Responses to Significant Comments on the 1996 Proposed Rule on the National Ambient Air Quality Standards for Particulate Matter

(December 13, 1996; 61 FR 65638)

Docket Number A-95-54

U.S. Environmental Protection Agency
July 1997

Table of Contents

List of Acronyms iii

Frequently Cited Documents iv

I. INTRODUCTION 1

II. RESPONSES TO SIGNIFICANT COMMENTS ON PROPOSED PM STANDARDS 2

A. Primary PM Standards 2

1. General comments on proposed primary standards 2

2. Specific comments on proposed primary $PM_{2.5}$ standards 3

a. Indicator for fine particles 3

b. Averaging times 24

c. Standard levels 26

d. Forms of the standards 40

e. Revisions to Appendix K for PM 47

3. Specific comments on proposed primary PM_{10} standards 50

a. Indicator for coarse particles 50

b. Averaging times 51

c. Standard levels 51

d. Form of 24-hour standard 53

e. Revisions to Appendix K for PM_{10} 54

4. Specific scientific/technical comments 54

a. Interpretation of epidemiological studies 54

b. Mechanistic and toxicological evidence 64

c. Issues related to causality and the consistency/coherence of the evidence 66

d. New studies and analyses 79

e. Health risk assessments 80

f. Altitude and temperature corrections 89

g. Characterization of background $PM_{2.5}$ concentrations 89

5. Comments on related programs 89

B. Secondary PM Standards 90

1. General comments on proposed secondary standards 90

2. Specific scientific/technical comments 96

C. Federal Reference Method for Monitoring $PM_{2.5}$ 97

1. General Comments on Sampler Design 97
2. Inlet and Impactor Design 99
3. Anodized Aluminum Surface 100
4. Filter for $PM_{2.5}$ Sample Collection 101
5. Filter Handling/Weighing/Conditioning Requirements 103
6. Sampler Performance Requirements 105

III. RESPONSES TO COMMENTS ON LEGAL, ADMINISTRATIVE, AND PROCEDURAL ISSUES RELATED TO THE REVIEW OF THE PM NAAQS 107
A. General Issues 107
1. Cost consideration 107
2. Margin of safety 110
4. Data availability for key health studies 111
5. Availability of FRM test data for public review 112
6. Consideration of disbenefits 112
7. Miscellaneous comments 119
B. Regulatory and Environmental Impact Analyses 125
1. Compliance with E.O. 12866 125
2. Regulatory Flexibility Act 125
3. Unfunded Mandates Reform Act 127

IV. MISPLACED COMMENTS 127
A. Comments on implementation-related issues 127
1. Attainability of standards 127
2. Implementation issues 128
B. Comments on Regulatory Impact Analyses 128

APPENDICES: Expanded Responses to Scientific and Technical Comments on the Health Effects Evidence for Particulate Matter

Appendix A: Responses to Comments on General Issues Regarding the Use of Epidemiological Studies in Standard Setting
Appendix B: Responses to Comments on Use of Specific Epidemiological Studies
Appendix C: Studies Published after Completion of the Criteria Review
Appendix D: Response to Comments on Exposure Misclassification, the Role of Indoor Air, and Measurement Error

REFERENCES

List of Acronyms

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

Act	Clean Air Act
BS	British Smoke
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
COH	Coefficient of haze
COPD	Chronic Obstructive Pulmonary Disease
EPA	Environmental Protection Agency
FRM	Federal Reference Method
IMPROVE	Interagency Monitoring of Protected Visual Environment
NAAQS	National ambient air quality standards
NAPAP	National Acid Precipitation Assessment Program
OR	Odds Ratio
PM	Particulate matter
RR	Relative Risk
SMSA	Standard Metropolitan Statistical Area

Frequently Cited Documents

The following documents are frequently cited throughout EPA's response to comments, often by means of the short names listed below:

Criteria Document:	U.S. Environmental Protection Agency (1996a). Air Quality Criteria for Particulate Matter. Research Triangle Park, NC: National Center for Environmental Assessment. Office of Research and Development. April 1996. EPA report no. EPA/600/P-95/001aF-cF.
Preamble to the final rule:	Preamble to the Final Rule on the Review of the National Ambient Air Quality Standards for Particulate Matter; to be published in the *Federal Register* on July 18, 1997.
Proposal notice:	National Ambient Air Quality Standards for Particulate Matter: Proposed Decision. 61 FR 65638, December 13, 1996.
Staff Paper:	U.S. Environmental Protection Agency (1996b). Review of the National Ambient Air Quality Standards for Particulate Matter: Assessment of Scientific and Technical Information. OAQPS Staff Paper. Research Triangle Park, NC: Office of Air Quality Planning and Standards. July 1996. EPA report no. EPA-452/R-96-013.
Summary of Comments:	Abt Associates (1997). Final Summary of Significant Written Comments on the 1996 Particulate Matter NAAQS Proposal - Issue Report. EPA Docket # A-95-54.
	TRC Environmental Corporation (1997). PM Monitoring Technical Support Document (Part I). Summary of Public Comments on Proposed PM Monitoring Regulations (40 CRF Part 50 Appendix L, 40 CFD Part 53, 40 CFR Part 58).

Responses to Significant Comments on the 1996 Proposed Rule on the National Ambient Air Quality Standards for Particulate Matter

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) and several separate documents referred to below, presents the responses of the Environmental Protection Agency (EPA) to the more than 50,000 public comments received on the 1996 PM NAAQS proposal notice. All significant issues raised in the public comments have been addressed.

As reflected in the table of contents for this document, responses are organized by topics, which correspond to specific sections of a companion document that has been placed in the docket, the Summary of Significant Comments on the 1996 Particulate Matter NAAQS Proposal -- Organized by Issue (henceforth the "Summary of Comments").[1] Due to the large number of comments that addressed similar issues, as well as the sheer volume of the comments received, this response-to-comments document does not generally cross-reference each response to the commenters who raised the particular issue involved, although commenters are identified in some cases where they provided particularly detailed comments that were used to frame the overall response on an issue.

This document refers as appropriate to various support documents, available in the docket, that have been prepared to assist in presenting the more technical aspects of the Agency's responses. A complete list of references, including these support documents, is presented at the end of this document. In addition, separate summary and response to public comments documents have been prepared for issues raised in comments on the proposed new reference method for measuring fine particles as $PM_{2.5}$.[2]

The responses presented in this document, including its appendices, and in the separate documents referred to above are intended to augment the often extensive responses to comments that appear in the preamble to the final rule or to address comments not discussed in the preamble.

---

[1]A second summary document, the Summary of Significant Comments on the 1996 Particulate Matter NAAQS Proposal - Organized by Commenter, has also been placed in the docket to facilitate the review of comment summaries by commenter as well as by issue.

[2]The latter documents also includes responses to public comments on related proposals to revise 40 CFR Parts 53 and 58.

Although portions of the preamble are paraphrased in this and other documents where useful to add clarity to responses, the preamble itself remains the definitive statement of the basic rationale for the revisions to the standards adopted in the final rule.

In many instances, particular responses presented in the above documents include cross references to responses on related issues, either in those documents or in the preamble to the final rule.[3] In view of the large number of comments received, the cross references may not always reflect the extent to which information relevant to a particular comment is contained in responses to other comments. Accordingly, the above documents as a group, together with the preamble to the final rule, should be considered collectively as EPA's response to all of the comments submitted.

II. RESPONSES TO SIGNIFICANT COMMENTS ON PROPOSED PM STANDARDS

A. Primary PM Standards

1. General comments on proposed primary standards

A large number of comments on the proposed primary standards for PM were very general in nature, basically expressing one of two substantively different views: (1) support for revisions to the primary standards by addition of new standards for $PM_{2.5}$ (either the proposed standards or alternative standards more or less stringent than those proposed); or (2) opposition to the addition of $PM_{2.5}$ standards, with or without any revisions to the current PM_{10} 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. Comments of this nature on the PM proposal notice are summarized in section II.A.1 of the Summary of Comments, and those addressing both the PM and O_3 proposal notices are summarized in section I.A.

The preamble to the final rule in its entirety presents the Agency's response to these general views. More specifically, section II of the preamble responds to views that are health-based, including those related to the following factors: 1) the strengths and limitations of the scientific evidence on the effects of PM; 2) the need for and appropriateness of revising the standards by adding primary standards for $PM_{2.5}$ now, as opposed to waiting for additional research and monitoring for $PM_{2.5}$; and 3) the advice of the Clean Air Scientific Advisory Committee (CASAC) on the adequacy of the scientific evidence available for making a decision on the standards and individual CASAC Panel

---

[3]The terminology used in the preamble to the final rule as it appears in the Federal Register refers to various named sections of the preamble as "units." This response to comments document refers to these units as "sections" of the preamble.

members' personal views on the standards. Sections IV and VIII of the preamble respond to comments on certain legal and procedural issues.

2. Specific comments on proposed primary $PM_{2.5}$ standards

A large number of comments addressed specific elements of the proposed primary $PM_{2.5}$ standards, including the averaging time, level, and form of the standards, and the provisions relating to interpretation of the standards as specified in a revised Appendix K in the proposal and in Appendix N in the final rule. These comments are generally summarized in sections II.A.2.a and b of the Summary of Comments, and responses to the key issues raised in these comments are presented in sections II.C,D,E, and F and section V of the preamble to the final rule. More specific responses to the full range of significant issues raised in these comments are presented below.

a. Indicator for fine particles

A broad range of public comments were received in this area. A number of commenters raised various issues with regard to EPA's proposed general mass indicator for fine particles, $PM_{2.5}$. Some commenters expressed the view that no fine particle mass indicator is warranted for various reasons. Others provided comments as to how EPA should modify the proposed $PM_{2.5}$ indicator [and associated Federal Reference Method (FRM) monitor] to address various concerns. EPA notes that it considered a variety of indicators (e.g., PM_{10}, $PM_{2.5}$, PM_1, chemical component) during the review, as discussed in the Staff Paper. The comments are summarized primarily in section II.A.2.a.(1) of the Summary of Comments and significant comments are highlighted in the preamble to the final rule. In addition to the responses contained in sections II-B and II-C-1 of the preamble to the final rule, EPA provides the following responses to specific issues.

i. <u>Use of fine particle mass indicator</u>

The following comments raise issues as to why a fine particle mass indicator is not warranted:

(1) *Comment:* Many commenters expressed the view that a fine particle mass indicator in general, or a $PM_{2.5}$ indicator in particular, is not supported by the available scientific evidence. These views are based on assertions that there are too few $PM_{2.5}$ health effects studies and/or that the available $PM_{2.5}$ studies are too uncertain or flawed (e.g., confounded by other pollutants and/or weather, biased by measurement error, inadequate to prove causality) to be used as a basis for setting fine particle standards.

Response: See sections II.B and II.C.2 of the preamble to the final rule, for a general response to the overall adequacy of the scientific data base with regard to the need to revise the PM standards, including a discussion of general and specific issues with respect to the available epidemiological information on the effects of PM.

As outlined in sections II.B and II.C of the preamble to the final rule, the Staff Paper concludes that continued use of PM_{10} as the *sole* indicator for the PM standards would not provide the most effective and efficient protection from the health effects of PM (U.S. EPA, 1996b, pp. VII-4-11). Based on the recent health effects evidence and the fundamental physical and chemical differences between fine and coarse fraction particles, the Criteria Document and Staff Paper conclude that fine and coarse fractions of PM_{10} should be considered separately (U.S. EPA, 1996a, p. 13-93; 1996b, p. VII-18). Taking into account such information, CASAC found sufficient scientific and technical bases to support establishment of separate standards relating to these two fractions of PM_{10}. Specifically, CASAC advised the Administrator that "there is a consensus that retaining an annual PM_{10} NAAQS . . . is reasonable at this time" and that there is "also a consensus that a new $PM_{2.5}$ NAAQS be established" (Wolff, 1996b).

Beyond the general points about the basis for any revisions discussed in section II.A.1 above, these commenters argued either that the available epidemiological data did not provide a basis for separating fine and coarse fraction particles, or that there were not enough fine particle studies to support selecting standard levels. Most of these commenters also expressed concerns that there were insufficient ambient fine particle data by which to evaluate the relative protection afforded by new standards.

EPA notes that issues relating to the basis for separating PM_{10} fractions were addressed in the Criteria Document and/or Staff Paper assessments, and these perspectives were also available for CASAC consideration in developing its recommendations. As noted in the Staff Paper, the main basis for separating the fine and coarse fractions of PM_{10} is that, because they are fundamentally different PM components with significantly different physico-chemical properties and origins (U.S. EPA 1996b, Section V.D), separate standards would permit more effective and efficient regulation of PM. While the difficulty of separating these classes of particles in the epidemiological studies is recognized in the Staff Paper assessment, the preponderance of the available evidence suggests that strategies to control fine particles will more effectively reduce population exposure to substances associated with health effects in the recent epidemiological studies. Although the number of studies using fine PM indicators is more limited than for PM_{10}, there are more than 20 community studies showing significant associations for a consistent set of mortality and morbidity effects. A substantial subset of these studies (Tables V-12 to V-13; U.S. EPA, 1996b) provides a sufficient quantitative basis for selecting standard levels, without the need to rely on estimates based on $PM_{2.5}/PM_{10}$ ratios.

See also section II.A.4 and Appendices A, B and D below on interpretation of the epidemiological studies and issues such as consistency, coherence, confounding and measurement error.

(2) *Comment:* Many commenters expressed the view that an indicator based on fine particle mass is inappropriate because it does not differentiate specific causal agents within the mix of fine

particle components. A number of commenters expressed concerns that various portions of fine particles might not be responsible for any observed effects. As a result, local and/or regional control strategies may be misdirected toward fine particle components that are not related to health effects. In addition, a commenter (API, IV-D-2250) asserted that the proposal notice understates the variety among the $PM_{2.5}$ constituents.

Response: See preamble to the final rule, sections II.B and II.C.2.

Consistent with CASAC advice, this review considered the merits of alternative indicators, including $PM_{2.5}$ mass as well as indicators based on specific components of PM. The Criteria Document extensively evaluated health effects information on many specific components, including sulfates, acids, nitrates, organics, and transition metals. In addition, during the review EPA specifically highlighted the diversity within the fine and coarse particle mix (e.g., see Table IV-2 in the Staff Paper). Based on this extensive review, staff concluded, with CASAC concurrence, that a $PM_{2.5}$ indicator was appropriate. In so doing, staff also specifically considered the likely effect of the use of such an indicator for control of PM components and key gas-phase precursors of PM.

As noted in the preamble to the final rule, EPA continues to conclude that it is appropriate to control fine particles as a group, as opposed to singling out particular components or classes of fine particles. The more qualitative scientific literature, evaluated in Chapter 11 of the Criteria Document and summarized in Section V.C of the Staff Paper, has reported various health effects associated with high concentrations of a number of fine particle components (e.g., sulfates, nitrates, organics, transition metals), alone or in some cases in combination with gases. Community epidemiological studies have found significant associations between fine particles and/or PM_{10} and health effects in various areas across the U.S. where such fine particle components correlate significantly with particle mass. As noted in the Staff Paper, it is not currently possible to rule out any one of these components as contributing to fine particle effects. Thus, the Administrator finds that the present data more readily support a standard based on the total mass of fine particles.

Information suggesting that observed PM-related health effects are related to specific components of regional or local concern is not nearly as extensive as information relating health effects to particle mass (U.S. EPA 1996a, chapters 12 and 13). In addition, EPA is required to establish national standards, and states and local governments are not precluded from establishing additional standards that may be deemed appropriate to address concerns about particular classes of fine particles. In specifying a precise size range for a fine particle standard, both the staff and CASAC recommended $PM_{2.5}$ mass concentration as the indicator of fine particles (Wolff, 1996b). As noted in the Staff Paper, $PM_{2.5}$ encompasses all of the potential agents of concern in the fine fraction, including most of the particle number in the entire PM

distribution as well as most sulfates, acids, fine particle metals, organics, ultrafine particles and most of the aggregate surface area (U.S. EPA 1996b, p.VII-15).

The central question of which particulate components to regulate has been an issue since the inception of the first PM standards. Other ambient pollutants (e.g., NO_2 or CO) are uniquely defined as individual chemicals, whether or not they serve as proxies for a larger class of substances (e.g., ozone as an index of photochemical oxidants). Regulating PM in general, as opposed to multiple chemical components of PM, raises questions as to whether particulate components of varying composition, size, and other physicochemical properties are likely to produce identical effects.

Both EPA's past and present regulatory experience with PM control programs and its successive reviews of the standards have reaffirmed the wisdom of retaining standards that control particles as a group, rather than eliminating such standards and waiting for scientific research to develop information needed to identify more precise limits for the literally thousands of particle components that may potentially be of concern. Each such decision recognized the possibility that potentially less harmful particles might be included in the mix that was regulated, but concluded that the need to provide protection against serious health effects nonetheless required action under section 109 of the Act. The success of this approach is evident in early U.S. control programs that dramatically reduced "smoke" and "TSP" in major cities in the 1960's and 1970's and in the continued improvement in air quality through the current PM standards. The major refinements that have been recommended through the course of reviews of PM standards have been to improve the focus of control efforts by defining scientifically based size classes (i.e., moving from TSP to PM_{10} and now, $PM_{2.5}$) that will permit more effective and efficient regulation of those fractions most likely to present significant risks to health and the environment.

As discussed in the preamble to the final rule, the current review has examined the available evidence to determine whether it would tend to support inclusion or exclusion of any physical or chemical classes of PM, for example sulfates, nitrates, or ultra-fine particles. That examination concludes that, while both fine and coarse particles can produce health effects, the fine fraction appears to contain more of the reactive substances potentially linked to the kinds of effects observed in the recent epidemiological studies (U.S. EPA 1996b, Section V.F.). However, the available scientific information does not rule out any one of these components as contributing to fine particle effects. Indeed, it is reasonable to anticipate that no single component will prove to be responsible for all of the effects of PM.

EPA recognizes that whether the standards are set for PM_{10} only or also for fine particles, there are uncertainties with respect to the relative risk presented by various components of PM. In this regard, the EPA is placing greater weight on the concern that by failing to act now, the PM NAAQS would not control adequately those components of air pollution that are most

responsible for serious effects, than on the possibility they might also control some component that is not.

EPA also recognizes that different components may be of interest in different areas (e.g., woodsmoke, sulfates, etc). EPA notes that the epidemiological studies were conducted in locations around the nation with different mixes of components but with reasonably similar results in terms of responses. Consequently, EPA selected a mass-based fine particle indicator. In attaining the $PM_{2.5}$ standards, areas may choose to focus their control strategies on these different components. However, EPA believes that the general particle indicator remains an appropriate approach to protecting public health.

(3) *Comment*: EPA should use PM_{10} as the indicator to control fine particle mass since PM_{10} correlates as well with reported health effects as do various fine particle indicators, including $PM_{2.5}$, and /or because current PM_{10} control programs already function in some areas to control fine particles.

Response: See preamble to the final rule, sections II.B and II.C.

Based on both the staff review (U.S. EPA, 1996b, p. VII-3) and the recommendations of some commenters (e.g., California EPA, IV-D-2251), EPA has considered two alternative approaches for providing additional health protection in revising the standards: 1) adopt more protective PM_{10} standards and 2) develop separate standards for the major components of PM_{10}, including $PM_{2.5}$. Conceptually, the first approach would give weight to the view that standards should be based on pollutant indicators for which the most data have been collected, with less consideration of the evidence that suggests that the current standards provide adequate protection against the effects of coarse particles, and that tightening the current standards to control fine particles would place unnecessary requirements on coarse particles. Because the PM_{10} network is in place, a more health protective PM_{10} standard would also respond to commenters who have expressed a desire for more immediate implementation of revised standards. The second approach is based on the view that in the long run, more effective and efficient protection can be provided by separately targeting appropriate levels of controls to fine and coarse PM.

The Staff Paper examined this issue in detail (U.S. EPA 1996b, p. VII-3 to 11), and concluded that the available information was sufficient to develop separate indicators for fine and coarse fractions of PM_{10}, based on the recent health evidence, the fundamental differences between fine and coarse fraction particles, and implementation experience with PM_{10}. Further, the staff concluded that:

> [C]onsideration of comparisons between fine and coarse fractions suggests that fine fraction particles are a better surrogate for those particle components

> linked to mortality and morbidity effects at levels below the current standards. In contrast, coarse fraction particles are more likely linked with certain effects at levels above those allowed by the current PM_{10} standards. In examining alternative approaches to increasing the protection afforded by PM_{10} standards, the staff concludes that reducing the levels of the current PM_{10} standards would not provide the most effective and efficient protection from these health effects. [U.S. EPA 1996b; p. 7-45.]

As discussed in section II.C of the preamble to the final rule, EPA concludes that it is more appropriate to provide additional protection against the risk posed by PM by adding new standards for the fine fraction of PM_{10}, than by tightening the current PM_{10} standards. Although fewer epidemiological studies have used $PM_{2.5}$ and other fine particle indicators (e.g., sulfates, acids), there are nonetheless significant indications from the scientific evidence drawn from the physicochemical studies of PM, air quality and exposure information, toxicological studies, and respiratory tract deposition data that this approach will provide the most effective and efficient protection of public health.

(4) *Comment:* Some commenters argued that the results of a study by Schwartz et al. (1994), which EPA used in support of a $PM_{2.5}$ standard, more readily suggest that PM_{10} is a better indicator of PM in health effects studies.

Response: Schwartz et al. (1994) analyzed symptom diary data from children in six cities for associations with daily measurements of ambient air pollutants. In this report, results were presented for associations between three symptom groups and air pollutants. The findings for PM and PM components are presented in the table below.

SUMMARY OF RESULTS FROM SIX CITIES SYMPTOMS STUDY
(Schwartz et al., 1994)

	Cough OR (95% CI)	**Lower respiratory symptoms** OR (95% CI)	**Upper respiratory symptoms** OR (95% CI)
PM_{10} (30 μg/m^3)	1.27 (1.06-1.52)	1.53 (1.20-1.95)	1.22 (0.98-1.52)
$PM_{2.5}$ (20 μg/m^3)	1.19 (1.01-1.42)	1.44 (1.15-1.82)	1.22 (1.00-1.49)
Fine particle sulfur (5 μg/m^3)	1.23 (0.95-1.59)	1.82 (1.28-2.59)	reported not significant
Nephelometry (1 km^{-1})	1.21 (1.02-1.45)	1.36 (1.14-1.63)	reported not significant
Aerosol acidity (25 nmol/m^3)	1.06 (0.87-1.29)	1.05 (0.25-1.30)	1.06 (0.98-1.15)

Commenters have focused on the following conclusion reached by the authors based on these results: "There was no evidence that other measures of particulate pollution including aerosol acidity were preferable to PM_{10} in predicting incidence of respiratory symptoms." (Schwartz et al., 1994) However, EPA notes the same could as easily be said about $PM_{2.5}$. The Staff Paper and Criteria Document note the difficulty in separating the effects associated with these overlapping indicators of PM, particularly in comparing fine particle components such as sulfates or acids with $PM_{2.5}$, and $PM_{2.5}$ with PM_{10}. In this study, $PM_{2.5}$ apparently comprises about 2/3 of PM_{10} mass, which suggests that any attempt to separate the two in this study is questionable, despite the authors' conclusions and commenters' emphasis on this portion of the results. (These commenters in general do not note that the PM_{10} concentrations associated with effects in this study are generally well below those permitted by the current standards.)

In evaluating the usefulness of $PM_{2.5}$ as an indicator, the Staff Paper focused not on comparisons between PM_{10} and $PM_{2.5}$, but on comparing the relative effects associations between fine and coarse fraction particles that, taken together, comprise PM_{10}. Although the Schwartz et al. (1994) work did not report results separately for $PM_{2.5}$ and $PM_{10-2.5}$, a number of other studies, including the six city mortality study, did provide useful results in this regard (U.S. EPA, 1996b; Section V.D). In essence, the staff assessment found that fine particles or fine particle components are generally stronger predictors of adverse health effects where such comparisons are possible. As summarized in the Staff Paper (pp. V-58 to V-67), EPA believes that the decision to establish a $PM_{2.5}$ standard is well supported by the available science.

ii. Inclusion of Constituents in Measured $PM_{2.5}$

A number of commenters raised made alternative suggestions for how EPA should modify the proposed $PM_{2.5}$ indicator (and associated FRM monitor) to better address the collection of fine particle components of concern, with some recommending elimination of one or more components, and others recommending more complete capture of nitrates and certain other semi-volatile components in the FRM. Specific comments in this area are summarized and responded to below. As a general response, however, EPA notes that the fundamental approach to selecting a fine particle indicator was based on consistency with the monitoring used in the underlying epidemiological studies. The specific philosophy and the approach used for the FRM was reviewed by a CASAC Technical Subcommittee for Fine Particle Monitoring at a public meeting held March 1, 1996, in Chapel Hill, NC. This CASAC subcommittee consisted of monitoring and other experts who concurred with EPA's proposed approach, recognizing the inherent challenges of being consistent with the studies on which the levels of the standards are based and the goal of fully characterizing the aerosol in many diverse settings across the country using a consistent approach required by an equitable national standard (Price, 1996). The subcommittee found that, "Under the circumstances, EPA has made an appropriate choice to establish a good practice standard for filter sampling and analysis technology" (Price 1996). Furthermore, the subcommittee endorsed EPA's specific approach with respect to nitrates: "Since the recent epidemiological studies have used a variety of methods with different performance characteristics, no one FRM can match them all; however, [EPA's FRM approach] matches most in the choice not to use a more complex design that includes denuding and backup filtration to improve the sampling of the ambient particulate nitrate compounds" (Price 1996, emphasis added).

(1) *Comment*: If a fine particle standard is promulgated, the EPA should exclude nitrates in the definition of $PM_{2.5}$, or EPA should allow States to set standards for PM excluding nitrates, due to the lack of toxic effects from airborne nitrates. One commenter (Ohio Edison, IV-D-2275) asserts that failure to exclude nitrates from the definition of particulate matter would lead to conflict with a previous EPA decision to not revise the current national ambient air quality standards for NO_2. Another commenter (PG&E, IV-D-2183) recommends that nitrates should be excluded from fine PM mass collected on the basis of its assessment of a list of studies from available effects literature on particulate and gas phase inorganic nitrates.

Response: As discussed in the preamble to the final rule, EPA continues to conclude that it is appropriate to control fine particles as a group, as opposed to singling out particular components or classes of fine particles. The more qualitative scientific literature, evaluated in Chapter 11 of the Criteria Document and summarized in Section V.C of the Staff Paper, has reported various health effects associated with high concentrations of a number of fine particle components (e.g., sulfates, nitrates, organics, transition metals), alone or in some cases in combination with gases. Community epidemiological studies have found significant associations between fine particles or PM_{10} and health effects in various areas across the U.S. where such fine particle components correlate significantly with particle mass. As noted in section II.C of

the preamble, it is not possible to rule out any one of these components as contributing to fine particle effects.

With respect to the specific comment that the inclusion of nitrates would be at odds with other NAAQS decisions, it is important to distinguish nitrate-bearing particles from NO_2, which is a gas, as well as from nitric acid when it occurs as a vapor. While commenters are correct that particulate nitrates and nitric acid are generally formed from atmospheric conversion of nitrogen oxides emissions, (just as sulfates are formed from atmospheric transformations of sulfur oxides emissions), the recent reaffirmation of the NO_2 standards was based principally on the effects of NO_2 itself, and not on the atmospheric transformation products of NO_2. NO_x is already recognized as a precursor to ozone and PM_{10} . Therefore, EPA does not consider the existence of a separate gaseous NO_2 standard to be relevant to the inclusion of nitrate particles in the indicator for PM. Whether or not there is a correlation between atmospheric levels of NO_2 and nitrate particles, EPA believes that it is preferable to rely on health effects studies that used exposures to nitrate- or nitric acid-bearing particles in order to draw any conclusions regarding the health effects of particles with associated nitrates or nitric acid. Thus, EPA does not agree with the premise that the studies of NO_2 exposure are directly relevant to a discussion of toxic effects from exposure to nitrates or nitric acid. EPA sees no cause for concern about a regulatory conflict between the NAAQS for PM and NO_2. The primary PM NAAQS is based on studies of the health effects from exposure to PM, including acid aerosols. This decision is independent of any decisions made regarding the NO_2 NAAQS.

With regard to the claim that EPA did not consider certain studies, EPA disagrees. Chapter 11 of the PM Criteria Document, which discusses controlled human and toxicological studies of PM components, specifically cross references documents in which the specific studies on the effects of nitrates have been reviewed, including the 1982 PM Criteria Document, the 1989 EPA Acid Aerosols Issues Paper, and the 1993 NO_x Criteria Document (U.S. EPA, 1996a: p 11-5). The document notes that the more limited recent information on nitrates is summarized in sections on multi-component studies (such as that of Kleinman et al., 1995). The EPA staff considered the results of relevant studies on nitrates in reaching conclusions on the appropriate indicator for fine particles. Indeed, the studies examined by EPA also included nitrate studies that commenters chose not to cite.

In examining the list of studies submitted for further consideration by PG&E (IV-D-2183), EPA notes that two of the nine (Braun-Fahrlander et al., 1992, and Dockery et al., 1992) did not use separate quantitative measurements of nitrates or nitric acid aerosols, but rather relied on measurements of NO_2. EPA did consider these studies with regard to PM, but they are not considered to be directly relevant to a discussion of health effects from nitrate-bearing particles. However, EPA notes that in the Braun-Farhlander et al. (1992) study the annual average of NO_2 was associated with the duration of upper respiratory symptoms.

Because relatively few epidemiological studies have included separate quantitative measures of nitrate particles or nitric acids, the Criteria Document did not set apart a discussion of nitrates or nitric acids from the overall review of health effects from acid aerosol exposures. The commenter cites three epidemiologic studies (Ostro et al., 1991; Burnett et al., 1989; Burnett et al., 1994) as finding no associations between nitrate levels and asthma symptoms or lung function. EPA notes that commenters omitted other studies cited in the Criteria Document that reported positive associations with nitrates. Fine particulate nitrates were associated with increased symptoms and bronchodilator use in Perry et al. (1982), and associations were found with aerosol nitrate and nitrous acid by Hoek and Brunekreef (1994). In addition, several epidemiological studies reporting statistically significant associations between PM exposures and serious health effects (e.g., mortality) were conducted in areas in which nitrate levels are expected to be relatively high (e.g., Los Angeles, Utah Valley). Nitrate particles are expected to be present to some degree in most urban areas in the U.S. (See Criteria Document Chapter 6 and Figures 6-85a-c and Staff Paper Figure IV-3). Although nitrates were not measured quantitatively, these epidemiological studies lend support to the inclusion of the fraction of nitrate present in these types of studies. However, EPA emphasizes that, in reviewing the available epidemiological data, no evidence has been found to give the agency cause to distinguish this subset of particulate matter for the purposes of regulation.

In addition to the epidemiological studies, the commenter (PG&E) also included several toxicological and clinical studies of nitrate or nitric acid exposure. The toxicological studies were available for previous reviews of air quality standards. In the PM Criteria Document, almost all of the more recent clinical or toxicological studies on acid aerosols that were available for review used sulfuric acids or sulfate particles. It is of note that a pattern of positive and negative responses to nitrates mirrors the much more numerous findings for sulfates. Human studies of nitric acid vapor exposure have generally not found significant effects on spirometric measures of lung function. The PM Criteria Document cites the toxicological studies listed by the commenter and recognizes that health effects were found in studies that used high nitrate concentrations (p. 11-7), as observed by the commenter. Commenters are incorrect, however, in stating that nitrates have been shown to be uniformly less toxic than other PM components. Although limited studies in humans (cited in both the Acid Aerosol Issue Paper and the NOx Criteria Document) show minimal effects on spirometric measures of lung function and respiratory symptoms, Kleinman et al. (1995) observed an increase in lung permeability in relation to exposure to a high (350 $\mu g/m^3$) concentration of particulate nitrate. These observations indicate that nitrate cannot be ignored and treated as an “inert” particle.

Commenters also submitted two unpublished abstracts of studies that were not available for inclusion in the Criteria Document. Disregarding the appropriateness of relying on such more recent studies, the results of Balmes et al., who found no significant incremental effects in particular endpoints after short-duration exposures of humans to nitric acid vapor and nitrates, are consistent with previous controlled human exposures to these materials. However, as is the

case for similar findings for acid sulfates, such results cannot be said to disprove any role of nitrates in the observed findings of epidemiologic studies, which include different endpoints, far larger numbers of people, significantly more sensitive populations, and considerably longer exposure durations than can be achieved in controlled human studies. The unpublished results by Kleinman et al. in animals apparently find effects of nitrates at levels as low as 100 $\mu g/m^3$ and increased potency with respect to other PM components at levels of 350 $\mu g/m^3$. If the results of this study were to be considered, assuming they were sustained following peer review, publication, and inclusion in the next criteria review, they would serve to add markedly to, not diminish, concerns about nitrates. In addition, commenters did not cite another recent study of nitric acid vapor that was published after the NO_x Criteria Document was completed (Schlesenger et al., 1994). This study found that inhalation of nitric acid vapor levels as low as 50 $\mu g/m^3$ may adversely affect pulmonary health in animals by altering the production of superoxides and the release of tumor necrosis factor by alveolar macrophages. In essence, the mixed results of these recent findings, if fully considered, would not support commenters' recommendation to exclude nitrates.

Based on an examination of the information submitted by the commenter, as well as the earlier staff integrated assessment of the available health effects information (largely the same information), EPA maintains its conclusion that the available evidence is not sufficient to exclude nitrates or any other class of fine particles that are collected by PM monitors comparable to those used in the recent epidemiological studies.

(2) *Comment:* A number of commenters expressed the view that semivolatile components of fine particles, such as nitrates and organics, should be more completely captured than is done in the proposed Federal Reference Method Sampler. Other commenters suggested that water should be excluded.

Response: As noted above, EPA believes the available evidence supports the inclusion of nitrates and other semivolatile species, to the extent they were collected in the underlying community epidemiological studies. EPA has developed its monitoring approach with this objective in mind. While acknowledging the FRM may involve some loss of semivolatile substances, EPA does not believe it would be appropriate to collect amounts of such materials in significantly greater proportions than did the study monitors. Specifically, as discussed above, the CASAC subcommittee acknowledged the complex technical issue and endorsed EPA's approach with respect to nitrates since it "matches most in the choice <u>not</u> to use a more complex design that includes denuding and backup filtration to improve the sampling of the ambient particulate nitrate compounds" (Price 1996, emphasis added).

In implementing the fine particulate indicator through a FRM, EPA notes that some portion of semivolatile species is included; however, this may vary depending on local conditions (e.g., ambient temperature changes during measurement period, general atmospheric chemistry).

EPA does note that the particle mix in certain areas (e.g., Western locations) will probably contain more semivolatile species such as nitrates and organics than others (See Staff Paper Figure IV-3).

In developing the FRM, EPA worked to minimize semivolatile fraction losses and rejected some existing candidate FRM technologies that offered other performance advantages because of semivolatile species losses that are inconsistent with the underlying health database. EPA also notes that other methods that would retain more of the semivolatile material could also capture additional water, which is undesirable for compliance with the primary standard. With respect to addressing this issue, Appendix L specifies that handling of samples requires equilibration under defined conditions to standardize water content in the measurements.

EPA encourages the measurement and speciation of all particulate matter, including the semivolatile fraction, both for defining air quality and for conducting research relevant to subsequent reviews. EPA also notes that full characterization of the chemistry of the aerosol, including semivolatile species and water, is an important component of assessing impact on visibility in the context of Regional Haze programs. Visibility programs have a long-standing monitoring protocol (i.e., the IMPROVE network, which has been in operation since 1987). See responses in Section II.B of this document for additional information.

(3) *Comment:* Some commenters suggested that intrusion of any coarse particles derived from naturally occurring crustal materials should be excluded because, according to the commenters, these particles are not of health concern. Some of these commenters supported exclusion of coarse particles from either PM_{10} or $PM_{2.5}$ standards. Some of these commenters argue that PM_1 (particles with sizes less than a nominal 1 μm) would be a more appropriate indicator for fine particles. Some commenters expressed the view that, if EPA adopts $PM_{2.5}$ standards, the Agency should provide a method that would result in better separation of fine and coarse fraction particles because there may be some intrusion of coarse material into the $PM_{2.5}$ measurement.

Response: See preamble to the final rule, section II.B, for further discussion of relevant health effects information.

EPA disagrees with the comment that crustal particles or "naturally occurring" particles are not of health concern. The preamble to the final rule and the Staff Paper conclude that coarse fraction particles are clearly linked with certain morbidity effects, and CASAC clearly supported retention of a PM_{10} indicator to protect against the effects of coarse fraction particles. The Criteria Document and Staff Paper conclude that epidemiological information, together with dosimetry and toxicological information, support the need for a particle indicator that addresses the health effects associated with coarse fraction particles within PM_{10} (i.e., $PM_{10-2.5}$). As noted above, coarse fraction particles can deposit in those sensitive regions of

the lung of most concern. Although the role of coarse fraction particles in much of the recent epidemiological results is unclear, limited evidence from studies where coarse fraction particles are the dominant fraction of PM_{10} suggests that significant short-term exposure effects related to coarse fraction particles include aggravation of asthma and increased upper respiratory illness. In addition, qualitative evidence suggests potential chronic effects associated with long-term exposure to high concentrations of coarse fraction particles.

EPA agrees that it is appropriate to separate fine and coarse fraction particles for regulatory purposes. As stated in the preamble to the final rule, EPA adopted the 2.5 µm limit based on the potential for growth of true fine mode particles into that size, the comparability with epidemiological studies and other monitoring, and the recommendations of CASAC. In the Staff Paper, EPA notes that the $PM_{2.5}$ measurement does have some potential for intrusion of the "tail" of the coarse mode (U.S. EPA 1996b, P. VII-16 and Appendix A). Following the recommendations of CASAC, EPA has selected a FRM with a sharp cut to minimize this potential intrusion of coarse mode particles. While EPA notes that it does not anticipate such intrusions to be significant in most situations, to the extent that problems in this regard occur in some locations, this issue can and should be addressed on a case-by-case basis in the monitoring and implementation programs (e.g., through a policy similar to the natural events policy). In such situations, the programs will be guided by the fact that the PM_{10} standards are intended to protect against the effects of coarse fraction PM, and that fine standards are directed at smaller sizes. Therefore, consideration of the kinds of exclusions recommended by commenters will be taken up in developing implementation guidance.

EPA notes that a $PM_{2.5}$ indicator is more appropriate at this time than a PM_1 indicator. PM_1 has not been used directly in health studies or widely used in the field, although in most cases mass should be similar for cutpoints of 2.1 or 2.5 µm. While PM_1 could reduce intrusion of fugitive dust, it might also omit portions of hygroscopic acid sulfates in high humidity episodes. In the Staff Paper, EPA notes that of some concern is the theoretical possibility that different flow velocities for the smaller cut might increase the loss of semivolatile materials relative to a larger cut (U.S. EPA 1996b, p. VII-16 and Appendix A).

iii. Consideration of alternative fine particle indicators

(1) *Comment*: One commenter (CAAP, IV-D-8258) expressed the view that EPA should use a particle number indicator rather than particle mass.

Response: Information suggesting that observed PM-related health effects are related to particle number is not nearly as extensive as information relating health effects to particle mass (U.S. EPA 1996a, chapters 12 and 13). Community epidemiological studies have found significant associations between fine particle or PM_{10} mass and health effects in various areas across the U.S. Consistent with the recommendation of 19 of 21 CASAC panel members,

EPA proposed to use a $PM_{2.5}$ mass concentration indicator. As noted in the Staff Paper, $PM_{2.5}$ encompasses all of the potential agents of concern in the fine fraction, including most of the particle number in the entire PM distribution as well as most sulfates, acids, fine particle metals, organics, ultrafine particles and most of the aggregate surface area (U.S. EPA 1996b, p.VII-15).

The available information shows that particle number is dominated by directly emitted "ultrafine" (<0.1 μm) particles, which quickly aggregate into larger sizes, as well as particles that form in the air from reaction of gases such as sulfur dioxide. A standard based on numbers of particles would essentially focus exclusively on these ultrafine particles. Both the Criteria Document and the Staff Paper examine the potential contribution of directly emitted ultrafine particles to the observed effects of particulate matter. The Criteria Document points out that such ultrafine aerosols (<0.1 μm) are a class of fine particles that have the potential to cause toxic injury to the respiratory tract as seen in several animal studies (p. 13-76). The Staff Paper assessment includes the following evaluation of potential risk:

> Because of their short lifetime, it is unclear that unaggregated ultrafine particles make up any significant fraction of the mass of fine particles or of PM_{10}, other than in the vicinity of significant sources of ultrafine particles. The relationship between ultrafine numbers (or mass) and the mass of fine or thoracic [PM_{10}] particles found in typical community air pollution has not been established. Although the Criteria Document provides little direct information, it might be expected that penetration and persistence of unaggregated ultrafine particles to indoor environments would be limited. For these reasons, it is questionable whether ultrafine aerosols could be playing a major role in the reported epidemiologic associations between the measured mass of fine or PM_{10} particles and health effects in sensitive populations [Staff Paper, p. V-72-73.]

In summary, given their much longer atmospheric lifetime and broader dispersion from source regions, the larger fine particles appear to be of greater risk to public health. Because of the potential toxicity of ultrafine particles and the opportunity for exposure near combustion sources, however, they represent an area where additional research is necessary. In any event, strategies that control fine particles will focus new attention on both directly emitted and atmospherically formed ultrafine particles. EPA believes the available information clearly supports selection of a mass-based indicator, as opposed to a number-based particle standard.

(2) *Comment*: One commenter (U. Of Rochester, IV-D-894) expressed concern that a reduction in accumulation mode mass would lead to an increase in the number of ultrafine particles (aerodynamic diameter <0.1 μm). This would be undesirable if the number of particles, rather than the mass of particles, were the crucial factor in causing health effects.

Response: The suggestion that portions of fine particle mass are a "sink" for ultrafine particles is theoretically correct, but EPA's examination of the issue, which is discussed below, suggests that the practical implications may be quite limited. In essence, while there are situations in which a reduction in "accumulation mode"[4] mass could lead to an increased persistence of directly emitted ultrafine particles, there are significant limits on how large an increase in ultrafine particle number would occur and how long such increase in ultrafine particles would last. More importantly, strategies developed for reducing accumulation mode mass will almost certainly involve a reduction in the rate of formation of ultrafine particles. EPA anticipates that the reduction in formation of ultrafine particles, as part of an overall PM control program, will cause a reduction in ultrafine particle number even though the accumulation mode mass is reduced. These points are developed more fully below.

As discussed in detail in the PM Criteria Document (U.S. EPA, 1996a; Chapters 3 and 6), ultrafine particles are condensed phase species with very low equilibrium vapor pressure, formed by nucleation of gas phase species. In the atmosphere there are three major classes of sources which yield particulate matter with equilibrium vapor pressures low enough to form ultrafine particles:

(1) Particles containing heavy metals. Ultrafine particles of metal oxides or other metal compounds are generated when metallic impurities in coal or oil are vaporized during combustion and the vapor undergoes nucleation. Metallic ultrafine particles are also formed from metals in oil or fuel additives that are vaporized during combustion of gasoline or diesel fuels.
(2) Elemental carbon or soot, C_e. C_e particles are formed primarily by condensation of C_2 molecules generated during the combustion process. Because C_e has a very low equilibrium vapor pressure, ultrafine C_e particles can nucleate even at high temperatures.
(3) Sulfates. Sulfuric acid (H_2SO_4), or its neutralization products with ammonia (NH_3), ammonium sulfate ($(NH_4)_2SO_4$) or ammonium acid sulfate (NH_4HSO_4), are generated in the atmosphere by conversion of sulfur dioxide (SO_2) to H_2SO_4. As H_2SO_4 is formed, it can either nucleate to form new ultrafine particles or it can condense on existing ultrafine or accumulation mode particles.

The concentration of ultrafine particles would be expected to increase with a decrease in accumulation mode mass, but to decrease with a decrease in the rate of generation of H_2SO_4. The rate of generation of H_2SO_4 depends on the concentration of SO_2 and OH, which is generated primarily by the photolysis of O_3. Thus, the reductions in SO_2 and O_3 that will form

---

[4]Accumulation mode particles generally extend from about 0.1 to as large as 1 to 3 μm in aerodynamic diameter. Ultrafine or nuclei-mode particles coagulate or grow by condensation into the accumulation mode. The fine mode consists of both (U.S. EPA, 1996b; p. IV-2-IV-3).

a major basis for attaining $PM_{2.5}$ and O_3 standards and implementation of Title II and Title IV Clean Air Act programs should lead to a decrease in the rate of generation of H_2SO_4 and a decrease in the concentration of ultrafine particles.

The commenter advances a theoretical argument but does not provide any quantitative assessment. In order to provide additional insight into the potential magnitude of the possible changes in particle numbers, EPA used a readily available aerosol formation model (Binkowski et al., 1996; Binkowski and Shankar, 1995) to illustrate the effects of changing accumulation mode mass and ultrafine particle generation rates. This aerosol dynamics model simulates the processes of nucleation, condensation, and coagulation of particles. The rate of condensation depends on the surface area available for condensation. The rate of coagulation depends on the number of particles and their sizes. Two representative situations have been examined, as described below. Details of the simulations are given in the accompanying Table.

The first simulation is similar to that posited by the commenter and addresses the first two classes of ultrafine particles outlined above. In essence, a pulse of ultrafine particles is added to an atmosphere with several different concentrations of accumulation mode particles. Only coagulation is modeled. This simulates the injection of auto exhaust into an air parcel moving across a busy street or highway or, with less precision, a plume of ultrafine particles near a stationary combustion source moving into an air parcel. The results of the simulations (cases 1-4 in the table) are shown in Figure 1. Simulations were performed for the injection of pulses of 5 and 2.5 $\mu g/m^3$ of ultrafine particles into an air parcel containing 50, 25, or 12.5 $\mu g/m^3$ of accumulation mode particles. All simulations show the rapid coagulation of ultrafine particles into the accumulation mode, such that the majority of the pulse is gone in 20 to 40 minutes. The characteristic short lifespan of ultrafine particles, as illustrated in Figure 1, is one of the reasons they do not appear likely to be responsible for PM-mortality effects associations that have been observed in epidemiological studies of sensitive populations that spend the majority of the time indoors. (U.S. EPA, 1996; p. V-72 toV-73).

It is clear from the model results in Figure 1 that relatively large reductions in fine mass (e.g., from 50 to 25 $\mu g/m^3$; or from 25 to 12.5 $\mu g/m^3$) lead to only a small slowing of the disappearance of ultrafine pulses, and the increase at any time appears to be 10% or smaller. Although more significant effects might occur at much higher fine particle concentrations, given measured and estimated $PM_{2.5}$ air quality expected in U.S. cities, it is unlikely that implementing annual standards in the range of 15 $\mu g/m^3$ or 24-hour standards in the range of 65 $\mu g/m^3$ would produce fine mass changes as large as those simulated. Thus, these simulations indicate that, even in the unlikely event that fine particle strategies resulted in no reductions of directly emitted ultrafine particles, any effect on resultant ultrafine exposures would be small. To the extent that reductions in such ultrafine emissions do occur, the simulation results in Figure 1 (as illustrated in the reduced ultrafine pulse cases) show that the benefits of reducing the formation of ultrafine particles appear to be much greater than any effect of reduced accumulation mode mass.

In the second simulation, the formation rate of H_2SO_4 and the accumulation mode mass are varied and the three processes of nucleation, condensation, and coagulation are modeled (class 3 ultrafine particles as described above). This dynamic situation is more complex, and strongly dependent on relative sources and concentrations of fine particles, SO_2, ozone, relative humidity, and other factors, including conditions that favor more rapid transformation of SO_2 to sulfates. In this context, it is also important to note that one of the major strategies for reducing fine particle mass includes reduction of SO_2 emissions, which itself would tend to reduce the formation of ultrafine sulfate particles.

DESCRIPTION OF ULTRAFINE PARTICLE NUMBER MODEL AND CASES

A. INITIAL VALUES FOR PULSE SIMULATIONS FOR FIGURE 1

Background	**Case 1**	**Case 2**	**Case 3**	**Case 4**
Mass ultrafine, $\mu g/m^3$	0.25	0.25	0.25	0.25
Mass accumulation, $\mu g/m^3$	50	25	25	12.5
Number ultrafine, $\#/m^3$	3.91×10^{10}	3.91×10^{10}	3.91×10^{10}	3.91×10^{10}
Number accumulation, $\#/m^3$	1.78×10^{10}	8.90×10^{9}	8.90×10^{9}	4.45×10^{9}
Ultrafine Pulse				
Mass, $\mu g/m^3$	5	5	2.5	2.5
Number, $\#/m^3$	7.82×10^{11}	7.82×10^{11}	3.91×10^{11}	3.91×10^{11}

Note: All calculations done at one atmosphere, 295EK and 50% Relative Humidity. The geometric standard deviations for the ultrafine and accumulations modes are held constant at 1.7 and 2.0, respectively. The initial geometric mean diameters for the ultrafine and accumulation modes are 15 and 105 nanometers, respectively; however, these are allowed to vary with time. The background is assumed to contain ultrafine and accumulation mode, and the added pulse is assumed to be ultrafine mode. The aerosol dynamics model used is described in Binkowski and Shankar (1995) as modified by Binkowski et al. (1996).

B. INITIAL VALUES IN DYNAMIC SIMULATIONS FOR FIGURE 2

Initial Values:	**Case 6** (5@2)	**Case 7** (5@2)	**Case 8** (2.5@2)
Production Rate of Sulfuric Acid ($\mu g/m^3 s$)	1.11×10^{-4}	1.11×10^{-4}	5.57×10^{-5}
SO_4 ($\mu g/m^3$), ultrafine	0.25	0.25	0.25
SO_4 ($\mu g/m^3$), accumulation	25.00	12.50	12.50
Number ($\#/m^3$), ultrafine	3.91×10^{10}	3.91×10^{10}	3.91×10^{10}
Number ($\#/m^3$), accumulation	8.90×10^{9}	4.45×10^{9}	8.90×10^{9}

Note: All environmental conditions as well as the initial diameters and geometric standard deviations of modes as in A. above. The notation 5@2 denotes the SO_2 concentration in (5 ppb) and the conversion

rate to sulfuric acid (2% per hour). Model described in: Binkowski and Shankar (1995) and Binkowski et al. (1996), as above.

INSERT FIGURES 1 AND 2 PAGE HERE

Figure 2 shows the variation in number of ultrafine particles for realistic variations in accumulation mode mass and H_2SO_4 production rates. With an accumulation mode mass of 25μg/m^3, an H_2SO_4 production rate of 2% h^{-1}, and 5 ppb of SO_2, the model predicts a slow increase in ultrafine particles with the concentrations raising from an initial value of 4×10^{10} particles/m^3 to 5.5×10^{10} after two hours (Case 6). If the accumulation mode mass is reduced to 12.5 μg/m^3, holding SO_2 concentration and oxidation rate constant, the number of ultrafine particles increases, reaching a maximum of 6.7×10^{10} at 45 min but then dropping to 4×10^{10} at two hours (Case 7). This suggests a factor of two reduction in non-sulfur related accumulation mode mass, unaccompanied by SO_2 reductions, could lead to a moderate increase in ultrafine particle number followed by a decline. However, if the fine mass reduction is at least partially attained by reducing SOx precursor emissions (as simulated in case 8 by reducing SO_2 from 5 to 2.5 ppb), or reductions in ozone and related precursors also occur, the formation rate of ultrafine sulfates slows and the total number is more likely to decrease with time due to coagulation of the ultrafine particles present in the assumed initial distribution. These simulations used a relative humidity of 50%. At higher humidities, characteristic of summertime photochemical episodes, the relative rate of ultrafine generation would be lower.

The following general conclusions can be drawn from an examination of the model output. For the same ultrafine particle or precursor input, a reduction in accumulation mode mass may lead to an increase in ultrafine particle number. However, at common concentrations in U.S. cities, the increase in ultrafine particles is much less than proportional to the decrease in accumulation mode mass. More importantly, reductions in ultrafine particle or precursor input dramatically reduce the number of ultrafine particles even when the accumulation mode mass is proportionally reduced.

Based on a consideration of the above factors, EPA concludes that a reduction in accumulation mode mass is more likely to be accompanied by a reduction in the generation rate of ultrafine particles so that the number of ultrafine particles will not increase. Even if there were to be a small increase in ultrafine particle number this would be offset by the public health benefits of a reduction in accumulation mode mass. The reasons EPA believes that mass, which is the metric correlated with effects in the epidemiological studies, is a more appropriate indicator than particle number, are discussed above. As noted in the Staff Paper, EPA believes that preliminary studies of the effects of ultrafine particles, including those of the commenter, suggest the potential for enhanced toxicity of this size range, and that further research in this area is of some importance. It is possible that freshly generated ultrafine particles relatively near significant sources could present an additional risk to health, above those associated with particle mass. It is also important to monitor particle number as well as mass to further delineate the relative effectiveness of strategies for reducing both particle mass and particle number.

iv. Consideration of separate/additional sulfate standard

Comment: Some commenters expressed the view that EPA should add a separate sulfate standard instead of $PM_{2.5}$ standards. Additional commenters (e.g., Resources for the Future, IV-D-2670; Colorado ALA and PIRG, IV-D-2095) expressed the view that EPA should add an additional sulfate standard to augment the $PM_{2.5}$ standards, while others (Ohio Edison, IV-D-2275) commented that EPA should exclude sulfates.

Response: See preamble to the final rule, sections II-B and II-C-1.

In the Staff Paper EPA noted that the most substantial laboratory and epidemiological data for any single class of fine particles exists for sulfates and associated acids (U.S. EPA 1996b, VII-14). The data for acids, which are more difficult to measure, is less consistent than for sulfates. Relatively strong correlations exist between acids, sulfates, and fine particles, making it difficult to single out any factor with confidence (U.S. EPA 1996a; p.13-93). Indeed, EPA considers sulfates useful as an indicator of fine particles for assessing the health effects literature. This literature suggests that reductions of regional sulfates as part of a fine particle control program would likely reduce mortality and morbidity risks for sensitive populations who reside in the East. For these reasons EPA concludes that it is not appropriate to exclude sulfates and that it is not appropriate at this time to establish a separate sulfate standard, alone or in combination with fine particle standards. Furthermore, EPA concludes that a sulfate standard, even if understood as an indicator of all fine particles, would be less likely to lead to controls of the other potentially harmful components of fine particles.

This information was presented to CASAC during EPA's review of the PM standards, and CASAC generally agreed with staff recommendations on this issue. The Committee advised the Administrator that "there is a consensus that retaining an annual PM_{10} NAAQS . . . is reasonable at this time" and that there is "also a consensus that a new $PM_{2.5}$ NAAQS be established" (Wolff, 1996b). Accordingly, EPA continues to conclude that it is appropriate to control fine particles as a group, as opposed to singling out particular components or classes of fine particles. The more qualitative scientific literature, evaluated in Chapter 11 of the Criteria Document and summarized in Section V.C of the Staff Paper, has reported various health effects associated with high concentrations of a number of fine particle components (e.g., sulfates, nitrates, organics, transition metals), alone or in some cases in combination with gases. Community epidemiological studies have found significant associations between fine particles or PM_{10} and health effects in various areas across the U.S. where such fine particle components correlate significantly with particulate mass. As noted above, it is not possible to rule out any one of these components as contributing to fine particle effects. Thus, EPA believes that the present data more readily support a standard based on the total mass of fine particles.

b. Averaging times

EPA received comparatively few public comments on the proposed averaging times. Those supporting $PM_{2.5}$ standards also strongly supported adopting both annual and 24-hour averaging times. Many of those opposing $PM_{2.5}$ standards, for the reasons discussed in Section II.B in the preamble to the final rule, provided contingent comments that variously supported both averaging times for $PM_{2.5}$ standards in the event the Administrator disagreed with their overall recommendations. Other opponents of $PM_{2.5}$ standards disagreed with having two standards on administrative grounds, or because some CASAC members did not support both averaging times.

Responses to comments on the relationship between standards for the two averaging times are presented in Section II.D of the preamble to the final rule and below. In essence, based on its examination of the effects data and air quality relationships, EPA believes that a single $PM_{2.5}$ standard (24-hour or annual) either would not provide adequate protection against effects of concern for all averaging times, or would be inefficient in the sense that it was more stringent than necessary for at least one averaging time. Contrary to commenters who focused on minority CASAC opinions, EPA notes that a clear majority of CASAC supported both 24-hour and annual standards. Of the 19 panel members who joined in the consensus for $PM_{2.5}$ standards, 17 (90%) recommended a 24-hour standard and 13 (70%) recommended an annual standard (Wolff, 1996b).

i. Annual standard as generally controlling standard

(1) *Comment:* Several Western state and local governments commented that the approach of using the annual standard as the controlling standard would not provide adequate protection in the Western U.S. where $PM_{2.5}$ emissions are seasonal in nature and characterized by short-term excursions. Other commenters (e.g., State of Washington, IV-D-7822) expressed the view that EPA's conclusion that a restrictive annual standard will control for high 24-hour levels is questionable because it is based on analysis of data from large, urban areas primarily in the east where emissions are relatively steady-state. These commenters asserted that evaluation of actual $PM_{2.5}$ data monitored in Spokane supports the claim that an annual standard would not effectively control for 24-hour events in the typical western setting.

Response: In its proposal, EPA specified the suite of PM standards such that the annual standard would be generally controlling, acknowledging that this would not be the case in every situation across the country because of the observed diversity of air quality distributions. Commenters are correct in observing that the annual standard is more likely to be controlling in areas with higher regional or wide urban area concentrations, such as is found in the Eastern U.S. and in Los Angeles. However, EPA maintains that the most appropriate risk management strategy, given the nature of the available epidemiological data, is to reduce area-wide population exposure and risk through a generally controlling annual standard and protect against higher short-term peaks by an appropriate 24-hour standard.

As discussed in the preamble to the final rule, strategies for meeting a short-term standard focus on a characteristic "design value" episode responsible for peak concentrations. For PM, such peak values can be associated with single source contributions. Meteorology, relative source contributions, and resulting particle composition for that day may or may not be typical for the area or for the year. Yet the short-term exposure epidemiological results are largely drawn from studies that associated variations in area-wide effects with monitor(s) that gauged the variation in daily levels over the course of up to 9 years. The strength of the associations in these data is demonstrably in the numerous "typical" days in the upper to middle portion of the annual distribution, not on the peak days.[5] For these reasons, strategies that focus only on reducing peak days are less likely to achieve reduction of the mix and sources of urban and regional-scale PM pollution most strongly associated with health effects. Although designing control strategies to reduce annual levels may be more difficult than for 24-hour standards, the available short- and long-term exposure epidemiological data suggest it is also likely to result in a greater reduction in area-wide population exposure and risk.

(2) *Comment:* Some commenters questioned EPA's rationale for using an annual standard to protect against 24-hour effects because there is stronger evidence for a 24-hour standard from the more numerous short-term exposure studies. Others disagreed with the proposition that EPA's proposed approach would necessarily provide the most effective and efficient standards. In the view of some who opposed $PM_{2.5}$ standards, the likelihood that there are thresholds below which no effects occur means that a 24-hour standard would be more efficient than an annual standard. In this view, the reductions made on days that were below the threshold would provide no protection.

Response: EPA has fully responded to these comments in Section II.D. of the preamble to the final rule.

ii. Comments supporting alternative averaging times

(1) *Comment*: Some commenters (e.g., C.A.S.E., IV-D-4399) recommended shorter averaging times (e.g., 1-hour or 8-hour standards) to protect against short-term peak exposures.

Response: See preamble Section II.D.1 for discussion of response to this comment.

---

[5] This point is buttressed by studies that have taken out a limited number of higher PM concentration days with little effect on the effects estimates or significance of the association (e.g., Schwartz et al., 1996; Pope and Dockery, 1992). One commenter (Bay Area Air Quality Management District IV-D-6502) provided an extended analysis of this kind for the Santa Clara County, California mortality-pollution data that finds the same result in this Western data set.

(2) *Comment:* One commenter noted that an argument could be made for a multi-year standard based on the prospective cohort mortality studies. Another commenter recommended quarterly standards be set.

Response: As discussed in the preamble to the final rule, community epidemiological studies have reported associations of annual and multi-year average concentrations. The EPA has considered this evidence, which in short suggests that some health endpoints may reflect the cumulative effects of PM exposures over a number of years. In such cases, an annual standard would provide effective protection against persistent long-term (several years) exposures to PM. EPA notes that the form of the annual standard requires three years of data. Requiring a much longer averaging time would also complicate and unnecessarily delay control strategies and attainment decisions.

EPA also explicitly considered the suggestion of using a quarterly (i.e., 3-month) average, in view of the observed seasonality of concentrations of fine particles and their precursors in some areas (e.g., wintertime smoke from residential wood combustion, summertime regional acid sulfate and ozone formation). However, different seasons are likely of concern in different parts of the country, and the current evidence does not provide as satisfactory a quantitative basis for setting a national fine particle standard in terms of a seasonal averaging time as for an annual standard, in combination with a 24-hour standard. Ultimately, EPA rejected a seasonal averaging time in this review, focusing the 24-hour standards on protecting against seasonal excursions not adequately addressed by the annual standard.

c. Standard levels

i. Characterization of CASAC views regarding $PM_{2.5}$ standard levels

Comment: Some commenters expressed the view that because CASAC did not agree on specific levels and averaging times for the standards, it would be inappropriate to establish any standard. Some also provided various characterizations of CASAC opinions, for example by combining the views of panel members supporting standard levels higher than those EPA proposed with the views of panelists who chose not to recommend levels as constituting a majority that did not support EPA's proposals. These commenters also noted that only one CASAC panel member recommended annual standards as low as EPA proposed. Additional comments stated that CASAC did not endorse EPA staff's recommended ranges in the Staff Paper.

Response: Before responding to the specific points raised by these commenters, EPA notes that some of them appear to rest on questionable assumptions about the role and purposes of CASAC review. Briefly stated, Congress expected CASAC to advise the Administrator on the scientific basis for NAAQS decisions and to recommend such revisions in the air quality

criteria and NAAQS as it considers appropriate. The Administrator, in turn, must consider CASAC's advice and recommendations but is not bound by them. There is no requirement that there be a consensus on scientific issues before the Administrator may revise standards or establish new ones. See, e.g., Lead Industries Ass'n v. EPA, 647 F.2d 1130, 1154-55 and n.51, 1160-61 (D.C. Cir. 1980). Indeed, as discussed in section IV.A of the preamble to the final rule, uncertainty and controversy on scientific issues are inherent in the statutory scheme, which in effect requires decisions "at the very 'frontiers of scientific knowledge'" where "disagreement among the experts is inevitable." 647 F.2d at 1147, 1160. Section 109(d)(1) of the Act nonetheless requires the Administrator to review the criteria and NAAQS at least once every five years, to decide whether revisions are appropriate, and, if so, to make the appropriate revisions.

By statute as well as historical practice, CASAC includes representatives of a variety of disciplines. As a result, individual panel members differ in the expertise they bring to particular scientific issues, and individual members often choose not to express opinions on matters outside their own areas of expertise. CASAC has also been careful to distinguish between the advice and recommendations it provides as a Committee and the views expressed, orally or in writing, by individual panel members. In addition, CASAC typically acknowledges, as it did in this review (Wolff 1996), that NAAQS decisions require the Administrator to make public health policy judgments as well as determinations of a strictly scientific nature. Since the Committee began advising EPA in the late 1970's, in fact, it has generally stopped short of recommending specific standard levels, as opposed to advising on ranges of possible levels, developed by EPA staff, for the Administrator's consideration.

Thus, the lack of a consensus among CASAC panelists on such matters as specific levels and averaging times is clearly no bar to revising existing standards. Indeed, the lack of a consensus would not excuse the Administrator from her statutory duty to determine whether revisions are appropriate and, if so, to make the appropriate revisions. In this context, counting the "votes" of individual CASAC panelists on such issues as standard levels is of interest and can be illuminating, but it is ultimately less important than careful consideration of the substance of the Committee's advice on the underlying scientific issues.

In any case, the characterizations of CASAC recommendations and guidance given by many of these commenters do not reflect an appropriate and complete summary of the advice given by the panel. Indeed, given the variety of opinions expressed by individual panelists and the variety of summaries submitted by various sources, it is clear that any simple summary of the advice given by individual panelists is subject to question. For these reasons, EPA believes it is important to examine the advice and recommendations of the committee *per se* before attempting to consider the views of individual panelists.

In its March and June letters, CASAC provided general closure statements indicating that both the Criteria Document and the Staff Paper, which contains conclusions and recommendations on standards, were scientifically adequate for use in the regulatory decision-making process. Individual members made comments regarding the recommended staff ranges and, in response to the Chairman's request, many gave their own opinions either on ranges or on specific standards they would recommend. However, the Committee made no attempt to discuss or put forward any specific consensus recommendation on a range or specific standard levels, nor to comment as a group on the staff range. The summary table in the Committee's June 13, 1996, letter reflects the diversity of the specific opinions registered by the individual members.

As indicated above, the lack of convergence with respect to opinions on specific standards by the 11 individual members who offered them does not relieve the Administrator of the responsibility to make a decision on the need to revise the standards, about which there was a clear CASAC consensus, or the need to select specific averaging times, forms, and levels for revised standards. The 8 panelists who chose not to recommend specific ranges cannot be counted as not supporting adoption of specific $PM_{2.5}$ standards at this time. Instead, they left this judgment to the Administrator, guided by their comments on the staff ranges. While it appears that *any* standard the Administrator could choose will be at variance with the opinion of one or more CASAC members, a decision is nevertheless required. Moreover, the spread of opinion in this case (e.g., support for 24-hour standards ranging from 20 to 75 µg/m3) is actually smaller than the range CASAC recommended for the 24-hour PM_{10} standard in 1982 (150 - 350 µg/m3) (Friedlander, 1982). The fact that none of the current CASAC PM panel recommended relaxing the level of protection afforded by the current PM standards indicates a clear consensus for more stringent standards than was evidenced in the earlier review.

A fair reading of the opinions expressed on the averaging time for $PM_{2.5}$ standards is that, of the 19 panel members who joined in the consensus for $PM_{2.5}$ standards, 17 (90%) recommended a 24-hour standard and 13 (70%) recommended an annual standard. This clearly supports the Administrator's proposal to adopt both averaging times. All members speaking to the issue of form recommended a more robust form, such as that adopted in the final decision. The largest divergence of opinion was on the levels for the standards, and on the relative protection afforded by 24-hour as opposed to annual standards.

EPA believes that most of the CASAC panelists' opinions on averaging times reflected their judgments on the greater relative strength of the short-term exposure epidemiological studies, a judgment that EPA shares. Based on the recommendations of staff and some CASAC members, the Administrator proposed to use the annual standard to provide protection against both short- and long-term exposures. This led to a tighter level for the proposed annual standard relative to the proposed 24-hour standard. EPA believes this approach is neither inconsistent with the underlying science nor discordant with the overall advice of CASAC. In evaluating these recommendations, it is also important to note that panelists were reacting to

staff recommendations for levels that were expressed in a single exceedance form (24-hour) with no spatial averaging; for similar levels, these forms are clearly more stringent than the forms proposed and adopted for the final standards. Indeed, when the projected relative protection afforded by the combination of $PM_{2.5}$ standards originally proposed by EPA is compared with the combined 24-hour and annual opinions of each of the 11 CASAC panelists, the protection afforded by the proposed and final standards (in terms of the estimated number of people living in areas that need improved air quality) is toward the middle portion of that estimated for the combined 24-hour and annual range of recommendations by the 11 individual CASAC panelists. Among those recommending ranges of standards including combined levels generally tighter than or close to those proposed by EPA were two epidemiologists, a health expert, a toxicologist, and an air quality expert. By contrast, only two of the six recommending less protective standards were health scientists. In short, a simple comparison of CASAC panelists' June 1996 opinions on standard levels with EPA's proposal or final rules cannot convey the full extent to which the Administrator incorporated the panel's scientific judgments as well as the personal views of individual panel members in reaching her final decision on the proposal.

With respect to specific summaries of CASAC opinions on standard levels presented by some commenters, EPA does not think it is appropriate to combine the recommendations of members who expressed personal opinions on the standard levels with those who stated that they preferred not to express such opinions. For example, with respect to the 24-hour standard, the table of opinions in the CASAC closure letter shows four panelists who recommended specific 24-hour standards at or above the upper bound of the range recommended by EPA staff, and four who recommended standard ranges that extended well below that adopted by the Administrator. As noted above, EPA considered the results of the daily studies in reaching a decision on the annual standard. It is therefore appropriate to note that the final annual standard achieves a level of protection that falls in the upper portion of the combined range of recommended 24-hour and annual levels put forth by this latter group of panelists. EPA recognizes that some panel members who did not express an opinion on any specific standard levels did comment with respect to the upper end and lower portions of the staff range. For example, two such panelists commented that the upper portion of the 24-hour standard may be too low. In recommending that the upper portion of the range be widened, these two particular panelists did not recommend that the staff modify the lower bound of the range, and it would be appropriate to conclude that they believed the science supported consideration of 24-hour standard levels in a relatively wide range that extended well below that proposed or adopted in the final decision.

As indicated above, it is important to separate the personal opinions that individual members might express on particular policy choices such as standard levels from their scientific conclusions on the range of options that is supported by the science and should be considered by the Administrator. It is also important to recognize that individual members who chose not to offer their own specific options or ranges were not necessarily in disagreement with the

ranges put forward by EPA staff or opposed to selection of a particular set of numbers by the Administrator. Indeed, it would be illogical to recommend the adoption of $PM_{2.5}$ standards without recognizing the responsibility of the Administrator to decide upon levels that are consistent with the underlying science in the criteria and the legal mandates to protect public health that are inherent in the requirements of the Clean Air Act.

Speaking as a committee, CASAC clearly recommended that the current PM standards be revised by establishing $PM_{2.5}$ standards at the conclusion of the present review, and that -- as stated prominently in the Staff Paper -- the data are adequate to support levels for both 24-hour and annual standards. The lack of a consensus on particular levels in no way invalidates the overall conclusions that new standards should be established nor the need for the Administrator to come to specific conclusions in discharging her statutory duty.

ii. Consideration of "equivalent" levels and other levels above those proposed

Comment: Numerous commenters opposed revised standards but provided "contingent" comments that recommended levels well above those proposed by the Administrator. These commenters placed great weight on (1) factors outlined elsewhere in the Summary of Comments that led them to oppose any revisions to the PM standards, including the uncertainties and limitations in the available health effects studies considered individually, such as the possible existence of effects thresholds and unanswered questions regarding the causal agent(s) responsible for the reported health effects; and (2) the limited amount of research currently available that has measured $PM_{2.5}$ directly. A substantial group recommended that $PM_{2.5}$ standards be selected so as to be equivalent to or close in stringency to the current PM_{10} standards, and cited the opinions of some CASAC PM panel members as support. Some of these commenters provided supplemental analyses of air quality data, arguing that they demonstrate that "equivalent" standards would be at $PM_{2.5}$ levels higher than the highest proposed (65 $\mu g/m^3$, 24-hour average and 20 $\mu g/m^3$ annual average), reaching as high as approximately 95 $\mu g/m^3$ 24-hour average and 27 $\mu g/m^3$ annual average.

Response: Having evaluated these comments, the EPA rejects both their underlying rationale and the specific recommendations for $PM_{2.5}$ standard levels that result in similar or only marginally more protection than that afforded by the current PM_{10} standards. In the first instance, there is no scientific basis for complete "equivalence" when one measure (PM_{10}) contains coarse particles and the other ($PM_{2.5}$) does not. As CASAC recognized in its review, the wide variability in $PM_{2.5}/PM_{10}$ ratios in time and location precludes defining uniform $PM_{2.5}$ standards that would provide close to "equivalent" protection to the current standard in all or even most areas. Aside from such technical problems, which are inherent in the commenters' supporting analyses on the issue of defining "equivalent" standards, this approach would be inconsistent with the Administrator's conclusions regarding the adequacy of the current standards and the need to provide additional protection as articulated in the preamble to the

final rule. The EPA believes that, despite well recognized uncertainties, the consistency and coherence of the epidemiological evidence and the seriousness of the health effects require a more protective response than provided by "equivalence" or a marginal strengthening of the standards. Moreover, EPA believes that the standard levels should be based on the most recent assessment of the scientific criteria for PM, not on applying uncertain ratios to standard decisions based on much more limited evidence in 1987.

The EPA also rejects the premise of some who suggest that adopting standards that prompt little or no additional control would cause no delay in risk reduction as compared to conducting monitoring and research now and setting more stringent standards after the next review. These comments do not consider the realities of implementing air quality standards, which ensure that such an approach would add several years to the risk reduction process. Thus, aside from her obligations under the statute, the EPA believes that the most prudent and appropriate course is to establish appropriately protective standards now that put into motion monitoring, and strategy development programs, while at the same time pursuing an expanded research program to improve implementation and to inform the next periodic review of the criteria and standards.

iii. Proposed levels inappropriate

(1) *Comment:* Several commenters (e.g., Transportation Corridor Agencies, IV-D-2533; Ford Motor Co., IV-D-5323) objected to the specific levels EPA proposed for the standards on the basis that the proposed annual and/or 24-hour levels approach or are below "background" levels in non-urban areas. Some objected to EPA's use of pristine and high elevation sites to estimate background levels.

Response: In any discussion of "background" PM, it is important to define what is included. With the air pollution community, the term "background" is sometimes used in reference to uncontrollable pollution levels from "natural" sources, and sometimes used to mean the observed concentrations in unpopulated or rural areas. In the latter case, the term includes controllable pollutant levels derived from regional anthropogenic as well as natural sources. For clarity, CASAC advised that the Criteria Document and Staff Paper define "background PM" as "the distribution of PM concentrations that would be observed in the U.S. in the absence of anthropogenic emissions of PM and precursor emissions of VOC, NO_x, and SO_x in North America" (U.S. EPA 1996b; p IV-12). In essence, this fraction represents that portion of PM that cannot be reduced by controlling U.S. or other anthropogenic sources on the continent.

EPA disagrees that its annual and/or 24-hour standards approach or are below the estimated background concentrations for $PM_{2.5}$ that are based on the assessment contained in the Criteria Document and Staff Paper, and reviewed by CASAC. The estimated annual average regional background $PM_{2.5}$ levels are 2 to 5 $\mu g/m^3$ in the East, and 1 to 4 $\mu g/m^3$ in the West (Staff

Paper, Table IV-3). The highest background estimates values are therefore about 3 to 4 times lower than the proposed annual $PM_{2.5}$ standard. Absent forest fires, which are exempted under EPA's Natural Events Policy, peak background 24-hour $PM_{2.5}$ values nationwide are expected to be lower than 15 to 20 $\mu g/m^3$. When accounting for the exceedances allowed under the 98th percentile form and level of the 24-hour standard, these background levels are about 4 times or more lower than allowed by either the proposed or final standards.

This assessment of background levels as defined in the Staff Paper was not predicated solely on the observed levels at high elevation sites as suggested by commenters, but on published evaluations of the composition of observed levels in non-urban and other background locations around the country. The fact that annual levels as high as 7 to 13 µg/m3 are observed in some non-urban areas is generally reflective of either high regional anthropogenic contributions (e.g., in the Eastern U.S.) or the influence of local or urban scale sources on rural areas (e.g., the California Desert and some other western locations). Unlike natural or extra-continental background contributions, these sources are controllable.

In summary, although estimates of natural emissions and concentrations are uncertain, the available scientific evidence indicates that the proposed annual and 24-hour $PM_{2.5}$ standards are well above those that would occur under typical background conditions. The only exceptions to this involve short-term exceptional or episodic events (e.g,. forest fires, volcanic eruptions) that are routinely exempted in implementation policy under the current PM_{10} standards.

EPA agrees that regionally transported anthropogenic PM levels may approach or form a significant portion of the standard levels. Indeed, the annual standard is expected to result in region-wide reductions in fine particle concentrations. The fact that standards may require additional reductions from controllable pollution sources is not, however, an appropriate basis for selecting a level higher than that requisite to protect public health. Such regional or urban-scale reductions should lead to significant population risk reductions, because they affect large numbers of individuals across wide areas.

(2) *Comment:* One commenter (TVA, IV-D-2289), who generally opposed establishing any fine particle standard, recommended setting a $PM_{2.5}$ standard at a level equivalent to existing $PM_{2.5}$ concentrations, albeit varying across the country. Another commenter (Resources for the Future, IV-D-2670) recommended consideration of a $PM_{2.5}$ standard for the East and a $PM_{1.0}$ standard for the West of similar stringency. These commenters note that legal authority for their suggestions does not currently exist.

Response: See earlier response with respect to the concept of "equivalence" as a basis for standard setting in this review. With respect to varying standards by region, EPA is required by law to establish a uniform national standard to protect public health; thus, such options are not

appropriate for consideration. To the extent that regional differences in PM air quality exist, it is appropriate to consider accommodating them in implementing the standards.

(3) *Comment:* Some commenters who advanced arguments in favor of "equivalent" standards (see previous subsection) presented or relied on technical analyses of $PM_{2.5}/PM_{10}$ ratios to suggest that the upper bound of the ranges of standard levels presented in the staff paper were more stringent than EPA suggested, and further that this biased the selection of the proposed levels. AISI (IV-D-2242), in particular, also argued that EPA's approach to predicting $PM_{2.5}$ concentrations understated the estimated number of new non-attainment areas, and presented alternative estimates.

Response: As noted above, EPA does not believe the $PM_{2.5}$ standards should be based on "equivalence" with the current standards. EPA has addressed commenters' claims related to EPA's methodology to predict $PM_{2.5}$ values from the larger PM_{10} dataset in a staff memorandum (Fitz-Simons, 1997). As discussed therein and summarized below, EPA disagrees with commenters' claim that EPA data sets are biased towards rural sites and that EPA's predictive model is inherently biased. EPA staff did not ignore evidence submitted by commenters regarding the range of equivalence in various regions of the country in developing the staff range. The Staff Paper clearly states: "in some Eastern areas, a $PM_{2.5}$ level as high as about 100 $\mu g/m^3$ could correspond to the current 24-hour PM_{10} standard level, whereas in some Western areas the corresponding $PM_{2.5}$ level could be as low as about 50 $\mu g/m^3$. Thus, there is no 'equivalent' level that applies nationally based on information on ratios between $PM_{2.5}$ and PM_{10} " (Staff Paper, p. VII-24). Given that the level of the final 24-hour standard of 65 $\mu g/m^3$ is at the high end of the staff range, commenter's suggestion that the staff recommendation biased the decision to a still lower number is clearly without merit. Similarly, EPA clearly based the level of the annual standard on the available scientific evidence, without reference to equivalence with the current standards.

EPA also disagrees with the less germane comments regarding bias in EPA's projection methodology. EPA staff developed the methodology at the request of the CASAC, and the air quality experts on the panel, including the chairman, reviewed the underlying data bases, the approach and initial the results as presented in the Staff Paper. EPA has clearly noted the substantial uncertainties associated with such projections, but does not believe commenters have demonstrated inherent bias. The AISI comment that the underlying data base has a rural bias is without merit and inconsistent with the conclusions of the organization's expert consultant. Although the initial database developed by staff earlier in the standards review process may have over-represented rural sites, the version used in the Staff Paper and as the basis for EPA's projections and subsequent analyses is more balanced. The commenter's own consultant acknowledges this in an attachment to the comments submitted to EPA to support this claim (Attachment B of AISI, Cooper Environmental Services), stating that the EPA

database "is probably seasonally balanced and is now more geographically balanced because California data have been added."

Similarly, EPA believes that its predictive model developed from the dataset is uncertain, but unbiased. A review of the detailed comments finds that the analysis provided by commenters uses an inappropriate approach for assessing model bias (Fitz-Simons, 1997). Commenters' second basis for claiming the model is biased, namely because it underpredicts the number of non-attainment counties relative to commenters's estimates is also fundamentally flawed. Commenter relied on an assessment that actually used the regional $PM_{2.5}/PM_{10}$ ratios that were in EPA's data base. The increased number of counties projected was not related to model bias, but largely to the decision to include all counties in an SMSA if any county showed a predicted violation. This is an implementation policy assumption, not a model bias. EPA believes that, while its model provides only moderately accurate predictions given the differences in sources of fine and coarse particles across the country, the model does not systematically overpredict or underpredict $PM_{2.5}$ values.

(3) *Comment:* Colorado PIRG and Colorado ALA (IV-D-2095) claim that the Agency did not consider the magnitude of risk at the proposed level of the annual standard of 15 $\mu g/m^3$. The commenter cites a per capita risk analysis attatched as support for a more stringent level of the annual standard.

Response: EPA relied upon the scientific information in the Criteria Document and Staff Paper (not the RIA as the commenter also claims) in selecting the level of the NAAQS. In these documents as well as in the preamble to the proposed and final rules, EPA acknowledges that some risk of effect is seen across a substantial range of PM concentrations, including levels approaching the lowest in the scientific studies. Moreover, EPA specifically recognizes that its NAAQS are not risk-free but are designed to reduce risk sufficiently to protect the public health with an adequate margin of safety (see Section III.A.2). EPA has considered both the strengths and the limitations of the available evidence as well as alternative interpretations of the scientific evidence, as discussed above and in the Appendices. As illustrated in Figure 2 of the proposal, the risk at concentrations approaching 15 $\mu g/m^3$ is uncertain, and depend greatly on assumptions about the shape of the concentration-response function (Figure 2c). These increasing uncertainties limit the confidence that can be placed in the risk estimates at lower concentrations.

EPA examined the per capita risk estimates provided by commenters, and finds they are based on a questionable premise. The calculation follows an approach often used to estimate expected incidence for life time exposure to carcinogens. While it is certainly true that the relative risk in a single day may greatly understate the risk of exposure to PM in sensitive populations, this approach of estimating the risk of mortality carries the methology too far. The available studies used to provide the estimate were among those that found the risk of mortality

is primarily in the elderly (> 65 years) and those with pre-existing cardiopulmonary disease. As a result, the explicit calculation of a cumulative risk that assumes those individuals would live another 70 years (e.g., to age 135) is not reasonable. Moreover, the upper bound here appears inconsistent with long-term studies of cumulative PM risk (Pope et al., 1995). While the example provided by commenters may provide an interesting illustration, EPA does not agree that it represents a reliable estimate of risk.

iv. Consideration of more stringent levels

Many commenters, notably environmental groups and some States, strongly supported standard levels more stringent than those proposed by EPA. These commenters supported EPA's conclusions regarding the epidemiological studies but would place much less weight on uncertainties related to the concentration-response relationships for $PM_{2.5}$ as a surrogate for PM and the relative importance of various PM components. Based on their evaluation of the information, and citing the support of some CASAC panel members, these commenters variously recommended 24-hour $PM_{2.5}$ standards as low as 18 to 20 $\mu g/m^3$ and annual standards of 10 to 12 $\mu g/m^3$.

As discussed in section II.F of the preamble to the final rule, such standards would result in commensurate reductions in health risks only if, in fact, there is a continuum of health risks down to the lower end of the ranges of air quality observed in the key epidemiological studies, and only if the reported associations are, in fact, causally related to $PM_{2.5}$ at the lowest concentrations measured. Setting standards at low levels where the possibility of effects thresholds is greater, and where there is greater potential that other elements in the air pollution mix (or some subset of particles within the fine fraction) become more responsible for (or modify) the effects being causally attributed to $PM_{2.5}$, might result in regulatory programs going beyond those that are needed to effectively reduce risks to public health. While placing substantial weight on the results of the key health studies in the higher range of concentrations observed, EPA is persuaded that the inherent scientific uncertainties are too great to support standards based on the lowest concentrations measured in such studies, which approach the maximum range of $PM_{2.5}$ values estimated for short-term background conditions.

EPA notes that the range of levels recommended by these commenters for a 24-hour $PM_{2.5}$ standard is close to the lower bound levels recommended by four CASAC panel members (20 $\mu g/m^3$); however, no CASAC panelists supported an annual $PM_{2.5}$ standard as low as 10 to 12 $\mu g/m^3$. For reasons specified in the preamble to the final rule, EPA chose to use the annual standard, rather than the 24-hour standard, to be generally "controlling" with respect to health protection provided by both standards. The final annual standard level is at the lowest level recommended by any CASAC member, and the 24-hour standard is at the upper end of the range recommended by the EPA staff and most CASAC members. Taken together, these standards provide protection that is substantially greater than afforded by the current standards, well within the ranges recommended by CASAC and EPA staff.

The approach taken by EPA focuses primarily on standard levels designed to limit annual $PM_{2.5}$ concentrations to levels somewhat below those where the body of epidemiological evidence is most consistent and coherent, in recognition of both the strengths and the limitations of the full range of scientific and technical information on the health effects of PM, as well as associated uncertainties, as interpreted by the Criteria Document, Staff Paper, and CASAC. The Administrator believes that this approach appropriately reflects the weight of the evidence as a whole.

(3) *Comment:* Some commenters (Colorado PIRG IV-D-2095, NRDC IV-D-2267) argued that EPA should have followed the methodology it used to assess the epidemiological evidence for the purpose of establishing levels for the 1987 PM_{10} NAAQS. In that approach, EPA developed estimates for concentrations at which effects were "likely," "possible," and "no effects likely." Selection of EPA's level is based on the risk assessment and primarily on the long-term exposure studies with support from short-term exposure studies. Both Dockery et al. (1993) and Pope et al. (1995) indicate that mortality and morbidity effects continue down to exposures as low as 9 $\mu g/m^3$.

Response: The approach followed in the 1987 standard review is not fundamentally different than that used in the current review. The 1987 approach, which also involved converting concentrations from metrics such as British Smoke and TSP to PM_{10}, was drawn directly from the available scientific information as it was summarized in the Criteria Document and Addendum. Because that information was dominated by studies of high concentrations, particularly in the London episodes, the Criteria Document placed some emphasis on estimated concentrations at which PM effects were thought to be "likely," a term viewed by some as demonstrated effects levels at the concentrations involved in such studies. At the concentrations recorded in such studies it was possible to observe increased daily mortality on single episode days. There was little dispute among CASAC members and other scientists regarding causality at high concentrations, and the distinction between "likely" and "possible" was more relevant to levels then recently observed in the U.S. The remaining examination focused on the range where effects were possible, and lower levels where available evidence suggested no effects. The range of possible effects extended to the lowest levels observed in 14 London winters, which still reflected significant urban PM pollution. It was these levels that formed the basis for the lower end of the EPA staff and CASAC range of interest for standard setting. EPA concluded that, although the risk of mortality suggested by these London data extended to levels below those selected for the PM_{10} standards, the evidence was not sufficient to warrant more stringent levels.

In the present review, the Criteria Document focused on the numerous recent studies providing evidence that PM related effects occur at or below those allowed by the current standards. At these lower levels, it is not possible to readily detect unequivocal increases in mortality during single days, as in the early London data, and analyses in particular urban areas require months or years of daily data to reach conclusions regarding increased risk. The lowest observed

levels for daily studies overlap those of background conditions, not polluted urban atmospheres. Therefore, the emphasis of this review has been on the likelihood of effects at levels that were predominantly below the level of the current standards down to the lowest observed values. As evidenced by the spread of opinions among CASAC panelists, within that range, there is no general agreement on demonstrated effects levels; PM effects at levels at or below the current standards are recognized as at least possible by most, and judged likely by some.

The Criteria Document concludes that the observed PM effects-associations at levels at and somewhat below the current standards suggest a "likely" causal relationship. This cannot be interpreted to mean a demonstrated effects level. Moreover, unlike the London situation discussed above, it cannot be said either that effects are likely or even that the evidence indicates they are possible at the lowest observed levels, making consideration of such levels inappropriate for standard setting. For this reason, the lower bounds of staff recommended standard ranges were well above these levels. As discussed more fully in Section II.F of the preamble to the final rule, EPA believes the key uncertainties with respect to the available scientific evidence on PM at such levels are such that the standard should focus on the strongest data, which are at and above the mean levels observed in the short-term exposure studies. The likelihood of significant health risks, if any, becomes smaller as concentrations extent below these levels. In the end, the Administrator has selected standards based on consideration of the weight of the scientific evidence, recognizing that some risk of effects remains at still lower levels. In this respect, the approach followed in reaching this decision is completely consistent with that followed in the previous review.

(2) *Comment:* One commenter (Sonoma County APCD IV-D-7013) requested that EPA explain why short-term exposure health effects at 35 $\mu g/m^3$ are not significant enough to be prevented and why the proposed standard was not set to at least prevent health effects in the 40-50 $\mu g/m^3$ range.

Response: EPA has considered the weight of the scientific evidence including uncertainties in selecting the final standards, recognizing that some risk remains at still lower levels. This comment focuses only on the 24-hour standard level. By contrast, EPA selected an approach which considers the combined protection afforded by both the annual and 24-hour standards and treats the annual standard as generally controlling. As discussed above and in Section II.F of the preamble to the final regulation, EPA believes the key uncertainties with respect to the available scientific evidence on PM are such that the standard should focus on the strongest data. EPA considers the strongest evidence from the daily studies to be at concentrations toward the middle of the distribution of annual concentrations. Accordingly, the annual standard would serve to reduce short-term exposures in the range specifically raised by commenters in areas where such levels occur with enough frequency to cause annual levels above 15 $\mu g/m^3$, either in particular urban areas or in regions with elevated fine particle levels. EPA does not believe that the scientific evidence on the cumulative risk of very infrequent

excursions at such levels is certain enough to warrant the additional protection of a more stringent 24-hour standard.

(3) *Comment:* Some commenters supported annual $PM_{2.5}$ standard levels below levels recommended in the Staff Paper. They cite Staff Paper discussions of lower limit of detection or interpret lowest observed exposures in long-term exposure studies (e.g., noting that in Dockery *et al*. (1993) and Pope *et al*. (1995), mortality and morbidity effects continue down to exposures as low as 9 $\mu g/m^3$).

Response: As stated in the Staff Paper, the purpose of discussing lower limits of detection was to support sensitivity analyses performed in developing ranges of estimated risks. One of the elements needed for these sensitivity analyses is alternative PM concentration ranges over which reported concentration-response functions would be applied. The lower limits of detection would serve as the lower end of such ranges (Staff Paper, Appendix E). Indeed, staff recommendations regarding ranges for consideration did not extend this low due to the increasing uncertainties at lower levels such as the possibility of a threshold. The lower end of the staff recommended range in the Staff Paper for the annual standard was not related to and well above the lower limit of detection. The Staff Paper also notes that the central tendency (i.e., mean or median) concentration is generally the point for which there is the greatest confidence. As discussed above and more fully in Section II.F of the preamble to the final rule, EPA believes the key uncertainties with respect to the available scientific evidence are such that the standard should focus on the strongest data, which are at and above the mean levels observed in the short-term exposure studies. For reasons discussed in Section II.F of the preamble to the final rule, the level of the annual standard is based primarily on the annual levels observed in the short-term epidemiological studies; in the Administrator's judgment, the long-term exposure studies, which are subject to greater uncertainties, are consistent with the level she selected.

EPA also notes that the lowest fine particulate concentration reported in Pope *et al*., (1995) is a median value of 9.0 $\mu g/m^3$, not a mean value. The lowest mean value would be expected to be about 11 $\mu g/m^3$, based on Freas (1997) analysis of typical ratios related to $PM_{2.5}$ mean/median ratios (1.21). This is close to the lowest mean $PM_{2.5}$ level observed in the 6-city study (Dockery *et al*., 1993). This raises the levels underlying commenters' rationale to about as low as 11 $\mu g/m^3$, but has no implications for EPA's rationale, which gives primacy to the 24-hour studies, and uses the annual results in a supportive role in evaluating the margin of safety. EPA believes commenters' approach does not appropriately recognize the fundamental uncertainties regarding the risks at such lower concentrations. In the end, EPA has selected standards that protect public health, based on consideration of the weight of the scientific evidence.

(4) *Comment:* In partial support of the argument that $PM_{2.5}$ standards should be more stringent than those proposed by EPA, the Bay Area Air Quality Management District (IV-D-6502) submitted a new analysis of PM and mortality in Santa Clara County. This analysis finds that "a large number of premature deaths would still occur in the San Francisco Bay Area, even under attainment of the new standards" (commenter's Attachment 1). In addition, a brief report from a new study is attached that finds "a reduction in the proposed $PM_{2.5}$ 24-hour standard from 50 $\mu g/m^3$ to 30 $\mu g/m^3$ would result in a reduction of as many as 1300 deaths per year in the Bay Area" (commenter's Attachment 2).

Response: A provisional examination of these supplemental analyses of the Santa Clara data indicates that they appear to offer further evidence for health effects of $PM_{2.5}$ at low concentrations. In the first attachment the data set from a previous publication (Fairley, 1990) was divided into subsets that excluded days with higher PM levels. As discussed in the preamble, the HEI reanalysis of the earlier publication, using COH as the PM indicator, found essentially the same results as reported by the original investigator. The report in Attachment 1 adds two new facets to the original investigation, a conversion of COH to $PM_{2.5}$ and an examination of effects when data from high-exposure days are excluded for analysis. EPA has some concern about the methods used to extrapolate $PM_{2.5}$ values from COH measurements, and the validity of the resulting $PM_{2.5}$ estimates. As stated in the Criteria Document (p. 4-55), "Any attempt to relate COHs to $\mu g/m^3$ requires site-specific calibration of COH readings against mass measurements determined by a collocated gravimetric device, but the accuracy of such mass estimates are still subject to question." In this case, data from the same location (1980-1986) were used, but data collected at a later time (1990 and later) were used in the calibration of COH against $PM_{2.5}$, and PM levels had been reduced over this time period. This has clear implications for the applicability of the calibration.

It must also be recognized that the findings of these two analyses have not been subject to peer review or submitted for publication. As has been stated previously, the EPA's decision must be based on studies evaluated in the criteria review process, including review by CASAC. Were these analyses to be considered in this rulemaking process, it appears that they would offer evidence for health effects related to PM exposures in an area that is in attainment with the current PM standards. This is particularly true for the findings presented in the second attachment, which is a completely new study (though it is based on the same air pollutant data set) that expanded the analysis to the full year, and extends predicted mortality reductions to surrounding Bay Area counties. Although it appears unlikely that these analyses, standing alone, would materially change EPA's conclusions if considered in this rulemaking, EPA encourages the commenters to submit these studies for publication so that they may be considered in the next review of the PM standards.

d. Forms of the standards

A broad range of public comments were received in this area. The comments regarding the form of the annual $PM_{2.5}$ standard centered mainly on spatial averaging provisions. The comments on the form of the 24-hour standard focused on the adequacy of health protection, particularly for western areas, and/or comparisons with the 1-expected-exceedance form. The comments are summarized primarily in section II.A.2.a.(4) of the Summary of Comments and significant comments are highlighted in the preamble to the final rule. In addition to the responses contained in the preamble to the final rule in sections II-B and II-E, EPA provides the following additional responses to specific issues.

i. Spatial averaging

(1) *Comment:* A number of commenters objected to the concept of population-oriented monitors and expressed the view that any monitor regardless of where it was sited should be eligible for comparison to the annual $PM_{2.5}$ standard. They further maintained that the proposed provisions for spatial averaging would fail to provide adequate health protection because "clean areas" and "dirty areas" would be averaged together. Some commenters noted that the constraints EPA placed on spatial averaging proposed in 40 CFR Part 58 would be inadequate to prevent manipulation of spatial averaging to avoid pollution abatement. Several commenters raised environmental justice concerns, noting that minority communities or low income communities might live disproportionately in areas with higher concentrations.

Response: See preamble to the final rule, section II-E-1.

EPA agrees with commenters that the form of the standards, in conjunction with other components of the standards, must protect public health adequately against risks associated with PM. It was for this reason that EPA proposed a policy approach providing for maximum risk reduction for citizens in the community from exposures to the mix of urban and regional scale PM pollution most strongly associated with health effects. In specifically considering whether to allow for the use of spatial averaging, EPA placed great weight on consistency with the underlying body of health effects evidence. EPA notes that some of the commenters opposed to spatial averaging may not have fully understood the implications of the specific constraints and siting requirements discussed in the proposed revisions to 40 CFR Part 58. These constraints, summarized below, are intended to ensure that designated monitors will be reflective of community-wide exposures and that spatial averaging will not encourage "gaming" to avoid control through inclusion of non-representative monitored values from either "clean areas" or "dirty areas."

EPA is concerned that for some commenters, the term "population-oriented monitors," which was used in the proposal to indicate the kinds of sites to be included in spatial averaging, may have conveyed the impression that EPA was focused on protecting only high population centers

or locations, rather than smaller communities, whether within urbanized areas or not. This term, derived from air pollution monitoring guidance, simply means a site intended to measure population exposures, as opposed to maximum source impacts or transport. To clarify the intent, EPA has changed the term as it applies to monitors used in spatial averaging to "community-oriented monitors" in the final rules and guidance. The final rule also clarifies that either a single properly sited community-oriented monitor or an average of several such monitors may be appropriate indices of area-wide population exposures for the annual standard, and that both are consistent with monitoring approaches used in the community epidemiological studies upon which the standards are based.

In EPA's view, the final criteria and siting requirements contained in 40 CFR Part 58 address commenters' concerns regarding the adequacy of the proposed constraints on spatial averaging. The final requirements include provisions for a homogeneity constraint of +/- 20%. This limit governs which monitors may be averaged together such that no monitor may be more than 20% higher or lower than the average of all monitors. The final rules also include provisions requiring that state monitoring plans be available for public inspection. Additional requirements include demonstrations that the monitors to be averaged are influenced primarily by similar sources (e.g., to prevent the placement of monitors upwind in unrepresentative locations), EPA oversight of the monitoring program, which includes regular review and approval of state monitoring plans, and other criteria to ensure proper monitor siting.

Accordingly, the Agency continues to believe that an annual $PM_{2.5}$ standard reflective of area-wide exposures, in conjunction with a 24-hour standard designed to provide adequate protection against localized peak or seasonal $PM_{2.5}$ levels, represents the most appropriate approach to protection of public health against the effects of PM reported in the scientific literature.

(2) *Comment:* Some commenters agreed that spatial averages are closely related to the underlying air quality data used in the health studies and advocated the extension of spatial averaging, both to broad urban scales, as well as to the daily form of the standard; some also recommended less constrained spatial averaging to allow for averaging across entire metropolitan areas.

The Administrator is mindful that some community studies relied inherently on exposure and effects estimates that reflect comparatively broad spatial scales, as highlighted by those commenters desiring to extend permissible averaging. For example, the daily mortality studies generally use urban or metro-areawide effects statistics in conjunction with single or multiple monitors that index day-to-day pollution changes across the area. Ito et al. (1995) found that spatial averages from multiple PM_{10} monitors in Chicago were better correlated with daily mortality than were most single monitors, but that single monitors were also associated. A number of morbidity studies (e.g., Schwartz, 1994; Neas et al., 1995; Raizenne et al., 1996),

however, used community-oriented monitors and effects information from a defined group of subjects drawn from the community, who were more closely represented by the monitor.

The combination of studies suggests that extension of spatial averaging to even broader scales than permitted in the proposal would go beyond the exposure regimes of some community-oriented studies. Moreover, as indicated by a number of commenters opposed to any averaging or supporting tighter constraints, such an extension could result in encouraging the inappropriate manipulation of the averages to avoid controls. EPA believes unconstrained averaging would not be appropriate for all circumstances and might leave some areas without adequate protection. Furthermore, because the 24-hour standard is designed explicitly to address localized peaks, it would be inappropriate to extend spatial averaging to this standard.

(3) *Comment:* One commenter (API, IV-D-2247) suggested that the spatial averaging area should relate to the area that a typical individual might cover during a day to more accurately represent such an individual.

Response: EPA agrees that exposure considerations are important to selecting forms of the standards, but notes that the concentration-response information on PM is derived not from individual exposure studies, but from community population studies. These relationships already factor in population movement over the course of a year. EPA believes that available information in the Criteria Document, as well as prudent health policy considerations, more readily support the spatial averaging approach adopted in the final rule.

(4) *Comment:* The majority of comments from States stressed the need for flexibility in specifying network designs and spatial averaging given that the nature and sources of particle pollution vary from one area to another. One State agency specifically requested the flexibility to choose whether to use a single community-based monitor or a spatial average of several such monitors, arguing that it is appropriate to provide this flexibility as $PM_{2.5}$ monitoring networks evolve and to address the diversity of local conditions. Several comments from States suggested that a spatially averaged form would be difficult to communicate to the general public. Many comments from States stressed the need for additional funding for implementation of spatial averaging in new fine particle monitoring networks.

Response: See preamble to the final rule, section II-E-1.

As noted above, in response to these and other comments, the requirements contained in Appendix N and 40 CFR Part 58 have been revised to clarify that the implementing agencies have the flexibility to compare the annual $PM_{2.5}$ standard either to the measured value at a single representative community-oriented monitoring site, or to the value resulting from an average of community-oriented monitoring sites that meet the criteria and constraints enumerated in the 40 FR Part 58 notice.

EPA agrees with the importance of communicating information about air quality and risk to the public. EPA continues to believe, however, that an annual $PM_{2.5}$ standard reflective of area-wide exposures, in conjunction with a 24-hour standard designed to provide adequate protection against localized peak or seasonal $PM_{2.5}$ levels, is the most appropriate approach to protect public health against the effects of PM reported in the scientific literature. EPA will continue to work with the States and local governments to communicate this information in the context of the fine particle standards.

The issue of funding for monitoring networks raised by some commenters is not germane to the decision on standard form and is addressed elsewhere.

ii. Form of 24-hour standard

(1) *Comment:* A number of commenters maintained that EPA should use a 1-expected-exceedance form for the 24-hour $PM_{2.5}$ standard to limit the number of days per year that the standard is exceeded, as opposed to a concentration based form.

Response: See preamble to the final rule, section II-E-2.

As discussed in the Staff Paper, the proposal, and preamble to the final rule, since promulgation of the current 24-hour PM_{10} standard in 1987, a number of concerns have been raised about the 1-expected-exceedance form. These include, in particular, the year-to-year stability of the number of exceedances, the stability of the attainment status of an area, and the complex data handling conventions specified in Appendix N, including the procedures for making adjustments for missing data and less-than-every-day monitoring. In light of these concerns, the Staff Paper and several CASAC panel members (Wolff, 1996b) recommended that consideration be given to adoption of a more stable and robust form for 24-hour standards.

These commenters apparently gave little consideration to EPA's rationale that a concentration-based form is more directly related to ambient PM concentrations that are associated with health effects because it takes into account the magnitude of PM concentrations, not just whether the concentrations are above a specific level. These commenters also discounted the other advantages of a concentration-based percentile form outlined in the preamble to the final rule. Many of these commenters argue that a 1-expected-exceedance form offers an inherently more stringent level of protection. The level of protection is, however, a function of not only the form, but the level and averaging time. In this case, the 24-hour standard is intended to provide a supplement to protect against 24-hour peaks, thereby supplementing the protection provided by the annual standard with regard to both annual and 24-hour exposures.

EPA continues to believe that a concentration-based percentile form is more reflective of the health risk posed by peak PM concentrations, because it gives proportionally greater weight to

days when concentrations are well above the level of the standard than to days when the concentrations are just above the standard. This factor, coupled with the other advantages outlined above, leads EPA to conclude that a concentration-based percentile form will provide for more effective health protection than a 1-expected-exceedance form. EPA believes that the final combination of level and form of the 24-hour standard, in conjunction with the final annual standard, will protect the public health with an adequate margin of safety.

(2) *Comment:* A substantial number of commenters who either supported $PM_{2.5}$ standards (e.g., Great Basin Unified APCD, IV-D-6502) or provided "contingent" comments if such standards were adopted, strongly supported EPA's move away from the use of extreme values in attainment and planning decisions. Other commenters (e.g., ALA IV-D-2342) expressed the view that stability should not be a consideration, only health protectiveness.

Response: EPA agrees with commenters who suggest that standards can provide more stable targets, while at the same time providing adequate public health protection. EPA generally agrees that increased stability in the standards is desirable to avoid areas "flip-flopping" in and out of attainment, but disagrees that this goal is unrelated to health. In EPA's view, providing a more stable target for controls and more certainty in planning ultimately translates into improved health protection. See preamble to the final rule, section II-B and II-E-2.

(3) *Comment*: Many commenters supporting a single exceedance form or a more restrictive concentration-based percentile form (e.g. a 99^{th}percentile) expressed concern that the proposed 98^{th} percentile could allow too many high concentration excursions, and thus fail to provide adequate protection against localized peaks, or seasonal emissions problems. Specifically, some commenters expressed theoretically based concerns that in areas with strongly seasonal emissions, such as western areas with winter inversions, over a three year period an area could experience several excursions in which levels could reach as high as 250 $\mu g/m^3$ and still comply with both the annual and daily standards if the remainder of the days had low levels (e.g., 10 $\mu g/m^3$). Others objected to the proposal to limit attainment determinations to population-oriented monitoring sites, and expressed concerns that this would not adequately protect individuals or small communities located in or near localized "hot spots" with high PM levels.

Response: While commenters provided information on peak to mean ratios suggesting the theoretical possibility of such high $PM_{2.5}$ concentrations, there is little evidence that levels this high have occurred in recent years in U.S. urban areas, and the occurrence of such levels under the new standards is even less likely. To address the rare circumstances that might lead to such episodes, EPA intends to establish a significant harm level for $PM_{2.5}$ and associated guidance so States can develop appropriate emergency episode plans. The significant harm and episode criteria will be included in forthcoming guidance. In the interim, the existing PM_{10} emergency episode plans should be triggered by events of the magnitude suggested by these commenters.

EPA shares the concerns of these commenters that the 24-hour standard protect against localized peaks. As detailed in section II.D of the preamble to the final rule, one of the major purposes of the 24-hour standard is to supplement the overall protection of the annual standard in areas with periodic high peak values, including zones of high concentrations due to local sources. To provide adequate safeguards for those who live in or otherwise encounter such localized hot spot areas, attainment of the final standards will be determined by comparison with any population-oriented site within an area. As discussed specifically in the Part 58 final rule, population-oriented monitoring includes sites in residential areas, commercial areas, recreational areas, industrial areas, and other areas where a substantial number of people may spend a significant fraction of their day. In addition, EPA is modifying the Part 58 requirements to increase the required frequency of sampling in areas where the 24-hour standard is likely to be the controlling standard. This modification will more effectively detect infrequent peak concentrations in such areas.

EPA believes that, given the limits on truly episodic peak concentrations, an appropriately selected 24-hour standard with a concentration based 98th percentile form can provide a stable and adequately protective supplement to the annual standard in areas with periodic peak concentrations.

(4) *Comment:* Other commenters, who opposed setting $PM_{2.5}$ standards, recommended that if EPA proceeds with standards, a concentration percentile form should be used. Further, some such commenters recommended that alternative lower percentiles (e.g., 95th percentiles) be used to provide even more stability.

Response: As discussed in the proposal notice, EPA continues to hold the view that a 90^{th} to 95^{th} percentile form would not serve as an effective supplement to the annual standard because these forms would allow a large number of days with peak $PM_{2.5}$ concentrations above the level of the standard. Specifically, the 90^{th} and 95^{th} percentiles correspond to the 37th and 19th highest daily values in a 365-day data base, respectively.

(5) *Comment:* Several comments from States suggested that a 98^{th} percentile form would be difficult to communicate to the general public.

Response: EPA continues to believe that a concentration-based form of the 24-hour $PM_{2.5}$ standard designed to provide supplemental protection against localized peak or seasonal $PM_{2.5}$ levels, in conjunction with the annual standard, represents the most appropriate approach for protection of public health against health effects from exposure to PM. Although the statistical form of the standard may be a complex subject, EPA believes that the advantages of the form can and should be explained to the interested public. Concepts such as percentiles are routinely presented to the general public in other venues (e.g., interpreting students' scores on standardized tests, infants' height and weight statistics). As described above, EPA agrees with

the importance of communicating information about air quality and risk. EPA will continue to work with the States and local governments to communicate this information in the context of the fine particle standards.

(6) *Comment:* Some commenters recommended that EPA should adopt a form of the standard using a statistical test that creates a "too-close-to-call" category to reduce attainment flip flops.

Response: EPA has considered and rejected this approach for achieving stability in the form of the standard. In essence, if controls are applied to such a category, it is effectively non-attainment. If no controls are applied, then the "too-close-to-call" category effectively becomes an attainment category and the "level" of the standard has effectively been raised. While the use of a statistical test can reduce the misclassification rate (i.e., cases where truly attainment areas are classified as nonattainment, and vice versa), it can also delay the implementation of needed controls or, conversely, the time for an area to be redesignated from nonattainment back to attainment. The revised PM standards are an annual mean (which is very stable) and a concentration-based form of the 24-hour standard that is more stable than the one-exceedance standard used in the past.

(7) *Comment*: A number of commenters disagreed with averaging over three years for both the annual and 24-hour standards because of their desire for quick action in the initial implementation of $PM_{2.5}$ controls.

Response: The EPA recognizes the importance of promptly implementing appropriate control programs, but EPA does not believe that implementation start-up concerns are an adequate basis for adopting a form (e.g., a single year annual average) that would provide less stable risk reduction in the long-run. Therefore, the EPA continues to concur with the Staff Paper recommendation, supported by CASAC, to use the annual arithmetic mean and 98th percentile, averaged over 3 years, as the forms of the $PM_{2.5}$ standards. Nevertheless, EPA intends to address the concerns of those who commented that the 3-year form might prevent the public from being informed about the air quality status of their communities. As outlined in section II.H of the pramble to the final rule, EPA plans to issue revised Pollutant Standard Index criteria for $PM_{2.5}$, to ensure the public is informed promptly about air quality status.

e. Revisions to Appendix K for PM standards

The final rule for PM retains Appendix K to 40 CFR part 50 in its current form for use in connection with the continued applicability of the current PM_{10} standards during a limited transition period (see section VII of the preamble to the final rule). EPA's final action on the proposed revisions to Appendix K, intended for use with the revised PM NAAQS, is incorporated in a revised versionj of Appendix K that is designated as Appendix N in the final rule. Because the comments and issues related to the proposed revisions to Appendix K (now Appendix N) are similar for both the PM_{10} and

$PM_{2.5}$ standards, this section of the response to comments addresses comments included in both section II.A.2.a.(5) and section II.A.2.b.(5) in the Summary of Comments. For clarity, the statements of comments and EPA responses below use the designation Appendix N in referring to the proposed and final revisions to Appendix K.

i. Data completeness and missing data adjustments

(1) *Comment:* Some commenters disagree with retaining high 24-hour values when the 75% data completeness requirement is not met, yet not retaining low values when the 75% data completeness requirement is not met.

Response: The EPA response to this comment is addressed in section V of the preamble to the final rule.

(2) *Specific Comment* (State of North Carolina Office of the Governor, IV-D-7003): The commenter specifically questioned how the requirement for having 3 consecutive years of air quality data is affected by a situation in which years 1 and 3 have data above the standard while year 2 has incomplete data with no values above the standard.

Response: The EPA agrees that in some cases it makes sense to retain a particular year and use the data to show that the standard has or has not been met even though the year may have one or more quarters with less than complete data. Appendix N allows some cases of less than complete data to be used subject to the approval of the appropriate Regional Administrator. Thus, the requirement for 3 consecutive, complete years of air quality data still exists, but exceptions to having complete data may be allowed. The EPA plans to issue guidance on dealing with less than complete data.

(3) *Specific Comment* (State of North Carolina Office of the Governor, IV-D-7003): The commenter stated that to comply with the calculation of the 98th percentile a monitor must have at least 49 samples in a calendar year.

Response: Although there are many methods to define or calculate a percentile from a discrete set of data, the EPA has selected a method that is simple, is not biased high or low for all sample sizes, and yields reasonable results. The method as proposed and incorporated into Appendix N does not limit the sample size to above 49. The method used by the EPA results in the maximum value from 1 to 50 samples for a 98th percentile (1 to 100 samples for a 99th percentile). Therefore, the form of the standard does not limit the sample size. However, the EPA has set various data completeness requirements that must be satisfied when using data to compare with the levels of the standards.

(4) *Comment:* A number of air pollution control agencies were concerned that Appendix N does

not allow seasonal sampling. They argue in some areas it is appropriate to conduct seasonal sampling, reducing the frequency of monitoring during a period of expected low concentrations to save resources.

Response: Appendix N does not prohibit seasonal sampling, and refers matters of sampling frequency to 40 CFR Part 58.13. For clarification, the final Appendix N adds that exceptions to specified sampling frequencies, such as a reduced frequency during a season of expected low concentrations, shall be subject to the approval of the appropriate Regional Administrator. The EPA plans to issue guidance pertaining to exceptions to sampling frequency.

(5) *Comment:* Appendix N should address the data affected by special or uncontrollable events.

Response: Several commenters mentioned the handling of special or uncontrollable events in conjunction with Appendix N. The EPA believes that data resulting from uncontrollable or natural events, for example, fires or high winds, may require special consideration. In some cases, it may be appropriate to exclude these data because they could result in inappropriate values to compare with the levels of the PM standards. In other cases, it may be more appropriate to retain the data for comparison with the level of the PM standards and then allow the EPA to formulate the appropriate regulatory response. Appendix N clarifies that exclusion, retention, or adjustment of the data affected by uncontrollable or natural events is subject to the approval of the appropriate Regional Administrator. All relevant EPA guidance should be considered.

ii. Data handling and rounding conventions

(1) *Comment:* The requirement to compute quarterly averages when calculating the annual mean is unnecessary and too cumbersome to justify.

Response: The EPA considered not using quarterly means to compute annual means; however, the EPA disagrees that there is no justification for using quarterly means. Significant seasonal variation is observed in PM concentrations. Seasonal variation has also been observed in data completeness and sampling schedules. Computing an annual mean with quarters sampled at different rates could lead to an annual mean that is not representative of PM levels in an area. Calculating quarterly means with which to compute annual averages avoids this bias. The EPA, therefore, has retained the use of quarterly means when calculating an annual mean.

(2) *Comment:* The mathematical formulas for computing the percentiles are incorrect. Picking the next higher value or averaging the next highest value make the percentile too high. The formulas for computing the percentiles are too complex and are difficult to understand and explain to the public. The EPA formulas for 98th percentile are not defined for less than 48 samples in a year.

Response: EPA believes that the computational formulas in Appendix N are mathematically correct and consistent with the definition of a percentile. The convention of using the next highest value insures that the specified percentage of data is below the computed value. In Appendix N, EPA has altered the calculation from the proposed formula in an effort to simplify the calculation. Further, the EPA believes that a percentile form of the standards is easier to explain than an exceedance form which requires complex adjustments for different sampling schedules. The EPA also disagrees that the formula for the 98th percentile is not defined for less than 48 samples in a year. In fact, the formula for the 98th percentile will yield the maximum value in a year until the sample size is greater than 50, and the formula for the 99th percentile (in the case of PM_{10}) will yield the maximum value until the sample size is greater than 100.

(3) *Comment:* The annual and 24-hour forms of PM_{10} and $PM_{2.5}$ standards should have the same decimal precision. These differences are inconsistent with quantitative uncertainty and confusing.

Response: The EPA realizes that the different levels of precision for the standards can be confusing. The EPA disagrees that this is inconsistent with measurement precision and quantitative precision. The different levels of precision used for the annual and the 24-hour forms of the PM standards are due to the different levels of information in each form of the standard. The annual form is a mean involving all values in 3 years while the 24-hour is based on only 3 values (the 98th or 99th percentile from each year). The statistical characteristics of these two quantities are completely different. To regard them as having the same level of precision is unjustified. Therefore, the EPA has retained the different levels of precision in the annual and 24-hour forms of the PM standards.

(4) *Comment:* The rounding conventions used for the annual and 24-hour forms of the PM standards should be the same. Rounding up or down should not be allowed before comparing to the level of the standards.

Response: The EPA considered the complexity of different rounding conventions for the annual and 24-hour formulas of the PM standards. However, the rounding conventions proposed by the EPA reflect the precision inherent in the calculations for the different forms of the standard and mechanically follow standard mathematical practice of rounding up at 5 or greater and down at 4 or less (e.g. rounding 65.5 to the nearest 1 would be 66 while 65.4 would be 65). The EPA also feels that rounding is necessary before comparing to the level of the standard. Rounding is justified due to the actual measurement precision experienced in measuring PM. To ignore measurement precision is not scientifically defensible. Therefore, the EPA has retained the proposed rounding conventions in the revised Appendix N.

iii. <u>3-Year compliance period</u>

(1) *Comment:* The compliance test for the annual form of the PM standards should be on the basis of a rolling average of 12 quarters instead of 3 years. This would allow measured data to demonstrate compliance as much as a year earlier than the 3 year rolling average.

Response: The EPA agrees that compliance could be demonstrated earlier in some cases with measured data on the basis of a 12 quarter rolling average. However, adopting this form of the annual standard is not justified since all other PM standards will be on a 3 calendar year basis. Different periods for compliance demonstrations could lead to unnecessary confusion as to the actual status of an area and confusion as to what control strategies should be employed and when. The EPA has retained the 3 calendar year basis for both $PM_{2.5}$ and PM_{10} annual forms of the standard.

3. Specific comments on proposed primary PM_{10} standards

a. Indicator for coarse particles

Relatively few public comments were received in this area. Public comments received on the proposed indicators were overwhelmingly in favor of EPA's proposal to maintain PM_{10} as an indicator for PM, whether as an indicator of coarse particles in conjunction with a fine PM standard, or as the sole PM indicator. This near unanimity shows strong support for retaining general PM standards. The comments are summarized primarily in section II.A.2.b.(1) of the Summary of Comments and significant comments are highlighted in the preamble to the final rule.

(1) *Comment:* Several CASAC panel members suggested using the coarse fraction (i.e., $PM_{10-2.5}$) directly as the indicator.

Response: See preamble to the final rule, sections II-C-2.

(2) Comment: One commenter (NMA, IV-D-2158), although supporting the PM_{10} indicator, suggested that the coarse fraction be subtracted from the PM_{10} mass measured.

Response: A literal reading of this suggestion shows it would amount to establishing a standard for fine particles without a PM_{10} standard. These commenters base their recommendation on their assessment of the scientific evidence, which in their opinion effectively supports EPA's conclusions regarding the desirability of separating fine and coarse particles, but also concludes that coarse fraction particles at current and anticipated levels have no substantial health and welfare effects. EPA believes that establishing an indicator for fine PM is essentially consistent with these commenters' first recommendation, but disagrees that the evidence in any way warrants total elimination of coarse fraction PM standards and controls.

b. Averaging times

The comments addressed in this section are summarized primarily in section II.A.2.b.(2) of the Summary of Comments and significant comments are highlighted in the preamble to the final rule. Most comments focused on the proposed alternative of revoking the 24-hour PM_{10} standard. EPA received few comments supporting elimination of the 24-hour PM_{10} standard. The main exception were some industries, most notably the mining industry, who argued that the available data provide little evidence for coarse particle effects at current ambient levels. These groups, who generally opposed $PM_{2.5}$ standards, also argued that the daily PM_{10} standard could be eliminated if $PM_{2.5}$ standards were set. EPA has responded in full to these comments in sections II.B and II.G.1 of the preamble to the final rule.

c. Standard levels

The comments addressed in this section are summarized primarily in section II.A.2.b.(3) of the Summary of Comments. Significant comments are highlighted in sections II.B and II.G.2 of the preamble to the final rule.

(1) *Comment:* Colorado PIRG & Colorado ALA (IV-D-2095), asserted that EPA has "de-emphasized potential effects of coarse particles even though the available epidemiological evidence does not imply that acute exposure to coarse particles is benign or without effect."

Response: EPA does not agree that the effects of coarse particles are de-emphasized in the current rulemaking procedure. In its decision to retain standards for PM_{10}, EPA noted that certain health effects are plausibly associated with both long- and short-term exposures to coarse fraction particles. The studies cited by the commenter (Gordian et al., 1996; Hefflin et al., 1994) are discussed in the conclusions to the Staff Paper (p. VII-37) as evidence of these health effects. Both coarse particle studies involved unusually high exposures to fugitive dust or airborne volcanic ash, and both measured some increases in respiratory illness (asthma or bronchitis) with increases in PM_{10} that were primarily coarse particles.

As summarized in the Criteria Document (pp. 12-373 to12-377), where measures of both fine and coarse particles were used in health effects investigations, the researchers often found stronger associations with the fine particles or components. For example, in the Harvard Six Cities study (Dockery et al., 1993), of the three PM indices, $PM_{2.5}$ was most predictive of mortality for five of the six cities, but there were still associations found with coarse particle measures. EPA believes that the available scientific information indicates the need for additional regulatory attention to the fine component of PM. Although EPA has modified the form of the 24-hour PM_{10} standard to account for the additional protection provided by the additional $PM_{2.5}$ standards, both 24-hour and annual PM_{10} levels have been retained to provide adequate protection against the known and potential effects associated with the larger inhalable coarse fraction particles.

(2) *Comment:* The Ontario Ministry of Environment and Energy (IV-D-5262) urged the EPA to set more stringent standards for PM_{10}, stating: "The recent study in Anchorage, Alaska shows adverse effect associations with the coarse fraction. The study is discussed in the Health Effects section of the staff paper, but does not appear to have been considered in the decision making." In addition, the Clean Air Coalition (IV-D-7730) urged the EPA to "adopt California's PM_{10} standard which is two thirds stronger than the national standard." The commenters attached a copy of the recent scientific article by Gordian et al. (1996) in support of their comments. By contrast, the Alaska Department of Health and Social Services, Division of Public Health (IV-D-7005), in supporting EPA's proposed PM_{10} standards, offered a critical review of a recent report from the Gordian et al. (1996) study and argued that it should not be relied upon in the development of PM standards.

Response: EPA does not agree that the results of this study were not considered in the decision-making process; the Anchorage study was among the many studies whose findings were used in determining appropriate levels of PM standards. In particular, this study (Gordian et al., 1996) is one of the few that found evidence of health effects associations with PM_{10} that was conducted in an area where PM mass appears to be dominated by coarse fraction particles. As commenters have observed, the results of this study were reviewed and considered in the context of a limited set of other studies of exposure to PM_{10} with relatively high coarse fraction concentrations.

As noted in the Staff Paper, the 22-month average PM_{10} concentration in this study of 45.5 $\mu g/m^3$ is near the level of the annual average PM_{10} standard, and over the course of the study, multiple exceedances of the 24-hour standard occurred, with extreme values during the volcanic activity that occurred near the beginning of the study. In examining this study in the context of other relevant PM_{10} studies, staff noted some methodological weaknesses, but generally found the results supported retention of PM_{10} standards at levels at or near those of the current standards. Based on the overall evaluation of the scientific evidence, EPA believes that it is appropriate to maintain the current annual average standard for PM_{10} at 50 $\mu g/m^3$, and to retain the level of the 24-hour standard, but with a more robust concentration based form based on the 3-year average of the 99^{th} percentile 24-hour values.

(3) *Comment:* Some commenters, including some environmental groups and the State of California (Cal EPA, IV-D-2251), suggested that the large number of recent studies showing effects at PM_{10} levels below the current standards provides a basis for establishing stricter annual and 24-hour PM_{10} standards, in conjunction with $PM_{2.5}$ standards.

Response: See preamble to the final rule, sections II.B and II.G.2.

As discussed in Sections II.B and C, while these studies could be interpreted as supporting either a tightening of the PM_{10} standards or the addition of standards that focus control on the

fine fraction of PM_{10}, the weight of evidence from all of the relevant information more readily supports the development of additional protection for the $PM_{2.5}$ fraction. Given EPA's policy approach of useing PM_{10} as a coarse particle indicator, in EPA's judgment it is not appropriate to use these studies for both the $PM_{2.5}$ and PM_{10} standards.

d. Form of 24-hour standard

In general, comments received on the form of the 24-hour PM_{10} standard paralleled those on the form of the $PM_{2.5}$ standard. Substantial concerns were expressed by environmental groups, some states, and others that the 98th percentile would not provide an adequate limit on the number and magnitude of 24-hour peak PM_{10} excursions. While a number of these commenters suggested keeping the current 1-expected-exceedance form, EPA believes that a concentration based percentile form offers significant advantages, as discussed in section II.G of the preamble to the final rule and in the responses above in section 2.d, for both PM indicators.

Comment: Many commenters were concerned that the uncertainties in the available scientific information on the effects of coarse particles were a reason to be concerned that, assuming the current standard level was kept, a 98th percentile form would represent a significant relaxation in protection relative to the current standards. Some of these commenters recommended keeping the current 1 expected exceedance form, while others argued that the current form and level be maintained during a transition period, to prevent inappropriate reduction of health protections in interm implementation. Some air pollution control officials suggested consideration of a 99th percentile form with increased monitoring as an appropriately protective form.

Response: See section II. G of the preamble to the final rule. EPA notes that, unlike the situation for the new $PM_{2.5}$ standards, in the case of the PM_{10} standards, the 24-hour standard has generally been the "controlling" standard, making changes to the form of the 24-hour standard potentially more significant to the overall national level of protection afforded. It is clear that, if the level of the current standard is held constant, as suggested by staff and a number of CASAC panelists, the move to a 99th percentile could result in relaxation of current controls on coarse particles. Given the uncertainties with respect to the potential health effects of coarse fraction particles, the Administrator is persuaded that the somewhat more cautious approach recommended by many commenters is appropriate. For these reasons, EPA modified the final rule to express the daily standard in a 99th percentile concentration-based form, averaged over 3 years.

EPA shares commenters' concern with respect to keeping appropriate protection during the transition to the revised and new PM standards. Accordingly, as discussed in section VII of the preamble to the final rule, the current PM_{10} NAAQS will continue to apply during the transition period.

e. Revisions to Appendix K for PM_{10}

See combined response to comments on proposed revisions to appendix K (appendix N in the final rule) in section II.A.2.e above, as well as section V of the preamble to the final rule.

4. Specific scientific/technical comments

a. Interpretation of epidemiological studies

This section addresses comments included in section II of the Summary of Comments..

i) Comments on Specific Studies

(1) *Comment:* Many commenters (e.g., UARG IV-D-2250) asserted that EPA was selective in its use of epidemiological evidence, and cites as an "extreme example" the examination of evidence of pollutant effects on respiratory function in children. In particular, the commenter argues that EPA ignored the following conclusions drawn from the 24-city study by Dockery et al. (1996): "There appears to be *no evidence* that the prevalence of asthma or asthmatic symptoms in children is associated with chronic exposure to particulate, sulfur oxide, or ozone air pollution ... [A]ir pollution *does not appear to contribute* to the increased prevalence of new cases of asthma, as is often claimed in the popular press." (UARG p. 21, emphasis added by commenter). Commenter notes this study is not included in the summary of studies that appear in Figure 1 of the proposal notice.

Response: A general response to the comment that EPA ignored or downplayed numerous studies is contained in Section II.B of the preamble to the final rule, and in Appendix B of this document. The commenter's specific criticism that EPA did not include Dockery et al. (1996) in Figure 1 of the proposal preamble is misplaced. That figure includes only studies that were considered to represent short-term exposure studies, and the 24-city study is clearly a long-term exposure study. It is important to note that EPA outlined key information from the Staff Paper and the Criteria Document in the preamble to the proposed rule, but did not attempt to repeat in full the complete analysis of the literature that was summarized in the Criteria Document.

The commenter also asserted that the EPA has taken a biased, or selective approach in its review of the scientific literature. EPA accurately reported the findings of Dockery et al. (1996) with respect to the study not finding significant associations between pollutant exposures and all health endpoints measured. In fact, the specific observation made by the commenter -- that there were no statistically significant associations found between the pollutants and asthma symptoms or wheeze -- was noted in the Criteria Document (p. 12-187).

In their discussion of this study's findings, Dockery et al. (1996) distinguish between findings of asthma symptoms and bronchitic symptoms. The authors cite previous findings of earlier studies as supporting their observation that exposure to particles is not associated with increased reporting of asthma symptoms over an annual period. In the text as it is excerpted by UARG, it appears that Dockery and colleagues are arguing against potential respiratory health effects from PM. In fact, however, the results of this study support the original hypothesis that acid aerosol exposures can affect childrens' respiratory health. In their discussion, the authors conclude only that air pollution exposure does not appear to be associated with the development of asthma or wheeze, based on the lack of significant findings for asthma or wheezing. The full quote from Dockery et al. (1996) clearly indicates this:

> "There appears to be no evidence that the prevalence of asthma or asthmatic symptoms in children is associated with chronic exposure to particulate, sulfur oxide, or ozone air pollution. This does not imply that acute air pollution episodes do not trigger or exacerbate asthmatic attacks, as has been shown in multiple studies. However, air pollution does not appear to contribute to the increased prevalence of new cases of asthma, as is often claimed in the popular press."

Indeed, a number of other commenters on the proposed PM standards, as well as the proposed ozone standards, have erroneously characterized EPA as claiming that the observed increase in asthma prevalence is demonstrably related to air pollution, or that the observed the increase in asthma is not coherent with the decline in air pollution. As noted elsewhere, EPA has not made such claims, and for the reasons outlined by Dockery et al. (1996) above, does not believe there is any lack of coherence with respect to these observed trends and the observation from short-term exposure studies that acute air pollution excursions can trigger or aggravate asthma symptoms.

As pointed out in the PM Criteria Document, both short-term and long-term exposure epidemiological studies find that ambient PM is associated with decreased pulmonary function and increases in lower respiratory symptoms. In the companion report from the 24-city study, Raizenne et al. (1996) found significant decreases in several lung function parameters (FVC, $FEV_{1.0}$, $FEV_{0.75}$) with all measures of particulate matter. It may or may not be true that exposure to air pollutants plays some role in the increased prevalence of asthma found in many countries. Of clear concern here are not only the instant observation of increased symptoms and decreased lung function, but the potential consequences of longer-duration exposure in later life. As stated by Dockery and colleagues in their concluding paragraph: "These data indicate that chronic exposure to acid aerosol pollution may have observable negative consequences for the health of children. Although the long-term consequences of bronchitis in these children remain unclear, respiratory illnesses in childhood may be a risk factor for chronic obstructive disease..."

(2) *Comment:* Lipfert (IV-D-2180) also criticizes EPA's interpretation of the 24-city studies (Dockery et al., 1996; Raizenne et al., 1996), asserting that the study fails to show effects within the high-sulfates regions, but only shows effects between this region and others.

Response: The commenter focuses on the lung function finding, apparently placing greater weight on the graphical depiction of the results than on the accompanying statistical analyses of the data. The authors (Raizenne et al., 1996) report a statistically significant association between particle strong acidity and decreased FVC for the subgroup of Eastern cities where there are generally higher levels of acid aerosols and sulfates. These negative associations are found in all subregional analyses, and the authors conclude that "...no differences in the association were observed with regard to geography..." This would appear to contradict the commenters' observation. Even if the comment were correct, however, this finding would suggest a relation between acid sulfates and the observed effects. Moreover the 24-city studies have several features that serve to greatly reduce problems associated with traditional cross-sectional mortality studies of air pollution: (1) the quality and extent of monitoring in the study are high, (2) the suburban locations and young age of the subjects preclude significant concerns about much higher historical concentrations, and (3) the extent of subject-specific information on lifestyle and other potentially important co-factors in this cohort study. These features increase confidence in the results of the study.

(3) *Comment:* AISI (IV-D-2242), in asserting selective use of scientific studies by EPA, cites the use of Saldiva et al. (1995) but not Saldiva et al. (1994) in the Staff Paper.

Response: Both papers were reviewed in the Criteria Document and contained in the 38 studies in Table 12-2, all of which were cited by reference to the Criteria Document table in the short-term exposure mortality discussion in the Staff Paper. Saldiva et al. (1995) is not given any significant discussion in the Staff Paper, although it is referenced. The Staff Paper does not and cannot completely replicate the analysis from the Criteria Document, but focuses on key studies highlighted in the Criteria Document. Thus, EPA does not agree that it has overlooked the results of Saldiva et al. (1994) in its review of the PM-related health effects literature.

As stated in the Criteria Document (p. 12-74), Saldiva et al. (1995) found a significant association between PM_{10} and mortality in elderly (>65 years of age) people. In a multi-pollutant model, the association with PM_{10} remained significant but the associations with co-pollutants (SO_2, NO_x, CO) did not. The same data set was used in the earlier study (Saldiva et al., 1994) but the effect under study was mortality for respiratory causes in children under five years of age (Criteria Document, p. 12-76). Among five pollutants considered both individually and in a multipollutant model (CO, SO_2, NO_x, O_3 and PM_{10}), only an association with NO_x was found to be statistically significant. In Table V-9 of the Staff Paper, EPA summarized the Criteria Document assessment of subpopulations especially sensitive to PM-related health effects; the elderly are considered to be a sensitive subpopulation with regard to

mortality from acute exposure to PM, but no conclusions are drawn ("insufficient data" or +/-) for PM-related mortality in children. This is clearly consistent with the then available literature, including both Saldiva studies. EPA therefore does not agree with the commenter's assertion that the literature was used selectively. EPA believes that the two papers by Saldiva and colleagues were adequately characterized in the Criteria Document and that the Staff Paper accurately summarized the salient results.

(4) *Comment:* Several commenters assert that the EPA has relied excessively on a few individual scientists in reaching conclusions regarding PM and health effects. Engine Manufacturer's Association (IV-D-2328) states: "EPA relies disproportionately upon the opinions expressed by a small but prolific community of researchers (primarily Schwartz and his co-authors, including Pope and Dockery) in reaching its conclusions. Nearly two-thirds (19 out of 29) of the peer-reviewed journal articles cited by the EPA to support its conclusions and interpretations are authored or co-authored by these three investigators." Other commenters made statements that were similar, though differing somewhat in detail. For example, Exxon Chemical Americas (IV-D-2113) states: "of the 18 studies used as key, ... 15 of 18 involve only three authors (Schwartz, Pope or Thurston)."

Response: EPA does not agree with these commenters' assertions that over-reliance was placed on the findings or opinions of a few scientists. In the first instance, the comments themselves show this is clearly not a situation in which reliance is placed on a single study by a single investigator or group. Instead, a variety of different data sets, modeling procedures, study designs, and approaches have been used in a number of locations around the world. While it is true that Drs. Schwartz, Pope, Dockery and Thurston have conducted numerous studies and published many research reports on pollution-related health effects, an examination of the over 80 key studies summarized in Chapter 12 of the Criteria Document shows that dozens of other scientists have either published their own independent work or collaborated with these investigators on various projects. The fact that particular scientists are prolific or have an active research program does not give cause to question the validity of their research. Moreover, these investigators subjected their results to independent peer review and publication in respected scientific journals. Beyond that, in the development of the Criteria Document, each study was evaluated on its own merits by EPA scientists, outside researchers and the CASAC. A discussion of the consideration of studies by different investigators in the Criteria Document is outlined in Section II.B of the preamble to the final rule and in Appendix B of this Response to Comments.

It is also important to note that a number of the studies by these authors were subjected to reanalyses. In general, the Criteria Document concluded that the most comprehensive and thorough reanalyses were those in the series conducted for the HEI, which reanalyzed data sets used in studies from six urban areas in Phase I.A (Samet et al., 1995). Among others, the reanalyses included studies by Dockery et al. (1992), Pope et al. (1992), Schwartz and

Dockery (1992a), and Schwartz (1993). The most important finding in the HEI Phase I.A reanalyses of these studies is "the confirmation of the numerical results of the earlier analyses of all six data sets" (HEI, 1995). After replicating the original investigators' analyses, Samet et al.(1995) also found similar results analyzing the data using an improved statistical model. The HEI Oversight Committee found:

> [I]t is reasonable to conclude that, in these six data sets, daily mortality from all causes combined, and from cardiovascular and respiratory causes in particular, increases as levels of particulate air pollution indexes increase [HEI, 1995].

These reanalyses by respected independent scientists confirm the reliability and reproducibility of the work of the original investigators, which include those most frequently mentioned by the above commenters. Indeed, the level of scrutiny applied to the work of these investigators has given EPA a clearer basis for relying on their work in the context of the larger body of scientific information on the effects of PM.

(5) *Comment:* Some commenters took issue with EPA's characterization of the results of Thurston et al. (1994), both with respect to suggesting a greater association between hospital admissions and $PM_{2.5}$ than PM_{10}, and with respect to the statistical significance of any PM indicators when ozone was included in the model.

Response: EPA does not agree that the results of Thurston et al. (1994) were mischaracterized in the Staff Paper. The general conclusions drawn by the authors from this study were that ozone exposure "clearly dominates" the summertime air pollution association with hospital admissions, while a "substantial increase in respiratory admissions" is also associated with peak acid aerosol exposures. The results of single-pollutant models in this study show significant associations with all measures of particles but the coarse fraction, and that only H+ remains significant when the particle measures are modeled with ozone. These findings are precisely the results reported in EPA's Staff Paper. The quote from Thurston et al. (1994) cited by UARG -- "although the particulate matter mass measures initially appeared to be significantly correlated with hospital admissions, . . . it seems clear that these apparent associations were merely a statistical by-product of interpollutant confounding results from the shared day-to-day variations in dispersion conditions" -- is drawn from an extensive discussion of the interactions between pollutants in multi-pollutant models. Based on a full reading of the paper, it is clear that the authors are emphasizing the need to address the issue of interpollutant confounding between various measures of PM and other pollutants. The authors find that the associations found for ozone and airborne acids appear to be independent of one another, with the association found between airborne acids and hospital admissions remaining significant when ozone is added to the model. In the area in which the study was conducted, acid aerosols are a large component of airborne particles, and the significant finding of increased hospital admissions with increased

airborne acid levels is an indication of an adverse effect of exposure to a major component of airborne particles. In the paper's discussion section, this issue is more fully addressed:

> These analyses considered 10 different pollution variables, of which 7 were various particulate matter metrics. In the initial analysis, virtually every pollutant measure was significantly correlated with respiratory hospital admissions. Even nonthoracic particle mass (TSP-PM_{10}) approached statistical significance, which is biologically implausible. This association is likely due to the moderate to high correlation among the various pollutants, which results from the general influences of atmospheric dispersion conditions on all of them . .. . after controlling for these O_3 associations, the relative particle metric strengths of association with health effects were generally $H^+ > SO_4^= >$ FP > PM_{10} > TSP... These results are biologically plausible in that the largest (i.e., nonthoracic) particles are least associated with admissions, while the smallest and most irritant particles (i.e., submicrometer acid aerosols) are indicated to be most strongly associated with adverse effects. [Thurston et al., 1994.]

(6) *Comment:* American Petroleum Institute (IV-D-8045) assserts that there is an extremely limited amount of scientific information on directly measured $PM_{2.5}$. In addition, the commenter asserts that none of the $PM_{2.5}$ air quality data are more recent than 1988, so they have limited, if any, relevance to today's air quality.

Response: EPA disagrees with the commenter's assertions. While there are fewer studies that directly measured fine particles than PM_{10}, there are over 30 epidemiological studies that obtained data on indicators of fine particles. As compared to the data available for the 1987 decision to establish PM_{10} standards that this commenter now supports, far more studies exist today for fine particles than existed at that time for PM_{10} . In the final decision on the levels for the $PM_{2.5}$ standards, the EPA was able to rely 9 studies that used gravimetric measures of fine particles, including $PM_{2.5}$ and the nearly identical $PM_{2.1.}$ Contrary to commenters' assertion, three of these studies (Dockery et al., 1996; Raizenne et al., 1996; Neas et al. 1995) were based on directly measured fine particle data collected in 24 North American cities between 1988 and 1991.

Moreover, the suggestion that North American data more than 10 years old has little relevance to today's air quality has no basis in fact. While PM levels have declined on average, there are numerous examples of studies using data collected in the 1980's that contained PM levels and composition that are well within the ranges that exist today. As discussed in Section II.F of the preamble to the final rule, the long-term average concentrations in a number of studies finding significant fine particle effects is about 18 $\mu g/m^3$. More specifically, two of the six cities with significant associations between mortality and fine particles had annual $PM_{2.5}$ levels of 15.7 $\mu g/m^3$ and 18.6 µg/m3. The level of the annual standard of 15 $\mu g/m^3$ was selected to be below these levels. $PM_{2.5}$ data from 1993-95 show Washington, D.C. had annual levels of about 18

$\mu g/m^3$, Philadelphia had 17 $\mu g/m^3$, and Los Angeles had 30 µg/m3. Further, Chapter 6 of the Criteria Document shows that the dominant components of fine particles in various regions of the country have not changed significantly since the 1980's. An examination of the data clearly demonstrates that the commenter is in error and that both the quantity and the composition of the 1980's Six City data is directly relevant to current air quality.[6]

ii) Confounding issues

A large number of commenters expressed concerns that the available epidemiological relied upon by EPA did not adequately take into account a variety of potential confounders, including co-pollutants, weather, personal factors, and indoor air pollution. In particular, some commenters noted particular studies they felt had done a better job at addressing multiple pollutants or other confounders as "negative" studies that EPA ignored and down played. The issue of potential confounding or effects modification by co-occurring pollutants or other factors such as weather in epidemiological studies of PM was central in the review of the scientific criteria. As such, it received substantial attention and analysis in Chapter 12 of the Criteria document, and in Chapters V and elsewhere in the staff paper. The major findings from these documents were also summarized at some length in the proposal. Because this issue has several dimensions, aspects of this issue have been addressed in discussing consistency with respect to certain multi-pollutant studies EPA allegedly ignored (see above and Appendices A, B, and C), weather (see appendices B and C), indoor air pollution and exposure misclassification (see below and Appendix D), as well as in corresponding portions of section II.B. of the preamble to the final rule.

As discussed therein, EPA's assessment of numerous mortality studies concludes that when studies are evaluated on an individual basis, the PM-effects associations are valid and, in a number of studies, not seriously confounded by co-pollutants (U.S. EPA, 1996a; p. 13-57); and when a collection of studies from multiple areas with differing concentrations of PM and co-pollutants are examined together, the association with PM_{10} remains reasonably consistent across a wide range of concentrations of these potentially influential pollutants (U.S. EPA, 1996a, p. 12-33; U.S. EPA, 1996b, p. V-55). EPA has carefully considered the view advanced by some that the results of individual studies of multiple pollutants, such as the HEI Philadelphia studies, are more suggestive of an "air pollution" effect than an effect of PM alone. Indeed, the proposal notes that it is reasonable to expect that other pollutants may play a role in modifying the magnitude of the estimated effects of PM on mortality, either through pollutant interactions or independent effects. Based on the large body of evidence at hand, however, EPA cannot accept the suggestion that such multi-pollutant studies are in

---

[6]If these commenters are convinced that current levels are, in fact, below the the ranges in the recent studies including Boston and St. Louis and the 24 cities, then their otherwise non-germaine arguments with respect to the high costs of implementing the standards are without merit, on their own terms.

any way "negative" with respect to EPA's conclusions that PM, alone or in combination with other pollutants, is associated with adverse effects at levels below those allowed by the current standards. This conclusion is based not only on the consistency of PM effects across areas with widely varying concentrations of potentially confounding copollutants, but also on the extended analyses of the Philadelphia studies in the Criteria Document and Staff Paper.

iii) Statistical modeling issues

Some commenters argued that sufficient flexibility exists in the analyses of large data sets that it may be possible to obtain almost any result desired through choice of statistical method. Analytical choices include the specific statistical model; methods used to adjust for seasonal variation and the trends in the data; treatment of other variables (e.g., other pollutants, weather, day of week); "lag" structure; and study population. The issue of statistical modeling also received substantial attention and analysis in the criteria review, with a substantial discussion in Chapter 12 of the Criteria Document. The Criteria Document concludes that:

> [T]he largely consistent specific results, indicative of significant positive associations of ambient PM exposures and human mortality/morbidity effects, are not model specific, nor are they artifactually derived due to misspecification of any specific model. The robustness of the results of different modeling strategies and approaches increases our confidence in their validity [U.S. EPA, 1996a, p. 13-54].

Appendices A, B, and C all discuss statistical modeling issues in the context of particular studies, with a response to the general issue raised here presented in section II of Appendix B, and a summary response in section II.B of the preamble to the final regulation.

iv) Exposure misclassification issues

A range of public comments were received in this area. The comments are summarized primarily in sections II.A.3.a.(4), II.A.3.h., and II.A.3.e. of the Summary of Comments and significant comments are highlighted in the preamble to the final rule. In addition to the responses contained in the preamble to the final rule in section II.B, EPA provides the following additional responses to specific issues. Appendix D contains further technical discussion of exposure-related issues.

(1) *Comment:* The available PM epidemiological studies are flawed because they rely on central monitors, not personal monitors, as an index of exposure to PM. Some commenters further note studies that showed a lack of correlation in cross-sectional comparisons between outdoor PM measured at central locations and indoor or personal exposures to PM (which includes PM from the outdoor, indoor and personal environments).

Response: See section II.B of the preamble to the final rule, and the detailed discussion in

Appendix D.

EPA rejects the notion advanced by commenters that epidemiological studies must use personal exposure monitoring to be considered for regulatory purposes. With CASAC concurrence, the Criteria Document concluded that properly conducted monitoring can provide an adequate index of population exposure to ambient air pollution in epidemiological studies (U.S. EPA 1996a; Chapter 7). Although personal monitoring may be practical for some occupational and epidemiological studies and has been employed in some past studies of air pollution, it is not realistic to require personal monitors in air pollution studies of daily mortality, which require urban scale population data over a period of years. In addition, the central monitor measurements are related to day-to-day variations in population exposures to ambient sources of PM, which is a more appropriate metric for setting a national ambient air quality standard. Most personal monitoring done to date does not permit separation of PM derived from outdoor air pollution from that derived from indoor and personal sources (e.g., smoking, cooking, cleaning). As discussed more fully in Appendix D, this kind of combined PM exposure information would actually be less relevant to the assessment of the effects of ambient air pollution than are outdoor measurements.

EPA acknowledged and responded to observed cross-sectional comparisons of ambient and personal PM data in Chapter 7 of the Criteria Document and the proposal notice. As described therein, the major premise underlying commenters' arguments on this issue is incorrect. The question is not whether central monitoring site measurements contain a signal reflecting actual exposures to <u>total PM</u> from both outdoor and indoor sources at the individual level; the relevant question is whether central monitoring site measurements contain a signal reflecting actual exposures to <u>ambient PM</u> for the subject population, including both ambient PM, while individuals are outdoors, and ambient PM that has infiltrated indoors, while individuals are indoors. The PM standards are intended to protect the public from exposure to ambient PM, not PM generated by indoor or personal sources. There is ample evidence, as discussed in Chapter 7 of the Criteria Document, that personal exposure to ambient PM, while outdoors and while in indoor micro-environments, does correlate on a day-to-day basis with concentrations measured at properly sited central monitors (U.S. EPA, 1996a, p. 1-10). EPA has, therefore, concluded that it is reasonable to assume that a reduction in ambient PM concentrations will reduce personal exposure to ambient PM, and that this will protect the public from adverse health outcomes associated with personal exposure to ambient PM.

(2) *Comment:* In direct contrast to the comment responded to above, some commenters have argued that the PM epidemiological results are confounded because the weather and other factors that cause daily variations in outdoor pollution will cause similar daily variations in exposures to indoor generated air pollution.

Response: EPA disagrees with this assertion. For this to be true, *outdoor ambient* pollution

concentrations would have to be correlated with personal exposure to *indoor-generated* air pollution such as that from smoking, cleaning, and cooking. This argument is logically inconsistent with the other comments on the lack of any such correlation with personal exposure, and these commenters have offered no scientific evidence to support their claim. In response, EPA has performed conceptual as well as quantitative analyses of the relevant information from the PTEAM exposure study and finds no evidence for such a correspondence in the actual data (see Appendix D). Indoor-generated PM appears to be independent of and uncorrelated with the ambient PM measurements in the backyards of each home in the PTEAM study. Moreover, the PM data also call into question the suggestion that individuals tend to engage in behavior that increases their exposure to indoor air pollution as outdoor air pollution levels increase.

As documented in Chapter 7 of the Criteria Document, time-series community studies observed the effects of varying levels of ambient air pollution; therefore, the effects of indoor-generated air pollution would be independent of and *in addition* to the effects found in these studies. Commenters apparently believe EPA is claiming such studies are detecting the effects of total PM personal exposure. This misunderstanding is evidenced, for example, by Wyzga and Lipfert's (1995) treatment of the difference between ambient monitors and actual personal exposures as "exposure errors"; Brown's comment for API (IV-D-2247) that "if (ambient) PM is causally related to mortality/morbidity, then it is personal PM exposure that must be reduced to have an effect." On the contrary, it is personal exposure to *ambient* PM that must be reduced to address the risk identified in community air pollution studies. Any lack of significant correlation between outdoor PM concentrations and personal exposure to total PM from all sources is irrelevant, except to the extent it may decrease the power of time-series studies to detect the effects of ambient pollution.

(3) *Comment:* Commenters have also raised theoretically based concerns on a related issue, namely errors in the measurement of the concentrations of air pollutants.

Response: See section II.B of the preamble to the final rule, and the detailed discussion in Appendix D.

b. Mechanistic and toxicological evidence

Comment: A number of commenters pointed out the lack of demonstrated biological mechanisms derived from the controlled human, animal, and other laboratory studies of components of PM. Some have said that, absent clear mechanistic support for biological plausibility, EPA should not proceed to revise the standards, based solely on the available epidemiology. In some cases such commenters make reference to the evaluative criteria of Hill (1965).

Response: As noted in the preamble to the final rule, with respect to biological plausibility, Hill noted that "this is a feature I am convinced we cannot demand. What is biologically plausible depends upon the biological knowledge of the day" (Hill, 1965). This statement is clearly pertinent to the toxicological and mechanistic understanding of the effects of PM and associated air pollutants, especially at lower concentrations. It is also important to stress that while the mechanistic evidence published as of the time the Criteria Document closed does not provide quantitative support for the epidemiological results, neither can such limited evidence refute these findings (U.S. EPA, 1996a; p. 13-27 to 28). In fact, our understanding of biological mechanisms for PM pollution effects is not sufficient to explain the effects observed at much higher concentrations in air pollution episodes, for which causality is generally accepted. Moreover, the toxicological literature has only recently begun to examine animal models (or controlled human studies) that might reflect the sensitive populations in question (the elderly, individuals with chronic respiratory and cardiovascular disease) or that adequately reproduce all of the physico-chemical properties of particles in the ambient atmosphere. In short, the absence of evidence of a particular mechanism is hardly proof that there are no mechanisms that could explain the effects observed so consistently in the epidemiological studies.[7]

As discussed in the Staff Paper, under ideal circumstances, animal toxicology and controlled human exposure studies can provide qualitative and quantitative support for environmental epidemiology. In the case of PM, however, the lack of published experimental human and laboratory animal studies involving relevant exposure levels and experimental subjects representative of sensitive subpopulations identified in the epidemiological studies presents problems in providing an integrated assessment (U.S. EPA, 1996a; p 13-2). Epidemiological studies describe relationships between regionally and temporally variable mixtures of particles and gases in community air pollution and mortality and morbidity in sensitive populations -- most notably the elderly and individuals with cardiopulmonary disease, which includes adults and children with asthma.

In contrast, experimental studies of PM effects in humans tend to use healthy young adult humans (or those with only mild disease) and examine mainly reversible physiologic and biochemical effects from exposure to laboratory-generated acidic aerosols, sulfates or nitrates. Similarly, experimental studies on laboratory animals have tended to use genetically homogenous healthy animals to examine a broader range of effects from individual components of the PM mix. In both controlled animal and human studies, the limited number of individuals exposed greatly limits the ability to detect effects at concentrations close to ambient levels. For

---

[7] The absence of biological mechanisms did not deter CASAC from recommending revisions to the PM standards in 1982, in 1986, and again in 1996. The length of time it has taken to uncover mechanisms underlying the effects of cigarette smoking serves as an important caution to those commenters who suggest that regulations should not proceed absent mechanistic understanding.

example, at the very high PM levels observed during the worst London episode (i.e. >1000 $\mu g/m^3$), the increase in mortality rate was such that about 2 in 10,000 London residents expired in a given 24-hour period. Obviously, directly relevant controlled human studies of this effect are out of the question, suggesting the use of animal studies. If animals have similar susceptibility to the average humans in this population, however, experiments to detect such effects would be prohibitively expensive because of the large numbers that would have to be exposed to detect an effect. This means animal models that mimic the greater sensitivity to PM effects observed in susceptible human populations are important in furthering research, as are more sensitive indicators of processes that could lead to more serious effects. In general, however, extrapolation of quantitative and qualitative results from animal studies to human is encumbered by methodological difficulties from differences in dosimetry. The various species used in inhalation toxicological studies do not receive identical doses in comparable respiratory tract regions when exposed to identical aerosols. Consequently few laboratory experiments have used appropriate models of susceptibility to PM, which limits evaluation of possible mechanisms and potential quantitative effects comparisons.

However, at least qualitative support for some of the epidemiologic observations has been reported for specific components of the ambient particle mix in controlled clinical studies of humans as well as studies in animals. Although results are reported only for levels generally higher than those observed in the ambient air, for such studies, the biological responses occurring in the respiratory tract following PM inhalation encompass a range of effects including: respiratory symptoms such as wheeze and coughing, changes in pulmonary function, altered mucociliary clearance, inflammation, changes in lung morphology and tumor formation (U.S. EPA, p. 13-70, p. 11-1). Most of these changes are consistent with effects observed in the epidemiological, but at generally much lower concentrations.

For additional discussion of this issue, see Appendix A.

c. Issues related to causality and the consistency/coherence of the evidence

i) Comments on causality

Many commenters agreed with EPA's interpretation of the epidemiological data in the Criteria Document and Staff Paper as clearly indicating a need to revise the current PM standards. A number of commenters, however, citing accepted criteria used in evaluating epidemiological studies to assess the likelihood of causality (most notably those of Sir Austin Bradford Hill, 1965), disagreed with EPA's assessment of the likelihood that air pollution containing PM is causally linked to observed health effects.

In general, the commenters and their consultants applied these criteria to subsets of epidemiological studies evaluated in the Criteria Document. In addition to the general response to these

comments contained in Section II.B of the preamble to the final regulation, EPA has prepared more detailed responses to the papers and reports that were submitted as appendices to the comments of some groups. The major points made in these submissions and EPA's detailed responses to these commenters are presented in Appendix A. The response below addresses one of the comments most frequently made regarding causality.

(1) *Comment:* Most of the above commenters placed heavy reliance on one of Hill's criteria for inferring causality, namely the strength of the association. More specifically, such commenters argued that, in the absence of a demonstrated biological mechanism, the relative risks of effects in the PM epidemiological studies are too low (less than values variously cited as 1.5 to 2.0) to reach any conclusions regarding causality or to form the basis for regulations. Many gave examples of spurious statistical correlations as evidence that not all associations are causal.

Response: While Hill appropriately emphasized the strength of the association (e.g., size of the relative risk) as important, he also pointed out that "We must not be too ready to dismiss a cause-and-effect hypothesis merely on the ground that the observed association appears to be slight. There are many occasions in medicine when this in truth is so" (Hill, 1965). EPA believes that the effects of air pollution containing PM is such a case. The relative risks at the lower concentrations observed in the more recent epidemiological studies still imply very substantial numbers of sensitive individuals effected. Moreover, unlike the "textbook" examples of unlikely significant associations provided by some commenters (e.g., ice cream consumption correlated with heat stroke), the abundant epidemiological literature on combustion particles documents numerous occasions in which single short-term episodes of high air pollution produced unequivocally elevated relative risks. For the week of the well documented 1952 London air pollution episode, for example, the relative risk of mortality for all causes was 2.6, while the relative risk for bronchitis mortality was as high as 9.3 (Ministry of Health, 1954). Hospital admissions also increased by more than a factor of two. British epidemiologists in the 1950s concluded that increased mortality was likely when PM (as mass calibrated British Smoke <4.5 μm in aerodynamic diameter) exceeded 500 $\mu g/m^3$ (Martin and Bradley, 1960). This is only about a factor of 3 higher than that allowed by the current PM standard. Unlike the "textbook" and other unlikely statistical associations noted by some commenters, where the *only* evidence is for low relative risk, clear and convincing links between high-level PM concentrations and mortality and morbidity buttress the findings of similar associations at much lower PM concentrations as suggested in the more recent epidemiological literature.

These commenters also appear to ignore several epidemiological studies conducted at low PM concentrations in U.S. and European cities, including both short- and long-term exposures to PM air pollution, that find statistically significant relative risks of respiratory symptom categories in children in the range of 1.5 to 5 (see table below). Concentrations in these studies extend from moderately above to well below those permitted by the current PM_{10} standards. While most of the recent epidemiological studies of mortality and hospital admissions report comparatively small relative risks, the findings of relative risks well in excess of the 1.5 to 2 criterion cited by commenters (e.g., Gamble and Lewis, 1996) for earlier studies of high PM

episodes, as well as the relative risks of 1.5 to 5 reported in more recent studies of less serious, but still important effects categories, lend credibility to EPA's interpretation of the results.

RECENT U.S. PM STUDIES WITH RELATIVE RISKS >1.5 TO 2

Study	Relative Risk (95% Confidence Interval)	Concentration Difference / PM Indicator	Mean (max) PM level	Health Endpoint
Long-term Exposure Studies (1 or more years)				
Dockery et al., (1989)	5.39 (1.00-28.6) 3.26 (1.13-10.28) 2.93 (0.75-11.60)	50 µg/m^3 PM_{15}	(20.1-59) µg/m^3 *	cough bronchitis lower respiratory symptoms
Ware et al., (1986)	2.80 (1.17-7.03) 2.75 (1.92-3.94) 2.14 (1.06-4.31)	100 µg/m^3 TSP	(39.9-114) µg/m^3*	bronchitis cough lower respiratory symptoms
Dockery et al., (1996)	1.65 (1.12-2.42)	7 µg/m^3 sulfate	4.7 (7.4) µg/m^3	bronchitis
Short-term Respiratory Morbidity Studies				
Pope et al. (1991)[1]	7.03 (1.55-31.98) 5.24 (1.54-17.86) 2.51 (1.74-3.63) 1.94 (1.13-3.33)	184 µg/m^3 PM_{10}	46 (195) µg/m^3	extra medication use regular medication use lower respiratory symptoms upper respiratory symptoms
Pope and Dockery (1992)[2]	2.03 (1.37-2.99) 1.93 (1.29-2.89) 1.68 (1.13-2.50)	100 µg/m^3 PM_{10}	76 (251) µg/m^3	upper respiratory symptoms cough lower respiratory symptoms
Neas et al. (1995)[3]	1.71 (1.16-2.50)	15 µg/m^3 $PM_{2.1}$	24.5 (88.1) µg/m^3	cough
Schwartz et al. (1994)	1.53 (1.20-1.95)	30 µg/m^3 PM_{10}	30 (117) µg/m^3 **	lower respiratory symptoms

* Annual mean range from highest to lowest concentration across cities

** Median concentration all cities combined

1. Results from school-based sample
2. Results from symptomatic sample
3. Weighted by proportion of hours spent outdoors during prior 12 hours

ii) Consistency of the Epidemiological Studies

Many comments received explicitly agreed with EPA's finding that a large body of compelling evidence demonstrates that exposure to particulate matter pollution is associated with premature death,

aggravation of heart and lung diseases, increased respiratory illness and reduced lung function. They agreed with EPA that these studies present a consistent and coherent relationship between exposure to PM and both mortality and various measures of morbidity. By contrast another substantial body of commenters asserted that the epidemiological evidence on PM is not as consistent and coherent as EPA has claimed, and, in particular, charged that EPA ignored or downplayed a number of studies that the commenters argue contradict the evidence the Agency cited as supporting the consistency and coherence of PM effects.

The studies, all of which commenters contend do a better job of addressing one or more key issues, such as confounding pollutants, weather, exposure misclassification, and model specification, than earlier studies, include (1) several that were available during preparation of the Criteria Document, and (2) a number that appeared after the Criteria Document and Staff Paper were completed. Because the status of the later studies differs from that of the earlier ones, for purposes of decisions under Section 109, the two categories are discussed separately in the preamble to the final rule and in the responses presented below. An overview discussion of EPA responses to these latter comments is contained in the preamble to the final regulation, and more detailed responses to the major themes with respect to studies available for the criteria review are contained in Appendix A and Appendix B, and, with respect to more recent studies, in Appendix C. The remainder of the discussion presented here focuses on particular comments with respect to groupings of studies that EPA examined in the criteria and standards review.

(1) *Comment:* Some commenters, who argued that sufficient evidence does not now exist to establish standards for $PM_{2.5}$, raised specific questions about the consistency of the findings apparent in $PM_{2.5}$ and related epidemiological studies considered by EPA. For example, API (IV-D-2247) observed that "five of six $PM_{2.5}$ morbidity studies did not find a statistically significant association between $PM_{2.5}$ and adverse health effects." In addition, commenters asserted that EPA used inappropriate and uncertain ratios of $PM_{2.5}$ to PM_{10} in setting the standards.

Response: As stated in the Staff Paper, and consistent with CASAC recommendations for $PM_{2.5}$ standards, the criteria and staff review have found that sufficient scientific evidence exists to warrant establishment of separate standards for fine particles. While the decision on the need to revise the standards is based on the full range of the over 80 key epidemiological studies cited in Chapter 12 of the Criteria Document, over 30 such studies included some measure of fine particles (including fine mass, BS, COH, acids, or sulfates) and most of these studies had significant findings for the fine particle indicator. As noted in Section II.F of the preamble to the final rule, nine of these studies were determined by EPA to be key studies for quantitative assessment of health effects related to directly measured fine particle concentrations, and these studies are listed in Tables V-12 and V-13 of the Staff Paper. As described in detail in the Criteria Document and Staff Paper, the nine key fine particle studies include gravimetric measures of fine particles ($PM_{2.5}$ or $PM_{2.1}$), and in some cases, fine particle

components (such as sulfates or acids). The studies include one short-term exposure mortality study (Schwartz et al., 1996), one short-term exposure hospitalization study (Thurston, 1992, 1994), three short-term exposure studies of changes in symptoms or lung function (Schwartz et al., 1994; Ostro et al., 1991; Neas et al., 1995), two long-term exposure mortality studies (Dockery et al., 1993; Pope et al., 1995), and two long-term exposure morbidity studies (Dockery et al., 1996; Raizenne et al., 1996). In each of the nine studies, statistically significant relationships were found between fine particles and/or fine particle components and adverse health effects.

A number of commenters made statements similar to the comments made by Swidler & Berlin (IV-D-2519) and Lehigh Portland Cement Company (IV-D-3488) that refer to a specific number of epidemiological studies. Although shorter lists can be derived from tables or Figures (e.g. Figure 1 in the proposal) that EPA has used to show studies using single PM indicators (e.g PM_{10} or $PM_{2.5}$), in examining the weight of the evidence regarding the need to revise the PM standards, EPA has generally relied on the full set of epidemiological studies in the CD. Contrary to some commenters' statements, there are more than just two studies of health effects that measured fine particle concentrations.

EPA recognizes that, due to the large number of studies reviewed and the multiple tables and figures included in the Staff Paper, there has been some confusion regarding the specific list of studies upon which EPA relied in deciding to propose revisions to the PM standards. To assist in identifying the key epidemiological studies cited in summary tables in the Criteria Document, a chart of the 87 key studies has been prepared and is included in Appendix B. Nevertheless, the decision to propose new PM standards was not based on a simple count of studies: rather, it involved a detailed consideration of the whole body of scientific literature so that a decision could be made on the weight of the evidence for health effects related to $PM_{2.5}$. While the full body of studies was used in reaching the decision to revise the standards, in deciding upon the specific levels for the $PM_{2.5}$ standards, EPA placed greatest weight on the nine fine particle studies noted above.

API specifically refers to the $PM_{2.5}$ morbidity studies, stating that five of six studies do not show significant effects for $PM_{2.5}$. EPA believes the written record of these studies disproves this assertion; all of the morbidity studies that measured gravimetric fine mass have significant findings for fine particles or fine particle components. Although the point is not specifically discussed by the commenter, EPA believes that, for the purpose of assessing the health effects evidence, it is unreasonable to assert any significant distinctions between gravimetric measurements of $PM_{2.5}$ and $PM_{2.1}$. Both are clearly gravimetric indicators of fine mass. Moreover, where studies found statistically significant associations with $PM_{2.5}$ components (e.g., sulfates and/or acids, in Thurston et al., 1994; Dockery et al., 1996), EPA believes it is appropriate to use the corresponding $PM_{2.5}$ or $PM_{2.1}$ values from the study as an index of fine particle levels of concern. As noted in other responses and in the Criteria Document and Staff

Paper, it is clearly difficult to separate the effects of subcomponents from the overall fine mass indicator. This approach is consistent with the advice of CASAC panelists who recommended the citation of fine PM component studies in the key quantitative study summary tables in the Criteria Document and Staff Paper. One of the clear outcomes of implementing $PM_{2.5}$ standards is the reduction of such major components of $PM_{2.5}$ as sulfates and acids. EPA also notes that the approach it has followed to selecting the level of the fine particle standards involves no conversions from the original measurements of fine particles used in these studies

With respect to the 6 morbidity studies, significant associations were found in the Six Cities study (Schwartz et al., 1994), as noted by the commenter, for both cough and lower respiratory symptoms with $PM_{2.5}$. Neas et al. (1995) report significant increases in incidence of evening cough episodes with $PM_{2.1}$, sulfate particles and particle-strong acidity. In addition, these investigators found significant decreases in childrens' peak expiratory flow rate with both sulfate particles and particle-strong acidity, which are both components of fine particulate matter, although no association with $PM_{2.1}$. In a study by Ostro et al. (1991) in Denver, significant associations were found for cough and shortness of breath with exposure to acid aerosols, and there was a significant association between exposure to sulfates and shortness of breath. The authors also report a positive, but not significant, association between fine particles and increased asthma rating ($p<0.10$) (Ostro et al., 1991). Thurston et al. (1994) also found respiratory hospital admissions to be increased significantly with increases in aerosol acidity, $PM_{2.5}$ and sulfate concentrations, when examined individually, but only the acid component of fine mass remained significant in multiple pollutant analyses; the findings of this study are discussed in greater detail in a separate response. In the 24-city study, $PM_{2.1}$, sulfates and aerosol acidity were associated with reduced lung function (Raizenne et al., 1996) and sulfates and aerosol acidity were significantly associated with increased bronchitis (Dockery et al., 1996).

In addition to the six key morbidity studies, one short-term (Schwartz et al., 1996) and two long-term exposure (Dockery et al., 1993; Pope et al., 1995) mortality studies included direct gravimetric measurement of fine particles. Again, each of the three found significant associations between exposure to fine particles and mortality. The short-term exposure mortality study (Schwartz et al., 1996) found increases in risk of mortality with $PM_{2.5}$ exposure, and the relative risks in this study ranged from 1.020 to 1.056 in the six cities under study. On an individual city basis, three of the four cities with annual averages of $PM_{2.5}$ above 15 µg/m3 found statistically significant associations between mortality and $PM_{2.5}$. The fourth city, Steubenville, was nearly significant for $PM_{2.5}$ and significant for $PM_{10.}$ Given that the relative risk is in line with those from the other more populous cities, the most likely explanation for lack of full significance is the fact that Steubenville had a much smaller population (by a factor 6 to over 10) than the other three. The long-term exposure mortality studies (Dockery et al., 1993; Pope et al., 1995) found relative risks ranging from 1.10 to 1.46 for mortality with increased exposure to $PM_{2.5}$ or sulfates. In the long term six city comparison of similar sized cohorts,

Steubenville had a significantly elevated risk of mortality. Although EPA views the quantitative results of these long-term studies as more uncertain, they provide substantial support and insights into the potential nature of fine particle effects.

These nine studies were listed in the Staff Paper as key studies of the relationship between health effects and fine particle concentrations. As described above, each study reports significant findings for fine particles and/or fine particle components and increased mortality or morbidity. In its consideration of the need for additional PM standards, EPA weighed the findings of these key studies along with the results of other studies, including those using particle measures such as BS or COH. From this weight-of-evidence approach to reviewing the scientific literature, EPA has concluded that there is consistency and coherence even in the more limited number of studies that examined indicators of fine particles (EPA, 1996b; p. V-76).

In selecting the levels of the $PM_{2.5}$ standards, EPA relied most heavily on these studies, which actually measured fine particles, and not on estimates derived from the use of uncertain ratios. Because of the qualitative and quantiative consistency observed in the PM studies in general, however, EPA notes that if such ratios were to be used as a basis for selecting the levels for $PM_{2.5}$ standards using studies that measured PM_{10}, it is likely that the resultant standard levels would be in the same ranges as were consdered using the $PM_{2.5}$ studies.

(2) *Comment:* UARG (IV-D-2250) observed that, of the 13 study locations highlighted in the review of short-term mortality studies, 8 have relative risks for which the confidence interval includes the null result.

Response: EPA does not agree with the commenter's implication that most short-term mortality studies cited in the Criteria Document have nonsignificant results. As indicated in Appendix B of this document, 90% of the key 87 studies upon which EPA relied for this decision had statistically significant results for some or all of the health endpoints used in the study. In this specific comment, reference is made to the 13 studies of short-term exposures to PM_{10} and mortality that are listed in Table V-3 of the Staff Paper. Even here, 9 of these 13 studies had statistically significant findings reported by the investigators, with the remaining showing positive results that are at or near significance.

The table in question includes all mortality studies for which a quantitative comparison could be made with respect to relative risk per unit daily increase in PM_{10}, in this case 50 $\mu g/m^3$. The results shown in the table are the results of calculations made by EPA for the Criteria Document, in which the original results are transformed into this common metric, which in this case is rounded to two places after the decimal. As noted by the commenter, this results in five of the associations having confidence intervals that include 1.0, which is itself on the borderline of significance at the 95% level. This, however, is largely the result of rounding of the

calculated values for the table; the original results for all five studies were reported to be statistically significant by the original investigators. EPA calculated a lower bound confidence limit of 1.005 for 3 studies and 1.001 for the fourth, which are all above 1.0, but these were rounded to 1.0 in the table. In the fifth study (Kinney et al. 1995), the lower confidence limit of relative risk for PM_{10} alone is reported as 1.00, which as noted above, is at the threshold for significance.

Of the three remaining associations with confidence intervals that encompass 1.0, the original researchers report positive but not statistically significant results. One of the six cities, Portage, had a positive and nearly significant association (C.I.= 0.98 to 1.09), while a second, Topeka, was clearly not significant (C.I. = 0.90 to 1.05). The remaining positive but not significant result for Kingston, TN reported in Dockery et al. (1992) was for a study of about one year duration. As noted in Chapter 12 of the Criteria Document, such a short duration limits the statistical power in a relatively small study population. Support for this suggestion is provided by a follow-up study of mortality (Schwartz et al., 1996), which used multiple years of data from the same site and an expanded population and found a statistically significant association.

Although some studies report findings that are not statistically significant or of border line significance, EPA reiterates the observation that there is remarkable consistency in the positive associations found from one location to another. EPA believes that in focusing on the statistical significance threshold and ignoring the clear patterns of associations revealed even in Table V-3, commenters are ignoring the guidance of recognized epidemiological experts (Greenland, 1991). When the scientific literature on PM-related health effects is considered as a whole, it is clear that ambient PM is clearly associated with serious health effects.

(3) *Comment:* ATA (IV-D-2245) lists a "core database of 36 epidemiological studies" that were used by EPA, and states that over one-third of these studies showed no statistical association between PM and adverse health effects.

Response: The characterization of the studies listed in Exhibit 10 of ATA's comments as EPA's "core database" is erroneous and misleading, and the specific listings are both incomplete and contain some inaccuracies. The studies listed are all drawn from Table 12-2 in the Criteria Document, which lists epidemiological studies of short-term exposure to PM and mortality. Thus, the commenter has selectively chosen to include only studies that use mortality as an end-point, and only short-term exposure studies. The Criteria Document, the Staff Paper, and the proposal notice also clearly took into consideration results of studies that used other measures of health, including admissions to the hospital or emergency room, and changes in lung function or respiratory symptoms. An examination of Chapter 12 of the Criteria Document includes additional Tables that address these effects categories, which include Tables 12-8, 12-9, 12-10, 12-11, 12-12, 12-13, 12-16, 12-21, and 12-22.

Taken together, a total of 87 separate epidemiological studies are listed. A separate tabulation of the above studies is included in Appendix B to this document. As shown in this summary table, the vast majority of the studies had results indicating deleterious effects of PM on health; 68 reported statistically significant associations and 11 studies had "mixed" findings.[8] Eight of the listed studies found no significant associations between PM concentration and health, with none of the studies finding consistent statistically significant negative results (indicating that PM is protective of health). In other words, there were no studies reporting significant reductions in mortality or hospitalization or significant improvements in lung function with increases in PM concentration.

EPA also notes several inconsistencies between the ATA partial listing of studies and the corresponding table in the Criteria Document. Table 12-2 actually lists 38 studies, not 36. ATA omitted 3 of those studies (Ito et al., 1993; Katsouyanni et al., 1996; Saldiva et al,. 1995) and apparently counted Styer et al. (1995) as two separate studies by independently considering the results for Cook and Salt Lake Counties. If it is appropriate to consider the results of each city examined by Styer et al. (1995) as separate studies, then the results of Ito et al. (1995) for Los Angeles and Chicago should be treated similarly, as should the reports from the Six Cities study (Dockery et al., 1992; Schwartz et al., 1996). It is also not clear why three of the studies from the Criteria Document were excluded from the list in ATA's Exhibit 10. Of the three studies not included in ATA's list, two report significant associations with PM (Ito et al., 1993; Saldiva et al., 1995) while one has mixed findings (Katsouyanni et al., 1990b). Among the remaining studies, there is general agreement between ATA and EPA regarding findings of statistical significance. In two instances (Samet et al., 1996b; Wyzga and Lipfert, 1995b) the ATA designates the studies as "yes" for statistical significance, but they are considered to have mixed results by EPA. The reverse is true for two studies that are listed as statistically significant by EPA but designated as "no" by ATA (Touloumi et al., 1994; Ozkaynak et al., 1994). Of the remaining studies, six were found to have mixed results by EPA that were categorized as non-significant by ATA (Kinney and Ozkaynak, 1991; Moolgavkar et al., 1995a; Moolgavkar et al., 1995b; Li and Roth, 1995; Samet et al., 1996a; Xu et al., 1994). With respect to a summary for the subset of mortality studies listed by ATA, EPA concludes that 70% were positive and significant (similar to the 2/3 estimated by ATA), while 21% were mixed, and only 9% found no significant results.

With respect to the full set of 87 studies, 90% of those EPA relied upon in proposing new PM standards find at least some statistically significant associations, and 78% of the studies can be

---

[8]As discussed in Appendix B, the "mixed" category includes studies where results with respect to PM effects are less clear, including, for example, multi-pollutant studies in which the authors noted difficulties in separating the effects of PM from other pollutants, even if PM is significant by itself; e.g., Samet et al. (1996a,b); Moolgavkar et al., (1995b).

considered "fully significant" studies in that the PM associations remain significant when alternative analyses or multipollutant models are used. Only 8 of the 87 studies (9%) used as a basis for the health-based standard did not find statistically significant associations between PM and adverse health effects.

As discussed more fully in Appendix B and the response to the next comment, EPA examined the mixed and "negative" studies in an attempt to identify factors that could result in positive or mixed associations despite a lack of statistical significance. In many cases sample size (number of days or number of subjects) greatly limited statistical power (Figure 12-17; Table 12-25 ; U.S. EPA, 1996a). In the case of multiple pollutant studies, the criteria review notes the difficulty in isolating effects of PM from other pollutants in individual studies. However, EPA cannot accept the suggestion that such multi-pollutant studies are in any way "negative" with respect to EPA's conclusions that PM, alone or in combination with other pollutants, is associated with adverse effects at levels below those allowed by the current standards. This conclusion is based not only on the consistency of PM effects across areas with widely varying concentrations of potentially confounding copollutants, but also on the extended analyses of the Philadelphia studies in the Criteria Document and Staff Paper.

Based on its assessment of the full epidemiological literature, EPA is confident that the decision on the need to revise the PM standards is soundly based on a consistent set of epidemiological studies showing a multiplicity of PM effects in sensitive populations at levels permitted under the current NAAQS.

(4) *Comment:* Ford Motor Company (IV-D-5323) asserts that EPA "has neglected to seriously explore why many studies (e.g., about 25% for the morbidity studies) have failed to show a positive, statistically significant association."

Response: EPA notes that the commenter's observation indicates that approximately 75% of the studies on which the PM standards are based show positive, statistically significant associations. Of the remaining studies, EPA reiterates the observations noted in the preceding response -- that an additional 15% had near-significant or mixed positive results, while none of the studies had consistent, statistically significant "negative" associations, and only about 10% failed to find any significant or near significant "positive" associations. As noted in section II. B of the preamble and in Appendix B to this document, it is important to note that the somewhat artificial designations of "negative" and "positive" findings actually suggest findings of, respectively, protective and deleterious effects. When including studies that show mixed positive results, EPA has determined that 90% of the studies provide evidence for PM-related health effects.

EPA does not agree with the commenter's assertion that EPA has neglected to explore or explain reasons why studies do not find statistically significant associations. Extensive

discussions of issues that may affect epidemiological studies were included in Section 12-2 (Methodological considerations, pp. 12-9 to 12-27) and section 12-6 (Discussion, pp. 12-255 to 12-363) of the Criteria Document, along with a separate subsection on methodological issues in the discussion of long-term exposure mortality studies (pp. 12-139 to 12-147). The ability to detect an association between an exposure and an effect, if the relationship truly exists, is often referred to as statistical power. Some of the factors that can affect the statistical power of a study, and that were discussed in the Criteria Document, are sample size, the effects of simultaneous exposure to several pollutants, and model specification.

The one factor most commonly addressed in increasing the statistical power of a study is sample size. As described in the previous response, EPA evaluated the relationship between the t-ratio and sample size (in days) for a number of time series studies of mortality, and found close correspondence (Figure 12-17, EPA, 1996b). The t-ratio was found to increase with increasing sample size; using these data, EPA determined that the minimum sample size necessary (at 80% power) to detect a significant association between PM and mortality in a time-series study is 800 days (two-tailed test at the 0.05 level). It is notable that a number of time-series studies of mortality and PM exposure have had smaller sample sizes than that calculated by EPA to be the minimum needed to detect significant associations. For example, the studies in Kingston and St. Louis (Dockery et al., 1992) and Los Angeles (Kinney et al., 1995) had fewer than 400 days of observations, and both studies found positive associations that were either nonsignificant or at borderline significance.

Similarly, the analysis of data in subsets can result in sufficient loss of power so that a nonsignificant result cannot be interpreted as indicating the lack of an association. A number of researchers analyzed associations for each season of the year, thus reducing the sample size for each separate analysis. This form of subset analysis may be entirely appropriate in areas where PM concentrations vary by season, but the potential reduction in statistical power must be considered in interpreting the results of the analysis. One example of a study using subset analysis was conducted using data from Cook and Salt Lake Counties (Styer et al., 1995). The data set included six years of daily records, or over 2000 days of observations, and the researchers conducted subset analyses by both season and month. In the month-by-month analysis, PM_{10} was selected as an important explanatory variable during May and September for Cook County data, and during June and July using Salt Lake County data. EPA is not aware of a basis for presuming that an association between PM and mortality would vary by month of the year (other than seasonal variations that are accounted for in a season-by-season analysis); such extensive subdivisions of a data set can result in greatly reduced power and may produce essentially meaningless results. In addition, some researchers have created pollutant variables by dichotomizing the data into “high” and “low” categories, or dividing into categories such as quartiles or quintiles. Again, this may be entirely appropriate for the analysis of a particular data set, and EPA is not being critical of all studies that create categorical pollutant variables, but it must be recognized that some of the data may essentially be lost when data are

grouped in this manner.

The specification of variables in models is another factor that can influence the results of an analysis. Overspecification of a model can cloud the results so that true associations are buried in nonsignificant associations with extraneous variables. This issue is described in greater detail in Appendices A, B, and C.

As described previously, about 13% of the 87 health effects studies used as a basis for EPA's decision were found to have "mixed" results; positive associations were found that were statistically significant in some models but not significant in others. For the most part, the change that resulted in PM associations losing statistical significance was the addition of other pollutants to the models. A number of studies have found the effects of PM to be difficult to separate from associations with a co-pollutant; the particular co-pollutant of interest varies in different locations and with different health endpoints. The many analyses of mortality data from Philadelphia have found the effect of TSP difficult to distinguish from the effects of other pollutants, especially SO_2 (Samet et al., 1995), while hospitalization studies in Canada have found effects of fine particles that become nonsignificant when modeled with ozone (Thurston et al., 1994). The problem of addressing confounding or collinear pollutants was discussed at length in the Criteria Document, and EPA believes that this issue can only be addressed by considering studies from a variety of locations, as stated in Samet et al. (1996a): "Insights into the effects of individual criteria pollutants can be best gained by assessing effects across locations having different pollutant mixtures and not from the results of regression models of data from single locations." Indeed, associations from different study locations presented in several tables in the Staff Paper indicate the remarkable consistency of effects that has been seen, even where the associations are not statistically significant. Significant associations have been found in areas with low levels of SO_2 such as Spokane (Schwartz, 1996) and Utah Valley (Pope et al., 1992) and in locations in the U.S. and other nations with varying climates.

What is most striking about the scientific evidence on PM and health effects is the consistency that is seen between studies. The great majority of PM-related health studies report significant findings for deleterious health effects, and the magnitudes of the associations are consistent from one study to the next, even in those studies where the association is not statistically significant. In evaluating potential reasons for not reporting a significant association, it can be seen that many of the studies with nonsignificant or "mixed" results may suffer from low statistical power, or from difficulty in distinguishing health effects from concurrent exposures to multiple pollutants. EPA not only disagrees with the commenter's assertion that the Agency has failed to assess possible reasons for findings of nonsignificance, but also believes that some of the factors identified in the review of this issue may account for the reported nonsignificant results from some studies.

(5) Other comments on statistical significance and consistency noted that the pooled relative risk

for mortality associated with short-term PM_{10} exposures based on studies conducted in 10 locations is not statistically significant since the lower bound of the credible interval is less than 1.0 in Table VI-2 of the PM Staff Paper.

Response: EPA reexamined the pooled relative risk credible intervals reported in Table VI-2 of the Staff Paper and discovered that the intervals had not been corrected to reflect the methodology recommended by CASAC and actually used in the final Abt Associates 1996 risk assessment report (Abt Associates, 1996b). The correct 95% credible interval for the pooled relative risk based on these studies is (1.01 - 1.07). EPA has placed a memo in the docket (Richmond, 1997) that includes a corrected version of Table VI-2 reflecting the credible intervals reported in the final Abt Associates 1996 risk assessment report.

iii) Coherence

(1) *Comment:* Asthma incidence in the U.S. has been increasing in recent years despite the fact that PM levels have been decreasing. This would be inconsistent if PM were a cause of asthma.

Response: It is not believed, based on current evidence, that exposure to ambient PM is a major cause of asthma. The etiology of asthma is currently not well known, and numerous factors, such as family history of respiratory disease, have been shown to be associated with an increased risk of developing asthma. There is strong and convincing evidence, however, that exposure to air pollutants is associated with exacerbation of asthma. Therefore, EPA has considerable interest in asthma as a public health and as an environmental health issue.

As summarized in the CD and Staff Paper, increases in PM have been associated with increased hospitalization for asthma, worsening of symptoms, decrements in lung function and increased medication use; the available evidence does not demonstrate an association between PM exposure and asthma mortality. In the Staff Paper (p. V-35), EPA includes asthmatic individuals as one of the sensitive subpopulations that may be more susceptible to adverse health effects from exposure to ambient PM. A reduction in levels of PM or PM constituents is expected to reduce the number of asthma admissions to the hospital or the occurrence of asthma symptoms or medication use; EPA has not claimed that reducing PM pollution will necessarily reduce the incidence of new cases of asthma in a given year. It should be noted that, whether PM is a factor in causing an individual to develop asthma or not, the steadily increasing incidence of asthma means that a substantial portion of the population can be considered to make up the sensitive subpopulation. EPA believes that the scientific literature is supportive of a role for PM in exacerbation of asthma, and that this evidence along with evidence of other PM-related health effects provides ample reason to revise the standards for PM.

(2) *Comment:* The American Council on Science and Health (IV-D-2173) criticizes the use of "ecological" studies, and argues that there is insufficient evidence linking health effects to exposure to particulate matter. The commenters present a figure showing an overall decrease in PM_{10} concentration from 1987 to 1994, while there were small increases in mortality from COPD and asthma.

Response: Both Section II.B of the preamble to the final rule and Appendix A discuss the reasons EPA believes the available scientific evidence strongly supports the decision to revise the PM standards. In this case, the commenter ignores the strengths of time series studies of mortality or morbidity associations with PM exposure. These time series studies generally assess day-to-day changes in health with day-to-day changes in pollutant concentration, while accounting for such factors as seasonal or other trends and confounding influences, if necessary. They are certainly not of the oversimplified study design demonstrated in the commenter's comparison of annual changes in PM_{10} concentration with annual mortality rates. In fact, epidemiologists have recognized that PM concentrations have decreased, and studies with multiple years of data have incorporated a long-term trend variable to account for this change. In addition, there has been a trend of decreasing rate in overall and cardiovascular mortality. In the most recent HEI analyses of the mortality-PM relationship in Philadelphia, these trends are depicted graphically, and the analysts describe several methods that were tested to control for such long-term trends (Samet et al., 1996a,b). After controlling for long-term trends, confounders and other factors, the authors found a significant association between exposure to air pollutants and mortality. Using the approach advanced by the commenter, EPA could claim that the observed trends in mortality and pollution are clearly coherent with an effect of PM on overall and cardiovascular mortality, and the much smaller rates of COPD and asthma changes are dominated by some other uncontrolled factors. However, EPA believes that it is more appropriate to note that the commenter's argument and examination of coherence is without merit because it relies on excessive oversimplifications and exclusion of factors known to be associated with these long-term trends.

d. New studies and analyses

As discussed in section II.B of the preamble to the final rule, a number of epidemiological and related studies, characterized as so-called "negative" evidence ignored by EPA, that were published or otherwise made available only after completion of the Criteria Document and Staff Paper for PM. EPA agrees that it did not rely on these studies, based on its long-standing view that the Act requires NAAQS decisions to be based on studies and related information included in the pertinent air quality criteria and available for CASAC review. See section II.B of the preamble to the final rule.[9] Although

[9]Contrary to the views of one commenter, this does not necessarily limit the Administrator to consideration of information discussed in the criteria document for a pollutant (National Stone

the Administrator has not relied on the more recent studies in reaching her final decision, the Agency has conducted a provisional examination of these and other recent studies to assess their general consistency with the much larger body of literature evaluated in the criteria review; the examination is presented in Appendix C. This assessment, while much less inclusive and rigorous than a criteria review, finds no basis for commenters' assertion that full consideration of selected new studies in the final decision would materially change the Criteria Document and Staff Paper conclusions on the consistency and coherence of the PM data, or on the need to revise the current standards.

e. Health risk assessments

i. General methodology issues

This section addresses comments primarily summarized in Section II.A.3.f.(1) of the Summary of Comments document concerning various aspects of the methodology used to analyze health risks associated with alternative $PM_{2.5}$ standards. A number of industry commenters argued that EPA's risk assessments are flawed and incomplete and present an overestimate of the risks associated with PM exposure. Reasons cited by these commenters included: (1) criticisms about use of epidemiological studies which these commenters argued are inadequate for the reasons summarized in Section II.A.4.a. of this document, (2) disagreement with the assumption of a linear no-threshold concentration-response relationship, (3) disagreement with the basic assumption that $PM_{2.5}$ provides an appropriate indicator that is likely to be related to health effects, (4) concerns about the relative toxicity of components of $PM_{2.5}$ and whether or not reductions in $PM_{2.5}$ would result in reduction in the components responsible for any effects, (5) disagreement with the choice of background PM_{10} and $PM_{2.5}$ levels used in calculating risk in excess of background, and (6) concerns about lack of consideration of personal and indoor exposures in epidemiological studies used in risk analyses.

EPA notes that it is not the function of the risk analyses to address questions concerning causality, mechanisms, and related issues. Judgments about such issues are described elsewhere and the risk analyses show the results if one uses these judgments. Indeed, the risk analyses summarized in the Staff Paper and proposal notice and described in more detail in technical support documents (Abt Associates, 1996 a,b; Abt Associates, 1997 a,b) acknowledge these issues and uncertainties and illustrate the potential influence of many of these uncertainties in sensitivity and integrated uncertainty analyses. As discussed in Section II.B.2 of the preamble to the final rule, EPA believes that, even recognizing the large uncertainties, the key qualitative insights derived from the risk assessment and summarized in Section II.A.3. of the preamble to the final rule remain appropriate. While not placing

---

Association, IV-D-2999). To the extent that a staff paper or supporting document made available for CASAC review includes either scientific or technical information of the kinds specified in section 108(a)(2) of the Act but not evaluated in the corresponding criteria document, the Administrator considers that information to be part of the air quality criteria for the pollutant in question.

great weight on the specific numerical estimates, EPA believes that the risk analyses confirm the general conclusions drawn primarily from the epidemiological results themselves, that there is ample reason to be concerned that exposure to ambient PM at levels allowed under the current air quality standards presents a serious public health problem. Presented below are responses to various specific issues related to the health risk analyses, expanding upon the discussion contained in the preamble to the final rule.

(1) *Comment:* The assumption of causality is not appropriately addressed in the risk analyses.

Response: The issue of causality in the PM epidemiological evidence is addressed in Section II.B.2 of the preamble to the final rule and in Section II.A.4.c. of this document. EPA continues to believe that the assumption of causality of PM across a range of PM concentrations, either directly or as a useful index for the mixture of pollutants related to the health effects in question, is appropriately addressed in the Staff Paper discussion of the risk analyses (U.S. EPA, 1996b; p. VI-1). Moreover, in some specifications, including one illustrated in the proposal (Figure 2.c), the risk assessment assumed a threshold for the range of causal associations. See also next response.

(2) *Comment:* EPA inappropriately assumed linear, no-threshold concentration-response relationships were appropriate for its risk analyses. While the risk assessment included sensitivity analyses examining alternative potential thresholds, these estimates were not factored into the Agency's conclusions.

Response: As recognized by at least some of the commenters, EPA's risk analyses examined the impact on risk estimates of alternative concentration-response relationships that included various "thresholds" both in a series of sensitivity analyses and in an integrated uncertainty analysis. Contrary to the assertion made by some commenters that EPA ignored this information, the Staff Paper includes extensive discussion of the results of both the sensitivity and integrated uncertainty analyses (see Staff Paper, pp.VI-35-VI-43 and VI-54-VI-58). The Staff Paper discussion of key observations from the risk analyses (Staff Paper, pp.VI-58-VI-60) includes presentation of both base case (no threshold) and integrated uncertainty (various thresholds assumed) analyses estimates. Key observation number 4 in the Staff Paper (p.VI-59) states that, "Based on the results of the sensitivity analyses of key uncertainties and the integrated uncertainty analyses, the single most important factor influencing the uncertainty associated with estimates of PM health risk is whether or not a cutpoint concentration exists below which PM health risks are not likely to occur." Moreover, EPA displayed the results of the assumption of a potential threshold in the illustration of the distribution of annual risks associated with PM in Figure 2c of the proposal, and summarized the risk assesment conclusion on threshold both there and again in the preamble to the final rule. EPA has fully considered the uncertainty about the potential existence of a threshold in its final decision, as discussed in the preamble to the final rule.

(3) *Comment*: Environ International Corp., on behalf of Kennecott Corp (IV-D-2213) stated that the assumption of a log-linear no-threshold concentration-response function is not scientifically justified.

Response: The log-linear no-threshold model is the most common model for concentration-response functions in the literature on PM and health effects. In estimating the relationship between PM concentrations and a given health endpoint, researchers usually investigate the model form and choose a form that fits the data well. If there were clear evidence of a threshold, one would expect this to be reflected in threshold models having been chosen over log-linear models by researchers. There is not, however, clear evidence of a threshold. So far, there are insufficient data to determine whether a threshold model fits the data any better than a non-threshold model. Nevertheless, threshold models were examined in both the integrated uncertainty analyses and in sensitivity analyses. Because of lack of information concerning the likelihood of different possible thresholds, however, analyses of thresholds relied on professional judgment.

(4) *Comment:* Inadequate control of confounders likely to lead to substantial overstatement of PM health effects.

Response: The issue of confounders and whether or not their treatment in the epidemiological studies used by EPA was appropriate or likely to introduce a bias resulting in overestimation of health effects is addressed in the Staff Paper, proposal notice, and in Section II.B. of the preamble to the final rule. The issue is also discussed elsewhere in this document and its appendices.

(5) *Comment:* EPA's risk analyses are flawed because they do not recognize the lack of correlation between ambient PM concentrations and personal PM exposures and fail to evaluate how high indoor PM exposures may be confounding the results in certain epidemiological studies.

Response: Concerns related to ambient versus personal exposures in the context of interpreting the available epidemiological studies that relied on fixed-site monitors are addressed in Section II.B.2 of the preamble to the final rule and in Sections II.A.4.a. and II.A.4.c. and Appendix D of this document.

(6) *Comment:* Several commenters stated that EPA's risk analyses, as well as the standards, are based on an unfounded presumption that if $PM_{2.5}$ is controlled, the actual "culprit" related to any health effects will be controlled. Some commenters argue that, because it is difficult to separate the effects of PM from gaseous pollutants in some studies, the most that can be said is that air pollution may be related to mortality and other effects, with the role of PM unknown. They further assert that EPA has not shown whether or not any risk reduction or benefits will

occur as the result of reducing fine particles, and that the risk assessment ignored this issue.

Response: The underlying issue regarding the inclusion of various components in the $PM_{2.5}$ indicator is addressed in responses to comments above on the use of $PM_{2.5}$ as an indicator. However, EPA disagrees that the overall criteria and standards review ignored the implications of multipollutant studies or that the full risk assessment that comprises these documents ignored this issue. While EPA believes it is more likely than not that $PM_{2.5}$ and its components are related to serious health effects at levels permitted by the current PM standards, the alternative view that PM could be acting as a surrogate for pollutant gases or PM components was discussed and the implications of alternative hypotheses were examined in a qualiative risk assessment in Chapter VII of the Staff Paper.

In this qualitative assessment of the potential effectiveness of fine particles as a surrogate, EPA staff considered the results of various analyses of air pollution and mortality in Philadelphia (Moolgavkar et al., 1995; Wyzga and Lipfert, 1995; Samet et al., 1995; 1996a,b), as summarized in the following excerpt.

> The CD evaluation of these multiple investigations concludes that for this single city example, it appears most difficult to separate independent effects of PM (as TSP) and SO_2, concluding that the relationship between these pollutants and mortality may be inherently non-linear (CD, p 13-57). Several clearly hypothetical explanations have been advanced to explain these results. The following qualitative assessment of several speculative, but plausible hypotheses (in italics), outlines the potential implications of these alternatives for the effectiveness of fine particle control as a surrogate:
>
> C *The complex relationship is a statistical artifact and only one of the pollutants is causally related. If the pollutant is PM,* then fine particle control would clearly be beneficial. *If the pollutant is SO_2,* which occurs at moderate levels in Philadelphia, reductions in local and transported SO_2 precursor control prompted by a fine particle standard would reduce health risk.[10]
>
> C *The relationship is real and due to increased penetration of an SO_2 complex carried on carbonaceous or other non-acidic particles.* Then local controls of primary fine particle combustion sources would likely reduce risks, because reducing the aggregate particle surface area (by reducing fine mass) is more likely to reduce dose than SO_2 reductions.

[10] As noted in section V.E of the Staff Paper, the evidence across multiple areas shows that PM is consistently associated with mortality in areas with high and low SO_2, making the second explanation unlikely.

- *The relationship is due to the association between SO_2 and acidic sulfates, which are the active agent.* In this case, fine particle controls are clearly beneficial.

- *The relationship is due to the combined interactions of SO_2 and particles in different regions of the respiratory tract.* Again, control of fine particles would be beneficial.

The staff does not have to accept any one of these hypothesized explanations as more likely to conclude that control of fine particles as a class appears to be a reasonable approach to reducing health risks in this particular example of potential confounding. It is also useful to note that, because of their relatively low surface area and origin, such a conclusion would not be as applicable to control of coarse fraction particles.

Although the above examples of alternative consequences of the use of fine particles as a surrogate are limited to PM and SO_2 interactions, some of these outcomes would extend to PM interactions with other pollutants as well. Given the large surface area of aqueous droplet and/or dry fine particles, as well as the multiplicity of similar effects caused by common gaseous pollutants such as ozone and related photochemical products and precursors, and NO_2 in addition to SO_2, direct or indirect interactions among these pollutants would not be unexpected (Section V.F.; CD, p 13-9.). Because ozone precursors, including NO_2 and volatile organic compounds, are also secondary particle precursors, it is reasonable to expect that the control of fine particles could also prompt control of local and regional sources of some of these precursors as well as SO_2. On the other hand, beyond the possibility of effects modifications in the body, the potential for gas/particle interactions between PM and CO is limited. It is also less clear that fine particle control would prompt significant additional CO control, the major contributors of which, mobile sources, are already subject to significant national reduction requirements. The rationale for concluding that the existence of PM effects is unlikely to be due to confounding by other pollutants is discussed in Section V.E. [U.S. EPA, 1996b; p VII-12 to VII-13.]

Staff also explicitly considered the potential concerns raised about ultrafine particles, as discussed elsewhere in these responses.

The above examples also illustrate why, based on current information, it is reasonable to conclude that control of fine particles as a group is likely to reduce those components of air pollution that are responsible for the observed associations between air pollution and serious health effects. The qualitative assessment shows this is the case whether, as EPA concludes is likely to be the case, PM is contributing directly to effects - alone or in combination with other

pollutants, or PM is acting as a surrogate for other pollutants that are precursors to PM. It also indicates that EPA did consider this important risk assessment issue in an explicit examination of alternative possibilities. EPA believed this qualitative approach was more appropriate, given the greater likelihood that PM is playing a role in the observed effects.

(7) *Comment*: The Sapphire Group for AAMA (IV-D-2243) noted that based on the information provided in the Staff Paper on exposure and mortality (the risk ratio), it is not possible to duplicate the final results of the Agency's risk assessment upon which the standard is based.

Response: In the original risk analysis, PM levels were taken only down to the lowest observed level in the study (which was 9 $\mu g/m^3$ in Pope et al., 1995)[11]; if the annual mean is used, the change in PM would be from the lowest observed level of 9 to the annual mean. The annual mean in Philadelphia is rounded to 17 $\mu g/m^3$ in the Staff Paper, so the change in PM in Philadelphia would be: 9 - 17 = -8. The attributable fraction (i.e., the percent of all deaths attributable to PM) is calculated as [exp(PM coefficient * change in PM) - 1] -- i.e., the relative risk minus 1. The PM coefficient in Pope et al. (1995) is 0.006408. The attributable fraction in Philadelphia would therefore be 5% (4.997%). The annual mean in L.A. is rounded to 30 $\mu g/m^3$ in the Staff Paper. The change in PM is therefore calculated as: 9 - 30 = -21. The attributable fraction in L.A. would be 12.59%. The discrepancies between these attributable fractions and those in the Staff Paper (4.6% for Philadelphia and 11.9% for L.A.) are due to using the rounded annual means here. The actual means are 16.5 $\mu g/m^3$ in Philadelphia and 28.7 $\mu g/m^3$ in Los Angeles.

If PM levels were taken down to background instead of only to the lowest observed level in the study, then the change in PM in Philadelphia would be (3.5 - 16.5) = -13, and the change in PM in L.A. would be (2.5 - 28.7) = -27.2. The attributable fractions associated with these changes in PM would be 7.99% (in Philadelphia) and 16% (in L.A.). These attributable fractions are significantly higher than those reported (4.6% and 11.9%, respectively) because they correspond to larger changes in PM -- taking the annual mean down to background instead of only to 9 $\mu g/m^3$. A reported risk is always specific to a particular change in PM levels. The relative risks (or attributable fractions) reported in the risk assessment for Philadelphia and Los Angeles are completely consistent with the relative risk of 1.17 reported by Pope et al., 1995, for a change of 25 $\mu g/m^3$. They are simply specific to different PM changes. The risk assessment uses the concentration-response function identified in the epidemiological study it relies upon (e.g., Pope et al., 1995). One should be able to duplicate

---

[11]As noted in the preamble to the final rule, the original risk analysis used in this example erroneously assumed that the lowest level in this study was an annual mean. In fact, it is the annual median, which is equivalent to a somewhat higher mean (e.g., 11 $\mu g/m^3$). This has been corrected in the updated risk assessment and Staff Paper tables that have been placed in the docket (Richmond, 1997).

the results of the risk assessment using the information provided in the supporting documents.

(8) *Comment:* EPA's risk estimates for mortality associated with long-term exposure for Philadelphia and Los Angeles which are based on the concentration-response relationship developed from Pope et al. (1995) are in error because the value cited in Pope et al. as the mean of the mean concentrations across the 50 cities was actually the mean of the median values across these cities.

Response: EPA acknowledged this error in April 1997 and has placed in the docket June 5 and June 6, 1997, letter reports from Abt Associates that provide corrected risk estimates for mortality associated with long-term exposure that are now based on the mean of the median $PM_{2.5}$ concentrations across the cities examined in the Pope et al. (1995) study. EPA advised the CASAC of the error and its approach for addressing the issue in correcting the risk assessment and the Staff Paper. EPA also has placed in the docket a set of corrected tables and figures (Richmond, 1997) from the Staff Paper that are now based on the appropriate PM value from the Pope et al. (1995) study.

(9) *Comment:* Several commenters stated that the two areas included in EPA's risk analyses are not representative of national exposures to PM. More specifically one commenter (Ford Motor Company, IV-D-5323) argued that Philadelphia was a poor choice of city for which to conduct risk analysis because 3 out of 4 studies (Moolgavkar et al., 1995; Samet et al., 1995; Li and Roth, 1995) found that PM was not signficantly associated with mortality in Philadelphia. Also, it is indefensible to assume that Southeast Los Angeles County can adequately represent the Western U.S. or that Philadelphia County adequately represents the East.

Response: As discussed in section II.B of the notice to the final regulation and Appendices A and B, EPA disagrees with the above assessment of the Philadelphia data, which in any case relied on TSP and not $PM_{2.5}$. EPA selected Philadelphia County and Southeastern Los Angeles County because EPA was able to obtain relatively recent and fairly complete PM_{10} and $PM_{2.5}$ air quality data for these two areas. EPA reviewed its criteria for selection of cities for the risk analyses and its choice of these two areas with the CASAC at its February 1996 meeting. EPA has never claimed that either area completely represents all cities in either the western or eastern regions of the U.S. Rather, these two areas were chosen, given the constraints of air quality data availability, to illustrate the risks under current air quality and upon attaining alternative standards in two areas with quite different air quality patterns.

ii. Selection of studies used in analysis

This section addresses comments primarily contained in Section II.A.3.f.(1)b) of the Summary of Comments document.

Comment: EPA's risk analyses should not have relied on the population-based epidemiological studies for a variety of reasons including: actual exposures are not well understood, biological mechanisms not clear, concentration-response relationships not adequately characterized.

Response: See response to comments in Section II.A.4.a. regarding criticisms of the epidemiological studies used in EPA's risk analyses. As described in the Staff Paper (pp.VI-11 to V-14) and in the technical support document (Abt Associates, 1996a; p.47), the choice of studies to be used in the risk analyses was based on the Criteria Document tables of studies that were judged adequate by the Criteria Document to provide estimated concentration-response relationships for a variety of health endpoints associated with elevated PM_{10} and/or $PM_{2.5}$ exposures. The selection of studies was presented to the CASAC at its February 1996 meeting and drafts of the risk assessment methodology and the risk assessment results in the Staff Paper were reviewed at the May 1996 CASAC meeting, and subsequent to that meeting, by individual CASAC members reviewing staff revisions to the risk assessment.

iii. Calculation of excess risk relative to background

This section addresses comments primarily summarized in Section II.A.3.f.(1)c) of the Summary of Comments document concerning the background levels for PM_{10} and $PM_{2.5}$ used in the health risk analyses.

Comment: The background levels used in the PM risk analyses are unreasonably low.

Response: See responses to comments in Section II.A.3.g. of this document, which address criticisms of EPA's estimation of background concentrations for PM_{10} and $PM_{2.5}$. With respect to the choice of background concentrations for purposes of risk analyses, the CASAC concurred with EPA judgments presented in the Staff Paper that estimates of the annual average background level rather than a daily average (e.g., the maximum 24-hr level) be used since risks are aggregated for each day throughout the year (see Staff Paper, pp. VI-3 to VI-7). The midpoint of the estimated ranges for background cited in the Criteria Document (p. 6-44) were used in the base case risk analysis. The risk analyses also included sensitivity analyses that examined the impact of using the lower and upper bound values of the Criteria Document ranges for background on the health risk estimates. Finally, the integrated uncertainty analyses section of the risk assessment included uncertainty about background, again assuming that background fell within the range cited in the Criteria Document.

iv. Characterization of uncertainties

Comment: EPA's risk estimates are misleadingly precise and understate the degree of uncertainty because they do not address adequately the following issues: (1) whether or not $PM_{2.5}$ is the causative agent, (2) the effects of differential measurement error, (3) whether or

not a threshold exists, (4) inadequate control of confounders in the underlying epidemiology studies.

Response: EPA's extensive evaluation of these issues in the Criteria Document and elsewhere in the Staff Paper is referenced in response to other comments on these issues and uncertainties. The risk assessment discusses all of these sources of uncertainty qualitatively and, when possible, assesses them quantitatively as well. For some sources of uncertainty, however, information on which to base a quantitative assessment was judged to be insufficient. Uncertainty about whether the associations between PM and various health endpoints are causal relationships, for example, was addressed qualitatively, and it was concluded, with the support of CASAC, that "the weight of epidemiologic evidence indicates that ambient PM exposure has affected the public health of U.S. populations" (PM Criteria Document, p. 13-27). Information on which to base a reasonable quantitative assessment of this uncertainty, however, was considered insufficient. The uncertainty about possible thresholds was examined quantitatively, both in integrated uncertainty analyses and in sensitivity analyses. Because of lack of information concerning the likelihood of different possible thresholds, however, quantitative analyses of this uncertainty had to rely on professional judgment. To the extent that there is an "errors in variables" problem, the risk assessment can only discuss it qualitatively, because there is insufficient information to try to incorporate the associated uncertainty in any quantitative uncertainty analysis.

v. Public health implications

(1) *Comment:* EPA indicated in the proposal notice that most of the risk results from low level PM exposures rather than peak exposures. However, this is in contrast to experiences in well known air pollution incidences (e.g., London, Donora, and the Meuse Valley).

Response: Figures 2a,b, and c included in the proposal notice show that for a typical urban area the "low- to mid-range concentrations (e.g., 10-50 $\mu g/m^3$) account for the largest amount of estimated mortality risk on an annualized basis." As explained in the proposal notice, "Even though higher 24-hour concentrations, including peaks above 70 $\mu g/m^3$, clearly contribute more mortality per day than low- to mid-range concentrations, the much larger number of days within the low- to mid-ranges results in this interval being associated with the largest proportion of total risk." There is nothing inconsistent between this observation and the very different situations which occurred in Donora, London, and the Meuse Valley where extremely high PM levels occurred over a number of days. While the historic London episodes were quantitatively different from those assumed in the risk assessment, the record over 14 London winters indicates a continuum of effects down to the lowest levels. It is therefore likely that the cumulative increase in mortality calculated for all the days in the whole 14-year period would not be dominated by the more limited number of episode days.

(2) *Comment:* EPA's risk assessment for Philadelphia and Los Angeles provides additional support for a more stringent 24-hour $PM_{2.5}$ standard because a 25 $\mu g/m^3$ standard would prevent an additional 1,200 premature deaths, 500 hospital admissions for respiratory and cardiac causes, and 14,000 fewer cases of lower respiratory symptoms in children, compared to a standard of 50 $\mu g/m^3$.

Response: See discussion in Section II.F. of the preamble to the final rule.

f. Altitude and temperature corrections

Comments received on this issue were divided. A number of commenters supported EPA's proposal to eliminate these corrections for PM. A few States opposed the change because the lack of adjustment for very cold temperature in areas near sea level could make the standard more stringent. Some commenters were concerned that the proposed change would relax protection afforded for areas at high altitude. A few commenters expressed concern that "sojourners" who visit high altitude area would have higher ventilation rates and receive reduced protection as compared to local residents whose ventilation patterns were more adapted to these conditions. EPA's responses to these comments are presented in section VI.A of the preamble to the final regulations.

g. Characterization of background $PM_{2.5}$ concentrations

A number of commenters, who used differing definitions for "background," expressed concerns that EPA was establishing standards at levels that approached or was below background. These comments are further summarized and responded to in the responses to comments on levels above.

5. Comments on related programs

A variety of public comments were received in this area, including recommendations for establishing significant harm levels for $PM_{2.5}$ and revising those for PM_{10}, establishing an intervention program similar to the one EPA has proposed for SO_2, and comments on nondegradation programs and other voluntary programs. The comments are summarized in section II.A.2 of the Summary of Comments. In addition to the responses contained in section II.E of the preamble to the final rule, EPA provides the following responses to specific issues.

(1) *Comment:* Commenters recommended that EPA establish significant harm levels for $PM_{2.5}$ and revise the significant harm levels for PM_{10}. A State government (IV-D-2335) suggested that EPA consider an intervention level program similar to that considered for SO_2 to address shorter than 24-hour exposures. Other commenters recommended that EPA consider voluntary emissions reduction programs in conjunction with standards.

Response: EPA agrees that significant harm levels and episode criteria need to be established

for $PM_{2.5}$. The western U.S. may have distinct needs in this regard. To address episodic events, EPA intends to establish a significant harm level for $PM_{2.5}$ and associated guidance so States can develop appropriate emergency episode plans. EPA also plans to re-examine its significant harm levels with respect to $PM_{10.}$ During the time these programs are under development, EPA will continue to use the existing limits,and will encourage other voluntary programs and incentives discussed by commenters. The significant harm and episode criteria will be included in the forthcoming proposed revisions to 40 CFR parts 51 and 58. In the interim, the existing PM_{10} emergency episode plans should be triggered by events of the magnitude raised in public comment.

EPA notes that many areas use voluntary programs or incentive programs in conjunction with standards with good success, and EPA encourages their use. For example, several areas operate voluntary woodstove curtailment programs to prevent pollution episodes during winter inversions.

(2) *Comment:* A commenter (IV-D-2095) suggested the consideration of nondegradation program for PM_{10}.

Response: To ensure an effective transition between the current NAAQS and the revised NAAQS, EPA will retain the current standard in the interim period. See Section VII of the preamble to the final rule.

B. Secondary PM Standards

1. General comments on proposed secondary standards

a. Considerations for setting secondary standards identical to primary standards

This section addresses significant comments on EPA's decision to establish the secondary NAAQS for $PM_{2.5}$ equal to the primary NAAQS for the purpose of addressing welfare effects, including visibility impairment, soiling, and materials damage. Comments on the proposed sectiondary NAAQS are discussed in section III of the preamble to the final rule.

(1) *Comment:* Several commenters suggested that EPA should set separate $PM_{2.5}$ secondary standards at concentrations below those of the proposed primary standards to protect against a range of welfare effects associated with PM, including visibility impairment, acidic deposition, vegetation effects, materials damage, soiling, nuisance, and safety concerns. Some argued that while such standards may not address all adverse visibility impairment due to regional variations in levels and composition of natural background PM, such standards would address a substantial amount of impairment, particularly in the eastern U.S. Some commenters also felt

that a specific rationale for excluding acidic deposition from the secondary standard discussion should have been provided by EPA in the proposal.

Response: See Section III of the preamble to the final PM NAAQS for an extensive discussion regarding EPA's rationale for not establishing separate secondary standards at concentrations below those of the primary standards. EPA acknowledges the effects of PM and its precursors on the public welfare in addition to visibility impairment, including acidic deposition, vegetation effects, materials damage, soiling, nuisance, and safety concerns. However, EPA has determined in its review of relevant studies and new information that the available data do not provide a sufficient basis for establishing a separate secondary standard for effects other than visibility. As explained in the preamble and below, setting separate secondary NAAQS for visibility at concentrations below those of the primary standards is problematic for other reasons and EPA is adopting an alternative strategy to protect visibility.

A discussion of acidic deposition was not included in the PM secondary NAAQS proposal for two principal reasons. First, as discussed below, EPA had recently examined the appropriateness of establishing separate secondary NAAQS to protect against acidic deposition effects in the latest secondary NAAQS reviews for sulfur dioxide and nitrogen dioxide, the two pollutants which, along with the products of their chemical transformation in the atmosphere, are the principal contributors to acidic deposition. Second, the 1990 Amendments to the Clean Air Act established a separate program specifically to address acid deposition under title IV. CAA section 404 also required EPA to study the feasibility of an acid deposition standard.

In EPA's April 21, 1993 final decision that revisions to the secondary standard for sulfur dioxide were not appropriate (58 FR 21351), EPA took into account the significant reductions in SO_2 emissions, ambient SO_2 concentrations, and ultimately the deposition of sulfur that is expected to result from implementation of the title IV acid rain program. EPA also noted that it would be prudent to await the results of several studies and research programs, especially those designed to monitor progress resulting from the implementation of title IV, those assessing the comparative merits of secondary standards, and the section 404 acid deposition standard feasibility study (58 FR 21357).

In EPA's October 8, 1996 final decision that revisions to the primary and secondary standards for nitrogen dioxide were not appropriate (61 FR 52852), EPA concluded that the available scientific and technical evidence in the Criteria Document and Staff Paper did not provide an adequate basis for setting a separate secondary standard for nitrogen dioxide to address the effects associated with nitrogen deposition and acidification. EPA recognized the significant uncertainties associated with developing a consistent relationship between varying concentrations of NO_2 in the ambient air and atmospheric deposition of NOx and ultimately the appearance of nitrogen in surface waters. EPA also noted that in its review of the "Acid

Deposition Standard Feasibility Study: Report to Congress," the Acid Deposition Effects Subcommittee of the Ecological Processes and Effects Committee of the EPA's Science Advisory Board concluded that there was not an adequate scientific basis for establishing an acidic deposition standard. The report found that it was not appropriate to establish an acid deposition standard because of 1) the variable sensitivities of streams and lakes within the same region to acid deposition, and 2) the uncertainty inherent in selecting an appropriate level for such a standard. The same difficulties would apply to setting uniform national secondary standards to protect against acidic deposition.

The "total loadings" approach to reducing acid deposition that was adopted by Congress in title IV of the Act avoids the scientific difficulties referred to above, and it addresses the problem in the manner and to the degree Congress determined to be appropriate. For all the above reasons, EPA believes it is both infeasible and inappropriate to establish at this time a separate secondary standard for PM to address acidic deposition.

(2) *Comment*: There is no justification for setting any secondary standards for PM since the primary standards and a regional haze program will sufficiently address visibility and other welfare effects.

Response: Secondary standards are to be established to address any known or anticipated adverse effects on the public welfare associated with a criteria pollutant. It is clear that coarse and fine particles can cause adverse effects on visibility. The PM Criteria Document shows the unequivocal scientific evidence for these significant impacts on visibility. (See Criteria Document, Chapters 8 and 9.) Thus, EPA has determined that it is appropriate to establish secondary standards for $PM_{2.5}$. See section III.A of the preamble to the final rule.

(3) *Comment*: Several commenters supported setting secondary standards for PM equal to the primary standards.

Response: EPA agrees that secondary standards for $PM_{2.5}$ should be set equal to the primary standards, but emphasizes that in order to appropriately address the regional differences in adverse effects of PM on visibility, it is also essential to establish an effective new regional haze program for the protection of visibility in mandatory class I Federal areas. As noted in section III.A.1 of the preamble, regional reductions of emissions that impair visibility should benefit the public welfare by improving visibility and reducing other welfare effects, both within and outside class I areas.

(4) *Comment*: Several commenters supported establishment of a regional haze program in conjunction with secondary standards equal to the primary standards, while other commenters stated that such a program is not needed.

Response: EPA believes a regional haze program under section 169A of the Act will be a critical component of the strategy for addressing the adverse effects of PM on visibility and on public welfare. Regional haze regulations under the authority of section 169A of the Act were deferred by EPA at the time the original visibility regulations were issued in 1980 due to the need for better technical tools and knowledge of the effect of fine particle constituents on visual air quality. Since 1980, technical tools have improved to support a regulatory program to address the long-documented regional haze visibility impairment. This finding is confirmed by various technical studies of haze, including the National Academy of Sciences 1993 study *Protecting Visibility in National Parks and Wilderness Areas* (NAS 1993, p. 11). In addition, section 169B of the Act calls for regulations to be developed under section 169A within 18 months of receipt by EPA of the recommendations from the Grand Canyon Visibility Transport Commission (the Commission's report was issued in June 1996). Thus, the new regional haze program will also make for a more comprehensive visibility protection program as required under section 169A.

(5) *Comment*: Some commenters stated that before a nationally applicable regional haze program can be established, additional visibility transport commissions should be formed for regions of the country other than the Colorado plateau, and certain critical databases and strategies should be developed.

Response: Since adopted in 1977, section 169A of the Clean Air Act has authorized EPA to address regional haze visibility impairment. Section 169A(a)(1) establishes as the national visibility protection goal "the prevention of any future, and the remedying of any existing, impairment of visibility in mandatory class I Federal areas which impairment results from manmade air pollution." Thus, the national goal provides for visibility protection generally. Further, the national goal is the lodestar for EPA's visibility protection regulations. In section 169A(a)(4) Congress delegated to EPA authority to issue regulations to assure "reasonable progress toward meeting the national goal." As explained in Maine v. Thomas, 874 F.2d 883, 885 (1st Cir. 1989, "EPA's mandate to control the vexing problem of regional haze emanates directly" from these provisions of the Clean Air Act. In adopting section 169A, Congress evinced its intent to address impairment caused by "hazes" and the potential corresponding need to control a "variety of sources" and "regionally distributed sources." H.R. Rep. No. 294, 95th Cong., 1st Sess. at 204. While EPA deferred addressing regional haze in its original 1980 regulations it did so because of technical obstacles, not because of a limitation on its legal authority. 45 Fed. Reg. 80,084 (Dec. 2, 1980). Indeed, in the 1980 rule EPA expressed its intent to address regional haze in a future rulemaking under section 169A.

The provisions in section 169B of the Clean Air Act, adopted in 1990, grew out of Congress' frustration that EPA had not more expeditiously addressed regional haze under its section 169A delegated rulemaking authority. Congress authorized visibility transport commissions under section 169B and provided for regional haze-related research to facilitate EPA's development

of regional haze regulations. Congress made it clear that it did not intend section 169B to impinge upon EPA's long-standing obligation to address regional haze visibility impairment. See 136 Cong. Rec. S2878 (daily ed. March 21, 1990) (statement of Sen. Adams) ("[t]he authority to establish visibility transport regions and commissions is a supplement to the administrators [sic] obligation under current law" and "[t]he Administrator may not delay requirements under section 169A because of the appointment of a commission for a region under section 169B"); id. at S2887 (statement of Sen. Wirth); see also 136 Cong. Rec. H12883 (daily ed. Oct. 26, 1990) (statement of Rep. Wyden) ("[n]either the original House language nor the Senate language adopted in conference repealed or lessened EPA's obligations under the 1977 law"). Thus, visibility transport commissions are a potential tool for, but not a prerequisite to, the development of regional haze regulations.

Some of the commenters also raised concerns about the adequacy of representative monitoring data to support a national regional haze regulation, and other concerns related to the development and implementation of the regional haze rules. As noted, the National Academy of Sciences has concluded that there is an adequate technical basis for a regional haze regulatory program. In any event, the regional haze rules are in the process of being developed in a separate rulemaking proceeding, and EPA has reached no final decision about their content. Consequently, such comments are beyond the limited scope of the final NAAQS decision here but are properly raised in the actual regional haze rulemaking.

(6) *Comment:* Hunton and Williams for Utility Air Regulatory Group (IV-D-2250) stated that the EPA did not demonstrate that adverse effects to the public welfare would still exist if PM concentrations were reduced to the levels of the proposed PM2.5 primary standards (e.g., 15 micrograms annual average). Therefore, a secondary standard for visibility is not appropriate.

Response: See discussion of this issue in the preamble to the final PM NAAQS regulation and in response to comment (2) above. In the preamble to the final PM NAAQS, EPA references quantitative information demonstrating how fine particle levels at and below the level of the PM2.5 primary standards result in known or anticipated adverse effects on visibility, and indicates that the Grand Canyon Visibility Transport Commission and Southern Appalachian Mountain Initiative have expended significant time and resources assessing adverse visibility impacts in their respective regions. EPA believes that these adverse effects below the level of the primary standard are best addressed through a secondary standard equivalent to the primary standard in combination with implementation of a regional haze program by the States.

(7) *Comment*: Several commenters stated they did not believe that the proposed combination of secondary standards equivalent to the primary PM standards and a regional haze program would protect or improve visibility in urban areas (particularly in the western U.S.), in rural areas, and in non-class I areas.

Response: See section III of the preamble to the final PM NAAQS regulation. EPA believes that due to the regional nature of the regional haze problem, strategies to improve visibility in the 156 mandatory class I areas under a regional haze program will also benefit non-Class I areas. For example, PM emission reductions may be needed in and around certain urban areas in the West in order to make reasonable progress toward the national visibility goal in nearby class I areas, even though some of these areas are not expected to exceed the $PM_{2.5}$ standards. As noted in the preamble, EPA also intends to pursue opportunities to obtain additional information on urban and non-Class I area visibility and other welfare effects in the future through examination of available fine particle monitoring data. Current or planned monitoring networks and initiatives, such as monitoring and chemical analysis of $PM_{2.5}$ in urban and rural background sites, efforts to better characterize real-time environmental conditions in major population centers, and new automated airport visibility monitoring networks should provide data needed to evaluate trends in these areas. This information should also help to better characterize the nature and spatial extent of urban and non-class I visibility problems and thus serve to inform future decisions on NAAQS revisions or other appropriate measures.

(8) *Comment*: Several commenters stated that establishing the proposed secondary NAAQS equivalent to the primary NAAQS would allow additional short-term episodes that would cause visibility impairment, public safety concerns, materials damage, soiling, and nuisance effects. One commenter suggested a short-term secondary standard substantially below 50 ug/m3 to protect against visibility effects and encouraged the development of strategies beyond the primary NAAQS level.

Response: See section III of the preamble to the final rule. The annual and 24-hour secondary $PM_{2.5}$ standards will provide a significant, nationally uniform degree of protection against urban and broad regional visibility impairment while avoiding unduly harsh or burdensome impacts on any particular geographic area. The EPA acknowledges that this level of protection will not eliminate all localized instances of urban visibility impairment or adequately address impairment in western Class I Federal areas, due to various regional factors such as background PM levels, humidity levels, population density, and industrial activity, as well as local topography. In making its recommendations, the National Academy of Sciences report noted the difficulties presented by these regional variations in attempting to address all instances of visibility impairment, and therefore found that regional approaches would generally be more appropriate and responsive (NAS, 1993, p. 6). For this reason, in addition to the uniform degree of protection accorded by the secondary standards, welfare effects caused by impairment of visibility in mandatory Class I Federal areas will be addressed through a regional haze program under section 169A of the Act. A regional haze program will provide States the ability to address such nationally significant but regionally variable welfare effects through appropriate regional approaches. As noted in previous responses to comments, to the extent that such approaches are needed to address visibility impairment in a number of contiguous or geographically proximate Class I areas, significant visibility and other benefits are expected to

occur in nearby urban areas as well. As noted in the preamble, EPA believes that urban visibility impairment that is of concern in particular urban areas, but is not addressed through these regional approaches, is most appropriately addressed through State or local initiatives, as has been done through adoption of a local visibility standard for the city of Denver, Colorado.

2. Specific scientific/technical comments.

(1) *Comment* (Electric Power Research Institute, PM, IV-D-2329): The statement that one deciview represents the threshold of humanly perceptible change in visibility is an overstatement.

Response: In the December 1996 PM NAAQS proposal (61 FR 65663), EPA stated in a footnote that "[U]nder many scenic conditions, a change of 1 deciview is considered perceptible by the average person." EPA did not state that this was the "threshold of humanly perceptible change."

Due to the broad variety of scenic, atmospheric, and lighting conditions at mandatory Class I Federal areas across the country, at any specific time a given area may contain vistas for which slightly more or less than one deciview above background conditions represents a perceptible impact for the components of the scene. For example, a view of a snow-capped mountain may be more sensitive to changes in air quality than a view of a forest with the result that less than a 1.0 deciview change is perceptible for that portion of the scene. Conversely, in another scene a deciview change slightly greater than 1.0 may not be perceptible. In general, however, EPA believes that a 1.0 deciview change represents a perceptible change across the range of complex views found in all Class I areas. It is for this reason that in Appendix G to the PM Staff Paper, EPA stated that the deciview metric "may be useful in defining goals for perceptible changes in visibility conditions under future regulatory programs."

(2) *Comment* (National Mining Association, PM, IV-D-2158): Coarse particles at current ambient levels present no substantial health or welfare concerns.

Response: As discussed in section II above, EPA disagrees with this comment with respect to the effects of coarse PM on health; in addition, EPA disagrees that coarse PM has no effect on visibility or soiling and nuisance. Although fine particles are often the principal cause of visibility impairment in rural areas, coarse particles can account for a significant fraction of the light extinction budget at many western locations. Based on a review of 1993-95 data from the IMPROVE visibility monitoring network, coarse particles account for 10-23% of annual average reconstructed light extinction in many parts of the western U.S. outside the Pacific Northwest. Locally high concentrations of coarse particles can appear as visible dust clouds and "plume blight," and in such locations, coarse particles contribute significantly to soiling and nuisance effects.

(3) *Comment*: One commenter (IV-D-2329, Electric Power Research Institute) stated that the levels describing background PM and visibility conditions in the 1990 National Acid Precipitation Assessment Program study (Report 24, Visibility: Existing and Historical Conditions - Causes and Effects) were not endorsed by the scientific community.

Response: EPA disagrees with the commenter. The NAPAP study was subject to extensive peer review and the background values in the visibility chapter subsequently have been referenced in numerous other publications. Furthermore, the assessment of background levels included in the final Criteria Document and Staff Paper was the subject of significant discussion and review by CASAC. Although subject to recognized uncertainties, these estimates were peer reviewed and reflect the best available judgment on background based on the available scientific information.

C. Federal Reference Method for Monitoring $PM_{2.5}$

EPA proposed a new $PM_{2.5}$ reference method to determine attainment of the standards. EPA proposed to base the new method on a conventional type filter sampler that collects 24-hour integrated $PM_{2.5}$ samples on a 47 mm Teflon filter that is subsequently moisture and temperature conditioned and analyzed gravimetrically. The sampler is a low volume sampler that operates at a flow rate of 1 cubic meter per hour, for a total sample volume of 24 m^3 for the specified 24-hour sample collection period. The sampler is relatively modest in cost and easy to operate, operates over a wide range of ambient conditions, produces a measurement that is comparable to large sets of previously collected PM data in existing databases, and provides a physical sample that can be further analyzed for chemical composition. Numerous commenters provided technical comments on the design and operation of the instrument, quality assurance and specifications, as well as more general comments on the indicator and the suitability of the proposed method for measuring components of $PM_{2.5}$.

1. General Comments on Sampler Design

This section addresses comments in category I.B of the PM Monitoring Support Summary of Public Comments Document.

(1) *Comment*: Commenters suggested the use of a different indicator, use of a different size cut, inclusion of additional, more specific, constituents (e.g., acid aerosols, carbon, metals, and semi-volatiles), and/or use of a multi-filter method.

Response: Comments on the specific indicator and size cut are discussed in section II above. Early in the development process these issues were extensively evaluated, and design decisions were based on this internal evaluation, public input, and the advice of CASAC, including a technical subcommittee on $PM_{2.5}$ monitoring. Other factors affecting the basic design of the

method were the need for historical continuity, high measurement precision, and simplicity of operation, all in response to current national monitoring objectives and available time constraints imposed by the court ordered deadline. In selecting the basic measurement approach, substantial weight was given to maintaining comparability to $PM_{2.5}$ samplers, such as the "dichotomous sampler," that were used to obtain much of the data upon which the new standards are based. After evaluating these issues in light of the comments received, EPA concludes that the conventional PM measurement approach best meets the objectives and will provide $PM_{2.5}$ measurements that are comparable to the air quality data used in the health studies that provide the basis for the $PM_{2.5}$ standards.

Although the sampler is conventional in configuration, its design is much more sophisticated than that of previous PM samplers. This more sophisticated sampler, together with improved manufacturing and operational quality assurance, is necessary to achieve the more stringent data quality objectives established for $PM_{2.5}$ monitoring data. To meet precision requirements, the critical mechanical components of the inlet, particle size separator, downtube, and upper portion of the filter holder are specified by design, as proposed. Almost all other aspects of the sampler are described by performance-based specifications, also as proposed.

Although, for the reasons specified above, the FRM design and characteristics has focused on measurement $PM_{2.5}$ for attainment determinations, EPA strongly encourages the development and use of additional instruments capable of measuring specific substances and fractions of PM. Such information can be invaluable in identifying sources of various components for implementation as well as in conducting research on health effects.

(2) *Comment:* Several commenters felt that the portions of the sampler that were specified by design would stifle further improvements and innovations.

Response: Although the EPA specifies methods by performance whenever possible, for the $PM_{2.5}$ reference method, development of adequate performance specifications for inlet aspiration and particle size discrimination would have been a very difficult, costly, lengthy, and problematic process. Moreover, manufacturer testing of proposed inlet and particle size discrimination devices against such performance specifications would require elaborate specialized facilities and would be extremely costly. For these reasons, the EPA believes that specification of these critical components by design is a prudent and very cost-effective way to ensure good inter-manufacturer and intra-manufacturer precision of the $PM_{2.5}$ measurements. Therefore, these components are specified by design, and other aspects of the sampler are specified by performance, as proposed.

EPA encourages innovations and improved samplers or measurement methods and provided for as Class II and III equivalent methods (see 40 CFR Part 53), in particular the development of continuous or sequential samplers to facilitate more comprehensive sampling. As noted

above, EPA encourages use of innovative and supplemental approaches for special purpose monitoring to support implementation and scientific research.

2. Inlet and Impactor Design

This section addresses comments in category I.B.3 and I.B.4 of the PM Monitoring Support Summary of Public Comments Document.

(1) *Comment:* Several commenters addressed the inlet design, noting that the inlet could allow entrance of precipitation and possibly insects.

Response: In fact, the PM_{10} inlet selected for the sampler has been used effectively for many years to obtain many of the $PM_{2.5}$ and PM_{10} measurements that formed the basis of the epidemiological studies. While EPA acknowledges that there have been some reports of intrusion of precipitation, the Agency believes the problem is relatively minor. Nevertheless, the inlet has been modified to further reduce the possibility of precipitation (and possibly small insects) reaching the sample filter to damage the $PM_{2.5}$ sample. Extensive wind tunnel tests have shown no significant compromise in the $PM_{2.5}$ aspiration performance of the modified inlet.

In addition, a new provision has been added, in section 7.3.8, to require that the sampling air entrance of the inlet be at a specific height of 2 ±0.2 meters above the supporting surface to help ensure homogeneous air samples when collocated samplers of different types are operated simultaneously.

(2) *Comment:* Other commenters addressed the sharpness of the size cut and how it is obtained (e.g., whether more than two stages should be used and what size cut should be used for each stage).

Response: These aspects were carefully considered in selecting the sampler configuration. The selection by EPA of the previously used PM_{10} inlet established the size cut for the first stage, and the second stage was designed to be simple, reliable, and low in cost for user agencies. In EPA's estimation, the advantages of this configuration outweigh any modest advantage that might have been gained by designing a new inlet/separation configuration that would further refine the cut points at each of two (or more) stages.

(3) *Comment:* A few commenters questioned whether the inlet was wind speed dependent at high wind speeds.

Response: The selected inlet has been shown to perform well up to 24 km/hr with 10 µm aerosols and is expected to perform well at higher speeds with 2.5 µm aerosols. The EPA

again determined that the advantages of using the selected inlet (modified to reduce precipitation intrusion) outweighed the possible minor improvement in wind-speed characteristics that might have been obtained in a newly-designed different inlet.

(4) *Comment:* Some commenters felt that other types of particle discrimination techniques such as cyclones, virtual impactors, etc. should be allowed.

Response: Again, these alternatives were evaluated and the specified inlet and impactor were determined to best meet the various objectives of the sampler. However, EPA has provided for consideration of other particle size selection techniques or devices for approval if incorporated into candidate equivalent methods for $PM_{2.5}$.

(5) *Comment:* Several commenters addressed the impactor design, noting that the impactor should be changed (1) to sharpen the size-cut characteristic, (2) to address concerns regarding possible contamination and/or performance loss due to impactor oil, and (3) to improve ease of access to service.

Response: To address the first concern, the initial prototype impactor presented to CASAC in February 1996 had been modified slightly to sharpen its size-cut characteristic. The current impactor is designed to lower cost and to optimize cut sharpness, loading capacity, manufacturing simplicity, manufacturing quality control, serviceability, and reliability. A report containing the penetration efficiency of the impactor is available in Docket A-95-54. With regard to impactor oil concerns, the impactor oil selected has a very low vapor pressure, and testing has indicated no contamination of the sample filters with impactor oil. The EPA believes that the impactor design is as accessible as possible, given the design objectives. Some flexibility may be allowed for manufacturers to develop improved closure devices or other external modifications. Proper maintenance will, of course, be very important and will be stressed in the associated operator instruction manuals and in other training and guidance materials. The EPA has been performing field and laboratory tests that will provide the basis for detailed guidance for all necessary preventive maintenance. Proper installation procedures for the oil and the impactor filter, as well as all other maintenance requirements, will be available in the quality assurance procedures and guidance contained in a new section 2.12 to be added to the EPA's "Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Specific Methods" (EPA-600/R-94/038b).

3. Anodized Aluminum Surface

All internal surfaces exposed to sample air prior to the filter are required to be anodized aluminum (section 7.3.7).

Comment: A few commenters expressed concern that the anodized aluminum surfaces in high

volume PM_{10} samplers have shown substantial pitting, particularly in the venturi flow control device.

Response: The anodized aluminum surfaces are required in the $PM_{2.5}$ sampler to maintain comparability to previously used samplers. The EPA believes that the much lower flow rate in the $PM_{2.5}$ sampler will greatly reduce the pitting tendency, and the active flow control in the $PM_{2.5}$ sampler is not dependent on the physical dimensions of a critical orifice as it is in a venturi flow control device.

4. Filter for $PM_{2.5}$ Sample Collection

The proposed reference method called for the sample to be collected on a 47 mm Teflon filter. Many of the comments received on the measurement method concerned the proposed filter medium and its performance. This includes comments in category I.B.5 through I.B.8 of the PM Monitoring Support Summary of Public Comments Document.

(1) *Comment:* Commenters expressed concerns with the use of Teflon filters and with the selection of a single-filter method (as opposed to a multiple-filter technique). Several commenters recommended that alternative filter media be allowed, in most cases to support more detailed analysis and/or to allow the capture of additional PM components. Other comments noted potential advantages of other media in operating characteristics or chemistry requirements. Operational concerns expressed about Teflon filters included propensity for tearing, possible loss of integrity, and relatively high cost. Other concerns were that Teflon is generally not conducive to carbon analysis, and that Teflon filters may not hold deposited PM. Many commenters recommended use of a multi-filter sampler to support chemical speciation analysis in addition to the compliance determination.

Response: To address some of these general concerns about the performance of the specified filter material, some minor refinements to the filter specifications concerning the filter diameter and the filter support ring have been made to ensure proper performance of the filter in the specified filter holder. Additional clarifications have been made to the maximum moisture pickup and the filter weight stability requirements. Although Teflon may preclude certain chemical analyses (e.g., elemental and organic carbon), Teflon was used to derive $PM_{2.5}$ mass in epidemiological studies and the EPA believes that Teflon filter material is the best overall choice to meet the objectives of compliance monitoring and to provide good measurement precision. Other filter media are likely to provide reduced gravimetric precision and preclude more types of subsequent chemical analysis. The regulations, do not preclude the use of alternative filter media for use in special purpose monitors. Furthermore, additional or alternative samplers or filter types can be considered as candidate equivalent methods and can be used for non-compliance monitoring, where necessary.

The EPA reiterates that compliance monitoring based on mass concentration of $PM_{2.5}$ is the primary objective of the reference method. Multi-filter capability would have substantially increased the cost and complexity of the sampler. However, multi-filter samplers can be considered as candidate equivalent methods. In addition, multi-filter samplers can be used as special purpose monitors (SPMs) to perform characterization studies, develop control strategies, and conduct other special studies as has been done previously for PM_{10}.

In response to numerous comments received on Appendix L and on the provisions of part 58 regarding the need for chemical speciation, the EPA is requiring a chemical speciation trends network and is assigning a high priority to additional chemical speciation through its 105 grant allocation program. EPA will issue guidance describing the monitoring methods and scenarios under which speciation should be performed. The program will incorporate additional $PM_{2.5}$ samplers that allow for the simultaneous collection of aerosols on multiple filter media.

(2) *Comment:* Although a few commenters generally supported the requirement for archiving filters, many questioned the provision. Among the concerns of these commenters were the economic burden of archiving filters for such a long time, whether the potential existed for archiving to introduce artifacts and potential bias, and whether the number of filters archived and length of time should be reduced.

Response: The associated requirement for archiving filters has been removed from Appendix L (section 10.17) and relocated to 40 CFR, part 58, Appendix A. The basis for this change is that filter archiving is a supplemental monitoring requirement and not an integral part of the reference method for determining compliance with the $PM_{2.5}$ NAAQS. Furthermore, in Appendix A, the length of time for archiving filters has been reduced to 1 year to respond to these concerns.

(3) *Comment:* Several commenters to 40 CFR part 58 expressed concern that the recommended sampling frequency for many sites would require the timely development of sequential samplers.

Response: As part of this effort to expedite the development of sequential filter samplers, appropriate provisions of Appendix L have been clarified to apply not only to a single-sample sampler, but also to a sequential-sample sampler, provided that all specifications are met and no deviations, modifications, or exceptions are made to the inlet, downtube, impactor, or the upper portion of the filter holder (all of which are specified by design). Samplers that have minor changes or modifications in these components, have changes that alter the aerosol's flow path, or contain other significant deviations will be required to meet the requirements of Class I equivalent methods (see amendments to part 53 elsewhere in the Federal Register). Further, a provision has been added to require that sequential sample filters stored in a sequential sampler be adequately covered and protected from contamination during the storage periods in the sampler.

(4) *Comment:* A few commenters expressed concern about who must carry out filter tests to determine if they meet the filter specifications.

Response: In response, the filter specifications have been clarified to indicate that filter manufacturers should generally carry out most or all of the filter performance tests in order to certify that their filters meet the filter specifications for the $PM_{2.5}$ reference method. In addition, the EPA has historically conducted acceptance tests on filters procured for NAMS/SLAMS networks prior to distribution to State and local agencies and plans to continue this practice for the new $PM_{2.5}$ sampling program.

(5) *Comment:* Some commenters requested additional information on the requirement that an ID number be attached to each filter.

Response: Preliminary information indicates that it is not practical at this time for either filter manufacturers or users to print an ID number directly on the filter. However, the EPA is continuing to pursue this goal. In the meantime, alternative means, such as attaching an appropriate ID number to the filter's storage container, will be necessary. Additional details and possible alternative filter identification methods will be provided in the new Section 2.12 of the "Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Specific Methods."

5. Filter Handling/Weighing/Conditioning Requirements

This section addresses comments in category I.B.6 through I.B.8 of the PM Monitoring Support Summary of Public Comments Document.

(1) *Comment:* Although many commenters felt that requirements to control variations in these procedures were necessary to control an important aspect of measurement uncertainty, many other commenters felt that the filter handling requirements for collected $PM_{2.5}$ samples were too burdensome.

Response: EPA believes that handling of the exposed filter between retrieval from the sampler and commencement of the conditioning period is expected to be one of the most significant sources of $PM_{2.5}$ measurement variability. Thus, EPA concludes that specific requirements for this activity are necessary.

(2) *Comment:* Some commenters felt that the samples should be kept cold until analysis to prevent volatile losses.

Response: In response to this concern, the restriction on the maximum temperature exposure

for collected samples has been reduced from 32 to 25E C, and a recommendation has been added for sampler operators to keep the samples as cool as practical between retrieval from the sampler and delivery to the conditioning environment. Further, the length of time permitted between retrieval of the filter and post-collection weighing is increased from 10 to 30 days, *provided* that the sample is maintained at 4E C or less between retrieval and the start of the conditioning period. The new section 2.12 of the "Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Specific Methods" will provide guidance and techniques for keeping samples cool during this period and may suggest devices to document maximum temperature exposure of the sample.

(3) *Comment:*Commenters also requested additional specifications and guidance for field blanks.

Response: The EPA will provide additional clarification and detailed procedures and guidance regarding field blanks in the new section 2.12 of the "Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Specific Methods."

(4) *Comment:* Some commenters felt that the filter weighing requirements were too restrictive. Other commenters had questions about operational and calibration procedures for the balances.

Response: Because filter weighing is one of the most significant sources of $PM_{2.5}$ measurement variability, specific requirements and restrictions are deemed necessary. However, in response to some of the concerns expressed, the proposed requirement that both pre- and post-weighings be carried out by the same analyst has been reduced to a non-mandatory recommendation. Detailed recommendations and guidance on filter weighing and balance calibration, based on information obtained in current field tests, will be provided in new section 2.12 of the "Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Specific Methods."

(5) *Comment:* Several commenters questioned the filter conditioning requirements, with some requesting a lower humidity range.

Response: Since humidity can profoundly affect the weight of the $PM_{2.5}$ on the filter, EPA maintains that filter conditioning requirements need to be tight to control measurement variability and to ensure satisfactory precision. But in response to at least one of the concerns, the filter conditioning humidity requirement has been changed to allow conditioning at a lower relative humidity commensurate with the humidity during sample collection. Filter conditioning is permitted at a relative humidity within ±5 RH percent of the mean ambient humidity during sampling (down to a minimum of 20 RH percent) for samples collected at average ambient humidities lower than 30 percent. The EPA will provide further details on filter conditioning controls in new section 2.12 of the "Quality Assurance Handbook for Air Pollution

Measurement Systems, Volume II, Ambient Air Specific Methods."

6. Sampler Performance Requirements

Several commenters addressed sampler performance requirements, including (1) sampler flow control specifications, (2) filter temperature control, (3) sampler performance under extreme conditions, and (4) data reporting. This includes comments in category I.B.9-I.B.17 of the PM Monitoring Support Summary of Public Comments Document.

(1) *Comment:* Although a few commenters felt that requirements for flow control are necessary to ensure accurate size classification, several commenters thought the flow control specifications were too stringent and should be modified.

Response: In response to concerns that various sampler flow control specifications are too tight, EPA contends that good flow control is necessary to maintain uniform sampling, to ensure correct particle size discrimination, and to control measurement variability. Sampler manufacturers have been able to meet the specified flow control requirements, and field studies to date confirm that prototype samplers are able to meet these flow control requirements.

(2) *Comment:* Several commenters questioned the requirement for the temperature of the filter to be maintained at or below ambient temperature plus 3EC. Some felt it was not needed if, after sampling, the filter could sit for several days at temperatures up to 32EC. Others questioned whether and how such tight temperature control could be achieved.

Response: In response to comments about the ambient temperature plus 3 EC filter temperature control requirement, EPA believes that fairly tight control of the sample filter temperature is necessary to minimize losses of semi-volatile components over a wide temperature range, and tight temperature control has been strongly recommended by the Clean Air Scientific Advisory Committee (CASAC). Monitoring of the filter temperature difference from ambient temperature is necessary to verify that the sampler filter temperature control is functioning properly. Testing to date indicates that the proposed 3 EC (above ambient temperature) limit is somewhat difficult to meet; however, a 5 EC limit can be reasonably met. Therefore, the filter temperature control requirement has been relaxed slightly from 3 EC to not more than 5 EC above the concurrent ambient temperature. Ambient and filter temperature sensors will require periodic calibration or verification of accuracy. In response to a common comment, the method has been clarified to indicate that exceedance of the filter temperature difference limit would not *necessarily* invalidate the sample.

(3) *Comment:* Several commenters addressed the issue of sampler performance under extreme weather conditions (e.g., high or low temperatures, low pressures, high winds, high or low humidity, fog, and dust storms). Some commenters wanted the operating and testing conditions

to be expanded. Other commenters expressed concern about reduced data capture implications if samplers fail to operate under extreme conditions. Other commenters were concerned with the burden to State and local agencies to get the samplers to work under such conditions.

Response: In response to concerns about the performance of the sampler under extreme weather conditions, the EPA has established sampler specifications that are intended to cover reasonably normal environmental conditions at about 95 percent of expected monitoring sites. The sampler qualification tests in 40 CFR part 53 address most, if not all, of these operational requirements. Specification of the sampler performance for sites with extreme environmental conditions would substantially raise the cost of the sampler for other users, most of whom do not require the extra capability. Users requiring operation of samplers under extreme conditions are encouraged to develop supplemental specifications for modified samplers to cover those specific conditions. Sampler manufacturers have indicated a commitment to respond to the need for modified samplers for such extreme conditions.

(4) *Comment:* Several commenters expressed concerns about data reporting. Many questioned the need to report so much information, and some were concerned about the effort to develop data management systems to comply with the reporting requirements.

Response: Although concerns were expressed that the amount of data required to be reported from each sampler is excessive, EPA stresses that only a portion of the data collected by the sampler needs to be reported to AIRS. These limited data requirements (i.e., ambient and filter temperature, barometric pressure, sample volume, variation in sample flow rate) are important to establish or verify the reliability and confidence of the $PM_{2.5}$ measurements and to aid in utilization of those data. The substantial additional data are provided by the sampler for the site operator's use, to provide confirmation of a given sample's validity, and to aid in troubleshooting should outlier measurements appear in the monitoring data. A variety of current electronic devices and systems may be used to acquire and handle the data, and these devices can easily accommodate the amount of data required to be reported, as well as the additional, optional data. Printers, modem connections, and alternative data output connections or devices are not precluded. A provision has been added in section 7.4.17 to require sampler manufacturers to make available computer software to that will translate sampler output data into a standard spreadsheet format (since no specific format is specified for output of the sample data acquired by the sampler).

III. RESPONSES TO COMMENTS ON LEGAL, ADMINISTRATIVE, AND PROCEDURAL ISSUES RELATED TO THE REVIEW OF THE PM NAAQS

These responses address comments summarized in section IV and elsewhere in the Summary of Comments. Because of the emphasis public commenters placed on certain issues, EPA responded

directly to them in sections IV and VIII of the preamble to the final rule. Section IV of the preamble addresses the following legal and procedural issues: (1) whether EPA must consider costs and similar factors in setting NAAQS; (2) whether EPA erred in its selection of a methodology for determining the level of a NAAQS that protects public health with an adequate margin of safety; (3) whether EPA committed a procedural error by not entering into the rulemaking docket underlying data from certain epidemiological studies; and (4) whether the 1990 amendments to the Act preclude EPA from revising the PM NAAQS to establish a new $PM_{2.5}$ indicator. Section VIII of the preamble addresses issues raised in public comments with respect to EPA's obligations under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), and the Unfunded Mandates Reform Act.

A. General Issues

1. Cost consideration

This section addresses comments that EPA erred in not considering costs or other societal impacts in establishing NAAQS, particularly for non-threshold pollutants or in light of uncertain health effects information. Some commenters also maintained that costs should be considered in setting secondary NAAQS.

(1) *Comment*: EPA is not precluded from considering costs and similar factors; among other things, the judicial decisions relied upon by EPA as precluding consideration of such factors rest on faulty analysis that predates and cannot survive scrutiny under Chevron, U.S.A. v. Natural Resources Defense Council, 467 U.S. 837 (1984) (AISI, IV-D-2242; GM, IV-D-2694; ATA, IV-D-2245; UARG, IV-D-2250).

Response: Post-Chevron decisions have confirmed that costs and similar factors may not be considered in setting NAAQS. See section IV.A of the preamble to the final rule.

(2) *Comment*: Section 109 of the Act does not preclude consideration of cost/benefit analysis when read in pari materia with sections 108(a) and 302(h) (GM, IV-D-2694).

Response: See section IV.A of the preamble to the final rule. Reading section 109(b) together with sections 108(a) and 302(h) does not alter the conclusion that consideration of costs and similar factors is precluded in setting NAAQS. Section 109(b) provides that NAAQS are to be based on air quality criteria issued under section 108(a)(2). As the commenter indicates, section 108(a)(2) provides that information on welfare effects, as well as health effects, is to be included in the air quality criteria. That information, however, does not include costs and similar factors resulting from efforts to attain or maintain the NAAQS. Although section 302(h) defines "welfare" as including "effects on economic values," this phrase refers to the economic costs or pollution, not to the costs of controlling pollution. Lead Industries Ass'n v. EPA, 647 F.2d

1130, 1148 n.36 (D.C. Cir. 1980). Cf. Natural Resources Defense Council v. EPA, 824 F.2d 1146, 1157-59 (D.C. Cir. 1987).

(3) *Comment*: Section 109(d)(2)(c)(iv) requires EPA to consider the advice of its independent science advisors on any "adverse public health, welfare, social, economic, or energy effects" that might arise from implementing revised standards when establishing them (UARG, IV-D-2250).

Response: See section IV.A of the preamble to the final rule.

(4) *Comment*: If Congress intended to forbid consideration of costs and benefits under section 109, it would have enacted a preclusive section 302 definition of "health effect" or "margin of safety" similar to the section 302(h) definition of welfare effect (GM, IV-D-2694).

Response: Such a definition was unnecessary in view of other indicia of congressional intent discussed in section IV.A of the preamble to the final rule. See, e.g., Natural Resources Defense Council v. EPA, 824 F.2d 1146, 1157-59 (D.C. Cir. 1987).

(5) *Comment*: The selection of the level(s) for the PM NAAQS is a policy decision that must be cost-effective. If cost-effectiveness is not considered, there is no justification for stopping short of a "no adverse effects" level (AAMA, IV-D-2243).

Response: See sections IV.A and IV.B of the preamble to the final rule. Where there is a continuum of health effects for a given pollutant, with no apparent threshold, there is no indication that Congress intended the Administrator to eliminate all risks, and some indication that it did not. See e.g., H.R. Rep. No. 95-294, at 127 (1977). See also, e.g., Natural Resources Defense Council v. EPA, 824 F.2d 1146, 1153 (D.C. Cir. 1987) ("'safe'" does not mean "'risk-free'"). In such cases, section 109(b) essentially requires the Administrator to select a standard which, in her judgment, based on consideration of the nature and severity of the health effects involved, the size of the sensitive population at risk, and other health-related factors, will reduce the risks sufficiently to avoid unacceptable risks. Consideration of costs is not necessary to such a determination. See id. at 1165.

(6) *Comment*: Consideration of costs is especially appropriate in the context of a decision to regulate a new pollutant ($PM_{2.5}$) for the first time (GM, IV-D-2694).

Response: See section IV.A of the preamble to the final rule. In establishing $PM_{2.5}$ as an additional indicator for PM, EPA is not creating a newly regulated pollutant within the meaning of the Act. The regulated pollutant has been and continues to be PM.

(7) *Comment*: The language and legislative history of the CAA do not require EPA to ignore practical consequences when establishing a $PM_{2.5}$ standard based on ambiguous health data (AISI, IV-D-2242).

Response: See section IV.A of the preamble to the final rule.

(8) *Comment*: When construed together with E.O. 12866, UMRA and SBREFA, the CAA allows EPA to consider the economic consequences of a new $PM_{2.5}$ standard (AISI, IV-D-2242).

Response: See section IV.A of the preamble to the final rule.

(9) *Comment*: The EPA's evaluation of health effects in connection with the proposed $PM_{2.5}$ standards is flawed because it fails to consider the direct relationship between income and mortality. The cost of partial attainment equates to approximately 400 statistical lives lost (AAMA, IV-D-2243).

Response: See section IV.A of the preamble to the final rule. NAAQS are to be based on health effects caused by pollution, not effects that might result from control of pollution. Natural Resources Defense Council v. EPA, 902 F.2d 962, 972-73 (D.C. Cir. 1990).

(10) *Comment*: The Act prohibits consideration of non-health matters in setting standards; the place to consider costs is in the development and adoption of State implementation plans (NRDC, IV-D-2244).

Response: EPA agrees.

(11) *Comment*: In selecting among alternative secondary standards that provide a safe environment, the purposes of the Act (section 101(b)(1)) require EPA to conduct a holistic inquiry into all effects on the public welfare to ensure that its standard-setting will actually advance the public welfare. In doing so, EPA must take into account adverse social and economic effects that might result from implementing a secondary standard, as evidenced by the requirement (section 109(d)(2)(c)(iv)) that CASAC advise EPA on such effects (UARG, IV-D-2250).

Response: The comment is flawed in several respects. First, it appears to assume that proposal of alternative standards amounts to a finding that any of the alternatives would provide adequate protection of public welfare under section 109(b). This is incorrect; proposal of alternative standards (primary or secondary) reflects the Administrator's awareness that there may be a range of views on the scientific information on which NAAQS are to be based, as well as on how the information should be used in making the policy judgments required for the final choice of a standard. Only the Administrator's final decision on a standard, taking into account public comments on the proposal, can be said to represent her determination of what standard meets the statutory criteria.

Second, the purposes of the Act are stated in general terms and are, at best, only a general

guide to decisions under specific sections of the Act. To the extent they appear to conflict with more specific decision criteria stated in the statutory provision at issue, the more specific criteria are controlling. Under the decision criteria stated in section 109(b), consideration of costs and similar factors is precluded in setting NAAQS, and CASAC's responsibility to advise EPA on adverse effects that might result from implementation of standards does not alter that conclusion. See section IV.A of the preamble to the final rule.

2. Margin of safety

This section addresses comments on the approach used by the Administrator in specifying a PM standard that protects public health with an adequate margin of safety.

(1) *Comment*: In setting a NAAQS with an adequate margin of safety, EPA must define what constitutes "acceptable risk" for present and future rulemakings. In reaching such a determination, EPA must consider among other factors the results of cost-benefit analyses, the acceptability of risk judged in a "real world" context, and any adverse public health effects that might result from implementation of alternative standards. In other words, EPA must adopt a specific approach for specifying a standard that protects public health with an adequate margin of safety, and that approach must consider costs and other societal impacts (UARG, IV-D-2250; GM, IV-D-2694; ATA, IV-D-2245).

Response: See sections IV.A and IV.B of the preamble to the final rule.

(2) *Comment*: In setting a NAAQS with an adequate margin of safety, EPA must first identify the lowest observed effects level and then apply a margin of safety to address uncertainties and to protect the most sensitive individuals within the at-risk population(s). The use of risk assessment in establishing NAAQS is a departure from past practice, and this departure was not adequately explained (Yuhnke, IV-D-2095).

Response: See Section IV.B of the preamble to the final rule and the further response in section II above on level.

3. 1990 CAA amendments

This section addresses public comments expressing the view that the 1990 amendments of the Act preclude EPA from adopting $PM_{2.5}$ as an additional indicator for PM and establishing standards for $PM_{2.5}$.

(1) *Comment*: The plain language of title 1, part D, subpart 4 of the 1990 amendments precludes EPA from regulating $PM_{2.5}$ (GM, IV-D-2694; AAMA, IV-D-2243).

Response: See section IV.D of the preamble to the final rule.

4. Data availability for key health studies

This section addresses comments that EPA erred by not obtaining and making publicly available certain raw "data" underlying key health studies.

(1) *Comment*: EPA improperly relied on factual data not available to the public, in that the underlying raw data for the Dockery et al. (1993), Pope et al. (1995), and Schwartz et al. (1996) studies was not made publicly available or placed in the docket (NMA, IV-D-2158; AAMA, IV-D-2243; UARG, IV-D-2250; AISI, IV-D-2242; API, IV-D-2247; GM, IV-D-2694).

Response: See section IV.C of the preamble to the final rule. See also section II.B of the preamble to the final rule and section II.A of this response-to-comments document.

(2) *Comment*: A number of commenters argued that EPA has the ability to obtain the data underlying the Dockery and Pope studies and that EPA has refused to exercise its authority to obtain this data (AISI, IV-D-2242; AAMA, IV-D-2243; NMA, IV-D-2158).

Response: See section IV.C of the preamble to the final rule. It is uncertain whether EPA does in fact have the legal authority to require access to the data. The tapes are not "subject data" pursuant to 40 CFR 30. 1130, Appendix C, since they were not developed, produced or generated with EPA funds. Although a legal argument may potentially exist that EPA has a right of access to this data, EPA has never previously asserted such an argument and the argument remains untested in the courts. EPA has not attempted to shield itself from this data and in fact, consistent with the legal rights and obligations of the researchers, EPA has urged that the data be made public. Pursuant to EPA's request, Harvard and HEI have agreed to re-examine the data and make the results of that review public. EPA's ability to rely on these studies without obtaining the raw data should not depend upon whether some agency of the federal government funded the science or on the extent of EPA's ability to access the data using extraordinary means such as those described above. As noted in the preamble, EPA did not rely upon the raw data underlying the Dockery and Pope studies; it relied upon the studies themselves and has disclosed these studies to the public for review and comment. Only in the most extreme cases--for example where there are credible allegations of fraud, abuse or misconduct would a review of raw data be warranted. In this case, there is no such allegation and the studies in question have been subject to an extensive peer review process that has confirmed the scientific integrity of these studies and their suitability for use in the PM rulemaking. Moreover, as evidenced in the discussion of the selection of the standard levels in section II.F of the preamble to the final rule, even if these studies had not been considered in the final decision EPA would

have selected the same annual $PM_{2.5}$ standard based on other short- and long-term exposure studies. For all of the above reasons, EPA does not agree that review of the underlying data for these studies is necessary. Furthermore, it remains unclear whether EPA has a legal right of access to such data and, if access is available, a legal right to distribute the data.

5. Availability of FRM test data for public review

This section addresses public comments that EPA erred by not entering into the docket certain field test data concerning the proposed Federal Reference Method for measuring $PM_{2.5}$ in the ambient air.

Comment: Proposal of the $PM_{2.5}$ Federal Reference Method was premature because field test data were not available in the docket, precluding meaningful public comment. EPA's failure to include these data in the record violates the requirements of section 307(d) of the Act and the Administrative Procedure Act (UARG, IV-D-2250).

Response: See section VI.B of the preamble to the final rule. See also the accompanying Federal Register notice announcing a supplemental comment period to take comments on field and other test data.

6. Consideration of disbenefits

Comment: One commenter (GM, IV-D-2694) theorized that reductions in fine particle levels resulting from the proposed $PM_{2.5}$ standards may result in adverse effects from increased UV-B radiation such as skin cancer, cataracts, and immunosuppression. A similar comment was made on the proposed O_3 standard. A closely related issue raised by the same commenter is that the presence of fine particles may also play a major role in counteracting global warming. Based on this possibility, commenter argued that global warming caused by greenhouse gases would be much more intense if aerosol levels were significantly reduced by the proposed fine particle standard. In essence, the commenter argued that EPA erred in not considering these risk-risk tradeoffs involved in revising the PM standards

Response: EPA strongly disagrees with this commenter's suggestion that such "disbenefits" of tighter standards can and should be considered in reviewing and revising NAAQS, because it is inconsistent with the Clean Air Act and ill-advised from an environmental management policy perspective. Furthermore, the commenter has not pointed to any quantitative assessment or scientific evidence that supports its claim that the effects of implementing the final PM NAAQS would produce significant disbenefits. Each of EPA's reasons is discussed more fully below.

The clear intent of Congress in enacting the NAAQS provisions of the Clean Air Act prohibits EPA from considering in this rulemaking any health "disbenefits" that may result from the

implementation of a new, more stringent NAAQS. Where the intent of Congress on a specific issue is clear, as determined by traditional tools of statutory construction, it must be given effect by the implementing agency and the courts. Chevron, U.S.A. v. Natural Resources Defense Council, 467 U.S. 837, 842-45 (1984). As described below, Congress clearly intended to limit EPA's consideration in developing criteria and in setting NAAQS to the adverse health effects caused by the presence in the ambient air of the pollutant in question. Accordingly, EPA is not considering in this rulemaking the alleged health "disbenefits" from implementation that have been raised by commenters, and EPA did not include them in the discussion of the air quality criteria.

The NAAQS provisions of the Act are set forth in sections 108 and 109 and were first enacted in 1970. In that year, Congress set up a three-step process for the development of NAAQS -- first, EPA must prepare a list of air pollutants meeting certain requirements; second, EPA must develop criteria for the listed pollutants; and third, EPA must establish NAAQS for the pollutants based on the criteria. See 42 U.S.C. sections 7408, 7409. At each step, there is evidence that Congress intended the Agency to consider only the adverse health effects caused by the presence in the ambient air of the pollutant at issue.

As the initial step, Congress directed EPA in 1970 to list "each air pollutant - (A) which in his judgment has an adverse effect on public health or welfare; (B) the presence of which in the ambient air results from numerous or diverse mobile or stationary sources; and (C) for which . . . he plans to issue air quality criteria . . . ." 42 U.S.C. section 7408(a)(1). In paragraph (A), Congress expressly focused the entire NAAQS process on pollutants that have an adverse or harmful effect on public health.

In the second step, EPA must develop air quality criteria for each listed pollutant. Section 108(a)(2) states that the "criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air." Read out of context, the phrase "all identifiable effects" might be deemed sufficiently broad to encompass any health effect, whether positive or negative. But the phrase can clearly be read as meaning only harmful effects, and it is only part of a larger body of statutory language that evidences Congress' intent with respect to the NAAQS. Other language in sections 108 and 109 indicates that Congress had harmful effects of a pollutant in mind when it directed EPA to examine "all identifiable effects." Indeed, the immediately following sentence in section 108(a)(2) specifies three factors that the Agency must include in the criteria, and two of those three factors expressly direct EPA to focus on "adverse" effects on health and/or welfare.[12]

[12]The three factors are "(A) 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

Similarly, the listing process in section 108(a)(1)(A) in 1970 required the Administrator to list for criteria and NAAQS development each air pollutant "which in his judgment has an adverse effect on public health or welfare . . . ."[13] Together, these statutory excerpts (with the provisions of section 109, discussed below) evidence Congress' clear intent for EPA to focus on the harmful effects of a pollutant in developing the air quality criteria.

Also, the express language of section 108(a)(2) limits the scope of causality that[14] it is appropriate for EPA to consider. The language directs EPA to focus on "effects that may be expected from the presence of the pollutant in the ambient air." This language parallels that in the listing process, which directs EPA to list pollutants "the presence of which in the ambient air" results from numerous or diverse mobile or stationary sources (section 108(a)(1)(B)). In both provisions, Congress limited the causality consideration to the effects caused by the emitted pollutant's presence in the ambient air. There is no language to support the idea that Congress intended to focus on the indirect effects of implementation efforts to reduce pollution following the establishment of a NAAQS. Indeed, such considerations would be premature at this point in the process, when the Agency is focusing on the criteria that will form the basis for setting the NAAQS.

In the third and final step, section 109 directs EPA to set the NAAQS based on the air quality criteria issued under subsection 108(a)(2). 42 U.S.C. 7409(b)(1)-(2). The case law on considering cost in NAAQS reviews confirms that Congress limited the Agency's consideration to the factors specified in section 108(a)(2). See section IV.A of the preamble to the final rule. Further, the 1970 Senate report evinces Congress' intent to focus on adverse health effects when setting primary standards. The report emphasizes that the Agency should protect the

---

air pollutant; (B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and (C) any known or anticipated adverse effects on welfare." 42 U.S.C. 7408(a)(2)(A)-(C).

[13] In 1977, Congress amended the language in subsection 108(a)(1)(A). As revised, the subsection directs the Administrator to list each air pollutant "(A) emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare. . . ." The legislative history shows that Congress inserted this revised language into the Clean Air Act in several sections to clarify that proof of actual harm was not necessary under section 108 or the other revised provisions of the Act, and to create a uniform test for regulation to protect public health and welfare. See, e.g., H.R. Rep. 95-294, at 43-51 (1977). The statutory language ("endanger") and the legislative history make it clear that Congress remained focused on the adverse effects of pollution. See id.

[14] In 1977, Congress also added a provision to address stratospheric ozone depletion and the increase in UVb radiation exposure that it causes. P.L. 95-95, sections 150-159 (1977).

health of particularly sensitive citizens such as asthmatics, and declares that a NAAQS will be sufficient to protect the health of sensitive individuals "whenever there is *an absence of adverse effect* on the health of" an appropriate sample of such persons. S. Rep. No. 91-1196, at 10 (1970) (emphasis added).

Thus, it is clear from the language and legislative history of the 1970 amendments alone that Congress intended to limit EPA's focus to the adverse effects of a pollutant's presence in the ambient air. The repeated references to "adverse" effects, and Congress' focus on the effects caused by an emitted pollutant's presence in the ambient air, indicate that Congress did not want EPA to weigh the potential health "disbenefits" of pollution control against the adverse health effects from a pollutant's presence in the ambient air.

The 1977 and 1990 amendments to the Clean Air Act offer additional evidence confirming this conclusion.[15] In 1977 Congress made some significant changes to sections 108 and 109 but did not change its substantive instructions for setting NAAQS by amending subsections 108(a)(2) or 109(b). In new subsection 109(d), Congress directed EPA to review existing NAAQS periodically and established CASAC as a special advisory committee to advise the Administrator in such reviews. Congress expressly directed that both EPA's decisions and CASAC's recommendations on revisions of existing NAAQS be made in accordance with existing section 108 and subsection 109(b). 42 U.S.C. 7409(d)(1), (2)(A)-(B). As a separate task, Congress directed CASAC to offer advice to the Administrator in several areas, including any "adverse public health . . . effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards." 42 U.S.C. 7409(d)(2)(C). This language specifically addresses the potential for health "disbenefits" from implementation. It shows that Congress was aware of the potential for such effects, yet declined to include them among the section 108 factors to be considered in setting a NAAQS. Instead, Congress directed CASAC to offer advice on the potential health effects of implementation separately from its involvement in the establishment and revision of the NAAQS. The legislative history confirms that such advice was intended for the benefit of the States and Congress, who might wish to use it in developing implementation strategies or in fashioning future legislation. See H.R. Rep. No. 95-294, at 183 (1977).[16]

In 1990, Congress again amended the Clean Air Act substantially without changing the basis for setting NAAQS. At the same time, Congress expressly addressed the issues of

---

[15] Even if doubt were to remain about Congress' intent after review of the 1970, 1977, and 1990 amendments, EPA's longstanding interpretation of the statutory language is clearly reasonable, for the reasons discussed above. Moreover, EPA's interpretation is supported by the policy reasons set forth later in this response.

[16] In 1977, Congress also added provisions to address stratospheric ozone depletion and the increase in UV-B radiation exposure that it causes. P.L. 95-95, sections 150-159 (1977).

stratospheric ozone depletion and global warming that are the proximate causes of the health effects raised by commenters. Congress enacted Title VI (sections 601-618) to address stratospheric ozone depletion[17] and directed EPA in section 602(e) to consider the global warming potential of potential substitutes for stratospheric ozone depleting substances. These provisions demonstrate that Congress was aware of the potential environmental hazards of stratospheric ozone depletion and global warming but chose to address them separately from the process for setting and revising NAAQS. At the same time, other amendments show that Congress was aware EPA might revise the then existing NAAQS. For example, section 172(a)(1) expressly contemplates that EPA may revise a NAAQS in effect at the time of enactment of the 1990 Amendments.

The D.C. Circuit's decision in the PM_{10} case further supports the conclusion that Congress did not intend EPA to consider the implications for global warming and UV-B exposure from implementing strategies to reduce ozone and PM in accordance with the new NAAQS. In that litigation, AISI argued that EPA should have considered the potential human health effects of unemployment that might result from implementing the PM_{10} NAAQS. EPA had interpreted the statute as prohibiting the agency from considering such potential health effects of implementation in setting or revising a NAAQS. The court upheld EPA's conclusion, quoting subsection 108(a)(2) and stating that "it is only *health effects relating to pollutants in the air* that EPA may consider." Natural Resources Defense Council v. Administrator ("PM_{10}"), 902 F.2d 962, 972-73 (D.C. Cir. 1990) (emphasis in original).

As pertinent here, the potential health effects of UV-B radiation or global warming, like the potential health effects of unemployment, would not result from air pollution but from the implementation of pollution control. Like the potential health effects of unemployment, the potential health effects of both global warming and UV-B increases would not be caused by the presence of the applicable pollutant in the ambient air. In each case, there is an independent, intervening cause (unemployment, stratospheric ozone depletion, atmospheric increases in greenhouse gases) of the potential harmful effect. In each case, the argument for considering the potential effect is that implementing a new, tighter standard would "cause" an increase in the effect, but in each case the effect is actually a result of the intervening cause. In other words, without these intervening causes, there would be no health "disbenefit" to implementing the new NAAQS. In all three circumstances, the fact that the potential "disbenefit" would result from implementing the new NAAQS, rather than from the presence of the relevant pollutant in the air, means that EPA is prohibited from considering such effects.

The scenarios suggested by the commenter do differ from the unemployment concerns

---

[17] Title VI replaced the provisions regarding stratospheric ozone depletion enacted in 1977. P.L. 101-549, section 601 (1990).

presented in the $\underline{PM_{10}}$ litigation in one respect, and that difference argues yet more strongly against EPA's consideration of such concerns. In the $\underline{PM_{10}}$ litigation, AISI alleged that pollution control efforts would cause unemployment, which in turn would cause the harm to public health. In contrast, there is no causal connection whatsoever between ozone or PM reduction and either the buildup of greenhouse gases or stratospheric ozone depletion. Both of the environmental hazards cited by the commenter (and the health effects they potentially cause) would occur whether or not efforts were made to control PM or tropospheric ozone. All that this commenter alleges is that PM and tropospheric ozone mitigate the harm to public health caused by the independent environmental hazards known as global warming and stratospheric ozone depletion. Nothing in the statute or its legislative history suggests that Congress intended EPA to set a less protective NAAQS because the pollutant of concern might mitigate the harmful health effects of a wholly independent, environmental hazard. Indeed, as discussed above, the 1977 amendments and their legislative history indicate, to the contrary, that Congress did not intend EPA to set less protective NAAQS even if CASAC advised that implementation of NAAQS might cause adverse public health effects. Further, Congress' directive to protect particularly sensitive populations such as asthmatics would be vitiated if EPA had to set a less protective NAAQS to account for the NAAQS pollutant's potential to mitigate a different type of harm caused by an independent environmental problem that may affect other members of the public.

Even if the law had been written in such a way as to permit consideration of these hypothesized disbenefits and if, as the commenter has not shown, the available science permitted some quantification of such effects, EPA believes that it would be bad public policy to place any weight on this issue in reaching a decision on the PM standards. EPA does not believe it is appropriate or, as noted above, consistent with the intent of the framers of the Clean Air Act to consider increasing, or leaving at arbitrarily high levels, air pollutants that have direct effects on public health in certain sensitive populations in order to mitigate the effects of another pollution-induced problem, in this case increased UV-B or global warming. This would mean balancing the risks of adverse effects of breathing PM in the elderly, children that have asthma or other respiratory problems, and other sensitive groups with an attempt to intermittently reduce the risk of UV-B penetration that has been increased by CFC and other anthropogenic pollutants. Such a policy would ignore critical issues of equity and the distribution of relative risks.

Furthermore, this commenter has pointed to no convincing basis for considering such effects in the PM Criteria Document or elsewhere. The potential influence of aerosols in mid-latitude regions in controlling the transmission of solar UV-B radiation has been dealt with in only one article, Liu et al. (1991), which was mentioned by the commenter. This study was based on a model of the size distribution and optical properties of an idealized rural aerosol. Not enough information is available from this one calculation to permit an assessment of the effects of aerosol on UV-B transmission in urban areas or in rural areas with different aerosol properties. A quantitative risk assessment of the effects of aerosol reductions on the transmission of harmful

UV-B radiation to the surface would need to be based on radiative transfer calculations that incorporate data for the vertical distribution of the aerosol, the abundances of other scatterers and absorbers, the angular dependence of the scattered radiation (which requires information about the composition and size distribution of the aerosol), and the surface reflectivity (which requires information about surface characteristics) at a given location. This information is not available for potential changes in aerosol distribution that might result from meeting the fine particle standards. Moreover, because of the natural variability of pollutant concentrations in the atmosphere, the relative "protection" afforded by aerosol varies greatly from day to day, and any benefits would be irregular and unreliable. Estimates would have to be performed for a number of locations across the United States because of variations in all of the above parameters. In essence, the available information does not allow development of reliable estimates of any disbenefits.

Such information as is available suggests that any effect of a change in fine mass from current U.S. levels to those required by the new standards on aerosol UV-B shielding is likely to be small. Based on the observation that the stratosphere is responsible for on the order of 90% of shielding from UV-B, it is clear that the reductions in ozone depleting chemicals mandated by Title VI of the Act and the Montreal Protocol would dwarf the potential benefits of keeping tropospheric PM at levels that would not protect the health of populations sensitive to inhaling that pollutant. Reducing ozone depleting substances is clearly the appropriate way to address the effects of anthropogenic pollutants on UV-B, as it directly addresses the source of the largest problem.

Likewise, reliable assessments of the health effects due to climate change have yet to be performed. It is generally agreed that the negative radiative forcing exerted by tropospheric aerosols worldwide is sufficient in magnitude to offset the positive radiative forcing of the so-called greenhouse gases, at least in a globally averaged sense. However, it is not yet clear if this result can be directly translated into a cancellation of the potential climate response exerted by the greenhouse gases as the high degree of spatial heterogeneity of the aerosol burden may also lead to alterations in atmospheric dynamics. The tools to address these issues have yet to be developed.

For reasons detailed above, EPA rejects the recommendations of this commenter on legal, policy, and technical grounds. Most importantly EPA rejects the notion that air quality standards should be based on a principle of mitigating problems caused by anthropogenic emissions of pollutants such as CFCs and greenhouse gases by increasing -- or leaving at arbitrarily high values -- the levels of air quality standards for other pollutants whose presence in the air directly harms public health and welfare.

7. Miscellaneous comments

This section addresses various comments not addressed above.

(1) *Comment*: The EPA erred by not releasing, simultaneously with the revised air quality criteria, guidance on control techniques as required by § 108(b)(1) of the Act (AAMA, IV-D-2243; GM, IV-D-2694; Exxon, IV-D-2113; NAIMA, IV-D-2161).

Response: Any such error would not affect the validity of the NAAQS themselves, which are to be based on air quality criteria containing the kinds of information specified in section 108(a)(2). In any event, section 108(b)(1) relates only to the initial issuance of criteria for a newly listed air pollutant. Where, as here, the Agency reissues such criteria for a NAAQS pollutant, the controlling provision is section 108(c). Section 108(c) states: "The Administrator shall from time to time review, and *as appropriate*, modify and reissue any criteria or information on control techniques issued pursuant to this section." 42 U.S.C. 7408(c) (emphasis added). As the statutory language makes clear, whether and when the modification or reissuance of a control techniques document is appropriate is left to the Administrator's discretion. In this instance, EPA has periodically issued control techniques information for specific particulate matter source categories such as residual wood combustion, agricultural and silvicultural open burning, and for sources of open fugitive dust as a means of supplementing the document Control Techniques for Particulate Emissions from Stationary Sources, Volumes 1 and 2, issued in September 1982. As part of EPA's continuing efforts to periodically update control techniques information, EPA plans to issue in the near future new guidance on control techniques for industrial stationary sources of particulate emissions to support the States and others in implementing the revised PM NAAQS including the $PM_{2.5}$ standards.

(2) *Comment*: EPA did not provide sufficient notice for the public hearings, and holding simultaneous hearings at four different locations and limiting the time for presentations to five minutes precluded effective participation; some commenters also sought additional hearings in the Southeast and the Southwest (ATA, IV-D-2245; BRPC, IV-D-7983; Russell Corp., IV-D-7990).

Response: When announcing the proposed decisions on November 27, 1996, EPA made widely available copies of the proposal notice, which clearly indicated that the date and location of the public hearing would be announced in a separate notice. Because of the strong public interest expressed, EPA decided to hold separate hearings at four locations to give interested parties more opportunity to participate. The EPA announced the dates, times, and locations of the hearings as soon as the necessary arrangements had been made - 3 weeks in advance. Because of the unusually large number of individuals who wanted to participate, it was necessary to limit oral presentations to five minutes. Under the circumstances, it was not feasible to hold public hearings in every region of the country; by holding four public hearings,

EPA has more than satisfied the requirements of the Act to provide an opportunity for oral comments. In addition to the public hearings, EPA also solicited comment by voice mail, e-mail, fax, and written comments.

(3) *Comment*: EPA must explain the PM proposal's departure from prior decisions to reaffirm NAAQS for sulfur oxides and nitrogen dioxide, which were based on scientific evidence no more solid than the highly uncertain evidence on which EPA proposes a revised PM standard (GM, IV-D-2694).

Response: The basis and rationale for EPA's decisions that revisions to sulfur oxides (SO_2) and nitrogen dioxide (NO_2) NAAQS were not appropriate were discussed in detail in the preambles to those rules (see 61 FR 25566, May 22, 1996; 61 FR 52852, October 8, 1996). Section II of the PM proposal notice (61 FR 65719, December 13, 1996) discusses in detail the basis and rationale for EPA's proposed decision to revise the PM standards. In EPA's periodic reviews of NAAQS, such factors as the nature and severity of the health effects involved, the size of sensitive population(s) at risk, the types of health information available, and the kind and degree of uncertainties that must be addressed vary from one pollutant to another. As a result, the decision whether and, if so, how the NAAQS for a given pollutant should be revised is necessarily specific to that pollutant and to the state of scientific knowledge available to the Administrator at the time of her decision. Thus, each standard review must be based on careful assessment of the available information in the air quality criteria for the pollutant in question. In the present case, EPA believes that the basis and rationale for the Administrator's decision to revise the PM NAAQS are fully explained in the preamble to the final rule and supporting documents, and that the decision is amply supported by the record.

(4) *Comment*. The EPA's decision to modify the NAAQS for particulate matter, which includes sulfates and nitrates derived from SO_2 and NO_2, but not the SO_2 and NO_2 standards, to control sulfates and nitrates appears inconsistent and arbitrary (GM, IV-D-2694).

Response: It has been EPA's longstanding position that secondary particles, such as sulfates and nitrates, should be considered during review of the PM NAAQS (see 49 FR 10408, March 20, 1984). The SO_2 and NO_2 NAAQS focus on the direct health effects of the gas phase precursors to PM.

(5) *Comment*: Revision of the PM standard is not appropriate or should be deferred in light of continuing improvements in air quality and reductions in PM resulting from the implementation of 1990 Act amendments (UARG, IV-D-2250; AAMA, IV-D-2243; AISI, IV-D-2242).

Response: Under section 109(d), the fact that air quality is improving is not an appropriate basis for declining to revise the NAAQS for PM or for deferring revisions the Administrator judges to be appropriate. Emission reductions to be achieved through the 1990 Amendments and

resulting improvements in $PM_{2.5}$ ambient concentrations will be taken into account in developing control strategies for implementing the revised PM standards.

(6) *Comment*: EPA's proposal violates virtually every aspect of the legal standard for setting NAAQS under section 109, which requires EPA to demonstrate that the pollutant in question has an actual adverse effect on public health, because: 1) EPA has not substantiated its methodologies for predicting health risk at levels below the current standards, 2) EPA has not established that the existing PM_{10} standards present an unacceptable risk of harm to public health, and 3) EPA has not shown that any $PM_{2.5}$ standard more stringent than the current PM_{10} standards is requisite to protect public health (UARG, IV-D-2250).

Response: Section 109(d) requires the Administrator to review the air quality criteria and NAAQS for a pollutant periodically and to "make such revisions in such criteria and standards and promulgate such new standards as may be appropriate" in accordance with sections 108(a) and 109(b), respectively. Section 109(b)(1) requires the Administrator to set NAAQS at levels which, in her judgment, will protect public health with an adequate margin of safety. Thus, where the Administrator finds that serious health effects occur, or may occur, on a widespread basis at pollutant concentrations lower than those specified in existing NAAQS, she clearly has discretion to conclude that revision of the NAAQS is appropriate. In doing so, she may weigh risks, project trends, extrapolate from limited data, and so forth, to carry out the preventive and precautionary purposes of the Act; proof of actual harm is not required. See, e.g., H.R. Rep. No. 95-294, at 43-51 (1977). See also, e.g., Lead Industries Ass'n v. EPA, 647 F.2d 1130, 1153-56 & n.50 (D.C. Cir. 1980). For discussion of the technical points raised by the commenter, see section II of the preamble to the final rule.

(7) *Comment*: EPA has not applied the proper legal criteria for selecting a new PM standard, because 1) EPA may establish a new NAAQS only if it first finds that the pollutant presents a "significant risk" to public health, and 2) EPA's proposal failed to focus on a representative sample of the sensitive population, as opposed to allowing the responses of particularly sensitive individuals within that group to drive the decision making process, thus departing improperly from past practice as in the SO_2 NAAQS decision (focusing on 20-25% of the sensitive individuals tested)(AAMA, IV-D-2243).

Response: Given the evidence that premature mortality and other serious health effects may occur at levels below the current NAAQS, the nature and potential magnitude of the public health risks involved, and the need to consider the fine and coarse fractions of PM_{10} as distinct classes of particles, both the Administrator and CASAC concluded that the current PM standards should be revised. This conclusion is amply supported by the record and was well within the Administrator's discretion under section 109(d). See section II of the preamble to the final rule and response to comment III.B.7(6) above.

The Administrator's decisions on the final PM standards are based on overall risks to the sensitive population and not on the responses of particularly sensitive individuals within that group. See section II.A of the preamble to the final rule. In any event, the Administrator's task in revising NAAQS is to select standards which, in her judgment, will protect the public health with an adequate margin of safety. The factors relevant to that determination vary from one pollutant to another, and NAAQS decisions are necessarily specific to the pollutant and to the record before the Administrator at the time. See response to comment III.B.7(3) above. In other words, no single approach to determining what standards will protect public health with an adequate margin of safety is likely to be appropriate in all circumstances. Accordingly, both Congress and the courts have left to the Administrator's discretion the selection of an approach that will best fulfill the goals of the Act. See section IV.B of the preamble to the final rule.

(8) *Comment*: The public comment period on the PM proposal is inadequate and should be extended for periods ranging from 60 days to at least 1-year (Lange, Inc., IV-D-1257; Zurn, IV-D-5612).

Response: A 67-day comment period was originally provided, based on the schedule oredered by the court in American Lung Association v. Browner CIV-93-643 TUC-ACM (D. Ariz.). Additional time was available to interested parties because EPA distributed copies of the proposal notice widely when it was signed and announced on November 27, 1996, and the comment period itself did not commence until December 13, 1996. Also, the proposal was preceded by a lengthy scientific assessment process, in which the public had numerous opportunities, over a period of several years, to comment on EPA's assessments of the scientific information that was the basis for the proposal. At the request of commenters, EPA sought a 60-day extension of the public comment period, but the court only granted a 3-week extension.

(9) *Comment*: If rulemaking follows the current course, the final rulemaking will have to be vacated for failure to comply with section 307(d) because 1) underlying raw data has not been placed in the docket, 2) there is inadequate time for meaningful comment, and 3) there is inadequate time for EPA to respond to public comments. EPA has had numerous opportunities to discharge the court order, appeal it, or limit the impact of the order, and EPA has not taken advantage of those opportunities (UARG, IV-D-2250).

Response: With respect to the issue of underlying raw data, see section IV.C of the preamble to the final rule and response to comment III.B.5 (1) above. In EPA's judgment, the 89-day comment period, including the extension granted by the court, provided sufficient opportunity for the public to prepare and submit comments on the proposed rule. That this time was sufficient is evidenced by the number and volume of comments on these standards, which are more numerous and extensive than those for any prior NAAQS review. Finally, EPA believes there has been adequate time to respond to public comments as evidenced by the extensive

discussion of comments in the preamble to the final rule and by responses to other significant comments in this document.

(10) *Comment*: EPA's use of the PM risk assessment exceeds the scope of EPA's authority under section 108 because EPA concedes it cannot establish whether the risk assessment is measuring effects of PM on public health or, instead, is measuring the effects of a complex mixture of pollutants in urban air for which PM may serve as an index. Although section 108(a)(2) allows some consideration of co-pollutants in establishing a NAAQS, EPA cannot rely exclusively and excessively on the measurement and effects of co-pollutants in establishing NAAQS instead of evaluating the identifiable effects of PM. Further, EPA cannot rely on the risk assessment because the underlying "raw" data of the studies used as the basis for assessment were not publicly disclosed (NMA, IV-D-2158).

Response: Use of risk assessments per se is proper under section 109(b), in that NAAQS decisions are to be based on air quality criteria issued under section 108(a)(2), which are to include the latest scientific knowledge "useful in indicating the kind and extent" of the health effects that "may be expected" for varying ambient levels of the pollutant in question. The commenter's objection really goes to whether the pertinent epidemiological studies support the Administrator's conclusion that reported health effects are attributable to PM as opposed to a mixture of pollutants for which PM may serve as an index. As indicated in the Criteria Document (p. 13-31), reduction of PM exposure would lead to reductions in the frequency and severity of the health effects in question, whether the effects are attributable to PM, to a mixture of pollutants for which PM is a surrogate, or to both. In any event, EPA believes the Administrator's conclusion is amply supported by the record. See section II.B of the preamble to the final rule. Finally, the risk assessment, like the Administrator's decision on the final standards, is based on the pertinent epidemiological studies, not on the data underlying those studies, and the studies have been available for public scrutiny in the usual manner. In the circumstances presented, there is no bar to using the studies in the risk assessment or in the Administrator's ultimate decision on the standards. See section IV.C of the preamble to the final rule.

(11) *Comment*: The use of unpublished references in drafts of the criteria document and staff paper is inappropriate and unprecedented. EPA failed to make key references (e.g., Schwartz et al., 1996 manuscript) publicly available soon enough in the criteria document and staff paper development period to permit adequate time for public comment (API, IV-D-2247).

Response: It has been EPA's practice to cite papers that have been accepted for publication in the peer review literature, as well as other "gray" literature, during the preparation of drafts of the criteria document and staff paper so they can undergo the rigorous CASAC review process. Only those papers that are found to be of acceptable scientific quality are retained in the final documents. The EPA believes that there was sufficient time to review the Schwartz et

al., 1996 manuscript during the development of the Criteria Document and Staff Paper. Interested parties also had opportunities to review and comment on the paper during the more than six month period between its acceptance for publication in a peer-reviewed journal, when it was made available as an "in-press" manuscript for citation in the Criteria Document, and the publication of the proposal and to submit comment on the published paper during the 89-day public comment period.

(12) *Comment:* The current review did not provide adequate time to fully assess the available scientific information, particularly when contrasted to the last PM NAAQS review that took approximately 8 years to complete (AAMA, IV-D-2243, NMA, IV-D-2158).

Response: During the last review of the PM NAAQS, EPA developed three successive drafts of the joint Criteria Document for PM and sulfur oxides (SO_x), which added additional complexity to the task, for review by CASAC and the public. Interspersed with the preparation of these drafts, several workshops on different sections of the document were also held. The EPA also prepared two drafts of the PM Staff Paper that were reviewed by CASAC at two separate public meetings. Overall, the scientific assessment phase of the last review of the PM NAAQS, including CASAC's rendering of advice and recommendations for revised standards, was completed two years and three months after formal commencement of the review.

After formally commencing the present review, EPA held several workshops on key aspects of the Criteria Document and developed three successive drafts of all or portions of the document. The EPA also prepared two drafts of the Staff Paper. Throughout this process, the public had opportunity to express views at the public workshops, as well as at public CASAC meetings on the Criteria Document and Staff Paper drafts. Overall, the scientific assessment phase of the present review, including recommendations by CASAC and staff that the existing PM_{10} NAAQS be revised, was completed two years and two months after the initial announcement. This is only one month less than it took to reach a comparable point in the previous review.

While it is true that in the prior review it took an additional two years beyond CASAC closure on the science, to propose revisions to the original standards and an additional three years to promulgate those revisions, this is not an appropriate model for NAAQS reviews. The delay between completion of the scientific assessment phase and proposal was not occasioned by the need for further scientific assessment, but by the focus of EPA decision makers on unrelated issues, including a change in EPA management and the transition to a new Administrator and Assistant Administrator. Ultimately, these unrelated factors stretched the process to such a degree that, for both PM and SO_x, it was deemed necessary to update the Criteria Document and Staff Paper to reflect additional scientific findings. These updated findings did not alter the fundamental components of CASAC's recommendations or the proposed decisions on PM.

Although EPA has been under court order imposing a schedule for completion of the current review, EPA has sought and obtained modifications to provide additional time for the conduct of the scientific assessment phase of this review. As a result, the time provided for this aspect of the review was only two weeks shorter than the time EPA initially sought from the court. Notwithstanding the constraints imposed by the court order, EPA has conducted a thorough, comprehensive review of the scientific criteria and standards for PM. The procedures permitted full public participation in the process, and the time taken was commensurate with that taken in the previous review.

B. Regulatory and Environmental Impact Analyses

1. Compliance with E.O. 12866

This section addresses comments that EPA failed to comply with the provisions of E.O. 12866.

(1) *Comment*: Commenters assert that EPA erred by not complying with the requirement of E.O. 12866 to select among regulatory alternatives that are most cost-effective and maximize net benefits. Further, they say EPA did not examine alternative means to achieving its objectives that are more cost-effective, as it did in the SO_2 NAAQS decision (see API, IV-D-2247; State of N.C., IV-D-7003; NMA, IV-D-2158).

Response: For reasons discussed in section IV.A of the preamble to the final rule, the cited requirement of E.O. 12866 is inapplicable to NAAQS decisions. Moreover, the SO_2 NAAQS decision is not analogous to this rulemaking. In SO_2, EPA determined, based on its assessment of relevant scientific and technical information, that revisions to the SO_2 NAAQS were not appropriate for the reasons discussed in the preamble to the final rule (61 FR 25566; May 22, 1996). As in this case, EPA did not consider cost-effectiveness or the results of the Regulatory Impact Analysis in reaching its decision on the SO_2 NAAQS.

2. Regulatory Flexibility Act

This section addresses comments that EPA's failure to prepare a regulatory flexibility analysis and to convene a Small Business Advocacy Review Panel violates the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Act.

(1) *Comment*: A large number of commenters maintained that EPA's certification that the proposed revision to the PM NAAQS would not have significant economic impact on a substantial number of small entities and EPA's failure to prepare a regulatory flexibility analysis or convene a Small Business Advocacy Review Panel clearly violated the intent and plain language of the law. To support this position, several commenters presented extensive legal

analysis (see NAM, IV-D-2274; ATA, IV-D-2245; AAMA, IV-D-2243).

Response: See section VIII.B. and section IV.A of the preamble to the final rule.

(2) *Comment*: It was also maintained 1) that the NAAQS itself will have significant impact on small business and that small business will bear a disproportionate impact; 2) that EPA's position that it cannot prepare a regulatory flexibility analysis is baseless (citing the PM RIA); 3) that EPA's informal, ad hoc overtures to small business are inadequate to satisfy SBREFA; and 4) that had EPA complied with statutory requirements, alternatives with less burdensome impacts on small business would have been identified (see ATA, IV-D-2245; NAM, IV-D-2274; AAMA, IV-D-2243; API, IV-D-2247; UARG, IV-D-2250).

Response: See section VIII.B. and section IV.A of the preamble to the final rule. See also summary and response to comments for the small business outreach meetings.

(3) *Comment*: A commenter argued that the only possible and appropriate time for EPA to comply with the RFA as amended by SBREFA is at the NAAQS revision stage since EPA acknowledges that it will not perform an RFA analysis at the SIP approval stage and if it were to do so, conducting 50 different RFAs would result in bureaucratic duplication and inefficiency. The commenter argued that EPA cannot "segment" its analysis in order to completely avoid RFA requirements (AAMA IV-D-2243).

Response: See sections VII.B and IV.A of the preamble to the final rules. As noted therein, the Clean Air Act requires EPA to set a NAAQS and calls on States to develop and submit SIPs within a specified period of time after EPA issues the standard. Any "segmentation" that occurs thus results from the structure and requirements of the Clean Air Act and not from any EPA action or design. More importantly, the purpose of the RFA is to motivate federal regulators to design federal regulations in a way that fits the scale of the entities that will be subject to those regulations. That purpose cannot be served in the case of the NAAQS, since NAAQS simply define a level of air quality to be achieved everywhere in the country primarily through State regulation. Further, the RFA does not require or authorize EPA to disapprove a State's implementation plan because of the State's choice of sources to regulate. Fundamentally, the congressionally-designed mixture of Federal and State responsibilities for achieving clean air makes the RFA inapplicable to either setting or implementing the NAAQS, except to the extent EPA promulgates federal regulations establishing control requirements that will apply to small entities (e.g., reformulated gasoline standards).

(4) *Comment:* A number of commenters argued that EPA's claim that it cannot perform an RFA analysis is baseless and cited a variety of figures from EPA's RIA suggesting economic

disruption or differential impact on small businesses (NAM IV-D-2274; API IV-D-2233; UARG, IV-D-2253; NMA, IV-D-2247).

Response: See sections VII.B and IV.A of the preamble to the final rules. As explained therein, EPA has attempted in the RIA to provide some insight into the potential impact on small entities of NAAQS implementation. In light of States' role in implementing the NAAQS, however, the RIA can assess only hypothetical State control strategies. As such, the RIA cannot and does not take the place of an RFA analysis, which is supposed to identify the types of small entities that will be subject to the federal rule being promulgated and ways of tailoring the rule to the size of the small entities being regulated. The RIA's small entity analysis, by necessity, depends on hypothetical State control strategies that may not occur and that EPA is not in a position to control.

3. Unfunded Mandates Reform Act

This section addresses comments that EPA failed to comply with the requirements of the Unfunded Mandates Reform Act (UMRA).

(1) *Comment*: EPA erred because it failed to comply with the requirements of UMRA. EPA is obligated to prepare a section 202 written statement, to conduct outreach efforts with small governments pursuant to a small government plan under section 203, and to solicit and evaluate input from State, local, and tribal officials under section 204. Finally, EPA's present failure to comply with UMRA is inconsistent with the SO_2 and NO_2 NAAQS decisions in which EPA did not disclaim application of UMRA. (NAM, IV-D-2274; ATA, IV-D-2245; AAMA, IV-D-2243; API, IV-D-2247).

Response: See section VIII.D and section IV.A of the preamble to the final rule. See also summary and response to key issues raised at outreach meetings with State and local officials.

IV. MISPLACED COMMENTS

A. Comments on implementation-related issues

1. Attainability of standards

This section addresses comments pertaining to the attainability of the proposed PM standards.

(1) *Comment*: Attaining a $PM_{2.5}$ standard would impose significant economic burdens, and such a standard may not be attainable in some areas (API, IV-D-2242).

Response: As discussed in section IV.A of the preamble to the final rule, the costs and technological feasibility of attaining ambient standards are not to be considered in setting them.

2. $PM_{2.5}$ Monitoring Issues

This section addresses comments that the $PM_{2.5}$ monitoring program will have a financial impact on the States.

Comment: Several commenters expressed concern about the financial burden that establishment of a $PM_{2.5}$ monitoring program would impose upon the States (IES Industries, IV-D-2150; Maricopa Co., Arizona, IV-D-2227).

Response: The preamble to the final 40 CFR part 58 requirements addresses comments concerning the cost of the $PM_{2.5}$ monitoring network.

2. Implementation issues

A number of commenters submitted comments regarding implementation issues that are not relevant to the PM NAAQS review. Therefore, they are not being responded to in this document.

B. Comments on Regulatory Impact Analyses

This section addresses comments concerning the adequacy of the Regulatory Impact Analysis (RIA).

(1) *Comment*: The RIA is inadequate because it assesses the cost of only partial attainment of the proposed standards. In addition, the benefit estimates were artificially high. Further, the analysis is incomplete because it fails to analyze the full range of control measures likely to be imposed on the transport industry, does not assess indirect impacts (e.g., increased fuel costs), and does not assess the cost of administrative burdens (ATA, IV-D-2245; AAMA, IV-D-2243).

Response: Because the costs of implementation cannot be considered in setting or revising ambient air quality standards (see section IV.A of the preamble to the final rule), the RIA was not considered in EPA's decision on the standards. For the same reason, comments on the RIA were not considered in the decision. Comments on the draft RIA were considered, as appropriate, in developing the final RIA.