ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[AD-FRL 3141-9(a)]

Revisions to the National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In 1971, EPA promulgated primary and secondary national ambient air quality standards for particulate matter, measured as "total suspended particulate matter" or "TSP." The primary standards were set at 260 $\mu g/m^3$, 24-hour average not to be exceeded more than once per year, and 75 $\mu g/m^3$, annual geometric mean. The secondary standard, also measured as TSP, was set at 150 $\mu g/m^3$, 24-hour average not to be exceeded more than once per year. In accordance with sections 108 and 109 of the Clean Air Act, EPA has reviewed and revised the health and welfare criteria upon which these primary and secondary particulate matter standards were based.

On March 20, 1984 (49 FR 10408), EPA proposed changes in the standards based on its review and revision of the criteria. Today's notice announces EPA's final decisions regarding these changes. The final decisions include: (1) replacing TSP as the indicator for particulate matter for the ambient standards with a new indicator that includes only those particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM_{10}), (2) replacing the 24-hour primary TSP standard with a 24-hour PM_{10} standard of 150 $\mu g/m^3$ with no more than one expected exceedance per year; (3) replacing the annual primary TSP standard with a PM_{10} standard of 50 $\mu g/m^3$, expected annual arithmetic mean; and (4) replacing the secondary TSP standard with 24-hour and annual PM_{10} standards that are identical in all respects to the primary standards.

Today's notice also announces a new Federal Reference Method for measurement of PM_{10} in the ambient air. The method is contained in a new Appendix J to Part 50. This notice also announces a new Appendix K to Part 50, which provides rules for applying the statistical form of the revised standards. In addition, certain clarifying changes to Appendix B and Appendix G are set out.

Related notices published elsewhere in today's **Federal Register** set out final regulations concerning Ambient Air Monitoring Reference and Equivalent Methods (40 CFR Part 53), Ambient Air Quality Surveillance (40 CFR Part 58), Regulations for Implementing Revised Particulate Matter Standards (40 CFR Part 51) with associated guidelines, Approval and Promulgation of Implementation Plans (40 CFR Part 52), and Prevention of Significant Deterioration (Parts 51 and 52).

EFFECTIVE DATE: This action is effective July 31, 1987.

ADDRESSES: A docket (No. A-82-37) containing information related to EPA's review and revision of the particulate matter standards is available for public inspection between 8:00 a.m. and 3:00 p.m. on weekdays at EPA's Central Docket Section, South Conference Center, Room 4, 401 M St., SW., Washington, DC. A reasonable fee may be charged for copying. The information in the docket constitutes the complete basis for the decisions announced in this notice. For the availability of related information see **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Mr. John Haines, Strategies and Air Standards Division (MD-12), U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711, telephone (919) 541-5531 (FTS 629-5531).

SUPPLEMENTARY INFORMATION:

Availability of Related Information

The revised criteria document, Air Quality Criteria for Particulate Matter and Sulfur Oxides (three volumes, EPA-600/8-82-029af-cf, December, 1982; Volume I NTIS #PB-84-120401, $24.95 paper copy and $6.50 microfiche; Volume II NTIS #PB-84-120419, $48.95 paper copy and $6.50 microfiche; Volume III NTIS #PB-84-120427, $48.95 paper copy and $13.50 microfiche, the Second Addendum to Air Quality Criteria for Particulate Matter and Sulfur Oxides (1982): Assessment of Newly Available Health Effects Information, (EPA/600/8-86-020-F, NTIS #PB-87-176574, $24.95 paper copy and $6.50 microfiche), the 1982 staff paper, Review of the National Ambient Air Quality Standards for Particulate Matter: Assessment of Scientific and Technical Information-OAQPS Staff Paper (EPA-450/5-82-001, January, 1982; NTIS #PB-82-177874, $24.95 paper copy and $6.50 microfiche), and the staff paper addendum, Review of the National Ambient Air Quality Standards for Particulate Matter: Updated Assessment of Scientific and Technical Information (EPA-450/ 5-86-012, December 1986; NTIS #PB-87-176871, $18.95 paper copy and $6.50 microfiche) are available from: U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (add $3.00 handling charge per order). A limited number of copies of other documents generated in connection with this standard review, such as the control techniques document, can be obtained from: U.S. Environmental Protection Agency Library (MD-35), Research Triangle Park, N.C. 27711, telephone (919) 541-2777 (FTS 629-2777).

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I. Background

A. Legislative Requirements Affecting This Rule

1. The Standards

Two sections of the Clean Air Act govern the establishment and revision of national ambient air quality standards (NAAQS). Section 108 (42 U.S.C. 7408) directs the Administrator to identify pollutants which may reasonably be anticipated to endanger public health or welfare and to issue air quality criteria for them. These air quality criteria are to reflect the latest scientific information useful in indicating the kind and extent of all identifiable effects on public health or welfare that may be expected from the presence of a pollutant in the ambient air.

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants identified under section 108. Section 109(b)(1) defines a primary standard as one the attainment and maintenance of which, in the judgment of the Administrator, based on the criteria and allowing for an adequate margin of safety, is requisite to protect the public health. A secondary standard, as defined in section 109(b)(2), must specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on the criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. Welfare effects are defined in section 302(h) (42 U.S.C. 7602(h)) to include effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, climate, damage to and deterioration of property, hazards to transportation, and effects on economic values and on personal comfort and well-being.

The U.S. Court of Appeals for the D.C. Circuit has held that the requirement for an adequate margin of safety for primary standards was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980), *cert. denied*, 101 S. Ct. 621 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1177 (D.C. Cir. 1981), *cert. denied*, 102 S. Ct. 1737 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, by selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful, but also to prevent lower pollutant levels that he finds pose an unacceptable risk of harm, even if that risk is not precisely identified as to nature or degree.

In selecting a margin of safety, EPA has considered such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. Given that the "margin of safety" requirement by definition only comes into play where no conclusive showing of harm exists, such factors, which involve unknown or only partially quantified risks, have their inherent limits as guides to action. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association v. EPA, supra*, 647 F.2d at 1161–62.

Section 109(d) of the Act (42 U.S.C. 7409(d)) requires periodic review and, if appropriate, revision of existing criteria and standards. The process by which EPA has reviewed the original criteria and standards for particulate matter under section 109(d) is described in Sections I.C. and I.D. of this notice.

2. Related Control Requirements

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the Act (42 U.S.C. 7410), States are to submit, for EPA approval, State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. Other Federal programs provide for nationwide reductions in emissions of these and other air pollutants through the Federal Motor Vehicle Control Program under Title II of the Act (42 U.S.C. 7501 to 7534), which involves controls for automobile, truck, bus, motorcycle, and aircraft emissions, and through the development of New Source Performance Standards under section 111 (42 U.S.C. 7411) and National Emission Standards for Hazardous Air Pollutants under section 112 (42 U.S.C. 7412).

B. Particulate Matter and Original Standards for TSP

"Particulate matter" is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes. Particles originate from a variety of stationary and mobile sources. They may be emitted directly or formed in the atmosphere by transformations of gaseous emissions such as sulfur oxides, nitrogen oxides, and volatile organic substances. The chemical and physical properties of particulate matter vary greatly with time, region, meteorology and source category, thus complicating the assessment of health and welfare effects. The characteristics, origins, concentrations, and potential effects of particulate matter are discussed in more detail in the staff paper (SP) (EPA, 1982a), in the revised criteria document (CD) (EPA, 1982b), in the criteria document addendum (CDA) (EPA, 1986a) and in the staff paper addendum (SPA) (EPA, 1986b). The executive summary of the staff paper addendum is reprinted in Addendum III to this notice.

On April 30, 1971 (36 FR 8186), EPA promulgated the original primary and secondary NAAQS for particulate matter under section 109 of the Clean Air Act. The reference method for measuring attainment of these standards is the "high-volume" sampler (40 CFR Part 50, Appendix B), which collects particulate matter up to a nominal size of 25 to 45 micrometers (μm) (so-called "total suspended particulate," or "TSP"). Thus, TSP is the current indicator for the particulate matter standards. The existing primary standards for particulate matter (measured as TSP) are 260 $\mu g/m^3$, 24-hour average not to be exceeded more than once per year, and 75 $\mu g/m^3$, annual geometric mean. The secondary standard (measured as TSP) is 150 $\mu g/m^3$, 24-hour average not to be exceeded more than once per year. The scientific and technical bases for these standards are contained in the original criteria document, Air Quality Criteria for Particulate Matter (DHEW, 1969).

C. Development of Revised Air Quality Criteria for Particulate Matter

In 1976, as a result of internal Agency review and the recommendations of a committee of EPA's Science Advisory Board, EPA decided to revise the existing criteria document for particulate matter. Because of competing priorities regarding revision of other criteria documents, and because of the need to complete additional research on particulate matter, the process was scheduled to commence in 1979. With the endorsement of the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board, EPA decided to review and revise the criteria document for particulate matter concurrently with that for sulfur oxides and to produce a combined particulate matter/sulfur oxides (PM/SO_x) criteria document. On October 2, 1979 (44 FR 56731), EPA announced that it was in the process of revising the criteria document and reviewing the existing air quality standards for possible revisions.

In developing the revised criteria document, EPA has provided a number of opportunities for review and comment by organizations and individuals outside the Agency. Three drafts of the revised particulate matter/sulfur oxides criteria document, prepared by EPA's Environmental Criteria and Assessment Office (ECAO), were made available for external review on April 11, 1980 (45 FR 24913), January 29, 1981 (46 FR 9746), and October 28, 1981 (46 FR 53210). EPA received and considered numerous and often extensive comments on each of these drafts. CASAC held three public meetings to review successive drafts of the document on August 20–22, 1980 (45 FR 5164, August 4, 1980), July 7–9, 1981 (46 FR 31746, June 17, 1981), and November 16–18, 1981 (46 FR 53210, October 28, 1981). These reetings were open to the public and were attended by many individuals and representatives of organizations who provided critical reviews and new information for consideration. In accordance with CASAC recommendations made after the first review meeting, five additional public meetings were held at which EPA, its consulting authors and reviewers, and other scientifically and technically qualified experts selected by EPA discussed the various chapters of the draft document and suggested ways of resolving outstanding issues (45 FR 74047, November 7, 1980; 45 FR 78224, November 25, 1980; 45 FR 76790, November 20, 1980; 45 FR 80350, December 4, 1980; 46 FR 1775, January 7, 1981).

The comments received on the successive drafts of the revised criteria document were considered in the final document, issued simultaneously with the proposal of revisions to the standards. A summary of EPA's responses to the comments on the three external review drafts of the documents is in the public docket (Docket No. A-82–37). Transcripts of the three CASAC meetings are also in the docket. In accordance with its established procedures, CASAC prepared a "closure" memorandum to the Administrator indicating its satisfaction with the final draft (December, 1981) of the criteria document and outlining key issues and recommendations. The closure memorandum, dated January 29, 1982, stated that the EPA office that prepared this document was "responsive to Committee advice as well as to comments provided by the general public . . ." The closure memorandum further stated that the criteria document "fulfills the requirements set forth in section 108 of the Clean Air Act, which requires that the criteria document 'shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare' from sulfur oxides and particulates in the ambient air." The CASAC closure memorandum on the criteria document is reprinted in its entirety in Addendum I to this notice. Following closure, minor technical and editorial refinements were made to the criteria document for printing (EPA, 1982b).

A number of scientific and technical issues were raised during the public review process. With respect to the particulate matter portions of the criteria document, the major issues included the relationship among various measures of particulate matter air quality, the implications of particle deposition and other studies for selecting a particulate matter indicator, and the development and application of criteria for deciding which epidemiological studies are most appropriate for use in revising air quality standards. A summary of these and other major scientific issues, as well as CASAC's conclusions, is included in the closure memorandum on the criteria document (Addendum I).

D. Review of the Standards: Development of Staff Paper

In the evolving process of revising the national ambient air quality standards, EPA has found it useful to prepare a document that helps bridge the gap between the scientific review of health and welfare effects contained in the criteria document and the judgments required of the Administrator in setting ambient standards. This document, known as the staff paper, has become an important element in the standards review process, providing an opportunity for public comment on proposed staff recommendations before they are presented to the Administrator.

In the spring of 1981, EPA's Office of Air Quality Planning and Standards (OAQPS) prepared the first draft of the staff paper, Review of the National Ambient Air Quality Standards for Particulate Matter: Assessment of Scientific and Technical Information. This draft staff paper, based on the then existent draft of the revised criteria document, evaluated and interpreted the available scientific and technical information most relevant to the review of the air quality standards for particulate matter and presented staff recommendations on alternative approaches to revising the standards. This and a second draft of the paper were reviewed at two CASAC meetings on July 7–9, 1981 (46 FR 31746, June 17, 1981), and November 16–18, 1981 (46 FR 53210, October 28, 1981). Numerous written and oral comments were received on the drafts from CASAC, representatives of organizations, individual scientists, and other interested members of the public. A summary of major revisions made in response to comments on the first draft is contained in an October 31, 1981 letter to CASAC (Padgett, 1981). Following the second CASAC meeting, the staff made further revisions in response to comments and prepared an executive summary that was reviewed by CASAC members before preparation of the closure memorandum on the staff paper. In January, 1982, EPA released the final OAQPS staff paper (EPA, 1982a), which reflects the various suggestions made by CASAC and members of the public. The January 29, 1982, CASAC closure memorandum states that the staff paper "has been modified in accordance with recommendations made by CASAC," is consistent with the criteria document, and provides the Administrator "with the kind and amount of technical guidance that will be needed to make appropriate revisions to the standard." This closure memorandum is reprinted in Addendum II to this notice.

A number of major issues were raised during the public review process. The more important issues are outlined below.

1. Substantial discussion concerned the maximum size of particles (or particle size fraction) to be used in measuring particulate matter for regulatory purposes. Some groups favored retaining TSP as an indicator;

others called for alternative size-specific standards with nominal "size cuts" ("D_{50}"; see discussion in Section III.A.) of 15 μm, 10 G6mm, 5–7 G6mm, and 2.5 G6mm. After CASAC closure on the staff paper and criteria document, comments were received from one group favoring a so-called "D_0" of 10 μm (approximately equivalent to a nominal size cut [D_{50}] of 6 μm).

2. Much attention was focused on selecting the level of the primary standards and on the question of which health effects studies were most appropriate for this purpose. Significant criticisms were received on the major epidemiological studies of particulate matter exposures, highlighting their limitations for use in standard setting. In a number of comments, specific suggestions for standards were made.

3. With respect to secondary standards, most attention focused on the possible need for a fine (≦2.5 G6m) particle standard designed to protect visibility.

These and other major issues are discussed more fully in the executive summary of the staff paper and in later sections of this notice. CASAC's discussion of these issues and its recommendations are contained in the closure memorandum on the staff paper (Addendum II).

E. Proposed Revisions to the Standards

On March 20, 1984 (49 FR 10408) EPA proposed a number of revisions to the primary and secondary particulate matter standards. The proposed revisions, based on the revised criteria, included:

(1) Replacing TSP as the indicator for particulate matter for the primary standards with a new indicator that includes only those particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM_{10});

(2) Changing the level of the 24-hour primary standard to a value to be selected from a range of 150 to 250 μg/m³ and replacing the deterministic form of the standard, which permitted not more than one observed exceedance of the standard per year, with a statistical form that would permit one expected exceedance per year;

(3) Changing the level of the annual primary standard to a value to be selected from a range of 50 to 65 μg/m³, and changing the form from an annual geometric mean to an expected annual arithmetic mean; and

(4) Replacing the current 24-hour secondary TSP standard by an annual TSP standard selected from a range of 70 to 90 μg/m³, expected annual arithmetic mean.

The Administrator expressed an inclination to select the primary standards from the lower portions of the above ranges. With respect to the secondary standards, the Administrator was inclined to select the final standard from the upper portion of the range, but also called for comment on the alternative of using PM_{10} as the particulate matter indicator for the secondary standards and making the secondary standards identical in all respects to the primary standards. The proposal notice sets forth the rationale for these and other proposed revisions of the particulate matter NAAQS and background information related to the proposal.

F. Supplemental Criteria Revisions and Standards Review Following Proposal

Following publication of the proposal, EPA held a public meeting in Washington, D.C. on April 30, 1984 to receive comments on the proposed standards revisions. A transcript of the meeting has been placed in the public docket (Docket No. A–82–37). After the close of the original public comment period (June 5, 1985), the CASAC met on December 16–17, 1985 to review the proposal and to discuss the relevance of certain new scientific studies on the health effects of particulate matter that had emerged since the Committee completed its review of the criteria document and staff paper in January, 1982. A transcript of this meeting is also available in the Docket. Based on its preliminary review of these new studies, the Committee recommended that the Agency prepare separate addenda to the criteria document and staff paper for the purpose of evaluating the relevant new studies and discussing their potential implications for standard-setting. The Agency announced its acceptance of these recommendations on April 1, 1986 (51 FR 11058). On July 3, 1986, EPA announced (51 FR 24392) the availability of the external review draft document entitled: Second Addendum to Air Quality Criteria for Particulate Matter and Sulfur Oxides (1982): Assessment of Newly Available Health Effects Information. At the same time, the Agency announced a supplementary comment period on the March 20, 1984 proposal to provide the public an opportunity to comment on the implications of the new studies and addenda for the final standards. On September 16, 1986, EPA announced (51 FR 32878) the availability of the draft staff paper addendum entitled Review of the National Ambient Air Quality Standards for Particulate Matter: Updated Assessment of Scientific and Technical Information. CASAC held a public meeting on October 15–16, 1986 to review both the criteria document addendum and the staff paper addendum. At this meeting, CASAC members as well as representatives of several organizations, provided critical review of both EPA documents. A transcript of the CASAC meeting has been placed in the public docket (A–82–37).

The CASAC sent a closure letter on the criteria document addendum to the Administrator dated December 15, 1986, which concludes "that this 1986 Addendum along with the 1982 Criteria Document, previously reviewed by CASAC, represent a scientifically balanced and defensible summary of the extensive scientific literature on these pollutants" (Lippmann, 1986b). The closure letter on the criteria document addendum is reprinted in Addendum I of this notice. The Committee sent their closure letter on the staff paper addendum to the Administrator dated December 16, 1986, stating "The Committee believes that this document provides you with the kind and amount of technical guidance that will be needed to make appropriate revisions to the standards" (Lippmann, 1986c). The closure letter on the staff paper addendum, which also discusses major issues addressed by the CASAC and the Committee's recommendations concerning these issues, is reprinted in Addendum II to this notice. The final addenda to the criteria document (EPA, 1986a) and the staff paper (EPA, 1986b), which include revisions to reflect comments from CASAC and the public, are available from the address listed above. Where there are differences between the 1982 Criteria Document and staff paper and the more recent addenda, the addenda supersede the earlier document. The executive summary of the staff paper addendum is reprinted in Addendum III to this notice.

II. Summary of Public Comments

The following discussion summarizes in general terms the comments received from the public and from governmental agencies regarding the proposed revisions to the indicator, form, averaging times, and levels of the primary and secondary standards. Many of these comments had been made previously by the public during public deliberations on drafts of the criteria document and staff paper and were reviewed and addressed by EPA in revisions to those documents. Salient comments on all aspects of the proposal and Agency responses to those comments are summarized by category in Section VI of this notice. A more

detailed description of individual comments and Agency responses has been entered in the public docket (No. A-82-37).

A. Comments on 1984 Proposal

Extensive written comments were received during the original comment period on the proposal, which closed June 5, 1985. Of some 312 written submissions, 153 were provided by individual industrial concerns or industry groups, 93 by State, local, and Federal government agencies and organizations, 32 by environmental and public interest groups, and 34 by individual private citizens.[1] The comments on the key elements of the proposed standards are summarized below:

(1) *Indicator for the Primary Standard:* The overwhelming majority of the comments received on this issue favored a size-selective indicator for the PM standard. Of the 147 written comments received on this issue, 108 supported the PM_{10} indicator proposed by the Agency. Most of the remaining comments were in support of alternative smaller particle size indicators including PM_6 (28 comments) and $PM_{2.5}$ (8 comments). The principal support for PM_6 came from mining and related industries.

(2) *Levels of the Primary Standards:* Comments on the proposed levels for the two primary standards were more polarized than those on the indicator. Most industry comments favored selecting the level of the standards at the upper end of the proposed ranges or above, while most of the remaining commenters favored standard levels at the lower bound of the ranges, and in some cases lower. Additional comments from individual citizens, environmental groups, and government agencies urged that the level of protection afforded by the current particulate matter standards be maintained or strengthened.

(3) *Secondary Standards:* Of the 105 written comments received on the proposed secondary standard, 44 supported retaining TSP as the indicator and 61 opposed the use of TSP. Most of the latter commenters supported the proposed alternative of making the secondary standards equal in all respects to the primary standards. Industry commenters were virtually unanimous in opposing a TSP secondary standard, while a majority (35 of 47) of government agency comments on this issued favored retaining the TSP indicator. Some of the latter commenters, however, recommended testing attainment of the TSP standard with PM_{10} monitors. Environmental groups commenting on this issue favored retaining the TSP indicator.

(4) *Form of the Standards:* A majority of the 52 comments received on this subject supported some kind of statistical 24-hour standard, but a number of industry and State and local agency commenters raised concerns with aspects of the specific form proposed. The principal concern was that the proposed form could result in misclassification of areas as non-attainment. Some industry and governmental commenters favored alternative forms for the 24-hour standards including multiple exceedance (9 comments) and percentile (8 comments) forms. These forms would permit five or more exceedances per year of the 24-hour standard. Environmental groups and other government agencies opposed multiple exceedance forms. Of 38 submissions from industry and government agencies, 26 favored a geometric mean for the annual standard over the proposed arithmetic mean.

(5) *Federal Reference Method:* While most of the comments generally supported the performance-based approach to the Federal Reference Method, many commenters favored more stringent specifications for PM_{10} samplers to ensure accurate and reliable performance under all ambient sampling conditions. Other comments and recommendations addressed specific requirements of Appendix J such as flow calibration and measurement, flow regulation, filter media, humidity control and sampler maintenance.

B. Comments on Subsequent Notice

As discussed earlier in this notice, EPA announced an additional public comment period on July 3, 1986 to address the implications of new scientific studies on the health effects of particulate matter [51 FR 24392]. Approximately 20 additional written submissions were received by the close of this comment period on November 17, 1986, 17 of which were provided on behalf of industry groups or companies, 2 from environmental groups, and 1 from a state agency. Much of the material related to evaluations of specific studies and their treatment in the staff paper addendum. The industry comments, which included submissions from consulting scientists and analysts, generally found that the new studies suffered from deficiencies that preclude placing much weight on them in standard setting. These commenters concluded that their original recommendations (summarized above) with respect to the standards remained valid. The two environmental groups felt that the findings in these new studies necessitated standards below the lower bounds of the proposed ranges.

III. Rationale for the Primary Standards

In selecting primary standards for particulate matter, the Administrator must specify: (1) the particle size fraction that is to be used as an indicator of particulate pollution; (2) the appropriate averaging times and form(s) of the standards; and (3) the numerical levels of the standards. These specifications must be considered collectively in evaluating the margin of safety afforded by particulate matter standards. Based on the assessment of relevant scientific and technical information in the criteria document and addendum, the staff paper and staff paper addendum (hereinafter "SP" and "SPA," respectively) outline a number of key factors to be considered in making decisions in each of these areas (SP, Section VI; SPA, Section IV). Both the staff and CASAC made recommendations to focus consideration on a discrete range of options. In most respects, the Administrator has adopted the recommendations and supporting reasons contained in the staff paper and addendum and the CASAC closure statements (Friedlander, 1982; Lippmann, 1986c). Rather than reiterating those discussions at length, the following discussion of the standards revisions focuses primarily on those considerations that were most influential in the Administrator's selection of particular options, or that differ in some respect from considerations that influenced the staff and/or CASAC recommendations.

A. Pollutant Indicator

Based on the staff assessment of the available scientific information, EPA concludes that (1) a separate particulate matter standard (as opposed to a combination standard for particulate matter and SO_2) remains a reasonable public health policy choice, and (2) given current scientific knowledge and uncertainties, a size-specific (rather than chemical-specific) indicator should be used. In assessing the information in the criteria document, the staff reached several conclusions summarized here (see SP, pp. 71-75):

[1] This numerical distribution of comments in each category should be compared with caution. For example, the American Iron and Steel Institute and the American Petroleum Institute submitted comments on behalf of 63 and 230 individual companies respectively, in lieu of having each of their member companies send separate comments. Similarly, comments from interest groups such as NRDC represent the views of a number of individuals.

(1) Health risks posed by inhaled particles are influenced both by the penetration and deposition of particles in the various regions of the respiratory tract, and by the biological responses to these deposited materials. Smaller particles penetrate furthest in the respiratory tract. The largest particles are deposited in the extrathoracic (head) region with somewhat smaller particles depositing in the tracheobronchial region. Still smaller particles can reach the deepest portion of the lung, the alveolar region.

(2) The risks of adverse health effects associated with deposition of typical ambient fine and coarse particles [2] in the thorax (tracheobronchial and alveolar regions of the respiratory tract) are markedly greater than those associated with deposition in the extrathoracic (head) region. Maximum particle penetration to the thoracic region occurs during oronasal or mouth breathing.

(3) The size-specific indicator for primary standards should represent those particles small enough to penetrate to the thoracic region (both the tracheobronchial and alveolar regions). The risks of adverse health effects from extrathoracic deposition of typical ambient particulate matter are sufficiently low that particles depositing only in that region can safely be excluded from the indicator.

Considering these conclusions together with other information on air quality composition, respiratory tract deposition and health effects, the need to provide protection for sensitive individuals who may breathe by mouth and/or oronasally, and the similar convention on particles penetrating the thoracic region recently adopted by the International Standards Organization (ISO, 1981), the staff recommended that the size-specific indicator include particles of diameters less than or equal to a nominal 10 μm "cut point."[3] The factors considered in the original staff recommendations for a 10 μm cut point are outlined in the staff paper (SP, pp. 75–79). This indicator is referred to as "thoracic particles" (TP) in the 1982 staff paper; it is now generally referred to as "PM_{10}." Such an indicator is conservative with respect to health protection in that it includes all of the particles small enough to penetrate to the sensitive alveolar region, and includes approximately the same proportion of larger particles as would be expected to reach the tracheobronchial region. It places substantially greater emphasis on controlling smaller particles than does a TSP indicator, but does not completely exclude larger particles from all control.

The assessment of more recent information on respiratory tract deposition in the criteria document and staff paper addenda reinforces the conclusions reached in the original staff assessment. In particular, the staff paper addendum found that: (1) the recent data do not provide support for an indicator that excludes all particles larger than 10 μm in diameter; [4] (2) the analysis used to support an alternative indicator with a nominal size cut of 6 G6mm (Swift and Proctor, 1982) significantly underestimated thoracic deposition of particles larger than 6 μm in diameter under natural breathing conditions; (3) the PM_{10} indicator generally includes a similar or larger fraction of the range of particles that can deposit in the tracheobronchial region, although it appears to be somewhat less conservative in this regard than previously thought with respect to large (G6<10 μm) particle deposition under conditions of natural mouthbreathing; and (4) the studies of tracheobronchial deposition generally involved adult subjects; recent information indicating even greater tracheobronchial deposition of particles in children than in adults provides an additional reason for an indicator that includes particles capable of penetration to the tracheobronchial region (SPA, p. 36). Consideration of these and the earlier conclusions led the staff to reaffirm its recommendation for a PM_{10} indicator (SPA, pp. 36–37). The CASAC also restated its recommendation for PM_{10} in its review of the proposal and the closure letter to the Administrator (Lippmann, 1986 a, c).

The Administrator accepts the recommendations of the staff and CASAC and their underlying rationale and has decided to replace TSP as the particle indicator for the primary standards with a new indicator that includes only those particles less than a nominal 10 μm in diameter, as specified in the Federal Reference Method (Appendix J to 40 CFR Part 50) being promulgated today. In defining the standards for particulate matter, this new indicator is termed PM_{10}.

B. Averaging Time and Form of the Standards

Few comments on the proposed standards contested the need for both 24-hour and annual primary standards for particulate matter. EPA's assessment of more recent scientific information found that the new data confirm the need for both short- and long-term standards. The alternative of a single averaging time would not provide adequate protection against potential effects from both long- and short-term exposures without being unduly restrictive. The forms for the 24-hour and annual standards are discussed below.

1. 24-hour Standard

EPA proposed that the 24-hour standard be stated in a statistical form that uses more than one year of data and accounts for variations in sampling frequency in order to predict the actual number of exceedances to be expected in an average year. When used with an appropriate standard level, the statistical form can provide improved health protection that is less sensitive to changes in sampling frequency than the deterministic form, and also can offer a more stable target for control programs. Recognition of the limitations of the deterministic form has led EPA to promulgate a statistical form for the ozone standard (44 FR 8202).

The interpretation of the statistical form of the particulate matter standard is detailed in Appendix K of the proposed regulation. The standard would be attained when the expected number of exceedances of the 24-hour standard level is no more than one per year. The expected number of exceedances per year is equivalent to the long-term average number of exceedances per year, assuming no changes in underlying emissions. Generally, the determination of the expected number of exceedance will be based on three consecutive years of data.

As a result of EPA's evaluations of evidence submitted and comments received during the public review process, the following changes have

[2] Particles in ambient air usually occur in two somewhat overlapping size distributions, fine (diameter less than 2.5 μm) and coarse (diameter larger than 2.5 pm). The two size fractions tend to have different origins and composition (SP, Appendix D).

[3] The more precise term is 50% cut point or 50% diameter (D_{50}). This is the aerodynamic particle diameter for which the efficiency of particle collection is 50%. Larger particles are not excluded altogether, but are collected with substantially decreasing efficiency and smaller particles are collected with increasing (up to 100%) efficiency. Ambient samplers with this cut point provide a reliable estimate of the total mass of suspended particulate matter of aerodynamic size less than or equal to 10 μm. See additional discussion regarding the Federal Reference Method in section V below and in the accompanying notice revising 40 CFR Part 53.

[4] The American Mining Congress (AMC, 1982) had recommended such an indicator, with a "D_0" of 10 μm. EPA estimated that the "D_{50}" of this indicator would be 6 μm.

been made to Appendix K of the proposed rule regarding:

(1) Data Capture Requirements—Appendix K to the proposed standards contained minimum data capture requirements for determining attainment of the standards. The amount of data required varies with the sampling frequency and the number of years of record. The Ambient Air Quality Surveillance regulations (40 CFR Part 58) proposed in 1984 and being promulgated today require that sampling be performed every day or every other day in areas where there is a substantial probability of nonattainment of the standards. The proposed Appendix K to the standards, however, would have permitted states to demonstrate attainment of the standards with only 12 samples per calendar quarter, even in those areas where everyday or every other day sampling is required. Commenters have argued that, for the same reasons that everyday or every other day sampling is required in areas with a substantial probability of nonattainment, 12 samples per quarter are not sufficient to establish attainment in those areas. These commenters also argued that 75 percent data capture is achievable at all sampling frequencies. EPA agrees, and therefore the final rule requires that 75 percent of the required samples must be captured each calendar quarter to establish attainment of the NAAQS.

Additional criteria for situations in which less than 3 years of representative data are available are also contained in the final rule. These criteria are intended to permit areas to determine their air quality status in a reasonable time frame during the period in which new PM_{10} monitoring is initiated, while minimizing the probability of errors in classification. Appendix K specifies that the various data requirements do not apply when the data available establishes nonattainment unambiguously. Furthermore, data not meeting the various criteria may also be sufficient to show attainment; however, such exceptions will have to be approved by the Regional Administrator in accordance with established guidance.

(2) Exceedance Calculations—EPA is modifying the formulas used to account for incomplete data in the estimation of the expected number of exceedances per year. In the proposal, these calculations were based on the assumption that the fraction of missing values that would have exceeded the standard level is identical to the fraction of measured values above that level for the entire calendar year. In the final rule, these calculations will be required on a quarterly basis, thereby taking into account possible seasonal differences in exceedance rates as well as differences in sampling frequency or data capture. The estimated annual number of exceedances is defined as the sum of the estimated exceedances for each calendar quarter. This change will accommodate situations in which sampling frequency has been increased to everyday according to the requirements of Part 58.13, and situations in which the Regional Administrator has granted a waiver of increased sampling frequency requirements for part of the calendar year under provisions of those monitoring regulations.

(3) Interpretation of the First Observed Exceedance—EPA is additionally modifying Appendix K with respect to the treatment of the first observed exceedance in order to reduce the chance of misjudging attainment status. Under the aforementioned formulas which adjust for incomplete data, a single observed exceedance could cause a site to fail the test for attainment, even if the true expected number of exceedances is less than or equal to one. Such an occurrence is especially likely if sampling is performed less frequently than everyday. In order to reduce the chances of occurrence of this situation, the final rule contains a provision that the first observed exceedance shall not be adjusted for incomplete sampling if (1) everyday sampling had not been required previously by 40 CFR 58.13, (2) there was only one observed exceedance in the calendar quarter, and (3) sampling frequency has been subsequently increased for the next 4 calendar quarters in accordance with 40 CFR 58.13. The associated reduction in misclassification errors is discussed in "Revising the National Ambient Air Quality Standards for Particulate Matter—A Selective Sampling Monitoring Strategy" which has been placed in the public docket.

With this change, the first observed exceedance can be interpreted as the only true exceedance which has occurred in the calendar quarter. This assumption is believed to be reasonable since incomplete sampling is permitted only in areas for which state implementation plans are not initially required and in areas in which maximum PM_{10} concentrations are estimated to be less than 80 percent of the level of the standard. If an area is truly in nonattainment, additional exceedances would be expected during the subsequent year of everyday sampling. If, however, everyday sampling is not initiated as required by the monitoring regulations, all observed exceedances shall be adjusted for incomplete sampling and accordingly considered in the evaluation of PM_{10} air quality status.

2. Annual Standard

The Administrator has decided to change the form of the annual standard from the current annual geometric mean to a statistical form expressed as an expected annual arithmetic mean. The expected annual arithmetic mean is equivalent to the long-term arithmetic average concentration level, assuming no changes in underlying emissions. The expected arithmetic mean is more directly related to the available health effects information than is the annual geometric mean, which is the current form of the standard. Because the arithmetic mean concentration is proportional to the sum of the daily means, it reflects the total cumulative dose of particulate matter to which an individual is exposed. Therefore, it is an appropriate indicator to protect against any health effect that depends on total dose. It is also a reasonable indicator for protecting against health effects that depend on repeated short-term high concentrations; short-term peaks have an influence on the arithmetic mean that is proportional to their frequency, magnitude, and duration. The geometric mean, on the other hand, deemphasizes the effect of short-term peak concentrations, and is heavily influenced by days of relatively clean air. For these reasons, the staff and CASAC recommended the change to an arithmetic mean.

The interpretation of the statistical form of the standard is detailed in Appendix K to the proposed regulation. Under the statistical form, the expected annual arithmetic average is determined by averaging the annual arithmetic averages from three successive years of data. The current deterministic form of the standard does not adequately take into account the random nature of meteorological variations. In general, annual mean particulate matter concentrations will vary from one year to the next, even if emissions remain constant, due to the random nature of meteorological conditions that affect the formation and dispersion of particles in the atmosphere. If only one year of data is considered, compliance with the standard and, consequently, emission control requirements, may be determined on the basis of a year with unusually adverse or unusually favorable weather conditions. The

problem of year-to-year variability is, however, reduced by averaging three years of data.

C. Level of the Standards

The original staff paper and CASAC recommendations set forth a framework for determining the levels for the proposed particulate matter standards that would protect public health with an adequate margin of safety. The discussion that follows relies heavily on that framework and on the supporting material in the staff paper and its addendum as well as the CASAC closure letters. The essential steps in this framework are summarized here.

1. Assessment of the quantitative epidemiological studies.

The criteria document and its addendum identify a small number of community epidemiological studies that are useful in determining concentrations at which particulate matter is likely to affect public health. The staff used these quantitative studies to examine concentration-response relationships and to develop numerical "ranges of interest" for possible PM_{10} standards.

A number of uncertainties associated with use of these studies must be considered in selecting an appropriate margin of safety. As discussed in the staff paper and the criteria document, and the addenda to those documents, epidemiological studies are generally limited in sensitivity and subject to inherent difficulties involving confounding variables. Moreover, many of the quantitative studies were conducted in times and places where pollutant composition may have varied considerably from current U.S. atmospheres. Most also have used British Smoke [5] or TSP as particle indicators. None of the published studies used the proposed PM_{10} indicator. Thus, assumptions must be used to convert the various results to common (PM_{10}) units (SP, pp. 96–100; SPA pp. 9–11).

2. Identification of additional margin of safety considerations.

The criteria document identifies an additional substantial body of scientific literature that, while not providing reliable concentration-response relationships for ambient exposures, does provide important qualitative insights into the health risks associated with human exposure to particles. This literature includes both quantitative and qualitative epidemiological studies, controlled human exposure experiments, and animal toxicological studies. The staff assessed this literature to identify additional factors and uncertainties that should be considered in selecting the most appropriate margin of safety (SP, pp. 100–101; 107–111, SPA pp. 52–53; 59).

3. Selection of the levels that might be considered to provide an adequate margin of safety.

The intent of the margin of safety requirement was to direct the Administrator to set air quality standards at pollution levels below those at which adverse health effects have been found or might be expected to occur in sensitive groups. Experience with the requirement has shown that the scientific data are often so inconclusive that it is difficult to identify with confidence the lowest pollution level at which an adverse effect will occur. Moreover, in cases such as the present one, the evidence suggests that there is a continuum of effects, with the risk, incidence, or severity of harm decreasing, but not necessarily vanishing, as the level of pollution is decreased.

In the absence of clearly identified thresholds for health effects, the selection of a standard that provides an adequate margin of safety requires an exercise of informed judgment by the Administrator. The level selected will depend on the expected incidence and severity of the potential effects and on the size of the population at risk, as well as on the degree of scientific certainty that the effects will in fact occur at any given level of pollution. For example, if a suspected but uncertain health effect is severe and the size of the population at risk is large, a more cautious approach will be appropriate than would be if the effect were less troubling or the exposed population smaller.

EPA staff originally recommended a range of potential standards for the Administrator's consideration (SP, pp. 111–114). The recommended range was below the levels at which the staff, with the concurrence of CASAC, had concluded from the available data that adverse health effects were "likely," but in the domain where the data suggested that such effects were "possible." The Administrator proposed refined ranges of standard levels that were based on the original staff and CASAC recommendations. After consideration of the new scientific evidence contained in the criteria document addendum, the staff revised its recommendations for ranges of standards (SPA, pp. 60–62). The Administrator has considered the revised assessments and the recommendations of CASAC (Lippmann, 1986b) in making his final decision on the standard levels. The rationales for the levels of the 24-hour and annual standards are presented below.

1. 24-Hour Standard

The revised staff assessment of the short-term epidemiological data is summarized in Table 1; particulate matter levels are expressed in both the original (British Smoke ["BS"] or TSP) and PM_{10} units. The "effects likely" row in Table 1 denotes concentration ranges derived from the criteria document and its addendum at or above which a consensus judgment suggests greatest certainty that the effects studied would occur, at least under the conditions that occurred in the original studies. In the "effects possible" range, the staff found credible scientific evidence suggesting the existence of adverse health effects in sensitive populations, but substantial uncertainty exists regarding the conclusions to be drawn from such evidence.

[5] British Smoke (BS) is a pseudo-mass indicator related to small particle (aerodynamic diameter less than a nominal 4.5 μm) darkness. This particulate matter indicator was widely used in British and other European studies. See the criteria document for a more detailed treatment of BS (CD, pp. 1–88 to 1–90 and 14–8 to 14–11).

TABLE 1.—UPDATED STAFF ASSESSMENT OF SHORT-TERM EPIDEMIOLOGICAL STUDIES

(After Table 4-1, SPA)

Effects/Study	Measured British smoke levels (as μg/m³) (24-hr. avg.)			Measured TSP levels (μg/m³) (24/hr. avg.)	Equivalent PM_{-10} Levels (μg/m³)
	Daily Mortality in London [1]	Aggravation of bronchitis [2]	Combined range	Small, reversible declines in lung function in children [3, 4]	Combine range [5]
Effects Likely	1000	250–*500*	250–500		350–600
Effects Possible	?	<250*	<250	220*–420 [3]—200–250 [4]	140–350

TABLE 1.—UPDATED STAFF ASSESSMENT OF SHORT-TERM EPIDEMIOLOGICAL STUDIES—Continued

(After Table 4-1, SPA)

Effects/Study	Measured British smoke levels (as $\mu g/m^3$) (24-hr. avg.)			Measured TSP levels ($\mu g/m^3$) (24/hr. avg.)	Equivalent PM_{10} Levels ($\mu g/m^3$)
	Daily Mortality in London [1]	Aggravation of bronchitis [2]	Combined range	Small, reversible declines in lung function in children [3, 4]	Combine range [5]
No Significant Effects Noted				125* [4]—160 [3]	<125

*Indicates levels used for upper and lower bound of range.

[1] Various analyses of daily mortality encompassing the London winter of 1958-59, 14 winters from 1958-72, in aggregate and individually. Early winters dominated by high smoke and SO_2 from coal combustion with frequent fogs. From 1982 CD: Martin and Bradley (1960); Ware et al., (1981); Mazumdar et al. (1981). From 1986 CD Addendum: Mazumdar et al. (1982); Ostro (1984); Schwartz and Marcus (1986). Later studies show association across entire range of smoke, with no clear delineation of "likely" effects or threshold of response possible.

[2] Study of symptoms reported by bronchitis patients in London, mid-50's to early 70's; Lawther et al. (1970).

[3] Study of pollution "episodes" in Steubenville, Ohio, 1978-80; Dockery et al. (1982).

[4] Study of 1985 pollution episode in Ijmond, The Netherlands; Dassen et al. (1986).

[5] (a) *Conversion of BS readings to PM_{10} levels:* Assumes for London conditions and BS readings in the range 100-500 $\mu g/m^3$, $BS < PM_{10} < TSP$. Precise conversions are not possible. Uncertainty in measurements of BS and conversion relationships preclude quantitative estimates of range for lower BS levels. The upper bound assumption ($PM_{10} = TSP = BS + 100$ $\mu g/m^3$) overestimates PM_{10} levels, while the lower bound assumption ($PM_{10} = BS$) understates PM_{10} levels.

(b) *Conversion of TSP to PM_{10} for Dockery et al. results:* Based on analysis of particle size fraction relationships in Steubenville (Spengler et al. 1986). The lower bound TSP of 220 $\mu g/m^3$ was the peak reported for the Spring 1980 study. A PM_{15}/TSP ratio of about 0.8 occurred at a nearby site on days surrounding this peak. Using lower bound of PM_{10}/PM_{15} ratio from later year (0.8), the PM_{10} to TSP ratio estimate used in 0.64. The 160 $\mu g/m^3$ reflects peak level in Fall 1980 from episode with no significant functional decline noted.

(c) *Conversion of Dassen et al. results to PM_{10}:* Both PM indices (Respirable Suspended Particles [RSP] and TSP) reached similar levels. Results suggest TSP levels too low, but PM_{10} levels unlikely to be much higher than RSP. Thus $RSP = PM_{10}$ assumed for conditions of higher concentrations in this study. The 125 $\mu g/m^3$ entry reflects an excursion occurring 2 days prior to date on which no decrements noted.

The data do not provide evidence of clear thresholds in expnsed populations. Instead, they suggest a continuum of response for a given number of exposed individuals with both the likelihood (risk) of any effects occurring *and* the extent (incidence and severity) of any potential effect decreasing with concentration. This is particularly true for the statistical analyses of daily mortality in London. Substantial agreement exists that wintertime pollution episodes produced premature mortality in elderly and ill populations, but the range and nature of association provide no clear basis for distinguishing any particular lowest "effects likely" levels or for defining a concentration below which no association remains. The recent lung function studies in children also provide evidence of effects at concentrations in the range listed in Table 1, but the relationships are not certain enough to derive "effects likely" levels for PM_{10}. The lung function studies do, however, suggest levels below which detectable functional changes are unlikely to occur in exposed populations. Following CASAC recommendations, the staff used the combined range listed in the "effects possible" row as a starting point for developing alternative standards.

The original range proposed by the Administrator, drawn from the 1982 staff analysis, was 150 to 250 $\mu g/m^3$ PM_{10}, 24-hour average with no more than one expected exceedance per year. The lower bound of this range was derived from the original assessment of the London mortality studies. As a result of its updated assessment of reanalyses of the London mortality and more recent U.S. morbidity studies, the staff reduced the level of the lower bound of the range of interest to 140 $\mu g/m^3$ (SPA, p. 51), while noting that the difference between it and original lower bound (150 $\mu g/m^3$) is within the range of uncertainty associated with converting the morbidity study results from TSP to PM_{10}.

As indicated in Table 1, the study of Lawther et al. (1970) judged to provide evidence that health effects are likely at particulate matter concentrations above 250 $\mu g/m^3$ (as BS). The effects observed in this study (related to aggravation of bronchitis) are of concern both because of their immediate impact and because of the potential for inducing longer-term deterioration of health status in a significant sensitive group. There were approximately 6.5 million bronchitics in the U.S. in 1970 (DHEW, 1973). Based on the uncertain conversion between smoke and PM_{10} outlined in Table 1, the lowest "effects likely" level derived from the Lawther study (250 $\mu g/m^3$ as BS) should be in the range of 250 to 350 $\mu g/m^3$, in PM_{10} units.

The assessment of this study formed the basis for the upper bound of the range of PM_{10} standards proposed by the Administrator in 1984. Considering this study alone, a PM_{10} standard of 250 $\mu g/m^3$ might appear to contain some margin of safety, even for the sensitive bronchitics studied, because it incorporates a conservative British Smoke/PM_{10} conversion factor and because of differences between exposure conditions in the British study and current U.S. air quality (SP, pp. 100-101). Because bronchitics are identified as a group particularly sensitive to particulate pollution, a standard of 250 $\mu g/m^3$ (as PM_{10}) also might provide some margin of safety for other, less sensitive, groups. Nevertheless, this study of bronchitics in London has inherent limitations in sensitivity that preclude derivation of unequivocal "effects thresholds" at 250 $\mu g/m^3$ as BS, and by extension PM_{10}. The criteria document notes that associations between pollution and health status persisted at lower BS concentrations in selected, more sensitive individuals. Although the lead author of the study objects to attaching any importance to these latter findings (Lawther, 1986), EPA, with CASAC concurrence, finds no basis for asserting that this study demonstrates a population threshold at 250 $\mu g/m^3$.

In evaluating the margin of safety for a 24-hour standard, it is also important to consider the London mortality studies. A standard at the upper portion of the proposed range (250 $\mu g/m^3$) would he well below the levels (500 to 1000 $\mu g/m^3$ as BS) of the historical London episodes in which the scientific consensus indicates that pollution was responsible for excess mortality (CD, Table 14-7). The portions of the population at greatest risk of premature mortality associated with particulate matter exposures in such episodes

include the elderly and persons with pre-existing respiratory or cardiac disease. Although the extent of life shortening (days, weeks, or years) cannot be specified, the seriousness of this effect strongly justifies a margin of safety for it (below the consensus effects levels) that is larger than that warranted for the effects on bronchitics.

The staff assessment of the several reanalyses of London mortality suggests, however, that the risk of premature mortality to sensitive individuals extends to concentrations substantially lower than those which occurred in the "episodes." The more recent analyses (Mazumdar et al., 1982; Ostro, 1984; Shumway et al., 1983) provide no objective support for a population threshold below which such a risk no longer exists. Although the risk to individuals may be small at concentrations of 250 $\mu g/m^3$ and below, the number of people exposed to lower concentrations given current U.S. levels is substantially larger than the number exposed to higher levels (SPA, Table 2-1). The increased number of individuals exposed increases the risk that effects will occur in the total population exposed.

Differences in the composition of particles and gases among U.S. cities and between current conditions in the U.S. and those in London at the time the mortality and morbidity data were gathered add to the complexity of assessing the risk associated with particulate matter in the U.S. In the case of the mortality studies, however, the staff found that at least one of the more recent studies (Ozkaynak and Spengler, 1985) provides qualitative support for an association between daily mortality and particle concentrations in nearly contemporary U.S. atmospheres (SPA, pp. 43-44).

The 1982 assessment of the mortality studies and related factors prompted the Administrator to consider standard levels that extended from 250 $\mu g/m^3$ down to the lower bound of the original staff range of interest (150 $\mu g/m^3$) and even lower. The more recent analyses of the London mortality data provide additional evidence that serious adverse health effects may occur at particulate concentrations below 250 $\mu g/m^3$. These analyses have addressed a number of the uncertainties associated with the earlier studies, and have reinforced the Administrator's concern that a 24-hour standard at the upper end of the proposed range may not provide an adequate margin of safety. However, given the uncertainties in converting from BS to PM_{10} measurements, particularly at lower concentrations, and the possible differences in particulate composition between London at the time the data were gathered and the contemporary U.S., it is difficult to use these studies to set a precise level for a PM_{10} standard (SPA, pp. 49-51).

Given these difficulties, it is important to examine contemporary studies that utilize gravimetric measurements of particulate concentrations. The staff found the studies of Dockery et al. (1982) and Dassen et al. (1986) to be particularly useful. The Dockery study observed physiologically small but statistically significant decreases in lung function in a group of children exposed to peak PM_{10} levels of 140-250 $\mu g/m^3$. The decrements persisted for 2-3 weeks following the exposures. The study also suggested the possibility of larger responses in a subset of the children, including those with existing respiratory symptoms. The Dassen study recorded similar decrements in children in the Netherlands following exposure to PM_{10} levels estimated at 200 to 250 $\mu g/m^3$, but no observable effects two days after exposure to PM_{10} levels estimated at 125 $\mu g/m^3$. The particle composition, at least in the Dockery study, is more representative of contemporary U.S. cities and the associated aerometry provides a more reliable estimate of PM_{10} levels than do the measurements used in the London studies. It is reasonable to expect that the effects observed (small reversible reductions in lung function in children) are, in most cases, more sensitive to air pollution than those observed in the London studies. These effects are, of themselves, of uncertain significance to health, but might be associated with aggravation of respiratory symptoms in children with preexisting illness (SPA, p. 47). Long-term examination of respiratory health in the same community studied by Dockery et al. (1982) suggests that the children in that community have a higher incidence of respiratory illness and symptoms than children in communities with lower particle levels, but the data show no evidence for any persistent reduction in lung function (Ware et al., 1986). Uncertainties with respect to the effects of other pollutants (e.g., SO_2), the consistency of the changes, and exposures preclude specifying unequivocal "effects likely" levels based on this study. The staff assessment therefore suggests that short-term lung function effects in children are possible across a range of 140-250 $\mu g/m^3$ or more as PM_{10} (SPA, p. 50).

In making a decision on a final standard level, the Administrator also considered information from the more qualitative studies of PM assessed by the staff (SP, pp. 101-103; SPA, pp. 52-53). These suggest increased risks for sensitive groups (asthmatics) and risks of potential effects (morbidity in adults) not demonstrated in the more quantitative epidemiological literature. The qualitative studies do not provide clear information on effects levels, but do justify consideration of effects of particulate matter that have not been sufficiently investigated.

Based on the scientific assessment at the time, the Administrator in 1984 expressed an inclination to select a 24-hour level from the lower portion of the proposed range of 150-250 $\mu g/m^3$. The present Administrator finds that the updated scientific assessment supports the original inclination and, if anything, suggests an even wider margin of safety is warranted. The recent analyses of daily mortality are of particular concern in this regard. The Administrator has, therefore, decided to set the final standard at the extreme lower bound of the range originally proposed; that is, at 150 $\mu g/m^3$. This standard provides a substantial margin of safety below the levels at which there is a scientific consensus that particulate matter causes premature mortality and aggravation of bronchitis. Such a margin is necessary because of the seriousness of these effects and because of the recent analyses of daily mortality that suggest adverse effects may occur at particulate matter levels well below the consensus levels. The standard is in the lower portion of the range where sensitive, reversible physiological responses of uncertain health significance are possibly, but not definitely, observed in children. Using a conservative assessment of lung function/particle relationship from Dockery et al., a change in concentration from background levels ($\sim$20 $\mu g/m^3$) to 150 $\mu g/m^3$ would produce lung function changes of at most 10 to 15% in less than 5% of exposed children (SPA, p. 48). Based on the results of Dassen et al. (1986), it appears unlikely that any functional changes would be detected one or two days following such exposures (SPA, p. 50). Thus, the maximum likely changes in lung function appear to present little risk of significant adverse responses. Standards set at a somewhat higher level would, however, present an unacceptable risk of premature mortality and allow the possibility of more significant functional changes. Furthermore, a standard level of 150 $\mu g/m^3$ is fully consistent with the

recommendations of CASAC on the 24-hour standard (Lippmann, 1986c).

2. Annual Standard

The updated staff assessment of important long-term epidemiological data is summarized in Table 2. Long-term epidemiological studies are subject to additional confounding variables that reduce their sensitivity and make their interpretation more difficult than that of short-term studies. The "effects likely" levels are derived from the criteria document, but again, no clear thresholds can be identified for all effects categories. Evidence exists of effects at lower levels—the "effects possible levels"—but the evidence is inconclusive and effects are difficult to detect in the available epidemiological studies.

TABLE 2.—UPDATED STAFF ASSESSMENT OF LONG-TERM EPIDEMIOLOGICAL STUDIES (AFTER TABLE 4-2, SPA)

Effects/Study	Measured BS levels (as $\mu g/m^3$)	Measured TSP levels ($\mu g/m^3$)					Equivalent PM_{10} levels ($\mu g/m^3$)
	Increased respiratory disease, reduced lung function in children [1]	Increased respiratory disease, symptoms, small reduction in lung function in adults [2]	Increased respiratory symptoms in adults [3]	Increased respiratory symptoms and illnesses in children [4]	Reduced lung function in children [4]	Combined range	Combined range [5]
Effects likely	230–300	*180				>180	>80–90
Effects possible	<230	*130–180	60–150(110)	*60–114		60–180	40–90
No significant [6] effects noted		80–130			40–114	<60	<40

*Indicates levels used for upper and lower bound of range.

[1] Study conducted in 1963–65 in Sheffield, England (Lunn et al., 1967). BS levels (as $\mu g/m^3$) uncertain.

[2] Studies conducted in 1961–73 in Berlin, NH (Ferris et al., 1973, 1976). Effects likely level (180 $\mu g/m^3$) based on uncertain 2-month average. Effects in lung function were relatively small.

[3] Study conducted in 1973 in two Connecticut towns. (Bouhuys et al., 1978). Exposure estimates reflect 1965–73 data in Ansonia. Median value (110 $\mu g/m^3$) used to indicate long-term concentration. No effects on lung function, but some suggestion of effects on respiratory symptoms.

[4] Study conducted in 1976–1980 in 6 U.S. cities (Ware et al., 1986). Exposure estimates reflect 4-year averages across cities. Comparable pollution/effects gradients not noted within cities.

[5] Conversion of TSP to PM_{10} equivalents for Berlin, Ansonia studies based on estimated ratio of PM_{10}/TSP for current U.S. atmospheres (Pace, 1983). The estimated ratio ranged between 0.45 and 0.5. Conversion for six-city study based on site-specific analysis of particle size data (Spengler et al., 1986).

[6] Ranges reflect gradients in which no significant effects were detected for categories at top. Combined range reflects all columns.

Based on a recent assessment of PM_{10}/TSP ratios in areas with elevated TSP levels, the updated staff assessment revised the "effects likely" levels from the Ferris et al. (1973) study to 80 to 90 $\mu g/m^3$ as PM_{10} (SPA, p. 58). Because of limitations in sampling duration as well as the conversion to PM_{10}, this estimate is particularly uncertain. As indicated in the table, effects are possible at lower concentrations. Of greatest concern is the possibility of long-term deterioration of the respiratory system in exposed populations, the potential for which is indicated by lung function (mechanical pulmonary) changes and increased incidence of respiratory disease. One set of studies (Ferris et al., 1973, 1976) provides some evidence for a "no observed effects" level for these effects at or below 60 to 65 $\mu g/m^3$ (130 $\mu g/m^3$ as TSP) while another study (Bouhuys et al., 1978), suggests some possibility of symptomatic responses in adults at long-term median levels at or below about 50 to 55 $\mu g/m^3$ as PM_{10}. The importance of these symptomatic responses, which were unaccompanied by lung function changes, to long-term respiratory health is unclear.

The most important recent study of long-term effects is an ongoing examination of six U.S. cities (Ware et al., 1986). The study indicates the possibility of increased respiratory symptoms and illnesses in children at multi-year levels across a range of 40 to over 58 $\mu g/m^3$ as PM_{10}, but found no evidence of reduced lung function at such concentrations. This study did not find similar gradients in symptoms and illness within some of the cities, which had somewhat smaller localized pollution gradients. The results of a separate series of studies of long and intermediate term (2 to 6 weeks) exposures in a number of U.S. metropolitan areas (Ostro, 1987; Hausman et al., 1984) are more supportive of the possibility of effects within cities (respiratory related activity restrictions in adults) at comparable U.S. exposure levels. The results of these more recent studies are generally consistent with the earlier U.S. studies listed in Table 2 (SPA, 57). In particular, the finding of symptomatic responses in children with no change in lung function (Ware et al., 1986) is consistent with similar findings in adults (Bouhuys et al., 1973) at estimated long-term PM_{10} levels down to 50 $\mu g/m^3$. However, the information available to support the existence of significant adverse effects at annual PM_{10} levels below 50 $\mu g/m^3$ — especially when 24-hour levels are maintained below 150 $\mu g/m^3$—is quite limited and uncertain.

Because of the uncertainties in (SP, pp. 104–110; SPA, 54–59), as well as the limited scope and number of, these long-term quantitative studies, it is particularly important to examine the results of qualitative data from a number of epidemiological, animal, and ambient particle composition studies when evaluating what constitutes an adequate margin of safety for an annual standard. These studies justify concern for serious effects not directly evaluated in the studies listed in Table 2. Such effects include damage to lung tissues contributing to chronic respiratory disease, cancer, and premature mortality (SP, pp. 109–111). Substantial segments of the population may be susceptible to one or more of these effects (SP, p. 46). Although the qualitative data do not provide evidence for major risks of these effects at current annual particulate matter levels in most U.S. cities, the Administrator believes that the seriousness of the potential effects and the large population at risk warrant caution in setting the standard.

Based on the then current scientific assessment, the Administrator proposed in 1984 to select the annual standard level from a range of 50 to 65 $\mu g/m^3$. In the proposal, the Administrator favored a standard in the lower portion of the range. The more recent evidence, although subject to substantial uncertainty, serves to reinforce this inclination. In light of the updated assessment and in accordance with the recommendation of CASAC, the Administrator has decided to set the level of the annual standard at the lower bound of the original range, 50 $\mu g/m^3$, expected annual arithmetic mean. This standard provides a reasonable margin of safety against the serious effect of long-term degradation in lung function, which has been judged likely at estimated PM_{10} levels above 80–90 $\mu g/m^3$ and for which there is some evidence at PM_{10} levels above 60 to 65 $\mu g/m^3$. Such a standard also provides reasonable protection against the less serious symptomatic effects for which some studies provide evidence at PM_{10} levels down to 50 $\mu g/m^3$. Although some small risk of increased respiratory symptoms may exist at this concentration, the available data are currently inconclusive on this point. Moreover, the staff and CASAC have recommended that the combined protection afforded by both 24-hour and annual standards be considered in selecting the final standard level. In this regard, analyses of air quality data show that implementation of the 24-hour standard will substantially reduce annual levels in a number of areas to below 50 $\mu g/m^3$, adding to the protection afforded by the annual standard in areas with higher 24-hour peak to mean ratios (SPA, p. 61; Freas, 1986). Based on the present evidence with respect to risks associated with annual exposures, the Administrator finds that the annual and 24-hour standards announced today provide an adequate margin of safety.

IV. Rationale for the Secondary Standards

Section 109(b)(2) of the Clean Air Act states that secondary NAAQS should be set at a level requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of an air pollutant in the ambient air. The criteria document and staff paper examined the effects of particulate matter on such aspects of public welfare as visibility and climate, man-made materials, vegetation, and personal comfort and well being. Each aspect is discussed in some detail in those documents. The following discussion of the rationale for the secondary standards focuses primarily on considerations that were most influential in the Administrator's decision or that differ in some respect from, or expand upon, considerations that influenced the staff and/or CASAC recommendations.

A. Soiling and Nuisance

At high enough concentrations, both large and small particles may soil household and other surfaces, or otherwise become a nuisance. Both effects can result in increased cleaning costs and decreased enjoyment of the environment (SP, p. 140). Efforts to control particulate matter in U.S. cities from 1970 to 1978 were estimated to have produced substantial economic benefits because of reduced soiling and nuisance (CD, p. 1–51). The staff paper therefore recommended consideration of soiling and nuisance generated by dust and other particles in setting a secondary standard (SP, p. 141).

In proposing secondary standard(s) for particulate matter, the Administrator first examined whether the pollutant indicator (PM_{10}), averaging times and form, and range of levels of the proposed primary standards would provide adequate protection against soiling and nuisance. This examination was complicated by uncertainties in the scientific data base that largely preclude accurate quantification of the extent of effects associated with specific particle sizes and concentrations or deposition, and by the fact that the protection afforded by primary standards depends upon the particular combination of levels chosen within the ranges that were proposed for the primary standards. The Administrator proposed a separate indicator and range of secondary standards, while also soliciting comment on the alternative of making the secondary standards identical in all respects to the proposed primary standards for PM_{10}. In so doing, the Administrator noted that "depending on the exact levels of primary standards chosen, the combined requirements for meeting both 24-hour and annual primary standards for PM_{10} might be considered adequate to protect against possible adverse effects relating to soiling and nuisance from all relevant particle sizes." (49 FR 10418).

The decision to adopt the specific revised primary standards discussed in section IV above permits a more definitive assessment of the protection afforded by those standards against potential adverse welfare effects. In addition, information submitted in the public comments, the review of the March 20, 1984 proposal by the CASAC, and further analysis of the welfare effects information by Agency staff have amended the basis for the final decision on the secondary standards. The basis for the original proposal and the implications of the more recent findings are summarized below.

The Administrator originally proposed (1) to retain TSP as the indicator for the secondary standard and (2) to select the standard level from a range of 70–90 $\mu g/m^3$, expected annual arithmetic mean. Given the nature of the evidence available, the Administrator expressed an inclination to select the level for the standard from the upper portion of the range.

The proposal noted that both PM_{10} and TSP could be useful indicators for a secondary standard for soiling and nuisance. PM_{10} is useful because in a qualitative sense: (1) Particles smaller than 10 μm in diameter are more likely than larger particles to penetrate indoors; they are also more likely than larger particles to soil vertical surfaces (SP, pp. 136–137) and (2) due to the characteristic size distributions and origins of particles in the atmosphere (SP, pp. 14–19), control of particles less than 10 μm in diameter would also limit the concentration of larger particles. The TSP indicator was proposed, however, because of the lack of data permitting clear distinctions among size ranges with respect to soiling and nuisance, the more inclusive nature of TSP, and the fact that most of the available information relating soiling and nuisance to air pollution used TSP as an indicator.

Information submitted in the public comments expanded on some of the limitations of TSP as an indicator that were noted in the preamble, namely: (1) The collection efficiency of the high volume sampler, which measures TSP, decreases rapidly for particles with diameters in excess of 25–40 μm; thus, the TSP measurement itself can omit a substantial fraction of the very large particles that can make a substantial contribution to soiling of horizontal surfaces; and (2) because the collection efficiency of the high volume sampler varies more with windspeed than do PM_{10} samplers, TSP may be a less reliable indicator of elevated concentrations of larger particles than PM_{10}.

In light of these considerations, the CASAC in reviewing the March 20 proposal package concluded that it could find no convincing scientific support for maintaining TSP as an indicator for the secondary standards (Transcript of December 16, 1985 CASAC meeting, pp. 56–71; Docket No. A–82–37).

In developing a range of levels for the secondary standard, EPA found that the available data base provides compelling evidence that elevated levels of particulate matter can produce adverse welfare effects, but provides little quantitative information on concentration-effects relationships. Physical damage and economic studies tend to show no obvious welfare effects "thresholds" for soiling. With time, particulate matter may accumulate on surfaces even at low concentrations. At very low concentrations, however, the amounts of particulate matter may be virtually invisible to the human eye or be so slight as to be ignored by most people (Carey, 1959; Hancock et al., 1976). Up to a point, the buildup of particles on surfaces may not be generally regarded as a social problem because it is removed by rain or routine cleaning and maintenance before substantial accumulation can occur. Moreover, even if an accumulation is large enough to be noticed, it is not necessarily considered to be a problem. Thus, the critical judgment for selecting a standard level is to determine a particulate matter concentration at or above which the soiling effect becomes important enough that it should be regarded as an "adverse" effect under section 109(b)(2) of the Act.

The available information suggests that the public does make a distinction between concentrations at which particulate pollution is merely noticeable and higher levels at which it is considered a nuisance. A study of the response of a panel of human subjects to dust on surfaces concluded that the level of dustiness that is found to be objectionable is higher than the level that can be perceived or discriminated (Hancock et al., 1976). It is not, however, possible to derive unique ambient concentration thresholds for adverse effects from this kind of study. A more direct study of perception of air pollution as a nuisance (CD, p. 9–67) suggested that people considered air pollution a nuisance in areas where annual levels were at or somewhat above the level of the current annual primary TSP standard (75 $\mu g/m^3$, annual geometric mean). The upper bound of the proposed range of interest (90 $\mu g/m^3$ TSP), expected annual arithmetic mean, was derived by taking that level and making appropriate conversions to account for the expected arithmetic mean form.

The lower bound of the proposed range (70 $\mu g/m^3$) was supported by a rough analysis of economic benefits of reduced outdoor soiling that might be associated with decreased TSP levels in U.S. cities (CD, p. 10–73). During the public comment period, one of the authors of the analysis that formed the basis for these estimates submitted a more recent analysis which called the earlier analysis into question (Watson and Jaksch, 1984). The author claimed that estimates of benefits from reduced TSP concentrations were significantly overstated because they did not take into account the extent to which the public could perceive improvements associated with reduced concentrations. Other commenters indicated that the underlying experimental data suggested a threshold for economic soiling effects at an annual TSP level of about 150 $\mu g/m^3$.

EPA staff examined the underlying experimental data used in the original analysis. This staff examination (Haines, 1987) has been placed in the rulemaking docket. The staff found that of 27 household cleaning activity categories examined in the underlying experiment (Booz, Allen, Hamilton, 1970), 6 (5 outdoor) were statistically significantly associated with particulate matter across some concentration gradient. In further comparing areas with differing concentrations of in TSP, it was found that the number of significant associations decreased with decreasing TSP levels. The staff concluded that these data provide no convincing evidence to support estimates of significant economic benefits from reducing PM levels below 90 to 100 $\mu g/m^3$.

Following the original inclination of the Administrator and the more recent findings, an annual TSP level of 90 $\mu g/m^3$ was used as a benchmark in an analysis to determine whether the primary particulate matter NAAQS would protect against soiling and nuisance (SP, Table 2–1). An earlier version of these results was presented at the December 16, 1985 CASAC meeting. The analytical approach, assumptions, and limitations of the methodology used in the analysis are discussed in a separate report, which has been placed in the rulemaking docket (Pace et al. 1986). The results indicated that the combined implementation of the primary 24-hour and annual PM_{10} standards announced above would substantially reduce TSP levels to the extent that only 6 counties nationwide would experience annual mean TSP levels in excess of 90 $\mu g/m^3$ and none would exceed 100 $\mu g/m^3$.

In short, EPA has determined that there is no convincing evidence of significant adverse soiling and nuisance at TSP levels below 90–100 $\mu g/m^3$, and that the primary standards promulgated today would permit few, if any, areas to sustain TSP levels above 90–100 $\mu g/m^3$. On the basis of these determinations, the Administrator concludes that a secondary standard different from the primary standards is not requisite to protect the public welfare against soiling and nuisance. This conclusion is supported by the CASAC's determination that there is no scientific support for a TSP-based secondary standard. (Transcript of December 16, 1985, CASAC meeting, p. 71; Docket No. A–82–37). Therefore, the Administrator has decided to set 24-hour and annual secondary PM_{10} standards that are equal in all respects to the primary standards.

B. Other Welfare Effects

The other welfare effects of particulate matter of principal interest are impairment of visibility, potential modification of climate, and contribution to acidic deposition. All three of these effects are believed to be related to regional-scale levels of fine particles, and control programs designed to ameliorate them would likely involve region-wide reductions in emissions of sulfur oxide (SP, p. 147; Friedlander, 1982).

Because of the likely overlap between control measures designed to protect visibility and control measures designed to address acidic deposition, EPA, in its March 20, 1984, notice of proposed rulemaking on the particulate matter standards, did not propose a secondary standard designed to protect visibility. Instead, the Agency decided to defer action pending development of compatible strategies to address both of these related regional air quality problems.

Since publication of the notice of proposed rulemaking, EPA has continued to gather information on acidic deposition and on visibility, and to analyze the potential impact on visibility of strategies designed to control acidic deposition. In particular, EPA has received the report of an Interagency Task Force on Visibility. In light of the Task Force's recommendations as well as other information gathered by the Agency, EPA is now reassessing its position with regard to consideration of a secondary fine particle standard for visibility. In particular, the Agency is considering whether, given the time that would be required to develop, propose, promulgate, and implement a visibility based standard, it would now be appropriate to proceed with consideration of a visibility based standard in parallel with work on acid deposition, so that compatible strategies

for dealing with the two problems can be developed at the implementation stage.

Accordingly, EPA is publishing elsewhere in today's **Federal Register** an advance notice of proposed rulemaking soliciting public comment on the appropriateness of a separate secondary fine particle standard designed to protect visibility, and on a number of issues that would have to be resolved in proposing such a standard.

The Administrator also concurs with the staff suggestions that a separate secondary particle standard is not needed to protect vegetation or to prevent adverse effects on personal comfort and well-being (SP, pp. 143–144).

V. Federal Reference Method

The reference method for the measurement of atmospheric particulate matter as PM_{10}, promulgated today as Appendix J to 40 CFR Part 50, is based on selection of PM_{10} particles by inertial separation, followed by filtration and gravimetric determination of the PM_{10} mass on the filter substrate. The particle size discrimination characteristics of reference method samplers (or sampler inlets) are prescribed as performance specifications in amendments to 40 CFR Part 53, promulgated elsewhere in today's **Federal Register**.

The requirements in Appendix J are generally prescribed as functional or performance specifications in order to allow sampler manufacturers flexibility in designing or configuring their PM_{10} samplers. Sampler shape, inlet geometry, operational flow rate, degree of automation, and other sampler characteristics or features are specified only in terms of required function or performance.

While most of the comments received on Appendix J generally supported the performance-based approach to specifying PM_{10} reference methods, many commentors felt that the sampler performance specifications in the proposed Appendix J and 40 CFR Part 53 were not adequate to ensure accurate collection of PM_{10} under all conditions of ambient sampling. In response to such comments, the sampler performance specifications in Part 53 and the corresponding references to such requirements in Appendix J have been revised. Other comments were received on various requirements of Appendix J such as flow calibration and measurement, flow regulation, filter media, filter equilibration, and sampler maintenance. Specific changes to Appendix J resulting from these comments and from review of other pertinent information are discussed below.

A. Specific Changes to Appendix J

Section 3.0 has been revised to specify that all samplers should be capable of measuring 24-hour PM_{10} mass concentrations of at least 300 $\mu g/m^3$ while maintaining the operating flow rate within specified limits.

In Section 4.0 the term "reproducibility" has been changed to "precision" and the specification for PM_{10} samplers has been changed from 15 percent or better to 7 percent or 5 $\mu g/m^3$, whichever is higher. The particle size for 50 percent sampling effectiveness in Section 5.0 has been changed from 10± 1 micrometers to 10±0.5 micrometers. These changes are a result of corresponding changes in the PM_{10} sampler performance specifications in 40 CFR Part 53, promulgated elsewhere in today's **Federal Register**. Refer to the Part 53 action for further discussion of these changes.

In Section 6.0 the subsection on nonsampled particulate matter has been removed. The design of particle size discriminating inlet systems for PM_{10} samplers essentially precludes the transport of windborne particulate matter to the particle collection filter during periods when the sampler is idle. Although windborne particles could potentially enter a PM_{10} sampler's air inlet opening during idle periods, they would have to take a tortuous path with several changes in direction to reach the collection filter.

References to "automatic flow controller" throughout Appendix J have been changed to "flow control device". The latter term is less restrictive and more clearly allows the use of any type of flow regulation device, provided that the other flow-related requirements of Appendix J are met. In particular, Section 7.1 has been changed to require that a PM_{10} sampler have a flow control device capable of maintaining the sampler's operating flow rate within the limits specified for the sampler inlet. The requirement that the flow control device have a flow rate adjustment capability has been removed to allow for the use of certain types of flow controllers (e.g., Venturi-type critical flow devices) that regulate flow at a constant but unadjustable rate. Flow controllers of this type generally employ a fixed-geometry orifice and control the sampler's flow rate without any moving parts or electronic components. The requirement that the flow control device be disabled during calibration has also been removed because it is only applicable to certain types of devices (e.g., electronic flow controllers). Sampler-specific operational requirements such as this are better addressed in the sampler manufacturer's instruction manual.

Subsection 7.1.6 has also been changed to explicitly require that the instruction manual associated with the sampler include detailed procedures for calibration, operation, and maintenance of the sampler. Since much emphasis is placed on the role of the sampler manufacturer's instruction manual in Appendix J, it is important that it contain detailed information on all aspects of sampler operation. The instruction manual for each designated reference method would be reviewed and approved as part of the Part 53 reference method designation process.

The filter alkalinity specification in Subsection 7.2.4 has been changed from <0.005 milliequivalents/gram of filter to <25 microequivalents/gram of filter. In addition, the method used for the alkalinity determination has been changed to a newly developed, more sensitive, and more reliable method. The change in the magnitude of the specification results from the change in procedures (alkalinity measurements are approximately 5 times higher with the new method), and from the change in the measurement units.

Section 7.3 includes specifications and other requirements for the flow rate transfer standard used during sampler calibration. The specifications for the reproducibility and resolution of the flow rate transfer standard have been removed and replaced with an accuracy specification. The revised Section 7.3 requires that the flow rate transfer standard be capable of measuring the sampler's operating flow rate with an accuracy of ±2 percent. An accuracy specification, stated in this context, is more meaningful and useful than specifications for reproducibility and resolution. In addition, the requirement that the flow rate transfer standard include a means to vary the sampler's flow rate during calibration is not appropriate for all types of samplers and/or flow rate transfer standards and has been removed. This is another example of a sampler-specific requirement that is better addressed in the sampler manufacturer's instruction manual.

The humidity requirement for the filter conditioning environment in Section 7.4 has been changed from a single specification of 45±5 percent relative humidity (RH) to separate specifications for humidity range (20 percent to 45 percent RH) and humidity control (±5 percent RH). Under the revised requirements, filters may be equilibrated at any preselected humidity between 20

and 45 percent RH, provided that the humidity is controlled to within 5 percent RH. Language has also been added to Section 9.0 to require that the same temperature and humidity conditions be used for both pre- and post-sampling filter equilibration.

The calibration and operational procedures for PM_{10} samplers vary considerably depending on the type of sampler (e.g., high-volume, medium-volume, low-volume) and the type of flow control and flow measurement devices employed in the sampler. Accordingly, the calibration and procedure sections of Appendix J (Sections 8.0 and 9.0) have been revised substantially to be more general in nature. The revised procedures serve to illustrate the steps involved in the calibration and operation of a PM_{10} sampler, and place more emphasis on the sampler manufacturer's instruction manual and the Quality Assurance Handbook for specific guidance.

A new section on sampler maintenance has been incorporated into Appendix J to explicitly require that PM_{10} samplers be maintained in strict accordance with the procedures provided in the sampler manufacturer's instruction manual. The performance of some PM_{10} samplers may be adversely affected by the buildup of substantial quantities of non-PM_{10} particulate matter within the sampler inlet. Such samplers may require periodic cleaning and other maintenance to ensure accurate collection of PM_{10} particulate matter. This new section has been added as Section 10.0, and the calculations and references sections have been renumbered accordingly.

When temperature and pressure corrections to sampler flow indicator readings are required, corrections based on existing temperature and pressure at the time the readings are taken (or daily average values during the sampling period in some cases) are preferable. However, incorporation of site or seasonal average temperatures and barometric pressures into the sampler calibration to avoid daily temperature and pressure corrections is also allowed. When temperature and pressure corrections to flow indicator readings are required, existing temperature and pressure at the time the readings are taken (or daily average values during the sampling period in some cases) must be used. Likewise, the calculations section has been changed to require that the average barometric pressure and average ambient temperature *during the sampling period* be used to calculate Q_{std}. Site or seasonal average values for temperature and barometric pressure may be required in the adjustment of the set-point of certain types of flow control devices (e.g., mass flow controllers). Site or seasonal average values for temperature and pressure are used in these cases to ensure that the deviations in actual volumetric flow rates, resulting from daily changes in temperature and pressure at the monitoring site, are centered about the sampler inlet's design flow rate.

Other minor wording changes have been made throughout Appendix J to clarify the requirements.

B. Designation of Reference Methods for PM_{10}

Before a method for PM_{10} is approved as a PM_{10} reference method, it must meet the requirements of Appendix J and be tested and designated as a reference method in accordance with the provisions of 40 CFR Part 53. Testing of candidate reference methods will generally be conducted by the sampler manufacturers. A notice will be published in the **Federal Register** in accordance with Part 53 whenever an application for a PM_{10} reference method determination is received by EPA. Likewise, a notice of designation and other information pertinent to the designation will be published in the **Federal Register** each time a PM_{10} reference method is approved for use. PM_{10} sampler manufacturers are required to provide sampler purchasers with an operation or instruction manual containing detailed procedures for the calibration, operation, and maintenance of the sampler. Additional guidance and recommendations regarding filter media, type of analytical balance required for mass determinations, and other requirements of the method should also be provided in the manual. Part 53 requires submission of the manual as part of a manufacturer's application for a reference method determination. The instruction manual will be reviewed for technical accuracy and consistency with the requirements of Appendix J and must be approved as part of the requirements for designation of the method as a reference method.

C. Technical Change to Appendix G

Because the high-volume method described in Appendix B will continue to be used in conjunction with Appendix G ("Reference Method for the Determination of Lead in Suspended Particulate Matter Collected from Ambient Air") and for other purposes that may be specified, EPA is promulgating the technical changes to Appendix G as proposed. Under the final rule the reference 10 in Appendix G has been deleted and section 5.1.1 of the Appendix has been revised to read as follows:

"High Volume Sampler. Use and calibrate the sampler as described in Appendix B to this Part." The Appendix has also been revised to specify more directly that the high-volume method described in Appendix B is to be used in conjunction with the reference method for lead.

VI. Summary of Salient Public Comments and Agency Responses

An overview of public comments on the major aspects of the March 20, 1984 proposal are presented in Section II. The most important comments on specific issues are categorized and summarized below together with Agency responses. A more comprehensive compilation of comments and Agency responses is contained in a separate Response to Comments Document that has been placed in the Docket (No. A–82–37).

A. Health Effects Criteria and Selection of the Primary Standards

1. Indicator for the Primary Standards

Comments: PM_6 rather than PM_{10} should be used as the indicator for the primary standards because PM_6 more accurately reflects particle deposition in the thoracic regions, provides an ample margin of safety in protecting health, and puts less emphasis on coarse particles that are relatively inert than does PM_{10}.

Agency Response: EPA considered the major analysis (Swift and Proctor, 1982) and preliminary arguments (AMC, 1982) in support of a PM_6 indicator in developing the 1984 proposal. Although EPA deferred judgment pending additional analysis and review, the decision to propose PM_{10} and not PM_6 was based, in part, on reservations concerning the PM_6 indicator. The likelihood that the available data from mouthpiece studies overstated thoracic deposition during "natural" breathing was recognized in a qualitative sense by CASAC (cf. July 1981 transcript, p. 581; Docket No. A–82–37) and presented as one reason for recommending PM_{10} rather than PM_{15} or TSP as an indicator. The 1982 staff paper reflected this argument in recommending 10 μm rather than 15 μm as the cutpoint for the indicator (SP, pp. 76–77). The criteria document addendum points out that assumptions used in the quantitative analyses used to support PM_6 (Swift and Proctor, 1982) appear to underestimate thoracic particle deposition; this underestimation would reduce any margin of safety associated with an

indicator derived from these data. Extension of the Swift and Proctor analysis itself suggests that approximately 10 to 20% of 10 μm particles could penetrate to the thoracic region, rather than the 0% penetration implied by some commenters who argued for a "D_0" at 10 μm.

The Swift and Proctor analysis as well as several more recent analyses and experimental studies of particle deposition are reviewed in the criteria document and staff paper addendum. The more recent assessments tend to support the original proposal of PM_{10}. The criteria document addendum compares the work of Miller et al. (1986), using the more recent deposition data, with the Swift and Proctor analysis and confirms that the latter understates deposition of particles larger than 6 μm in individuals who habitually breathe through the mouth.

The more recent data also show some fraction of particles of 10 μm and larger can penetrate as far as the alveolar region (CDA, Figure 2-1). The risk associated with deposition of insoluble coarse particles in this region is of particular concern because of slow clearance time (CDA, p. 2-6). Although removal in the tracheobronchial region is more rapid, deposition of coarse particles in the tracheobronchial region may be associated with bronchoconstriction and alteration of clearance mechanisms (SP, Table 5-2). The 1982 staff paper took these factors into account in the original recommendation for a 10 μm indicator that included all of the fine and a portion of the coarse fraction.

After considering these updated assessments, the EPA staff reaffirmed its original recommendation of PM_{10} as an indicator for the standards (SP, p. 32). In reviews of the March 20, 1984 proposal and of the criteria document and staff paper addenda, the CASAC also reaffirmed its recommendation for PM_{10} as an indicator (Lippmann 1986 a,c). The majority of public comments on this issue also favored PM_{10}.

In summary, EPA finds that the presently available record clearly favors the PM_{10} indicator over the alternative PM_6 indicator.

Comments: Some commenters suggested that while PM_{10} represents an improvement over TSP, the fine fraction (<2.5 μm) is of relatively greater concern to health than the coarse fraction (2.5 to 10 μm). Such commenters suggest that a $PM_{2.5}$ standard is needed—in addition to or, in some comments, instead of a PM_{10} standard.

Agency Response: The possibility of a fine particle indicator for the primary standard was examined in the staff paper (pp. 68-70). This suggestion is based in part on the recognition that ambient particle mass and volume are distributed such that a rough division "minimum" at about 1 to 3 μm separates the "fine" (smaller) and "coarse" fractions. Each fraction has somewhat distinct chemical and physical properties and sources. The staff, however, noted a number of difficulties in using fine particles (less than a nominal 2.5 μm) alone instead of PM_{10} as the indicator for the primary standards. These include:

(1) Substantial overlap can occur between the two modes and in some cases the division minimum can disappear. Moreover, despite the differing origins and chemistries of the modes, each is chemically heteorgeneous. The respiratory tract, in effect, alters the ambient distribution, with a mixture of fine and coarse modes being deposited in both the tracheobronchial and alveolar regions. Indeed, the 2.5 μm "cut" is within the size range of maximum efficiency for alveolar deposition (2 to 4 μm). The mixing of these size fractions in the respiratory tract and the heterogeneity within each fraction therefore blurs the distinction between the fractions in terms of health effects.

(2) Coarse dusts have been associated with responses such as bronchoconstriction, altered clearance and alveolar tissue damage (SP, Table 5-2). Given current information, it would be premature to ascribe all of the effects in the British, U.S., and other epidemiological studies to the fine fraction, or to any single chemical entity within that fraction.

EPA believes that a separate fine particle standard in addition to the PM_{10} standard is not warranted for the following reasons:

(1) Fine mass typically comprises on the order of 40 to 70% of PM_{10}. Therefore, the PM_{10} standards provide substantial limits on fine mass, and

(2) The limited epidemiological data presently available must provide the principal basis for any particulate matter standard. Because these data do not separate the effects of fine and coarse fractions, it is most reasonable to use these data to support a single set of standards.

(3) To the extent that emerging information suggests additional protection may be necessary, it may be more appropriate to consider the addition of chemical-specific (e.g., acid aerosols) standards rather than a fine particle standard in future primary standard revisions.

2. Interpretation of Community Epidemiological Studies

Comments: A number of commenters took issue with EPA's interpretation of the various analyses of London mortality data. These commenters suggest that (a) the London data can be used to show only an association of excess mortality with high concentrations of pollution during unique episodes in which BS and SO_2 levels exceeded 500 to 1000 μg/m³, (b) a number of the analyses suffer from methodological flaws precluding valid conclusions, (c) the conclusion that effects may be possible at low pollution levels (e.g., <250 μg/m³) or that there is a continuum of association with no identifiable threshold is not supportable, (d) the results of Mazumdar et al. (1982) and Ostro (1984) are more consistent with the hypothesis that particulate matter is acting as a surrogate for some other causal agent rather than as a causal agent itself, and (e) it is biologically implausible that mortality could be affected by particulate matter at levels below those shown by Lawther et al. (1970) to produce morbid effects in sensitive populations.

Agency Response: EPA's assessment of the various London mortality analysis is discussed at length in the criteria document, the staff paper, and the addenda to these documents. The 1982 criteria document found that in the context of historical London exposures, these data indicate clear increases in daily mortality occurred with BS and SO_2 concentrations in excess of 1000 μg/m³ with some indications of likely increases in daily mortality at levels of both pollutants in the range of 500 μg/m³ or more (CD, Table 14-7). These original conclusions on likely effects levels, based largely on the Martin and Bradley (1960) and Ware et al. (1981) analyses, appear reasonably consistent with the original assessment of these data by the original British investigators and the 1969 criteria document. From the re-examination of these data by Ware et al. (1981) and the analysis of subsequent London winters by Mazumdar et al. (1981), the criteria document also concluded small increases in daily mortality might occur at levels below 500 μg/m³. The more recent analyses of these data by Mazumdar et al. (1982), Ostro (1984), and Shumway et al. (1983) all serve to reinforce the possibility that effects were associated with particulate matter at concentrations below 500 μg/m³. A number of commenters, however, including some of the original British investigators (Holland et al., 1985), object to this latter suggestion.

EPA has carefully examined these studies and the various criticisms of them submitted as comments on the proposal. In order to respond fully to these criticisms, EPA conducted more sophisticated reanalyses of the original London data to further determine the degree of reliance that can be placed on the published results (Schwartz and Marcus, 1986, CDA, Appendix A). Each of these studies does suffer from limitations and uncertainties delineated in EPA's updated assessment (SPA pp. 17–23; 39–44); these limitations preclude definitive conclusions with respect to causality as well as identification of clear "no observed effects" levels. Nevertheless, EPA maintains its original interpretation, supported by its external science advisors, that these data at least suggest the possibility of effects of particulate matter at BS levels as low as 150 $\mu g/m^3$ and possibly even lower. None of the difficulties in statistical methodology or alternative mechanisms cited by commenters provide an adequate explanation for the consistent finding of association between particulate pollution and mortality at levels below 500 $\mu g/m^3$3 (as BS). The association was found for the majority of 14 winters (analyzed individually) spanning a period when pollution in London and indoor heating practices showed marked changes, and including winters in which BS levels did not exceed 250 $\mu g/m^3$. The relative consistency of the results from year-to-year despite these changes suggests that the observed effect is not explained by indoor air pollution or by long-term demographic shifts in the population. The findings were consistent among different investigators, and persisted after taking SO_2, temperature, and other weather variables into account, and after correcting for autocorrelation structure.

The principal arguments for the suggestion by some (including Mazumdar et al., 1982) that smoke may be acting as a surrogate for some more toxic pollutant or related non-pollution variable are: (1) The coefficients in the regression equations appear to increase with decreasing pollution across the 14 winters, (2) surrogate behavior is commonly observed in statistical analyses, (3) the work of Lawther suggests a threshold for morbidity at around 250 $\mu g/m^3$ as BS; hence mortality would not be expected at lower levels. While the possibility of surrogate behavior remains, the above arguments do not demonstrate that smoke acts as a surrogate for non-pollution variables. The trend toward higher coefficients with lower pollution is not clearly consistent in the Mazumdar and Ostro regressions. The existence of higher coefficients in later years, however, prompted these authors to suggest some plausible alternative to non-pollution surrogates, including: (a) The possibility that the composition of pollution changed with time, with an increase in more toxic components, and (b) because the gravimetric mass of particles in the range under 10 μm may not have declined as much as did the black carbon content detected in the smoke measurement (Lodge, 1986), coefficients related only to smoke might be expected to increase. An additional possibility suggested by Schwartz and Marcus is that the effect of higher pollution episodes in earlier winters was blunted by public awareness (and hence reduced exposure) or by a tendency for the most susceptible individuals to succumb on an early day of a multi-day pollution episode.

The use of the Lawther morbidity data as a threshold for mortality is questionable. The London mortality data involve an unequivocal endpoint in a relatively large population (several hundred per day) over a 14 year period. As pointed out by Roth et al. (1986), although the bronchitic population studied was clearly susceptible, the effects indicator used by Lawther was a relatively insensitive one. Moreover, the threshold was determined not by rigorous analysis, but by visual examination of strip chart data. Although the principal author strongly objects (Lawther, 1982), the criteria document points out that the data do not clearly indicate an effects threshold at 250 $\mu g/m^3$. Furthermore, the simple correlation results provided by Lawther et al. (1970) suggest the possibility that a more sophisticated analysis jointly incorporating pollution and weather factors might have found increased morbidity occurring at lower levels. The recent findings of small changes in pulmonary function at lower particulate matter levels in the U.S. and the Netherlands (See Table 1) support the notion that 250 $\mu g/m^3$ (in this case as PM_{10}) is not a reliable effects threshold.

Comments: The derivation of the proposed range of levels for the annual primary standard is without scientific basis. In particular, limitations in the two major series of studies used preclude finding effects of particulate matter at the lower TSP levels shown. In addition, the conversion of the results of these studies to PM_{10} uses an inappropriately low PM_{10}/TSP ratio.

Agency Response: EPA's assessment of studies used to derive the range of levels for the primary standard (Ferris et al., 1973, 1976;) and Bouhuys et al., 1978) (CD, pp. 14–44 to 46 and SP, pages 61–62 and 104 –107) was reviewed by CASAC and found to be an appropriate basis for developing revised standard levels (Friedlander, 1982). The assessment clearly points out the limitations and strengths associated with the uses of these studies.

The Ferris et al. work (See Table 2 above) involved a "longitudinal" tracking of lung function and respiratory illness in adults vs. pollution over a 12 year period in Berlin, NH, a small town in which a pulp mill was a major pollution source. As commenters note, the "effects likely" level drawn from the first year of this study is particularly uncertain, as it is based on very limited aerometry. This level, however, was not important in developing the range for the proposed standard. Because of the seriousness of the effect (a prolonged decrement in lung function), the by then decreased concentration observed in the first followup study (130 $\mu g/m^3$ as TSP), was used in developing the upper bound of the range of proposed annual standards. This concentration was based on a full year of monitoring. Based on the historical record, there can be little doubt that pollution declined in this community from 1961 to 1967, the year of the first follow-up. The nature of the particular pollution source (a pulp mill) in this study, together with a finding of very low British smoke level, indicates that a variety of particles, not just products of combustion, may be associated with adverse effects. Although commenters have suggested that other pulp mill emissions may have been responsible for the effects, ambient levels of the gaseous effluents from such sources (reduced sulfur compounds and SO_2) have not been shown to cause reduced lung function.

Estimating PM_{10} levels from this study by using typical national average PM_{10}/TSP ratios does not—as some commenters argued—clearly understate PM_{10} levels. These commenters argued that high PM_{10}/TSP ratios (e.g., 0.8) should be used because sites in the eastern U.S. tend to have higher ratios. The data on PM_{10}/TSP ratios, however, also show a general tendency for lower ratios to occur in industrialized areas with high TSP concentrations (Pollack, et al., 1985). Moreover, air quality measurements taken in the 1960's document the presence of substantial quantities of larger size particles, as evidenced by high dust fall levels and low soiling indexes (Kenline, 1962). The latter author concludes that this would be expected "if the majority of particles present had diameters of 10 microns or

greater . . . ." EPA therefore believes that the use of ratios characteristic of industrialized areas with high particle concentrations is justified and does not contribute to any excess margin of safety in the estimated effects levels.

The Bouhuys et al. (1978) study (see Table 2 above) was used to set the lower bound for the proposed standard range, which is the level at which the final standard is being promulgated. The study found a difference in three of five respiratory symptoms but no differences in lung functions between two Connecticut towns (Ansonia and Lebanon) that had a historically large (but currently small) difference in levels of particulate matter. Although the authors believed that air pollution did not play a role in the observed differences in symptoms, the data presented do not demonstrate that the differences were due solely to other factors associated with the conduct of the study. Moreover, the finding of excess respiratory symptoms unaccompanied by a persistent change in lung function is not unique. Similar findings were also obtained in the Ferris (1973) follow up study and the more recent six city study results (Ware et al., 1986).

Some commenters argued that the estimated TSP levels derived for the Bouhuys study were too low. EPA disagrees. The staff took the median TSP values reported by Bouhuys et al. over the previous several years as the relevant exposure level for this study because (1) the current gradient in pollution appeared to be too small to result in such effects, and (2) it is unreasonable to attribute all of the observed gradient in effects among urban and rural residents, as measured in 1973, to the maximum historical concentrations reported 8 to 10 years prior to that time. EPA's position is supported by the observations of Ferris et al. (1973, 1976), which show an apparent measurable reduction in symptoms and improved lung function after only a five to six year decline in pollution. This decline suggests that any gradient in effects due to pollution eight to ten years ago would be diminished relative to effects that may be associated with the more recent past. The median value used by EPA for the Bouhuys study is, in fact, also relatively close to the weighted average of all TSP observations reported for Ansonia for the seven years preceding the Bouhuys et al., (1978) measurements, which were taken in 1973 (Lounsbury, 1986).

The approach used to convert the TSP measurements in this study to PM_{10} equivalents was also questioned. The staff rejected use of the limited (15 days) particle size data for Ansonia as unrepresentative because of questions concerning their quality and because they were taken in 1973, after particulate matter concentrations had been reduced to lower levels (SP, p. 62). Absent reliable site-specific particle size data, the staff used the median PM_{10}/TSP ratio seen at other sites in the eastern U.S. with higher than average PM_{10} levels. Because the long-term ratio can vary between 0.3 and 0.65 among such sites, such estimates are admittedly uncertain. Nevertheless, the staff examination of historical air quality and source data associated with the Bouhuys et al. study found no factors that would make the ratio unusually high or low relative to other high concentration sites in the eastern U.S. The analysis by Spengler et al. (1986) of trends in particle size ratios from the 1970's to the present in six eastern cities suggests that the ratio of PM_{10} to TSP in early years with higher TSP levels tends to be comparable to or somewhat lower than the current ratios.

The basis for the final ambient standard is considerably strengthened by the recent results from the six-cities study (Ware et al., 1986). This work also suggests an increased risk of respiratory illness and symptoms, but no differences in lung function, in children across a gradient of pollution that extends to concentrations below those observed in the previous studies. The results are therefore qualitatively consistent with both of the earlier studies. In addition, the associated aerometry permits substantially better estimates of historical PM_{10} data. Taken together, these studies provide substantial support for an annual standard of 50 $\mu g/m^3$.

3. Margin of Safety

Comments: The Agency has incorporated an unrecognized three-fold margin of safety in the 24-hour standards through the means used to convert British Smoke measurements into PM_{10}.

Agency Response: British Smoke measurements collect particles smaller than about 4.5 microns in diameter ($PM_{4.5}$) on a substrate and then measure their absorption of light. Because the measurement depends on light absorption, it is sensitive only to the dark, "sooty" component of the particulate matter. EPA has relied on gravimetric calibrations, performed during the earlier years of the mortality and morbidity studies, that related the British Smoke measurements to particulate mass concentrations that included light-colored as well as dark particles.

The commenters note that the dark, sooty component of the particulate matter in London today constitutes only 40% as large a fraction of the total particulate mass as it did during the period of the studies on which EPA has relied. They argue that the use of those studies to set standards for contemporary particulate pollution therefore introduces an error of a factor of 2.5 (1/0.4). Multiplying this by a typical ratio of PM_{10} to $PM_{4.5}$ of 1.2 (Lodge, 1986), the commenters arrive at an alleged error of a factor of three arising from the Agency's use of the British Smoke measurements.

The commenters rely on the unstated assumption that it is only the dark fraction of particulate pollution that affects human health, and that, since the dark fraction has declined since the time of the studies, the particulate matter in the atmosphere today is less dangerous than that present at the time of the studies. EPA disagrees with this assumption and believes that a more plausible and prudent assumption is that effects on health depend on the mass concentration of particles and not on their color.

Although it is possible that dark, carbonaceous particles were primarily responsible for the observed effects on human health in the London studies, this has not been documented, and there is no evidence to support the assumption that light-colored particles have no significant effect on human health. EPA staff has compared the composition of particulate matter in historical London and in the current U.S. and has concluded that, given the variety of particle types present in the U.S., there is no clear basis for imputing higher acute toxicity to the historical London particles (SP pp. 21–22, 100).

The commenters support their argument with the assertions that the decrease in the dark, sooty fraction of particulate matter in London has been accompanied by the elimination of pollution-related health effects, and that current excursions of fine particle mass in excess of 250 $\mu g/m^3$ have not been associated with health effects in London or elsewhere. EPA finds these assertions to be unsupported. The studies of mortality in London over a 14-year period of declining pollution from 1958 through 1971 found that the relationship between pollution and mortality persisted throughout the period and that, in fact, the regression coefficients assigned to mortality appeared to increase over the period. (Mazumdar et al., 1982; Ostro, 1984). Moreover,

continuing studies in the contemporary U.S. and Europe have suggested health effects at PM_{10} levels below 250 $\mu g/m^3$ (Dockery et al., 1982; Ozkaynak and Spengler, 1985; Dassen et al., 1986).

For these reasons, EPA concludes that it is reasonable and prudent to use the mass concentration estimates derived from historical British Smoke measurements to set ambient standards for current U.S. atmospheres under the assumption that current U.S. particles are equal in toxicity to those found in London at the time of those measurements. Any margin of safety inherent in the British Smoke/PM_{10} conversion for the earlier years when gravimetric calibrations were available is more likely to be on the order of a factor of 1.2 (the ratio of $PM_{4.5}$ to PM_{10} estimated by Lodge, 1986) rather than the factor of three suggested by the commenters. For particulate levels lower than those observed in the earlier years, EPA has supplemented the London studies with the more contemporary American and European studies using direct gravimetric measurements.

Comments: Several commenters expressed concerns that the margin of safety for the range of levels proposed for the 24-hour standard is insufficient. Commenters based these concerns on: (a) Calculations suggesting that even the lower bound may be less stringent than the current standards, (b) evidence from the more recent studies of lung function decrements in children and the analyses of London mortality data, and (c) various studies found to be mainly of qualitative value. In general, such commenters felt that, in view of the available evidence, the standard should be set at levels at or below the lower bound of the proposed ranges.

Agency Response: The overriding consideration in selecting a standard is how well it protects public health, not its relative stringency as compared to the previous standard. EPA believes that standards chosen provide an adequate margin of safety irrespective of the relationship to the former TSP standards. Nevertheless, EPA has compared the stringency of the revised standards with that of the existing standards by estimating the number of areas that would be expected not to attain each set of standards. By this measure, the new PM_{10} standards are equivalent to or somewhat more stringent than the TSP standards (SP, Table 2-1). Commenters who calculated or asserted otherwise often did not take all of the aspects of the standards into account. The margin of safety is a function not only of level, but also of the indicator and form of the standards. The revised form, in particular, makes direct comparison of the relative stringency of proposed range with the current TSP standard inappropriate.

EPA agrees that the analyses of mortality in London justify caution in selecting a 24-hour standard level, and that the recent studies of lung function provide a useful basis for selecting the level. EPA does not, however, believe that these studies compel a standard more stringent than the one chosen. As discussed in Section III.C.1 above, uncertainties in estimating PM_{10} equivalents of low British Smoke concentrations in the later years of the London studies make it difficult to use the studies to set a precise level for a PM_{10} standard. Therefore, it is important to examine the more contemporary studies of lung function that permit a more direct estimation of PM_{10} effects levels. In considering these studies in conjunction with the London mortality and other relevant health studies, EPA finds that a 24-hour standard of 150 $\mu g/m^3$ provides an adequate margin of safety. EPA does not agree with commenters suggestions that it is necessary to prevent any detectable changes in lung function. As discussed in Section III.C.1, a standard of 150 $\mu g/m^3$ will clearly prevent lung function decrements that might be considered to be indicative of adverse effects in well over 95% of children exposed; in fact the evidence suggests that even reversible lung function changes ($FEV_{0.75}$) in excess of 10% are unlikely at this level. EPA therefore believes that the standard provides an adequate margin of safety.

Some commenters favoring standards below the lower bounds of the proposed ranges relied on studies or analyses found by EPA and CASAC to be of little quantitative value for establishing ranges of concern. EPA considered a number of such studies in selecting a margin of safety (e.g., SPA 52-53; SP 109-111), but in EPA's judgment they do not provide a sufficient basis for establishing standards at levels below those derived from the more quantitative studies summarized in Tables 1 and 2 above.

Comments: Some commenters argued that in selecting annual standards much greater weight be given to the results of Ware et al. (1986), which suggest a possible gradient of effects at concentrations extending to the lowest levels observed in the six cities studied (25 $\mu g/m^3$).

Agency Response: EPA disagrees. EPA staff found that the pollution and effects gradient in the three cleanest cities to be too small to provide any strong suggestion of effects at such levels. Moreover, the lack of consistency for "within city" effects in this study argue against placing undue reliance on the suggestion of effects at levels outside of the range suggested by the other long-term studies of interest (Ferris et al., 1973, 1976, Bouhuys et al., 1978). In addition, the 24-hour standard provides an increased margin of safety against annual exposures at levels below 50 $\mu g/m^3$, in areas where long-term exposures are dominated by repeated short-term peaks (Freas, 1986).

B. Secondary Standards

1. Soiling and Nuisance

Comments: The Agency should maintain a secondary TSP standard. Some commenters felt that the proposed secondary annual TSP standard is inadequate, and that the current 24-hour TSP standard should be retained.

Agency Response: As discussed in Section IV.A. above, the CASAC found little scientific support for maintaining a secondary TSP standard. It follows that little data exist to support maintaining the present level or an alternative level for a 24-hour standard designed to protect against soiling and nuisance. Nevertheless, the changes made in the final standard result in both a 24-hour and annual secondary PM_{10} standard. Analysis of the relative protection afforded by the 24-hour PM_{10} standard indicate that it is relatively more stringent than the upper portion of the proposed range for an annual TSP standard. Thus, the final standards should provide more protection than that afforded by the proposed TSP alternative toward which the Administrator was initially inclined. As detailed above, the data do not provide convincing evidence of significant soiling and nuisance effects at concentrations below that permitted by the primary standards.

2. Visibility

Comment: A secondary fine particle standard is needed to protect against visibility impairment and related effects.

Agency Response: The Administrator deferred judgment with respect to a secondary fine particle standard in order to examine the relationship between control programs for regional visibility and the related problems of acid deposition. The initial phase of that examination has now been completed (EPA, 1985). Based on the available information, the Administrator has decided to issue an Advance Notice of Proposed Rulemaking on a secondary fine particle standard in a separate notice in today's **Federal Register**.

C. Averaging Time and Form of the Standards

1. Expected Exceedances for the 24-hour Standard

Comment: Several commenters were opposed to the proposed statistical form and either favored the current simpler deterministic form or preferred a multiple exceedance or percentile form of the 24-hour standard. Others supported the proposal to adopt a single expected exceedance statistical form. Many of the opposing commenters were concerned that the adjustment for incomplete sampling could cause areas with less than one actual exceedance per year to be misclassified as nonattainment and that the method is sensitive to spurious high concentrations. Those in favor of adopting a single exceedance statistical form recognized the need to account for missing data and argued that this form provides proper health protection.

Agency Response: EPA has carefully reviewed these comments and has decided to maintain the basic proposed statistical form for the 24-hour standard but has made some technical changes and clarifications in response to reviewers comments. The Agency believes that a single exceedance form for the primary standards and the proposed adjustments for incomplete sampling appropriately reflect the health basis for the standard. When sampling is performed less frequently than every day, the number of observed exceedances of the standard level will obviously be, in general, fewer than the actual number of exceedances. If, for example, sampling is performed only every sixth day, as is permitted by the Air Quality Surveillance regulations (40 CFR Part 58) being promulgated today, then, on average, the number of observed exceedances will only be one-sixth of the actual number of exceedances. To fail to correct for this effect would be irrational and would seriously degrade the health protection afforded by the standards. The Agency believes that adequate procedures for handling spurious high concentrations are provided in the "Guideline on the Identification and (Use of Air Quality Data Affected by Exceptional Events", EPA–450/4–86–007. Moreover, single high concentrations will not necessarily cause a location to fail the test for attainment. Appendix K has been modified so that the first observed exceedance is not adjusted for incomplete sampling, if the sampling frequency is promptly increased to every day in accordance with 40 CFR Part 58.13. Accordingly, sites sampling once in six days must observe at least two exceedances in order to fail the test for attainment. Sites sampling every other day or every day must record three or four exceedances over a three-year period in order to fail the test. This change reduces the chances for misclassifying a site as nonattainment.

Although a multiple exceedance form of the 24-hour standard could reduce sampling requirements, such a form would reduce the level of health protection by allowing particulate levels to exceed, on multiple days, the levels that the Administrator has determined to pose an unacceptable health risk. An analysis of alternative numbers of exceedances found that, in the long run, the single exceedance form provided much more consistent health protection than did the percentile form recommended by some commenters (Biller, 1984; 1986).

In response to comments regarding the potential for seasonal variation in particulate matter concentrations, as well as possible intrayear changes in sampling frequency as described in Part 58 of this Chapter, the Agency has decided to require that adjustments for incomplete sampling be performed on a quarterly basis instead of a yearly basis.

2. Expected Arithmetic Mean for the Annual Standard

Comment: Many commenters favored retaining the geometric mean to describe annual average particulate matter concentrations but several supported the proposed use of the arithmetic mean. Those opposed to the proposed method noted that the geometric mean is a more stable statistic and is less sensitive to occasional high readings. In addition, opposing commenters were concerned that a change to an arithmetic mean increases the stringency of the annual standard and that the arithmetic mean does not properly relate to health effects.

Response: As discussed above, EPA has decided to adopt annual primary and secondary standards in terms of expected annual arithmetic mean PM_{10}. The Agency believes that the annual arithmetic mean is a more appropriate indicator for a long-term primary air quality standard than is the geometric mean. It provides a better estimate of total exposure and, with its multiple-year averaging, more appropriately takes into account year-to-year fluctuations in meteorology. As discussed in the rationale, the effect of averaging multiple years of data in order to estimate the expected annual value as well as the use of the arithmetic mean were both considered in setting the concentration level of the standard. The use of the arithmetic mean does not necessarily increase the stringency of the standard level; the stringency depends at the combination of the form, indicator, and level. Holding all else equal, however, the arithmetic form is relatively more protective in areas subject to multiple elevations in 24-hour concentrations. EPA views this as a desirable characteristic.

VII. Regulatory and Environmental Impacts

A. Regulatory Impact Analysis

Under Executive Order 12291, EPA must judge whether a regulation is a "major" regulation for which a Regulatory Impact Analysis (RIA) is required. At the time of the proposal, the Agency judged the proposed revisions to the particulate matter NAAQS to be a major action, and made available to the public a draft analysis entitled: Regulatory Impact Analysis of the National Ambient Air Quality Standards for Particulate Matter—Draft (EPA, 1983). The draft RIA was based on information developed by several EPA contractors (inter alia., Argonne, 1983; Mathtech, 1983) and provided estimates of costs, benefits, and net benefits associated with alternative standards.

In announcing the availability of the draft RIA, the Agency stated that neither the RIA nor the contractors' reports were considered in developing the proposed revisions. Subsequent to the release of the draft RIA, the public and other governmental agencies raised a number of questions regarding the underlying data bases and analyses discussed in the draft RIA. In response to these questions, the Agency modified the cost model used and made other, more limited, changes to the benefits analyses. The number and extent of the changes were constrained, however, by the underlying model structure and the available data. The Agency has carefully evaluated the revised analysis and has concluded that despite the significant improvement made, fundamental questions remain with regard to certain aspects of the methodology used, particularly with respect to the emission reduction/air quality improvement relationship which affects the subsequent cost and benefit calculations. Consistent with its past practice, the Agency has not considered the final Regulatory Impact Analysis of National Ambient Air Quality Standards for Particulate Matter (EPA, 1986c) in reaching decisions on the final standards.

The final RIA has been submitted to the Office of Management and Budget (OMB) for review under Executive

Order 12291. Comments from OMB and EPA's responses to those comments have been placed in the docket.

Reporting Requirements

This final rule does not contain any information collection requirements subject to OMB review under the Paperwork Reduction Act of 1980 U.S.C. 3501 *et seq.*

B. Impact on Small Entities

Under the Regulatory Flexibility Act, 5 U.S.C. 600–612, EPA must prepare initial and final regulatory flexibility analyses that assess the impact a proposed or final rule will have on small entities, which include small businesses, small not-for-profit enterprises, and governmental entities with jurisdiction over populations of less than 50,000. The requirement of preparing such an analysis is waived, however, if the Administrator certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The national ambient air quality standards do not have a direct impact on small businesses or enterprises because the standards themselves do not contain emission limits or other pollution controls. Rather, such controls are contained in State implementation plans promulgated under section 110 of the Act, 42 U.S.C. § 7410. The States are given considerable discretion in selecting a mix of controls to attain and maintain the ambient standards, and the impact on small entities depends on how the States choose to exercise their discretion.

Nonetheless, EPA conducted an analysis of the impact of a hypothetical control strategy, designed to minimize costs, on entities in the industries that would be most affected under that hypothetical control strategy. That analysis, discussed in the notice of proposed rulemaking, 49 FR at 10422, indicated that less than 20% of the entities in those industries would be affected by the proposed standards.

During the public comment period, EPA received no comments on the regulatory flexibility analysis. On the basis of that analysis, the Administrator certifies that the revisions being promulgated today will not have a significant impact on a substantial number of small entities.

VIII. Other Reviews

This final rule was submitted to the Office of Management and Budget (OMB) for review. Comments from OMB and EPA's responses to these comments have been placed in the docket.

List of Subjects in 40 CFR Part 50

Air pollution control, Carbon monoxide, Ozone, Sulfur oxides, Particulate matter, Nitrogen dioxide, Lead.

Dated: June 2, 1987.

Lee M. Thomas,

Administrator.

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Addendum I—CASAC Review and Closure of the 1982 Criteria Document for Particulate Matter/Sulfur Oxides and the 1986 Second Addendum to the Criteria Document

January 29, 1982.

Subject: CASAC Review and Closure of the Criteria Document for Sulfur Oxides/Particulate Matter

From: Sheldon K. Friedlander, Chairman, Clean Air Scientific Advisory Committee (CASAC)

To: Anne M. Gorsuch, Administrator

On November 16, 1981, the Clean Air Scientific Advisory Committee of the Science Advisory Board completed its third review of the air quality criteria document for sulfur oxides/particulate matter (SOx/PM). The Committee notes with satisfaction the improvements made in the quality of the document during the course of previous CASAC reviews on August 20-22, 1980 and July 7-9, 1981. The staff of the Environmental Criteria and Assessment Office, directed by Dr. Lester Grant, have proven responsive to Committee advice as well as to comments provided by the general public, and deserve to be commended for the high quality of the document.

The purpose in writing you is to summarize the Committee's major conclusions to assist you in reviewing the scientific data and associated studies relevant to the establishment of revised ambient air quality standards for sulfur dioxide and particulate matter as required by law. This letter further advises you of the Committee's conclusion that the criteria document fulfills the requirements set forth in Section 108 of the Clean Air Act as amended, which requires that the document "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare" from sulfur oxides and particulates in the ambient air.

The Committee is preparing a separate letter to you summarizing the conclusions of its reviews of the Draft Staff Paper for Particulate Matter. In addition, CASAC will prepare a similar report on the Draft Staff Paper for Sulfur Oxides once that document

becomes available and its review is completed.

Major Scientific Issues and CASAC Conclusions in the SO_x/PM Criteria Document Review

Chapter 1: Executive Summary.

In general, the revised draft Executive Summary critically synthesizes the key points of information discussed at length in the individual chapters. Its conclusions and interpretations of scientific data, studies, and issues are consistent with those presented in each chapter. Relationships among individual chapters are clearly defined; redundancies that do appear are reasonable given the complexity of the subject.

The quality of the Executive Summary would be further improved if more specific statements and/or tables were added to clarify certain important interrelationships. These include the differences in chemical composition associated with each of the several significant size ranges of particulate matter; and the health effects associated with the respiratory tract deposition patterns of particulate matter in the several size ranges and different chemical compositions. Quantitative health effects information useful in defining specific concentrations or ranges of concentrations of size-specific and/or chemical specific PM associated with the occurrence of health effects should also be highlighted. In view of evidence that total thoracic (tracheobronchial and alveolar) particle deposition is of public health concern, it would also be helpful to include a discussion of the likely equivalency among British Smokeshade (BS), Total Suspended Particles (TSP), and size selective particle aerometric measurements that would sample or index atmospheric concentrations of those sized particles identified with tracheobronchial or alveolar deposition.

Chapter 2: Physical and Chemical Properties of SO_x/PM.

This chapter is well written and addresses the important issues relevant to a criteria document. It presents a good summary of current knowledge of the factors affecting the physics and chemistry of sulfur dioxide and the pathways and kinetics of its transformation into sulfuric acid. It also provides a good summary of particle characteristics, dynamics, and hygroscopic growth.

Chapter 3: Techniques for the Collection and Analysis of SO_x/PM.

The revised chapter provides an excellent summary of the measurement of sulfur oxides and particulates. Especially important is the discussion of the capabilities of the various measurement techniques and the profile of pollutants in the ambient air which these measurements yield. The chapter correctly notes that British Smoke (BS), Coefficient of Haze (COHS), and Total Suspended Particulate (TSP) measurements do not adequately reflect key physical or chemical properties of particulate matter in the contemporary ambient air. Precise interconversion among units of BS, COHS, and TSP is not possible. In the context of a particulate standard, British Smoke is applicable only to a "sooty" smoke aerosol. It may not be a valid health effects indicator for the aerosol compositions observed in recent summertime episodes in the United States and Europe. Thus, it is unlikely that BS can provide a sensitive index of hazard for today's air pollution.

Chapter 4: Sources and Emissions.

Both natural and man-made sources emit sulfur dioxide and particulate matter into the ambient air. Given the limitations of our ability to derive reliable estimates from both types of sources, the criteria document presents an adequate discussion of current knowledge.

Chapter 5: Environmental Concentrations and Exposure.

This chapter is largely acceptable in its present form. Most of the comments and suggestions which were made for previous drafts have been effectively incorporated. The most important omission from the chapter is information related to chemical composition with respect to particle size. Abundant information of this type is available for sulfates and some trace metals. Given the strong dependence of deposition rates and light scattering on particle size, it might have been worthwhile to refer to this literature in Chapter 5 or to direct attention to other document chapters (e.g., Chapter 2) where such relationships are discussed.

Chapter 6: Atmospheric Transport, Transformation and Deposition.

This chapter is concise, well-written, and effective in communicating information related to the current status of mathematical models for air pollution. The utility of various models is clearly discussed, and the inadequacy of current models for quantitative extrapolation is pointed out. Topics which had been omitted from the previous draft of this chapter have been added to other chapters with overlapping content. The chapter is now acceptable as written.

Chapter 7: Acidic Deposition.

The Committee has recognized the desirability of incorporating existing information on acidic deposition in the present criteria document. Chapter 7 provides an abbreviated but adequate summary of the contribution of sulfur oxides and particulates to the formation, transport, and effects of acidic deposition. The Committee has concluded that Chapter 7 is a scientifically adequate summary with the conditional understanding that EPA is preparing a Critical Assessment Document for Acidic Deposition for its review that recognizes and incorporates information on causes, effects, and data bases for all of the various pollutants relevant to acidic deposition. CASAC has been briefed several times by Agency officials regarding the status of this document. The Committee looks forward to the submission of this integrated assessment for its critical review.

Chapter 8: Effects on Vegetation.

In response to CASAC recommendations and public comments, this chapter on vegetation effects has been greatly improved compared to earlier drafts reviewed by the Committee. It now includes a more concise and interpretive critical evaluation of those few key studies yielding quantitative dose-effect or dose-response information of most use for criteria development and standard-setting purposes. It also reasonably includes tables in the appendices which summarize studies of particulates and sulfur dioxide related vegetation effects that are of less utility for criteria development and standard setting.

The Committee concurs with Chapter 8 evaluations which point to the lack of dose-response data to establish quantitative evidence of deleterious effects on vegetation from particulates at presently encountered U.S. ambient air concentrations. In contrast to particulates, much clearer evidence exists by which to define quantitative exposure-effect relationships for sulfur dioxide effects on vegetation. Laboratory experiments in particular have demonstrated the greater relative toxicity to vegetation from high short-term exposures of sulfur dioxide. This is especially important in view of the fact that ambient air concentrations of sulfur dioxide from point sources often fluctuate widely and result in high intermittent short-term exposures of plants to sulfur dioxide concentrations against a background of longer-term but much lower annual average sulfur dioxide levels. Also of much importance are differences in the relative sensitivity of various plant species to sulfur dioxide exposures. The degree of sensitivity depends in part on factors such as phase of growth at time of exposure, ambient

temperature and humidity levels, and plant water content. Among studies judged to be most useful for quantitative criteria development and standard setting are those of Dreisinger (1965, 1967) and Dreisinger and McGovern (1970) which demonstrate visible injury to white pine (a commercially important species in some U.S. areas) when natural stands of the tree in southern Canada were exposed for 4 hours to 0.30 ppm or for 8 hours to 0.25 ppm sulfur dioxide emitted from a nearby smelter. Roughly similar exposure-effect relationships were observed in studies reported by Jones et al. (1974) and McLaughlin (1981) on the effects of sulfur dioxide from a southeastern U.S. power plant on a wide variety of natural species in the vicinity of the point source. In these studies some crop and garden species showed visible injury effects with 3 hour exposures to 0.6–0.8 ppm sulfur dioxide, while certain other crop species (potato, cotton, corn, peach) did not show visible injury at levels below 0.8 ppm. In contrast, a chamber study by Hill et al. (1974) suggests that plants common to the southwestern U.S., with markedly lower moisture content and under generally lower ambient air humidity levels, may be able to withstand much higher ambient sulfur dioxide concentrations (up to 11 ppm for two hours) without visible injury.

Chapter 9: Effects on Visibility and Climate.

The technical aspects of this difficult problem are well characterized. The chapter does a good job of discussing the physics and public awareness of visibility. The relationship between fine particle mass concentrations and visibility has been well established. The criteria document thus provides an excellent technical basis for Agency decision-making on these issues.

Chapter 10: Effects on Materials.

This chapter adequately discusses the currently available scientific information concerning the effect of particulate matter and sulfur oxides on man-made materials. This includes critical assessments of available data concerning pertinent materials damage functions, uncertainties associated with existing characterizations of such functions, and limitations regarding estimation of monetary costs and/or benefits associated with the occurrence or control of such damage.

Chapter 11: Respiratory Deposition and Biological Fate of Inhaled Aerosols and Sulfur Dioxide.

This chapter is very much improved compared to earlier drafts reviewed by CASAC and is now a comprehensive and more informative summary of existing knowledge relevant to a criteria document. The existing knowledge in this area is, in many cases, incomplete. For example, a potentially very important factor is the influence of the integrity of lung epithelial barriers (both airway and alveolar) on deposition and clearance. To enhance the chapter's comprehensiveness, this issue should be discussed more sufficiently in the criteria document, despite the paucity of available data.

Chapter 12: Toxicological Studies.

This chapter is quite comprehensive as it describes essentially all toxicological studies relevant to a criteria document on sulfur oxides and particulates. Also, it provides commentary on many studies and the Significance of their findings to potential human health effects. In addition, the presentation of the information is more polished than the previous draft because of improved editing.

Chapter 13: Controlled Human Studies.

This is a chapter which thoroughly discusses the published material on controlled human experiments. The scientific criteria for good studies discussed at the beginning of the chapter cannot be overemphasized. While not all studies meet these criteria, the Committee recognizes that EPA must take account of the available literature and believes the studies cited in the chapter have been appropriately selected and discussed. Overall the chapter is well-written and directed toward addressing those questions to which answers are needed. One of the most important criteria for good human clinical studies is that they be double-blind. Unfortunately, most of the studies in the literature were not so performed. This factor is especially significant when sensitive population groups, such as asthmatics, are under study.

The chapter is also improved by the discussion of exposures administered through the nose and mouth during controlled studies. It appropriately notes that caution should be used in any attempted extrapolation of observed quantitative exposure/effects resulting from such protocols, particularly when compared to results that might be expected under ambient exposure conditions. The chapter identifies additional research results from studies using either face mask or open chamber oronasal breathing that would better resolve this issue, and it discusses existing studies in a balanced and thorough fashion.

Chapter 14: Epidemiological Studies.

The current draft of this chapter represents considerable change and improvement over previous drafts reviewed by CASAC. Following discussion with the Committee, EPA has applied a set of guidelines for deciding which epidemiological studies are most appropriate for use in revising ambient air quality standards.

More specific comments on the chapter include the following: (1) the integration of Chapter 14 with Chapter 3 has advanced the "real world" understanding concerning the application of epidemiological methods; (2) the epidemiological studies providing the most useful quantitative concentration/response information for revising the 24-hour ambient particulate standard include: Lawther et al, 1958 and 1970; Martin and Bradley 1960; Martin 1964; Ware et al, 1981; and Mazumdar et al, 1981; (3) the epidemiological studies providing the most useful quantitative concentration/response information for revising the annual ambient particulate standard include: Ferris and Anderson 1962; Lunn et al, 1967; Ferris et al, 1971 and 1976; and Bouhuys et al, 1978; and (4) the studies by Lave and Seskin, 1970, and Mendelsohn and Orcutt, 1979 suggest an association between chronic exposure to high concentrations of sulfates and increases in the level of mortality, but they do not indicate any threshold or safe level from such exposures, and they are not refined enough to provide estimates of the quantitative effect of sulfate concentrations on mortality.

Summary

The Committee made numerous comments of an editorial nature. These remarks, as well as a more detailed discussion of the recommendations and review provided above, are included in the transcripts of the three CASAC meetings held to review this document. With the understanding that the advised changes will be incorporated in the final criteria document, the Committee is satisfied that the air quality criteria document for sulfur oxides/particulate matter is scientifically adequate for use in standard setting.

December 15, 1986.

The Honorable Lee M. Thomas,
Administrator, U.S. Environmental Protection Agency, Washington, DC 20460

Dear Mr. Thomas: The Clean Air Scientific Advisory Committee (CASAC) has completed its review of two documents related to the development of National Ambient Air Quality Standards (NAAQS) for Particulate Matter and Sulfur Oxides. These two documents are the 1982 *Air Quality Criteria for Particulate Matter and Sulfur Oxides*, and the 1986 *Second Addendum to Air Quality Criteria for Particulate Matter and Sulfur Oxides (1982)*, both prepared by the Agency's

Environmental Criteria and Assessment Office (ECAO).

The Committee was impressed with the efforts of the staff of ECAO in preparing a well written, integrated and thorough review of recent relevant scientific studies. The Committee unanimously concluded that this 1986 Addendum, along with the 1982 Criteria Document previously reviewed by CASAC, represent a scientifically balanced and defensible summary of the extensive scientific literature on these pollutants.

Several important issues are discussed in the 1986 Addendum which the Committee believes should be emphasized. These issues were raised during our review of recent studies which relate primarily to guidance at the lower bounds of the ranges for the standards. These studies include the recent reanalyses of the London mortality data, two episodic lung function studies in the Unites States and the Netherlands, and the comparison of respiratory symptoms and pulmonary function levels of children living in six U.S. cities. Further discussion of these studies and reanalyses, as well as a more detailed discussion of the basis for the Committee's conclusions, are contained in the attached report.

The Committee also reviewed the Staff Papers for particulate matter and for sulfur oxides at the October 15–16, 1986 meeting, and is preparing separate reports reflecting its conclusions and recommendations on each of these two documents.

Thank you for the opportunity to present the Committee's views on these important public health issues.

Sincerely,

Morton Lippmann, Ph.D.,

Chairman, Clean Air Scientific Advisory Committee.

cc: A. James Barnes, Lester Grant, Vaun Newill, Craig Potter, Terry Yosie.

Summary of Major Scientific Issues and CASAC Conclusions on the 1986 Addendum to the 1982 Particulate Matter/Sulfur Oxides (PM/SO_x) Criteria Document

The Committee concentrated its review on newer studies and analyses which relate primarily to guidance on the lower limit of the proposed ranges for the standards. In general, the Committee believes the Criteria Document Addendum has appropriately summarized and interpreted the designs, analyses and conclusions of studies that should be considered in the standard setting process. The following is a brief chapter by chapter summary of issues that the Committee wishes to emphasize, or which require further clarification.

Chapter 1: Introduction

In general, this chapter provides an excellent summary of the physical and chemical properties and ambient measurement methods for PM and SO_x. However, the chapter could be strengthened by inclusion of a discussion of direct reading monitors for particulate mass concentrations including beta attenuation, light scattering, or other techniques which may be the dominant measurement techniques in the States in the future. This was discussed at the December 1985 CASAC meeting, with emphasis on the need to move to automated and continuous monitoring for particles.

Chapter 2: Respiratory Tract Deposition and Fate

The presentation in this chapter could be expanded by clarifying the discussion concerning the concept of impaired lungs and the deposition that would occur there as opposed to that in normal subjects. Further, the discussion of broncho-constriction being protective (Svartengren et al., 1984) and the discussion of other types of altered breathing patterns could be made clearer, perhaps by reorganizing this information by specific points.

Chapter 3: Epidemiology Studies

We wish to emphasize several studies and analyses discussed at the October 1986 CASAC meeting. One of these studies (Dassen et al.) should be integrated into this chapter, as was recognized by Agency staff in their remarks at the October 1986 meeting.

(1) The two episodic lung function studies show a consistency of results in Steubenville, Ohio (Dockery et al.) and Ijmond, Netherlands (Dassen et al.), lending credence to reported effects of a mixture of PM and sulfur oxides (SO_x) on respiratory function in children. This is consistent with the earlier work of Stebbings. These studies provide a relatively sensitive indication of possible short term physiological responses of uncertain health significance to PM. The roles of exposure times and duration of functional decrement need better definition.

(2) The London mortality studies, including recent analysis by Agency staff, provide strong evidence that particulate matter is more closely associated with daily mortality than sulfur dioxide concentrations. The criteria document should recharacterize distinctions made between "likely" and "possible" effects levels for establishing upper bounds.

(3) The Six-Cities study has reported that cough and bronchitis are twice as prevalent in children living in cities with PM_{10} in the range of 40–60 $\mu g/m^3$, in comparison to cities with a range of 20–30 $\mu g/m^3$.

Chapter 4: Controlled Human Exposure Studies of SO_2 Health Effects

Although this chapter was well done, the Committee suggests that it be strengthened by modifying its existing discussions and by addition of further discussion and tabular material concerning short term exposure effects presented by Drs. Horstman and Folinsbee at the October 1986 CASAC meeting.

Conclusion

The 1986 Addendum to the 1982 Air Quality Criteria Document on PM/SO_x was prepared by EPA at the request of CASAC for the purpose of updating the knowledge of recent scientific studies and analyses. The Committee commends the Agency staff for its efforts in preparing a concise and well written document. The Addendum summarizes key findings from the earlier documents and provides a reasonably complete summary of newly available information concerning particulate matter and sulfur oxides, with major emphasis on evaluation of human health studies published since 1981. The Committee unanimously concludes that this 1986 Addendum, with the incorporation of the changes noted above, represents a scientifically balanced and defensible summary of the extensive scientific literature on these pollutants. These documents fulfill the requirements under section 108 of the Clean Air Act as amended, which requires that the document(s) ". . . shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare . . ." from particulate matter and sulfur oxides in the ambient air.

Addendum II—CASAC Review and Closure of the 1982 OAQPS Staff Paper for Particulate Matter and the 1986 Addendum to the Staff Paper

January 29, 1982.

Subject: CASAC Review and Closure of the OAQPS Staff Paper for Particulate Matter

From: Sheldon K. Friedlander, Chairman, Clean Air Scientific Advisory Committee

To: Anne M. Gorsuch, Administrator

The Clean Air Scientific Advisory Committee (CASAC) recently completed its second and final review of the document entitled *Review of the National Ambient Air Quality Standards for Particulate Matter: Assessment of Scientific and Technical Information, OAQPS Staff Paper.* The Committee notes with satisfaction the improvements made in the scientific quality and the completeness of the staff paper. It has been modified in accordance with the recommendations made by CASAC in July and November 1981. This document is also consistent in all significant respects with the scientific evidence presented and interpreted in the combined criteria document for sulfur oxides and particulate matter. It has organized the data relevant to the establishment of particulate primary and secondary ambient air quality standards in a logical and compelling way, and the Committee believes that it provides you with the kind and amount of technical guidance that will be needed to make appropriate revisions to the standards.

CASAC has prepared this closure memorandum to inform you more specifically of its major findings and conclusions concerning the various scientific issues and studies discussed in the staff paper. In addition, the Committee's review of the scientific evidence leading to the particulate

standard revision leads to a discussion of its own role in the process for setting the standard.

CASAC Conclusions and Recommendations on Major Scientific Issues and Studies Associated With the Development of Revised NAAQS for Particulates

1. Based upon the review of available scientific evidence, a separate general particulate standard remains a reasonable public health policy choice.

2. CASAC reaffirms its initial recommendation of July 1981 to establish a 10 micrometer cut point for a revised primary particulate standard. This recommendation is based upon a recognition of the periodic, and sometimes frequent, tendency of both healthy and sensitive populations to breathe through their mouths and/or oronasally. This practice increases the amount of particulate matter that can penetrate into the thorax because the larger particles are not filtered in the oronasal passages. Deposition of particulates into this region is of special concern to those individuals with pre-existing respiratory problems and children. In addition, the collection of particles of less than 10 micrometer diameter size more closely resembles particles passing into the thoracic region of the human body than the collection of larger sized particles. Furthermore, monitors equipped for a 10 micrometer cut are less wind dependent and can provide a more accurate profile of the contemporary ambient air than samplers which measure total suspended particles.

CASAC's recommended size cut is also similar to proposals of other scientific associations. For example, 88% of the national members of the Air Quality Committee of the International Standards Organization recently voted for a particulate cut point at 10 micrometers for sampling particles which can deposit in the lungs.

The CASAC recommendation is based upon available scientific data. Other individuals and groups have discussed the possibility of establishing a revised particulate standard at a size cut considerably less than 10 micrometers. However, for the current revision of the standard, the scientific data more readily support a 10 micrometer size cut.

3. CASAC reached several major conclusions concerning the revision of the 24-hour and annual particulate standards. At the upper bound of the proposed ranges of 150–350 $\mu g/m^3$ for the 24-hour and 55–110 $\mu g/m^3$ for the annual averages, detectable health effects occur in the populations evaluated in the epidemiological studies. Since the upper end of these ranges contain little or no margin of safety, it would be appropriate to consider lower values for revising the 24-hour and annual standards. In addition, the stated ranges are based solely on quantitative evidence reported in epidemiological studies. A final decision on a revised standard should also incorporate information generated through controlled human, animal toxicology, and from other less quantitative epidemiological studies discussed in the criteria document.

There is an absence of a clearly definable exposure-response relationship for particles, as amply discussed in the criteria document and the staff paper. In addition, because airborne particles are heterogeneous in composition, the potential toxic effects of individual constituents should be considered in setting the standard. Thus, compared to margins of safety set for pollutants such as ozone and carbon monoxide, where exposure-response relationships are better established and small margins of safety are more justifiable, CASAC believes you should consider a revised standard with a wider margin of safety.

4. The Committee reached general agreement that the annual particulate standard should consist of an arithmetic mean. It is recommended that the 24-hour standard include a statistical form and that the number of exceedances is set in relation to the revised standard level.

5. During the past decade, the link between visibility and fine particle mass concentrations has been convincingly documented. Visibility is a sensitive indicator of accumulated man-made pollutants in the ambient air. The public cares about visibility and is willing to pay something for clean air. However, the quantitative basis for establishing a psychological, economic, transportation or any other welfare cost associated with visibility impairment has not been established. In addition, controls required to achieve a given visibility standard are not known due to the complexities of pollutant transport and transformation.

Defining acceptable levels of visibility is a social/policy judgment as well as a scientific decision, but science can provide some guidance. The upper end of the 8–25 $\mu g/m^3$ range for fine particles (those particles with a diameter size of less than 2.5 micrometers) would tend to maintain the status quo for the eastern United States and some western urban areas, but would permit air quality degradation for large areas in the west including national parks. Also, it is highly uncertain that the recommended thoracic particle ranges for the primary standard will protect visibility. The 8–25 $\mu g/m^3$ range for fine particles suggested for visibility protection is a seasonal and spatial average, unlike peak values which will be recommended for the primary standard.

The strongest case for a visibility related standard is one that links emissions of nitrogen oxides and sulfur dioxide with the interrelated aspects of acidic deposition, possible climatological effects, and visibility. Each of these three air quality issues is related to the fine particles which originate both as primary particulate emissions and as secondary aerosols from atmospheric conversions of sulfur dioxide and nitrogen oxides emitted as vapors. In terms of a control strategy to protect public welfare, it may be more efficient to consider a common standard linked to fine particles than to establish a separate set of controls for each of these problems and pollutants.

6. The Committee's evaluation of scientific data and studies in the criteria document and the staff paper lead it to conclude that there is no scientific justification for the establishment of a particulate standard for the specific protection of vegetation.

7. The Committee discussed what effect elimination of a Total Suspended Particulate (TSP) standard would have on the environment. The soiling and nuisance aspects of TSP are essentially local air quality problems because such coarse particles are not transported great distances. This contrasts with visibility or oxidant related problems which are distinctly issues of long range pollution transport. Individuals who serve on the Committee made various recommendations regarding retention or elimination of a secondary standard for TSP, but no clear consensus evolved.

The Process for Setting the Ambient Particulate Standard

In its report of September 21, 1981, CASAC made several major recommendations relating to the process for setting ambient air standards. The Committee is aware that your staff is analyzing its report and is awaiting a response.

A major underlying assumption of the Committee's recommendations was the need to make more explicit the relationship between the scientific evidence in the criteria document and the staff paper and the eventual selection of a numerical level for individual standards. The Committee strongly believes in the need to clarify the standard setting process by

identifying the key studies that will shape the determination of a standard. Intensive evaluation of such studies by CASAC and the public will considerably increase your ability to set a scientifically supportable standard.

The Committee is greatly encouraged by your decision to improve the format and content of OAQPS scientific issue staff papers. In the Draft Staff Paper for Particulate Matter key studies are identified and their implications for setting primary and secondary standards are discussed. More importantly, the inclusion of numerical ranges and their supporting rationale enable the Committee and the public to critically examine the staff's proposed use of the studies. This led to a marked improvement in the quality of the public dialogue concerning the scientific basis for revising the standard. CASAC commends your effort and recommends that all staff papers developed for ambient air standards contain numerical ranges.

CASAC recognizes that your statutory responsibility to set standards requires public health policy judgments in addition to determination of a strictly scientific nature. While the Committee is willing to further advise you on the particulate standard, we see no need, in view of the already extensive comments provided, to review the proposed particulate standards prior to their publication in the **Federal Register.** In this instance, the public comment period will provide sufficient opportunity for the Committee to provide any additional comment or review that may be necessary.

December 16, 1986.

The Honorable Lee Thomas,
Administrator, U.S. Environmental Protection Agency, Washington, DC 20460.

Dear Mr. Thomas: The Clean Air Scientific Advisory Committee (CASAC) has completed its review of the 1986 Addendum to the 1982 Staff Paper on Particulate Matter *(Review of the NAAQS for Particulate Matter: Assessment of Scientific and Technical Information)* prepared by the Agency's Office of Air Quality Planning and Standards (OAQPS).

The Committee unanimously concludes that this document is consistent in all significant respects with the scientific evidence presented and interpreted in the combined Air Quality Criteria Document for Particulate Matter/Sulfur Oxides and its 1986 Addendum, on which the CASAC recently issued its closure letter. The Committee believes that this document provides you with the kind and amount of technical guidance that will be needed to make appropriate revisions to the standards. The Committee's major findings and conclusions concerning the various scientific issues and studies discussed in the Staff Paper Addendum are contained in the attached report.

Thank you for the opportunity to present the Committee's views on this important public health issue.

Sincerely,

Morton Lippmann, Ph.D.,
Chairman, Clean Air Scientific Advisory Committee.

cc: A. James Barnes, Gerald Emison, Vaun Newill, John O'Connor, Craig Potter, Terry Yosie.

Summary of Major Scientific Issues and CASAC Conclusions on the 1986 Draft Addendum to the 1982 Particulate Matter Staff Paper

The Committee found the technical discussions contained in the Staff Paper Addendum to be acceptable with minor revisions.

Particle Size Indicator

The CASAC reaffirms its January 29, 1982 recommendation that a particle size indicator that includes only those particles less than or equal to a nominal 10 um aerodynamic diameter, termed PM_{10}, is appropriate for regulation of particulate concentrations. This judgment is based on analysis of the earlier available data, and the analysis of the recent scientific studies discussed in the 1986 Addendum to the Air Quality Criteria for Particulate Matter/Sulfur Oxides and the 1986 Addendum to the Particulate Matter Staff Paper.

Implications of London Mortality Studies

Further analyses of the London mortality studies, including recent analysis by Agency staff, suggest that:

(1) the data provide no evidence for a threshold for the association between airborne particles and daily mortality or a change of coefficient with changes in particle composition;

(2) mortality effects can be associated with PM alone (with or without sulfur oxides);

(3) there is no reliable quantitative basis for converting British Smoke (BS) readings to PM_{10} gravimetric mass at low (<100–200 $\mu g/m^3$) BS levels, and hence the mortality data are not readily useful for establishing a lower bound for 24-hour PM_{10} NAAQSA, although the suggestion of mortality at relatively low PM levels must be given serious consideration in selecting a margin of safety.

Interpretation of Lung Function Studies for 24-hour Standard

Although the lung function decrements observed in children during and after air pollution episodes are of uncertain health significance, the two episodic lung function studies (Dockery et al., 1986; Dassen et al., 1986) are consistent with each other and the earlier work of Stebbings. They provide a relatively sensitive indication of possible short term physiological responses. Given the difficulty in deriving a lower limit from the mortality studies, these lung function studies can be useful in determining lower bounds for a 24-hour PM_{10} standard.

Interpretation of the Six Cities Study for Annual Standard

In general, the Committee felt that the six cities data are useful in establishing the lower bound of the range for the annual standard. In addition, the following are suggested by the data:

(1) Cough and bronchitis, as defined in this study, are about twice as prevalent in children living in cities with PM_{10} in the range of 40–60 $\mu g/m^3$ in comparison to cities with 20–30 $\mu g/m^3$;

(2) Because factors other than particulate matter may affect the inter-city differences, it is difficult to determine whether these associations should be designated as "likely" health effects;

(3) The results are consistent with the Ostro studies in terms of morbidity responses at long-term average particulate matter exposures within current particulate ambient air quality standards; and

(4) The results are consistent with the Bouhuys study in terms of symptoms without changes in pulmonary function.

Ranges for 24-hour and Annual Standards for PM_{10}

In its January 2, 1986 letter to the Administrator, the CASAC noted that its preliminary analyses of the more recent data do not indicate the need for fundamental changes in the structure of the proposed particle standards; however, the Committee pointed out that these new data suggest the need to focus consideration on standards at or perhaps below the low ends of the ranges proposed in the March 20, 1984 **Federal Register** Notice. The ranges of interest then proposed were 150–250 $\mu g/m^3$ for 24-hour standard, and 50–65 $\mu g/m^3$ for annual standard.

Since then, EPA staff have proposed updated ranges of interest for both the 24-hour standard (140–250 $\mu g/m^3$), and the annual standard (40–65 $\mu g/m^3$), based on short-term and long-term epidemiological data, respectively. The Committee finds these ranges of interest reasonable, given the scientific data and related uncertainties; however, a final decision should also weigh evidence from clinical and toxicological studies

as well. The Committee agrees with EPA staff that selection of final standards must include consideration of the combined protection afforded by the 24-hour and annual standards taken together.

The Committee recommends that you consider setting the revised standards at the lower ends of the proposed ranges for both the 24-hour and annual standards. The Committee recognizes that the exact levels to be chosen for the 24-hour and annual standards represent a policy choice, influenced by the need to include a margin of safety. Given the uncertainty in the supporting scientific data, the Committee cannot distinguish the health effects that may be observed at different levels near the lower bound, such as the health significance of setting the 24-hour standard at 140 $\mu g/m^3$ compared to 150 $\mu g/m^3$.

Addendum III—Executive Summary of the 1986 Addendum to the Staff Paper

Review of the National Ambient Air Quality Standards for Particulate Matter: Updated Assessment of Scientific and Technical Information—Addendum to the 1982 OAQPS Staff Paper (EPA, 1986b).

Executive Summary

This paper evaluates and interprets the updated scientific and technical information that the EPA staff believes is most relevant to decision making on revised primary (health) national ambient air quality standards (NAAQS) for particulate matter and is an addendum to the 1982 particulate matter staff paper. The paper assesses the factors the staff believes should be considered in selecting the pollutant indicator and level for the primary particulate matter standards, updating and supplementing previous staff conclusions and recommendations in these areas to incorporate more recent information. This assessment is intended to help bridge the gap between the scientific review contained in the EPA criteria document addendum "Second Addendum to Air Quality Criteria for Particulate Matter and Sulfur Oxides (1982): Assessment of Newly Available Health Effects Information" and the judgments required of the Administrator in making final decisions on revisions to the primary NAAQS for particulate matter that were proposed in March 1984 (49 FR 10408). The staff paper and this addendum are, therefore, important elements in the standards review process and provide an opportunity for public comment on proposed staff recommendations before they are presented to the Administrator.

Particulate matter represents a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) ranging in size from molecular clusters of 0.005 micrometers (μm) to coarse particles on the order of 1000 μm. The major chemical and physical properties of particulate matter vary greatly with time, region, meteorology and source category, complicating the assessment of health and welfare effects as related to various indicators of particulate pollution. The original measurement method for the particulate matter NAAQS was the "hi volume" sampler, which collects particles of sizes up to a nominal 25–45 μm (so-called "Total Suspended Particulate" or TSP). EPA has proposed to replace this particulate matter indicator with one that includes only particles with aerodynamic diameters smaller than a nominal 10 μm, termed "PM_{10}". Although a large number of PM_{10} monitors are now in place, reliable and consistent data are, at present, limited. Data from 39 sites in EPA's IP network show long-term urban PM_{10} levels range between 25 and 75 $\mu g/m^3$ and maximum 24-hour values range from 50 to 175 $\mu g/m^3$. Higher values are likely as more data become available. Both fine (<2.5 μm) and coarse (>2.5 um) particles are substantial components of PM_{10} mass, with a tendency for higher coarse contributions in western U.S. locations with higher concentrations. National estimates of PM_{10} levels are derived from applying measured PM_{10}/TSP ratios to the wider TSP data set. This analysis (for 1983–85 data) estimated that 193 counties exceeded the lower bound of the ranges proposed for PM_{10} standards (150 $\mu g/m^3$ 24 hour, 50 $\mu g/m^3$ annual) while 136 counties had sites that exceeded the current primary TSP standards.

Particle Indicator

Based on an examination of air quality composition, respiratory tract deposition, and health effects and related considerations, the 1982 staff paper recommended adoption of the size specific indicator (PM_{10}) proposed in 1984. The present staff assessment of the more recent information on respiratory tract deposition contained in the criteria document addendum reinforces the conclusions reached in the original staff assessment in 1982. The staff finds that the recent data do not support alternative indicators that have been suggested, which exclude all particles larger than 10 μm. The PM_{10} indicator is generally conservative over the range of tracheobronchial deposition.

Recent information suggesting enhanced tracheobronchial particle deposition for children relative to adults provides an additional reason for an indicator that includes particles capable of such penetration. Given these considerations and its earlier conclusions, the staff reaffirms its recommendation to replace TSP as the particle indicator for the primary standards with a new indicator that includes only those particles smaller than a nominal 10 μm in aerodynamic diameter (PM_{10}). The previously developed effectiveness criteria for samplers are acceptable for regulatory purposes.

Level of Standards

The major scientific basis for selecting PM standards that have an adequate margin of safety remains community epidemiological research, with mechanistic support from toxicological and controlled human investigations. The limitations of epidemiological studies for these purposes must, however, be recognized. Such studies, while representing real world conditions, can only provide associations between a complex pollutant mix measured at specific locations and times and a particular set of observable health points. Difficulties in conducting and interpreting epidemiological studies limit the reliance that can be placed on the results of any single study. None of the available studies have used PM_{10} as a direct measure of pollution, requiring—where appropriate—further conversion of results to estimated PM_{10} units.

The 1982 criteria document and the criteria document addendum identify a limited set of epidemiological studies most useful for developing quantitative conclusions regarding the effects of particulate matter. This updated staff assessment incorporates the previous evaluation of the earlier studies as well as the present assessment of more recent studies.

The updated staff assessment of the short-term epidemiological data is summarized in Table 1; levels are expressed in both the original (British smoke—"BS" or TSP) and PM_{10} units. The "effects likely" row denotes concentration ranges derived from the criteria document and its addendum at or above which a consensus judgment suggests greatest certainty that some effects would occur, at least under the conditions that obtained in the original studies. The data do not, however, show evidence of clear population thresholds but suggest a continuum of response with both the risk of effects occurring *and* the magnitude of any potential effect decreasing with concentration.

This is particularly true for the statistical analyses of daily mortality in London. Substantial agreement exists that wintertime pollution episodes produced premature mortality in elderly and ill populations, but the range and nature of association provide no clear basis for distinguishing any particular lowest "effects likely" levels or for defining a concentration below which no association remains. The recent lung function studies in children suggest that effects are possible in the range listed in Table 1, but the relationships are not certain enough to derive "effects likely" levels for PM_{10}. They do suggest levels below which detectable functional changes are unlikely to occur.

Table 1. Updated Staff Assessment of Short-Term Epidemiological Studies

Effects/study	Measured British smoke levels (as $\mu g/m^3$) (24-hr. avg.)			Measured TSP levels ($\mu g/m^3$ (24-hr. avg.)	Equivalent PM_{10} levels ($\mu g/m^3$)
	Daily mortality in London [1]	Aggravation of bronchitis [2]	Combined range	Small, reversible declines in lung function in children [3,4]	Combined range [5]
Effects Likely	1000	250*–500*	250–500		350–600
Effects Possible	?	<250*	<250	220*–420 [3]—200–250 [4]	140–350
No Significant Effects Noted				125*[4]–160 [3]	<125

* Indicates levels used for upper and lower bound of range.

[1] Various analyses of daily mortality encompassing the London winter of 1958–59, 14 winters from 1958–72, in aggregate and individually. Early winters dominated by high smoke and SO_2 from coal combustion with frequent fogs. From 1982 CD: Martin and Bradley (1960); Ware et al., (1981); Mazumdar et al. (1981). From 1986 CD Addendum: Mazumdar et al. (1982); Ostro (1984); Shumway et al., (1983); Schwartz and Marcus (1986). Later studies show association across entire range of smoke, with no clear delineation of "likely" effects or threshold of response possible.

[2] Study of symptons reported by bronchitis patients in London, mid-50's to early 70's; Lawther et al. (1970).

[3] Study of pollution "episodes" in Steubenville, Ohio, 1978–80; Dockery et al. (1982).

[4] Study of 1985 pollution episode in Ijmond, The Netherlands; Dassen et al. (1986).

[5] (a) *Conversion of BS readings to PM_{10} levels:* Assumes for London conditions and BS readings in the range 100–500 $\mu g/m^3$, BS <PM_{10} < *TSP* Precise conversions are not possible. Uncertainty in measurements of BS and conversion relationships preclude quantitative estimates of range for lower BS levels. The upper bound assumption (PM_{10} = TSP = BS + 100 $\mu g/m^3$) overestimates PM_{10} levels.

(b) *Conversion of TSP to PM_{10} for Dockery et al. results:* Based on analysis of particle size fraction relationships in Steubenville (Spengler et al. 1986) The lower bound TSP of 220 $\mu g/m^3$ was the peak reported for the Spring 1980 study. A PM_{15}/TSP ratio of about 0.8 occurred at a nearby site on days surrounding this peak. Using lower bound of PM_{10}/ PM_{15} ratio from later year (0.8), the PM_{10} to TSP ratio estimate used is 0.64. The 160 $\mu g/m^3$ reflects peak level in Fall 1980 from episode with no significant functional decline noted.

(c) *Conversion of Dassen et al. results to PM_{10}:* Both PM indices (Respirable Suspended Particles [RSP] and TSP) reached similar levels. Results suggest TSP levels too low, but PM_{10} levels unlikely to be much higher than RSP. Thus RSP = PM_{10} assumed for conditions of higher concentrations in this study. The 125 $\mu g/m^3$ entry reflects an excursion occurring 2 days prior to date on which no decrements noted.

Based on this staff assessment of the short-term epidemiological data, the range of 24-hour PM_{10} levels of interest are 140 to 250 $\mu g/m^3$. The upper end of the range reflects the judgment of the Administrator with regard to the maximum level proposed in 1984 for a 24-hour standard, based on his consideration of the earlier criteria and assessments. Although the recent information provides additional support for the possibility of effects at lower levels, it does not demonstrate that adverse effects would occur with certainty at a PM_{10} concentration of 250 $\mu g/m^3$. This level, therefore, remains an appropriate upper bound. The recent data suggest that the range of levels under consideration of alternative standards can be reduced to 140 $\mu g/m^3$, although the original lower bound of 150 $\mu g/m^3$ is within the range of uncertainty associated with expressing the data as PM_{10}. Neither the studies used to derive this range nor the more qualitative studies of effects in other sensitive population groups (e.g., asthmatics) or effects in controlled human or animal studies provide convincing scientific support for health risks of consequence below 140 $\mu g/m^3$ in current U.S. atmospheres. These qualitative data, as well as factors such as aerosol composition and exposure characteristics, should also be considered in evaluating margins of safety associated with alternative standards in the range of 140 $\mu g/m^3$ to 150 $\mu g/m^3$.

The amended staff assessment of the more quantitative long-term epidemiological data is summarized in Table 2. Long-term studies are subject to additional confounding variables that reduce their sensitivity and make interpretation more difficult. The most important new study shows a gradient of responses in children among six U.S. cities that follows the measured gradient in particulate matter, but response comparisons for locations with somewhat smaller pollution gradients within some of these cities do not follow the same patterns. The results of a separate series of studies on long and intermediate term (2–6 weeks) exposures in a number of U.S. cities (Ostro, 1983, 1987; Hausman et. al, 1984) is more supportive of the possibility of within city effects as comparable U.S. exposure levels. Thus some risk of effects is possible at levels somewhat below those suggested by the 1982 assessment, but it is uncertain given the potential for confounding present in these more recent studies.

Table 2. Updated Staff Assessment of Long-Term Epidemiological Studies

Effects/study	Measured BS levels (as $\mu g/m^3$)	Measured TSP Levels ($\mu g/m^3$)					Equivalent PM_{10} levels ($\mu g/m^3$)
	Increased respiratory disease, reduced lung function in children [1]	Increased respiratory disease, symptoms, small reduction in lung function in adults [2]	Increased respiratory symptoms in adults [3]	Increased respiratory symptoms and illnesses in children [4]	Reduced lung function in children [4]	Combined range	Combined range [5]
Effects likely	230–300	180*				>180	>80–90
Effects possible	<230	130–180*	60–150(110)	60*–114		60–180	40–90
No significant [6] effects noted		80–130			40–114	<60	<40

* Indicates levels used for upper and lower bound of range.

[1] Study conducted in 1963–65 in Sheffield, England (Lunn et al., 1967). BS levels (as $\mu g/m^3$) uncertain.

[2] Studies conducted in 1961–73 in Berlin, N.H. (Ferris et al., 1973, 1976). Effects likely level (180 $\mu g/m^3$) based on uncertain 2-month average. Effects in lung function were relatively small.

[3] Study conducted in 1973 in two Connecticut towns. (Bouhuys et al., 1973). Exposure estimates reflect 1965–73 data in Ansonia. Median value (110 $\mu g/m^3$) used to indicate long-term concentration. No effects on lung function, but some suggestion of effects on respiratory symptoms.

[4] Study conducted in 1976–1980 in 6 U.S. cities (Ware et al., 1986). Exposure estimates reflect 4-year averages across cities. Comparable pollution/effects gradients not noted within cities.

[5] Conversion of TSP to PM_{10} equivalents for Berlin, Ansonia studies based on estimated ratio of PM_{10}/TSP for current U.S. atmospheres (Pace, 1983). The estimated ratio ranged between 0.45 and 0.5. Conversion for six-city study based on site-specific analysis of particle size data (Spengler et al., 1986).

[6] Ranges reflect gradients in which no significant effects were detected for categories at top. Combined range reflects all columns.

Based on this updated assessment of the long-term epidemiological data, the staff recommends that the range of annual PM_{10} levels of interest be 40 to 65 $\mu g/m^3$. The upper end of the range reflects the judgment of the Administrator with regard to the maximum level proposed for an annual standard, based on his consideration of the earlier criteria and assessment. The staff concludes that this level remains a useful upper bound. The recent data prompt consideration of a standard level below the previous lower bound (50 $\mu g/m^3$) to values as low as 40 $\mu g/m^3$. Uncertain data from one recent study of six cities suggest that at this level some risk may remain of respiratory effects in children, but no detectable increases in pulmonary function are expected in children or adults.

When evaluating margins of safety for an annual standard, it is particularly important to examine the results of qualitative data from a number of epidemiological, animal, and air quality studies. These suggest concern for effects not directly evaluated in the studies used to develop the ranges. Such effects include damage to lung tissues contributing to chronic respiratory disease, cancer, and premature mortality. The available scientific data do not suggest major risks for these effects categories at current ambient particle levels in most U.S. areas. Nevertheless, the risk that both fine and coarse particles may produce these responses supports the need to limit long-term levels of PM_{10} for a variety of aerosol compositions.

When selecting final standard levels, consideration should be given to the combined protection afforded by the 24-hour and annual standards taken together. For example, a 24-hour standard at 150 $\mu g/m^3$ would substantially reduce annual levels in a number of areas below 50 $\mu g/m^3$ adding to the protection afforded by an annual standard in areas with higher 24-hour peak to annual mean ratios.

Because of different form, averaging procedures, size range, and limited PM_{10} data, precise comparison between the above ranges of PM_{10} standards and the current primary TSP standards is not possible. A staff analysis of PM_{10}/TSP ratios applied to recent TSP data shows that the revised lower bounds, taken together, would result in standards clearly more stringent than the current standards. In various analyses, standards at the lower bound of the previous range (150,50) have appeared to range from more stringent to approximately comparable to the present primary standards. Standards at the upper end of the range could, however, result in about a four-fold decrease in the number of areas exceeding the primary standards.

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

For reasons set forth in the preamble, Part 50 of Chapter 1 of Title 40 of the Code of Federal Regulations is amended as follows:

1. The authority citation for Part 50 continues to read as follows:

Authority: Secs. 109 and 301(a), Clean Air Act, as amended (42 U.S.C. 7409, 7601 (a)).

2. Section 50.6 is revised to read as follows:

§ 50.6 National primary and secondary ambient air quality standards for particulate matter.

(a) The level of the national primary and secondary 24-hour ambient air quality standards for particulate matter is 150 micrograms per cubic meter ($\mu g/m^3$), 24-hour average concentration. The standards are attained when the expected number of days per calendar year with a 24-hour average concentration above 150 $\mu g/m^3$, as determined in accordance with Appendix K to this part, is equal to or less than one.

(b) The level of the national primary and secondary annual standards for particulate matter is 50 micrograms per cubic meter ($\mu g/m^3$), annual arithmetic mean. The standards are attained when the expected annual arithmetic mean concentration, as determined in accordance with Appendix K to this part, is less than or equal to 50 $\mu g/m^3$.

(c) For the purpose of determining attainment of the primary and secondary standards, particulate matter shall be measured in the ambient air as PM_{10} (particles with an aerodynamic

diameter less than or equal to a nominal 10 micrometers) by:

(1) A reference method based on Appendix J and designated in accordance with Part 53 of this chapter, or

(2) An equivalent method designated in accordance with Part 53 of this chapter.

§50.7 [Removed and reserved]

3. Section 50.7 is removed and reserved.

4. In Appendix G, reference 10 is removed and reserved and section 5.1.1 is revised to read as follows:

5.1.1 *High-Volume Sampler.* Use and calibrate the sampler as described in Appendix B to this Part.

5. Appendix I is added and reserved.

Appendix I [Reserved]

6. Appendix J is added to read as follows:

Appendix J—Reference Method for the Determination of Particulate Matter as PM_{10} in the Atmosphere

1.0 *Applicability.*

1.1 This method provides for the measurement of the mass concentration of particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM_{10}) in ambient air over a 24-hour period for purposes of determining attainment and maintenance of the primary and secondary national ambient air quality standards for particulate matter specified in § 50.6 of this chapter. The measurement process is nondestructive, and the PM_{10} sample can be subjected to subsequent physical or chemical analyses. Quality assurance procedures and guidance are provided in Part 58, Appendices A and B, of this chapter and in References 1 and 2.

2.0 *Principle.*

2.1 An air sampler draws ambient air at a constant flow rate into a specially shaped inlet where the suspended particulate matter is inertially separated into one or more size fractions within the PM_{10} size range. Each size fraction in the PM_{10} size range is then collected on a separate filter over the specified sampling period. The particle size discrimination characteristics (sampling effectiveness and 50 percent cutpoint) of the sampler inlet are prescribed as performance specifications in Part 53 of this chapter.

2.2 Each filter is weighed (after moisture equilibration) before and after use to determine the net weight (mass) gain due to collected PM_{10}. The total volume of air sampled, corrected to EPA reference conditions (25° C, 101.3 kPa), is determined from the measured flow rate and the sampling time. The mass concentration of PM_{10} in the ambient air is computed as the total mass of collected particles in the PM_{10} size range divided by the volume of air sampled, and is expressed in micrograms per standard cubic meter ($\mu g/std\ m^3$). For PM_{10} samples collected at temperatures and pressures significantly different from EPA reference conditions, these corrected concentrations sometimes differ substantially from actual concentrations (in micrograms per actual cubic meter), particularly at high elevations. Although not required, the actual PM_{10} concentration can be calculated from the corrected concentration, using the average ambient temperature and barometric pressure during the sampling period.

2.3 A method based on this principle will be considered a reference method only if (a) the associated sampler meets the requirements specified in this appendix and the requirements in Part 53 of this chapter, and (b) the method has been designated as a reference method in accordance with Part 53 of this chapter.

3.0 *Range.*

3.1 The lower limit of the mass concentration range is determined by the repeatability of filter tare weights, assuming the nominal air sample volume for the sampler. For samplers having an automatic filter-changing mechanism, there may be no upper limit. For samplers that do not have an automatic filter-changing mechanism, the upper limit is determined by the filter mass loading beyond which the sampler no longer maintains the operating flow rate within specified limits due to increased pressure drop across the loaded filter. This upper limit cannot be specified precisely because it is a complex function of the ambient particle size distribution and type, humidity, filter type, and perhaps other factors. Nevertheless, all samplers should be capable of measuring 24-hour PM_{10} mass concentrations of at least 300 $\mu g/std\ m^3$ while maintaining the operating flow rate within the specified limits.

4.0 *Precision.*

4.1 The precision of PM_{10} samplers must be 5 $\mu g/m^3$ for PM_{10} concentrations below 80 $\mu g/m^3$ and 7 percent for PM_{10} concentrations above 80 $\mu g/m^3$, as required by Part 53 of this chapter, which prescribes a test procedure that determines the variation in the PM_{10} concentration measurements of identical samplers under typical sampling conditions. Continual assessment of precision via collocated samplers is required by Part 58 of this chapter for PM_{10} samplers used in certain monitoring networks.

5.0 *Accuracy.*

5.1 Because the size of the particles making up ambient particulate matter varies over a wide range and the concentration of particles varies with particle size, it is difficult to define the absolute accuracy of PM_{10} samplers. Part 53 of this chapter provides a specification for the sampling effectiveness of PM_{10} samplers. This specification requires that the expected mass concentration calculated for a candidate PM_{10} sampler, when sampling a specified particle size distribution, be within ±10 percent of that calculated for an ideal sampler whose sampling effectiveness is explicitly specified. Also, the particle size for 50 percent sampling effectivensss is required to be 10±0.5 micrometers. Other specifications related to accuracy apply to flow measurement and calibration, filter media, analytical (weighing) procedures, and artifact. The flow rate accuracy of PM_{10} samplers used in certain monitoring networks is required by Part 58 of this chapter to be assessed periodically via flow rate audits.

6.0 *Potential Sources of Error.*

6.1 *Volatile Particles.* Volatile particles collected on filters are often lost during shipment and/or storage of the filters prior to the post-sampling weighing [3]. Although shipment or storage of loaded filters is sometimes unavoidable, filters should be reweighed as soon as practical to minimize these losses.

6.2 *Artifacts.* Positive errors in PM_{10} concentration measurements may result from retention of gaseous species on filters [4, 5]. Such errors include the retention of sulfur dioxide and nitric acid. Retention of sulfur dioxide on filters, followed by oxidation to sulfate, is referred to as artifact sulfate formation, a phenomenon which increases with increasing filter alkalinity [6]. Little or no artifact sulfate formation should occur using filters that meet the alkalinity specification in section 7.2.4. Artifact nitrate formation, resulting primarily from retention of nitric acid, occurs to varying degrees on many filter types, including glass fiber, cellulose ester, and many quartz fiber filters [5, 7, 8, 9, 10]. Loss of true atmospheric particulate nitrate during or following sampling may also occur due to dissociation or chemical reaction. This phenomenon has been observed on Teflon® filters [8] and inferred for quartz fiber filters [11, 12]. The magnitude of nitrate artifact errors in PM_{10} mass concentration measurements will vary with location and ambient temperature; however, for most sampling locations, these errors are expected to be small.

6.3 *Humidity.* The effects of ambient humidity on the sample are unavoidable. The filter equilibration procedure in section 9.0 is designed to minimize the effects of moisture on the filter medium.

6.4 *Filter Handling.* Careful handling of filters between presampling and postsampling weighings is necessary to avoid errors due to damaged filters or loss of collected particles from the filters. Use of a filter cartridge or cassette may reduce the magnitude of these errors. Filters must also meet the integrity specification in section 7.2.3.

6.5 *Flow Rate Variation.* Variations in the sampler's operating flow rate may alter the particle size discrimination characteristics of the sampler inlet. The magnitude of this error will depend on the sensitivity of the inlet to variations in flow rate and on the particle distribution in the atmosphere during the sampling period. The use of a flow control device (section 7.1.3) is required to minimize this error.

6.6 *Air Volume Determination.* Errors in the air volume determination may result from errors in the flow rate and/or sampling time measurements. The flow control device serves to minimize errors in the flow rate determination, and an elapsed time meter (section 7.1.5) is required to minimize the error in the sampling time measurement.

7.0 *Apparatus.*

7.1 *PM_{10} Sampler.*

7.1.1 The sampler shall be designed to:

a. Draw the air sample into the sampler inlet and through the particle collection filter at a uniform face velocity.

b. Hold and seal the filter in a horizontal position so that sample air is drawn downward through the filter.

c. Allow the filter to be installed and removed conveniently.

d. Protect the filter and sampler from precipitation and prevent insects and other debris from being sampled.

e. Minimize air leaks that would cause error in the measurement of the air volume passing through the filter.

f. Discharge exhaust air at a sufficient distance from the sampler inlet to minimize the sampling of exhaust air.

g. Minimize the collection of dust from the supporting surface.

7.1.2 The sampler shall have a sample air inlet system that, when operated within a specified flow rate range, provides particle size discrimination characteristics meeting all of the applicable performance specifications prescribed in Part 53 of this chapter. The sampler inlet shall show no significant wind direction dependence. The latter requirement can generally be satisfied by an inlet shape that is circularly symmetrical about a vertical axis.

7.1.3 The sampler shall have a flow control device capable of maintaining the sampler's operating flow rate within the flow rate limits specified for the sampler inlet over normal variations in line voltage and filter pressure drop.

7.1.4 The sampler shall provide a means to measure the total flow rate during the sampling period. A continuous flow recorder is recommended but not required. The flow measurement device shall be accurate to ±2 percent.

7.1.5 A timing/control device capable of starting and stopping the sampler shall be used to obtain a sample collection period of 24 ±1 hr (1,440 ±60 min). An elapsed time meter, accurate to within ±15 minutes, shall be used to measure sampling time. This meter is optional for samplers with continuous flow recorders if the sampling time measurement obtained by means of the recorder meets the ±15 minute accuracy specification.

7.1.6 The sampler shall have an associated operation or instruction manual as required by Part 53 of this chapter which includes detailed instructions on the calibration, operation, and maintenance of the sampler.

7.2 *Filters.*

7.2.1 *Filter Medium.* No commercially available filter medium is ideal in all respects for all samplers. The user's goals in sampling determine the relative importance of various filter characteristics (e.g., cost, ease of handling, physical and chemical characteristics, etc.) and, consequently, determine the choice among acceptable filters. Furthermore, certain types of filters may not be suitable for use with some samplers, particularly under heavy loading conditions (high mass concentrations), because of high or rapid increase in the filter flow resistance that would exceed the capability of the sampler's flow control device. However, samplers equipped with automatic filter-changing mechanisms may allow use of these types of filters. The specifications given below are minimum requirements to ensure acceptability of the filter medium for measurement of PM_{10} mass concentrations. Other filter evaluation criteria should be considered to meet individual sampling and analysis objectives.

7.2.2 *Collection Efficiency.* >99 percent, as measured by the DOP test (ASTM–2986) with 0.3 μm particles at the sampler's operating face velocity.

7.2.3 *Integrity.* ±5 μg/m³ (assuming sampler's nominal 24-hour air sample volume). Integrity is measured as the PM_{10} concentration equivalent corresponding to the average difference between the initial and the final weights of a random sample of test filters that are weighed and handled under actual or simulated sampling conditions, but have no air sample passed through them (i.e., filter blanks). As a minimum, the test procedure must include initial equilibration and weighing, installation on an inoperative sampler, removal from the sampler, and final equilibration and weighing.

7.2.4 *Alkalinity.* <25 microequivalents/gram of filter, as measured by the procedure given in Reference 13 following at least two months storage in a clean environment (free from contamination by acidic gases) at room temperature and humidity.

7.3 *Flow Rate Transfer Standard.* The flow rate transfer standard must be suitable for the sampler's operating flow rate and must be calibrated against a primary flow or volume standard that is traceable to the National Bureau of Standards (NBS). The flow rate transfer standard must be capable of measuring the sampler's operating flow rate with an accuracy of ±2 percent.

7.4 *Filter Conditioning Environment.*

7.4.1 Temperature range: 15° to 30° C.

7.4.2 Temperature control: ±3° C.

7.4.3 Humidity range: 20% to 45% RH.

7.4.4 Humidity control: ±5% RH.

7.5 *Analytical Balance.* The analytical balance must be suitable for weighing the type and size of filters required by the sampler. The range and sensitivity required will depend on the filter tare weights and mass loadings. Typically, an analytical balance with a sensitivity of 0.1 mg is required for high volume samplers (flow rates >0.5 m³/min). Lower volume samplers (flow rates <0.5 m³/min) will require a more sensitive balance.

8.0 *Calibration.*

8.1 *General Requirements.*

8.1.1 Calibration of the sampler's flow measurement device is required to establish traceability of subsequent flow measurements to a primary standard. A flow rate transfer standard calibrated against a primary flow or volume standard shall be used to calibrate or verify the accuracy of the sampler's flow measurement device.

8.1.2 Particle size discrimination by inertial separation requires that specific air velocities be maintained in the sampler's air inlet system. Therefore, the flow rate through the sampler's inlet must be maintained throughout the sampling period within the design flow rate range specified by the manufacturer. Design flow rates are specified as actual volumetric flow rates, measured at existing conditions of temperature and pressure (Q_a). In contrast, mass concentrations of PM_{10} are computed using flow rates corrected to EPA reference conditions of temperature and pressure (Q_{std}).

8.2 *Flow Rate Calibration Procedure.*

8.2.1 PM_{10} samplers employ various types of flow control and flow measurement devices. The specific procedure used for flow rate calibration or verification will vary depending on the type of flow controller and flow indicator employed. Calibration in terms of actual volumetric flow rates (Q_a) is generally recommended, but other measures of flow rate (e.g., Q_{std}) may be used provided the requirements of section 8.1 are met. The general procedure given here is based on actual volumetric flow units (Q_a) and serves to illustrate the steps involved in the calibration of a PM_{10} sampler. Consult the sampler manufacturer's instruction manual and Reference 2 for specific guidance on calibration. Reference 14 provides additional information on the use of the commonly used measures of flow rate and their interrelationships.

8.2.2 Calibrate the flow rate transfer standard against a primary flow or volume standard traceable to NBS. Establish a calibration relationship (e.g., an equation or family of curves) such that traceability to the primary standard is accurate to within 2 percent over the expected range of ambient conditions (i.e., temperatures and pressures) under which the transfer standard will be used. Recalibrate the transfer standard periodically.

8.2.3 Following the sampler manufacturer's instruction manual, remove the sampler inlet and connect the flow rate transfer standard to the sampler such that the transfer standard accurately measures the sampler's flow rate. Make sure there are no leaks between the transfer standard and the sampler.

8.2.4 Choose a minimum of three flow rates (actual m³/min), spaced over the acceptable flow rate range specified for the inlet (see 7.1.2) that can be obtained by suitable adjustment of the sampler flow rate. In accordance with the sampler manufacturer's instruction manual, obtain or verify the calibration relationship between the flow rate (actual m³/min) as indicated by the transfer standard and the sampler's flow indicator response. Record the ambient temperature and barometric pressure. Temperature and pressure corrections to subsequent flow indicator readings may be required for certain types of flow measurement devices. When such corrections are necessary, correction on an individual or daily basis is preferable. However, seasonal average temperature and average barometric pressure for the sampling site may be incorporated into the sampler calibration to avoid daily corrections. Consult the sampler manufacturer's instruction manual and Reference 2 for additional guidance.

8.2.5 Following calibration, verify that the sampler is operating at its design flow rate (actual m³/min) with a clean filter in place.

8.2.6 Replace the sampler inlet.

9.0 *Procedure.*

9.1 The sampler shall be operated in accordance with the specific guidance provided in the sampler manufacturer's instruction manual and in Reference 2. The

general procedure given here assumes that the sampler's flow rate calibration is based on flow rates at ambient conditions (Q_a) and serves to illustrate the steps involved in the operation of a PM_{10} sampler.

9.2 Inspect each filter for pinholes, particles, and other imperfections. Establish a filter information record and assign an identification number to each filter.

9.3 Equilibrate each filter in the conditioning environment (see 7.4) for at least 24 hours.

9.4 Following equilibration, weigh each filter and record the presampling weight with the filter identification number.

9.5 Install a preweighed filter in the sampler following the instructions provided in the sampler manufacturer's instructional manual.

9.6 Turn on the sampler and allow it to establish run-temperature conditions. Record the flow indicator reading and, if needed, the ambient temperature and barometric pressure. Determine the sampler flow rate (actual m^3/min) in accordance with the instructions provided in the sampler manufacturer's instruction manual. NOTE.—No onsite temperature or pressure measurements are necessary if the sampler's flow indicator does not require temperature or pressure corrections or if seasonal average temperature and average barometric pressure for the sampling site are incorporated into the sampler calibration (see step 8.2.4). If individual or daily temperature and pressure corrections are required, ambient temperature and barometric pressure can be obtained by on-site measurements or from a nearby weather station. Barometric pressure readings obtained from airports must be station pressure, not corrected to sea level, and may need to be corrected for differences in elevation between the sampling site and the airport.

9.7 If the flow rate is outside the acceptable range specified by the manufacturer, check for leaks, and if necessary, adjust the flow rate to the specified setpoint. Stop the sampler.

9.8 Set the timer to start and stop the sampler at appropriate times. Set the elapsed time meter to zero or record the initial meter reading.

9.9 Record the sample information (site location or identification number, sample date, filter identification number, and sampler model and serial number).

9.10 Sample for 24±1 hours.

9.11 Determine and record the average flow rate (Q_a) in actual m^3/min for the sampling period in accordance with the instructions provided in the sampler manufacturer's instruction manual. Record the elapsed time meter final reading and, if needed, the average ambient temperature and barometric pressure for the sampling period (see note following step 9.6).

9.12 Carefully remove the filter from the sampler, following the sampler manufacturer's instruction manual. Touch only the outer edges of the filter.

9.13 Place the filter in a protective holder or container (e.g., petri dish, glassine envelope, or manila folder).

9.14 Record any factors such as meteorological conditions, construction activity, fires or dust storms, etc., that might be pertinent to the measurement on the filter information record.

9.15 Transport the exposed sample filter to the filter conditioning environment as soon as possible for equilibration and subsequent weighing.

9.16 Equilibrate the exposed filter in the conditioning environment for at least 24 hours under the same temperature and humidity conditions used for presampling filter equilibration (see 9.3).

9.17 Immediately after equilibration, reweigh the filter and record the postsampling weight with the filter identification number.

10.0 *Sampler Maintenance.*

10.1 The PM_{10} sampler shall be maintained in strict accordance with the maintenance procedures specified in the sampler manufacturer's instruction manual.

11.0 *Calculations.*

11.1 Calculate the average flow rate over the sampling period corrected to EPA reference conditions as Q_{std}. When the sampler's flow indicator is calibrated in actual volumetric units (Q_a), Q_{std} is calculated as:

$$Q_{std} = Q_a \times (P_{av}/T_{av})(T_{std}/P_{std})$$

where

Q_{std} = average flow rate at EPA reference conditions, std m^3/min;

Q_a = average flow rate at ambient conditions, m^3/min;

P_{av} = average barometric pressure during the sampling period or average barometric pressure for the sampling site, kPa (or mm Hg);

T_{av} = average ambient temperature during the sampling period or seasonal average ambient temperature for the sampling site, K;

T_{std} = standard temperature, defined as 298 K;

P_{std} = standard pressure, defined as 101.3 kPa (or 760 mm Hg).

11.2 Calculate the total volume of air sampled as:

$$V_{std} = Q_{std} \times t$$

where

V_{std} = total air sampled in standard volume units, std m^3;

t = sampling time, min.

11.3 Calculate the PM_{10} concentration as:

$$PM_{10} = (W_f - W_i) \times 10^6 / V_{std}$$

where

PM_{10} = mass concentration of PM_{10}, μg/std m^3;

W_f, W_i = final and initial weights of filter collecting PM_{10} particles, g;

10^6 = conversion of g to μg.

Note.—If more than one size fraction in the PM_{10} size range is collected by the sampler, the sum of the net weight gain by each collection filter [$\Sigma(W_f - W_i)$] is used to calculate the PM_{10} mass concentration.

12.0 *References.*

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7. Appendix K is added to read as follows:

Appendix K—Interpretation of the National Ambient Air Quality Standards for Particulate Matter

1.0 *General.*

This appendix explains the computations necessary for analyzing particulate matter data to determine attainment of the 24-hour and annual standards specified in 40 CFR 50.6. For the primary and secondary standards, particulate matter is measured in the ambient air as PM_{10} (particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers) by a reference method based on Appendix J of this part and designated in accordance with Part 53 of this chapter, or by an equivalent method designated in accordance with Part 53 of this chapter. The required frequency of measurements is specified in Part 58 of this chapter.

Several terms used throughout this appendix must be defined. A "daily value" for PM_{10} refers to the 24-hour average concentration of PM_{10} calculated or measured from midnight to midnight (local time). The term "exceedance" means a daily value that is above the level of the 24-hour standard after rounding to the nearest 10 $\mu g/m^3$ (i.e., values ending in 5 or greater are to be rounded up). The term "average" refers to an arithmetic mean. All particulate matter standards are expressed in terms of expected annual values: expected number of exceedances per year for the 24-hour standard and expected annual arithmetic mean for the annual standards. The "expected annual value" is the number approached when the annual values from an increasing number of years are averaged, in the absence of long-term trends in emissions or meteorological conditions. The term "year" refers to a calendar year.

Although the discussion in this appendix focuses on monitored data, the same principles apply to modeling data, subject to EPA modeling guidelines.

2.0 *Attainment Determinations.*

2.1 *24-Hour Primary and Secondary Standards.*

Under 40 CFR 50.6(a) the 24-hour primary and secondary standards are attained when the expected number of exceedances per year at each monitoring site is less than or equal to one. In the simplest case, the number of expected exceedances at a site is determined by recording the number of exceedances in each calendar year and then averaging them over the past 3 calendar years. Situations in which 3 years of data are not available and possible adjustments for unusual events or trends are discussed in Sections 2.3 and 2.4. Further, when data for a year are incomplete, it is necessary to compute an estimated number of exceedances for that year by adjusting the observed number of exceedances. This procedure, performed by calendar quarter, is described in Section 3. The expected number of exceedances is then estimated by averaging the individual annual estimates for the past 3 years.

The comparison with the allowable expected exceedance rate of one per year is made in terms of a number rounded to the nearest tenth (fractional values equal to or greater than 0.05 are to be rounded up; e.g., an exceedance rate of 1.05 would be rounded to 1.1, which is the lowest rate for nonattainment).

2.2 *Annual Primary and Secondary Standards.*

Under 40 CFR 50.6(b), the annual primary and secondary standards are attained when the expected annual arithmetic mean PM_{10} concentration is less than or equal to the level of the standard. In the simplest case, the expected annual arithmetic mean is determined by averaging the annual arithmetic mean PM_{10} concentrations for the past 3 calendar years. Because of the potential for incomplete data and the possible seasonality in PM_{10} concentrations, the annual mean shall be calculated by averaging the four quarterly means of PM_{10} concentrations within the calendar year. The formulas for calculating the annual arithmetic mean are given in Section 4. Situations in which 3 years of data are not available and possible adjustments for unusual events or trends are discussed in Sections 2.3 and 2.4. The expected annual arithmetic mean is rounded to the nearest 1 $\mu g/m^3$ before comparison with the annual primary standard (fractional values equal to or greater than 0.5 are to be rounded up).

2.3 *Data Requirements.*

40 CFR 58.13 specifies the required minimum frequency of sampling for PM_{10}. For the purposes of making comparisons with the particulate matter standards, all data produced by National Air Monitoring Stations (NAMS), State and Local Air Monitoring Stations (SLAMS) and other sites submitted to EPA in accordance with the Part 58 requirements must be used, and a minimum of 75 percent of the scheduled PM_{10} samples per quarter are required.

To demonstrate attainment of either the annual or 24-hour standards at a monitoring site, the monitor must provide sufficient data to perform the required calculations of Sections 3 and 4. The amount of data required varies with the sampling frequency, data capture rate and the number of years of record. In all cases, 3 years of representative monitoring data that meet the 75 percent criterion of the previous paragraph should he utilized, if available, and would suffice. More than 3 years may be considered, if all additional representative years of data meeting the 75 percent criterion are utilized. Data not meeting these criteria may also suffice to show attainment; however, such exceptions will have to be approved by the appropriate Regional Administrator in accordance with EPA guidance.

There are less stringent data requirements for showing that a monitor has failed an attainment test and thus has recorded a violation of the particulate matter standards. Although it is generally necessary to meet the minimum 75 percent data capture requirement per quarter to use the computational formulas described in Sections 3 and 4, this criterion does not apply when less data is sufficient to unambiguously establish nonattainment. The following examples illustrate how nonattainment can be demonstrated when a site fails to meet the completeness criteria. Nonattainment of the 24-hour primary standards can be established by (a) the observed annual number of exceedances (e.g. four observed exceedances in a single year), or by (b) the estimated number of exceedances derived from the observed number of exceedances and the required number of scheduled samples (e.g. two observed exceedances with every other day sampling). Nonattainment of the annual standards can be demonstrated on the basis of quarterly mean concentrations developed from observed data combined with one-half the minimum detectable concentration substituted for missing values. In both cases, expected annual values must exceed the levels allowed by the standards.

2.4 *Adjustment for Exceptional Events and Trends.*

An exceptional event is an uncontrollable event caused by natural sources of particulate matter or an event that is not expected to recur at a given location. Inclusion of such a value in the computation of exceedances or averages could result in inappropriate estimates of their respective expected annual values. To reduce the effect of unusual events, more than 3 years of representative data may be used. Alternatively, other techniques, such as the use of statistical models or the use of historical data could be considered so that the event may be discounted or weighted according to the likelihood that it will recur. The use of such techniques is subject to the approval of the appropriate Regional Administrator in accordance with EPA guidance.

In cases where long-term trends in emissions and air quality are evident, mathematical techniques should be applied to account for the trends to ensure that the expected annual values are not inappropriately biased by unrepresentative data. In the simplest case, if 3 years of data are available under stable emission conditions, this data should be used. In the event of a trend or shift in emission patterns, either the most recent representative year(s) could be used or statistical techniques or models could be used in conjunction with previous years of data to adjust for trends. The use of less than 3 years of data, and any adjustments are subject to the approval of the appropriate Regional Administrator in accordance with EPA guidance.

3.0 *Computational formulas for the 24-hour standard.*

3.1 *Estimating Exceedances for a year.*

If PM_{10} sampling is scheduled less frequently than every day, or if some scheduled samples are missed, a PM_{10} value will not be available for each day of the year. To account for the possible effect of incomplete data, an adjustment must be made to the data collected at each monitoring location to estimate the number of exceedances in a calendar year. In this adjustment, the assumption is made that the fraction of missing values that would have exceeded the standard level is identical to the fraction of measured values above this level. This computation is to be made for all sites that are scheduled to monitor throughout the entire year and meet the minimum data requirements of Section 2.3. Because of possible seasonal imbalance, this adjustment shall be applied on a quarterly

basis. The estimate of the expected number of exceedances for the quarter is equal to the observed number of exceedances plus an increment associated with the missing data. The following formula must be used for these computations:

$$e_q = v_q + [(v_q/n_q) \times (N_q - n_q)] = v_q \times N_q/n_q \quad [1]$$

where

e_q = the estimated number of exceedances for calendar quarter q,
v_q = the observed number of exceedances for calendar quarter q,
N_q = the number of days in calendar quarter q,
n_q = the number of days in calendar quarter q with PM_{10}, and
$_q$ = the index for calendar quarter, q = 1, 2, 3 or 4.

The estimated number of exceedances for a calendar quarter must be rounded to the nearest hundredth (fractional values equal to or greater than 0.005 must be rounded up).

The estimated number of exceedances for the years, e, is the sum of the estimates for each calendar quarter.

$$e = \sum_{q=1}^{4} e_q \quad [2]$$

The estimated number of exceedances for a single year must be rounded to one decimal place (fractional values equal to or greater than 0.05 are to be rounded up). The expected number of exceedances is then estimated by averaging the individual annual estimates for the most recent 3 or more representative years of data. The expected number of exceedances must be rounded to one decimal place (fractional values equal to or greater than 0.05 are to be rounded up).

The adjustment for incomplete data will not be necessary for monitoring or modeling data which constitutes a complete record, i.e., 365 days per year.

To reduce the potential for overestimating the number of expected exceedances, the correction for missing data will not be required for a calendar quarter in which the first observed exceedance has occurred if: (a) there was only one exceedance in the calendar quarter, (b) everyday sampling is subsequently initiated and maintained for 4 calendar quarters in accordance with 40 CFR § 58.13 and (c) data capture of 75 percent is achieved during the required period of everyday sampling. In addition, if the first exceedance is observed in a calendar quarter in which the monitor is already sampling every day, no adjustment for missing data will be made to the first exceedance if a 75 percent data capture rate was achieved in the quarter in which it was observed.

Example 1

During a particular calendar quarter, 39 out of a possible 92 samples were recorded, with one observed exceedance of the 24-hour standard. Using formula [1], the estimated number of exceedances for the quarter is

$e_q = 1 \times 92/39 = 2.359$ or 2.36

If the estimated exceedances for the other 3 calendar quarters in the year were 2.30, 0.0 and 0.0, then, using formula [2], the estimated number of exceedances for the year is $2.36 + 2.30 + 0.0 + 0.0$ which equals 4.66 or 4.7. If no exceedances were observed for the 2 previous years, then the expected number of exceedances is estimated by $(1/3) \times (4.7 + 0 + 0) = 1.57$ or 1.6. Since 1.6 exceeds the allowable number of expected exceedances, this monitoring site would fail the attainment test.

Example 2

In this example, everyday sampling was initiated following the first observed exceedance as required by 40 CFR § 58.13. Accordingly, the first observed exceedance would not be adjusted for incomplete sampling. During the next three quarters, 1.2 exceedances were estimated. In this case, the estimated exceedances for the year would be $1.0 + 1.2 + 0.0 + 0.0$ which equals 2.2. If, as before, no exceedances were observed for the two previous years, then the estimated exceedances for the 3-year period would then be $(1/3) \times (2.2 + 0.0 + 0.0) = 0.7$, and the monitoring site would *not* fail the attainment test.

3.2 *Adjustments for Non-Scheduled Sampling Days.*

If a systematic sampling schedule is used and sampling is performed on days in addition to the days specified by the systematic sampling schedule, e.g., during episodes of high pollution, then an adjustment must be made in the formula for the estimation of exceedances. Such an adjustment is needed to eliminate the bias in the estimate of the quarterly and annual number of exceedances that would occur if the chance of an exceedance is different for scheduled than for non-scheduled days, as would be the case with episode sampling.

The required adjustment treats the systematic sampling schedule as a stratified sampling plan. If the period from one scheduled sample until the day preceding the next scheduled sample is defined as a sampling stratum, then there is one stratum for each scheduled sampling day. An average number of observed exceedances is computed for each of these sampling strata. With nonscheduled sampling days, the estimated number of exceedances is defined as

$$e_q = (N_q/m_q) \times \sum_{j=1}^{m_q} (v_j/k_j) \quad [3]$$

where

e_q = the estimated number of exceedances for the quarter.
N_q = the number of days in the quarter,
m_q = the number of strata with samples during the quarter,
v_j = the number of observed exceedances in stratum j, and
k_j = the number of actual samples in stratum j.

Note that if only one sample value is recorded in each stratum, then formula [3] reduces to formula [1].

Example 3

A monitoring site samples according to a systematic sampling schedule of one sample every 6 days, for a total of 15 scheduled samples in a quarter out of a total of 92 possible samples. During one 6-day period, potential episode levels of PM_{10} were suspected, so 5 additional samples were taken. One of the regular scheduled samples was missed, so a total of 19 samples in 14 sampling strata were measured. The one 6-day sampling stratum with 6 samples recorded 2 exceedances. The remainder of the quarter with one sample per stratum recorded zero exceedances. Using formula [3], the estimated number of exceedances for the quarter is

$e_q = (92/14) \times (2/6 + 0 + \ldots + 0) = 2.19$

4.0 Computational Formulas for Annual Standards.

4.1 Calculation of the Annual Arithmetic Mean.

An annual arithmetic mean value for PM_{10} is determined by averaging the quarterly means for the 4 calendar quarters of the year.

The following formula is to be used for calculation of the mean for a calendar quarter:

$$\bar{x}_q = (1/n_q) \times \sum_{i=1}^{n_q} \bar{x}_i \quad [4]$$

where

$\bar{x}_q$ = the quarterly mean concentration for quarter q, q = 1, 2, 3, or 4,
n_q = the number of samples in the quarter, and
$\bar{x}_i$ = the ith concentration value recorded in the quarter.

The quarterly mean, expressed in $\mu g/m^3$, must be rounded to the nearest tenth (fractional values of 0.05 should be rounded up).

The annual mean is calculated by using the following formula:

$$\bar{x} = (1/4) \times \sum_{q=1}^{4} \bar{x}_q \quad [5]$$

where

$\bar{x}$ = the annual mean, and
$\bar{x}_q$ = the mean for calendar quarter q.

The average of quarterly means must be rounded to the nearest tenth (fractional values of 0.05 should be rounded up).

The use of quarterly averages to compute the annual average will not be necessary for

monitoring or modeling data which results in a complete record, i.e., 365 days per year.

The expected annual mean is estimated as the average of three or more annual means. This multi-year estimate, expressed in $\mu g/m^3$, shall be rounded to the nearest integer for comparison with the annual standard (fractional values of 0.5 should be rounded up).

Example 4

Using formula [4], the quarterly means are calculated for each calendar quarter. If the quarterly means are 52.4, 75.3, 82.1, and 63.2 $\mu g/m^3$, then the annual means is

$$\bar{x} = (1/4) \times (52.4 + 75.3 + 82.1 + 63.2 = 68.25 \text{ or } 68.3$$

4.2 Adjustments for Non-scheduled Sampling Days.

An adjustment in the calculation of the annual mean is needed if sampling is performed on days in addition to the days specified by the systematic sampling schedule. For the same reasons given in the discussion of estimated exceedances (Section 3.2), the quarterly averages would be calculated by using the following formula:

$$\bar{x}_q = (1/m_q) \times \sum_{j=1}^{m_q} \frac{k_j}{i=1} (x_{ij}/k_j) \qquad [6]$$

where

$\bar{x}_q$ = the quarterly mean concentration for quarter q, q = 1, 2, 3, or 4,

x_{ij} = the ith concentration value recorded in stratum j,

k_j = the number of actual samples in stratum j, and

m_q = the number of strata with data in the quarter.

If one sample value is recorded in each stratum, formula [6] reduces to a simple arithmetic average of the observed values as described by formula [4].

Example 5

During one calendar quarter, 9 observations were recorded. These samples were distributed among 7 sampling strata, with 3 observations in one stratum. The concentrations of the 3 observations in the single stratum were 202, 242, and 180 $\mu g/m^3$. The remaining 6 observed concentrations were 55, 68, 73, 92, 120, and 155 $\mu g/m^3$. Applying the weighting factors specified in formula [6], the quarterly mean is

$$\bar{x}_q = (1/7) \times [(1/3) \times (202 + 242 + 180) + 55 + 68 + 73 + 92 + 120 + 155] = 110.1$$

Although 24-hour measurements are rounded to the nearest 10 $\mu g/m^3$ for determinations of exceedances of the 24-hour standard, note that these values are rounded to the nearest 1 $\mu g/m^3$ for the calculation of means.

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