3d at 13.

110(a)(2)(D) interstate transport SIPs, including the provisions in section 110(a)(2)(D)(i)(I) regarding significant contribution to nonattainment and interference with maintenance. However, as noted above, the D.C. Circuit's recent opinion in EME Homer, 696 F.3d at 31, concluded that a SIP cannot be deemed to lack a required submission under section 110(a)(2)(D)(i)(I) until after the EPA has defined the state's good neighbor obligation. Although this decision is not yet final as the mandate in EME Homer has not been issued and the EPA has petitioned for rehearing *en banc* in that case, in the meantime EPA intends to act in accordance with the holdings in the EME Homer opinion. Nothing in the EME Homer opinion, however, affects the state's obligation to submit SIPs addressing the requirements of CAA sections 110(a)(2)(D)(i)(II) and 110(a)(2)(D)(ii) by the deadline established in CAA section 110(a)(1).

(3) *Comment:* Some commenters suggested that the EPA should not require anything more than a "traditional infrastructure SIP" to satisfy CAA section 110 requirements for the $PM_{2.5}$ NAAQS, stating that "the EPA has indicated that it will call for only the traditional elements of infrastructure SIPs and will not purport to require specific emission control strategies as part of infrastructure SIPs."

Response: The EPA agrees with these commenters and does not intend to require in $PM_{2.5}$ infrastructure SIP submittals any specific emission control strategies for the purpose of attaining the standard. Such strategies will be required in nonattainment area plans.

(4) *Comment:* One commenter supported the EPA's approach to allow states to make a certification that their current infrastructure SIPs are sufficient to implement the revised NAAQS. Another group of commenters cautioned that a streamlined certification option "may not be available to States that last updated their infrastructure SIPs before the applicability of requirements governing condensable particulate emissions and PSD permitting elements specific to $PM_{2.5}$," and further stated that the EPA should identify in any future guidance changes in requirements that have become effective since the last round of infrastructure SIPs.

Response: The EPA notes that states may be able to certify that for selected infrastructure SIP elements, existing state regulations are sufficient for meeting the new infrastructure SIP obligations associated with the revised $PM_{2.5}$ NAAQS. A SIP submittal in the form of a certification should provide citations to the relevant provision already approved by the EPA that meet the particular infrastructure SIP element requirements, but it would not have to include a paper copy of those provisions. Like any other SIP submittal, such a certification should be made and submitted to the EPA only after the state has provided reasonable notice and opportunity for public hearing, as required in CAA section 110.

The EPA agrees that for infrastructure SIPs to be approvable for the revised $PM_{2.5}$ NAAQS, SIP submissions need to address all infrastructure-related requirements that have become applicable since the $PM_{2.5}$ NAAQS were revised in 2006. The EPA's forthcoming guidance on infrastructure SIPs for all NAAQS, including the revised $PM_{2.5}$ NAAQS, will include discussion of these requirements.

C. Specific Comments Related to Implementing the Proposed Revised Primary Annual $PM_{2.5}$ NAAQS in Nonattainment Areas

As explained in section IX of the preambles to the proposed and final rules, the EPA will be undertaking a separate effort to develop and finalize an implementation rule for the revised $PM_{2.5}$ NAAQS through a formal notice-and-comment rulemaking process. To help inform that effort, in the PM NAAQS proposal we sought preliminary input from stakeholders on implementation issues to update or address in a future implementation rule proposal. The EPA received a number of comments related to a variety of implementation issues either specifically raised in the proposal or in addition to those raised in the proposal. Topics raised by commenters included, but were not limited to, monitoring requirements, treatment of $PM_{2.5}$ precursors, requirements for Reasonable Further Progress (RFP) and Reasonable Available Control Technology/Reasonable Available Control Measures (RACT/RACM), and NAAQS implementation burden. We are not taking any final actions with regard to these or other implementation issues in this final rule.

We will provide a separate comment period for the submission of comments on the future implementation rule proposal. At that time, parties who submitted preliminary implementation-related comments as part of this rulemaking (to revise the PM NAAQS) may choose to resubmit their comments for formal consideration as part of the $PM_{2.5}$ NAAQS implementation rulemaking. Comments received on the PM NAAQS proposed rule will not be considered to be comments “submitted in advance” on any future implementation rule proposal.

1. Transition Period

The EPA sought preliminary comment in the proposal on the potential concept of a transition period during which any changes in monitoring requirements would not affect attainment plans and maintenance plans for the 1997 and 2006 $PM_{2.5}$ NAAQS. The EPA received comments in support of and in opposition to such a concept.

(1) *Comment:* In support of a transition period for 1997 and 2006 $PM_{2.5}$ SIPs, one commenter argued that attainment demonstrations and redesignation requests for existing standards should not be impacted by the revised standards and requirements. Other commenters specified that the EPA should provide a 3-year transition period for updating attainment plans or maintenance plans for the 1997 and 2006 $PM_{2.5}$ NAAQS as they may relate to any new monitoring requirements. Another commenter stated that EPA will need to address outstanding "transition period" issues resulting from changes in the monitoring regulations, especially with respect to the effect of this information on designations and the collection of pre-and post-construction monitoring for projects. The same commenter noted that states should not be obligated to change their SIPs as part of the transition to the revised standards in the absence of a SIP call.

In objecting to the concept of a transition period described in the proposal, a group of commenters argued that the EPA cannot ignore valid data if it raises questions about assumptions or conclusions of SIPs for the 1997 or 2006 $PM_{2.5}$ standards. The commenters insisted that the CAA “places upon EPA an affirmative duty to ensure that

SIP revisions will not interfere with any applicable requirement concerning attainment," and that the "EPA should be clear that agencies must consider available data and determine, on a case-by-case basis, whether it is relevant and significant to the planning decision being made."

Response: As explained in section IX.C of the preamble to the final rule, in consideration of comments received and upon further analysis of the potential effect of monitoring requirement changes, we believe that it will not be necessary to provide for a transition period in any future implementation rule because the changes in monitoring requirements included in this final PM NAAQS rule would not automatically affect attainment plans and maintenance plans for the 1997 or 2006 $PM_{2.5}$ NAAQS. Specifically, there are currently approximately ten $PM_{2.5}$ air quality monitors that have been identified as not comparable to the annual standard as part of the annual state monitoring plan revision process. If a state chooses to revise the status of one of these monitors in order to make it comparable to the annual standard because it is determined to be representative of many other similar locations, it would propose a change in status for that monitor in the next revision of the state $PM_{2.5}$ monitoring plan (state revisions are due in June of each year). The EPA would then review and take action on the state's proposed change. The EPA believes that the monitoring plan revision process provides adequate procedural steps for identifying which monitors are to be comparable to the annual $PM_{2.5}$ standard. For this reason, we believe that there is no need to include any "transition period" in a future rule.

2. Timing and Development Process for Implementation Rule and Tools

The EPA received several comments that raised concerns about the timing of an implementation rule or guidance and compliance tools for the revised PM2.5 NAAQS, as well as about the development process for an implementation rule. While many of these comments were not relevant to the PM NAAQS review itself, we addressed some of these comments in section IX.C of the preamble to the final rule, where we reiterated our intentions to develop a separate implementation rule through a formal notice-and-comment rulemaking process.

(1) *Comment:* Several commenters communicated a need for the EPA to issue an implementation rule, either in proposed or final form, simultaneous with the final PM NAAQS rule. Some of these commenters insisted that implementation requirements should be specified at the time a NAAQS is promulgated, while others stated that the EPA should issue the implementation guidance prior to making the new NAAQS effective and no later than the date the areas are initially designated. Several state commenters noted that a lack of timely implementation guidance can prevent them from meeting their own state obligations. Another commenter asked for the EPA to commit to firm deadlines rather than target dates for the proposed and finalized implementation rule and revised monitoring regulations. The commenter was specifically concerned about timely guidance for reasonably available control technology (RACT) and reasonably available control measures (RACM) and infrastructure guidance to align with the timing of states' SIP development process.

Response: As noted in the preamble to the final rule, the EPA acknowledges states' need for timely guidance on how to implement the revised NAAQS. However, due to the number of unique and complex issues associated with the PM NAAQS proposal and uncertainty about the outcome of the final NAAQS, at this time the EPA is not able to propose an implementation rule or finalize any aspect of the implementation program beyond a limited set of PSD permitting issues. The EPA intends to address state implementation planning issues and requirements through a formal notice-and-comment rulemaking process and to finalize a PM2.5 NAAQS implementation rule around the time the initial area designations process is finalized. We believe this schedule for proposing and finalizing such a rule is timely. With respect to infrastructure guidance, the EPA intends to issue, in the very near future, a guidance document on section 110 infrastructure SIP requirements, which will aim to help states develop SIP submissions for all NAAQS, including the revised $PM_{2.5}$ NAAQS.

(2) *Comment:* Several commenters stated that it is critical that the EPA not promulgate NAAQS prior to the development of tools and techniques suitable for states and regulated entities to use for implementation.

Response: The EPA notes that fine particle standards have been implemented by states and regulated entities for a number of years already and there are a number of technical tools in place already to facilitate the implementation of a newly revised $PM_{2.5}$ standard. These tools (such as air quality models, emission factors, and emission inventories) continue to be updated and refined over time.

(3) *Comment:* A few commenters urged the EPA to consult with stakeholders, particularly with states and local agencies, prior to developing any rules or guidance for the revised NAAQS and throughout the process.

Response: As stated in the preamble to the final rule, the EPA agrees that it is beneficial to engage with air agencies early in the rule development process. We have initiated such discussions to help inform the development of an upcoming proposed implementation rule, and expect to have additional such discussions during 2013.

D. Specific Comments on Prevention of Significant Deterioration and Nonattainment New Source Review

This section responds to comments received on the PSD and Nonattainment NSR (NNSR) programs and potential impacts associated with the revised PM NAAQS. Several of these comments are addressed in detail in section IX.D of the preamble to the final rule, and in those cases, the reader is referred to the appropriate subsection(s) of the preamble for the EPA's responses. Responses to comments not specifically addressed in the preamble to the final rule are provided below.

As a general matter, we note that, with the exception of the PSD grandfathering provisions, the EPA is not taking final action to address NSR implementation in this NAAQS package. Nevertheless, we did receive several comments raising NSR implementation issues, some of which argued that particular issues may be of greater concern under the revised

NAAQS. Some comments further suggested changes to NSR policy or rules—beyond the grandfathering provision—to alleviate these concerns. This section provides responses to those issues by describing, as appropriate, current and future EPA efforts to facilitate NSR implementation for the $PM_{2.5}$ NAAQS. The responses generally indicate that the EPA is committed to working with air agencies and other stakeholders to address these issues in the appropriate forum (which could include rulemaking, guidance, or case-by-case determinations). Thus, again with the exception of grandfathering, our responses here do not reflect final decisions by the agency on these issues but instead are provided for informational purposes only. In addition, we note that while the particular implementation issues raised or the burden associated with them will receive further consideration by the Agency as noted above, they are not relevant to the decisions made on revisions to the NAAQS, including establishing the level of the standard.

1. Prevention of Significant Deterioration

a. Transition Provision (Grandfathering)

(1) *Comment:*

- The majority of commenters, including all industry and state agency representatives, supported the EPA's proposed grandfathering provision based on the purpose and rationale described in the preamble to the proposal. These commenters agreed that grandfathering certain pending PSD permit applications was reasonable to balance the CAA objectives to protect the NAAQS on one hand, and to avoid delays in processing PSD permit application on the other. They also agreed grandfathering provides a reasonable transition into the PSD requirements associated with the revised NAAQS. Industry commenters also indicated that such a provision was important to economic growth and recovery, and was consistent with the purposes of the PSD program, i.e., to ensure that economic growth will occur in a manner consistent with preservation of air quality. Several state commenters pointed out that finalizing the revised $PM_{2.5}$ NAAQS without a grandfathering provision would result in a significant additional resource burden on both permit applicants and air agencies, which would have to reopen pending permit applications that have reached advanced stages in processing to address the revised standard. The commenters further noted that there would likely be little if any environmental benefit afforded by such a process. One state agency commenter performed a preliminary review of recent PSD permitting actions and determined that in all cases, the proposed primary annual $PM_{2.5}$ standard would not have led to tighter permit restrictions or reduced emissions, and that a re-noticing of the preliminary permit decisions would accomplish nothing more than to change the margins of compliance. In other words, re-noticing would have led to project delays with no reduction in $PM_{2.5}$ impacts.

- Four environmental group commenters (one representing a coalition of a health advocacy group and several environmental groups) opposed the proposed grandfathering provision based either on concerns about further delay in implementation of the revised PM NAAQS or on a position that the proposed grandfathering provision exceeds the EPA's statutory authority and is unlawful. Commenters challenging EPA's legal authority to implement the proposed grandfathering provision contended that CAA sections 165 and 301 do not confer any authority on the EPA to grandfather PSD permit applications. The commenters asserted that CAA section 165(a) forecloses the EPA's proposed approach, specifically citing CAA section 165(a)(3)(B) which provides that no major emitting facility "may be constructed" unless the facility's owner or operator demonstrates emissions from the facility will not cause or contribute to the violation of "any . . . national ambient air quality standard in any air quality control region." These commenters further claimed that because Congress limited the applicability of the new PSD requirements in several ways, including specific grandfathering relief for sources constructed before the enactment of the 1977 Amendments to the CAA, the EPA is not authorized to waive otherwise applicable statutory requirements (citing *Andrus v. Glover Constr. Co.*, 446 U.S 608, 116-17 (1980)). A subset of these same commenters also stated that the EPA's proposed grandfathering approach undermines the policy choices made by Congress in adopting the PSD program that 1) it is preferable to prevent air pollution from becoming a problem in the first place, and 2) controls should be installed when new sources are being constructed rather than as retrofits on existing sources.

One commenter asserted that there is no conflict between CAA sections 165(a) and 165(c) as the EPA had implied; therefore, there is no need for the EPA to invoke the regulatory authority of CAA section 301. This commenter also concluded that the EPA's rationale of balancing of economic growth and the protection of air quality pursuant to CAA section 160(3) was unlawful, and that the EPA had not adequately explained the considerations it sought to balance and how the proposal would achieve its goals. The same commenter questioned the EPA's authority to leverage principles of equity and fairness in proposing the grandfathering provision. The commenter also objected to the EPA's rationale for choosing the public notice date of a draft permit as the milestone triggering the grandfathering provision, stating that the approach was contrary to statute because it would deprive interested persons of their statutory right to comment on elements of the application related to the current NAAQS.

- Regarding the need for a sunset clause for the grandfathering provision, the majority of commenters supported, as proposed, not including such a clause, and no commenters specifically recommended that a sunset clause be established. Commenters pointed out that permit applicants and reviewing authorities already have strong incentives to issue final permits in a timely manner following the public notice stage, and that a sunset clause would not add any meaningful incentive to expedite the permitting process, rather potentially causing additional delays. One commenter stated that permitting authorities have ample discretion, which they routinely use, to refuse to issue a draft permit if additional information is requested during a comment period or the agency itself wants additional information following publication of a draft permit or preliminary determination. The same commenter indicated that permitting authorities also have sufficient discretion to reopen permit proceedings if they consider information in an application to be stale.

- Several of the commenters supporting the proposed grandfathering provision in general recommended that the EPA establish the grandfathering milestone as the date that a complete permit application is submitted (or that a submitted permit application is deemed complete by the reviewing agency) rather than the publication date of public notice for a draft permit or preliminary determination as proposed. These commenters pointed out the significant level of effort, resources and time involved in preparing all of the information necessary for a complete permit application, including a BACT analysis, air quality analysis, additional impacts analyses, and a Class I area impact analysis. They claimed that it would be unfair to establish a grandfathering milestone past the complete application date because the processes and timeframes involved in generating the draft permit or preliminary determination materials and publishing the public notice are largely out of the control of the permit applicant and vary from agency to agency. They further stated that requiring reevaluation of a proposed project to assess impacts with respect to the revised NAAQS after a permit application has been deemed complete would result in significant additional cost and delay. Several such commenters cited prior EPA grandfathering provisions that relied upon that milestone, including the 1987 PM_{10} NAAQS (52 FR 24672, July 1, 1987) and the 1988 NO_2 increments (53 FR 40656, October 17, 1998), and contended that the EPA had not justified the use of an alternative date for purposes of the proposed revisions to the $PM_{2.5}$ NAAQS. Some state commenters also indicated that the proposed draft permit public notice date milestone could result in additional resource burden on the agency to expedite completion of draft permit packages and process public notices. Other state commenters supported the EPA's proposed draft permit or preliminary determination public notice date as the appropriate grandfathering eligibility milestone, indicating that this approach would provide states and industry certainty on the NAAQS demonstration required during the $PM_{2.5}$ NAAQS transition period.

- A few industry commenters suggested, as an alternative to the proposed approach, that the EPA should effectively grandfather PSD permit actions from meeting requirements associated with the revised PM NAAQS by extending the effective date of the NAAQS by one year.

Response: The EPA has provided detailed responses to these comments in section IX.D.1.a.ii of the final rule preamble.

(2) *Comment*: One local government and one industry commenter suggested that the EPA should extend grandfathering to non-PSD permits, e.g., minor source permits and synthetic minor permits.

Response: The commenters did not demonstrate the need for grandfathering of minor NSR permits nor did they provide any other supporting rationale for such grandfathering. The EPA did not propose, and is not finalizing, any grandfathering provisions for minor NSR permit applications.

(3) *Comment*: One state agency commenter suggested that the grandfathering provision be consistent with the EGU GHG NSPS rule.

Response: The proposed EGU GHG NSPS ("Standards of Performance for Greenhouse Gas Emissions for New Stationary Sources: Electric Utility Generating Units," 77 FR 22392, April 13, 2012) proposed requirements for any electricity generating unit (EGU) that meets the definition of an "affected facility." Under CAA section 111(a)(2), any source that is covered by a proposed NSPS and that commences construction after the date of the proposal must meet the requirements of the NSPS that EPA finalizes. However, in this proposal, EPA made clear that certain types of sources would not be treated as "affected facilit[ies]," including "transitional sources." A "transitional source" was defined as, in general, an EGU that had received a complete PSD permit prior to April 13, 2012, and that commences construction within 12 months after the April 13, 2012, date of the proposal. Therefore, under this proposal, a source that qualifies as a "transitional source" would not be subject to the requirements of the NSPS when the rule is finalized. Although the comment is not specific, apparently it is this "transitional source" provision that the comment considers to be the grandfathering provision.

As stated in Section IX.D.1.a.i of the preamble to the final rule, longstanding EPA policy interprets the CAA and EPA regulations at 40 CFR 52.21(k)(1) and 51.166(k)(1) to generally require that PSD permit applications include a demonstration that new major stationary sources and major modifications will not cause or contribute to a violation of any NAAQS that is in effect as of the date the PSD permit is issued (Page, 2010a; Seitz, 1997). Accordingly, a source that has received a final PSD permit prior to the effective date of the final NAAQS would not be required to meet any new requirements associated with the revised standards regardless of the scope of the grandfathering provision finalized in this rule. In this sense, this longstanding EPA policy already is consistent with the proposed "transitional source" provision because under the latter, sources with PSD permits prior to the date of proposal (and that commence construction within one year after proposal) would not be subject to the final NSPS requirements. Accordingly, there is no need to make the grandfathering provision in this rule consistent with the "transitional source" provision in the proposed EGU GHG NSPS.

b. Surrogacy Approach for Proposed Secondary Visibility Index NAAQS

The EPA received a large number of comments on the proposed implementation of a surrogacy approach for addressing PSD requirements associated with the proposed distinct secondary visibility index NAAQS. As described in section VI of the final rule, the EPA is not finalizing a distinct secondary visibility index standard at this time and therefore the proposed surrogacy approach for implementing such a standard under the PSD program is unnecessary. Accordingly, the EPA is not responding to comments on the proposed surrogacy approach for the proposed secondary visibility index NAAQS here. Comments received on the proposed surrogacy approach and associated technical memorandum that are relevant to the EPA's final decision not to establish a distinct secondary visibility NAAQS at this time are addressed in section VI.D.2 of the final rule preamble and section IV of this response to comments document.

c. *Modeling Tools and Guidance Applicable to the Revised Primary Annual $PM_{2.5}$ NAAQS*

(1) *Comment:* Several industry commenters identified a generally common suite of issues and limitations associated with currently available modeling tools and guidance for performing required PSD air quality impact analyses for $PM_{2.5}$ (i.e., the requirement that PSD permit applicants demonstrate that source emissions will not cause or contribute to a violation of the $PM_{2.5}$ NAAQS). These commenters stated that the current regulatory air quality model, AERMOD, is unable to predict the impact of a single source on ambient $PM_{2.5}$ concentrations, including secondary particle formation from $PM_{2.5}$ precursors. They further stated that the EPA has yet to provide adequate guidance on how applicants are to address the PSD air quality demonstration requirements for the current $PM_{2.5}$ NAAQS. Many of these commenters also contended that current modeling tools and guidance result in over-predictions and/or overly conservative estimates of impacts, and that this, in combination with lower NAAQS levels, would result in project delays and adverse impacts on the economy. Commenters speaking to the same issue referred to a "narrow window" for source-related impacts under the proposed revised $PM_{2.5}$ NAAQS. Many of these commenters indicated that the EPA should resolve the identified $PM_{2.5}$ modeling issues prior to finalizing the $PM_{2.5}$ NAAQS, and do so through notice-and-comment rulemaking. One industry commenter stated the EPA should not require point source modeling of $PM_{2.5}$ until the Agency has an effective modeling tool available.

Response: To address PSD air quality demonstration requirements for current $PM_{2.5}$ NAAQS, EPA issued, on March 23, 2010, a guidance memorandum entitled "Model Procedures for Demonstrating Compliance with $PM_{2.5}$ NAAQS" (Page, 2010b) that recommended certain interim procedures to address compliance with the $PM_{2.5}$ NAAQS and acknowledged that there are technical complications associated with the ability of existing models to estimate the impacts of secondarily formed $PM_{2.5}$ in the atmosphere resulting from emissions of $PM_{2.5}$ precursors. The EPA is currently preparing draft $PM_{2.5}$ permit modeling guidance that recommends appropriate technical approaches for conducting a $PM_{2.5}$ NAAQS compliance demonstration that includes the use of the AERMOD modeling system to account for impacts of directly emitted $PM_{2.5}$ and a more adequate accounting for contributions from secondary formation of ambient $PM_{2.5}$ concentrations resulting from a proposed new or modified source's precursor emissions. This draft $PM_{2.5}$ permit modeling guidance is necessary to inform case-by-case determination of appropriate methods as sources should now conduct a $PM_{2.5}$-based analysis under NSR and PSD to demonstrate compliance with the $PM_{2.5}$ NAAQS rather than relying upon a PM_{10}-based analysis in accordance with past EPA guidance. (76 FR 28646, 28648, 28659 (May 18, 2011); Page, 2010b). The EPA expects that technical issues related to the PSD compliance demonstration will be resolved during the consultation process with the EPA's regional offices pursuant to section 5.2.2.1.c so that the most appropriate analytical techniques can be used on a case-by-case basis to address the impacts of individual sources on secondary $PM_{2.5}$ formation.

The EPA has provided presentations regarding the draft guidance at the 10th Conference on Air Quality Models in March 2012 and at the Regional/State/Local Modelers Workshop in May 2012 which are available at:

http://www.epa.gov/ttn/scram/conferenceindex.htm. The EPA intends to provide this draft guidance for public review and comment soon after final rule signature, no later than end of calendar year, with the intent of issuing final guidance in Spring 2013. This guidance extends the guidance from the previous March 23, 2010 memo and takes into account specific recommendations from the NACAA $PM_{2.5}$ Modeling Implementation Workgroup, public comments received from the 10th Modeling Conference, and our case-by-case involvement with recent applicant-submitted $PM_{2.5}$ compliance demonstrations.

(2) *Comment:* One industry trade association commenter provided detailed comments on implementation issues for $PM_{2.5}$ modeling including a review of existing models, including AERMOD and CALPUFF, and pointed out specific characteristics and limitations associated with those models. In summary, the commenter stated that there was a critical need for EPA modeling tools to evaluate secondary $PM_{2.5}$ impacts, and that the EPA should develop a research plan, including funding requirements, for addressing model development. The commenter also stated that the "EPA cannot proceed with modeling implementation of the $PM_{2.5}$ NAAQS until field studies with speciated $PM_{2.5}$ observations focused upon a single source are available and used in evaluation of new state-of-the-science models."

Response: The EPA acknowledges the need to conduct a thorough review and evaluation of existing and developing models and modeling techniques to address the complexities of accounting for $PM_{2.5}$ impacts from single sources. As part of the 10th Modeling Conference in March 2012, the EPA dedicated a session to this issue of emerging models and techniques with detailed presentations on the current state of the science which included model evaluations with available field study data (see presentations at http://www.epa.gov/ttn/scram/10thmodconfpres.htm). The EPA sponsored a similar session at the 11th Annual CMAS Conference in October 2012 where additional model developments and evaluations were presented (See presentations from afternoon of October 16th at: http://www.cmascenter.org/conference/2012/agenda.cfm). The EPA will continue engaging with the modeling community on the evaluation of current models and modeling techniques as part of its commitment to engage in rulemaking to update Appendix W and, as appropriate, incorporate new analytical techniques or models for secondary $PM_{2.5}$ impacts from single sources.

In terms of current compliance demonstrations under $PM_{2.5}$ NAAQS, as noted in the previous comment response, the EPA is preparing draft $PM_{2.5}$ permit modeling guidance that will provide recommendations on appropriate technical approaches for conducting a $PM_{2.5}$ NAAQS compliance demonstration for a proposed new major stationary source or major modifications. This draft $PM_{2.5}$ permit modeling guidance is necessary to inform case-by-case determination of appropriate methods as sources should now conduct a $PM_{2.5}$-based analysis under NSR and PSD to demonstrate compliance with the $PM_{2.5}$ NAAQS rather than relying upon a PM10-based analysis in accordance with past EPA guidance. (76 FR 28646, 28648, 28659 (May 18, 2011); Page, 2010b). The EPA expects that technical issues related to the PSD compliance demonstration will be resolved during the consultation process with the EPA's regional offices pursuant to section 5.2.2.1.c so that the most appropriate analytical techniques can be used on a case-by-case basis to address the impacts of individual sources on secondary $PM_{2.5}$ formation.

(3) *Comment:* One industry commenter made several specific suggestions to improve model accuracy. The commenter suggested that model inputs should be adjusted by: 1) not assuming simultaneous maximum allowable emissions when a reasonable worst case actual emissions scenario is available, and 2) eliminating the inputs for non-stack sources (e.g., haul roads, pits, roof monitors) until adequate studies of source-specific test data is conducted to establish a discount factor to offset over-prediction bias in the model results. The commenter suggested that model outputs should be refined by 1) eliminating downwash assumptions during low wind speed events that are contrary to the observed plume rise under these meteorological conditions, and 2) foregoing the modeling of secondary formation of $PM_{2.5}$ until there is a clear understanding of when and where it will affect ambient air quality. The commenter also stated that the EPA should "encourage the use of available monitored data to 'ground truth' the air model results and, where appropriate, use the monitor data to establish calibration factors for adjusting the model results."

Response: The EPA will be addressing the commenter suggestions as part of its response to comments from the at the 10th Conference on Air Quality Models and, as appropriate, will consider updates to current modeling requirements for PSD compliance demonstrations as part of future rulemaking to revise EPA's *Guideline on Air Quality Models* (published as Appendix W of 40 CFR Part 51).

(4) *Comment*: One industry coalition commenter suggested that the EPA's pending revised $PM_{2.5}$ modeling guidance be co-proposed as a draft for public comment with the final PM NAAQS rulemaking. This commenter also suggested that until the new guidance can be finalized, the final rule should indicate that "the 2010 Guidance be used judiciously for general directions and that air quality planning and permitting authorities can deviate from the 2010 guidance based on their professional judgment.". The commenter requested that the EPA remind air agencies in the final PM NAAQS rulemaking that "Section 10 of Appendix W allows for the placement of post-construction monitors in lieu of modeling to collect emissions information where modeling suggests future nonattainment issues, particularly in view of the inadequacy of current $PM_{2.5}$ modeling techniques and the stringency of the current and the proposed new $PM_{2.5}$ NAAQS."

Response: As noted in previous comment response, the EPA is currently preparing draft $PM_{2.5}$ permit modeling guidance that recommends appropriate technical approaches for conducting a $PM_{2.5}$ NAAQS compliance demonstration. This draft $PM_{2.5}$ permit modeling guidance is necessary to inform case-by-case determination of appropriate methods as sources should now conduct a $PM_{2.5}$-based analysis under NSR and PSD to demonstrate compliance with the $PM_{2.5}$ NAAQS rather than relying upon a PM_{10}-based analysis in accordance with past EPA guidance. (76 FR 28646, 28648, 28659 (May 18, 2011); Page, 2010b). The EPA expects that technical issues related to the PSD compliance demonstration will be resolved during the consultation process with the EPA's regional offices pursuant to section 5.2.2.1.c so that the most appropriate analytical techniques can be used on a case-by-case basis to address the impacts of individual sources on secondary $PM_{2.5}$ formation.

EPA will continue to remind air agencies of the applicability of Section 10 of Appendix W that allows for monitoring in lieu of modeling to demonstrate compliance under PSD for those situations where it has been determined in consultation with the appropriate reviewing authority that the modeling techniques are not appropriate for use. It is important to note that the commenter mischaracterizes this guidance as "placement of post-construction monitors" conceivably in the case of a new source, but the applicability of Section 10 is only in the case of an existing source, where monitoring data could be used in a NAAQS assessment following the recommendations in that guidance.

(5) *Comment:* One state agency commenter raised a concern that the EPA appeared to be planning to make substantive changes to the PSD modeling requirements through guidance instead of through rulemaking, without the opportunity for public comment. The commenter further stated that any substantive changes to $PM_{2.5}$ modeling, including any substantive changes to how secondary formation of $PM_{2.5}$ is handled for PSD purposes, should be done thorough public notice and comment rulemaking (referring to 40 CFR 52.21, 51.166 and Appendix W).

Response: The EPA is currently preparing draft $PM_{2.5}$ permit modeling guidance that recommends appropriate technical approaches for conducting a $PM_{2.5}$ NAAQS compliance demonstration that includes the use of the AERMOD modeling system to account for impacts of directly emitted $PM_{2.5}$ and a more adequate accounting for contributions from secondary formation of ambient $PM_{2.5}$ concentrations resulting from a proposed new or modified source's precursor emissions. This draft $PM_{2.5}$ permit modeling guidance is necessary to inform case-by-case determination of appropriate methods as sources should now conduct a $PM_{2.5}$-based analysis under NSR and PSD to demonstrate compliance with the $PM_{2.5}$ NAAQS rather than relying upon a PM_{10}-based analysis in accordance with past EPA guidance. (76 FR 28646, 28648, 28659 (May 18, 2011); Page, 2010b). The EPA expects that technical issues related to the PSD compliance demonstration will be resolved during the consultation process with the EPA's regional offices pursuant to section 5.2.2.1.c so that the most appropriate analytical techniques can be used on a case-by-case basis to address the impacts of individual sources on secondary $PM_{2.5}$ formation. This guidance extends the previous March 23, 2010, memo and takes into account specific recommendations from the NACAA $PM_{2.5}$ Modeling Implementation Workgroup, public comments received from the 10th Modeling Conference, and our case-by-case involvement with recent applicant submitted $PM_{2.5}$ compliance demonstrations. The EPA intends to provide this draft guidance for public review and comment soon after final rule signature, no later than the end of calendar year 2012, with the intent of issuing final guidance in Spring 2013.

(6) *Comment:* Three industry commenters, in support of their position that current PM models over-predict impacts, cited the adoption of section 234 of the CAA and the EPA's recognition of these concerns in communications with Wyoming in which the EPA allowed some areas to demonstrate PM_{10} NAAQS compliance by us of extensive monitoring rather than inaccurate fugitive dust models (citing Proposed Approval of

Wyoming SIP, 57 FR 38641, 38646-48, August 26, 1992). These commenters also stated that modeling tools and guidance should be developed through an open process with peer review opportunities to improve the data relied upon in regulatory decisions. Two of these commenters encouraged the EPA adopting modeling changes consistent with the NMA's comments regarding the 10th Modeling conference (NMA, 2012). One state agency commenter indicated that the agency did not require short-term fugitive PM modeling, and that that approach was affirmed in *Sierra Club v. Wyo. Dept. of Envl. Quality, 2011 WY42, 251 P.3d 310 (Wyo. 2011)*. The same commenter referenced that the AERMOD Implementation Guide acknowledges that the model has shortcomings and may overestimate area source concentrations.

Response: The EPA will be addressing the commenters' suggestions as part of its response to comments from the 10th Conference on Air Quality Models and, as appropriate, will consider updates to current modeling requirements for PSD compliance demonstrations as part of future rulemaking to revise the EPA's *Guideline on Air Quality Models* (published as Appendix W of 40 CFR Part 51).

(7) *Comment:* One industry coalition commenter identified that current modeling tools are not appropriate to address fugitive PM emissions, and that industry has already provided the EPA with a short-term fix to this problem called an "emissions pre-processing step." As described, the pre-processing step reduces emission factors for fugitive emissions sources to account for inadequacies in the model. The commenter stated that EPA is already using a pre-processing step in regional modeling, and recommended that the EPA extend the approach to point-source modeling, indicating that this approach would improve PM modeling and reduce some implementation burden. The commenter also stated that it would be willing to "bring resources to the table to help EPA find a long-term solution and verify that solutions effectiveness."

Response: The EPA will be addressing the commenters' suggestions as part of its response to comments from the 10th Conference on Air Quality Models and, as appropriate, will consider updates to current modeling requirements for PSD compliance demonstrations as part of future rulemaking to revise the EPA's *Guideline on Air Quality Models* (published as Appendix W of 40 CFR Part 51).

d. PSD Screening Tools: Significant Emissions Rates, Significant Impact Levels, and Significant Monitoring Concentration

(1) *Comment:* The EPA received several comments from industry and state agencies regarding the existing PSD screening tools and the potential need to adjust associated values based on the revised primary annual $PM_{2.5}$ NAAQS. The majority of these commenters supported retaining the existing SERs, SILs and SMC for $PM_{2.5}$ (and $PM_{2.5}$ precursors in the case of the SERs), indicating that there was no compelling technical reason for revision based on the proposed revision to the primary $PM_{2.5}$ NAAQS. One industry commenter indicated that there might be a need to revise the annual $PM_{2.5}$ SILs based on the approach used in establishing the current value. However, this commenter and others recommended that any revisions to the PSD screening levels for $PM_{2.5}$ be

accomplished through a separate notice-and-comment rulemaking. Several state commenters that supported retention of the current $PM_{2.5}$ SILs also urged the EPA to provide guidance on the use of those existing SILs.

Response: As described in section IX.D.1.c of the final rule preamble, the EPA did not propose to make and is not finalizing any changes to the existing $PM_{2.5}$ SERs, SILs and SMC as part of the final rule. The EPA intends to consider the need for any future changes to these values in light of today's revision of the primary annual $PM_{2.5}$ NAAQS and considering public comments received. The EPA will address any changes to the $PM_{2.5}$ SERs, SILs and SMC in a subsequent PSD implementation rulemaking if deemed necessary or appropriate. The EPA will determine the need for, and develop such rulemaking expeditiously, and any such forthcoming rulemaking will provide an additional opportunity for public comment on specific proposed revisions to the PSD screening tool values for $PM_{2.5}$. Until any rulemaking to amend existing regulations is completed, permitting decisions should continue to be based on the SERs for $PM_{2.5}$ (and its precursors) and the SILs and SMC for $PM_{2.5}$ in existing regulations.

(2) *Comment*: One set of collaborative comments from health and environmental advocacy groups stated that the EPA's proposal to leave in place the PSD screening tools adopted with the previous PM NAAQS had no rational basis and was contrary to statutory requirements. Referring the SILs and SMCs, these commenters contended that the EPA has no legal authority to create such de minimis exemptions in the PSD program and that even if EPA could adopt such exemptions, to leave in place exemptions based on PM NAAQS promulgated at higher levels has no technical basis. The commenters further stated that the EPA has offered no evidence that sources with impacts below the proposed SILs or SMCs will never cause or contribute to violations of NAAQS or increments, or that the gain from regulating such sources would be trivial, and that the EPA's proposal to leave the preexisting exemptions in place is unreasonable given that the analysis supporting those exemptions was tied to a specific standards that EPA has now found inadequate to protect public health and welfare. Further, the commenters contended that a single national number that defines "trivial" impact for all attainment areas is fundamentally flawed, given that even a very small impact can be of great significance in an area that is very close to exceeding an increment or a NAAQS. Finally, these commenters stated that the EPA must reassess its SERs, because the SERs cannot be disconnected from the level of the NAAQS and the EPA must provide a rational basis for concluding that the existing SERs continue to be appropriate. One additional set of collaborative comments from academic researchers also supported reconsideration, and possible lowering of the PSD screening levels, citing, in the context of the SERs, the fact that there is no safe threshold and a linear dose response curve for $PM_{2.5}$. These same commuters recommended that the EPA consider screening levels for other indicators, including ultra fine and nano PM and that those indicators be established based on particle number instead of mass to account for surface area and volume.

Response: As described in section IX.D.1.c of the final rule preamble and in the response to comment VI.C.1.d. (1) above, the EPA did not propose to make and is not finalizing any changes to the existing $PM_{2.5}$ SERs, SILs and SMC as part of the final rule. The EPA intends to consider the need for any future changes to these values in light of today's revision of the primary annual $PM_{2.5}$ NAAQS and considering public comments received. The EPA will address any changes to the $PM_{2.5}$ SERs, SILs and SMC in a subsequent PSD implementation rulemaking if deemed necessary or appropriate. The EPA will determine the need for, and develop such rulemaking expeditiously, and any such forthcoming rulemaking will provide an additional opportunity for public comment on specific proposed revisions to the PSD screening tool values for $PM_{2.5}$.

The commenters' claims that the *de minimis* nature of the SILs and SMCs are unsubstantiated and that the EPA has no statutory authority to establish SILs and SMC for $PM_{2.5}$ are the subject of current litigation in *Sierra Club v. EPA*, No. 10-1413 (D.C. Cir. filed Dec. 17, 2010). The EPA's argument in support of the existing PSD screening tools is contained in a brief filed in that case, which is included in the docket for the final rule. *Id.*, Brief of Respondent at 26-56 (June 26, 2012).

e. *PSD Increments*

(1) *Comment:* The EPA received few comments on whether there was any need or justification to revise the existing PSD increments for $PM_{2.5}$. Industry and state agency commenters generally supported retaining the existing increments. One industry commenter indicated that there may be a need to reevaluate the annual $PM_{2.5}$ increment. Commenters again recommended that any revisions to the PSD increments for $PM_{2.5}$ be accomplished through a separate notice-and-comment rulemaking.

Response: As described in section IX.D.1.d of the final rule preamble, the EPA did not propose to make and is not finalizing any changes to the existing PSD increments for $PM_{2.5}$ as part of the final rule. The EPA will consider whether it is appropriate to propose any revised PSD increments for $PM_{2.5}$ in the future. Any such forthcoming rulemaking will provide an additional opportunity for public comment on specific proposed revisions to the PSD increments for $PM_{2.5}$. Until any rulemaking to amend existing regulations is completed, permitting decisions should continue to be based on the PSD increments for $PM_{2.5}$ in existing regulations.

f. *Other PSD Transition Issues*

(1) *Comment:* Several industry commenters expressed concern that a permitting problem would result from the fact that, upon promulgation of the revised $PM_{2.5}$ NAAQS, ambient air quality monitoring data would show that for some areas, $PM_{2.5}$ concentrations exceed the revised NAAQS, although those areas would not be formally designated as "nonattainment" until a later date pursuant to the designations process provided by the CAA. The commenters noted that sources locating in such areas would be required to obtain a PSD permit in order to construct or modify, but could not do so because the requirement that the new or modified source must demonstrate that it will not cause or contribute to a NAAQS violation, even though the area would technically already be in nonattainment. The commenters further noted that once the nonattainment designation is made, section 173 of the CAA provides a nonattainment area permit program that specifies conditions under which a permit will be issued, including obtaining offsetting

reductions in emissions rather than demonstrating through modeling or other analysis that the source will not cause or contribute to a violation of the NAAQS as required in PSD. Thus, the commenters urged the EPA to offer an interim approach that would avoid the imposition of an effective construction ban on such areas until such time as the nonattainment area designations and the nonattainment NSR offset requirements are in place instead of the PSD requirements. Some of the commenters specifically requested that the EPA provide either a surrogacy approach based on showing compliance with the pre-existing annual $PM_{2.5}$ NAAQS or a PSD offset approach to avoid a construction moratorium in such areas.

Response: The EPA has provided a detailed response to these comments in section IX.D.1.e of the final rule preamble.

(2) *Comment:* One state agency commenter objected to the EPA's policy that the state must implement a permitting requirement that has not yet been adopted into the SIP, stating that the EPA should not burden SIP-approved states with the requirement to immediately develop permitting procedures to demonstrate compliance with a new NAAQS. The commenter recommended that the EPA promulgate in rule a phase-in period that would require the demonstration after implementation guidance and tools (including single-source models) are available.

Response: As stated in section IX.D.1.a.i of the preamble to the final rule, longstanding EPA policy interprets the CAA and EPA regulations at 40 CFR 52.21(k)(1) and 51.166(k)(1) to generally require that PSD permit applications include a demonstration that new major stationary sources and major modifications will not cause or contribute to a violation of any NAAQS that is in effect as of the date the PSD permit is issued (Page, 2010a; Seitz, 1997). As described in section IX.D.1.a.iii of the preamble to the final rule, the EPA is finalizing a grandfathering provision under the PSD regulations that is designed to help provide a workable transition to implementing the revised $PM_{2.5}$ NAAQS under the PSD permitting program. The CAA does not authorize the type of additional phase-in period recommended by the commenter. Furthermore, the commenter did not provide any substantive supporting basis for the need for such a phase-in period. The final rule establishes a revised level of the primary annual $PM_{2.5}$ NAAQS. Permitting procedures and tools should already be in place for the previously existing primary annual $PM_{2.5}$ NAAQS, and these same procedures and tools are applicable to the revised standard. Response to comments on modeling tools and guidance are provided in section VI.C.1.c of this document.

(3) *Comment*: One industry coalition commenter, in support of a general comment that NSR solutions are needed to resolve the difficulty in obtaining NSR permits for $PM_{2.5}$ emissions, provided some specific suggestions. They suggested that the EPA should explore the voluntary use of $PM_{2.5}$ "offsets" as an alternative to air quality demonstration requirements under the current regulations. They asked that the EPA explore whether offsets can be utilized in attainment or unclassified areas to reduce the burden of ambient air impact analyses. They also requested that the EPA "address the ability for source operators in attainment areas to buy NO_X or SO_2 credits from cap-and-trade participants

in affected states/regions in addition to traditional offsets representing sources that are deactivated at the time a new 'source' starts up." They suggested another potential mechanism which was to "'tier' requirements post construction to levels of actual emissions from a new project." Finally, the commenter requested that the EPA "affirm in the final rulemaking the use of the existing provisions in Appendix W and Section 10 for the use of 'post-construction' monitoring where models may predict certain future air quality impacts from a project."

Response: The commenter presented several alternative means of addressing the alleged problem of obtaining a PSD permit where a source's modeled impact would show the source would cause or contribute to a violation of the $PM_{2.5}$ NAAQS. With regard to the commenter's recommendation that the EPA explore the voluntary use of $PM_{2.5}$ offsets as an alternative to an air quality demonstration under the current PSD regulations, we point the commenter to our response to comment f.1, above, which is contained in section IX.D.1.e of the final rule preamble. In brief, we believe that the offsets option is already available to proposed new major stationary sources and major modifications whose emissions are shown to cause or contribute to violation of any NAAQS.

The commenter's second recommended alternative is to allow a source to "buy NO_X or SO_2 credits from cap and trade participants in affected states/regions." The EPA places the same criteria on offsets obtained for PSD purposes as are required under the Act for nonattainment areas. Accordingly, any emissions reduction, in order to be creditable as an emissions offset, must be surplus, permanent, quantifiable and federally enforceable. To the extent that credits purchased from a cap and trade participant meet the required creditability criteria, then we believe they may be considered for use as emissions offsets (*see, e.g.*, Rothblatt, 2007). An additional consideration that will need to be made with regard to any credit used for PSD offsetting purposes is the location of the offset relative to the proposed emissions increase. That is, an appropriate emissions offset must be shown to affect the same area as the new emissions so as to provide effective compensation for the adverse impact of the new emissions. *See* 40 CFR 51.165(b)(3) ("sufficient emissions reductions to, at a minimum, compensate for its adverse ambient impact where the source would otherwise cause or contribute to a violation of any [NAAQS]").

Thirdly, the commenter recommended that the EPA "tier requirements post construction to levels of actual emissions from a new project." Unfortunately, it is not clear what the commenter meant by "tiering" the requirements, or how using the project's post-construction actual emissions would address a potential NAAQS violation. Thus, we are unable to respond to this particular comment as presented.

Finally, the commenter recommended that the EPA use the existing provisions in section 10 of Appendix W (Guideline on Air Quality Models) to allow post-construction monitoring "where models may predict certain future air quality impacts from a project." As indicated in the response to comment c.4 of this section, the EPA will continue to remind air agencies of the applicability of Section 10 of Appendix W that allows for monitoring in lieu of modeling to demonstrate compliance under PSD for existing sources in situations where it has been determined in consultation with the appropriate reviewing authority that the modeling techniques are not appropriate for use.

(4) *Comment*: One industry trade association commenter, stated that EPA should prepare for NSR/PSD implementation to avoid a practical "permitting moratorium" in areas where existing air quality is such that PSD air quality analyses must be performed to demonstrate compliance with the NAAQS, but cannot in practice because current air quality is: (1) currently monitored at a level greater the new NAAQS level before model results are considered; or (2) currently monitored at a level in the range of 10-12 $\mu g/m^3$ (or 13 $\mu g/m^3$) and would have such a small margin available that a major source or major modification could not practically model a small enough impact attributable to the source that, when added to the background, could demonstrate compliance with the NAAQS. The commenter stated that in many areas, based on the EPA's 2009-2011 Design Values, modeling of new source growth can be anticipated to be very challenging.

Response: As we indicated in the responses above (f.1 and f.3), we believe that adequate policy exists to enable states to issue permits to proposed new and modified sources that model violations of the NAAQS, as long as those sources provide sufficient compensation for their modeled adverse impacts. Accordingly, it is not appropriate to conclude that sources proposing to construct or modify in areas already showing exceedances of the annual $PM_{2.5}$ NAAQS or experiencing levels near the NAAQS face an automatic "permitting moratorium."

E. Nonattainment New Source Review

(1) *Comment:* Several industry commenters recommended that the EPA establish a grandfathering provision for NNSR as was proposed under the PSD program. A subset of these commenters recommended that grandfathering be accomplished by establishing an effective date for designations 1 year after initial publication in the Federal Register.

Response: The EPA has provided detailed responses to these comments in section IX.D.2 of the final rule preamble.

(2) *Comment:* A few industry and state agency commenters addressed the issue of potential dual review (applying NNSR and PSD simultaneously) based on distinct designations for separate averaging times of the $PM_{2.5}$ NAAQS. These commenters generally agreed with the EPA's conclusion that it was reasonable to apply only the NNSR permitting requirements to such situations and not PSD.

Response: The EPA has provided detailed responses to these comments in section IX.D.2 of the final rule preamble.

F. Other NSR Implementation Comments

(1) *Comment:* One industry coalition commenter and one industry trade association commenter identified issues related to in-stack $PM_{2.5}$ test methods. These commenters stated that available test methods for $PM_{2.5}$ from wet stacks overestimate emissions and therefore will subject more sources to NSR/PSD. One of the commenters indicated that the EPA had committed to study this issue further when it finalized revisions to

Reference Method 202 for condensable particulate, and the other that API and the National Council for Air and Stream Improvement, Inc. (NCASI) are working with the EPA to develop a validation test plan for candidate methods, but that this process will take time.

Response: The EPA recognizes the need to develop a method which quantifies $PM_{2.5}$ emissions in a wet stack environment. Since the proposal of Method 201A, the EPA has been engaged in the development of this capability. In addition, the EPA has been following the efforts of a contractor retained by API to develop this capability but with a somewhat different approach. While these efforts are promising, the EPA is several years from having a validated test method which all stakeholders are confident is reliable and capable of being performed by most stack test consultants.

(2) *Comment*: One industry association and one state agency commented on the lack of accurate emissions information and technical guidance concerning $PM_{2.5}$. The industry association commenter cited deficiencies in EPA's AP-42, including the fact that most emission factors are for total PM, the limited data on particle size distribution, the lack of data on condensable PM, and the low quality rating of available emission factors. The state agency commenter stated that the lack of reliable emission factors and data on the condensable portion of $PM_{2.5}$ makes it difficult for air agencies and/or sources to fairly and effectively implement the standards, and that this would be exacerbated by lowering the standards.

Response: The EPA recognizes that many of the emissions factors in AP-42 are outdated and/or deficient for many source categories. This situation has arisen due to the inability to obtain and process source test information in an efficient and cost effective way to develop new and revised emissions factors. As a result the EPA is updating the way that stack test reports are documented and processed to develop emissions factors. In 2004, the EPA developed the Electronic Reporting Tool (ERT) for documenting stack tests. The ERT revises the paper method of documenting the requisite information so that the remainder of the emissions factor development does not require the level of resources required with paper test reports. Since the development of the ERT, the EPA has required sources to use this tool to report the results of stack test data required for regulatory development efforts. In addition, the EPA has promulgated several rules for specific source categories that require sources to submit stack test reports t using the ERT. On January 1, 2012, the EPA activated the Central Data Exchange (CDX) portal for submitting stack test reports. The EPA will be developing a data system to replace the existing WebFIRE which will use test data submitted with the ERT through the CDX to update existing emissions factors or to develop new emissions factors. To the extent that sources submit their stack test data to the EPA with the ERT, updated emissions factors will be made available for use by regulated sources' air agencies.

(3) *Comment*: One industry coalition commenter suggested that a transition period may be needed for pre- and post-construction monitoring of $PM_{2.5}$ under the PSD program to address changes in the monitoring regulations.

Response: The EPA does not anticipate that the changes to the monitoring regulations contained in the final NAAQS rule would affect pre- or post-construction monitoring under the PSD program that may be in progress or pending at the time the changes become effective. Therefore, the EPA does not believe that a regulatory transition period is necessary. In the unlikely event that case-specific PSD pre- and/or post-construction monitoring may be affected by the monitoring regulation changes contained in the final rule, the EPA and permitting authorities may have the discretion to mitigate such impacts by providing a transition period or mechanism tailored to the specific permit action to avoid unreasonable delays and additional burden.

G. Specific Comments Related to Transportation Conformity

(1) *Comment:* One commenter was pleased to see that, if the proposed changes to the $PM_{2.5}$ monitoring regulations concerning replacing the term "community oriented" with "area-wide" and revoking the requirement that monitoring sites be population oriented are finalized, the EPA would update its guidance on conducting quantitative $PM_{2.5}$ hot-spot analyses for transportation conformity purposes. The commenter stated that to avoid confusion the guidance will need to be revised expeditiously.

Response: The changes to the monitoring regulations are designed to align different elements of those regulations for consistency. The EPA intends to quickly revise its guidance entitled, **"Transportation Conformity Guidance for Quantitative Hot-spot Analyses in $PM_{2.5}$ and PM10 Nonattainment and Maintenance Areas"**[51] to address these revisions to the monitoring regulations. The preamble to the final PM NAAQS rule describes how the EPA intends to address the overall transition from the current monitoring regulations to the revised monitoring regulations. The EPA intends the current PM Hot-spot Guidance to continue to apply to any quantitative $PM_{2.5}$ hot-spot analysis that was begun before the effective date of today's revisions to the monitoring regulations. Revised guidance would apply to any quantitative $PM_{2.5}$ hot-spot analysis begun after the effective date of the revised monitoring regulations. Nonattainment and maintenance areas are encouraged to use their interagency consultation processes to determine whether an analysis for a given project was started before the effective date of the revised monitoring regulations.

(2) *Comment:* Two commenters raised issues related to having one or more separate secondary NAAQS for $PM_{2.5}$ making transportation and air quality planning and transportation conformity more complex and costly by requiring that conformity be demonstrated by comparing future emissions to multiple sets of $PM_{2.5}$ motor vehicle emissions budgets. The commenters were also concerned that the EPA will not be able to completely revoke the 1997 annual $PM_{2.5}$ NAAQS as has been the practice as the ozone NAAQS has been revised meaning that areas will have to continue to demonstrate conformity to the 1997 annual $PM_{2.5}$ NAAQS. One commenter notes that revoking the previous less stringent NAAQS conserves resources because the areas no longer have to demonstrate conformity for the earlier NAAQS after it is revoked.

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[51] Hereafter, referred to as "PM Hot-spot Guidance" in this document. **EPA420-B-10-040, December 2010. U.S. EPA (2010j). See www.epa.gov/otaq/stateresources/transconf/policy.htm#project.**

Response: As discussed in the final rule the EPA retained the 1997 annual secondary $PM_{2.5}$ NAAQS of 15.0 ug/m^3, and did not finalize the proposed visibility-related standard because we determined that retaining the current 24-hour $PM_{2.5}$ NAAQS provides visibility protection equivalent to the proposed visibility-related secondary NAAQS. The EPA will work with areas through the conformity rule's interagency consultation process to determine efficient ways to fulfill conformity requirements for each of the $PM_{2.5}$ NAAQS that apply in each area in order to minimize the impact on the area's resources. The comment on revocation is beyond the scope of the current final rule. The potential revocation of the 1997 annual $PM_{2.5}$ NAAQS will be addressed in the planned implementation rule for the 2012 annual $PM_{2.5}$ NAAQS.

(3) *Comment:* In order to reduce the possibility of diverting transportation funds from addressing regional air quality which benefits the population of the entire nonattainment area to addressing near road or hot-spot problems, the EPA should work closely with transportation professionals when developing implementation policies for these types of issues.

Response: The EPA will work with a wide range of stakeholders as it develops SIP requirements for implementing the $PM_{2.5}$ NAAQS through a future rulemaking.

(4) *Comment:* Given the potential implications for transportation planning and transportation projects the EPA should consult with transportation agencies on changes to implementation and designation requirements, transportation conformity requirements including hot-spot requirements, and monitoring requirements.

Response: The EPA will work with a wide range of stakeholders as it develops SIP requirements for implementing the $PM_{2.5}$ NAAQS in a future rulemaking. The EPA will also update existing transportation conformity or issue new guidance as needed, as the Agency has historically done for conformity transitions to new NAAQS.

(5) *Comment:* Adding additional requirements on top of requirements that have not yet been fully implemented could result in transportation projects that had been in compliance with the Clean Air Act being determined to be out of compliance which would expose them to litigation.

Response: It is not clear what the commenter is referring to, since the comment provides no information regarding which specific "additional requirements" it is referring to, or how transportation projects could be determined to be out of compliance with the CAA. Therefore, we are unable to respond to this comment.

(6) *Comment:* The commenter seeks assurance that $PM_{2.5}$ nonattainment areas will be eligible to receive Congestion Mitigation and Air Quality Improvement (CMAQ) funds even though they will not be classified.

Response: $PM_{2.5}$ nonattainment and maintenance areas are eligible to receive CMAQ funds from the Federal Highway Administration. On July 6, 2012, the President signed the Moving Ahead for Progress in the 21st Century Act (MAP-21) into law. MAP-21 authorizes transportation funding through the end of federal fiscal year 2014 and amends the federal transportation law. Under MAP-21, a State with $PM_{2.5}$ areas must use a portion of its funds to address $PM_{2.5}$-related emissions in such areas; eligible projects to mitigate $PM_{2.5}$ include diesel retrofits. MAP-21 also retains the direction to states and metropolitan planning organizations to give priority to funding projects in $PM_{2.5}$ nonattainment or maintenance areas that are proven to reduce $PM_{2.5}$, including diesel retrofits.

H. Specific Comments Related to Exceptional Events

Comments related to exceptional events focused on the schedule for data flagging and documentation submittal for the primary standard and the schedule for data flagging and documentation submittal for the secondary standard to address the "unique" components of the secondary standard. Each of these is addressed below. The responses to these comments are also discussed in section VII.B of the preamble to the final rule.

(1) *Comment:* The majority of commenters supported the schedule by which agencies must flag ambient air data that they believe have been affected by exceptional events, submit initial descriptions of those events, and submit detailed justification to support the exclusion of those data from EPA-monitoring-based determinations of nonattainment with the primary annual $PM_{2.5}$ NAAQS. A few commenters suggested schedule extensions for one of two reasons: the potential resource burden associated with preparing and submitting multiple wildfire exceptional event demonstrations for events in the unusually active wildfire years of 2010 to 2012 and data reporting lags and "unique" monitoring elements associated with the secondary standard.

Response: The EPA is finalizing the exceptional events schedule as proposed and as supported by multiple commenters. For air quality data collected in 2010 and 2011, the EPA is extending to July 1, 2013, the otherwise applicable generic deadlines of July 1, 2011 and July 1, 2012, respectively, for flagging data and providing an initial description of an event (40 CFR 50.14(c)(2)(iii)). The EPA is retaining the existing generic deadline in the Exceptional Events Rule of July 1, 2013, for flagging data and providing an initial description of events occurring in 2012. Similarly, the EPA is revising to December 12, 2013, the deadline for submitting documentation to support exceptional events occurring in 2010 through 2012 and potentially influencing compliance with the revised primary annual $PM_{2.5}$ NAAQS. If an air agency intends the EPA to consider in the revised primary annual $PM_{2.5}$ designations decisions whether $PM_{2.5}$ data collected during 2013 influence compliance with the primary annual $PM_{2.5}$ NAAQS, then the air agency must flag these data by the generic Exceptional Event Rule deadline of July 1, 2014. The EPA is finalizing August 1, 2014, as the deadline for submitting documentation to justify $PM_{2.5}$-related exceptional events occurring in 2013 and potentially influencing compliance with the revised primary annual $PM_{2.5}$ NAAQS. The EPA believes these revisions/extensions will provide adequate time for air agencies to review potential $PM_{2.5}$ exceptional events influencing compliance with the revised primary annual $PM_{2.5}$

NAAQS, to notify the EPA by flagging the relevant data and providing an initial description in AQS, and to submit documentation to support claims for exceptional events. These schedule revisions will also allow the EPA to fully consider and act on the submitted information during the initial area designations process for the revised primary annual $PM_{2.5}$ NAAQS.

The EPA acknowledges commenter concerns that numerous wildfires occurred between 2010 and 2012 and that air agencies may determine that these wildfires influenced ambient air quality concentrations potentially affecting compliance with the revised primary annual $PM_{2.5}$ NAAQS. The EPA further acknowledges that air agencies may submit detailed exceptional events documentation associated with multiple wildfires. Although some commenters noted that 1 year to provide documentation of these potential exceptional events may not be sufficient, the EPA believes that the promulgated schedules provide sufficient time for air agencies to submit information related to the annual standard and for the EPA to fully consider and act on the submitted information during the initial area designations process. The EPA recently released draft exceptional events guidance that clarifies key provisions of the 2007 Exceptional Events Rule, provides examples of best practices, and streamlines the documentation development process. The guidance provides approaches that are broadly applicable to all event/pollutant combinations and would apply to many PM events, including wildfire/PM combinations. Additionally, the EPA has posted several concurred upon wildfire/PM exceptional event demonstration packages on its website at http://www.epa.gov/ttn/analysis/exevents.htm. Considered together, the EPA believes this guidance will help air agencies submit information in a timely manner.[52] The EPA notes that under the promulgated schedule, except for events that occur in December 2012, air agencies will have more than 1 year to provide documentation for these potential events. The EPA intends to work with potentially affected areas to identify, screen and prioritize events potentially influencing compliance with the primary annual $PM_{2.5}$ NAAQS and associated area designations.

For the reasons stated in section VI.D.2 of the preamble to the final rule, the Administrator has decided not to establish the proposed distinct secondary standard to address visibility impairment. Therefore, the EPA will not promulgate initial area designations for a secondary PM visibility index standard and, as a result, has not promulgated exceptional event schedule revisions for events that might influence compliance with the secondary standard.

(2) *Comment:* Several commenters asked that the EPA clarify the preamble language and the associated promulgated exceptional events schedule to specifically identify the NAAQS to which the exceptional event schedule revisions apply.

Response: In response to comment, the EPA clarified that the preamble language and the associated promulgated exceptional events schedules apply only to the NAAQS that the

[52]U.S. EPA (2012e). Draft Guidance to Implement Requirements for the Treatment of Air Quality Monitoring Data Influenced by Exceptional Events, U.S. Environmental Protection Agency. June 2012. Available: http://www.epa.gov/ttn/analysis/exevents.htm.

EPA is newly promulgating or revising in this action, that is, the revised primary annual $PM_{2.5}$ NAAQS. The promulgated exceptional event schedule revisions do not apply to the retained PM standards (i.e., secondary PM standards, primary 24-hour PM_{10}, primary 24-hour $PM_{2.5}$). Further, the revised/extended exceptional event schedules apply only to those data the EPA will use to establish initial area designations for the revised primary annual $PM_{2.5}$ NAAQS.

VII. RESPONSES TO SIGNIFICANT COMMENTS ON LEGAL, ADMINISTRATIVE, PROCEDURAL, OR MISPLACED COMMENTS

A number of comments were received that addressed a wide range of issues including legal, administrative, and procedural issues. Many legal issues are addressed generally throughout the preamble to the final rule. Specific legal issues are more fully addressed in section VII.A as well as in the previous RTC sections above. Comments related to the Statutory and Executive Orders are addressed generally in section X of the preamble to the final rule and discussed more fully in section VII.B below. In addition, a number of comments were submitted related to issues that are not germane to the review of the NAAQS. Such comments have been categorized as "misplaced" comments and are discussed in section VII.C below.

A. Legal Issues

A number of commenters submitted comments addressing specific legal issues. These issues are generally discussed throughout the preamble to the final rule and more specifically below. A number of legal issues specifically addressing comments related to the secondary standards are addressed in section VI.C.1.g of the preamble to the final rule and in section IV.B.8 above.

(1) *Comment:* One commenter asserted that the EPA has failed to "review and consider the latest science in an unbiased, factual manner…raising the potential that its decision to propose a lower standard violates the Clean Air Act" (ACC, 2012, p.2). This commenter further argued that the proposal "presents inadequate justification for revising the level and form of the primary annual $PM_{2.5}$ standard and the EPA has "failed to address the 2009 D.C. Circuit remand" *Id.*

Response: The EPA strongly disagrees with this comment. The final decisions discussed in the preamble to the final rule reflect decisions based on air quality criteria representing ""the latest scientific knowledge" within the meaning of section 108 (a) (2) of the Act. The CASAC reviewed this enormous body of material and found it a sufficient basis for agency action with respect to review of the PM standards, including the primary fine particle standards. Moreover, the EPA is addressing the remand of the 2006 standards by the D.C. Circuit by revising the primary and secondary standards for $PM_{2.5}$ in a manner consistent with the court's opinion and mandate.

(2) *Comment:* A group of commenters argued that the "EPA's failure to seek comment on the existing primary annual standard inappropriately prejudges the outcome, leads to inherently biased rulemaking and is contrary to law" (e.g., NAM, 2012, p. 6).

Response: The commenter suggests that the EPA somehow prejudged the outcome of the rulemaking , or otherwise committed procedural error, by not proposing to retain the 2006 NAAQS. This is in error. First, the EPA provided far more process through this review than the amount required by law. Commenters had multiple opportunities to review and comment on multiple drafts of all of the critical documents underlying the review (notably the ISA, the REAs, and the PA), as well as on all of the critical scientific and policy issues, assumptions, and factual data informing the review. Given that the basic question being addressed throughout this proceeding is whether or not it is appropriate to revise the 2006 standard (CAA section 109 (d)), that issue was necessarily before the public for comment (as evidenced by all the comments urging retention of the standard, among other indicia of proper notice). Nor does the EPA's proposal indicate a pre-judgment of the outcome of the review. Rather, the proposal reflected the EPA's consideration of the body of scientific data and analysis comprising the record for this review.

The EPA strongly disagrees that the currently available scientific evidence and technical information supports consideration for retaining the annual standard level at 15 $\mu g/m^3$ and consequently did not propose to do so (just as the EPA did not propose to make the standard less stringent). As discussed in section III.D.3. of the preamble for the final rule, having carefully considered CASAC advice and the public comments on the proposal as discussed in section III.D.2 of the preamble to the final rule and in section II.B.1 above, the EPA believes the fundamental scientific conclusions on the effects of $PM_{2.5}$ reached in the ISA, and discussed in the PA, are valid. The Agency believes that since the last review the overall uncertainty about the public health risks associated with both long- and short-term exposure to $PM_{2.5}$ has been diminished to an important degree. The remaining uncertainties in the available evidence do not diminish confidence in the associations between exposure to fine particles and mortality and serious morbidity effects. Based on the Agency's increased confidence in the association between exposure to $PM_{2.5}$ and serious public health effects, combined with evidence of such an association in areas that would meet the current standards , the Administrator agrees with CASAC that revision of the current suite of $PM_{2.5}$ standards to provide increased public health protection is necessary. Based on these considerations as discussed in section III.D.3 of the preamble to the final rule, the Administrator concludes that the current suite of primary $PM_{2.5}$ standards is not sufficient, and thus not requisite, to protect public health with an adequate margin of safety, and that revision is needed to increase public health protection. Furthermore, as discussed in section III.E.4.e of the proposal, the Administrator provisionally concluded that the available scientific information supported consideration of an annual standard level no higher that 13 $\mu g/m^3$. In considering public comments on the proposal as discussed in sections III.E.4.c.i and III.E.4.d of the preamble for the final rule and in section II.B.5.a above, the Agency concludes there is no scientific basis for considering retaining the annual standard level at 15 $\mu g/m^3$ (absent a drastically lower level of the 24-hour standard). These conclusions represent reasoned consideration of the body of evidence comprising the record for this proceeding, not impermissible bias.

(3) *Comment:* One group of commenters argued that the EPA is not bound by the CASAC recommended range or any other CASAC recommendations (e.g., NAM, 2012, p. 10).

Response: The EPA agrees that the Agency is not bound by the CASAC recommended range or any other CASAC recommendations, however, the Agency believes it needs to give careful consideration to CASAC's advice and recommendations, and has done so here. The EPA is also clearly required to explain the reasons for any significant differences in approach. CAA section 307 (d) (3). The EPA's deviation from CASAC advice and recommendations, and its failure to adequately explain those deviations, was one of the reasons for the remand of the 2006 primary annual $PM_{2.5}$standard. *See American Farm Bureau Federation v. EPA,* 559 F. 3d at 521.

The EPA has carefully considered CASAC's advice and recommendations in this review, understanding that CASAC's views are not binding on the agency. Under sections 108 and 109 of the CAA, the Administrator is required to make decisions in reviewing the NAAQS using her own "judgment" in determining what standard is "requisite" in light of all of the evidence, and is not required to accept or follow CASAC's recommendations on what revisions are appropriate. The merits of the Administrator's decision is not determined solely based on whether she did or did not agree with CASAC, but based on a review of the record as a whole, including any explanation the Administrator provides for accepting or rejecting a recommendation from CASAC. The EPA has provided such explanations here as discussed in the preamble to the final rule, both where the Administrator's actions are consistent with CASAC's advice (e.g., final decisions on the primary $PM_{2.5}$ standards) and where in her judgment a different course of action than recommended by CASAC was appropriate (e.g., final decision on the primary PM_{10} standard).

(4) *Comment:* A group of commenters argued that "issuing a revised lower PM NAAQS that is both complicated and legally infirm will produce regulatory delay and uncertainty that could result in adverse rather than beneficial health impacts (NAM, 2012, p. 26). These commenters further noted the delay in the EPA's response to the 2009 remand of the 2006 PM NAAQS and argued that "issuing a final rule that promotes regulatory and legal uncertainty may delay or even foreclose investments that could reduce overall PM emissions from the manufacturing sector." *Id.*

Response: The EPA does not believe the revised standards are legally infirm. Moreover, the remand of the 2006 primary annual standard for $PM_{2.5}$ was due to the EPA's inability to adequately explain why that standard was not more stringent, not less stringent as this commenter would prefer.

(5) *Comment*: Many commenters asserted that the standards must protect at-risk populations – children, older adults, persons with pre-existing heart and respiratory disease, and persons with an adequate margin of safety (e.g., CHPAC, 2012; ALA et al., 2012, pp. 29 to 38).

Response: The EPA agrees with this comment and has carefully considered effects on at-risk populations in considering whether and how to revise the $PM_{2.5}$ NAAQS. As noted in section II.A of the preamble to the final rule, the CAA requires the EPA Administrator to establish primary standards that provide an adequate margin of safety. The legislative history of section 109 of the CAA 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). 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 the Administrator's judgment, the final decisions articulated in the final rule represent primary PM standards that are sufficient but not more protective than necessary to protect the public health, including at-risk populations, with an adequate margin of safety from effects associated with PM exposures.

(6) *Comment*: Some commenters argued that the EPA must adopt a precautionary approach to the standard setting, and set standards in a manner that deals with uncertainty not by ignoring effects but rather by protecting against adverse health effects (e.g., ALA et al., 2012, pp. 9 to 10). In support of this argument, these commenters specifically cited *Ethyl Corp v. EPA,* 541 F. 2d at 15, H. Rep No. 294, 95th Cong, 1st Sess. At 49 to 51 (1977) (explaining amendments designed *inter* alia "[t]o emphasize the preventive or precautionary nature of the act, i.e., to assure that regulatory action can effectively prevent harm before it occurs"), and *American Trucking Association v. EPA*, 283 F. 3d at 355, 369 ("the Act requires EPA to promulgate protective primary NAAQS even where… the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree'").

Response: The EPA agrees generally with this comment, but notes further that a general invocation of precautionary principles does not determine where in the range of reasonable values the EPA could establish the level of a standard. Section III.E.4.d to the preamble to the final rule explains in detail why it is appropriate to revise the annual standard level to 12.0 $\mu g/m^3$ in conjunction with retaining the 24-hour standard level at 35 $\mu g/m^3$. The EPA notes further that this choice is consistent with case law in the D.C. Circuit (not cited by the commenter) that the Administrator is to carefully examine all of the relevant studies in the record, but need not base the level of the standard on either the highest or lowest value in these studies. Rather, an informed judgment is called for. *API v. EPA*, 665 F. 2d at 1187; *NRDC v. EPA*, 902 F. 2d 962, 970. Section III.E.4.d to the preamble to the final rule states the basis for the Administrator's exercise of informed judgment here in setting the levels of the primary annual and 24-hour $PM_{2.5}$ standards.

B. Administrative/Procedural Issues

Several comments addressed administrative and procedural issues related ot he review of the PM NAAQS. These comments are addressed below.

(1) *Comment:* Several commenters argued that the timeline for issuing the final rule will likely mean that the EPA will not have time to adequately review and respond to comments filed on the proposal (ACC, 2012, p. 2, NAM, 2012, pp. 5 and 15 to 17; Dow, 2012, p. 1; US. Chamber of Commerce, 2012. pp. 2 to 5).

Response: Although the EPA sought to justify a longer schedule in the scheduling litigation leading up to the District Court issuing a preliminary injunction and lodging the governing consent decree, the EPA believes that it has adequately considered and responded to all of the substantive public comments. The EPA also notes that it provided multiple opportunities to review and comment on all of the critical documents underlying the review (notably multiple drafts of the ISA, the RA, the UFVA, and the PA), as well as on all of the critical scientific and policy issues, assumptions, and factual data informing the review. In addition to affording multiple opportunities for public comment, review of those comments gave the EPA opportunity to consider commenters' views throughout the process of reviewing the standards. Consequently, the EPA was already informed of many of the key points raised in the comments to the proposal in advance of the proposal. The EPA notes further that the time between proposal and final rule, although relatively brief, is not significantly different from that of other NAAQS reviews, including the 2006 PM NAAQS (proposed in January 2006 and signed in September 2006 – eight months versus six months here).

(2) *Comment:* Further, some of these commenters asserted that in following the current schedule for completing the final rule (i.e., signature by December 14, 2012), the Agency will not have the results of the EPA Inspector General's investigation of CASAC's role in reviewing the EPA"s PM NAAQS recommendations to inform its final decisions (NAM, 2012, pp. 5 and 17 to 18).

Response: As stated in an earlier response in this RTC section, the decision on whether to revise a NAAQS is the EPA's alone. By statute, that decision is informed by CASAC's advice and recommendations, but not determined by it. Moreover, the EPA is fully capable of assessing the scientific merit of CASAC's advice and recommendations. Review of the EPA's decision rests on the administrative record, not on some possibly forthcoming report by a non-scientific entity not involved in the review proceeding. Thus, EPA does not see that this comment has merit.

(3) *Comment:* One commenter asserted "it is farcical that EPA claims the proposed rule does not have Tribal implications as specified by Executive Order (EO) 13175" (NTAA, 2012, p. 4). Further this commenter argued that the EPA did not conduct meaningful consultation with Tribes in accordance with EO 13175. *Id.*

Response: The EPA disagrees with this comment. As summarized in section X.F of the preamble to the final rule, this rule concerns the establishment of national standards to address the health and welfare effects of particulate matter. Historically, the EPA's definition of "tribal implications" has been limited to situations in which it can be shown that a rule has impacts on the tribes' ability to govern or implications for tribal sovereignty. Based on this historic definition, this action does not have Tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), i.e. because it does not have a substantial direct effect on one or more Indian tribes, since tribes are not obligated to adopt or implement any NAAQS. Nevertheless, the Agency was aware that many tribes would be interest in this rule and we undertook a number of outreach activities to inform tribes about the PM NAAQS review and offered two consultations with tribes.

Although Executive Order 13175 does not apply to this rule, the EPA undertook a consultation process including: prior to proposal on March 29,2012 we sent letters to tribal leadership inviting consultation on the rule and then sent a second round of letters offering consultation after the proposal was issued on June 29, 2012. No tribe requested a formal consultation with the EPA. We conducted outreach and information calls to tribal environmental staff on May 9, 2012; June 15, 2012; and August 1, 2012. The EPA also participated on the National Tribal Air Association (NTAA) call on June 28, 2012.

As a result, we received comments from the NTAA, the Southern Ute Mountain Ute Tribe, and the Navajo Nation EPA. In general, these tribal organizations were supportive of the EPA's proposal.

C. Misplaced Comments

Some comments received on the proposed PM NAAQS addressed issues that are not relevant for consideration in the review of the NAAQS. These comments and other "misplaced comments are discussed more fully below.

(1) *Comment*: One group of commenters argued that the EPA should ensure that its final rule "does not impose unnecessary costs on the regulated community" (NAM, 2012, p. 29). Another commenter asserted that the EPA should consider the broader regulatory burden that is being imposed through application of multiple PM standards which collectively serve to address many of the same health effects – in addition implementing revised primary NO_2 and SO_2 standards (AFPM, 2012, p. 23).

Response: The EPA strongly disagrees with this comment. As discussed in section II.A of the preamble to the final rule, in setting NAAQS, the EPA may not consider the costs of implementing the standards. *See* generally, *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001). Likewise, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards." *American Petroleum Institute v. Costle*, 665 F. 2d at 1185.

(2) *Comment:* Some commenters provided comments related to the EPA's Regulatory Impact Analysis (RIA) for the proposal which was issued in June 2012.

Response: As discussed in section II.A of the preamble to the final rule, because the costs of implementation cannot be considered in setting or revising the NAAQS, the results of the RIA were not considered in the EPA's decisions on the PM standards. Comments on the RIA for the proposal were considered, as appropriate, in developing the RIA for the final rule.

(3) *Comment:* The EPA received several comments critical of the development process and timing of a revised PM NAAQS implementation rule. One commenter stated that the EPA should not finalize the proposed revisions without considering and responding to comments regarding implementation issues, particularly with respect to the secondary standard. Another commenter stated that the EPA needs to be clear what issues are going to be final in this (PM NAAQS) rulemaking versus a future implementation rulemaking. Another commenter interpreted EPA's request for comment on the NAAQS as purposefully seeking more information about how to implement the standard, which they claimed was problematic due to limited implementation guidance or rulemaking to comment on prior to finalization of the NAAQS.

Response: These comments reflect a possible misunderstanding of the scope of the PM

NAAQS rulemaking with respect to implementation issues. As explained in Section IX of the preamble to the final rule, the EPA will be undertaking a separate effort to develop an implementation rule for the revised NAAQS through a formal notice-and-comment rulemaking, which we intend to finalize around the time the initial area designations process is completed. The EPA will seek input from a wide range of stakeholders and the public throughout the implementation rulemaking process. To the extent the EPA sought comment on any state implementation planning issues as part of the PM NAAQS proposal, the Agency stated that we would take under consideration comments received as we developed a separate future implementation rule proposal. (Note, however, that certain PSD issues are specifically addressed in the final PM NAAQS rulemaking; issues related to implementing a secondary standard are not relevant as the Agency is not finalizing the proposed secondary standard relating to visibility in this final rule.)

We will provide a separate comment period for the submission of comments on any future implementation rule proposal. At that time, parties who submitted preliminary implementation-related comments as part of this rulemaking (to revise the PM NAAQS) may choose to resubmit their comments for consideration as part of the $PM_{2.5}$ NAAQS implementation rulemaking. Comments received on the PM NAAQS proposed rule will not be considered to be comments “submitted in advance” on any future implementation rule proposal.

(4) *Comment:* One commenter suggested that the EPA should, through the appropriations process, request adequate funds for air agencies to implement any revised or new NAAQS.

Response: This comment is on EPA’s budget request and is not relevant to the PM NAAQS rulemaking.

(5) *Comment:* The commenter asserts that complying with transportation conformity requirements will delay transportation projects that are intended to address traffic congestion.

Response: This comment is outside the scope of this rulemaking. In addition, we do not understand the basis of the commenter’s claim that complying with transportation conformity requirements results in the delay of projects designed to address traffic congestion. Areas are successfully implementing conformity requirements for the current suite of transportation–related NAAQS (ozone, $PM_{2.5}$, PM_{10}, carbon monoxide and nitrogen dioxide) including meeting relevant deadlines. All areas that were designated nonattainment for the 1997 and 2006 $PM_{2.5}$ NAAQS successfully complied with the requirement to demonstrate conformity within one-year of the effective date of their nonattainment designation. The conformity rule also exempts certain congestion-related projects from conformity requirements, including traffic signal synchronization projects (40 CFR 93.128) and certain intersection and interchange projects (40 CFR 93.127). If the commenter is concerned that project-level conformity requirements could delay congestion relief projects, the commenter should be aware that a hot-spot analysis is only required if the project is determined through interagency consultation to be a project of air quality concern.

(6) *Comment:* One commenter opines that the transportation conformity process needs to be examined. The commenter supplies examples of several concerns that they have with transportation conformity implementation. The other commenter opines that due to transportation conformity requirements transportation projects can only proceed in nonattainment and maintenance areas if they do not result in increased emissions.

Response: These comments address requirements of the existing conformity rule and are not relevant to the PM NAAQS rulemaking.

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APPENDIX A: Provisional Science Assessment

December 2012
EPA/600/R-12/056F

United States Environmental Protection Agency

Provisional Assessment of Recent Studies on Health Effects of Particulate Matter Exposure

National Center for Environmental Assessment RTP Division
Office of Research and Development
U.S. Environmental Protection Agency
Research Triangle Park, NC 27711

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Table of Contents

List of Tables

List of Figures

Authors, Contributors, Reviewers

Executive Direction

Dr. John Vandenberg (Director) – National Center for Environmental Assessment-RTP Division, U.S. Environmental Protection Agency, Research Triangle Park, NC

Ms. Debra Walsh (Deputy Director) – National Center for Environmental Assessment-RTP Division, U.S. Environmental Protection Agency, Research Triangle Park, NC

Dr. Mary Ross (Branch Chief) – National Center for Environmental Assessment, U.S. Environmental Protection Agency, Research Triangle Park, NC

Principal Authors

Mr. Jason Sacks (Team Lead) – National Center for Environmental Assessment, U.S. Environmental Protection Agency, Research Triangle Park, NC

Dr. Ellen Kirrane – National Center for Environmental Assessment, U.S. Environmental Protection Agency, Research Triangle Park, NC

Dr. Thomas Luben – National Center for Environmental Assessment, U.S. Environmental Protection Agency, Research Triangle Park, NC

Dr. Elizabeth Oesterling Owens – National Center for Environmental Assessment, U.S. Environmental Protection Agency, Research Triangle Park, NC

Contributors

Ms. Laura Datko-Williams – Oak Ridge Institute for Science and Education Research Fellow, National Center for Environmental Assessment, U.S. Environmental Protection Agency, Research Triangle Park, NC

Reviewers

Dr. Dan Costa, Air, Climate, and Energy Research Program, Office of Research and Development, U.S. Environmental Protection Agency, Research Triangle Park, NC

Dr. Aimen Farraj, National Health and Environmental Effects Research Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, NC

Dr. Ian Gilmour, National Health and Environmental Effects Research Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, NC

Ms. Beth Hassett-Sipple, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC.

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

Dr. Lucas Neas, National Health and Environmental Effects Research Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, NC

Mr. Steven Silverman, Office of General Council, U.S. Environmental Protection Agency, Washington, D.C.

Dr. Lindsay Wichers Stanek, National Exposure Research Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, NC

Executive Summary

In the proposed rule on the National Ambient Air Quality Standards for particulate matter (PM), EPA committed to conduct a review and assessment of the numerous studies relevant to assessing the health effects of PM that were published too recently to be included in the 2009 PM Integrated Science Assessment (ISA). This report presents the findings of EPA's survey and provisional assessment of such studies. EPA has screened and surveyed the recent literature and developed a provisional assessment that places those studies of potentially greatest relevance to the current PM NAAQS review in the context of the findings of the 2009 PM ISA. The focus is on: (a) epidemiologic studies that used $PM_{2.5}$ (i.e., fine PM) or $PM_{10-2.5}$ (i.e., coarse PM) and were conducted in the U.S. or Canada, and (b) toxicological or epidemiologic studies that compared effects of PM from different sources, PM components, or size fractions. The provisional assessment is not intended to critically review individual studies or integrate the scientific findings to draw causal conclusions as is done for an ISA.

This survey and assessment finds that that the new studies expand the scientific information and provide important insights on the relationships between PM exposure and health effects of PM. However, the new information and findings do not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the 2009 PM ISA. In brief, this report finds the following:

- Recent epidemiologic studies, most of which are extensions of earlier work, continue to support the conclusions of the 2009 PM ISA for *long-term exposure to* $PM_{2.5}$ and mortality, cardiovascular effects, respiratory effects, and reproductive and developmental effects. Notably, updated findings from the Harvard Six Cities and American Cancer Society cohorts continue to observe an association between long-term $PM_{2.5}$ exposure and mortality, which supports the findings from previous studies conducted in these cohorts. Additionally, a new Canadian multicity study observed associations with mortality at long-term mean $PM_{2.5}$ concentrations below those reported in the PM ISA. Recent cause-specific mortality studies also provide more evidence for cardiovascular mortality associations, especially in women, and additional evidence for respiratory mortality including lung cancer. Studies of cardiovascular effects provide evidence of myocardial infarction, hypertension, diabetes, and stroke, especially among women, which is consistent with the conclusions of the 2009 PM ISA. Recent studies continue to demonstrate associations with respiratory morbidity including respiratory symptoms and hospital admissions, as well as incident asthma among children. Reproductive and developmental effects studies continue to provide evidence for associations between long-term exposure to $PM_{2.5}$ and reduced birth weight.

- Recent epidemiologic studies have also continued to report associations between *short-term exposure to* $PM_{2.5}$ and mortality and morbidity health endpoints, which further support the causality determinations presented in the 2009 PM ISA. These include multiand single-city analyses that demonstrate consistent positive associations across all respiratory and cardiovascular hospital admissions and emergency department visits as well as cause-specific outcomes, particularly asthma. Although limited to single-city studies, recent studies continue to demonstrate associations between short-term fine PM exposures and nonaccidental and cardiovascular mortality. Additionally, new evidence for stroke which focuses on assigning exposure from the time of stroke onset, instead of entry to the hospital, provides new information regarding an uncertainty recognized in the PM ISA.

- New toxicological and epidemiologic studies have continued to link health outcomes with a range of *$PM_{2.5}$ sources and components.* Several new epidemiologic analyses continue to demonstrate health effects attributed to multiple sources and PM components including combustion activities (e.g., motor vehicle emissions, coal combustion, oil burning, power plants, and wood smoke/vegetative burning), crustal sources, and secondary sulfate. Toxicological studies examined various source categories and found that no source consistently showed the strongest association with cardiovascular health effects. Additionally, an examination of a number of $PM_{2.5}$ components found associations with various components and both cardiovascular and respiratory endpoints.

- Only a few recent epidemiologic studies have examined health effects of *short- and long-term exposures to coarse particles ($PM_{10-2.5}$)*. A short-term exposure and respiratory emergency department visits (ED) visits study found a positive and significant association with pediatric asthma ED visits in Atlanta, GA. One long-term exposure and mortality study did not find any evidence of an association with all-cause mortality though there was a positive but not statistically significant association with coronary heart disease (CHD) mortality.

1. INTRODUCTION AND METHODOLOGY

EPA is currently in the final stages of the review of the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM). As described in more detail in the Federal Register Notice of EPA's proposed rule on the PM NAAQS (77 FR 38890), EPA has prepared the *Integrated Science Assessment for Particulate Matter* (hereafter 2009 PM ISA) which reviewed, summarized, and integrated the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare that may be expected from the presence of PM in the ambient air in varying quantities, as required by section 108 of the Clean Air Act (CAA) (U.S. EPA, 2009). As noted in the PM proposal,[1] EPA is aware that numerous studies potentially relevant to assessing the health effects of ambient PM have been published recently that were not included in the 2009 PM ISA (U.S. EPA, 2009). The proposal notice also indicates the Agency's intent to conduct a review and assessment of these new studies before a final decision is made on the PM NAAQS. The purpose of this report is to present the findings of EPA's survey and provisional assessment of potentially relevant recent studies on the health effects of PM exposure. This provisional assessment will inform a decision by the EPA Administrator to proceed with final rulemaking or to revise the ISA to include the new studies.

This provisional assessment is focused on those studies most important to the major conclusions presented in the 2009 PM ISA and most relevant to the considerations of the current review of the PM NAAQS. EPA, therefore, identified potentially relevant studies by applying the following selection criteria to those studies published through August 2012: (1) epidemiologic studies that used $PM_{2.5}$ (i.e., fine PM) or $PM_{10-2.5}$ (i.e., coarse PM) and were conducted in the U.S. or Canada, and (2) toxicological or epidemiologic studies that compared effects of PM from different sources, PM components, or size fractions. In addition, we considered studies identified by public comments submitted to the docket of the proposed rule. Studies that met these criteria were evaluated by EPA staff and their key findings were summarized. This preliminary assessment was then developed to place those new studies of potentially greatest relevance in the context of the findings of the 2009 PM ISA including a judgment as to whether the new studies materially change the major conclusions of the 2009 PM ISA. The provisional assessment presented here does not attempt to critically review individual studies or to provide the kind of full integration found in a typical ISA.

The literature search and submissions from public commenters found that more than 1,500 studies have been published since the ISA closed on the health effects of particulate matter.

[1] As stated in the PM NAAQS proposal: "The EPA is aware that a number of new scientific studies on the health effects of PM have been published since the mid-2009 cutoff date for inclusion in the Integrated Science Assessment. As in the last PM NAAQS review, the EPA intends to conduct a provisional review and assessment of any significant new studies published since the close of the Integrated Science Assessment, including studies that may be submitted during the public comment period on this proposed rule in order to ensure that, before making a final decision, the Administrator is fully aware of the new science that has developed since 2009. In this provisional assessment, the EPA will examine these new studies in light of the literature evaluated in the Integrated Science Assessment. This provisional assessment and a summary of the key conclusions will be placed in the rulemaking docket." (77 FR 38899)

Application of the selection criteria resulted in a list of over 100 studies that are summarized in the main body of this report. Additional details of the air quality distributions observed in these studies can be found in the annex to this report. The most significant studies are discussed in the assessment, and where feasible, quantitative results are compared to those from the 2009 PM ISA. A comprehensive list of studies identified as being potentially relevant through the survey effort, including those studies not discussed in detail in this report can be found here: http://hero.epa.gov/pm . Studies not discussed in detail include controlled human exposure studies, and toxicological studies that examined health effects attributed to specific PM size fractions, as well as studies that focused on ultrafine particles.

The overview in the main body of this report is organized into three main sections:

(1) epidemiologic studies on effects associated with long-term exposure to PM, focusing on U.S. and Canadian studies with measurements of $PM_{2.5}$ or $PM_{10-2.5}$; (2) epidemiologic studies on effects associated with short-term PM exposure, again focusing on U.S. and Canadian studies with measurements of $PM_{2.5}$ or $PM_{10-2.5}$; and (3) toxicological and epidemiologic studies that have evaluated health effects with exposure to PM components and PM from different sources. This last section includes results of studies that assessed the effects of a range of PM sources or components, including those using source apportionment methods or comparing effects for numerous PM components, and not on studies of individual components. Most studies have focused on components or sources of $PM_{2.5}$, but information related to sources of $PM_{10-2.5}$ was also included to the extent available. Unless otherwise noted, the majority of new studies included in this assessment did not examine the robustness of single-pollutant results in copollutants models.

2. OVERVIEW OF RECENT HEALTH STUDIES RESULTS

As stated in the 2009 PM ISA, EPA integrated the scientific evidence from toxicological, controlled human exposure, and epidemiologic studies in combination with evidence from atmospheric chemistry and exposure assessment studies and developed causal determinations for health outcomes categories (e.g., respiratory effects, cardiovascular effects, mortality, etc.) for different exposure durations (i.e., short- or long-term) and PM size fractions. Causal judgments drawn for short- and long-term exposure to $PM_{2.5}$ and short-term exposure to $PM_{10-2.5}$ are included in Table 2.1.

Table 2.1. Causal Determinations for Short-and Long-Term Exposure to $PM_{2.5}$

Long-term Exposure to $PM_{2.5}$

Size Fraction	Outcome	Causality Determination
$PM_{2.5}$	Cardiovascular Effects	Causal
	Respiratory Effects	Likely to be causal
	Mortality	Causal
	Reproductive and Developmental	Suggestive
	Cancer, Mutagenicity, and Genotoxicity	Suggestive

Short-term Exposure to $PM_{2.5}$

Size Fraction	Outcome	Causality Determination
$PM_{2.5}$	Cardiovascular Effects	Causal
	Respiratory Effects	Likely to be causal
	Mortality	Causal

Short-term Exposure to $PM_{10-2.5}$

Size Fraction	Outcome	Causality Determination
$PM_{10-2.5}$	Cardiovascular Effects	Suggestive
	Respiratory Effects	Suggestive
	Mortality	Suggestive

The following sections of this document summarize the scientific evidence published since the completion of the 2009 PM ISA for each of the health outcome categories presented in Table 2.1.

2.1. Epidemiologic Studies of Long-Term Exposure

The majority of the epidemiologic evidence evaluated in the 2009 PM ISA (U.S. EPA, 2009) focused on health effects of $PM_{2.5}$ exposure, with very limited evidence for health effects of long-term exposure to $PM_{10-2.5}$. These studies demonstrated consistent positive associations between long-term $PM_{2.5}$ exposures and a variety of health effects (Chapter 7, (U.S. EPA, 2009)).

Sections 2.1.1 - 2.1.4 highlight results from epidemiologic studies of mortality, cardiovascular effects, respiratory effects, and reproductive and developmental effects, respectively, published since the completion of the 2009 PM ISA (U.S. EPA, 2009) because these were the health outcomes specifically taken into consideration in developing the proposed rule (77 FR 38890). Tables A.1 through A.5 (Appendix A) summarize the recent epidemiologic studies that evaluated relationships between health effects and long-term exposure to $PM_{2.5}$ and $PM_{10-2.5}$. The discussions below emphasize results of studies conducted in the U.S. and Canada.

2.1.1. Mortality

Long-term exposure to $PM_{2.5}$

Summary of 2009 PM ISA Conclusions

The 2009 PM ISA synthesized the epidemiologic literature characterizing the association between long-term exposure to $PM_{2.5}$ and increased risk of mortality and concluded that "a causal relationship exists between long-term exposure to $PM_{2.5}$ and mortality" (See Section 7.6 of the 2009 PM ISA). Long-term mean[2] $PM_{2.5}$ concentrations ranged from 13.2 to 32.0 µg/m^3 during the study periods in the areas in which these studies, comprising the entire body of evidence reviewed in the 2009 ISA, were conducted. When evaluating cause-specific mortality, the strongest evidence contributing to this causal determination was observed for associations between $PM_{2.5}$ and cardiovascular mortality. Positive associations were also reported between $PM_{2.5}$ and lung cancer mortality. Both the Harvard Six Cities (Laden et al., 2006; Dockery et al., 1993) and the American Cancer Society (ACS) (Krewski, 2009; Pope III et al., 2004; Pope et al., 2002) studies continued to provide strong evidence for the associations between long-term exposure to $PM_{2.5}$ and cardiopulmonary disease (CPD) and ischemic heart disease (IHD) mortality. Additional evidence from a study that used the Women's Health Initiative (WHI) cohort (Miller et al., 2007) found a particularly strong association between long-term exposure to $PM_{2.5}$ and cardiovascular disease (CVD) mortality in post-menopausal women.

Recent Mortality Studies

Since the completion of the 2009 PM ISA (U.S. EPA, 2009), a number of studies have been published that examined the association between long-term exposure to $PM_{2.5}$ and all-cause mortality (See Figure 2.1) and cause-specific mortality (See Figures 2.2 and 2.3), including updated results for both the Harvard Six Cities and ACS cohorts. Lepeule et al. (2012) extended the analysis of the Harvard Six Cities cohort using 11 additional years of follow-up and $PM_{2.5}$ monitoring data and explored a variety of issues that might affect the size and timing of the mortality effect. Generally, the authors observed results similar to those reported by Laden et al. (2006) for all-cause and cardiovascular mortality, though the central estimate was slightly diminished and had slightly narrower confidence intervals (all-cause mortality: RR=1.14 [95% CI: 1.07, 1.22][3] for Lepeule et al. (2012) versus RR=1.16 [95% CI: 1.07, 1.26] for Laden et al. (2006); cardiovascular mortality: RR=1.26 [95% CI: 1.14, 1.40] for Lepeule et al. (2012) versus RR=1.28 [95% CI: 1.13, 1.44] for Laden et al.(2006). The authors applied both spline and linear

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[2] For long-term exposure studies, the long-term mean $PM_{2.5}$ concentration refers to the average $PM_{2.5}$ concentrations reported across the entire study duration, which could equate to the monthly or annual $PM_{2.5}$ concentration averaged over many years.

[3] All effect estimates for associations between long-term exposure to $PM_{2.5}$ and mortality are presented for a 10 µg/m^3 increase in $PM_{2.5}$ concentration.

models to investigate the concentration-response relationship, and observed that for all-cause mortality, the model fit was better without the spline, indicating a no threshold, linear relationship with $PM_{2.5}$ down to the lowest observed concentration (i.e., 8 μg/m^3). Jerrett et al. (2009a) reanalyzed data from the ACS cohort, including data from 86 metropolitan statistical areas (MSAs) across the U.S with monitoring data for $PM_{2.5}$. The authors observed an association between $PM_{2.5}$ and all-cause mortality in single pollutant models (RR 1.048 [95% CI: 1.024, 1.071]) that increased in magnitude in a copollutant model adjusting for ozone (O_3) concentration (RR 1.080 [95% CI: 1.048, 1.113]). The associations were stronger when limited to mortality due to cardiovascular disease (CPD mortality: RR 1.129 [95% CI: 1.094, 1.071]; CVD mortality: RR 1.150 [95% CI: 1.111, 1.191]; IHD mortality: RR 1.211 [95% CI: 1.156, 1.268]); these associations also became stronger in copollutant models adjusting for O_3 concentration. No statistically significant association was observed between $PM_{2.5}$ and respiratory mortality in this re-analysis of the ACS cohort. In another analysis among the ACS cohort, McKean-Cowdin et al. (2009) examined the association between long-term exposure to $PM_{2.5}$ and brain cancer mortality. The authors observed no associations with brain cancer mortality.

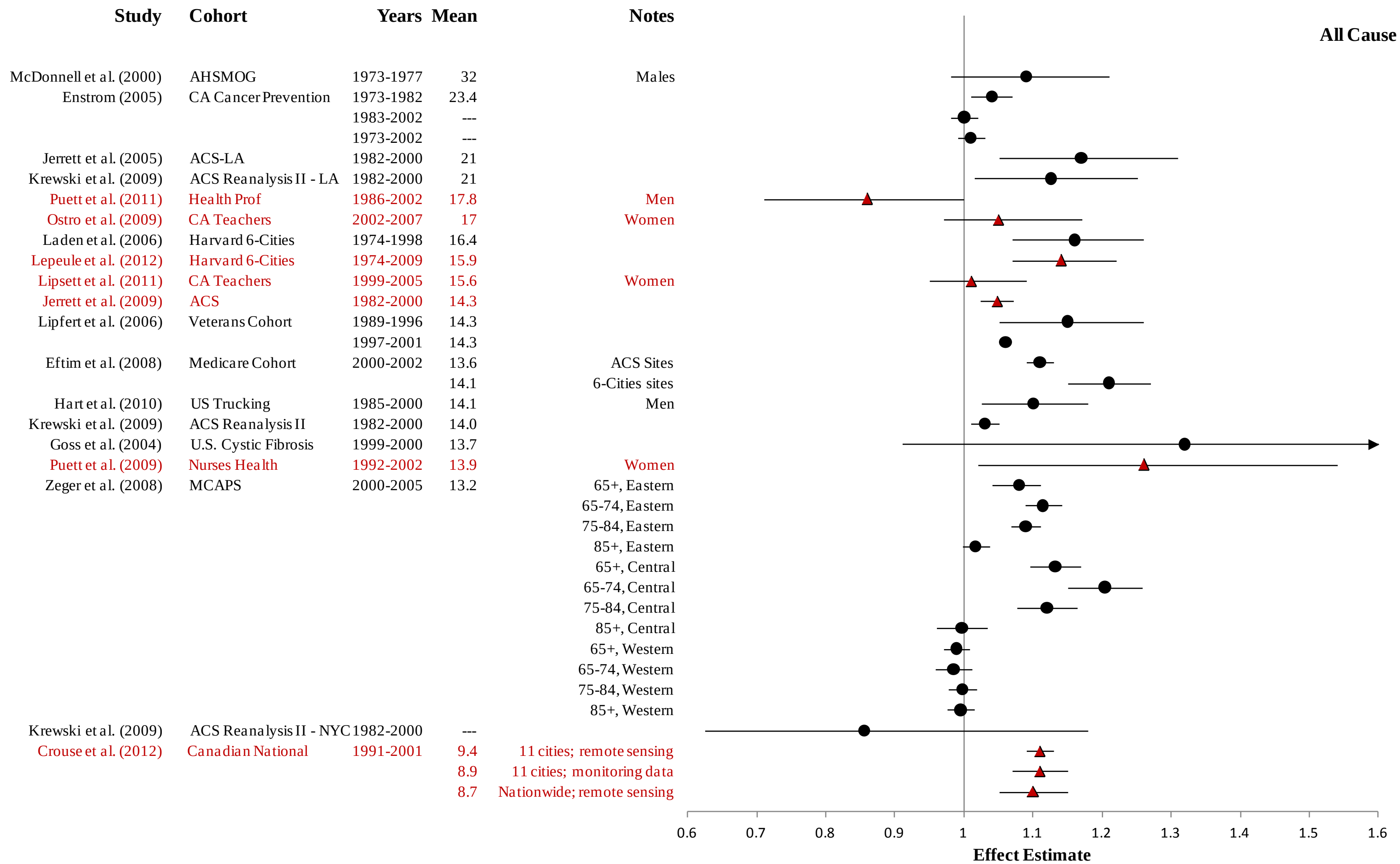

Figure 2.1. All-cause mortality risk estimates, long-term exposure to $PM_{2.5}$ in recent cohort studies. Red text and triangles represent new studies published since the completion of the 2009 PM ISA.

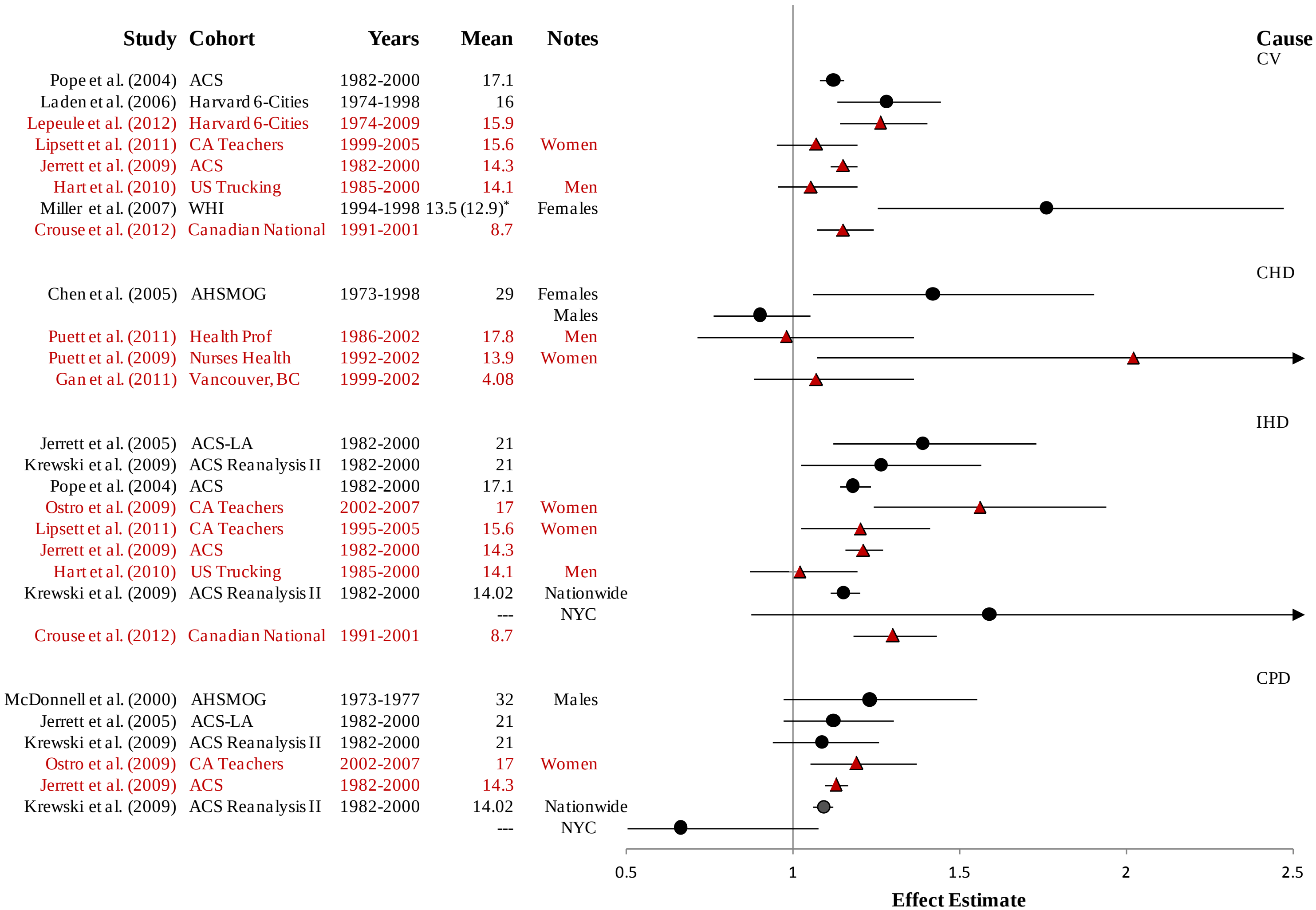

Figure 2.2. Cardiovascular mortality risk estimates, long-term exposure to $PM_{2.5}$ in recent cohort studies. Red text and triangles represent new studies published since the completion of the 2009 PM ISA. * As discussed in Federal Register Notice of EPA's proposed rule on the PM NAAQS (77 FR at 38929 and 38934 n. 82). CV = cardiovascular disease, CHD = coronary heart disease, IHD = ischemic heart disease, CPD = cardiopulmonary disease.

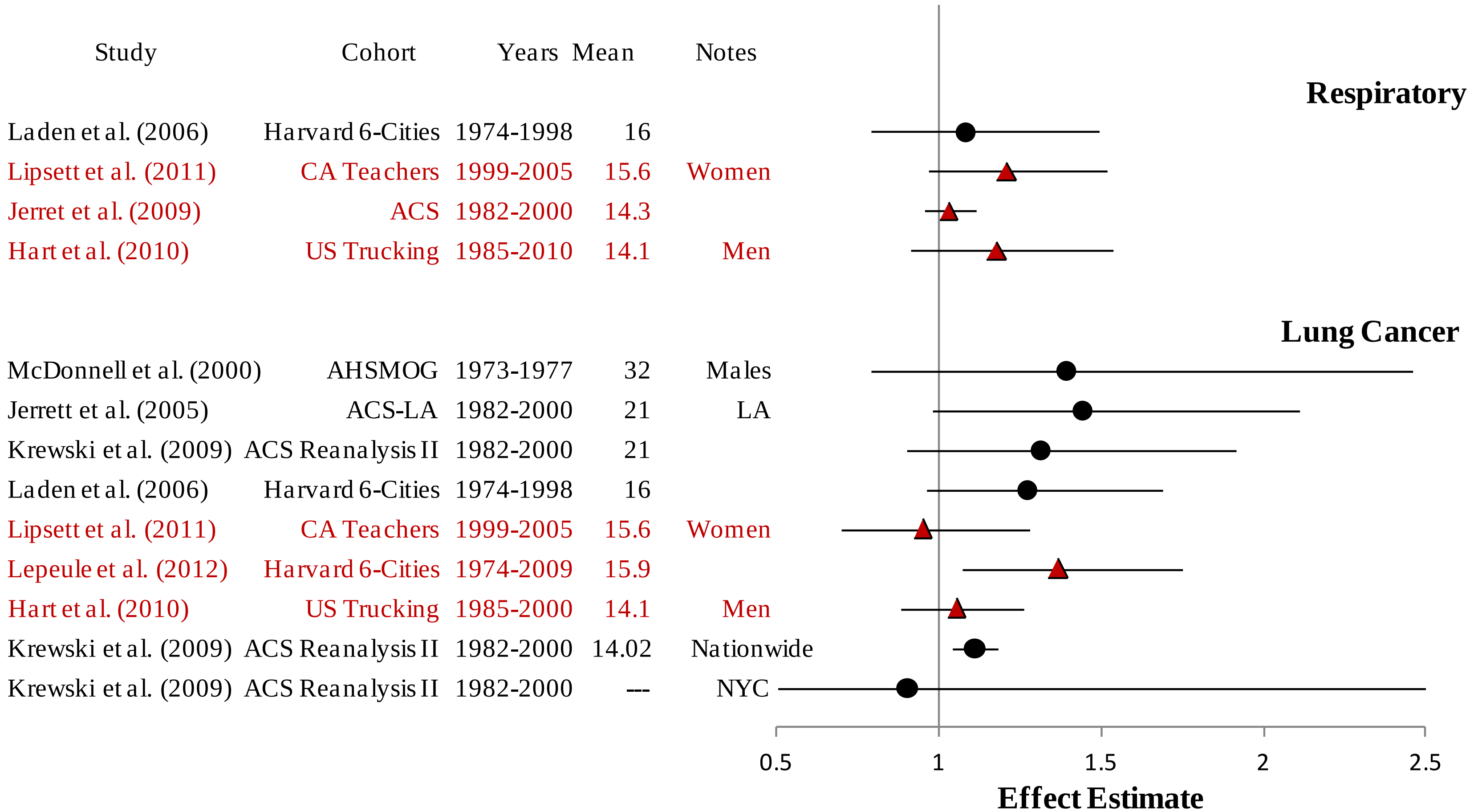

Figure 2.3. Respiratory mortality risk estimates, long-term exposure to $PM_{2.5}$ in recent cohort studies. Red text and triangles represent new studies published since the completion of the 2009 PM ISA.

In an update to a study by Janes et al. (2007), Greven et al. (2011) used data from a nationwide Medicare mortality cohort to develop a statistical approach for estimating the associations between monthly mean $PM_{2.5}$ concentrations averaged over the preceding 12 months and monthly mortality rates among subjects living within ZIP codes with a geographic centroid within a six mile radius of one of 814 monitoring stations from 2000 to 2006. The study authors decomposed the association between $PM_{2.5}$ and mortality into two components: (1) the association between the "national" trend in the monthly $PM_{2.5}$ concentrations averaged over the previous 12 months and the national average trend in monthly mortality rates (purely temporal association); and (2) the association between the "local" trend in the deviation in the community-specific trend from the national average trend of monthly averages of $PM_{2.5}$ and the deviation of the community-specific trends from the national average trend of mortality rates (residual spatio-temporal association). The authors posit that this second component provides evidence as to whether locations having steeper declines in $PM_{2.5}$ also have steeper declines in mortality relative to the national trend. The authors conclude that differences in effect estimates at these two spatiotemporal scales raise concerns about confounding bias in these analyses, with the association for the national trend more likely to be confounded than the association for the local trend. The authors observed no evidence for a "local" effect, but did observe evidence for a "national" effect. Similar to the study by Janes et al. (2007), Greven et al. (2011) eliminate all of the spatial variation in air pollution and mortality in their data set when estimating the "national" effect, focusing instead on sub-chronic (monthly) temporal differences in the data. As noted by the authors, this eliminates 90% of the variance in the data set used for these analyses that is attributable to spatial variability (Janes et al. (2007), Table 1). Only 5% of the variance in the data set used in these analyses is attributable to the space by time component, which was the focus of the papers by Janes et al. (2007) and Greven et al. (2011). Thus, while the results of the papers themselves provide evidence for an association between exposure to $PM_{2.5}$ and mortality, it is not possible to directly compare the results of these studies to the results of other cohort studies investigating the relationship between long-term exposure to $PM_{2.5}$ and mortality, which make use of spatial variability in air pollution and mortality data. As noted by Pope and Burnett (2007) and highlighted in the 2009 PM ISA (Section 7.6.1, (U.S. EPA, 2009)), the conclusions of Janes et al. (2007) "largely excludes the sources of variability that are exploited in those other [cohort] studies." These comments are also applicable to the study by Greven et al. (2011).

Crouse et al. (2012) conducted a nationwide study of the relationship between long-term exposure and $PM_{2.5}$ in Canada and provide new evidence for a positive association at relatively low concentrations of $PM_{2.5}$. The authors investigated the association between long-term exposure to ambient $PM_{2.5}$ and non-accidental mortality. The level of ambient $PM_{2.5}$ to which the study population was exposed was estimated from satellite observations and assigned to the cohort of 2.1 million Canadian adults that completed detailed census data in 1991. The study included deaths between 1991 and 2001. The authors observed a hazard ratio (HR) of 1.15 (95% CI: 1.13, 1.16) for non-accidental mortality. Using spatial random-effects models, the HR was slightly diminished (1.10 [95% CI: 1.05, 1.15]). The strongest association was observed for deaths due to ischemic heart disease (HR: 1.31 [95% CI: 1.27, 1.35]). Using spatial random-effects models did not substantially change the association (HR: 1.30 [95% CI: 1.18, 1.43]). The associations between $PM_{2.5}$ and deaths due to CVD and circulatory diseases were similar in magnitude to that observed for non-accidental mortality. There was a weaker association with mortality due to cerebrovascular disease (CBD) (HR: 1.04 [95%CI; 0.99, 1.10]). Sensitivity analyses including 11 Canadian cities with ground-based $PM_{2.5}$ measurements produced similar associations to those observed in the full cohort that utilized satellite observations to estimate $PM_{2.5}$ exposure (See Figure 2.1).

A number of studies have looked at the association between long-term exposure to ambient $PM_{2.5}$ and all-cause mortality among different occupational cohorts. Hart et al. (2010) examined the association between residential exposure to $PM_{2.5}$ and mortality among men in the U.S. trucking industry. The authors observed a 10% (95% CI: 2.5, 18) increase in all-cause mortality. This association was stronger when the cohort was restricted to truck drivers that maintained local routes, and long haul drivers were excluded (15% increase [95% CI: 5.0, 26.6] for all-cause mortality; 59.7% increase [95% CI: 18.7, 114.9%] for respiratory mortality). The associations for other causes of death (i.e., lung cancer, CVD, IHD, chronic obstructive pulmonary disease [COPD]) were generally positive, but were not statistically significant. Puett et al. (2009) examined the relationship of long-term $PM_{2.5}$ exposures with all-cause mortality among women from the Nurses' Health Study. The authors found an increased risk of all-cause mortality (HR 1.26 [95% CI: 1.02, 1.54]) and coronary heart disease (CHD) mortality (HR 2.02, 95% CI: 1.07, 3.78) associated with long-term exposure to $PM_{2.5.}$ More recently, Puett et al. (2011) used the same spatiotemporal exposure estimation models to characterize the association between long-term exposure to $PM_{2.5}$ and mortality among male subjects in the Health Professionals Follow-up Study. In this cohort, long-term exposure to $PM_{2.5}$ was not associated with all-cause or CHD mortality. Ostro et al. (2010) examined the association between long-term exposures to $PM_{2.5}$ and all-cause, CPD, IHD and pulmonary disease mortality among the subjects from the California Teachers Study. No associations were observed between all-cause mortality and $PM_{2.5}$. There was a positive association between long-term exposure to $PM_{2.5}$ and CPD mortality (HR: 1.19 [95% CI: 1.05, 1.37]) and IHD mortality (HR: 1.56 [95% CI: 1.24, 1.94]). In a follow-up study, Lipsett et al. (2011) examined the associations between long-term exposure to $PM_{2.5}$ and all-cause and cause-specific mortality among the subjects in the California Teachers Study. The authors did not observe an association between long-term exposure to $PM_{2.5}$ and all-cause mortality in this cohort, but observed an association with IHD mortality (HR 1.20 [95% CI: 1.02, 1.41]). They also observed positive associations for respiratory mortality and CBD mortality, though these associations were not statistically significant.

In a single-city study conducted in Toronto, Ontario, Canada, Jerrett et al (2009b) examined the association between long-term exposure to $PM_{2.5}$ and all-cause mortality among subjects from a respiratory clinic. The authors observed positive, though not statistically significant associations with all-cause, circulatory or respiratory mortality. A limited number of deaths in the cohort and low variability in $PM_{2.5}$ concentrations (limiting the exposure contrast) led the authors to conclude that “no definitive conclusions [could] be drawn about these associations with $PM_{2.5}$”. In a single-city study conducted in Vancouver, British Columbia, Canada, Gan et al. (2011) conducted a population-based cohort study to evaluate the association between traffic-related pollutants and risk of mortality due to CHD. Land-use regression models were used to estimate exposure over a 5 year period (1994-1998) and the cohort was followed up for 4 years (1999-2002). Exposure to $PM_{2.5}$ was weakly associated with CHD mortality.

Recent studies that examined the association between long-term $PM_{2.5}$ exposure and mortality further support the conclusions of the 2009 PM ISA. The strongest evidence for mortality was from the Harvard Six Cities (Laden et al., 2006; Dockery et al., 1993) and American Cancer Society cohorts (Krewski, 2009; Pope III et al., 2004; Pope et al., 2002), which was supported by a number of other cohort studies. Updated results from the Harvard Six Cities (Lepeule et al., 2012) and American Cancer Society (Jerrett et al., 2009a) cohorts support the findings of the 2009 PM ISA, while a new Canadian multicity study (Crouse et al., 2012) observed associations below those reported in the PM ISA (i.e., < 10 μg/m^3). In the 2009 PM ISA, for cause-specific mortality, the strongest evidence was for cardiovascular-related mortality, particularly among post-menopausal women (Miller et al., 2007). Respiratory-related mortality was also observed, particularly for lung cancer mortality (Naess et al., 2007). Recent studies provide more evidence for strong associations with cardiovascular-related mortality among women (Lipsett et al., 2011; Puett et al., 2009) and additional evidence for respiratory mortality including lung cancer mortality (Lepeule et al., 2012).

Long-term exposure to $PM_{10-2.5}$

Summary of 2009 PM ISA Conclusions

The 2009 PM ISA synthesized the epidemiologic literature characterizing the association between long-term exposure to $PM_{10-2.5}$ and increased risk of mortality and concluded that the evidence was too limited to adequately characterize the associations for $PM_{10-2.5}$. The findings from the AHSMOG (Chen et al., 2005) and Veterans (Lipfert et al., 2006) cohort studies provided limited evidence for associations between long-term exposure to $PM_{10-2.5}$ and mortality in areas with mean concentrations in the range of 16 to 25 μg/m^3. Overall, the evidence was determined to be inadequate to determine if a causal relationship exists between long-term exposure to $PM_{10-2.5}$ and mortality (See Section 7.6 of the 2009 PM ISA). Recent studies published since the completion of the 2009 PM ISA are characterized in Table A.1.

Recent Mortality Studies

Since the completion of the 2009 PM ISA, Puett et al. (2009) examined the relationship of long-term exposure to $PM_{10-2.5}$ with all-cause and CHD mortality among women from the Nurses' Health Study. The authors did not find an association between $PM_{10-2.5}$ and the risk of all-cause mortality (HR 1.03 [95% CI: 0.89, 1.18]). The association between $PM_{10-2.5}$ and CHD mortality was positive, but not statistically significant (HR: 1.14 [95% CI: 0.73, 1.77]). More recently, Puett et al. (2011) used the same spatiotemporal exposure estimation models to characterize the association between $PM_{10-2.5}$ and mortality among male subjects in the Health Professionals Follow-up Study. In this cohort, long-term exposure to $PM_{10-2.5}$ was not associated with all-cause or CHD mortality.

In summary, two new studies (Puett et al., 2011; Puett et al., 2009) evaluated the association between long-term exposure to $PM_{10-2.5}$ and mortality. The long-term mean $PM_{10-2.5}$ concentrations reported in these studies were lower than those reported in the 2009 PM ISA (7.7 and 10.1µg/m^3, respectively). These studies do not provide any additional evidence for an association between long-term exposure to $PM_{10-2.5}$ and mortality that would be sufficient to materially change conclusions made in the 2009 PM ISA.

2.1.2. Morbidity – Cardiovascular Effects

Summary of 2009 PM ISA Conclusions

The 2009 PM ISA concluded that "the evidence from epidemiologic and toxicological studies is sufficient to conclude that a causal relationship exists between long-term exposures to $PM_{2.5}$ and cardiovascular effects." The strongest evidence was provided by large, multicity, U.S.-based studies of cardiovascular mortality (See Section 7.2.10 of the 2009 PM ISA) with supporting evidence from a U.S.-based epidemiologic study (Miller et al. (2007)) that reported associations between $PM_{2.5}$ and incident stroke and myocardial infarction (MI) among post-menopausal women at mean $PM_{2.5}$ concentrations of 13.5 µg/m^3.[4]

Recent Cardiovascular Morbidity Studies

Several new studies of long-term exposure to $PM_{2.5}$ and cardiovascular disease were conducted since the completion of the 2009 PM ISA. In a study of male subjects enrolled in the Health Professionals Follow-Up Study, Puett et al. (2011) used spatiotemporal models to estimate exposure to $PM_{2.5}$ by combining data from available air monitoring networks with geographic information system (GIS) derived variables such as distance to roadway and elevation. The authors reported no association between long-term $PM_{2.5}$ and total CVD or ischemic stroke; however, in fully adjusted models (i.e. adjusted for covariates including body mass index (BMI), hypertension, hypercholesterolemia, diabetes, family history of MI, smoking physical activity, diet) elevated HRs for non-fatal MI and hemorrhagic stroke were observed (HR: 1.16 [95% CI: 0.81, 1.64] and 1.69 [95%CI: 0.59, 3.71])[5]. Associations of $PM_{2.5}$ with all-cause mortality and fatal CHD were not observed in this all male cohort. A cross-sectional study of male and female patients attending a pulmonary clinic after reporting respiratory complaints reported no associations of long-term $PM_{2.5}$ exposure with prevalent IHD, although an association with nitrogen dioxide (NO_2) was reported (Beckerman et al., 2012). Interactions among exposures, risk factors and potential confounders were tested and no statistically significant effect modifiers

[4] Listed as 12.9 µg/m^3 for the reasons stated in Federal Register Notice of EPA's proposed rule on the PM NAAQS (77 FR 38934 n. 82).
[5] All effect estimates for associations between long-term exposure to $PM_{2.5}$ and cardiovascular morbidity are presented for a 10 µg/m^3 increase in $PM_{2.5}$ concentration.

were identified. A study using satellite derived aerosol optical depth (AOD) measurements to predict $PM_{2.5}$ concentrations, reported a 3.12% (95% CI: 0.30, 4.29) increase in cardiovascular hospital admission among older adults for an increase in long-term $PM_{2.5}$ exposure (Kloog et al., 2012a). A similar increase in risk was reported for stroke hospital admissions (3.49 [95% CI: 0.09, 5.18]).

The stronger evidence linking long-term $PM_{2.5}$ exposure with cardiovascular disease was apparent in studies of women as originally demonstrated in the 2009 PM ISA. In a study of female teachers residing in California, Lipsett et al. (2011) used concentration data from 1999-2000 and applied inverse distance weighted interpolation techniques to develop monthly $PM_{2.5}$ concentration surfaces from ambient monitor data. This study reported an increased risk for incident stroke (HR: 1.15 95% CI 1.00-1.33), which was highest among post-menopausal women, but no association between $PM_{2.5}$ and incident MI (HR: 0.99 95% CI 0.84-1.15). This study supports the findings of Miller et al. (2007) linking incident stroke to long-term $PM_{2.5}$ exposure among post-menopausal women; however, they also reported an association with incident MI. Coogan et al. (2012) followed African American women who ranged in age from 21 to 69 years at enrollment in the Black Women's Health Study for 10 years to investigate incident hypertension and diabetes in association with long-term exposure to $PM_{2.5}$. $PM_{2.5}$ concentrations were spatially interpolated using monitoring data from state and local stations in the Los Angeles basin for the year 2000. This study reported an increased risk of incident hypertension (IRR: 1.48 95%CI: 0.95-2.31) . This risk was attenuated, but remained positive in a copollutant model containing NO_2 (IRR: 1.32 95%CI: 0.84-2.05).

Several studies have been published from the Multi-Ethnic Study of Atherosclerosis (MESA) that was designed to inform on mechanistic pathways by which $PM_{2.5}$ exposure may act on the cardiovascular system. Long-term $PM_{2.5}$ exposure was associated with increased prevalent QT prolongation (OR: 1.6 95% CI: 1.2-2.2) and intraventricular conduction delay (OR: 1.7 95% CI 1.0-2.6) (Van Hee et al., 2011). In addition, both long- and short-term $PM_{2.5}$ exposure was associated with a narrowing of retinal vessel diameter (Adar et al., 2010). Reductions in flow-mediated dilation have been observed in association with short-term exposures to $PM_{2.5}$ (See Section 6.2.4 of the PM ISA); however, O'Neill et al. (2011) found no association of long-term $PM_{2.5}$ exposure with chronic arterial stiffness.

Generally, the results of recent studies are consistent with the evidence for an association between long-term exposure to $PM_{2.5}$ and cardiovascular morbidity characterized in the 2009 PM ISA. Findings on incident stroke reported by Miller et al (2007) in a cohort of post-menopausal women are supported by a new study of female teachers (Lipsett et al., 2011), while a recent study of black women reports an association between $PM_{2.5}$ and incident hypertension (Coogan et al., 2012) at long-term mean $PM_{2.5}$ concentrations ranging from 15.6 – 21.5 $\mu g/m^3$ (Table A.3).

2.1.3. Morbidity – Respiratory Effects

Summary of 2009 PM ISA Conclusions

The epidemiologic evidence reviewed in the 2009 PM ISA demonstrated associations between long-term exposure to $PM_{2.5}$ and decrements in lung function growth, increased respiratory symptoms, and asthma development in study locations with mean $PM_{2.5}$ concentrations ranging from 13.8 to 30 $\mu g/m^3$ during the study periods (See Sections 7.3.1.1 and 7.3.2.1 of the 2009 PM ISA). These studies contributed to a body of evidence that was sufficient to conclude that "a causal relationship is likely to exist between long-term exposures to $PM_{2.5}$ and respiratory effects."

Recent Respiratory Morbidity Studies

Since the completion of the 2009 PM ISA, a number of studies have been published that examine the association between long-term exposure to $PM_{2.5}$ and respiratory outcomes (Table A.4). These recent studies are consistent with the associations observed for respiratory outcomes reported in the 2009 PM ISA and provide additional evidence for associations between long-term exposure to $PM_{2.5}$ and respiratory symptoms and asthma development. For example, in a recent prospective community intervention study in Libby, MT (Noonan et al., 2012) ambient $PM_{2.5}$ concentrations decreased by 26.7% over four winters following the replacement of over 1,100 wood stoves in the community with new lower emission wood stoves or other heating sources. This decrease in $PM_{2.5}$ concentrations was associated with decreases in reported wheeze and respiratory infections (including colds, bronchitis, influenza and throat infection) among school children. These results suggest that beneficial health impacts are associated with decreases in ambient $PM_{2.5}$ concentrations.

A number of other studies evaluated the association between long-term exposure to $PM_{2.5}$ and respiratory symptoms. Several nationwide U.S. studies that used data from the National Health Interview Survey reported associations between long-term exposure to $PM_{2.5}$ and respiratory symptoms among children (including respiratory allergy/hay fever (Parker et al., 2009), and respiratory allergy and frequent ear infections (Bhattacharyya and Shapiro, 2010) and adults (including asthma among African-Americans (Nachman and Parker, 2012); sinusitis (Nachman and Parker, 2012; Bhattacharyya, 2009); and hay fever (Bhattacharyya, 2009). Meng et al. (2010) examined long-term exposure to $PM_{2.5}$ in the San Joaquin Valley of California and weekly asthma symptoms among participants with physician-diagnosed asthma. They observed associations between annual average concentrations of $PM_{2.5}$ and frequent asthma symptoms. In a study conducted in New York City, Patel et al. (2009) examined long-term exposure to $PM_{2.5}$ and respiratory symptoms in children through 24 months of age. Long-term exposure to $PM_{2.5}$ was not associated with wheeze or cough in this study, though several $PM_{2.5}$ constituents were associated with wheeze and/or cough (see Section 2.4.2 for results on $PM_{2.5}$ constituents).

A substantial body of evidence exists that has evaluated short-term exposure to $PM_{2.5}$ and emergency department visits and hospitalizations for respiratory causes (See Section 2.2.2.1).

Several recent studies have evaluated the association between long-term exposure to $PM_{2.5}$ and respiratory hospitalizations. Karr et al. (2009a; 2009b) examined exposure to $PM_{2.5}$ averaged over an infant's lifetime (0-12 months) and did not observe an association between $PM_{2.5}$ and bronchiolitis hospitalizations in the Puget Sound Region of Washington (Karr et al., 2009a) or in the Georgia Air Basin of British Columbia, Canada (Karr et al., 2009b). Kloog et al. (2012a) investigated hospital admissions for all respiratory causes among residents of New England 65 years of age and older. The authors observed a 4.22% (95% CI 1.06, 4.75)[6] increase in respiratory hospital admissions associated with long-term $PM_{2.5}$ concentrations. Similarly, Neupane et al. (2010) restricted their analyses of pneumonia hospitalizations to those 65 years of age and older and found that long-term exposure to $PM_{2.5}$ was associated with hospitalization for community-acquired pneumonia (OR 13.64, 95% CI: 1.79, 101.01). Meng et al. (2010) examined long-term exposure to $PM_{2.5}$ in the San Joaquin Valley of California and asthma-related emergency department visits or hospitalizations (analyzed together) among participants with physician-diagnosed asthma. They observed associations between annual average concentrations of $PM_{2.5}$ and emergency department visits and hospitalizations.

The 2009 PM ISA identified a number of prospective cohort studies that provided evidence of an association between long-term exposure to $PM_{2.5}$ and the development of asthma. Recent studies contribute to this weight of evidence, reporting results that are consistent with those summarized in the 2009 PM ISA. Akinbami et al. (2010) conducted a nationwide U.S. study with data on children (ages 3-17 years) from the National Health Interview Survey and observed a positive association between county-wide annual average $PM_{2.5}$ concentration and current asthma (OR 1.43, 95% CI: 0.98, 2.10 comparing highest quartile of exposure to lowest) and/or a recent asthma attack (OR 1.30, 95% CI: 0.89, 1.90 comparing highest quartile of exposure to lowest). Two studies examining the relationship between long-term exposure to $PM_{2.5}$ and incident asthma were conducted in British Columbia, Canada. Carlsten et al. (2011) evaluated birth year exposure to $PM_{2.5}$ and physician-diagnosed asthma at age 7 and observed an association with an increased risk of incident asthma. Similarly, Clark et al. (2010) assigned exposure based on average $PM_{2.5}$ concentration during the first week of life and the association with incident asthma between ages 3 and 4. The authors did not observe an association between $PM_{2.5}$ and incident asthma. McConnell et al. (2010) characterized the relationship between childhood incident asthma and long-term exposure to $PM_{2.5}$ among the Southern California Children's Health Study participants. In this cohort, asthma-free kindergarten and first-grade children were followed up for three years and the authors observed a positive association (HR 1.34, 95% CI: 0.95, 1.90), though this association was diminished when the authors adjusted for traffic related pollution concentrations measured near the child's home and school.

In summary, the results of recent studies generally continue to demonstrate an association between long-term exposure to $PM_{2.5}$ and respiratory morbidity. Recent epidemiologic studies

[6] All effect estimates for associations between long-term exposure to $PM_{2.5}$ and respiratory morbidity are presented for a 10 $\mu g/m^3$ increase in $PM_{2.5}$ concentration.

reported associations with respiratory symptoms and respiratory hospitalizations. New findings on incident asthma among children are consistently positive, though not statistically significant. These recent studies demonstrate associations at long-term mean $PM_{2.5}$ concentrations ranging from 9.7 to 27 µg/m^3 (Table A.4).

2.1.4. Morbidity – Reproductive and Developmental Effects

Summary of 2009 PM ISA Conclusions

The 2009 PM ISA synthesized the epidemiologic literature characterizing the association between long-term exposure to $PM_{2.5}$ and increased risk of reproductive and developmental effects and concluded that the evidence was suggestive of a causal relationship between long-term exposure to $PM_{2.5}$ and reproductive and developmental outcomes (See Section 7.4 of the 2009 PM ISA). The strongest evidence was for reduced birth weight and infant mortality, especially due to respiratory causes during the post-neonatal period. The mean $PM_{2.5}$ concentrations during the study periods ranged from 5.3 – 27.4 µg/m^3, with effects becoming more precise and consistently positive in locations with mean $PM_{2.5}$ concentrations of 15 µg/m^3 and above. The epidemiologic literature did not consistently report associations between long-term exposure to $PM_{2.5}$ and preterm birth, growth restriction, birth defects or decreased sperm quality.

Recent Reproductive and Developmental Outcome Studies

Since the completion of the 2009 PM ISA, a number of studies have been published that examine the association between long-term exposure to $PM_{2.5}$ and reproductive and developmental outcomes (Table A.5). These recent studies are consistent with the associations observed for reproductive and developmental outcomes reported in the 2009 PM ISA, within similar concentrations (long-term mean $PM_{2.5}$ concentrations ranging from 11.0 – 19.8 µg/m^3), and provide additional evidence for associations between long-term exposure to $PM_{2.5}$ and reduced birth weight (Ghosh et al., 2012; Kloog et al., 2012b; Kumar, 2012; Darrow et al., 2011b; Bell et al., 2010; Morello-Frosch et al., 2010; Salihu et al., In Press). Recent evidence remains inconsistent for the association between exposure to $PM_{2.5}$ and preterm birth, with some studies providing evidence for an association (Chang et al., 2012b; Wu et al., 2009), while others did not (Rudra et al., 2011; Darrow et al., 2009).

2.2. Epidemiologic Studies of Short-Term Exposure

The 2009 PM ISA included the results of many new epidemiologic studies reporting associations between short-term exposure to PM and a range of health outcomes. The epidemiologic evidence evaluated in the ISA contributed to the determination that there is sufficient evidence to conclude that "a causal relationship exists" between short-term $PM_{2.5}$ exposure and cardiovascular effects and mortality, and a "likely to be causal relationship exists" between short-term $PM_{2.5}$ exposure and respiratory effects (Chapter 2, 2009 PM ISA). Additionally, the epidemiologic evidence contributed to a “suggestive” causal determination for short-term $PM_{10-2.5}$ exposure and cardiovascular and respiratory effects, and mortality (Chapter 2, 2009 PM ISA).

Sections 2.2.1 and 2.2.2 highlight results from recent epidemiologic studies. Tables A.6 through A.11 (Appendix A) summarize results of recent epidemiologic studies that evaluated relationships between health effects and short-term exposure to $PM_{2.5}$ and $PM_{10-2.5}$.

The 2009 PM ISA included a particular focus on results of multicity studies due to their evaluation of a wide range of PM exposures and large numbers of observations, which lead to generally more precise effects estimates than most smaller scale studies of single cities. The multicity studies also allowed investigation of homogeneity or heterogeneity of PM health relationships, evaluation of confounding by co-pollutants across communities with different air pollution mixtures, and assessment of potential effect modifiers. Since the completion of the 2009 PM ISA, numerous multicity analyses have been published that evaluate morbidity outcomes.

2.2.1. Mortality

Summary of 2009 PM ISA Conclusions

Overall, in the evaluation of multi- and single-city studies in the 2009 PM ISA and in the 2004 PM Air Quality Criteria Document (AQCD) (U.S. EPA, 2004) consistent positive associations were observed at mean 24-h average[7] $PM_{2.5}$ concentrations above 12.8 µg/m^3. This collective evidence contributed to the conclusion that “a causal relationship exists between short-term $PM_{2.5}$ exposure and mortality.” Building on the evidence presented in the 2004 PM AQCD (U.S. EPA, 2004), multi- and single-city studies evaluated in the 2009 PM ISA reported consistent positive associations between short-term $PM_{10-2.5}$ exposure and mortality (Section 6.5.2.3, 2009 PM ISA).

Recent Mortality Studies

Several recent studies evaluated the effects of short-term exposure to $PM_{2.5}$ on mortality in single city analyses. No new multi-city studies have been published. Additionally, no new studies have been published that examined associations between short-term $PM_{10-2.5}$ exposure and mortality in the U.S. or Canada.

New studies have continued to report associations between $PM_{2.5}$ and mortality that are consistent with the conclusions of the 2009 PM ISA as shown in Figure 2.4. Two of these studies were conducted in New York City. Ito et al. (2011a) examined the relationship between short-term exposure to $PM_{2.5}$ and PM components and cardiovascular disease (CVD) mortality for the population ≥ 40 years old in New York City for the years 2000-2006. $PM_{2.5}$ was associated with CVD mortality at lag 1 in the all-year and cold season (October-March) analyses, but the strongest association with CVD mortality was observed during the warm season (April-

[7] For short-term exposure studies the mean 24-h avg $PM_{2.5}$ concentration refers to the mean of all daily 24-h avg PM2.5 concentrations over the course of the study duration.

September) at lag 0 and 1. Also in New York City, Chang et al. (2012a) used a novel approach to examine the relationship between short-term exposure to $PM_{2.5}$ concentrations and cardiorespiratory mortality. The authors used a spatio-temporal deterministic model that was bias-corrected with monitoring data to predict daily $PM_{2.5}$ concentrations. The authors developed a statistical model to consider personal exposure to $PM_{2.5}$ from outdoor sources to improve exposure assessment. Using data from 2001-2005, positive associations were observed for those greater than 65 years old. The model that accounted for personal exposure found a higher risk of mortality (2.32% [95% CI: 0.68, 3.94] at lag 1)[8] compared to a model that used only $PM_{2.5}$ concentrations (1.13% [95% CI: 0.27, 2.00]) suggesting that risk estimates derived using ambient concentrations as a proxy for exposure are biased towards the null.

Additional single-city analyses were conducted in Seattle, Detroit, and Atlanta. Zhou et al. (2011) conducted a study using daily $PM_{2.5}$ data collected in Seattle and Detroit to examine the effect of short-term $PM_{2.5}$ exposure on all-cause, cardiovascular, and respiratory mortality for the years 2002-2004. In a distributed lag model of 0-2 days, a strong association was observed between $PM_{2.5}$ and all-cause and cardiovascular mortality, with some evidence of an association with respiratory mortality in Detroit during the warm season (April-September) (quantitative results not presented). There was no evidence of an association with $PM_{2.5}$ and any mortality outcome in Seattle in the warm season. In the cold season (October-March), the strongest associations were for all-cause and cardiovascular mortality in Seattle, while there was no evidence of an association between $PM_{2.5}$ and any mortality outcome in Detroit. Interestingly the magnitude of the cardiovascular mortality association in Seattle in the cold season is larger than that in Detroit in the warm season even though mean $PM_{2.5}$ concentrations are lower, 11.4 $\mu g/m^3$ and 14.9 $\mu g/m^3$, respectively. Klemm et al. (2011) conducted an extended analysis of two previously published studies (Klemm et al., 2004; Klemm and Mason, 2000) that examined the effect of air pollution on mortality in Atlanta, GA. This analysis included an additional 7.5 years of data and expanded the study location to include two additional counties. Focusing on deaths in individuals 65 years of age and older, the authors found a positive association between short-term $PM_{2.5}$ exposure and nonaccidental (0.78% [95% CI: -0.43, 2.0]; lag 0-1 for a 10 $\mu g/m^3$ increase in 24-h avg $PM_{2.5}$ concentrations) and cardiovascular mortality (0.83% [95% CI: -1.1, 2.8]), but no evidence of an association with respiratory mortality (-0.86% [95% CI: -4.4, 2.8]).

In summary, multi- and single-city studies evaluated in the 2009 PM ISA provided evidence of consistent positive associations between short-term $PM_{2.5}$ exposure and nonaccidental, cardiovascular, and respiratory mortality. Relatively few mortality studies have been published in the U.S. and Canada since the completion of the 2009 PM ISA and they are limited to single-city studies. These studies continue to demonstrate evidence of positive associations between short-term $PM_{2.5}$ exposures and mortality in the same range of concentrations as those studies

[8] All effect estimates for associations between short-term exposure to $PM_{2.5}$ and mortality are presented for a 10 $\mu g/m^3$ increase in $PM_{2.5}$ concentration.

included in the 2009 PM ISA (i.e., mean 24-h avg concentrations of 12.8 $\mu g/m^3$ and above in the multi-city studies).

Study	Location	Age	Lag	Mean	98^{th}
Nonaccidental					
Tsai et al. (2000)	Newark, NJ	All	0	42.1	---
Tsai et al. (2000)	Camden, NJ	All	0	39.9	---
Tsai et al. (2000)	Elizabeth, NJ	All	0	37.1	---
Moolgavkar (2003)	Los Angeles, CA	All	1	22.0*	---
Ostro et al. (2006)	9 California counties	All	0-1	19.9	
Klemm et al. (2004)	Atlanta, GA	65+	0-1	19.6	---
Ito (2003)	Detroit, MI	All	3	18.0	---
Klemm et al. (2011)	Atlanta, GA	65+	0-1	17.0	---
Franklin et al. (2007)	27 U.S. cities	All	1	15.6	45.8
Franklin et al. (2008)	25 U.S. cities	All	0-1	14.8	43.0
Klemm and Mason (2003)	6 U.S. Cities	All	0-1	14.7	---
Fairley (2003)	Santa Clara County, CA	All	0	13.6	59.0
Burnett and Goldberg (2003)	8 Canadian Cities	All	1	13.3	38.9
Zanobetti and Schwartz (2009)	112 U.S. cities	All	0-1	13.2	34.3
Burnett et al. (2004)	12 Canadian cities	All	1	12.8	38.0
Slaughter et al. (2005)	Spokane, WA	All	1	10.8	29.6
Villeneuve et al. (2003)	Vancouver, CAN	65+	0	7.9	---
Chock et al. (2000)	Pittsburgh, PA	< 75	0	---	---
Chock et al. (2000)	Pittsburgh, PA	75+	0	---	---
Dominici et al. (2007a)	100 U.S. cities	All	1	---	---
Cardio-respiratory					
Tsai et al. (2000)	Newark, NJ	All	0	42.1	---
Tsai et al. (2000)	Camden, NJ	All	0	39.9	---
Tsai et al. (2000)	Elizabeth, NJ	All	0	37.1	---
Dominici et al. (2007)	100 U.S. cities	All	1	---	---
Chang et al. (2012)	New York, NY	65+	1	13.3-17.5	---
Cardiovascular					
Ostro et al. (1995)	Southern California	All	0	32.5	---
Moolgavkar (2003)	Los Angeles, CA	All	1	22.0*	---
Ostro et al. (2006)	9 California counties	All	0-1	19.9	---
Ostro et al. (2007)	9 California counties	All	3	18.4	---
Ito (2003)	Detroit, MI	All	1	18.0	---
Lipfert et al. (2000)	Philadelphia, PA	All	1	17.3	---
Klemm et al. (2011)	Atlanta, GA	65+	0-1	17.0	---
Holloman et al. (2004)	7 NC counties	> 16	0	~15.6	---
Franklin et al. (2007)	27 U.S. cities	All	1	15.6	45.8
Franklin et al. (2008)	25 U.S. cities	All	0-1	14.8	43.0
Klemm and Mason (2003)	6 U.S. Cities	All	0-1	14.7	---
Ito et al. (2011)	New York, NY	40+	1	14.4	---
Zanobetti and Schwartz (2009)	112 U.S. cities	All	0-1	13.2	34.3
Mar et al. (2003)	Phoenix, AZ	All	1	13.0	---
Fairley (2003)	Santa Clara County, CA	All	0	13.0	25-88
Wilson et al. (2007)	Phoenix, AZ	> 25	0-5	13.0	31.6
Villeneuve et al. (2003)	Vancouver, CAN	65+	0	7.9	---
Respiratory					
Ostro et al. (1995)	Southern California	All	0	32.5	---
Moolgavkar (2003)	Los Angeles, CA	All	1	22.0*	---
Ostro et al. (2006)	9 California counties	All	0-1	19.9	---
Ito (2003)	Detroit, MI	All	0	18.0	---
Klemm et al. (2011)	Atlanta, GA	65+	0-1	17.0	---
Franklin et al. (2007)	27 U.S. cities	All	0-1	15.6	45.8
Franklin et al. (2008)	25 U.S. cities	All	1-2	14.8	43.0
Klemm and Mason (2003)	6 U.S. Cities	All	0-1	14.7	---
Zanobetti and Schwartz (2009)	112 U.S. cities	All	0-1	13.2	34.3
Fairley (2003)	Santa Clara County, CA	All	0	13.0	---
Villeneuve et al. (2003)	Vancouver, CAN	65+	0	7.9	---

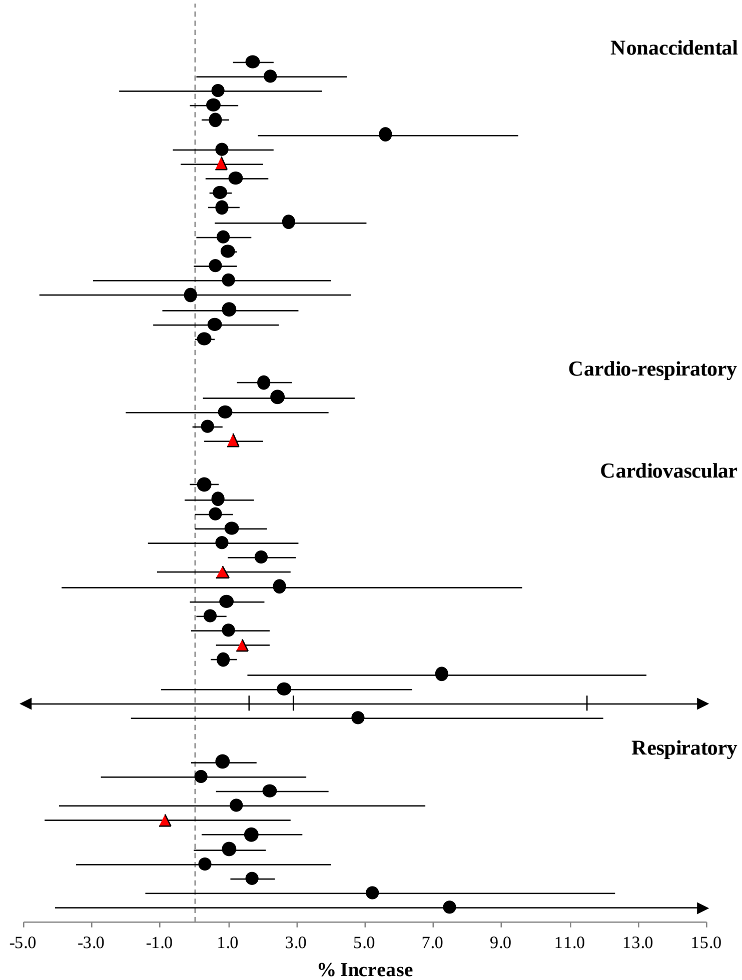

Figure 2.4. Percent increase in non-accidental and cause-specific mortality for a 10 µg/m3 increase in 24-h average $PM_{2.5}$ concentrations in single-pollutant models from U.S. and Canadian studies. Red text and triangles represent recent studies published since the completion of the 2009 PM ISA. Results presented from single-pollutant models for purposes of comparing results across studies that included different mixes of copollutants.

2.2.2. Morbidity

2.2.2.1. Associations between Short-Term Exposures to PM and Respiratory Morbidity

Summary of 2009 PM ISA Conclusions

The association between short-term $PM_{2.5}$ exposure and respiratory-related emergency department (ED) visits, hospital admissions, and physician visits was evaluated in Section 6.3.8 of the 2009 PM ISA (U.S. EPA, 2009). The numerous multi- and single-city studies evaluated reported consistent positive associations with respiratory ED visits and hospital admissions for COPD, asthma, and respiratory infection in study areas with mean 24-h average $PM_{2.5}$ concentrations ranging from 6.1 – 22 $\mu g/m^3$. However, associations for asthma were imprecise and not consistently positive when limiting analyses to children. The evidence from respiratory-related emergency department (ED) visits, hospital admissions, and physician visits studies contributed to the conclusion that a "causal relationship is likely to exist between short-term exposures to $PM_{2.5}$ and respiratory effects."

Additional epidemiologic studies evaluated in the 2009 PM ISA examined associations between short-term $PM_{10\text{-}2.5}$ exposure and respiratory hospital admissions and ED visits. This limited number of studies demonstrated consistent positive associations with respiratory-related hospital admissions and ED visits with the strongest evidence in children. The evidence from these studies in combination with the evidence from toxicological and controlled human exposure studies led to the conclusion that the collective evidence across disciplines "is suggestive of a causal relationship between short-term exposures to $PM_{10\text{-}2.5}$ and respiratory effects."

Recent Respiratory Hospital Admission Studies

Within this section, respiratory-related hospital admissions and ED visit studies are discussed separately. This is because ED visits for respiratory-related outcomes often represent less serious, but more common health effects. Additionally, only a small percentage of respiratory-related ED visits result in a hospital admission. Therefore, it is important to discuss the evidence for each respiratory-related health outcome separately.

Respiratory-related Hospital Admissions

A number of studies published since the completion of the 2009 PM ISA conducted multicity or multi-location analyses to examine the association between short-term $PM_{2.5}$ exposures and respiratory hospital admissions. Figure 2.5 summarizes the evidence from single-pollutant models from studies evaluated in the 2009 PM ISA as well as recent studies published since its completion. Bell et al. (2012) represented a consolidated and more detailed account of a number of previous publications, of which most were discussed in the 2009 PM ISA (Bell et al., 2009a; Bell et al., 2009b; Bell et al., 2008; Bell et al., 2007). In an all-year analysis of 187 U.S. counties, short-term exposure to $PM_{2.5}$ was positively associated with respiratory hospital admissions in individuals 65 years of age and older across lags of 0 to 2 days, with the strongest association at lag 2 (0.41% [95% CI: 0.09, 0.74])[9]. In seasonal analyses, the association at lag 2 was consistently positive across seasons, but the strongest association was at lag 0 (1.05% [95% CI: 0.29, 1.82]) in the winter season with the largest magnitude of an effect in the Northeast region. Of note the Northeast region comprised 53% of all counties included in the analysis. In an additional analysis using this data (Bell et al., 2009a), there was no evidence of a reduction in the association between $PM_{2.5}$ and respiratory hospital admissions when accounting for air conditioning use. In a multi-city study conducted in the New England region of the U.S., Kloog et al. (2012a) examined associations between short-term $PM_{2.5}$ exposure and respiratory hospital admissions in individuals 65 years of age and older. To estimate exposure the authors developed a novel prediction model that combined land use regression with physical measurements from satellite aerosol optical depth. The authors observed a 0.70% (95% CI: 0.35, 1.05) increase in respiratory hospital admissions for lags days 0-1. The results obtained using the novel approach presented (i.e., 0.70% increase in respiratory hospital admissions) were consistent with the percent increase in respiratory hospital admissions observed in a traditional time-series analysis (i.e., 1.51%).

In addition to the multicity studies presented above, a few single city studies were conducted in the U.S. that examined asthma and acute bronchitis. Silverman and Ito (2010) conducted a study to evaluate the effect of short-term $PM_{2.5}$ and O_3 exposure on asthma hospital admissions, both general and those that required a stay in the intensive care unit (ICU) in New York City. Analyses focused on four age groups (i.e., <6, 6-18, 19-49, and 50+) and were limited to the warm season (April-August). Positive associations were observed for each age group and for all ages combined when considering general asthma hospital admissions, with the strongest association for the age group 6-18 (15.5% [95% CI: 9.1, 22.0] at lag 0-1). When limiting the analysis to ICU asthma admissions, again the strongest association was for the age group 6-18 (21.1% [95% CI: 8.3, 35.5]). The observed associations remained robust in copollutant models with O_3. The authors also examined the shape of the concentration-response (C-R) relationship using linear, smooth functions, which allowed for a possible nonlinear relationship. This analysis found evidence that the linear fit is a reasonable approximation of the relationship between short-term $PM_{2.5}$ concentrations and asthma hospital admissions. Grineski et al. (2011) primarily focused on examining the effect of dust and low wind events on asthma and acute bronchitis hospital admissions in El Paso, TX; however, since daily $PM_{2.5}$ data were available the authors also examined associations between short-term $PM_{2.5}$ exposures and each respiratory health effect. The authors found that $PM_{2.5}$ was positively, but weakly associated with asthma (OR=1.02 [95% CI: 0.96, 1.09]) and acute bronchitis (OR=1.01 [95% CI: 0.92, 1.12]) hospital admissions.

[9] All effect estimates for associations between short-term exposure to $PM_{2.5}$ and morbidity are presented for a 10 $\mu g/m^3$ increase in $PM_{2.5}$ concentration.

Recent Respiratory-related ED Visits Studies

Of the recent studies identified that focused on short-term exposures to $PM_{2.5}$ and respiratory-related ED visits the majority consisted of single-city studies. However, a couple large, multi-city studies were conducted in the U.S. and Canada. Zanobetti et al. (2009) examined the association between short-term $PM_{2.5}$ exposure and respiratory ED visits in individuals 65 years of age and older in 26 U.S. communities. In an all-year analysis, $PM_{2.5}$ was strongly associated with respiratory ED visits (2.1 [95% CI: 1.2, 3.0] at lag 0-1), while in seasonal analyses positive associations were observed across seasons with the strongest association in the spring (4.3% [95% CI: 2.2, 6.5]). Stieb at al. (2009) conducted a study in 7 Canadian cities to examine the effect of air pollution on ED visits for multiple respiratory-related health outcomes including asthma, COPD, and respiratory infection. The authors found no evidence of an association between short-term $PM_{2.5}$ exposure and COPD ED visits at any of the single-day lags examined. In all-year analyses, positive associations were observed for asthma with the magnitude of the association decreasing as lag day increased (i.e., the strongest association was observed at lag 0, 2.1% [95% CI: -3.0, 7.5]). However, in a warm season analysis (April-September), the magnitude of the association between $PM_{2.5}$ and asthma was nearly 4 times higher (9.3% [95% CI: 6.3, 12.5]).

A couple of single city studies were also conducted that examined all respiratory, multiple respiratory effects, or asthma ED visits. Darrow et al. (2011a) examined the association between short-term air pollution exposure and respiratory ED visits in Atlanta using various exposure metrics (i.e., 1-h max, 24-h avg, Commute (0700-1000, 1600-1900 hours), Day-time (0800-1900 hours), and Night-time (2400-0600 hours). $PM_{2.5}$ (lag 1) was positively associated with respiratory ED visits across exposure metrics, with the magnitude ranging from 0.2% to 0.4%. Kim et al. (2011) examined the associations between short-term $PM_{2.5}$ exposure and hospital admissions in Denver, CO. The authors found no evidence of an association with all respiratory (-0.44% [95% CI: -5.6, 5.4]), COPD or pneumonia hospital admissions (quantitative results only presented for all respiratory). However, there was evidence of a delayed effect of $PM_{2.5}$ on asthma hospital admissions with effects not occurring until approximately lag day 4.

A number of studies focused on ED visits and hospital admissions for asthma. Strickland et al. (2010)conducted an analysis in Atlanta using the same air quality data as Darrow et al. (2011a) to examine the association between air pollution and pediatric (ages 5-17) asthma ED visits. $PM_{2.5}$ was strongly associated with pediatric asthma ED visits in both all-year (2.2% [95% CI: 0.2, 4.2] at lag 0-2) and warm season (4.7% [95% CI: 1.7, 7.6]) analyses. The magnitude of the association was robust to the inclusion of O_3 in the model. An examination of the C-R relationship through a quintile analysis and a loess C-R analysis using lag 0-2 day $PM_{2.5}$ concentrations found evidence of increased risk of pediatric asthma ED visits down to relatively low ambient concentrations (i.e., mean 24-h avg concentrations < 14 $\mu g/m^3$). In Tacoma, WA, Mar et al. (2010) also examined the association between short-term $PM_{2.5}$ exposure and asthma ED visits. Individual lag days of 0 to 5 days were examined with the strongest association occurring at lag 2 (5.7% [95% CI: 1.4, 10.1]). Li et al. (2011) examined the C-R relationship between short-term $PM_{2.5}$ exposures and asthma ED visits in children 2 to 18 years of age in Detroit. Associations were examined in both a time-series and time-stratified case-crossover study design assuming: (1) no deviation from linearity and (2) a change in linearity at 12 µg/m^3. In the analyses assuming linearity, similar effect estimates were observed in both models for a 0-4 day lag, (time series: RR=1.03 [95% CI: 1.00, 1.07]; case-crossover: OR=1.04 [95% CI: 1.01, 1.07]). In the models assuming a deviation from linearity at 12 µg/m^3, the authors reported slightly larger effect estimates, compared to the linear model, for asthma ED visits in the time-series (RR=1.07 [95% CI: 1.03, 1.11]; lag 0-4) and case-crossover analyses (OR=1.06 [95% CI: 1.03, 1.09]; lag 0-4), respectively. Glad et al. (2012) conducted a study in Pittsburgh, PA that found $PM_{2.5}$ to be positively associated with asthma ED visits in analyses of all ages and ages 18 to 64 for single lag days and the average of 0-5 days (i.e., all ages: OR=1.04 [95% CI: 0.98, 1.10] and 18 to 64: OR=1.053 [95% CI: 0.99, 1.12] at lag 0-5). Additionally, when stratifying by race there was some evidence for larger effects in African Americans compared to Caucasian Americans.

Study	Location	Age	Lag	Mean	98th
All Respiratory					
Ostro et al. (2009)	6 CA Counties	0-19	3	19.4	---
Peel et al. (2005)	Atlanta, GA	All	0-2	19.2	---
Tolbert et al. (2007)	Atlanta, GA	All	0-2	17.1	---
Darrow et al. (2011)*	Atlanta, GA	All	1	16.0	---
Zanobetti et al. (2009)	26 U.S. communities	65+	0-1	15.3	---
Bell et al. (2008)	202 U.S. counties	65+	2	12.9	34.2
Slaughter et al. (2005)	Spokane	All	1	10.8	29.6
Kloog et al. (2012)	New England	65+	0-1	9.6	---
Kim et al. (2012)	Denver, CO	All	0-14 DL	8.0	---
Fung et al. (2006)	Vancouver	65+	0-2	7.7	---
Chen et al. (2005)	Vancouver	65+	0-2	7.7	---
Asthma					
Peel et al. (2005)*	Atlanta, GA	All	0-2	19.2	---
Ito et al. (2007)*	New York, NY	All	0-1	---	---
Sheppard et al. (2003)	Seattle, WA	All	0	16.7	46.6
Strickland et al. (2010)*	Atlanta, GA	5-17	0-2	16.4	---
NYS DOH (2006)*	Bronx, NY	All	0-4	15.0	---
NYS DOH (2006)*	Manhattan, NY	All	0-4	15.0	---
Li et al. (2011)*	Detroit, MI	2-18	0-4	15.0	---
Glad et al. (2012)*	Pittsburgh, PA	All	0-5	13.3	---
Silverman and Ito (2010)	New York, NY	All	0-1	13.0**	---
Grineski et al. (2011)	El Paso, TX	1+	0-3	12.8	---
Mar et al. (2010)*	Tacoma, WA	All	2	12.3	---
Slaughter et al. (2005)*	Spokane, WA	All	1	10.8	29.6
Stieb et al. (2009)*	7 Canadian cities	All	0	6.7-9.8	---
Chimonas & Gessner (2006)	Anchorage, AK	0-19	0	6.1	---
Bronchitis					
Grineski et al. (2011)	El Paso, TX	1+	0-3	12.8	---
Respiratory Infection					
Peel et al. (2005)*	Atlanta, GA	All	0-3	19.2	---
Dominici et al. (2006)	204 U.S. counties	65+	2	13.3	34.8
Lin et al. (2005)	Ontario, CAN	< 15	0-3	9.6	---
Stieb et al. (2009)*	7 Canadian cities	All	0	6.7-9.8	---
Chimonas & Gessner (2006)	Anchorage, AK	0-19	0	6.1	---

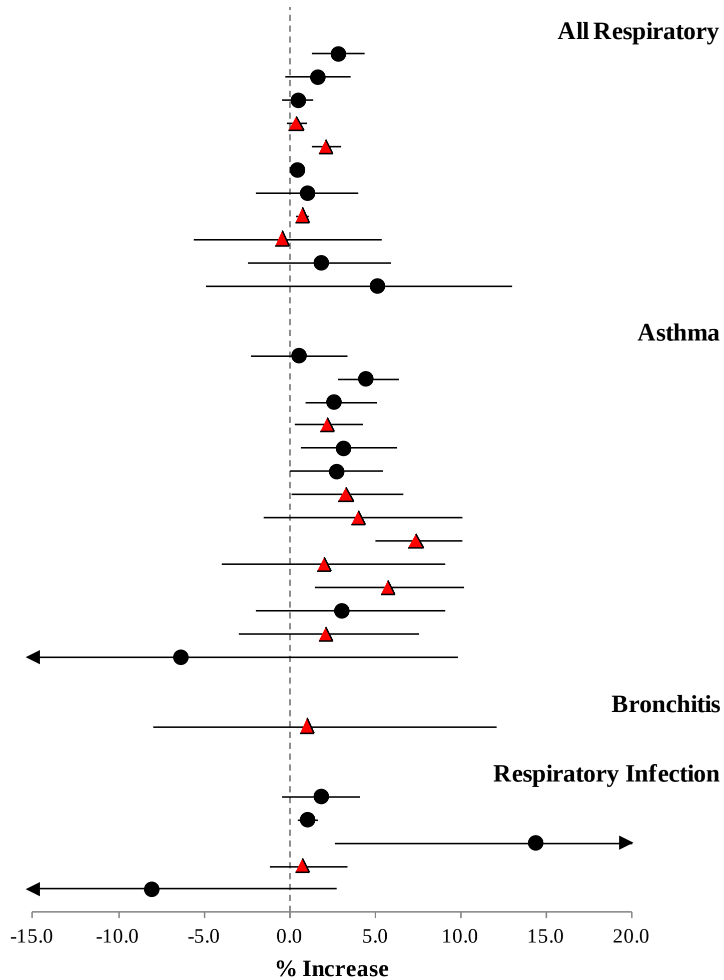

Figure 2.5. Percent (%) Increase in respiratory-related hospital admissions and ED visits for a 10 μg/m^3 increase in 24-h average $PM_{2.5}$ concentrations in single-pollutant models from U.S. and Canadian studies. Red text and triangles represent recent studies published since the completion of the 2009 PM ISA. * ED visit studies. ** Median concentration.

The 2009 PM ISA evaluated a number of multi- and single-city studies that found consistent positive associations with all and cause-specific respiratory hospital admissions and ED visits, specifically COPD and respiratory infections in study areas with mean 24-h $PM_{2.5}$ concentrations ranging from 6.1 – 22.0 $\mu g/m^3$. Additionally, there was evidence for asthma hospital admissions and ED visits, but the effects were not consistent in children. Recent multi- and single-city studies have continued to demonstrate consistent positive associations for all respiratory-related hospital admissions and ED visits, and provide additional evidence for increases in asthma hospital admissions and ED visits. The associations observed in the new studies occur in locations with mean concentrations similar (i.e., mean 24-h avg concentrations ranging from 6.7 – 16.4 $\mu g/m^3$) to those studies included in the 2009 PM ISA.

The 2009 PM ISA also found evidence that associations between short-term $PM_{10-2.5}$ exposures and respiratory-related hospital admissions and ED visits were strongest among children. A recent study by Strickland et al. (2010) that examined the association between short-term $PM_{10-2.5}$ exposure and pediatric asthma ED visits in Atlanta, GA further supports this conclusion. Positive associations were observed in both all-year (5.8% [95% CI: 1.9, 9.9] at lag 0-2) and seasonal analyses, with the strongest association in the cold season (7.0% [95% CI: 1.7, 12.7]). An examination of the C-R relationship in both quintile and smooth estimates of the concentration-response provided evidence of associations at relatively low ambient concentrations for all pollutants, including $PM_{10-2.5}$ (i.e., mean 24-h avg concentrations < ~12 $\mu g/m^3$)..

2.2.2.2. Associations between Short-Term Exposures to PM and Cardiovascular Morbidity

Summary of 2009 PM ISA Conclusions

The associations between short-term $PM_{2.5}$ exposure and cardiovascular-related hospital admissions and ED visits was evaluated in Section 6.2.10 of the 2009 PM ISA (U.S. EPA, 2009). Epidemiologic studies that examined the effect of $PM_{2.5}$ on cardiovascular ED visits and hospital admissions reported consistent positive associations (predominantly for IHD and congestive heart failure [CHF]) in study areas with mean 24-h average concentrations ranging from 7.0 – 18 $\mu g/m^3$. This evidence contributed to the conclusion that "a causal relationship exists between short-term $PM_{2.5}$ exposure and cardiovascular effects."

Epidemiologic studies of the association of short-term $PM_{10-2.5}$ exposure with cardiovascular hospital admissions and ED visits were also evaluated in the 2009 PM ISA, and the evidence from these studies contributed to the conclusion that the evidence "is suggestive of a causal relationship between short-term exposures to $PM_{10-2.5}$ and cardiovascular effects.

Recent Cardiovascular-related Hospital Admissions/ED Visits Studies

Recent multi-city and multi-location studies, as well as single-city studies, add to the collective body of evidence that examined associations between short-term $PM_{2.5}$ exposure and cardiovascular-related hospital admissions and ED visits evaluated in the 2009 PM ISA. Figure

2.6 summarizes the results from single-pollutant models from studies evaluated in the 2009 PM ISA as well as recent studies published since its completion. No new studies have been published that examined the association between short-term $PM_{10-2.5}$ exposure and cardiovascular hospital admissions or ED visits in the U.S. or Canada.

In a recent Health Effects Institute (HEI) report, Bell et al. (2012) compiled findings from several multicity analyses of Medicare data (older adults, ≥ 65 years of age) for 204 counties across the U.S. (some analyses included fewer counties). Although additional detail is provided in the HEI report, these analyses were largely included in the 2009 PM ISA (Bell et al., 2008; Dominici et al., 2006). In an analysis using the same data, Bell et al. (Bell et al., 2009a) found a higher prevalence of central air conditioning was associated with a decrease in the risk of $PM_{2.5}$ -associated hospitalization for cardiovascular disease.

Recent studies are consistent with the evidence assessed in the 2009 PM ISA. In a time-series analysis of Medicare records for older adults ≥65 years of age in 26 US communities for 2000-2003, Zanobetti et al. (2009) reported increases in hospital admissions for all CVD (1.89% 95%CI: 1.34 to 2.45), MI (2.25% 95%CI: 1.10 to 3.42) and CHF (1.85% 95%CI: 1.19 to 2.51; lag 0-1). Although the largest excess risks were observed in the spring, statistically significant excess risks were also observed in the winter. In a time-series analysis of hospital admissions in seven Canadian cities, a 17% (95%CI: 0 to 37%) increase in hospital admissions for heart failure was observed at lag 0 (Stieb et al., 2009). Weak, nonsignificant associations were observed between $PM_{2.5}$ and dysrhythmia and MI hospitalizations.

In a study of emergency hospitalizations among New York City residents ≥ 40 years of age, Ito et al. (2011a) reported an excess risk of 1.0% (95% CI: 0.40, 1.6, lag 0). The excess risk was stronger in the cold season (1.1% [95% CI 0.2 to 2.0]). These results were not sensitive to the choice of method used to control temperature. Using a subset of these emergency hospitalization data, Mathes et al. (2011) defined two cardiovascular syndromes from a database containing text descriptions of the chief complaint reported by the patient upon admission to the hospital. This study reported that $PM_{2.5}$ was associated with both cardiac and more general cardiovascular syndromes. In case-crossover analysis of cardiovascular disease admissions across New York state from 2001 to 2005, Haley et al. (2009) found a 3.9% increase in heart failure admissions per 10 $\mu g/m^3$ increase in $PM_{2.5}$ (lag 0-2). A case-crossover study of atrial fibrillation hospitalizations between 1993 and 2008 in Utah (Wasatch Front) reported consistently positive, but non-significant, associations across all lags examined in the study (lag 0 through 21 day moving average) (quantitative results not provided) (Bunch et al., 2011). Finally, a 1.03% (95% CI: 0.69, 1.34) increase in cardiovascular admissions was reported in a time-series study of hospitalizations across New England among older adults (65 years) with predicted PM2.5 concentrations using satellite-derived AOD measurements (Kloog et al., 2012b).

Acute Stroke

Wellenius et al. (2012) examined the association of $PM_{2.5}$ with neurologist-confirmed ischemic stroke in predominately white female patients admitted to the Beth Israel Deaconess Medical Center (BIDMC) in Boston from 1999 to 2008. Time of stroke symptom onset (exact or estimated) was available for most patients included in the study. The OR of stroke onset was 1.30 (95% CI: 1.08 to 1.58) per 10 $\mu g/m^3$ increase in $PM_{2.5}$ in the previous 24 hours. Authors report a 34% (95% CI: 13 to 58) higher risk of ischemic stroke during the previous 24 hours in an analysis comparing moderate $PM_{2.5}$ exposure ($\geq$15 $\mu g/m^3$) to good (<15 $\mu g/m^3$) exposure, as defined by EPA's Air Quality Index (AQI). These results were confirmed in an additional analysis conducted by Mostofsky et al. (2012) using a subset of the data (i.e., 2003-2008) used by Wellenius et al. (2012). Mostofsky et al. (2012) found a 22.7% (95% CI: 3.1, 47.0) increase in ischemic stroke onset for an increase in $PM_{2.5}$ over the previous 24 hours.

Out of Hospital Cardiac Arrests

The small number of studies of out-of-hospital cardiac arrest included in the 2009 PM ISA reported mixed results. A recent time series analysis of cardiac arrests in New York City reported an increased risk of 1.06 (95%CI 1.02, 1.10, lag 0-1) per 10 µg/m3 increase in $PM_{2.5}$ (Silverman et al., 2010). Case cross-over analysis of the same data produced a result that was similar in magnitude but did not reach statistical significance. The association with cardiac arrest was stronger in the warm season (1.09 95% CI: 1.03-1.15) compared to the cold season (1.01 95% CI 0.95 to 1.07).

In summary, the 2009 PM ISA found consistent positive associations between short-term $PM_{2.5}$ exposures and all and cause-specific cardiovascular hospital admissions and ED visits, specifically IHD and CHF in study areas with mean 24-h $PM_{2.5}$ concentrations ranging from 7.0 – 18.0 $\mu g/m^3$. New multi- and single-city studies further support associations with all cardiovascular hospital admissions and ED visits at mean 24-h $PM_{2.5}$ concentrations ranging from 6.7 – 15.3 $\mu g/m^3$. Additional support for associations between short-term $PM_{2.5}$ exposures and cardiovascular effects comes from a new study of stroke onset (Wellenius et al. (2012)).

Study	Location	Age	Lag	Mean	98th
All CVD					
Metzger et al. (2004)	Atlanta, GA	All	0-2	17.8	---
Tolbert et al. (2007)	Atlanta, GA	All	0-2	17.1	---
Zanobetti et al. (2009)*	26 U.S. Communities	65+	0-1	15.3	---
Ito et al. (2011)	New York, NY	40+	0	14.4	---
Bell et al. (2008)	202 U.S. Counties	65+	0	12.9	34.2
Slaughter et al. (2005)	Spokane, WA	All	1	10.8	29.6
Kloog et al. (2012)	New England	65+	0-1	9.6	---
Kim et al. (2012)	Denver, CO	All	0-2 DL	8.0	---
IHD					
Burnett et al. (1999)	Toronto, CAN	All	0-1	18.0	---
Ito (2003)	Detroit, MI	65+	1	18.0	---
Metzger et al. (2004)	Atlanta, GA	All	0-3	17.8	---
Dominici et al. (2006)	204 U.S. Counties	65+	0-2 DL	13.3	34.8
Pope et al. (2006)	Utah Valley, UT	All	0	10.1-11.3	---
MI					
Zanobetti et al. (2009)*	26 U.S. Communities	65+	0-1	15.3	---
Sullivan et al. (2005)	King County, WA	21-98	24 h	12.8	---
Peters et al. (2001)	Boston, MA	61.6a	24 h	12.1	28.2
Zanobetti & Schwartz (2005)	Boston, MA	65+	0	11.1**	---
Stieb et al. (2009)*	7 Canadian cities	All	0	6.7-9.8	---
CHF					
Burnett et al. (1999)	Toronto, CAN	All	0-2	18.0	---
Ito (2003)	Detroit, MI	65+	1	18.0	---
Metzger et al. (2004)*	Atlanta, GA	All	0-2	17.8	---
Symons et al. (2006)	Baltimore, MD	All	2	16.0	---
Zanobetti et al. (2009)*	26 U.S. Communities	65+	0-1	15.3	---
Dominici et al. (2006)	204 U.S. Counties	65+	0	13.3	34.8
Haley et al. (2009)	New York State	All	0-2	11.1-15.5	---
Pope et al. (2008)	Utah	All	0-13 DL	10.8	44.5
Stieb et al. (2009)*	7 Canadian cities	All	0	6.7-9.8	---
CBVD					
Metzger et al. (2004)*	Atlanta, GA	All	0-2	17.8	---
Dominici et al. (2006)	204 U.S. Counties	65+	0	13.3	34.8
Kloog et al. (2012)	New England	65+	0-1	9.6	---
Hypertension					
Szyszkowicz et al. (2012)*	Edmonton, CAN	All	0-3	8.5	---

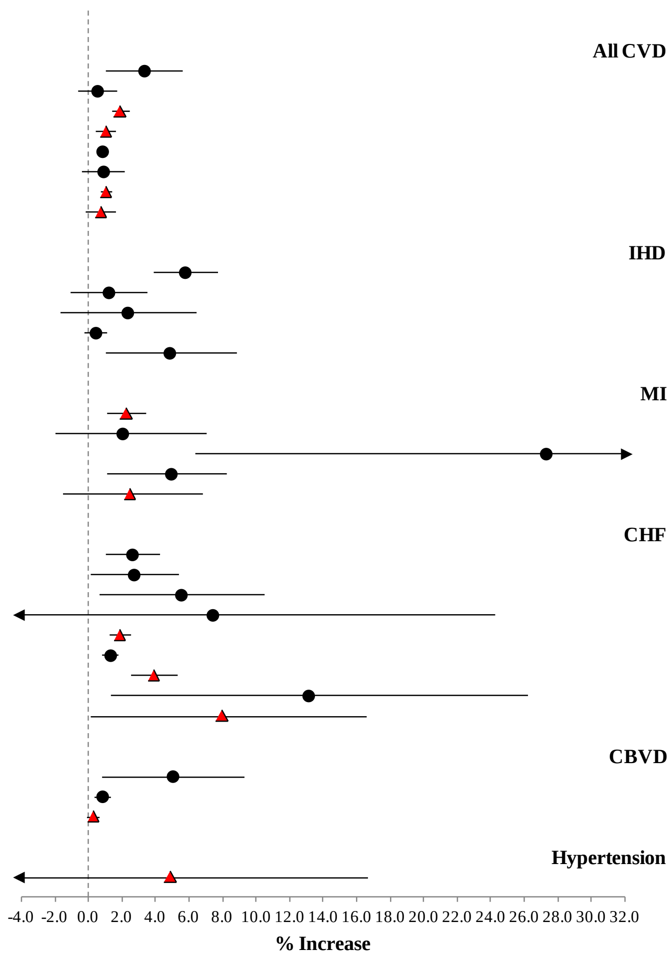

Figure 2.6. Percent increase in cardiovascular-related hospital admissions and ED visits for a 10 µg/m^3 increase in 24-h average $PM_{2.5}$ concentrations in single-pollutant models from U.S. and Canadian studies. Red text and triangles represent recent studies published since the completion of the 2009 PM ISA. * ED visit studies. ** Median concentration. a = study only presented mean age of participants.

2.3. Health Effects Related to Sources or Components of PM

Summary of 2009 PM ISA Conclusions

The 2009 PM ISA evaluated epidemiologic, toxicological, and controlled human exposure studies that examined health effects associated with ambient PM components and sources. These studies used a variety of quantitative methods and examined a broad set of PM components (Section 6.6), and found evidence of health effects from sources and components associated with a number of combustion activities (e.g., motor vehicle emissions, coal combustion, oil burning, power plants, and wood smoke/vegetative burning), crustal sources, and secondary sulfate. As a result, the ISA concluded that "the evidence is not yet sufficient to allow differentiation of those components or sources that are more closely related to specific health outcomes." These conclusions are consistent with those presented in the 2004 PM AQCD where the studies evaluated found evidence of health effects attributed to a number of source types, including motor vehicle emissions, coal combustion, oil burning, and vegetative burning.

Recent Studies of Health Effects Related to Sources or Components of PM

Recent studies have continued to examine whether specific PM components or sources are more closely related to specific health outcomes. For the purposes of this provisional assessment of new literature published since the release of the 2009 PM ISA, emphasis has been placed on studies that investigated the health effects related to PM sources or comparisons of various PM components. To highlight the scientific content of the recent literature while focusing on key PM study categories, this section focuses on results of studies that evaluated the effects of a range of sources or components. Thus, the discussion includes: (1) recent epidemiologic studies using source apportionment; (2) epidemiologic evidence on effects with PM components; and (3) results of new toxicological studies using source apportionment with exposures to concentrated ambient particles (CAPs) to provide insight into potential effects related to PM from different sources, and comparative toxicology studies using fine PM components. In addition, numerous epidemiologic and/or toxicology studies have reported effects of several ultrafine PM as discussed in the 2009 PM ISA. Specific findings for ultrafine PM are not discussed in detail; instead, the available new studies are included in the reference list: http://hero.epa.gov/pm .

2.3.1. Epidemiologic Studies Using Source Apportionment

Lall et al. (2011) examined the association between source-specific daily $PM_{2.5}$ mass and component data and hospital admissions in New York City for the years 2001-2002. The use of daily data allowed for the examination of both single-day lags and a distributed lag. Source categories identified through positive matrix factorization included long-range transported sulfates, traffic, residual oil, steel metal works dust, and soil. In single-day lag models, total respiratory hospital admissions were positively associated with residual oil at lag 2, but the strongest associations were with steel metal works dust at lag 0 and 3. For cardiovascular hospital admissions the strongest associations were observed with traffic at lag 0 and residual oil at lag 3. When examining associations between cause-specific cardiovascular and the traffic source category, the strongest associations were observed at lag 0 for total cardiovascular, heart failure, and stroke. For associations between cause-specific respiratory hospital admissions and the steel source category, pneumonia was associated with steel metal works dust at lag 3, while asthma was observed to have the largest magnitude of an association across all lags. The distributed lag model demonstrated a stronger association between traffic and cardiovascular hospital admissions and steel metal works dust and respiratory hospital admissions than the single-day lag models, indicating that single-day lags may underestimate the magnitude of associations. Finally, a sensitivity analysis using key tracers of each source (i.e., elemental carbon for traffic and manganese for steel metal works) found similar patterns of associations as the source-specific analyses.

2.3.2. Epidemiologic Studies on Effects of Fine PM Components and Sources

In addition to examining the association between short-term $PM_{2.5}$ exposures and mortality or hospital admissions and ED visits a number of studies also attempted to identify if an individual PM component or group of PM components could explain the observed association. The following section describes the results from these studies some of which have been aforementioned.

Short-term exposure to $PM_{2.5}$ components and sources and mortality

In addition to examining the association between short-term exposure to $PM_{2.5}$ and mortality, a few single-city studies also examined the effect of individual $PM_{2.5}$ components on mortality. Ito et al. (2011a) focused on key PM components (i.e., elemental carbon [EC], organic carbon [OC], sulfate [SO_4], nickel [Ni], vanadium [V], zinc [Zn], silicon [Si], selenium [Se], sodium [Na], and bromine [Br]) identified in previous source apportionment studies conducted in NYC. In all-year analyses, the strongest associations were observed at lag 1 for EC, OC, SO_4, Si, Se, and Br. In the warm season, strong associations were observed for secondary aerosols including OC and SO_4, Se, which is associated with transported coal emissions, EC, and Br. In the cold season, the components associated with residual oil burning, Ni, V, and Zn, all showed a similar pattern of associations, with the strongest effects at lag 3. Overall, the components representing regional transport showed a seasonal pattern of associations similar to those found with $PM_{2.5}$ mass, while associations were found throughout the year with EC and NO_2.

Zhou et al. (2011) examined the association between PM components with all-cause, cardiovascular, and respiratory mortality in seasonal analyses in Seattle and Detroit. The components selected for analysis represent the major emissions sources of the two cities: soil (aluminium [Al] and Si), smelter effluents (iron [Fe] and Zn), residual oil burning (Ni and V), coal burning (sulfur [S]), traffic (EC), sea salt (Na), and wood burning (potassium [K]). Daily component data was available in both cities, which allowed for the examination of a 0-2 day distributed lag. In Detroit, S was associated with all-cause and cardiovascular mortality and S and Ni were moderately associated with respiratory mortality in the warm season. No components were positively associated with any mortality outcome in the cold season in Detroit.

In Seattle, in the warm season no component was significantly associated with any mortality outcome, but Fe, K, and EC were positively associated with respiratory mortality. In the cold season, Al, K, Si, Zn, and EC were strongly associated with all-cause mortality, with the same components, minus Al, strongly associated with cardiovascular mortality. No components were associated with respiratory mortality in Seattle in the cold season. Overall, in Detroit the components associated with mortality are indicative of coal burning while in Seattle the components associated with mortality represent cold-season traffic and combustion sources, such as residual oil and wood burning.

In the study conducted by Klemm et al. (2011) in Atlanta, daily concentrations of the PM components EC, OC, nitrate [NO_3], and SO_4 were also available for the entire study duration. The authors found that EC, OC, and NO_3 were positively associated with nonaccidental mortality at lag 0-1 in individuals 65 years of age and older, with the strongest association for NO_3. In analyses of cause-specific mortality, a similar pattern of associations was observed for cardiovascular and respiratory mortality. SO_4 was not found to be associated with any of the mortality outcomes examined.

Respiratory-related Hospital Admissions and ED Visits

Recent multicity studies were identified that examined the effect of PM components on the relationship between short-term PM exposure and respiratory-related ED visits and hospital admissions. Zanobetti et al. (2009) conducted a second-stage analysis, using the same methodology as Franklin et al. (2008) (2009 PM ISA; p. 6-193-195) and examined whether season and community-specific long-term mean seasonal concentration ratios of PM components to $PM_{2.5}$ total mass modified the association between short-term $PM_{2.5}$ concentrations and respiratory ED visits. Of the components examined only Na^+ and Ni were found to modify the association between $PM_{2.5}$ and respiratory ED visits. Using a different approach, Levy et al. (2012) attempted to identify if some PM components are more toxic than others by focusing on the four components that dominate $PM_{2.5}$ mass and are highly correlated with $PM_{2.5}$ (i.e., EC, OC, SO_4, and NO_3). In a time-series analysis using Medicare data from 119 U.S. counties the authors examined the association between each component and respiratory hospital admissions across the U.S. and regionally (i.e., East and West). Of the components examined, only EC and OC were positively associated with respiratory hospital admissions.

A few single-city studies were also identified that examined associations between respiratory-related ED visits and hospital admissions and individual PM components. Strickland et al. (2010) focused on the PM components SO_4, EC, OC, and water-soluble metals. For each component positive associations were observed with pediatric asthma ED visits in all-year analyses. The strongest associations were observed in the warm season with the magnitude being similar across components. In addition, analyses including copollutant adjustment were conducted using warm season data. Risk estimates for $PM_{2.5}$, EC, and SO_4 were attenuated, but remained positive when including O_3 in the model. In LOESS C-R analyses, there was evidence of a positive C-R relationship for each component. Kim et al. (2011) examined the lag structure of associations between the PM components EC, OC, SO_4, and NO_3 and respiratory hospital admissions. The authors focused on these components because they comprise the majority of $PM_{2.5}$ mass in Denver. Consistent with the $PM_{2.5}$ results, there was no evidence of an association with COPD or pneumonia and any of the components. For both all respiratory and asthma hospital admissions there was evidence of greater effects with EC and OC compared to SO_4 and NO_3, and additional evidence for delayed effects occurring 2 to 5 days after exposure.

Cardiovascular-related Hospital Admissions and ED Visits

The 2009 PM ISA included multicity analyses of the effect of $PM_{2.5}$ components on cardiovascular hospital admissions that reported associations between oil combustion and traffic-related $PM_{2.5}$ and CVD hospitalizations.

Two recent studies investigated the association of $PM_{2.5}$ components with cardiovascular hospital admissions. Using Medicare data from 26 US communities, Zanobetti et al. (2009) examined the modification of the associations of $PM_{2.5}$ with CVD, MI and CHF hospital admissions by season- and community-specific $PM_{2.5}$ composition. Authors estimated the relative contribution of specific components (EC, OC, SO_4, NO_3, Na, Ni, V, Zn, Si, Se, Br) by computing concentration ratios (i.e. component species as a proportion of $PM_{2.5}$ mass). In the second stage of a hierarchical model, season- and community-specific estimates of the association between $PM_{2.5}$ and CVD hospitalizations were regressed on the concentration ratios. The association of $PM_{2.5}$ with all CVD hospitalizations was significantly modified when the proportion of Br, Na^+, Ni, V and Al in $PM_{2.5}$ was high. The association of $PM_{2.5}$ with all MI hospitalizations was significantly modified when the proportion of arsenic [As], chromium [Cr], manganese [Mn], OC, Ni, K and Na^+ was high. Additional increases in CVD hospitalizations per interquartile range (IQR) increase in the proportion of the component ranged from 0.53% to 0.9% (larger, less precise increases were reported for MI). None of the components significantly modified the association of $PM_{2.5}$ with CHF admissions (i.e. p-value > 0.05). Ito et al. (2011b) conducted a time series analysis of the lag structure and seasonal patterns in the association between emergency hospitalization for CVD and $PM_{2.5}$ chemical components. Same day concentration of most components examined was associated with CVD hospitalizations (EC, OC, SO_4, NO_3, Na, Ni, V, Zn, Se, and Br). The association and lag structure of EC with CVD hospitalization was constant across season; associations of OC, SO_4, Ni, Zn, Si, Se and Br with CVD hospitalizations were strongest in the cold season.

An additional study (Mostofsky et al., 2012) examined different approaches to modeling the association between PM components and health outcomes using ischemic stroke onset as an example. The authors used three different models that included parameters for the following: (1) component concentration, (2) component concentration adjusted for total $PM_{2.5}$ mass, which accounts for total $PM_{2.5}$ mass, and (3) component residuals, which eliminates confounding by total $PM_{2.5}$ mass. In model 1, positive associations were observed for a number of components including Al, calcium [Ca], Br, lead [Pb], Se, titanium [Ti], and Fe with the strongest associations for V, S, Ni, and black carbon [BC]. Models 2 and 3 resulted in relatively few components with positive associations, but the pattern of associations across pollutants was consistent between the two models with the strongest associations for V, Ni, and BC.

Long-term exposure to $PM_{2.5}$ components and mortality

Ostro et al. (2010) also examined the association between long-term exposures to $PM_{2.5}$ components (i.e., EC, OC, SO_4, NO_3, Fe, K, Si, Zn) and all-cause mortality among the subjects from the California Teachers Study. No associations were observed between all-cause mortality and any $PM_{2.5}$ component. In analyses of cause-specific mortality, Ostro et al. (2010) observed an association between long-term exposure to several $PM_{2.5}$ components and mortality from CPD, IHD and pulmonary disease. The authors observed positive associations of CPD and IHD mortality with each of the measured components, and between pulmonary mortality and SO_4 and NO_3. Of the components analyzed, there were positive associations with nitrate, sulfate and silicon for CPD mortality and all of the components were associated with mortality from IHD (See Table 2.2).

Table 2.2. Association between mortality outcomes and $PM_{2.5}$ components using a 30-km buffer (n=43,220) (adapted from Ostro et al. (2011))

Component (IQR, $\mu g/m^3$)	All-Cause*	CPD*	IHD*	Pulmonary*
EC (0.65)	1.02 (0.93, 1.12)	1.07 (0.94, 1.22)	1.46 (1.17, 1.83)	0.88 (0.68, 1.15)
OC (0.84)	1.00 (0.95, 1.04)	1.04 (0.98, 1.11)	1.13 (1.01, 1.25)	0.95 (0.84, 1.06)
SO_4 (2.2)	1.06 (0.97, 1.16)	1.14 (1.01, 1.29)	1.48 (1.20, 1.82)	1.04 (0.82, 1.31)
NO_3 (3.2)	1.03 (0.98, 1.09)	1.11 (1.03, 1.19)	1.27 (1.12, 1.43)	1.04 (0.90, 1.20)
Fe (0.13)	1.01 (0.93, 1.11)	1.05 (0.93, 1.19)	1.39 (1.13, 1.72)	0.88 (0.69, 1.13)
K (0.07)	1.01 (0.94, 1.08)	1.06 (0.97, 1.17)	1.27 (1.07, 1.49)	0.90 (0.74, 1.09)
Si (0.03)	1.02 (0.99, 1.06)	1.05 (1.00, 1.10)	1.11 (1.02, 1.20)	0.98 (0.89, 1.08)
Zn (0.01)	1.03 (0.96, 1.11)	1.09 (0.98, 1.20)	1.33 (1.12, 1.58)	0.97 (0.79, 1.18)

*Hazard ratio and 95% confidence interval for an increase in $PM_{2.5}$ components equal to the interquartile range (IQR)

Long-term exposure to $PM_{2.5}$ components and sources and morbidity

In a study conducted in New York City, Patel et al. (2009) examined long-term exposure to $PM_{2.5}$ components (Ni, V, Zn, EC) and respiratory symptoms in children through 24 months of age. Positive associations were observed between Ni and wheeze, but not cough. No other associations were observed between the other metals or EC and either wheeze or cough. $PM_{2.5}$ mass was not associated with wheeze and/or cough (see Section 2.1.3 for results on $PM_{2.5}$ mass).

Several recent studies have examined the association between exposure to $PM_{2.5}$ components and sources and birth outcomes, including birth weight and preterm birth. Studies examining birth weight and $PM_{2.5}$ components and sources found the strongest associations with metals/oil combustion (Bell et al., 2012; Darrow et al., 2011b; Bell et al., 2010) and elemental carbon/motor vehicles (Wilhelm et al., 2012; Darrow et al., 2011b; Bell et al., 2010). Similarly, when evaluating $PM_{2.5}$ components and preterm birth, the associations with metals, EC, OC and ammonium nitrate were strongest (Wilhelm et al., 2011; Darrow et al., 2009). Several $PM_{2.5}$ sources were associated with preterm birth, including biomass burning and diesel traffic (Wilhelm et al., 2011).

2.3.3. Toxicology Studies – Source Apportionment and Fine PM Components

The 2009 PM ISA examined health effects associated with exposure to ambient PM components and sources in animals. In vivo and in vitro studies reported a variety of sources and components were linked with cardiopulmonary effects; however, there was insufficient evidence overall to determine which sources or components were most closely related to the observed effects. Since the completion of the 2009 PM ISA, a small number of animal toxicology studies have continued to assess the role of PM sources and components on effects observed after exposure to $PM_{2.5}$.

2.3.3.1. Toxicology Studies Comparing Ambient Fine PM Sources and Components

Toxicology studies employing CAPs offer a relevant surrogate for atmospheric PM. Table 2.3 shows the endpoints that were associated with various source categories from rodents exposed to CAPs from four locations. These three studies compare electrocardiogram (ECG) responses during CAPs inhalation to $PM_{2.5}$ components associated with source factors (Kamal et al., 2011; Rohr et al., 2011; Chen et al., 2010).

Chen et al. (2010) compared subchronic CAPs inhalation exposures from two locations in New York, Sterling Forest (SF; undeveloped woodland park) and Manhattan in male hyperlipidemic mice. Using Manhattan CAPs (mean CAPs concentration, 122.9 ± 81.1 $\mu g/m^3$), heart rate (HR) decreased with increased current day CAPs mass at all lags and several measures of heart rate variability (HRV) increased with increased CAPs mass (i.e., standard deviation of the normal-to-normal intervals, SDNN; root mean square of the standard deviation of the normal-to-normal intervals, rMSSD; and frequency domain indices, high-frequency, HF, low-frequency, LF, and LF/HF ratio). Using SF CAPs (mean CAPs concentration, 133.3 ± 110.5 $\mu g/m^3$), CAPs mass was positively associated with HR, whereas HRV decreased with increased CAPs. Using Manhattan CAPs, ECG changes were associated with components related to residual oil combustion > long-range transport > traffic > iron/steel > incineration > soil. Using SF CAPs, ECG changes were associated with long-range transport > Ni refinery > soil > residual oil combustion/traffic. Chen et al. (2010) also performed single-element analysis and note that EC did not account for the acute ECG changes associated with $PM_{2.5}$ and that Ni may have an effect in Manhattan but not SF.

Rohr et al. (2011) reported altered ECG responses in spontaneously hypertensive rats following CAPs inhalation exposures from Detroit, Michigan over 13 consecutive days in both the summer and winter. Source factors were identified using positive matrix factorization. In summer (time weighted average CAPs concentration, 518 $\mu g/m^3$), decreased HRV (SDNN) was associated with cement/lime, iron/steel, and gasoline/diesel factors, and less so with sludge incineration. In winter (time weighted average CAPs concentration, 357 μg/m^3); decreased HR was associated with sludge incineration, cement/lime, and coal/secondary sulfate factors.

Kamal et al. (2011) also identified source factors (via positive matrix factorization) associated with ECG alterations in hypertensive rats exposed for 13 days to CAPs (from Steubenville, OH; mean CAPs concentration 406 ± 266 μg/m^3). Statistically significant associations were found between acute cardiac responses and PM components linked with incineration, metal processing, mobile sources, and iron/steel production. The strength of the association with each source was dependent upon wind direction; however, incineration was consistently found to be associated with changes in HR and HRV. Several individual CAPs components were also associated with cardiovascular responses, S, SO_2, Pb, and oxides of nitrogen (NO_x).

Table 2.3. CAPs Sources and Associated Endpoints

Source Category	Elemental Loading	Endpoint Affected	Location	Exposure Duration	References
Metal processing	V, Cr, Ti, Mo, La, Ce	↑ HR ↓ SDNN	Steubenville, OH	13 days (s)	Kamal et al. (2011)
Incineration (including sludge)	Zn, Cd	↓ HR ↓ SDNN	Steubenville, OH	13 days (s)	Kamal et al. (2011)
	Zn, Ba, Mn, Sr, Sb	↓ HR (w) ↓ SDNN (s)	Detroit, MI	13 days (s & w)	Rohr et al. (2011)
	Zn, Pb, Cu, Fe	ECG alterations	Manhattan, NY	6 months	Chen et al. (2010)
Pb	Pb, Cu	↓ HR	Detroit, MI	13 days (s & w)	Rohr et al. (2011)
Iron/Steel manufacturing	Fe, Mn, Cu, EC, Pb	↓ HR ↑ rMSSD	Steubenville, OH	13 days (s)	Kamal et al. (2011)
	Mn, Fe	ECG alterations	Manhattan, NY	6 months	Chen et al. (2010)
	Fe, Mn, Cu	↑ rMSSD (w) ↓ SDNN (s)	Detroit, MI	13 days (s & w)	Rohr et al. (2011)
Mobile/Traffic	Fe, Sb, As, K, CO	↓ SDNN ↑ rMSSD	Steubenville, OH	13 days (s)	Kamal et al. (2011)
	Fe, Ti, Zn	↓ SDNN (s) ↑ rMSSD (w)	Detroit, MI	13 days (s & w)	Rohr et al. (2011)
	EC, NO_2, Si, Fe, Cu	ECG alterations	Manhattan, NY	6 months	Chen et al. (2010)
Coal and Secondary Sulfate	S, Se, Al, V, P	↓ HR ↑ rMSSD	Steubenville, OH	13 days (s)	Kamal et al. (2011)
	S, Se	↓ HR (w) ↑ rMSSD (w)	Detroit, MI	13 days (s & w)	Rohr et al. (2011)
Oil refinery	La, Ce	↑ HR (w)	Detroit, MI	13 days (s & w)	Rohr et al. (2011)
Cement/lime processing	Ca, Sr, Mg	↓ HR (w) ↓ SDNN (s)	Detroit, MI	13 days (s & w)	Rohr et al. (2011)

Source Category	Elemental Loading	Endpoint Affected	Location	Exposure Duration	References
Residual oil combustion	V, Ni, EC, Fe	ECG alterations	Manhattan, NY	6 months	Chen et al. (2010)
Ni-refinery	Cr, Ni	ECG alterations	Sterling Forest, NY	6 months	Chen et al. (2010)
Soil	Al, Si, Ca, Fe	ECG alterations	Sterling Forest, NY Manhattan, NY	6 months	Chen et al. (2010)
Long range transport	S, Se, Br	ECG alterations	Sterling Forest, NY Manhattan, NY	6 months	Chen et al. (2010)

(w) winter season, (s) summer season, HR: heart rate, SDNN: standard deviation of the normal-to-normal intervals, rMSSD: root mean square of the standard deviation of the normal-to-normal intervals, Mo: molybdenum, La: lanthanum, Ce: cerium, Cd: cadmium, Ba: barium, Sr: strontium, Sb: antimony, Cu: copper, CO: carbon monoxide, P: phosphorus

Other studies have used regression and correlation approaches to estimate the relationship between various PM components and sources with health effects. Happo et al. (2010b) intratracheally instilled mice (10 mg/kg) with size-segregated ambient PM samples collected in six European cities over various seasons: Duisberg autumn, Prague winter, Amsterdam winter, Helsinki spring, Barcelona spring, Athens summer. PM exposure ($PM_{10-2.5}$ and $PM_{2.5-0.2}$) increased bronchoalveolar lavage fluid (BALF) total cell number and BALF protein concentration. No formal source apportionment was conducted, but oxidized organic compounds (e.g., dicarboxylic acids), transition metals (e.g., Fe and Cr), and source tracers for fuel oil combustion (i.e., Ni and V) were the most strongly correlated components of $PM_{2.5-0.2}$ contributing to the inflammatory response (i.e., BALF total cell number). These studies measured response to $PM_{10-2.5}$ and $PM_{2.5-0.2}$ PM samples, and generally report stronger inflammatory responses (e.g., BALF cytokines, cell number, and total protein) after exposure to coarse PM compared to fine. Source tracers for soil (K^+, magnesium [Mg^{2+}], Cu, manganese [Mn], Fe) and sea spray (Na^+, chlorine [Cl^-], and NO_3^-) found in $PM_{10-2.5}$ were the most strongly correlated with inflammatory response.

A few studies discuss how seasonal variation in PM components may affect PM-induced health effects. Happo et al. (2010a) intratracheally instilled mice (10 mg/kg) with size-fractionated ambient PM collected in Helsinki in the winter, spring, summer, and autumn. PM collected in the spring produced the highest relative inflammatory activity (i.e., total cell number, total protein, tissue necrosis factor alpha [TNF-α], interleukin-6 [IL-6], and keratinocyte-derived chemokine in BALF) when dose was adjusted to the PM per cubic meter of urban air, whereas the PM collected in the autumn produced the highest inflammation per equal mass dose. This difference was influenced by a greater PM mass concentration in urban air in the springtime. The overall inflammatory activity of PM decreased with particle size, such that $PM_{10-2.5}$ and $PM_{2.5-1}$ had a higher potency than $PM_{1-0.2}$ and $PM_{0.2}$. Components of road dust (Ca^{2+}, Fe, Mn, and Al) and trace metals (presumed to be the result of non-exhaust PM from traffic; Cu, Chromium [Cr], cobalt [Co]) were consistently correlated with BALF inflammatory response in $PM_{2.5-1}$. Resuspension of road dust was also strongly correlated with inflammatory responses to $PM_{10-2.5}$.

Farina et al. (2011) treated mice (100 µg, intratracheal aerosolization) with size-fractionated ambient PM collected from Milano, Italy in summer and winter. A stronger inflammatory activity was generally observed after administration of summer PM_{10} and $PM_{2.5}$ than winter PM. PM_{10} exposure resulted in a higher TNF-α concentration (in BALF) compared to $PM_{2.5}$, and this was attributed to the greater endotoxin concentration and bacteria content of PM_{10}.

Additional studies assessed the differential responses of PM collected at different distances from a highway. Cho et al. (2009) found similar composition in size-fractionated ambient PM collected near (20 m) and far (275 m) from a road in Raleigh, NC; however, PM collected near-road was enriched with metals and a greater concentration of endotoxin. Coarse PM samples, but not fine PM samples, produced pulmonary inflammation (i.e., BALF, macrophage inflammatory protein 2 [MIP-2], TNF-α, IL-6) in exposed mice (25 and 100 µg) irrespective of distance collected from the road. Zhang et al. (2011) reported greater increases in protein and lactate dehydrogenase [LDH] in BALF after instillation (7.5 mg/kg) of $PM_{2.5}$ collected near traffic compared to far from traffic in Beijing, China. Chemical analysis of the near-traffic PM revealed higher concentrations of polycyclic aromatic hydrocarbons [PAHs] and heavy metal elements (arsenic [As], Cd, Zn, S), but no statistical correlations were computed between these components and the health effects observed.

A number of studies have attempted to disentangle the role of PM and gaseous components in the health effects associated with ambient air pollution exposure by removing PM from the mixture using a high efficiency particle filter. A few recent studies report cardiovascular, respiratory, and reproductive effects after exposure to unfiltered (the whole mixture), but not filtered Sao Paulo urban air (20 m from road) (Pires et al., 2011; Matsumoto et al., 2010; Akinaga et al., 2009). These studies suggest that PM but not the gaseous components of the urban air play a role in these responses.

2.3.3.2. Toxicology Studies Comparing Source-Derived PM and Components

A number of studies attempted to characterize effects from ambient PM sources by exposing animals in the laboratory to PM derived from potential ambient sources (e.g., coal combustion, diesel).

A series of studies evaluated the health effects resulting from various coal-fired power plant emissions scenarios (Diaz et al., 2011; Godleski et al., 2011a; Godleski et al., 2011c; Godleski et al., 2011b; Lemos et al., 2011; Wellenius et al., 2011). Stack emissions were collected from three coal-fired power plants and various atmospheric transformations (e.g., oxidation, reaction with α-pinene, neutralization) were simulated to investigate the toxicity of primary and photochemically aged (secondary) particles. Particle mass concentrations varied from 43.8 to 257.1 $\mu g/m^3$ (Kang et al., 2011). Rats were exposed to these simulated emissions scenarios for 6 hours and demonstrated (1) increased BALF total cells, macrophages, and neutrophils (Godleski et al., 2011a); (2) moderately increased heart and lung reactive oxygen species (measured by in vivo chemiluminescence) (Lemos et al., 2011), 3) increased premature ventricular beat frequency, but no change in heart rate, HRV, or ECG intervals (Wellenius et al., 2011); and 4) breathing pattern changes (Diaz et al., 2011). Overall, specific PM components did not predict respiratory or cardiovascular effects observed after PM exposure as well as simulated atmospheric transformation scenarios.

Additionally, a few studies assessed respiratory, cardiovascular, and systemic effects following exposure to filtered and unfiltered simulated downwind coal combustion emissions (Barrett et al., 2011; Mauderly et al., 2011). Barrett et al. (2011) reported different respiratory effects after exposure to filtered and unfiltered emissions. Mauderly et al. (2011) found 17 out of 270 species-gender-time-outcome comparisons were affected by whole emissions and that PM participated in only 3 responses (liver weight, serum K^+, and MIP-2). The authors concluded that PM contributed to a few of the effects but that the pollutants responsible for the effects observed were not able to be identified.

Studies have also evaluated the role of PM in engine emissions on the progression of health effects. Tzamkiozis et al. (2010) instilled mice with PM collected from a gasoline Euro 3 car, a diesel Euro 2 car, and a diesel Euro 4 car (with a diesel particle filter). Significant pulmonary inflammation (i.e., BALF polymorphonuclear leukocytes (PMN) number) and injury (i.e., BALF protein concentration) occurred 24 hours after treatment. The strongest associations with these effects were observed for the PM components, P, Mn, Fe, Pb, reactive oxygen species (ROS), benz(*a*)anthracene, chrysene, and medium and heavy PAHs. A strong association was also observed between pulmonary injury and S.

A number of studies evaluated the impact of inhaled diesel exhaust on the cardiovascular system with and without filtration (Gordon et al., 2012; Lamb et al., 2012; Seilkop et al., 2012; Campen et al., 2010). Different cardiovascular effects were reported after filtration of diesel exhaust by Gordon et al. (2012) and Lamb et al. (2012). Campen et al. (2010) found that filtration of PM from diesel exhaust did not alter the vascular responses observed. Seilkop et al. (2012) ranked components of diesel or gasoline exhaust, wood smoke, or simulated “downwind” coal emissions by their ability to induce pro-atherosclerotic responses in the aorta of mice that inhaled these pollutant mixtures 6 hours/day for 50 days. Filtration of PM did not have a large effect on the responses measured. Gases (i.e., SO_2, ammonia (NH_3), NO_2, CO)) were found to be most highly predictive of the response indicators. These studies using filtration of PM from whole mixtures did not consistently identify whether PM or gases from whole air pollution mixtures led to the cardiovascular, respiratory, or reproductive effects observed.

Summary

The few epidemiologic studies that have been conducted since the completion of the 2009 PM ISA continue to report health effects with a number of sources and components. Toxicological studies have attempted to identify whether particular sources or components are responsible for the health effects observed by comparing the health effects, primarily cardiopulmonary effects, observed in response to exposures to ambient fine PM sources and components and source-derived PM and components. However, the toxicology studies did not find consistent evidence that one source or component is most closely related to a specific health effect. Collectively these studies continue to report that a variety of sources and components are linked with cardiopulmonary effects and mortality; however, there is still insufficient evidence to determine which sources or components are most closely related to the observed effects.

3. SUMMARY AND CONCLUSIONS

The new studies published since the completion of the 2009 PM ISA provide additional evidence indicating a relationship between exposure to ambient PM and health effects. The new studies provide important insights on the health effects of PM exposure, with the results continuing to support a relationship between PM exposure and health effects at ambient concentrations similar or lower than those observed in previous studies. Overall: (a) the new studies generally strengthen the evidence that acute and chronic exposures to fine PM; (b) although limited in number, coarse PM studies provide evidence of an association with short-exposures and pediatric asthma ED visits, but no association between long-term exposure and mortality; (c) some of the new epidemiologic studies report effects in areas with long-term mean or mean 24-h avg $PM_{2.5}$ concentrations lower than that reported in the 2009 PM ISA; and (d) new toxicology and epidemiologic studies continue to link various health outcomes with a range of fine PM sources and components. In conclusion, the results of the new studies identified and described in this provisional assessment does not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the 2009 PM ISA.

In summary, this provisional assessment found:

Long-term PM Exposure

- Mortality: Generally, the results of recent studies are consistent with the evidence for an association between long-term exposure to $PM_{2.5}$ and mortality (i.e., all-cause and cardiovascular) within the range of long-term mean $PM_{2.5}$ concentrations characterized in the 2009 PM ISA (i.e., 13.2 – 32.0 $\mu g/m^3$), with one new Canadian multi-city study showing associations at concentrations below 10 $\mu g/m^3$. New studies provide additional evidence for respiratory mortality, including lung cancer. Two recent studies that examined associations between long-term $PM_{10-2.5}$ exposure and mortality do not observe an association in either men or women.

- Cardiovascular morbidity: Recent studies continue to demonstrate the strongest cardiovascular effects in women, specifically for stroke, incident MI, and incident hypertension at long-term mean $PM_{2.5}$ concentrations ranging from 9.7 – 21.5 $\mu g/m^3$.

- Respiratory morbidity: Recent studies provide additional evidence for respiratory symptoms and incident asthma, as well as respiratory hospitalizations at long-term mean $PM_{2.5}$ concentrations ranging from 9.7 – 27.0 $\mu g/m^{3,}$ which is consistent with the conclusions of the 2009 PM ISA.

- Reproductive and Developmental Outcomes: Recent studies continue to provide evidence for developmental outcomes, specifically reductions in birth weight, at long-term mean $PM_{2.5}$ concentrations ranging from 11.0 – 19.8 $\mu g/m^3$, which further support the conclusions of the 2009 PM ISA.

Short-Term PM Exposure

- Mortality: The limited number of mortality studies conducted in the U.S. and Canada further support the conclusions of the 2009 PM ISA and continue to demonstrate associations between short-term $PM_{2.5}$ exposure and mortality at mean 24-h average concentrations greater than 12.8 $\mu g/m^3$. Since the completion of the 2009 PM ISA no new studies have been conducted that examined associations between short-term exposure to $PM_{10\text{-}2.5}$ and mortality.
- Respiratory hospital admissions/ED visits: New multi-city and single-city studies demonstrate consistent positive associations for all respiratory-related hospital admissions/ED visits, and provide additional evidence for increases in asthma hospital admissions/ED visits in areas with mean 24-h average $PM_{2.5}$ concentrations ranging from 6.7 – 22.0 $\mu g/m^3$, which further supports the conclusions of the 2009 PM ISA. One new study was identified that examined the association between short-term $PM_{10\text{-}2.5}$ exposure and respiratory-related ED visits, and provided evidence of increases in pediatric asthma ED visits.
- Cardiovascular hospital admissions/ED visits: New studies focusing primarily on all cardiovascular hospital admissions/ED visits continue to demonstrate consistent positive associations in areas with mean 24-h average $PM_{2.5}$ concentrations ranging from 6.7 – 15.3 $\mu g/m^3$. Additionally, there is new evidence for potential associations with hypertension ED visits, and a new study demonstrating an association with stroke onset.

Health Effects Related to Sources or Components of PM

- Consistent with those studies evaluated in the 2009 PM ISA, new studies continue to demonstrate cardiovascular and mortality effects with sources and components related to a number of combustion activities (e.g., motor vehicle emissions, coal combustion, oil burning, power plants, and wood smoke/vegetative burning), crustal sources, and secondary sulfate. Additional new studies also add to the limited number of studies that have examined associations between sources and components and respiratory and birth outcome effects, as well as, long-term exposure and mortality. Overall, new studies support the conclusions of the 2009 PM ISA that many PM components can be linked with differing health effects and the evidence is not yet sufficient to allow differentiation of those components or sources that are more closely related to specific health outcomes.

APPENDIX A. Studies Included in the PM Provisional Science Assessment

Table A.1. Characterization of Studies of Long-term Exposure to $PM_{2.5}$ and Mortality

Author	Years of Study	Location	Outcome	Population	Size Fraction	Long-term Mean Concen-tration (μg/m^3)	Upper Percentile Concen-trations (μg/m^3)
Crouse et al. (2012)	1991-2001	Canada (nationwide)	All-Cause, CVD, IHD Mortality	Nonimmigrant Canadian adults	$PM_{2.5}$	8.7	Max: 19.2
Gan et al. (2011)	AQ: 1994-1998; Deaths: 1999-2002	Vancouver, BC Canada	CHD Mortality	Adults (45-85) without known CHD at baseline	$PM_{2.5}$	4.08	Max: 10.24
Greven et al. (2011)	2000-2006	U.S. (nationwide)	All-Cause	Medicare recipients (65+ yrs)	$PM_{2.5}$	13.0	75th: 14.7
Hart et al. (2010)	AQ: 2000 Deaths: 1985-2000	U.S. (nation-wide)	All-Cause, Lung Cancer, CVD Disease, IHD, Respiratory Disease, COPD Mortality	Adult males from 4 U.S. trucking companies	$PM_{2.5}$	14.1	NR
Jerrett et al. (2009b)	1992-2002	Toronto, Canada	All-Cause, Circulatory Mortality	Adults from respiratory clinic	$PM_{2.5}$	8.71	75th: 8.83
Jerrett et al. (2009a)	AQ: 1999-2000 Deaths: 1982-2000	U.S. (nation-wide; 86 MSAs)	All-Cause, Cardiopulmonary, CVD, IHD, Respiratory	Adults	$PM_{2.5}$	14.3	NR
Lepeule et al. (2012)	1974-2009	U.S (6 cities in East and Midwest)	All Cause, CVD and Lung Cancer Mortality	Adults	$PM_{2.5}$	15.9 (six cities combined); means for individual cities ranged from 11.4-23.6	NR
Lipsett et al. (2011)	AQ: 1999-2005; Deaths: 1995-2005	California	All-Cause, CVD, Respiratory, Lung Cancer, IHD, CBD	Adults (Female teachers)	$PM_{2.5}$	15.64	Max: 28.35

Author	Years of Study	Location	Outcome	Population	Size Fraction	Long-term Mean Concen-tration (µg/m³)	Upper Percentile Concen-trations (µg/m³)
McKean - Cowden et al. (2009)	AQ: 1979-1983; 1999-2000; Deaths: 1982-2000	U.S. (nation-wide)	Brain Cancer Mortality	Adults	$PM_{2.5}$	1979-1983: 21.1 1999-2000: 14.0 Avg: 17.7	Max: 1979-1983: 30.0 1999-2000: 22.2 Avg: 23.6
Ostro et al. (2010)	AQ: 2002-2007	California	All-Cause, CPD, IHD Mortality	Adults (Female teachers)	$PM_{2.5}$ and components (EC, OC, SO_4, NO_3, Fe, K, Si, Zn)	17.0	Max: 34.7
Puett et al. (2009)	1992-2002	U.S. (East and Midwest)	All Cause and CHD Mortality	Adults (Female Nurses)	$PM_{2.5}$	13.9	$75^{th:}$ 15.6 Max: 27.6
Puett et al. (2011)	1986-2002	U.S. (East and Midwest)	All Cause and CHD Mortality	Adults (Male Health Professionals)	$PM_{2.5}$	17.8 (at baseline)	NR

CVD: Cardiovascular Disease, CHD: Coronary Heart Disease; IHD: Ischemic Heart Disease; COPD: Chronic Obstructive Pulmonary Disease; CBD: Cerebrovascular Disease; NR: Not reported

Table A.2. Characterization of Studies of Long-term Exposure to $PM_{10-2.5}$ and Mortality

Author	Years of Study	Location	Outcome	Population	Size Fraction	Long-term Mean Concentration (µg/m³)	Upper Percentile Concentrations (µg/m³)
Puett et al. (2009)	1992-2002	U.S. (East and Midwest)	All-Cause and CHD Mortality	Adults (Female Nurses)	$PM_{10-2.5}$	7.7	$75^{th:}$ 9.2 Max: 26.9
Puett et al. (2011)	1986-2002	U.S. (East and Midwest)	All-Cause and CHD Mortality	Adults (Male Health Professionals)	$PM_{10-2.5}$	10.1 (at baseline)	NR

CHD: Coronary Heart Disease; NR: Not reported

Table A.3. Characterization of Studies of Long-term Exposure to $PM_{2.5}$ and Cardiovascular Effects

Author	Study Years	Location	Outcome	Population	Size Fraction	Long-term Mean Concen-tration ($\mu g/m^3$)	Upper Percentile Concen-trations ($\mu g/m^3$)
Puett et al. (2011)	1989 - 2003	North-east and Midwest, U.S.*	All-cause Mortality, Nonfatal MI, fatal CHD, and Hemorrhagic and Ischemic Stroke	Health Professionals Follow-Up Study men, 40-75 yrs of age	$PM_{2.5}$, $PM_{10-2.5}$	Predicted $PM_{2.5}$ = 17.8 ± 3.4 Predicted $PM_{10-2.5}$ = 10.1 ± 3.3	Interquartile range (IQR): $PM_{2.5}$: 4.3 $PM_{10-2.5}$: 4.3
Lipsett et al. (2011)	1995-2000	California	All Cause Mortality, CVD mortality, IHD mortality, cerebro-vascular disease mortality, MI incidence, stroke incidence	California Teachers Study N=124,614 women, 20->80 yrs		15.64	Max: 28.35
Coogan et al. (2012)	1995-2005	Los Angeles, CA	Hypertension and Diabetes Mellitus (incidence)	Black Women's Health Study N=4204 (hypertension) N-3236 (diabetes) disease free at baseline	$PM_{2.5}$	20.7	75th: 21.6
Beckerman et al. (2012)	1992-1999	Toronto, Ontario	IHD (prevalence)	N=2360 pulmonary clinic patients	$PM_{2.5}$	50th percentile: 8.71	75th: 8.83
Adar et al. (2010)	2002-2003	6 US Cities**	Retinal Microvasculat ure	MESA, N=4,607 46-87 years , no clinical cardiovascular disease at baseline	$PM_{2.5}$	16 (±3)	75th: 17.2 personal PM prediction; 17.2; nearest monitor PM- 17.3 Max: personal PM prediction- 26.3; nearest monitor PM- 25.4

Author	Study Years	Location	Outcome	Population	Size Fraction	Long-term Mean Concen-tration (μg/m^3)	Upper Percentile Concen-trations (μg/m^3)
O'Neill et al. (2011)	2000-2002	6 US Cites**	Arterial Stiffness	MESA N=3,996 men and women, 44-84 yrs	$PM_{2.5}$	Imputed 20 yr avg: 21.47 ± 5.00 16.80 ± 3.90 (2005)	
Van Hee et al. (2011)	Jul 2000-Aug 2002	6 US Cites**	Ventricular Conduction and Repolarization Abnormalities	MESA N=4,783 45 to 84 yrs	$PM_{2.5}$		
Kloog et al. (2012a)	2000-2006	New England	Hospital Admissions	≥65 years	$PM_{2.5}$ (predicted)	**9.65**	**17.79**

Table A.4. Characterization of Studies of Long-term Exposure to $PM_{2.5}$ and Respiratory Effects

Author	Years of Study	Location	Outcome	Population	Size Fraction	Long-term Mean Concen-tration (μg/m^3)	Upper Percentile Concen-trations (μg/m^3)
Noonan et al. (2012)	2003-2009	Libby, MT	Respiratory infections (including bronchitis)		$PM_{2.5}$	19.0-27.0	NR
Bhattacharyya (2009)	1997-2006	US (Nation-wide)	Hay Fever and Sinusitis	National Health Interview Survey respondents	$PM_{2.5}$	13.4-11.6	NR
Bhattacharyya and Shapiro (2010)	1997-2006	US (Nation-wide)	Ear Infections	National Health Interview Survey respondents	$PM_{2.5}$	13.4-11.6	NR
Patel et al. (2009)	1998-2006	NYC, NY	Wheeze and Cough	Participants in Columbia Center for Children's Environmental Health birth cohort	$PM_{2.5}$	13.0	Max: 38.4

Author	Years of Study	Location	Outcome	Population	Size Fraction	Long-term Mean Concen-tration (μg/m^3)	Upper Percentile Concen-trations (μg/m^3)
Parker et al. (2009)	1999-2005	US (Nation-wide)	Respiratory Allergies	Children (ages 3-17) in National Health Interview Survey	$PM_{2.5}$	13.1	75th: 15.2
Nachman and Parker (2012)	2002-2005	US (Nation-wide)	Asthma, sinusitis, chronic bronchitis	National Health Interview Survey respondents	$PM_{2.5}$	12.1	75th: 14.4 Max: 27.5
Karr et al. (2009a)	1997-2003	Puget Sound Region, WA	Bronchiolitis hospital admission	Washington State Birth Events Registry Database	$PM_{2.5}$	12.0	75th: 14.0 Max: 36.9
Karr et al. (2009b)	1999-2003	Georgia Air Basin of BC, Canada	Inpatient or outpatient bronciolitis	Infants born between 1999-2002	$PM_{2.5}$	5.8	Max: 12.0
Kloog et al. (2012a)	2000-2006	New England	Respiratory hospital admission	Residents ≥65 years	$PM_{2.5}$	9.7	75th: 10.1 Max: 17.8
Neupane et al. (2010)	2003-2005	Hamilton, ON, Canada	Pneumonia hospital admissions	Residents ≥65 years	$PM_{2.5}$	10.7	75th: 113 95th: 12.4 Max: 13.0
Meng et al. (2010)	2000-2001	San Joaquin Valley, CA	Asthma Symptons; Asthma ED visits or hospitalizations	San Joaquin Valley residents participating in 2001 California Health Interview Survey)	$PM_{2.5}$	21.4	75th: 23.5
Akinbami et al. (2010)	2001-2004	US (Nation-wide)	Asthma prevalence	Children (ages 3-17) in National Health Interview Survey	$PM_{2.5}$	13.3	75th: 15.7
Carlsten et al. (2011)	1995-2003	Vancouver, BC, Canada	Incident Asthma	Birth cohort born in 1995	$PM_{2.5}$	5.6	NR

Author	Years of Study	Location	Outcome	Population	Size Fraction	Long-term Mean Concen-tration (μg/m^3)	Upper Percentile Concen-trations (μg/m^3)
Clark et al. (2010)	1999-2004	South-western BC, Canada	Incident Asthma	Children born in 1999 and 2000 and followed up to 3-4 yrs	$PM_{2.5}$	5.6	75th: 6.1
McConnell et al. (2010)	2002-2006	Southern California	Incident Asthma	Kindergarten and First grade children in Southern California Children's Health Study	$PM_{2.5}$	13.9	Max: 17.4

Table A.5. Characterization of Studies of Long-term Exposure to $PM_{2.5}$ and Reproductive and Developmental Effects

Author	Years of Study	Location	Outcome	Population	Size Fraction	Long-term Mean Concentration (μg/m^3)	Upper Percentile Concentrations (μg/m^3)
Lee et al. (2011)	1997-2001	PA	C-reactive protein	Healthy women	$PM_{2.5}$	16.4	75th: 18.7 95th: 26.2 100th: 40.8
Legro et al. (2010)	2000-2007	Northeastern US	In Vitro Fertilization (IVF) success	Women undergoing IVF	$PM_{2.5}$	14.0-14.5	NR
Vinikoor-Imler et al. (2012)	2000-2003	NC	Gestational Hypertension	All births in NC	$PM_{2.5}$	14.5	75th: 15.7
Rich et al. (2009)	1999-2003	NJ	Fetal Growth	All births in NJ	$PM_{2.5}$	13.8	NR
Chang et al. (2012b)	2001-2005	NC	Pre-term birth (PTB)	All births in NC	$PM_{2.5}$	13.0-15.3	NR
Darrow et al. (2009)	1994-2004	Atlanta, GA	PTB	All births in Atlanta (5 counties)	$PM_{2.5}$	16.5	Max: 34.1
Rudra et al. (2011)	1996-2006	Western WA	PTB	Healthy Women	$PM_{2.5}$	10.0	75th: 12.7 100th: 17.2
Wilhelm et al. (2011)	2004-2006	Los Angeles, CA	PTB	All births in LA county	$PM_{2.5}$	18.0	NR

Author	Years of Study	Location	Outcome	Population	Size Fraction	Long-term Mean Concentration (µg/m^3)	Upper Percentile Concentrations (µg/m^3)
Marshall et al. (2010)	1998-2003	NJ	Birth Defects (Oral Clefts)	All births in NJ	$PM_{2.5}$	13.4	NR
Bell et al. (2012)	2000-2004	CT and MA	birth weight (BW)	All births from 5 counties	$PM_{2.5}$	14.0	75th: 16.0
Bell et al. (2010)	2000-2004	CT and MA	BW	All births from 5 counties	$PM_{2.5}$	14.0	NR
Darrow et al. (2011b)	1994-2004	Atlanta, GA	BW	All births in Atlanta (5 counties)	$PM_{2.5}$	16.5	NR
Ghosh et al. (2012)	1995-2006	Los Angeles, CA	BW	All births in LA county	$PM_{2.5}$	19.8	NR
Kloog et al. (2012b)	2000-2008	MA	BW, PTB	All births in MA	$PM_{2.5}$	9.6	75th: 11.6
Kumar (2012)	2000-2004	Chicago, IL	BW	All births from Chicago MSA	$PM_{2.5}$	18.0	NR
Morello-Frosch et al. (2010)	1996-2006	CA	BW	All births in CA	$PM_{2.5}$	16.7	75th: 21.0
Salihu et al. (In Press)	2000-2007	Tampa, FL	BW, PTB	Women participating in Health Start Project	$PM_{2.5}$	11.0	Max: 23.2
Wilhelm et al. (2012)	2004-2006	Los Angeles, CA	BW	All births in LA county	$PM_{2.5}$	17.9	NR
Faiz et al. (2012)	1998-2004	NJ	Stillbirth	All births in NJ	$PM_{2.5}$	14.0	NR

Table A.6. Characterization of U.S. and Canadian Studies of Short-Term Exposure to $PM_{2.5}$ and Mortality

Author	Years	Location	Mortality	Population	Size Fraction	Mean 24-h avg Concentration (µg/m3)	Upper Percentile Concentrations (µg/m^3)
Ito et al. (2011a)	2000-2006	New York, NY	Cardiovascular	≥ 40	$PM_{2.5}$, PM components (EC, OC, SO_4, Ni, V, Zn, Si, Se, Na, Br, NO_3)	$PM_{2.5}$ All-Year: 14.4 Warm (April-September): 14.8 Cold (October-March): 14.1	NR
Zhou et al. (2011)	2000-2004	Detroit, MI Seattle, WA	Non-accidental, Cardiovascular, Respiratory	All	$PM_{2.5}$, PM components (Al, Fe, K, Na, Ni, S, Si, V, Zn, EC)	Detroit All-Year (Median): 13.2 Warm (April-September) (Mean):15.3 Cold (October-March) (Mean): 14.9 Seattle All-Year (Median): 7.9 Warm (April-September) (Mean): 8.0 Cold (October-March) (Mean): 11.4	Detroit Max: 65.8 Seattle Max: 41.3
Chang et al. (2012a)	2001-2005	New York, NY	Cardiovascular, Respiratory	≥ 65	$PM_{2.5}$	Spring (March-May): 14.3 Summer (June-August): 17.5 Fall (September-November): 13.3 Winter (December-February): 15.4	NR
Klemm et al. (2011)	1998-2007	Atlanta, GA (4 counties)	Non-accidental, Cardiovascular, Respiratory	≥ 65	$PM_{2.5}$, PM components (EC, OC, NO_3, SO_4)	17.0	75th: 21.6 Max: 72.9

Table A.7. Characterization of U.S. and Canadian Studies of Short-Term Exposure to $PM_{2.5}$ and Respiratory Hospital Admissions and Emergency Department Visits

Author	Years	Location	Hospital Admission/ ED Visit	Popul-ation	Size Fraction	Mean 24-h avg Concen-tration (μg/m^3)	Upper Percentile Concen-trations (μg/m^3)
Bell et al. (2012)	2000-2005	187 U.S. counties	Hospital admissions: All respiratory	≥ 65	$PM_{2.5}$, PM components	All-Year: 14.0 Summer: 16.2 Winter: 13.9	Max: All Year: 26.0 Summer: 28.5 Winter: 32.8
Zanobetti et al. (2009)	2000-2003	26 U.S. communities	ED Visits: All respiratory	≥ 65	$PM_{2.5}$, PM components (As, Al, Br, Cr, Fe, Pb, Mn, Ni, K, Si, V, Zn, NO3, SO4, NH4, Na^+, EC, OC)	15.3	$PM_{2.5}$ Max Spring: 24 (Riverside, CA) $PM_{2.5}$Max Winter: 29.9 (Fresno, CA)
Stieb et al. (2009)	1992-2003	7 Canadian cities	ED Visits: Asthma COPD Respiratory Infection	All	$PM_{2.5}$	Montreal (1/97-12/02): 8.6 Ottawa (4/92-12/00): 6.7 Edmonton (4/92-3/02): 8.5 Halifax (1/99-12/02): 9.8 Toronto (4/99-6/03): 9.1 Vancouver (1/99-2/03): 6.8	75th: Montreal: 10.9 Ottawa: 8.7 Edmonton: 10.9 Halifax: 11.3 Toronto: 11.9 Vancouver: 8.5
Levy et al. (2012)	2000-2008	119 U.S. counties	Hospital Admissions: All respiratory	≥ 65	PM components (EC, OC, SO4, NO3)	---	---

Darrow et al. (2011a)	1993-2004 ($PM_{2.5}$ collected from 8/1/98-12/31/04)	Atlanta, GA	ED Visits: All respiratory	All	$PM_{2.5}$	1-h max: 29 24-h avg: 16 Commute: 17 Day-time: 15 Night-time: 17	1-h max: 75th: 36 Max: 188 24-h avg: 75th: 21 Max: 72 Commute: 75th: 21 Max: 76 Day-time: 75th: 19 Max: 71 Night-time: 75th: 14 Max: 88
Strickland et al. (2010)	1993-2004 ($PM_{2.5}$ collected from 8/1/98-12/31/04)	Atlanta, GA	ED Visits: Asthma	5-17	$PM_{2.5}$, PM components (SO_4, EC, OC, water-soluble metals)	$PM_{2.5}$ All-Year: 16.4 Warm (May-October): 18.4 Cold (November-April): 14.3 $PM_{10-2.5}$ All-Year: 9.0 Warm: 9.7 Cold: 8.3	NR
Kim et al. (2011)	2003-2007	Denver, CO	Hospital Admissions: All respiratory COPD Asthma Pneumonia	All	$PM_{2.5}$, PM components (EC, OC, SO_4, NO_3)	8.0	59.4
Mar et al. (2010)	1998-2002	Tacoma, WA	ED Visits: Asthma	All	$PM_{2.5}$	12.3	NR
Kloog et al. (2012a)	2000-2006	New England	Hospital Admissions: All respiratory	≥ 65	$PM_{2.5}$	9.6	Max: 72.6
Li et al. (2011)	2004-2006	Detroit, MI	ED Visits: Asthma	2-18	$PM_{2.5}$	15.0	75th: 18.5 Max: 69.0
Glad et al. (2012)	2002-2005	Pittsburgh, PA	ED Visits: Asthma	All	$PM_{2.5}$	13.3	Max: 55.0

Grineski et al. (2011)	2000-2003	El Paso, TX	Hospital Admissions: Asthma Acute bronchitis	≥ 1	$PM_{2.5}$	12.8	75th: 15.6 95th: 26.6 Max: 119.1

Table A.8. Characterization of U.S. and Canadian Studies of Short-Term Exposure to $PM_{10-2.5}$ and Respiratory Hospital Admissions and Emergency Department Visits

Author	Years	Location	Hospital Admissions/ ED Visit	Population	Size Fraction	Mean 24-h avg Concentration (µg/m³)	Upper Percentile Concentrations (µg/m³)
Strickland et al. (2010)	1993-2004 (PM2.5 collected from 8/1/98-12/31/04)	Atlanta, GA	ED Visits: Asthma	5-17	$PM_{10-2.5}$	$PM_{10-2.5}$ All-Year: 9.0 Warm: 9.7 Cold: 8.3	NR

Table A.9. Characterization of U.S. and Canadian Studies of Short-Term Exposure to $PM_{2.5}$ and Cardiovascular Hospital Admissions and Emergency Department Visits

Author	Study Years	Location	Outcome	Population	Size Fraction	Mean 24-h avg Concentration (µg/m³)	Upper Percentile Concentrations (µg/m³)
Zanobetti et al. (2009)	2000-2003	USA (26 communities)	ED Visits: MI, CHF	Older adults ≥ 65 yrs	$PM_{2.5}$ $PM_{2.5}$ components: As, Al, Br, Cr, Fe, Pb, Mn, Ni, K, Si, V, Zn, NO3, SO4, NH4, Na^+, EC, OC	15.3	$PM_{2.5}$ Max Spring: 24 (Riverside, CA) $PM_{2.5}$Max Winter: 29.9 (Fresno, CA)
Stieb et al. (2009)	1990's-early 2000's (depending on city)	Candada (7 Cities)	ED Visits:Angina/MI, Heart Failure, Dysrhythmia		$PM_{2.5}$	City-specific means (range): 6.7-9.8	City Specific 75th Percentiles: 8.5-11.9

Author	Study Years	Location	Outcome	Population	Size Fraction	Mean 24-h avg Concentration (μg/m³)	Upper Percentile Concentrations (μg/m³)
Ito et al. (2011a)	2000-2006	New York, NY	ED Visits: CVD	≥40 yrs	$PM_{2.5}$ $PM_{2.5}$ components: EC, OC, SO4, NO3, Na+, Ni, V, Zn, Si, Se, Br	All year/Warm/Cold: 14.44/14.79/ 14.09 1.13/ 1.03/1.24 4.3/4.51/4.08 4.14/ 4.81/3.42 2.12/1.52/ 2.78 0.14/ 0.14/ 0.15 0.0171/0.0111/ 0.0236 0.0066/ 0.0054/0.0080 0.0300/ 0.0216/ 0.0389 0.0769/ 0.0886/ 0.0643 0.0013/0.0011/ 0.0015 0.0036/0.0031/0.0040	Not presented (Note: SD provided so we could compute)
Mathes et al. (2011)	2000-2002	New York, NY	ED Visits: CVD	≥40 yrs	$PM_{2.5}$	---	---
Szyszkowicz et al. (2012)	Apr 1992-Mar 2002	Canada (Edmonton)	ED Visits: Hypertension	N=5,365	$PM_{2.5}$	8.5	75th percentile: 10.9 Max: 1.3.1
Haley et al. (2009)	2001-2005	New York State	ED Visits	Discharges from all NYS hospitals	$PM_{2.5}$	NR	NR
Bunch et al. (2011)	1993-1998	Wasatch Front, Utah	Hospital Admissions	All	$PM_{2.5}$	City specific means (range): 9.3-11.1	City specific max: 9.3-11.1
Kloog et al. (2012a)		New England	Hospital Admissions	≥65	$PM_{2.5}$ (predicted)	9.6	72.59

Author	Study Years	Location	Outcome	Population	Size Fraction	Mean 24-h avg Concentration (μg/m^3)	Upper Percentile Concentrations (μg/m^3)
Kim et al. (2011)	2003-2007	Denver	Hospital Admissions	All	$PM_{2.5}$	7.98	59.41
					EC	0.47	3.02
					OC	3.09	10.28
					Sulfate	1.08	14.32
					Nitrate	1.03	19.72

Table A.10. Characterization of U.S. and Canadian Studies of Short-Term Exposure to $PM_{2.5}$ and Out of Hospital Cardiac Arrests

Author	Study Years	Location	Outcome	Population	Size Fraction	Mean 24-h avg Concentration (μg/m^3)	Upper Percentile Concentrations (μg/m^3)
Silverman et al. (2010)	2002-2006	USA (New York City)	Out-of-hospital cardiac arrests	N=8,216 <40 to ≥ 70 yrs	$PM_{2.5}$	Median: All year = 12 Apr-Sept = 12 Oct-Mar = 12	Upper (95%): All year = 30 Apr-Sept = 31 Oct-Mar = 28

Table A.11. Characterization of U.S. and Canadian Studies of Short-Term Exposure to $PM_{2.5}$ and Time of Stroke Symptom Onset

Author	Study Years	Location	Outcome	Population	Size Fraction	Mean 24-h avg Concentration (μg/m^3)	Upper Percentile Concentrations (μg/m^3)
Wellenius et al. (2012)	1999-2008	Boston, MA	Time of Symptom Onset (Ischemic Stroke)	Patients admitted to BIDMC	$PM_{2.5}$	NR	NR

BIDMC= Beth Israel Deaconess Medical Center

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