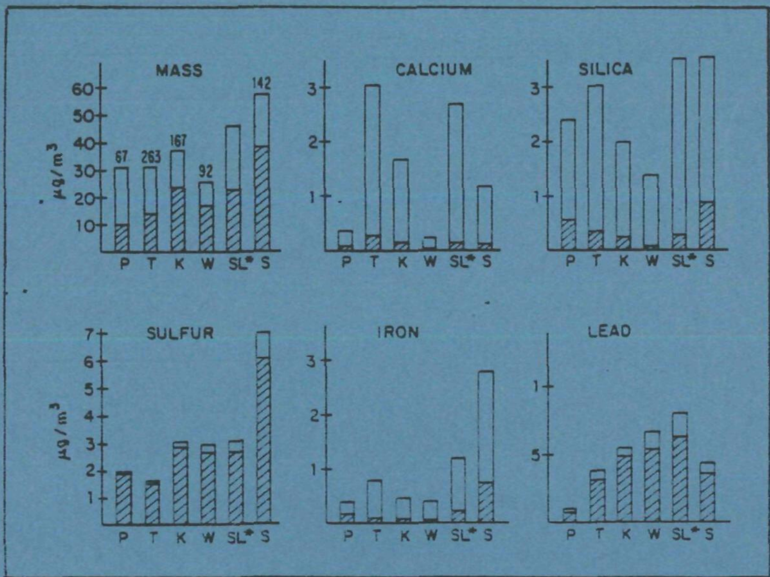
EPA

EPA 450/05 86-012

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



Strategies and Air Standards Division
Office of Air Quality Planning and Standards
U.S. Environmental Protection Agency
Research Triangle Park, N.C. 27711

December 1986

Cover Illustration. Mean concentration of components of particulate matter from dichotomous sampling (1978-79) in Portage, WI (P), Topeka, KS (T), Kingston, TN (K), Watertown, MA (W), St. Louis, MO (SL) *(1976), and Steubenville, OH (S). Shading represents fine fraction (< 2.5 μm), remainder is coarse fraction up to a nominal 15 μm. These communities are the subject of the Harvard "Six Cities Study" of the health effects of air pollution. The cities were chosen to reflect a gradient in PM and SO_x air pollution. Although a major component of this study--reflecting longitudinal analyses--has not been completed, the results of cross-sectional analyses (Ware et al., 1986) and a series of episode studies (Dockery et al., 1982) have been identified as being among the more important recent publications for examining the health effects of particulate matter. The data in the figure illustrate the variations in particle mass and composition among these cities during the period when these studies were being conducted.

Reference. Spengler, et al. (1980). Fine Particle Measurements in Six U.S. Cities. In Proceedings of the Technical Basis for a Size Specific Particulate Standard Speciality Conference. March 1980.

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

Strategies and Air Standards Division
Office of Air Quality Planning and Standards
U.S. Environmental Protection Agency
Research Triangle Park, N.C. 27711

December 1986

Acknowledgments

This staff paper is the product of the Office of Air Quality Planning and Standards. The principal authors include John Bachmann and Jeff Cohen. The report incorporates comments from OAQPS, the Office of Research and Development, the Office of Policy, Planning, and Evaluation, and the Office of General Counsel within EPA and was formally reviewed by the Clean Air Scientific Advisory Committee.

Helpful comments and suggestions were also submitted by a number of independent scientists, by officials from the California Air Resources Board, and by environmental and industry groups including the National Resources Defense Council, the American Lung Association, the American Iron and Steel Institute, the American Mining Congress, the Utility Air Regulatory Group, Consolidation Coal Company, the Mining and Reclamation Council of America, the Indiana Coal Council, Phelps Dodge Corporation, and Middle South Services.

The authors wish to thank Teresa Clemons and Tricia Holland for word processing, and Dick Atherton for graphics assistance.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

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 (um) to coarse particles on the order of 100 um. 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 um (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 um, 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 ug/m^3 and maximum 24-hour values range from 50 to 175 ug/m3. Higher values are likely as more data become available. Both fine (<2.5 um) and coarse (>2.5 um) particles are substantial components of PM_{10} mass, with a tendency for higher coarse contributions in western US 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 ug/m^3 24 hour, 50 ug/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 informaton 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 um 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 epidemilogical 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 occuring <u>and</u> 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.

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

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

	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 ($\mu g/m^3$)
Effects/Study	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 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.

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.

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 250 $\mu g/m^3$.

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 at 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

	Measured BS Levels (as μg/m^3	Measured TSP Levels (μg/m^3)					Equivalent PM_{10} Levels (μg/m^3)
Effects/Study	Increased Respiratory Disease, Reduced Lung Function in Children[1]	Increased Respiratory Disease Symtpoms, 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 BS	180*	-	-	-	$\geq$180	80-90
Effects Possible	<230 BS	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 μg/m^3) uncertain.
[2]Studies conducted in 1961-73 in Berlin, N.H. (Ferris et al., 1973, 1976). Effects level (180 μg/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 Anson. Median value (110 μg/m^3) used to indicate long-term concentration. No effects on lung function, but some suggesstion 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 μg/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 μg/m^3) to values as low as 40 μg/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 μg/m^3 would substantially reduce annual levels in a number of areas below 50 μg/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 that 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.

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

I. INTRODUCTION

A. Purpose

This paper evaluates and interprets the most relevant scientific and technical information reviewed in the EPA document, Second Addendum to Air Quality Criteria for Particulate Matter and Sulfur Oxides (1982): Assessment of Newly Available Health Effects Information (EPA, 1986) and represents an update of the 1982 particulate matter staff paper (EPA, 1982a). This staff paper addendum is intended to help bridge the gap between the scientific review of recent health effects information contained in the criteria document addendum and the judgments required of the Administrator in making final decisions on the proposed revisions to the primary national ambient air quality standards (NAAQS) for particulate matter (49 FR 10408). As such, particular emphasis in this paper is placed on conclusions, recommendations, and uncertainties regarding the pollutant indicator and levels for the primary standards. While the paper should be of use to all parties interested in the standards review, it is written for those decision makers, scientists, and staff who have some familiarity with the technical discussions contained in the criteria document addendum.

B. Background

1. Legislative Requirements

Since 1970 the Clean Air Act as amended has provided authority and guidance for the listing of certain ambient air pollutants which may endanger public health or welfare and the setting and revising of NAAQS for those pollutants. Primary standards must be based on health effects criteria and provide an adequate margin of safety to ensure protection of public health.

As several recent judicial decisions have made clear, the economic and technological feasibility of attaining primary standards are not to be considered in setting them, although such factors may be considered to a degree in the development of state plans to implement the standards (D.C. Cir., 1980, 1981). Further guidance provided in the legislative history of the Act indicates that the standards should be set at "the maximum permissible ambient air level . . . which will protect the health of any (sensitive) group of the population." Also, margins of safety are to be provided such that the standards will afford "a reasonable degree of protection . . . against hazards which research has not yet identified." (Committee on Public Works, 1974). In the final analysis, the EPA Administrator must make a policy decision in setting primary standards, based on his judgment regarding the implications of all the health effects evidence and the requirement that an adequate margin of safety be provided.

2. Original PM Standards and Proposed Revisions

The current primary standards for particulate matter (to protect public health) are 75 micrograms per cubic meter ($\mu g/m^3$) annual geometric mean, and 260 $\mu g/m^3$, maximum 24 hour concentration not to be exceeded more than once per year. The reference method for measuring attainment of the primary standards is the "hi-volume" sampler (40 CFR Part 50, Appendix B), which effectively collects particles in the range of up to 25-45 micrometers (μm) in diameter (so-called "total suspended particulate," or "TSP"). Thus, TSP is the current indicator for the particulate matter standards.

On March 20, 1984, EPA proposed changes in the standards (49 FR 10408) based on the Agency's review and revision of the health and welfare criteria. The proposed changes to the primary standards included:

1) replacing TSP as the indicator for particulate matter with a new indicator that includes only those particles with an aerodynamic diameter smaller than or equal to a nominal 10 µm (PM_{10});

2) changing the level of the 24-hour standard to a value to be selected from a range of 150 to 250 µg/m^3 and replacing the deterministic form of the standard with a statistical form that permits one expected exceedance of the standard level per year; and

3) changing the level and form of the annual standard to a value to be selected from a range of 50 to 65 µg/m^3, expected annual arithmetic mean.

Given the precautionary nature of the Act, the Administrator stated an inclination to select the primary standards from the lower portions of the above ranges. The proposal notice (49 FR 10408) sets forth the rationale for these and other proposed revisions of the particulate matter NAAQS and background information related to the proposal.

3. Developments Subsequent to Proposal

After the close of the public comment period on the proposed standards provisions, the Clean Air Scientific Advisory Committee (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. Based on its preliminary review of these new studies, the Committee recommended that the Agency prepare addenda to the criteria document and staff paper to evaluate the relevant new studies and consider their potential implications for standard setting. The Agency announced its decision to prepare these addenda on April 1, 1986 (51 FR 11058).

A preliminary draft of this paper was reviewed by the CASAC in October 1986. This final product incorporates the suggestions and recommendations of the

CASAC as well as other appropriate comments received on the initial draft. The CASAC closure memorandum (Lippmann, 1986) is reprinted in Appendix C.

C. Approach

The approach in this paper is to address the newly available health effects information in the criteria document addendum (CD addendum or CDA; EPA, 1986a) in the context of those critical elements which the staff believes have implications for the proposed revisions to the primary particulate matter standards. Particular attention is drawn to judgments related to the proposed indicator for the primary standards (i.e., PM_{10}), and the proposed ranges of interest for the level of the primary standards. Previous staff conclusions and recommendations related to the secondary standards will not be addressed here.

Sections II and III review important recent scientific and technical information relevant to standard setting. Section II provides a brief update of aspects of current and historical air quality information on particulate matter to support discussions of the standards. Section III addresses those essential elements of the health effects information that require re-examination in light of the new information in the CD addendum, which include:

1) respiratory tract deposition and clearance of inhaled particles; and

2) concentration/response relationships for both acute and long-term exposures to particulate matter derived from community epidemiological studies.

Drawing from the discussion in Sections II and III, Section IV identifies and assesses the factors the staff believes should be considered in selecting the particulate pollutant indicator and level of primary standards. Staff conclusions and recommendations on policy alternatives are updated and supplemented to incorporate the more recent information.

II. AIR QUALITY CONSIDERATIONS

More than any other criteria pollutant, "particulate matter" represents a broad class of chemically and physically diverse substances. Their principal common feature is existence as discrete particles in the condensed (liquid or solid) phase ranging in size from molecular clusters of 0.005 μm to coarse particles on the order of 100 μm.* The major chemical and physical properties of particulate matter vary greatly with time, region, meteorology, and source category. It is to be expected, then, that the effects of given quantities of particles on public health and welfare also will vary. This variable composition complicates the evaluation of the applicability of specific particle health and welfare studies for establishing national ambient air quality standards. The 1982 staff paper ("SP," 1982) (Section IV) summarized some key features of our understanding of historical and current particulate matter composition to provide perspective for interpretation of the effects studies derived from the 1982 criteria document ("CD," 1982b). This section of the addendum updates the original work in two areas: 1) an overview of recent measured and estimated PM_{10} concentrations and potential exposures, and 2) a summary of historical particle size relationships associated with six U.S. cities that are the subject of the most important new epidemiological studies.

---

*Where not otherwise specified, particle sizes reported in this paper reflect aerodynamic equivalent diameter (AED). A number of terms (e.g., fine, coarse, inhalable, thoracic, TSP) are used to describe various fractions of particulate matter. Many of these terms are defined by the instruments used for measurement. The major particle indicators discussed in this paper are defined in Appendix D of the 1982 staff paper.

A. Current PM_{10} Concentrations

Since the original staff and CASAC recommendations for a 10 μm cut-point for the primary particulate matter standards, a number of different sampling devices capable of measuring this fraction (termed PM_{10}) have been developed. Several hundred PM_{10} instruments are now being operated in the field by state and local agencies, industries, and researchers. Data from these sources are, however, fragmentary due in part to start-up and reporting limitations, and the available results have not yet been adequately screened. Thus, it is not yet possible to provide an adequate national assessment of PM_{10} concentrations.

Some idea of PM_{10} levels and composition across the country can, however, be derived from later years of EPA's "Inhalable Particle" (IP) network (Pace, 1986). Beginning in 1982, the 39 sites in this network with dichotomous samplers were retrofitted with PM_{10} inlets. These sites were chosen to represent areas with the highest particulate matter concentrations in the original 163 site network. As a group, they have considerably higher TSP levels than most sites in EPA's "SAROAD" data base. Because of the limited number and duration, however, it is virtually certain that other locations in the nation will record similarly high or even higher concentrations. The PM_{10} samplers came on line at various times in 1983 and 1984 and were operated on a 1 in 6 day sampling schedule. Thirty-eight of the sites provide useful data during this period, with a total collection of 11 to 113 readings per site.

With these limitations in mind, Figure 2-1 presents the annual and maximum 24-hour values from this network in 1983-84. These data suggest that both fine and coarse particles are major contributors to PM_{10} mass across all sites, with a tendency for sites with higher concentrations to

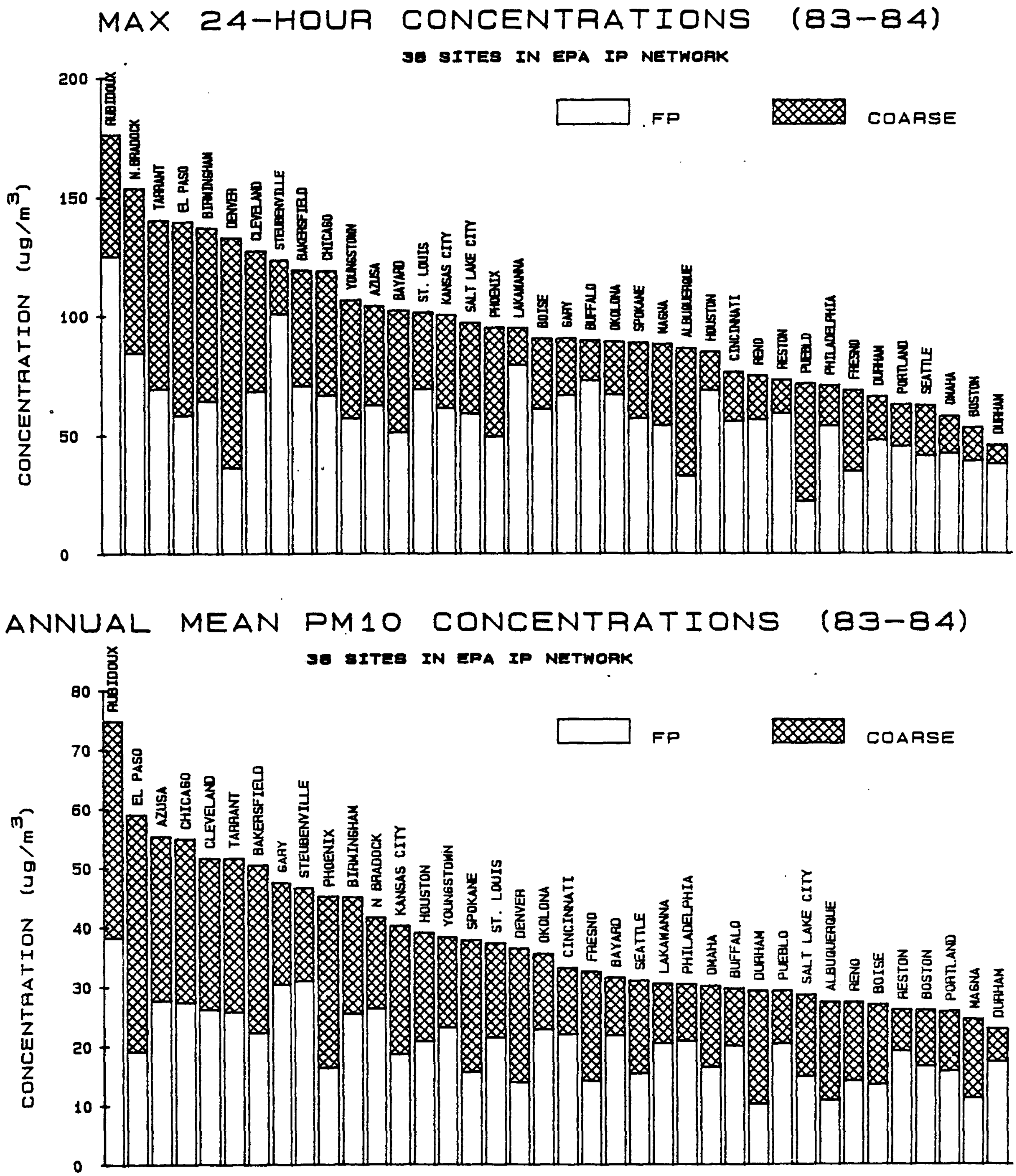


Figure 2-1. PM_{10} Concentrations from Dichotomous Samplers in EPA IP Network, ordered by concentration. a) Maximum 24-hour PM_{10} values with associated fine mass. Due to limited sampling frequency, these data probably understate the actual maxima. b) Annual means of PM_{10} and fine particles. Fine mass is a substantial fraction of PM_{10} mass particularly in eastern sites; coarse particles tend to constitute a large fraction at higher concentrations and at western sites. (Pace, 1986)

have a higher coarse fraction. This tendency holds for both maximum 24-hour and annual data over all sites on the days with highest PM_{10} concentration, the fine fraction average about 60% of PM_{10} mass.

The data in Figure 2-1 suggest that no more than eight sites would exceed the lower bounds of the ranges for PM_{10} standards proposed in 1984. As noted above, however, these results are likely to understate the extent of higher concentrations across the country. To provide some sense of the nature of such concentrations as well as potential human exposures to them, EPA staff have developed an approach for estimating the probability of exceeding particular PM_{10} values using available TSP measurements (Pace and Frank, 1984). The approach is based on a detailed examination of size fractionated data (PM_{10}, PM_{15}, and TSP) across the nation (Pollack et al., 1985). To provide a best estimate of the number of areas that would exceed particular PM_{10} values, staff applied PM_{10}/TSP relationships associated with a 50% probability of exceeding the specified limits to the national TSP data set for the years 1982-84. The results shown in Table 2-1 represent the estimated number of counties (and population residing therein) that would exceed combined PM_{10} standards set at the extreme upper and lower bounds of the proposed ranges. For comparison purposes, the effect of adding a secondary annual TSP standard of 90 $\mu g/m^3$ and the counties exceeding the current primary TSP standards are also shown. These estimates are highly uncertain, but give some perspective on the nature of current PM_{10} air quality and potential exposures with respect to the proposed standards. More definitive data from actual PM_{10} monitoring will be available in the near future.

TABLE 2-1. ESTIMATED COUNTIES EXCEEDING PROPOSED STANDARD LIMITS*

Standards (24 hr/annual, $\mu g/m^3$)	No. Counties Exceeding Limit	Population in Counties
Upper bound of PM_{10} ranges (250/65)	36	12 million
Upper PM_{10} + TSP secondary**	73	-
Lower bound of PM_{10} ranges (150/50)	173	60 million
Lower PM_{10} + TSP secondary**	176	-
Current primary TSP standards (260/75)	155	50 million

*Based on 1982-84 TSP data, counties with probability of exceeding standards (probex) $\geq$ 0.5, 1980 census data. Geographical area exceeding limits may, in many cases, be much smaller than county size. Accordingly, populations in the vicinity of such concentrations are lower than the total county populations.

**90 $\mu g/m^3$ annual arithmetic mean.

B. Historical Trends in Six Cities

The draft criteria document addendum indicates that two of the more important recent publications on the effects of particulate matter are derived from the Harvard "Six Cities" study. To aid in the assessment of these studies, EPA commissioned an examination of the relationships between TSP and size fractionated particle mass measurements in these cities (Spengler et al., 1986). The results, which span some seven years of size specific data, are useful both in examining trends and in permitting improved estimates of historical PM_{10} levels from TSP measurements. Details on the analysis, methodology, and relationship to health study sites are contained in a separate report (Spengler et al., 1986).

The results from Steubenville in Figure 2-2 are illustrative. Over the six year period of record, concentrations of all particle fractions

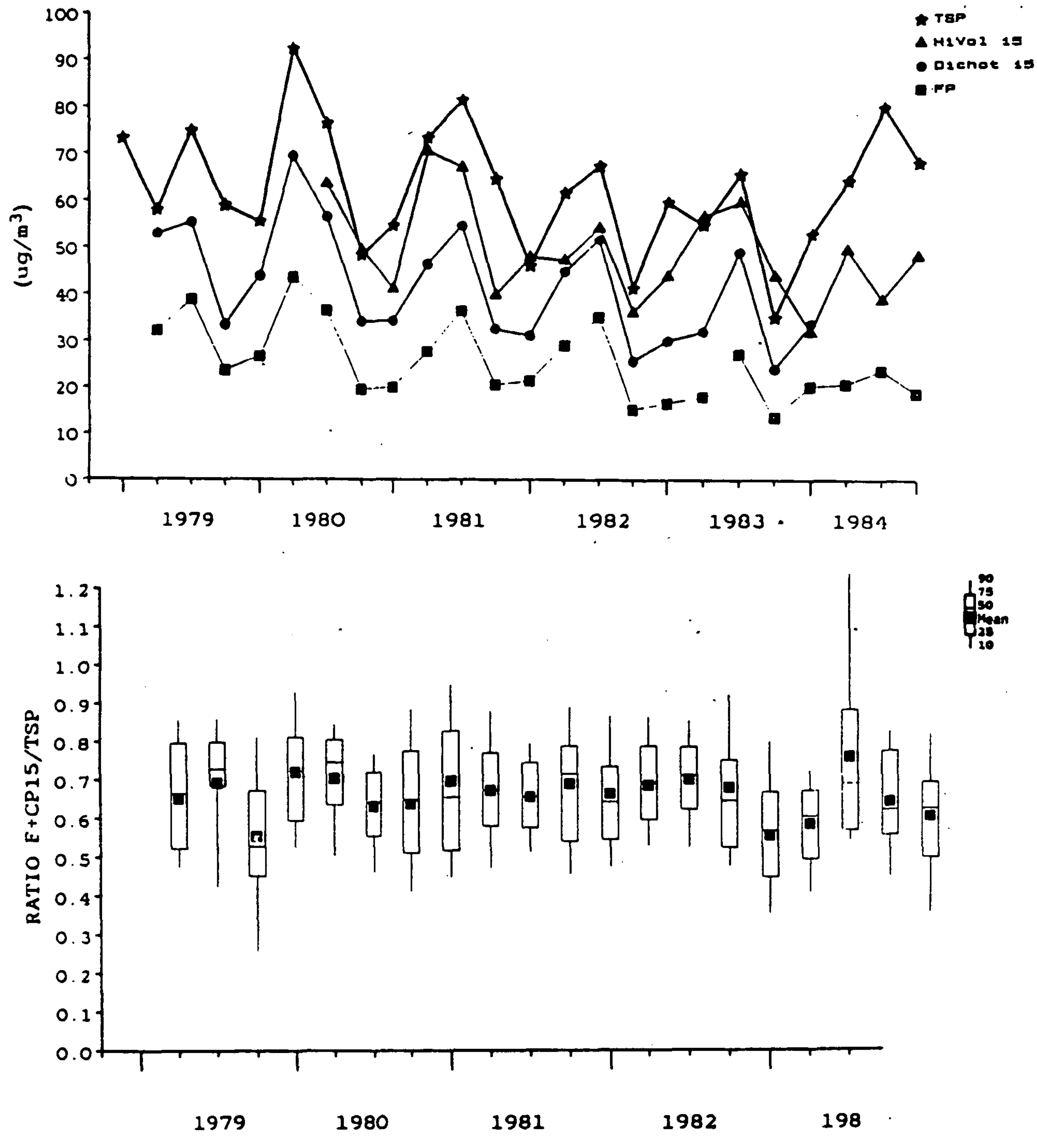


Figure 2-2. Trends in Seasonal Particle Fractions at Steubenville (Spengler et al., 1986). a) From 1979 on, all size fractions show similar seasonal trends with a general decline in all measures. b) The ratio of PM_{15}/TSP as measured by dichotomous sampler is, however reasonably stable over the same period. The ratios of these fractions at other six city sites also do not show clear trends, but in some cases the decrease in coarse particles (> 2.5 µm) is more pronounced than that for fine, suggesting that the historical ratios of PM_{10}/TSP were somewhat lower.

generally declined as source emissions declined, with some suggestion of an increase in 1984. The PM_{15}/TSP ratio remained reasonably stable through this period. This suggests that the PM_{10}/TSP ratio of 0.5 measured in 1984 would be reasonably representative of the recent historical past. Size fraction ratios at the other five sites also showed little in the way of trends, but the examination of trends in particle mass suggested that the PM_{10}/TSP ratio in three cities (St. Louis, Watertown and Topeka) were likely to have been somewhat lower in earlier years when TSP levels were higher (Spengler et al., 1986). Recent (1984) PM_{10}/TSP ratios for these cities are Portage, WI (0.64), Topeka, KS (0.46), St. Louis, MO (0.62), Harriman, TN (0.66), and Watertown, MA (0.54). The report notes that the PM_{10} and some other aerometric data for certain years were obtained by use of Beta-Gauge measurement rather than gravimetric mass. Based on an examination of trends, no perceptible difference is noted between these two measures, at least for determining longer-term averages.

The ratios derived from annual averages do not necessarily apply to any particular 24-hour period. Data presented in the Spengler et al. (1986) report (Figures IV-3 to IV-8) also include size fraction and ratio data that encompass the 1979 and 1980 episode studies reported in Dockery et al. (1982). On various days during the three study periods, the PM_{15}/TSP ratios measured by dichotomous samplers ranged between 0.4 and 0.8. Based on the overall ratios among fractions in Steubenville (Tables V-5,6 in the Spengler et al. report), the PM_{10}/TSP ratios would be expected to be a factor of about 0.8 to 0.9 of these PM_{15}/TSP ratios (see Appendix B).

III. CRITICAL ELEMENTS IN THE REVIEW OF THE PRIMARY STANDARDS

This section summarizes recent information on particle deposition in the respiratory tract and on concentration-response relationships from community studies. A comprehensive discussion of these and other critical elements, including mechanisms of toxicity, effects of concern, and sensitive populations, is contained in Section V of the 1982 staff paper (1982a). The present summary provides a basis for later discussions of the implications of the more recent studies for selecting the particle indicator and examining concentration/response relationships.

A. Mechanisms: Particle Deposition

The major relevant new information reviewed in the CD addendum concerning mechanisms related to penetration and deposition of particles in the respiratory tract falls into the following categories: (1) extension of experimental data on deposition and clearance of large (> 10 μm) particles; (2) assessment of particle deposition during oronasal breathing; and (3) information on variations in deposition and clearance for children and individuals with respiratory illness, as well as for altered breathing patterns. Each of these areas is briefly discussed below.

1. Thoracic Deposition of Large (> 10 μm) Particles

Figure 3-1 updates the range of available experimental data on alveolar and tracheobronchial particle deposition presented in the 1982 CD (Figure 2, CDA). The recent experimental deposition data on larger particles (> 10 μm) from three laboratories are represented as the individual points shown. The CD addendum notes that the data of Svartengren (1986) reflect an atypical inhalation pattern; accordingly, less emphasis should be placed on those data. Nevertheless, the major thrust of the new results, taken together, is to substantiate the original extrapolation of the upper bound of the

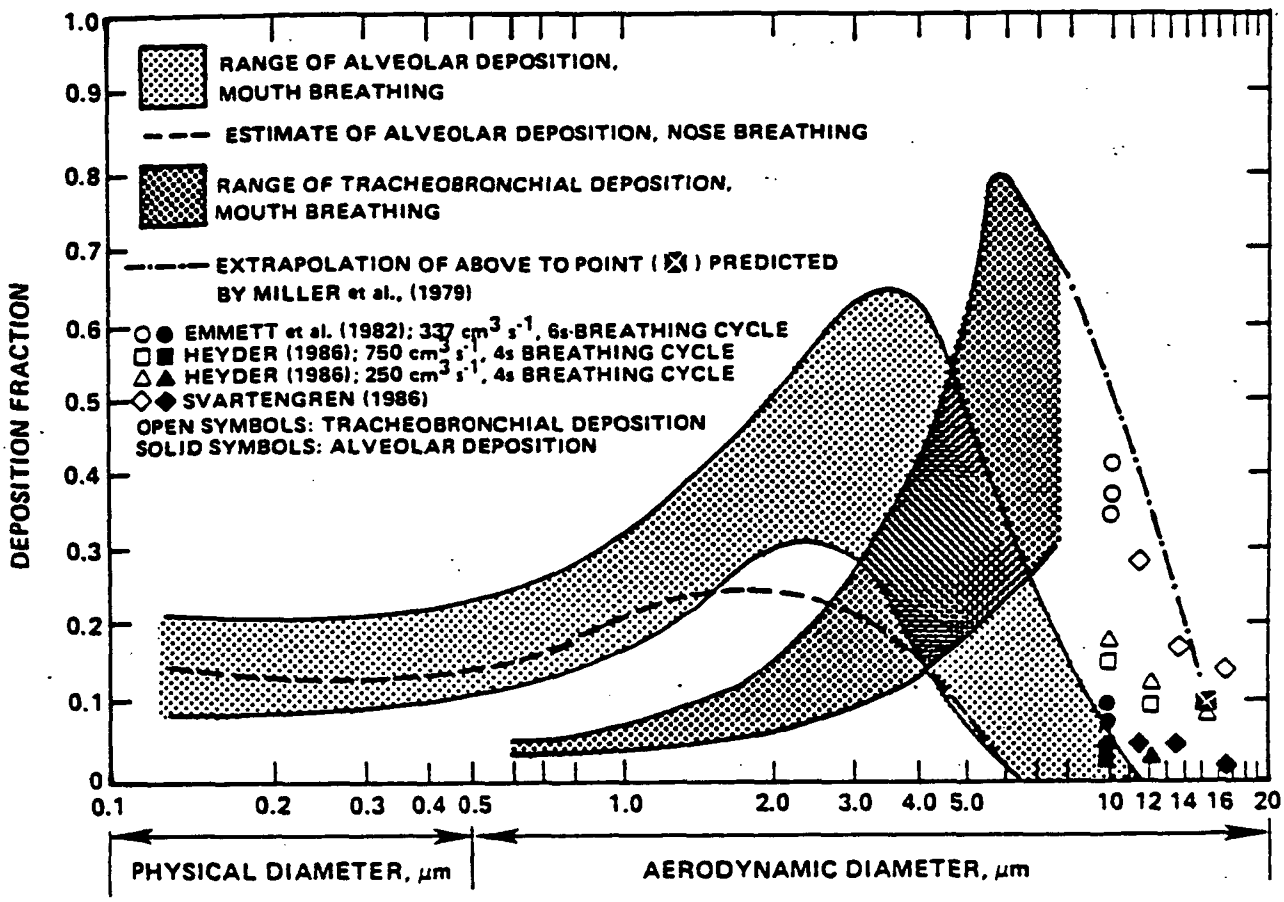


Figure 3-1. Regional deposition of monodisperse aerosols by indicated particle diameter for mouthpiece breathing (alveolar, tracheobronchial) and nose breathing (alveolar) (CDA, Figure 2). The alveolar band indicates the range of results found by different investigators using different subjects and flow parameters for alveolar deposition following mouth breathing. Variability is also expected following nasal inhalation. The tracheobronchial band indicates intersubject variability in deposition over the range of sizes as measured by Chan and Lippmann (1980). Deposition is expressed as fraction of particles entering the mouth (or nose). Also shown is an extrapolation of the upper bound of the TB curve to the point predicted by Miller et al. (1979). The extrapolation illustrates the likely shape of the curve in this size range but is uncertain. However, the data of Emmett et al. (1982), Heyder (1986), and Svartengren (1986) tend to substantiate this extrapolation. In the Svartengren (1986) studies, subjects took maximally deep inhalations at a flow of 500 cm^3 s^1.

tracheobronchial deposition curve in Figure 3-1 to the point predicted by Miller et al. (1979). With the exception of the Svartengren results, the newer data are also reasonably consistent with the range of alveolar deposition illustrated; taken together, however, the added points suggest slightly higher alveolar deposition for larger particles than did the previous data.

2. Assessment of Deposition During Oronasal Breathing

The experimental results depicted in Figure 3-1 were obtained from studies in which the subjects inhaled through a mouthpiece. Such results tend to overstate particle penetration under more natural oronasal breathing conditions. Swift and Proctor (1982) attempted to quantify this overstatement and simulate deposition under natural oronasal and oral breathing for ventilation rates corresponding to light activity. Based on their results, the authors predicted that little thoracic deposition would occur for particles larger than 10 μm with natural breathing conditions. The CD addendum points out that this conclusion does not appear to be consistent with the information available in 1982; moreover, the analysis itself has been superceded by improved simulations using more recent experimental data (Miller et al., 1984, 1986).

As indicated in the CD addendum, these latter analyses provide significantly improved fits of the deposition data and extend both the particle size range and ventilation patterns simulated. These results show that the Swift and Proctor simulation and related predictions understate thoracic deposition for particles larger than 10 μm under all conditions and understate deposition of particles larger than 6 μm for individuals who habitually breathe oronasally (mouth breathers) at light activity levels. The CD addendum concludes that the more recent deposition data shown in Figure 3-1 "are relevant to examining the potential of particles to penetrate to the lower respiratory tract and pose a potentially increased risk. Increased risk may be due to increased localized dose or to the exceedingly long half-times for clearance of larger particles (Gerrity et al., 1983)" (p. 2-18).

3. Variations in Deposition and Clearance for Children and Other Groups

Experimental deposition data discussed above are restricted to adults. The epidemiological evidence, however, indicates increased risk to young children exposed to ambient particulate matter. Phalen et al. (1985) have modeled tracheobronchial deposition of particles. Although not accounting for prior extrathoracic removal, the results suggest a tendency towards increased particle deposition efficiencies for the range of particle sizes modeled (0.5 to 10 μm) in smaller (younger) individuals (CDA, Figure 4). Attempts to quantify age-dependent differences in deposition will require improved information on differences in children related to alveolar and extrathoracic deposition, deposition over the entire breathing cycle, and clearance patterns.

Subject characteristics, disease states, and other factors can also alter the deposition and clearance of particles from more typically observed ranges. Recent work by Heyder (1982) examined biological variability of particle deposition in adults and found very small intrasubject variability mainly due to daily variations in breathing cycle and flow rate. The more extensive variability of deposition rate between subjects breathing the same aerosol was found to be less determined by the morphological constitution of the respiratory tract than by individual ventilatory patterns.

Several new studies on clearance mechanisms further support previous conclusions in the 1982 CD and Staff Paper regarding the consequences of retarded mucous transport when impaired by disease or other insults on residence times of inhaled particles, long-term clearance times of insoluble particle from the alveolar region, and the regional deposition of inhaled particles (Svartengren et al., 1986; Levandowski et al., 1985, Garrard et al., 1985; Bailey et al., 1982; Bohning et al., 1982; Philipson et al., 1985; Gerrity et al., 1983).

B. Concentration-Response Information

As discussed in the 1982 Staff Paper, associations between air pollution and both acute and chronic effects have been demonstrated in many countries and different population groups, supported by controlled laboratory exposures of animals and humans to various components of particulate matter (SP, section V.A,B,C; Appendix B). Assessing the precise level of particulate pollution associated with observed effects on health, however, has many problems. Suspended particulate matter is not a uniquely defined entity. The comprehensive physical and chemical characteristics are not only hard to measure and relate to health effects, but vary with monitoring device, geography, and time. This variability increases the uncertainty of any extrapolations from one set of circumstances to another, and greatly limits the utility of laboratory studies of single substances for quantifying health risks.

Epidemiological studies can provide strong evidence for the existence of pollutant effects, but are more limited for identifying accurate effects levels for specific pollutants or pollutant classes. Among the more important limitations of epidemiology as discussed in the 1982 CD are: 1) inadequate and inconsistent measurement of the exposure burden of individuals; 2) variability in the measurement of health endpoints (e.g., lung function, hospital admissions, frequency of symptoms) and in the sensitivity of populations studied; 3) failure, especially in cross-sectional studies, to control fully for confounding or covarying factors, such as cigarette smoking and socioeconomic status; 4) difficulty in distinguishing particles from other pollutants; and 5) inability to establish a causal relationship, or negate one, based only on statistical associations.

Recognizing these limitations, epidemiological studies still form the principal basis for developing concentration response assessments for particulate pollution. The key concentration-response information derived from the 1982 CD is discussed in the 1982 Staff Paper and in the 1984 PM proposal notice (49 FR 10408). The following review summarizes the recent epidemiological studies cited by the CD addendum as providing the most reliable exposure-response information on mortality and morbidity effects associated with acute and chronic exposures to particulate matter. Other recent studies that may provide reasonable evidence of exposure-response relationships or qualitative insights are summarized in tabular form in Appendix A. Further assessment of the epidemiological studies as applied to selecting alternative levels for air quality standards is presented in Section IV.

1. <u>Acute Exposures</u>

a) <u>Mortality</u>

Table 3-1 summarizes recent epidemiological studies providing the most useful concentration response information for assessing acute exposures to particulate matter. The initial entry reflects the newer CD addendum conclusions regarding reanalyses of daily London mortality in relation to short-term (24-hour) exposures to PM and SO_2 (Mazumdar et al., 1982; Ostro, 1984 Shumway

TABLE 3-1. SUMMARY OF RECENT (1982-86) EPIDEMIOLOGICAL STUDIES PROVIDING MOST USEFUL CONCENTRATION/RESPONSE INFORMATION FOR ACUTE PARTICLE EXPOSURES

)bserved ffects	Time	Observed Concentration Range PM(µg/m³)	SO₂(µg/m³)	Comments	Study
Increases in daily mortality in metropolitan ondon	1958-1972 winters	<500 BS*	>500 24-hr averages	Recently published studies reinforce 1982 CD, SP conclusions regarding likelihood of increased mortality at 500 to 1000 µg/m³ for BS and SO_2, with no clearly defined threshold for BS in the range of 150 to 500 µg/m³. Year-by-year analyses indicate significant BS-mortality associations in most to all winters. Nature of relationships vary significantly with model. Suggestion of surrogate behavior.	Mazumdar et al, 1982, 1983; Ostro 1984
				Recent unpublished analyses confirm major findings of the published studies with advanced statistical techniques accounting for auto-correlation and temperature effects. Schwartz and Marcus findings suggest significant association for BS at lowest levels (<100 µg/m³ BS), but not for SO_2 below about 500 µg/m³.	Shumway et al. 1983, Schwartz and Marcus, 1986
hort-term eductions in ung function in 330 school hildren, teubenville, H (330 total)	Four separate study periods of 3 weeks following pollution "episodes" in 1978-1980	1) 420 TSP 2) 270 TSP 3) 220 TSP 4) 160 TSP (max 24 averages for "alert" or "sham" episode)	280 460 170 190	First 3 episodes: small (2%-3%) but significant reversible declines in FVC up to 2-3 weeks after peak. Less consistent results for FEV. No significant effects after 4th "sham" episode. Baseline measurements for 1st, 4th taken on days with high pollution. Linear regression of pooled data for 330 children indicate significantly more negative slopes in functions vs. TSP and SO_2 across ranges (10-270 µg/m³, 0-280 µg/m³, respectively). Higher response in some children suggests sensitive subgroup.	Dockery et al, 1982
hort-term eduction in ung function n 179 school hildren in he etherlands Ijmond)	Before, during, after pollution episode Nov. 1984-Feb. 1985	200-250 TSP and RSP (D_{50} < 3.5 µm)	200-250 24-hr averages	Small (3-5%) reversible declines in several measures of airway function (FVC, FEV_1, MEF) during episode and 5 days later. No effect after 26 days or shortly after a day when TSP, RSP and SO_2 levels all averaged 100-150 µg/m³. Separate sub-groups of children tested on each day. Peak TSP levels possibly understated.	Dassen et al., 1986

British Smoke (BS) is a pseudo-mass indicator related to small particle (size less than a nominal 4.5 µm) darkness CD, pp. 1-88 to 1-90).

et al., 1983, Schwartz and Marcus, 1986). Among the important unresolved issues raised regarding these London data are identification of a practical threshold for PM-mortality associations, separating effects of PM and SO_2, the changes in coefficients obtained with different subsets of data sets and models, the effects of unmeasured variables such as other outdoor pollutants, demographic changes over time and indoor air pollution, and the appropriate statistical methods to account for long-term seasonal trends in mortality (Roth et al., 1986). When considering the available evidence, the CD Addendum finds that:

> "the following conclusions appear to be warranted based on the earlier criteria review (U.S. EPA, 1982a) and present evaluation of newly available analyses of the London mortality experience: (1) Markedly increased mortality occurred, mainly among the elderly and chronically ill, in association with BS and SO_2 concentrations above 1000 μg/m^3, especially during episodes when such pollutant elevations occurred for several consecutive days; (2) During such episodes coincident high humidity or fog was also likely important, possibly by providing conditions leading to formation of H_2SO_4 or other acidic aerosols; (3) Increased risk of mortality is associated with exposure to BS and SO_2 levels in the range of 500 to 1000 μg/m^3, for SO_2 most clearly at concentrations 700 μg/m^3; and (4) Convincing evidence indicates that relatively small but statistically significant increases in the risk of mortality exist at BS (but not SO_2) levels below 500 μg/m^3, with no indications of any specific threshold level having been demonstrated at lower concentrations of BS (e.g., at $\leq$ 150 μg/m^3). However, precise quantitative specification of the lower PM levels associated with mortality is not possible, nor can one rule out potential contributions of other possible confounding variables at these low PM levels" (CDA, p. 3-9).

Analyses of deviations in daily mortality from 15-day moving means for each of the 14 winters individually in two publications found that the mortality-BS relationship was significant in most to all of the years (Ostro, 1984, Mazumdar et al., 1982). In separate regressions involving a linear model of SO_2 and BS jointly, a linear model of BS alone, and a quadratic analysis of BS alone, Mazumdar et al. found that the BS-mortality relationship was significant in 7, 14, and 13 winters respectively. In a linear regression of year by year data for days when BS was below 150 μg/m^3, Ostro found significant regression coefficients in 7 of 12 winters with a substantial number of days with BS < 150 $\mu g/m^3$, including 6 of the most recent 7 winters. Both Mazumdar et al. and Ostro found a tendency for the regression coefficients to increase in later years in smoke only regressions; a trend is not apparent in the joint smoke-SO_2 regression.

From a methodological perspective, the recent report by Shumway et al. (1983) represents a significant addition to the London mortality analyses. Their investigations developed a complex time series structure that accounted for long-term trends in mortality as well as auto-correlation in the data. No attempt was made to separate the effects of BS and SO_2 and the effects of the two pollutants were found to be nearly identical. Total, cardiovascular, and respiratory mortality all increased with BS (or SO_2) concentration across the range of concentrations with no discernible threshold. Slopes decreased at higher concentrations similar to findings of Mazumdar et al. and Ostro for smoke alone. Temperature was also a significant predictor with the greatest impact when both current and 2-day lag temperature was used. Based on analyses of alternative time-lagged models, the authors concluded that (1) the mechanism by which these factors influence mortality has pollution acting strongly and instantaneously, and (2) the largest fraction of variance in daily mortality could be attributed to cyclical patterns in temperature and pollution that had 7-21 day periods. Taken together, these conclusions suggest that although relatively small elevations of pollution may influence daily mortality, larger effects are more likely when the elevated concentrations occur as part of a multi-day cycle than after short duration episodes.

In order to delineate further the degree of reliance that can be placed on the more recent analyses outlined above (Ostro, 1984; Mazumdar et al., 1982; Shumway et al., 1983), EPA conducted a reanalysis of the 14 winter London mortality data set (Schwartz and Marcus, 1986).* Schwartz and Marcus controlled for the effects of autocorrelation in separate time series regressions of daily mortality that incorporated various combinations of temperature, humidity, SO_2, and BS. They found that both "crude" (or absolute) daily mortality as well as deviations in daily mortality from a 15-day moving mean were positively and significantly correlated with increases in BS. Significant linear correlations of crude mortality with BS were observed for 13 of 14 winters (deviations were significant in all 14 winters), including 6 of the last 7 winters, during which the maximum daily BS levels were well below 500 $\mu g/m^3$. The overall effect of accounting for autocorrelation was to increase the strength of the associations. When compared to the previous published analyses, the magnitude of the regression coefficients for each year were comparable to those found by Mazumdar et al, (1982) and Ostro (1984). As in the earlier studies, Schwartz and Marcus found a tendency for the overall regression coefficients to increase in the later years with lower concentrations. This is also evidenced in an apparently concave concentration-response relationships when the data for all winters were grouped and plotted. When only days with BS < 200 $\mu g/m^3$ were included in the regression, however, the regression coefficients were more stable, with no clear tendency to increase with time. In essence, the BS/mortality relationship across and within individual winters appears to be concave, with no apparent threshold at various BS levels tested in this and earlier analyses (500 $\mu g/m^3$, 250 $\mu g/m^3$, 200 $\mu g/m^3$, 150 $\mu g/m^3$). The Schwartz and

*This paper and a summary memorandum (Marcus and Schwartz, 1986), are reprinted in full as Appendix A to the Criteria Document Addendum. Although not published, the paper was presented to the CASAC and the public for review at the October 15-16, 1986 meeting. Copies were made available to the public at the time of the meeting. Subsequently, EPA received and considered comments on this study from industry and environmental groups and from members of the scientific community.

Marcus results thus reinforce the findings of Ostro (1984) regarding the absence of an apparent threshold and both Ostro and Mazumdar et al., (1982) with respect to the magnitude of the regression coefficients. The suggestion by Mazumdar of a "quadratic" concentration-response relationship with a threshold at 300 $\mu g/m^3$ is not supported by the reanalyses.

Schwartz and Marcus also examined further the suggestion raised by Mazumdar et al. (1982) that the effects of smoke are separable from those of SO_2. In regressions involving both pollutants, the collinearity between the two tended to deflate the apparent significance of both. However, the overall results for all years combined and for those individual years with lower correlations between BS and SO_2 ($r < 0.9$) show that the mortality effects of BS remain significant and relatively large even when SO_2 is included in the model, while the inclusion of BS in the model reduces the SO_2 coefficients to insignificant values. Thus, while an independent effect of SO_2 cannot be excluded, particularly at higher concentrations, these analyses add weight to previous suggestions that BS is significantly correlated with mortality independent of SO_2.

Based on the various studies discussed above, it is currently not possible to derive an appropriately quantitative model for a gravimetric particulate matter/daily mortality relationship across the range of concentrations observed in London or to specify a concentration below which no association remains. It is even more problematic to apply such relations to locations other than London. However, the results of Mazumdar et al. (1982) provide some perspective on the relative magnitude of any effects during various winters. Using a linear model with coefficients comparable to those found in other studies, these investigators found the mean effects of smoke accounted for on the order of 4 to 9% of daily mortality in London during the early winters and about 2 to 3% in later winters.

Other recent studies discussed in the CD addendum and Appendix B of this document examined pollutant/mortality relationships in more contemporary atmospheres in New York City, Pittsburgh, and Athens, Greece. The Ozkaynak et al. (1986) reanalysis of 14 years of N.Y.C. data (1963-1976) found significant associations between excess daily mortality and PM, SO_2 and temperature using time-series methods to control for autocorrelation. Differences in the rate of change of SO_2 and PM indicators during the study period allowed estimation of their separate effects. In joint regression analysis across all years, PM indicators (coefficient of haze and visibility extinction coefficient) together accounted for significantly greater excess mortality than did SO_2. Although their findings are considered preliminary for risk assessment purposes, these results are of particular interest given the possibility that fairly contemporaneous particulate air pollution in a U.S. urban area could be contributing to mortality (CDA p. 3-10 to 3-12).

The work of Mazumdar and Sussman (1983) in Pittsburgh and that of Hatzakis et al. (1986) in Athens, however, found conflicting results. The first found significant association between particulate matter and excess deaths in Pittsburgh, but no effect of SO_2, while the Athens study found an association with SO_2 but not with smoke measurements. The CD addendum points out that limitations in both studies with respect to measuring particulate matter as well as methodological difficulties prevent meaningful conclusions from these studies with respect to the effects of particulate matter and SO_2.

b) Morbidity

Previous conclusions regarding concentration-response relationships for morbidity effects of daily PM/SO_2 exposures were based primarily on studies of bronchitic subjects in London during the 1950's through early 1970's. Results more relevant to contemporary U.S. conditions are presented by Dockery et al. (1982) and summarized in Table 3-1 along with a comparable recent study from the Netherlands (Dassen et al., 1986).

The CD addendum concludes that the repeated measurements of lung function by Dockery et al. (1982) showed statistically significant but physiologically small and apparently reversible group mean declines in Forced Vital Capacity (FVC) and Forced Expiratory Volume at 0.75 seconds ($FEV_{0.75}$) associated with short-term increases in PM and SO_2 air pollution (p. 3-16). The small, reversible decrements appear to persist for up to 3-4 weeks after episodic exposures to these pollutants.

The data were analyzed for each episode separately and also for pooled results for all four study periods. Taken individually, statistically significant declines in FVC (2-3%) were seen consistently during the first three study periods while FEV declines were significant only for the second and third. This suggests that significant effects on lung function occurred in these children for those episodes with maximum 24-hour TSP levels of 220 to 422 $\mu g/m^3$. The possibility of effects below 220 $\mu g/m^3$ can not be dismissed, but the absence of effects on either FVC or FEV in the fourth study period (Fall 1980) suggests that the peak TSP level measured during that period (160 $\mu g/m^3$ 24-hour maximum) might be considered as a practical no effects level.

The interpretation of the episode results is, however, complicated by the frequent moderate peaks in pollution that occurred at various times through each episode. TSP levels in excess of 150 μg/m^3 occurred during three of the baseline measurements in the 1978 episode, potentially diminishing the apparent significance of any declines as measured following the subsequent alert. Similarly, TSP levels during some "baseline" periods in the Fall 1980 study approached or exceeded those during the rest of the study. Moreover, the presence of intermediate peaks following an alert can cloud interpretation of the time to recovery from the functional depressions. In these respects, the Fall 1979 study and to a lesser extent the Spring 1980 study, both with relatively low pollution during baseline measurements, offer the clearest results. The Spring study, however, had intermediate TSP peaks that at a second site reached about 240 μg/m^3 (Spengler et al., 1986) at about the time of the second follow-up measurement. Since this suggests exposures at or above those following the "sham," no firm conclusions regarding the effects of the first peak can be drawn from this follow-up.

In contrast to the episode studies, the pooled regression analysis assumed that functional response resulted from the previous day pollution levels across the range of measured concentrations. The authors concluded that because a significantly greater number of subjects had negative regression coefficients for both lung function measures vs. TSP and SO_2, lung function might be altered across the full range of TSP and SO_2 levels. As the authors note, however, a non-linear threshold model cannot be precluded, especially given the absence of pulmonary function effects in the Fall 1980 study. The CD addendum also notes that the regression analysis apparently included a large number of subjects with data only from the first study with the highest pollution and largest FVC changes. This might have unduly affected the regression results. Ancillary regression data showing a significant negative slope for the testing days in the Spring 1980 study

(Ferris et al., 1983) suggest, however, that excluding the 1978 data would not change the conclusions.

Although the group mean changes in lung function during individual episodes were small (generally 2 to 4%), the pooled data suggests the possibility that some children showed enhanced responses. The CD addendum notes that the predicted changes in FVC per unit TSP for the upper quartile of children was -0.386 ml/μg/m^3, or 5 times higher than that for the group mean. The distribution of individual regression slopes (Figure 3 in Dockery et al.) indicates that approximately 5% of the children had negative slopes of 1 ml/μg/m^3 TSP or more. Some of the larger negative slopes are likely to be due to chance or non-pollution factors such as reduced effort in follow-up functional measurements. Some of those children, however, may have been substantially more sensitive to pollution than the group mean.

A study of episodic exposures of children to particulate matter and SO_2 conducted in the Netherlands by Dassen et al. (1986) produced results similar to the episode component of Dockery et al. Pulmonary function values measured during an air pollution episode in which 24-hour average measurements of TSP, RSP* and SO_2 at a 6 station network all reached a range of 200-250 μg/m^3, were significantly lower (3-5%) than baseline values measured 1-2 months earlier for the same subgroup of children. Lung function parameters that showed significant declines on the second day of the episode included FVC and FEV, as well as measures of small airway function (e.g., maximum mid-expiratory flow, maximum flow at 50% of vital capacity). Declines from baseline were observed 16 days after the episode in a different subset of children, but not after 25 days in yet a third subgroup. Shortly before the last set of measurements, 24-hour average TSP,

*Respirable Suspended Particles, reportedly $D_{50} \leq 3.5$ by cyclone sampler.

RSP and SO_2 jointly reached 100-150 μg/m^3, suggesting that these levels were not associated with observable functional effects (CDA, p. 3-17).

The authors note that TSP values may be somewhat low, but partially overlapping measurements at a local network suggest they were unlikely to be underestimated by more than 10 to 20%. Overall, collocated RSP measurements were 0.79 to 0.94 of TSP, with network averages actually exceeding TSP during the episode. The authors indicate rain, north winds, and snow may have accounted for the apparent low levels of coarse particles during this period.

In comparison with the Steubenville episodes, the pattern of pollution is much less problematic. Baseline and intermediate concentrations, with one exception, were low. Thus, the finding of a similar time course of response (two to three weeks for recovery) provides additional support for an extended depression in function following a single episode. The absolute magnitude of functional changes appears somewhat greater in the Dutch episode, but much of the difference is due to the fact that the latter results were adjusted for lung function growth over the course of the study while the Steubenville results were not. A confounding aspect of the Dutch study is the use of different subgroups during follow-up measurements.

The findings of these recent episode studies are consistent with those of other, more qualitative, community studies identified in the 1982 staff paper reporting pulmonary function changes in children and adults exposed to high short-term levels of particles alone (Lebowitz et al., 1974) or in combination with SO_2 (Van der Lende et al., 1975; Stebbings et al. 1979; Saric et al., 1981).

Other recent studies on the relationship between short-term exposures to particles and acute morbidity effects are characterized in the CD the CD addendum as allowing no definitive interpretations at this time (Mazumdar and Sussman, 1983; Perry et al., 1983; Bates and Sizto, 1983, 1985).

2. Long-Term Exposures

Recent cross sectional studies of the association between long-term particulate matter concentrations and mortality are summarized in Appendix B. While these may be of qualitative interest in supplementing prior analyses, at present there is no basis by which to derive exposure-response information given their unstable results, inadequate exposure characterization, and internal inconsistencies.

A number of newly available studies have examined the long-term effects of exposures to particles (with and without SO_2) on respiratory mechanics, symptoms, and illness (Table A-3). The CD addendum identifies only the Ware et al. (1986) paper (summarized in Table 3-2) as possibly providing results by which to derive quantitative conclusions concerning exposure-effect relationships on morbidity. The remainder are either too preliminary to interpret definitively (van der Lende et al., 1986) or are subject to significant uncertainties regarding the nature of any gradients in PM exposure levels (e.g., Pengelly et al., 1985; CEC, 1983).

Ware et al. (1986) found significant, positive associations between some respiratory symptoms and illness in children and concentrations of TSP, and the sulfate fraction of TSP (TSO_4), and between one symptom and SO_2. However, an examination of somewhat smaller pollution variance within two of the cities did not produce the expected gradient in response, with the exception of illness before age two. Pulmonary function parameters were not associated with pollutant concentrations within the observed ranges. The authors note that the between-city results may represent

TABLE 3-2. SUMMARY OF EPIDEMIOLOGICAL STUDY PROVIDING MOST USEFUL CONCENTRATION/RESPONSE INFORMATION FOR LONG-TERM PARTICLE EXPOSURES (1982-86)

)bserved				City Mean Pollution (in $\mu g/m^3$)				
ffects	Population	City	Time	TSP	SO_2	TSO_4	Comments	Study
'ossible increased rates of cough, bronchitis, lower respiratory illness No differernce in lung function	10,000 6-9 year olds in 6 U.S. cities	Portage	76-79	39	12	5.4	Well designed. Preliminary cross-sectional results from ongoing longitudinal study. Symptom, illness data based on parental recall, suggestion of elevated response in spring vs. fall surveys. Nine air quality regions with 3 cohorts (1 per year) generated 27 cohorts for analysis. Effects adjusted for 1) age, sex, parental education and smoking and 2) random city, region, year variability. SO_2 associated significantly only with cough. Within city results not consistent with inter-city findings. Pollution gradient maintained when adjusted by city specific PM_{10} ratios (Spengler et al., 1986).	Ware et al 1986
		Topeka	77-80	63	3	5.4		
		Watertown	74-77	46	18	8.4		
		Kingston/ Harriman	75-78	62	25	9.5		
		St. Louis	75-78	94	68	11		
		Steubenville	76-79	114	61	19		
		Within City Gradients:						
		Steubenville						
		-Valley		133	80	-		
		-Ridge		95	54	-		
		St. Louis						
		-Carondelet		116	98	-		
		-Remainder		73	38	-		

differences unrelated to pollution exposure such as cultural factors, persistent differences between cities in illness or reporting rates, or better recall of illnesses in more polluted cities. These cities tended to be visited in the spring, while some of the cities with lower pollution were visited in the fall when past winter illnesses were more remote.

The CD addendum concludes that the Ware et al. (1986) study:

> "provides evidence of respiratory symptoms in children being associated with particulate matter exposures in contemporary U.S. cities without evident threshold across a range of TSP levels from 30 to 150 $\mu g/m^3$ with more marked effects notable in the 60-150 $\mu g/m^3$ range in comparison to lower levels... The medical significance of the observed increase in symptoms unaccompanied by decrements in lung function remains to be fully evaluated but is of likely health concern. Caution is warranted, however, in using these findings for risk assessment purposes in view of the lack of significant associations for the same variables when assessed from data within individual cities included in the Ware et al. (1986) study" (p. 3-49).

The CD addendum further notes that:

> "the reported stronger associations between TSO_4 levels and other measures of ambient air FP concentrations are highly suggestive of possible associations between health effects observed in the Ware et al. (1986) study and exposure to small particles in contemporary U.S. atmospheres.... However, full interpretation of the strength and significance of these findings is difficult at this point, in light of further follow-up of these children still being in progress and the expectation that longitudinal analyses will later be carried out which will relate health data to more extensive aerometric data (including such data collected in later years)" (p. 3-37).

A series of studies by Ostro and coworkers (Ostro, 1983, 1987; Hausman et al., 1984) provide qualitative indication of morbidity in adults in U.S. cities with particulate matter concentrations overlapping those found in the six cities study. The series of investigations encompassed both annual and shorter term (2 week) exposures. The most recent work (Ostro, 1987; Hausman et al., 1984) examined Health Interview Survey (HIS) data and yielded associations between particulate pollution and increases in restricted activity days (RAD), respiratory related RAD, and work loss days, as well as other, even more generalized health indicators. The most consistently significant correlations were for effects and average exposure occurring 2 to 4 week previously (2 period lag). This somewhat puzzling result raises some questions about the mechanism of action. It is, however, consistent with the kind of delayed response suggested by the Steubenville and Netherlands episode studies. Additional questions raised in the CD addendum include the nature of the HIS data, the statistical modeling used, and the estimates of fine particle concentrations based on airport visibility data. Only limited pollution data are provided in the published reports, but in 1976 annual TSP levels ranged between 40 to 133 $\mu g/m^3$ and the mean estimated FP level for these cities was 22 $\mu g/m^3$. Other issues include the degree for which the fixed effects model accounts for city specific effects, the role of ozone and other pollutants not included in the regressions and consistency among other examinations of the HIS data (Portney and Mullahy, 1986). The results from further analyses that address many of these issues are expected in the near future (Ostro, 1986). At present, however, the CD addendum concludes that these analyses:

> "have found consistent associations between PM and morbidity measures for adults that are reasonably consistent between and within contemporary American cities. As such, the results tend to reinforce the plausibility of the Ware et al. (1986) findings of associations between morbidity measures in children and PM concentrations found in contemporaneous American urban air sheds. However, the Ostro analyses do not allow for the estimation of quantitative relationships between morbidity effects and more usual 24-hr or annual average direct gravimetric measures of particulate matter air pollution (e.g., TSP, PM_{10}, etc.)" (p. 3-40).

IV. FACTORS TO BE CONSIDERED IN SELECTING PRIMARY STANDARDS FOR PARTICLES

This section, drawing upon the previous summary of newly available scientific information, enumerates key factors that should be considered by the Administrator in making decisions on the proposed revisions to the primary standards for particulate matter. The staff conclusions and recommendations on the most appropriate policy options presented update and supplement those made in the 1982 staff assessment. Where the original conclusions and recommendations and supporting rationale are unchanged by the newly available information, they are summarized without restating the supporting discussions. Particular emphasis is placed on aspects of the new information that amend or revise the original assessment. The key standard components discussed are the pollutant indicator, averaging time, and levels for the primary standards.

A. Pollutant Indicator

Based on the re-evaluation of available scientific information, the staff finds that the following conclusions reached in the 1982 assessment remain valid:

1) A separate general particulate matter standard (as opposed to a combination standard for particulate matter and SO_2) remains a reasonable public health policy choice.

2) Given current scientific knowledge and uncertainties, a size-specific (rather than chemical-specific) indicator should be used.

3) 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.

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

5) The risks of adverse health effects from extrathoracic deposition of general ambient particulate matter are sufficiently low that particles which deposit only in that region can safely be excluded from the standard indicator.

6) The size-specific indicator for primary standards should represent those particles capable of penetrating to the thoracic region, including both the tracheobronchial and alveolar regions.

Considering these conclusions in light of data 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 less than or equal to a nominal 10 μm "cut point."* This indicator, referred to as "thoracic particles" in the 1982 staff paper, has been termed "PM_{10}" for regulatory purposes.

*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 collected with substantially lower efficiency and smaller particles with greater (up to 100%) efficiency. In practical usage, acceptable 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 the notice of proposed revisions (49 FR 10408).

Figure 4-1 summarizes many of the more relevant aspects of the recent particle deposition studies contained in the CD addendum and discussed in Section III.A of this paper. The figure represents thoracic deposition of particles under nasal and oronasal breathing as estimated by Miller et al. (1986). Superimposed on the figure are the estimates of the band of thoracic deposition by Swift and Proctor (1982). The latter analysis has been used to support recommendations for an alternative particle size indicator, which would have a "D_0" of 10 μm and a D_{50} of approximately 6 μm. The figure shows that such an indicator would omit the non-trivial fraction of thoracic deposition contributed by particles larger than 10 μm for all breathing conditions and would also understate deposition of particles larger than 6 μm for "mouth" breathers.

The sampler effectiveness curves for two prototype PM_{10} inlets also plotted in Figure 4-1 illustrate the generally conservative nature of the PM_{10} indicator when compared to these data. The samplers reach 100% efficiency for particles of 7 μm and smaller, while the respiratory tract deposition data do not quite reach 50% (in effectiveness terms). Practical samplers could not, of course, realistically match this performance. Thus, a better way to compare the deposition data with the sampler effectiveness is to scale the data such that the maximum deposition point represents "1," or 100%. Viewed from this perspective, the maximum point for the distribution illustrated in Figure 4-1 generally lies between 3 and 5 μm and the 50% point tends to be in the vicinity of 10 μm. In this relative sense, the PM_{10} indicator follows the "inlet" portion of respiratory tract penetration pattern, but substantially overcollects fine particles smaller than 3 to 5 μm relative to lung deposition. The figure indicates that most fine mass is not deposited in the respiratory tract, while PM_{10} samplers would collect

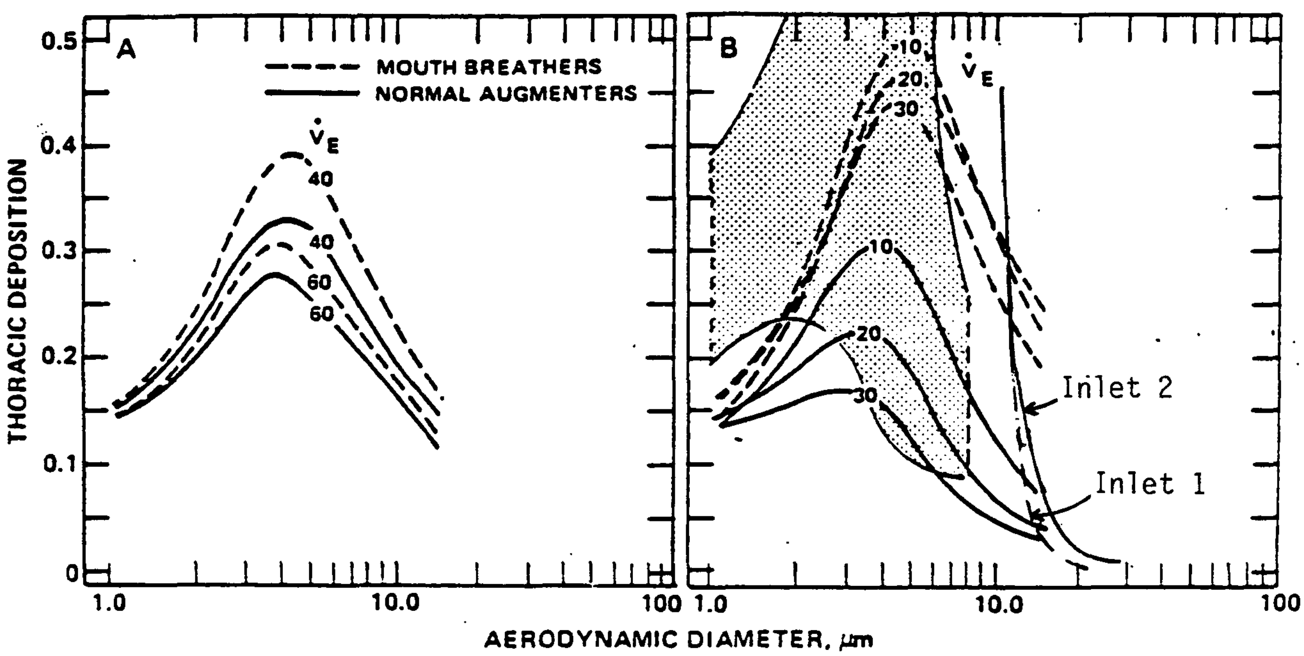


Figure 4-1. Estimates of thoracic deposition of particles between 1 and 15 µm by Miller et al. (1986) for normal augmenters (solid lines) and mouth breathers (broken lines) are shown for minute ventilation (V_e) exceeding the switch point of 35 L min^{-1}(A) and for lower V_e (B). Normal augmenters are individuals who normally use oronasal breathing to augment respiratory airflow when V_e exceeds about 35 L min^{-1}, while mouth breather refers to those individuals who habitually breathe oronasally (Niinimaa et al., 1981). The shaded area (B) is a composite of the computed bands of thoracic deposition of particles less than 8 µm by Swift and Proctor (1982) for V_e of approximately 24.6 and 15 L min.^{1} Also plotted are the sampler effectiveness curves for two representative PM_{10} inlets.

100% of this fraction. As stated in the 1982 staff paper, given the larger surface area in the fine mode as well as other concerns, the greater weight given fine vs. coarse particles by a 10 μm indicator remains prudent and appropriate.

In summary, the staff assessment of more recent information on respiratory tract deposition contained in the criteria document addendum reinforces the conclusions reached in the original staff assessment in 1982. In particular, the staff finds that:

1) the recent data do not provide support for an indicator that excludes all particles greater than 10 μm;

2) the analysis used to specify an alternative indicator with a nominal size cut of 6 μm (Swift and Proctor, 1982) can significantly understate thoracic deposition of particles larger than 6 μm under natural breathing conditions;

3) the PM_{10} indicator appears somewhat less conservative than previously thought with respect to large (> 10 μm) particle deposition under conditions of natural mouthbreathing. Nevertheless, this indicator is generally conservative for tracheobronchial deposition; and

4) 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 (Section III).

Given these considerations and the 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 less than a nominal 10 μm (PM_{10}).

In the previous assessment, the staff also made recommendations with respect to the shape of sampler effectiveness curves. Analysis of the influence of cutpoint and effectiveness curves under various simulated ambient conditions have tended to show that (1) the D_{50} of the inlet has the major influence, and (2) for a fixed cutpoint, the mass collected does not vary greatly with the shape of the effectiveness curve (Rodes et al., 1981; Van der Meulen, 1986). For this reason, and because of the difficulty in precisely matching the most recent respiratory tract deposition estimates, the staff concludes that, for regulatory purposes, the effectiveness criteria developed based on the 1982 CD remain acceptable.

B. Level of the Standards

1. General Considerations

This treatment of the implications of more recent studies follows the framework and maintains the underlying philosphy of the 1982 staff paper as discussed therein (SP, pp. 83-89). The following general considerations are drawn from that more complete discussion.

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 quantitative evaluation of the health risks of particulate matter under current U.S. conditions are detailed in the 1982 criteria document (EPA, 1982b) and its addendum (EPA, 1986) as well as in the 1982 PM staff paper (pp. 83-86). 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. Furthermore, even the best studies often provide no clear evidence of population "thresholds." Thus the approach of identifying specific "lowest demonstrated effects" levels for current U.S. exposures and adding margin of safety considerations is less appropriate in this case. Instead, the approach followed in the 1982 staff paper and here is to assess the nature of health risks along a continuum of exposure using the full range of available information. It follows that, although the scientific literature provides substantial information on the potential health risks associated with various mixes and levels of particles, selection of any general particulate standard remains largely a public health policy judgment.

Because particulate matter is a pollutant class with variable composition, and none of the published studies have used the proposed PM_{10} indicator, the range of aerosol composition and size indices must be considered in using the relevant epidemiological studies for developing standards. For example, in order to translate the results of historical British studies into terms useful for setting U.S. standards, general relationships between British smoke readings and particle mass units (i.e., PM_{10}), estimated in the 1982 staff paper are used here. Those relationships were based on available calibration data from the study periods, incorporating reasonable assumptions concerning pollution composition, relative role of particles, and the nature of U.S. vs. British exposure regimes (SP, pp. 7-13, 96-100). Conversions are also made between TSP concentrations measured in the U.S. studies and corresponding PM_{10} levels, in some cases using more detailed site-specific data.

The following sections present a brief staff assessment of the concentration/response relationships suggested by the most significant epidemiological studies in the CD addendum. This assessment supplements the quantitative information in the 1982 staff paper and indicates how these studies may be applied in developing ranges for final decision-making on standards for particulate matter, as indicated by PM_{10}. The presentation also outlines a qualitative assessment of the key factors that affect the margins of safety (risk) associated with the concentration-response relationships derived from these studies, as translated to contemporary U.S. exposures. The margins of safety associated with the levels of interest for PM_{10} derived from the quantitative studies should also be evaluated with respect to any potential effects that may reasonably be anticipated from qualitative human and animal health studies summarized in the 1982 staff paper. Short- and long term exposure are discussed separately.

2. Short-term Exposures

a. Derivation of Range of Interest from Epidemiological Studies

i) Concentration-Response Relationships

The 1982 CD indicates that the epidemiological studies most useful for developing quantitative conclusions regarding the effects of short-term exposures to particulate matter include a series of studies and analysis of daily mortality in London (Martin and Bradley, 1960; Martin, 1964; Ware et al., 1981; Mazumdar, et al., 1981) and studies of bronchitis patients, also in London (Lawther et al., 1970).

The assessment of the earlier London mortality studies in the 1982 CD concluded that 1) clear increases in excess daily mortality occur at BS and SO_2 levels at or above 1000 $\mu g/m^3$, and 2) some indication of likely increase in excess mortality exists in the range of 500 to 1000 $\mu g/m^3$ BS and SO_2, with greatest certainty of increases occurring when both pollutants exceed 750 $\mu g/m^3$ (CDA, Table 1). These estimates represent judgments with respect to the most scientifically reliable "demonstrated effects likely levels" for daily smoke (and SO_2) and mortality at least in the context of historical London pollution exposures.

Because of the severity of the health endpoints in these studies, and the need to provide an adequate margin of safety in standard setting, the 1982 CD and staff paper also examined these studies to determine whether the data support the possibility of health risks at lower BS levels. This assessment concluded that data from the earlier London studies do not provide clear evidence of absolute population thresholds, and suggest instead a continuum of response, with both the likelihood and extent of any effects occurring decreasing with concentration. Thus, based on these earlier studies, effects were judged to be "possible" at levels below 500 to 1000 $\mu g/m^3$ smoke down to a practical lower bound of 150 $\mu g/m^3$ (as BS) derived from the Martin and Bradley (1960) study. The analysis stressed that because evidence is less clear, the nature and extent of risks at lower levels are much more uncertain.

The more recent analyses of London mortality during the winters between 1958 and 1972 cited in the CD addendum include Mazumdar et al. (1982), Ostro (1984), Shumway et al. (1983), and Schwartz and Marcus (1986). In essence, these analyses add to the evidence for the possibility that particulate pollution accounted for a small but statistically significant portion of daily mortality at levels extending well below 500 $\mu g/m^3$ BS (24-hour avg.), with no discernible threshold. Considering the findings of these more recent studies, the staff amends its earlier assessment of the London mortality data (SP, pp. 89-95) with the following conclusions:

1) The finding of significant associations between BS and mortality in the majority of the 14 winters by different investigators in published (Mazumdar et al., 1982; 1983; Ostro, 1984) and unpublished (Schwartz and Marcus, 1986) analyses using several approaches strengthens the plausibility of the associations. The findings of significant associations in later

"non-episodic" years when particle composition and levels began to approach U.S. conditions is of particular significance.

2) The finding in some analyses of a trend towards increased regression coefficients with decreased concentration and the concave shape apparent across the range of mortality-BS data as plotted by Schwartz and Marcus (See Figure 4-2) raises questions regarding whether the statistical association reflects a causal relationship. The possibility that smoke may be acting as a "surrogate" for unmeasured factor(s) at lower BS levels, as suggested by Mazumdar et al. (1982) cannot be precluded. Non-pollution factors such as weather, demographic shifts and indoor pollution exposures have been advanced as possible alternatives (Roth et al., 1986). To date, however, smoke/mortality relationships have retained (or even increased in) significance when meteorological factors (temperature and humidity) are included and the year-to-year consistency of association, particularly for BS < 200 $\mu g/m^3$, argue against the observed effect being explained by changing indoor-heating practices in London or by long-term demographic shifts (CDA, p. 3-7). Moreover, as Mazumdar et al. points out, BS might be a surrogate for other particulate components rather than some as yet unanalyzed non-pollution variable. Schwartz and Marcus (1986) suggest that the decreasing response with higher pollution may result from the effect of higher pollution in earlier winters being blunted by public awareness (and hence reduced exposure) or by a tendency for the most susceptible individuals to succumb on the earliest day of very high pollution in a multi-day episode. Some of the curvilinear shape between BS and mortality might also be due to the non-linear relationship between BS and gravimetric mass at lower BS levels. In a qualitative sense, adjusting for this relationship would make the corresponding particle mass/response relationship more linear.

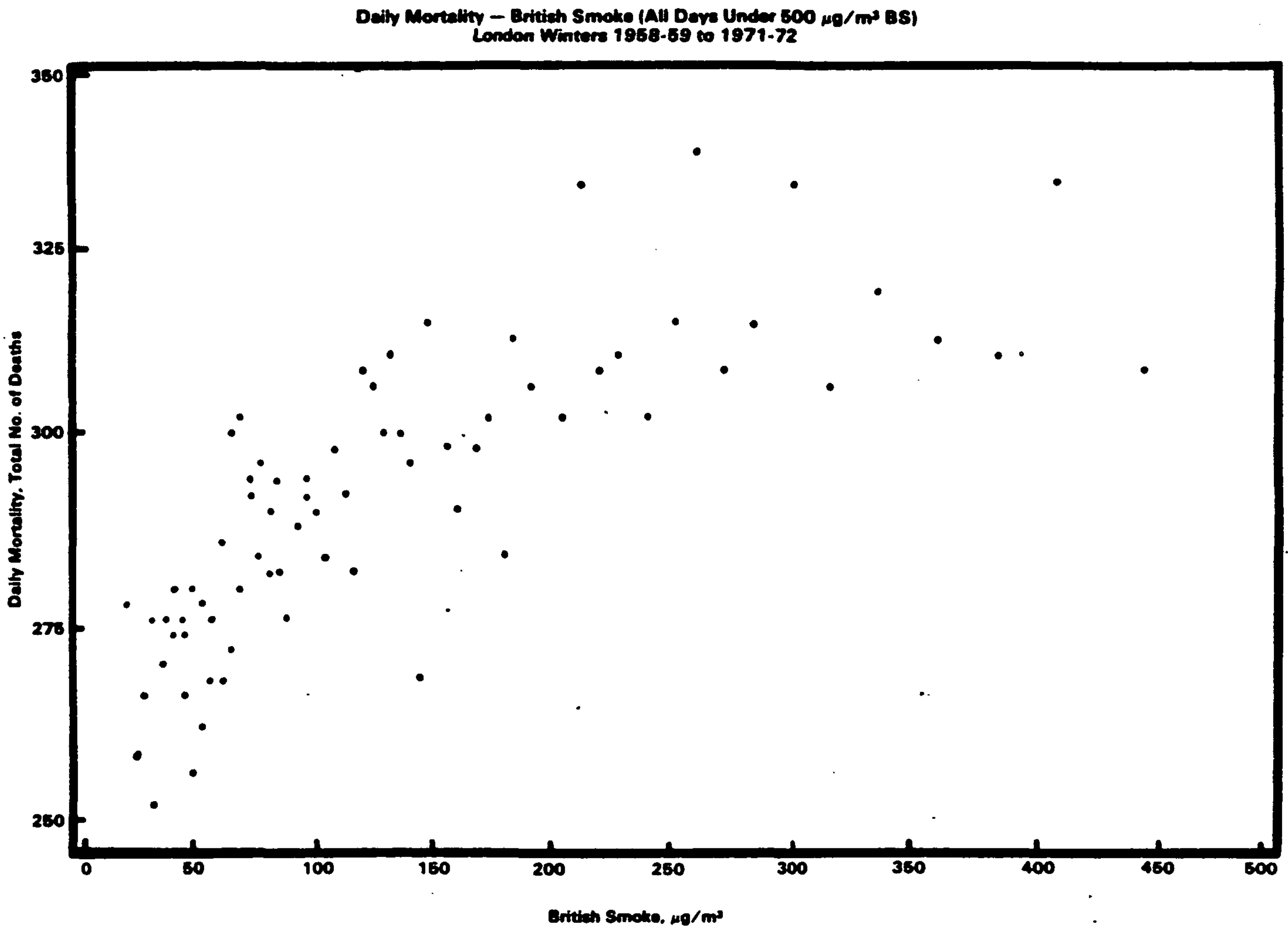


Figure 4-2. Mean daily mortality vs. mean British Smoke (BS) for days with BS < 500 µg/m^3 during 14 London winters (1958-72) (Schwartz and Marcus, 1986). Each point represents the mean "crude" daily mortality and BS for 20 adjacent values of BS. Grouping data points in this fashion (c.f. Ware et al., 1981; SP, Figure 6-2) reduces scatter and reveals an apparently concave relationship extending to the lowest observed BS levels with a decreasing slope at higher concentrations. This is consistent with the findings of higher regression slopes in years with lower average concentrations (Mazumdar et al., 1982; Ostro, 1984). The concave shape may, however, be an artifact. Some possible explanations include a non-linear relationship between BS and gravimetric mass, reduced population exposures during publicized high pollution episodes and correlations of BS with unmeasured non-pollution variables that are causally related to mortality (see text).

3) The approach of Shumway et al., (1983) is an important addition to the literature that, while reinforcing the above findings, suggest additional complexity in the potential concentration response function, particularly with respect to the influence of temperature and nature of temporal patterns in pollution. Temperature appears to exert a same-day positive effect, with higher daily mortality associated with an increase in temperature. The lag result in Shumway et al., however, also suggests that reduced mortality is likely during a cold spell after a dip in temperature. This phenomenon could be explained by increased outdoor-related activities on warmer days in the winter. The Schwartz and Marcus analyses subsumes any such lag effect of temperature in the autoregressive model. Further analyses are desirable to examine possible interactions or non-linear responses involving temperature, humidity, fog, and windspeed.

4) While it is still difficult to separate the effects of SO_2 and BS on mortality, the preliminary findings of Schwartz and Marcus (1986) support the suggestion (Mazumdar et al., 1982) that at lower SO_2 values mortality effects may be associated with particulate matter alone.

5) Taken together, the analyses to date do not permit identification of a clear "no effects" level. The lower bound derived from earlier analyses is no longer appropriate. The individual regression analyses, however, provide some suggestion that effects do not always achieve significance in the last two winters when mean smoke levels were below 75 to 100 $\mu g/m^3$ (Ostro, 1984; Schwartz and Marcus, 1986).

As the earlier assessment noted, the London data--even in more recent winters--have inherent limitations when applied to assessing effects in U.S. atmospheres. The pollution composition, meteorological patterns, indoor sources, population characteristics, and other factors in

London may have been uniquely responsible for the observed results. Thus, the findings from recent reanalyses of daily mortality during 14 years in New York City (1963-1976) (Ozkaynak and Spengler, 1985, Ozkaynak et al., 1986) are of particular interest. The results, although preliminary, showing associations between mortality and particle concentrations (indicated by coefficient of haze, or CoHs, and atmospheric visibility readings) add to the evidence for a more general association between elevated particulate matter levels and increased mortality. This recent work reinforces earlier qualitative findings of PM/mortality associations in New York City (Schimmel and Murawski, 1976; Schimmel, 1978).

The 1982 CD evaluation of the Lawther et al. (1958, 1970) studies concluded that a worsening of health status of chronic bronchitic patients could occur on days with BS $\geq$ 250-500 $\mu g/m^3$ and SO_2 > 500-600 $\mu g/m^3$. The 1982 CD also noted that associations between pollution and health status persisted at lower levels in selected, more sensitive individuals, although over the vigorous objection of the lead investigator (Lawther, 1986). Better evidence for effects on morbidity at lower concentrations is provided by the two recent studies of U.S. and Dutch children exposed during pollution episodes with elevated 24-hour TSP and SO_2 levels (Dockery et al., 1982; Dassen et al., 1986).

The U.S. study found evidence of small but significant (2-3%) reductions in lung function (FVC, $FEV_{0.75}$) in Steubenville following periods when 24-hour TSP levels reached 220 to 420 $\mu g/m^3$ and SO_2 reached 280 to 455 $\mu g/m^3$, but no significant changes following 24-hour TSP and SO_2 maxima of 160 and 190 $\mu g/m^3$, respectively. The Dutch study found comparable functional reductions during and following an episode when concentrations of TSP, RSP, and SO_2 were each in the range of 200 to 250 $\mu g/m^3$ (based on six monitoring sites) for 2 to 4 days, with no significant reduction shortly after a more modest 24-hour pollution increase when levels of all 3 pollutants averaged 100 to 150 μg/m^3.

Taken together, these studies suggest that functional declines associated with episodic exposures occur rapidly and persist for up to 2 to 3 weeks before recovery, with a tendency for larger declines to occur following episodes with higher concentrations of smaller size particles. This is illustrated in Figure 4-2, which compares the Dutch findings with the Steubenville episode (Fall 1979) that has the most comparable air quality patterns (see Section III.B). In both studies, functional measurements show a substantial decline, as measured a day or two into the episode, that persists for 16 to 18 days. Given the lack of decline in the Steubenville "sham" (2 weeks after baseline) and the fact only two test days (episode and 1st follow-up) showed declines in the Netherlands, it seems unlikely that lack of interest in follow-up tests could account for the pollution related results.

Comparison of the magnitude of response between two different investigations with children of overlapping but different ages should be viewed with caution. Although the results may suggest slightly larger functional changes during the Dutch episode, it is not clear whether any differences would be significant. With both TSP and RSP levels at 200 to 250 μg/m^3, it is reasonable to assume intermediate to small particle indicators (PM_{15} or PM_{10}) levels were in the same range in Ijmond. Based on size specific measurements of Steubenville during the Fall 1979 episode (Spengler et al., 1986) maximum concentrations of small particles were somewhat lower in Steubenville. Applying factors appropriate for that episode (Section II), peak PM_{10} levels were on the order of 150 to 170 μg/m^3. An earlier Steubenville

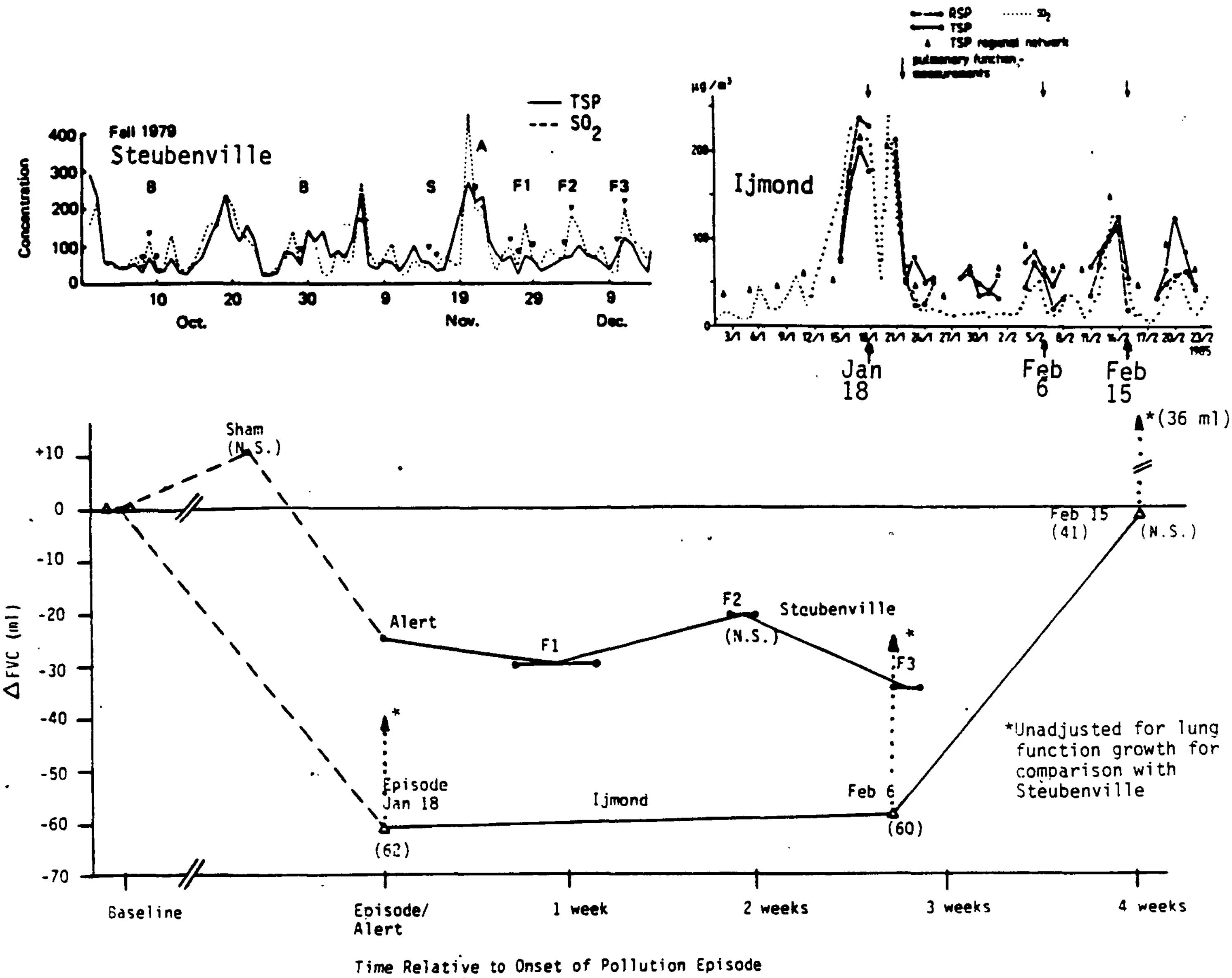


Figure 4-3. Mean change in FVC compared to baseline for children in relation to occurrence of pollution episodes in Steubenville, Ohio (Dockery et al., 1982) and the Ijmond area of the Netherlands (Dassen et al., 1986). Inserts: Air quality during each study period. Steubenville study: Fall, 1979 episode, 184 3rd and 4th grade children with 69 tested during alert, all tested during follow up. Netherlands study: Winter, 1985 episode, 179 children aged 7 to 11 years, with each follow up reflecting a different group; FVC adjusted for growth (light triangles). Arrows show results unadjusted for growth (Brunkreff, 1986) for direct comparison with Steubenville results, which are also not adjusted. The patterns in response for the two studies show a remarkable similarity. The maximum unadjusted mean changes for the Netherlands episode are comparable to slightly larger than Steubenville (~1 to 2%). Although maximum TSP levels are similar for each episode (see inserts), based on corollary measurements of PM_{15} (Spengler et al., 1986) in Steubenville and RSP in Ijmond, concentrations of smaller sized particles (as PM_{15}, PM_{10}, or $PM_{3.5}$) were higher in Ijmond. SO_2 peaks were, however, higher in Steubenville.

episode (Fall 1978) with levels of small particles potentially approaching those of the Dutch episode (Fall, 1978) found comparable to larger unadjusted maximal declines in FVC (~ 50 ml).

Although it is difficult to separate the effects of particles from SO_2, peak levels of SO_2 were higher in the 1979 Steubenville study (455 $\mu g/m^3$), and lower in both the Dutch (200 to 250 $\mu g/m^3$) and Fall 1978 (280 $\mu g/m^3$) study that had comparable to larger changes in FVC. Other pollutants possibly associated with functional changes (O_3, NO_2) were unlikely to confound these studies. The effects of seasonal patterns temperature or other meteorological factors cannot be ruled out, but neither study found any significant correspondence between lung function and temperature.

Other important aspects of these two studies are as follows:

1. It appears reasonable to expect that short-term changes in lung function in children following acute exposures to particulate matter is, in most cases, a more sensitive response than premature mortality or worsening of bronchitic symptoms.

2. Fairly contemporary atmospheric conditions were studied and, particularly in the case of the Steubenville study, particle composition is fairly representative of contemporary U.S. cities, significantly increasing the applicability of the results to current standard setting.

3. The observed lung function declines beneath baseline never exceeded 3 to 5% on average, and recovery apparently began after 2-3 weeks. It is difficult to assess the significance of such reductions. Dockery et al. note that they might be associated with aggravation of respiratory symptoms in children with pre-existing illness. Long-term examination of Steubenville children suggest higher rates of respiratory illnesses and symptoms compared to other U.S. cities with lower PM levels, but no evidence for any persistent reductions in lung function (Ware et al., 1985).

The extent to which some children may be considered to be "responders" has not yet been formally examined. Dockery et al., however, also show that the upper quartile (25%) of children included in their pooled analysis of lung function vs. TSP had individual regression coefficients of FVC and $FEV_{0.75}$ 5 and 17 times the median, respectively, suggesting a correspondingly greater than average decline in lung function across the range of pollution levels. As noted in Section III.B., a smaller subset representing the upper 5% of these children showed even more substantial negative regression coefficients (for FVC, $\leq$ -1 ml/$\mu g/m^3$ TSP). Assuming a linear response with no threshold across the range of TSP concentrations observed in the regression study (11 to 272 $\mu g/m^3$), this group would have a predicted decline in FVC on the order of 10 to 15%. Such calculations almost certainly overstate the percentage of potentially sensitive children because some or all of the larger responses may be due to a random distribution of results. (Section III.B.). Nevertheless, this assessment suggests that functional changes of potential concern--even on a transient basis--might occur in some small sensitive subgroups of children.

4. Although the data suggest that decrements in lung function may occur during or immediately following a single day of high particulate matter levels, it is not clear whether or not multi-day episodes are required to produce more prolonged (2 to 3 weeks) decrements. Results from controlled human and animal toxicological studies provide support for mechanisms by which short or longer term functional declines could result from particle exposures (Table 5-2, 1982 SP). Little evidence exists, however, that would support prolonged declines from single short-term SO_2 exposures at these concentrations.

5. Although questions can be raised regarding potential variability in lung function testing throughout the study period (especially given the

youth of the subjects), it appears that state-of-the-art measurement procedures were used as well as appropriate controls for inter-observer bias and extreme or missing values.

6. The results of these more recent studies are consistent with earlier more qualitative acute studies in Pittsburgh (Stebbings et al., 1975), Tuscon (Lebowitz et al., 1974), and the Netherlands (van der Lende et al., 1975).

ii) Translation to PM_{10} Indicator

Table 4-1 summarizes the updated staff assessment of the more recent and earlier available quantitative short-term epidemiological studies. Following the approach in the 1982 staff paper, the assessment incorporates available data and assumptions necessary to express results obtained using different particle indicators in terms of the recommended particle indicator.

The "effects likely" row in Table 4-1, based on the 1982 CD, reflects the previous staff assessment and underlying rationale (SP, pp. 96-100). As discussed therein and above, effects are possible at concentrations below those consensus "effects likely levels." In light of the assessment of the more recent London mortality studies outlined above, no lower bound smoke concentration is indicated in the "effects possible" column. Due to the lack of a clear threshold in these studies, the uncertainty in translating these results to contemporary U.S. atmospheres, and the availability of more recent U.S. data involving potentially more sensitive effects the staff has chosen not to attempt to derive any lower bound PM_{10} concentration from the London data. The approach used previously to bound BS/PM_{10} relationships does not apply to lower values (< 100 $\mu g/m^3$ BS), and it is also unclear to what extent BS readings were calibrated to mass measurements in the later years when smoke levels had declined appreciably. Thus the lowest pollutant levels of interest in the remaining short-term studies are

TABLE 4-1. UPDATED STAFF ASSESSMENT OF SHORT-TERM EPIDEMIOLOGICAL STUDIES

	Measured British Smoke Levels (as μg/m³) (24-hr. avg.)			Measured TSP Levels (μg/m³) (24-hr. avg.)	Equivalent PM_{10} Levels (μg/m³)
Effects/Study	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 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 μg/m³, 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 μg/m³) overestimates PM_{10} levels.
b) Conversion of TSP to PM_{10} for Dockery et al. results (see Appendix B): Based on analysis of particle size fraction relationships in Steubenville (Spengler et al. 1986). The lower bound TSP of 220 μg/m³ 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 μg/m³ reflect 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 μg/m³ entry reflects an excursion occurring 2 days prior to date on which no decrements noted.

250 μg/m^3 (BS) and 500 μg/m^3 SO_2 (based on the earlier bronchitic studies) and 200 to 420 (TSP) and 190 to 455 μg/m^3 (SO_2) (based on the recent studies of lung function in children). The recent studies provide some suggestion of "no observed effects" levels with TSP concentrations of 100 to 160 μg/m^3. The relative importance of SO_2 in these studies cannot be specified, but collectively the data suggest a greater role for particles. Thus the conservative assumption (for particles) is made that the response might have occurred without substantial amounts of SO_2 present.

Conversion of the British data to PM_{10} equivalents is particularly uncertain, and the approach is discussed in the earlier assessment (pp. 98-101). The original upper bound of a range of interest for a 24-hour standard derived from the Lawther study was 350 μg/m^3 as PM_{10} (SP, p. 97-99). Because this level contained little or no margin of safety, staff and CASAC recommended that consideration of standard levels begin at lower concentrations. Accordingly, the Administrator, considering this advice, as well as other factors, proposed 250 μg/m^3 as the upper bound of the range of levels for a possible 24-hour standard (49 FR 10408). Thus, the upper bound for the range of interest is 250 μg/m^3, as PM_{10}. The translation of the Steubenville and Netherlands results to PM_{10} is summarized in Table 4-1. Based on these results, the lowest PM_{10} level of interest derived from the short-term studies can be reduced to 140 μg/m^3, although the original lower bound of 150 μg/m^3 is within the range of uncertainty of the conversion. A level of 140 μg/m^3 contains a large margin of safety against exposures clearly associated with the more serious effects of particulate matter and is at the lower end where reversible, physiological responses of uncertain health significance may be observed. However, the original lower-bound recommended by staff and CASAC also contains a substantial margin of safety.

b) Additional Factors to be Considered in Evaluating Margins of Safety and Risks - Short-term Exposures

The 1982 staff paper identified a number of factors to be considered in developing a standard with a margin of safety. In applying the results of the more recent studies to determine the margin of safety for sensitive populations provided by alternative PM_{10} standards in the above range, the following additional factors should be considered:

(i) Aerosol Composition

1. As noted above, the likelihood of high ozone levels during the U.S. and Dutch episodes seems low. Where high photochemical smog levels are present, the observed effects of ozone on lung function (e.g., McDonnell et al., 1983) suggest the possibility of interactive responses not accounted for by these or the British studies.

2. When particle components differ substantially from those in the communities studied, risk will vary. The variability of composition (e.g., relative fraction of sulfate, nitrate, secondary organics, carbonaceous material, and coarse particles) is high. Accordingly, the risks associated with PM_{10} will vary among U.S. cities.

(ii) Exposure

Although the assessment of the mortality studies suggest any risk of premature mortality to sensitive individuals may be small at lower concentrations, the number of people exposed to lower concentrations is substantially larger than the number exposed to higher levels. Table 2-1 shows that at present, the total U.S. population living in counties with PM_{10} levels in excess of 250 $\mu g/m^3$ is on the order of the size of the London population. The number in counties in excess of 150 $\mu g/m^3$ is estimated at six times larger. The increased number of sensitive individuals exposed increases the risk that some effects will occur in the total population exposed.

Relative exposures and indoor/outdoor pollution relationships are an important consideration in interpreting the British studies; these are discussed elsewhere (SP, p. 101). With respect to the more recent morbidity studies, for comparable outdoor concentrations, the overall exposures to maximum 24-hour outdoor pollution in Steubenville and in the Netherlands was likely as high as typically occurs in contemporary U.S. exposure situations during the fall through spring seasons. Summertime exposures, would, however, tend to be greater in many areas.

(iii) Risks For Other Sensitive Groups, Effects Not Evaluated

Consistent with evidence from toxicological, controlled human and qualititative epidemiological data, the studies used to derive ranges of interest identify a number of groups and effects as particularly susceptible to ambient particles: (1) premature mortality in very sensitive individuals with chronic respiratory and cardiovascular diseases, individuals with influenza, and the elderly, (2) aggravation of disease in bronchitic patients, and (3) lung function declines in children.

While other groups may be affected by ambient particle exposures, such as asthmatics or even younger children, the previous assessment found no data to support the existence of significant effects below the suggested range (SP, pp. 102-103). The most significant new information in this regard is the finding of restricted activity in adults associated with earlier particle exposures of 2 week or longer durations (Ostro, 1987). At present, the results cannot be interpreted as demonstrating such effects occur at 24-hour levels below the range of interest.

Additional short-term effects of particulate matter suggested by qualitative evidence, such as altered respiratory clearance, possibly resulting in infections, are identified in the 1982 staff paper (p. 103).

3. Long-Term Exposures

a) Derivation of Range of Interest from Epidemiological Studies

Earlier cross sectional and longitudinal studies useful in establishing ranges of interest for long-term (annual) PM_{10} standards are identified in and discussed in the 1982 staff paper (pp. 57-63; 103-107) and CD. Of the newly available studies, the CD addendum cites the Ware et al. (1986) cross-sectional study of children in 6 U.S. cities as providing potentially useful results for examining quantitative relationships.

In interpreting the Ware et al. (1986) study the CD addendum concludes that there is evidence of respiratory symptoms in children associated with particulate matter exposures without apparent threshold across the range of measured TSP levels (CDA, p. 5-6). As for all cross sectional studies, however, these results--though adjusted for a number of confounding factors--should be viewed with caution. A particular concern is the apparent absence of the expected gradient in response for results within cities. The lack of within city effects does not necessarily negate the results among cities. Possible explanations include movement of the population throughout the area (reducing the within city gradient), the presence of a lesser gradient in smaller sized particles, or a tendency for hyperresponders to move to cleaner areas of the city (consistent with the negative and significant within city gradient for wheeze). Results of a separate series of studies of long- and intermediate-term (2 to 6 weeks) exposures indicate consistent associations between respiratory-related restrictions in adults and PM gradients within, as well as among, a number of U.S. cities (Hausman et al., 1984; Ostro, 1983, 1987). While these results cannot be used to estimate quantitative relationships between morbidity effects and PM_{10}, the CD addendum indicates they do provide qualitative support for the possibility of within-city effects related to comparable U.S. exposure levels. Nevertheless, until further results are available, the within-city anomaly of the Ware et al. results as well as other uncertainties (e.g., parental recall in spring vs. fall) noted in Section III.B. caution against interpreting the results as demonstrating "effects likely" levels. Considering the assessment in the CD addendum, however, the six city results do suggest the possibility of effects, at least in the more polluted areas.

In deriving a range of possible effects levels from this study, it is useful to examine the gradient in PM_{10} terms, based on applying the ratios developed by Spengler et al. (1986) to the data. Because the staff previously recommended an expected annual mean PM_{10} standard and because Ware et al. (1986) found that long-term (life-time) TSP exposures were also significantly associated with respiratory effects, the PM_{10} levels are estimated in terms of multi-year averages. Figure 4-3 plots the relationship between long-term averages in frequency of cough and estimated PM_{10} levels across the six cities. This is the same effect plotted against annual TSP levels in the Ware et al. paper (Figure 5, CDA), originally chosen because it was most consistently associated with TSP levels across cities.

As illustrated in Figure 4-3, three "cleaner" cities--Portage, Watertown, and Topeka--consistently had the lowest frequencies of respiratory illnesses and symptoms. The highest symptom prevalence rates were consistently found in Kingston/Harriman, St. Louis and Steubenville. Based on this very qualitative break-down, the staff concludes that the most convincing evidence for the possibility of effects is for the latter three cities, with long-term average TSP levels between 60 and 114 $\mu g/m^3$ and corresponding PM_{10} values between 40 and 60 μg/m3.

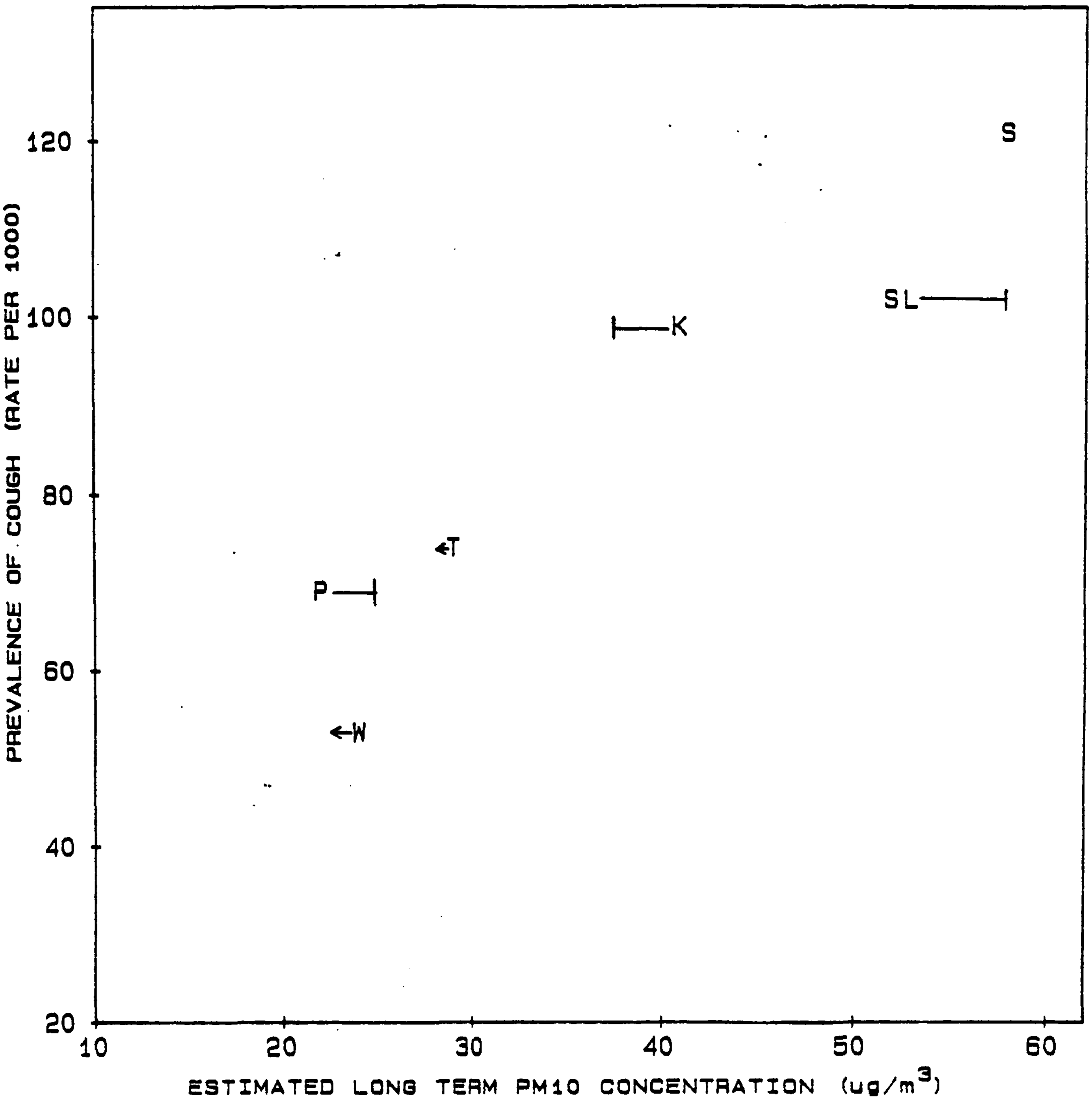


Figure 4-4. Adjusted frequency of cough for children living in 6 U.S. cities (1976-79) vs. 4-year average estimated PM_{10} levels (from Ware et al., 1986). PM_{10} levels converted from TSP levels based on sitespecific particle size data; arrows indicate cases where data suggest historical PM_{10}/ TSP ratios for study period may have been lower (Spengler et al., 1986). Placement of letters and ranges reflect 1984-85 ratios and recommendations in Spengler et al. (p. 16-18). City wide average concentration-response relationship plotted masks within-city results which do not show similar trend. (W = Watertown; P = Portage; T = Topeka; K = Kingston-Harriman; S.L. = St. Louis, S = Steubenville). Although a continuum of response across all concentrations cannot be excluded when compared in this fashion, the results suggest a small gradient without the 3 cleaner cities with elevated effects most apparent in the 3 more polluted areas.

Table 4-2 amends the previous staff assessment of the the most useful long-term epidemiological data to reflect this newer information; particulate matter levels are expressed in both the original and converted PM_{10} units. The "effects likely" row reflects the earlier assessment based on the pre-1982 studies. In adding the six cities results to the "effects possible" row, it is interesting to note some consistency among the U.S. studies with respect to concentration at which functional and symptomatic effects occur. The Ferris et al. work (1973, 1976) suggests functional effects may occur down to levels of 130 $\mu g/m^3$ TSP, but none of these studies find such effects at lower concentrations. The finding of symptomatic responses in children with no change in lung function in the range of 60 to 114 $\mu g/m^3$ (as TSP) (Ware et al. 1986) is consistent with similar findings in adults for a long term mean of 110 $\mu g/m^3$ (60 to 150 $\mu g/m^3$) TSP from the Bouhuys et al. (1973) study.

The conversion of the earlier studies to PM_{10} in Table 4-2 reflects more recent information. In considering the earlier assessment and recommendations, the Administrator proposed that the level of the annual standard be no higher than 65 $\mu g/m^3$ PM_{10} (49 FR 10408). This, therefore, is the upper bound of the present range of interest. The lower bound is lowered from the previous assessment to 40 $\mu g/m^3$ as PM_{10}, based on the recent results of Ware and coworkers. The staff, therefore, recommends a range of interest between 40 and 65 $\mu g/m^3$ for decision making on an annual standard for PM_{10}.

The results of the original studies, assessment of risks at lower levels, and conversion to a common indicator all are subject to considerable uncertainties. Furthermore, effects are not demonstrated within the ranges listed above; the lower bounds represent conservative estimates where some risk of effect is not ruled out by the data.

Table 4-2. UPDATED STAFF ASSESSMENT OF LONG-TERM EPIDEMIOLOGICAL STUDIES

	Measured BS Levels (as $\mu g/m^3$	Measured TSP Levels ($\mu g/m^3$)					Equivalent PM_{10} Levels ($\mu g/m^3$)
Effects/Study	Increased Respiratory Disease, Reduced Lung Function in Children[1]	Increased Respiratory Disease Symtpoms, 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 BS	180*	-	-	-	$\geq$180	80-90
Effects Possible	<230 BS	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 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 Anson. Median value (110 $\mu g/m^3$) used to indicate long-term concentration. No effects on lung function, but some suggesstion 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.

b) Additional Factors to be Considered in Evaluating Margins of Safety and Risks - Long-term Exposures

When evaluating margins of safety (risks) in this range, additional factors identified in the 1982 assessment (SP, p. 106-111) should be considered.

(i) Aerosol Composition

1. SO_2 levels in the six cities studied by Ware et al. generally covaried with TSP. Where high SO_2 levels co-exist with PM_{10}, the above range would appear to be protective.

2. The six cities study is directly relevant to current U.S. atmospheres with periodic elevations of ozone.

3. The risks of lung function and respiratory illness noted in these long-term studies can be expected to vary with particle composition among different regions. Although reliable comparisons of relative aerosol toxicity on a unit mass basis are not available, the potential impact of such variability is reduced by the fact that Ware et al. (1986) compared cities of distinct pollution and geographic characteristics.

(ii) Risk for Other Sensitive Groups, Effects Not Evaluated

Because of the limited scope and number of long-term quantitative studies, it is important to examine the results of qualitative data from epidemiological and animal studies. These studies justify concern for other sensitive groups (asthmatics, bronchitic subjects, the elderly, individuals with cardiopulmonary disease), and for serious effects (damage to lung tissue from acid aerosols and mineral dusts, cancer, premature mortality) not directly evaluated. Available data do not suggest major risks for these effects categories or populations at current ambient particle levels in most U.S. areas. Nevertheless, the risk that both fine and coarse mode particles may produce these responses adds to the need to limit long-term levels of PM_{10} for a variety of aerosol compositions.

C. Summary of Staff Conclusions and Recommendations

The major updated staff conclusions and recommendations made in Section IV.A,B are briefly summarized below.

1. 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 less than or equal to a nominal 10 μm, termed PM_{10}. The previously developed effectiveness criteria for samplers are acceptable for regulatory purposes.

2. Based on an updated staff assessment of the short-term epidemiological data the range of 24-hour PM_{10} levels of interest is 140 to 250 μg/m^3. The upper end of the range reflects the judgment of the Administrator with regard to the maximum level proposed 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 μg/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 μg/m^3, although the original lower bound of 150 μg/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 μg/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 μg/m^3 to 250 μg/m^3.

3. Based on an updated staff assessment of the long-term epidemiological data, the range of annual PM_{10} levels of interest is 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 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.

4. 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 standards 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 comparisons between the above ranges of PM_{10} standards and the current primary TSP standards are 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 somewhat 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 areas exceeding the primary standards.

APPENDIX A. SUMMARY OF RECENT EPIDEMIOLOGICAL STUDIES ON PARTICULATE MATTER

A.1 INTRODUCTION

This appendix presents a tabular summary and assessment of the community epidemiological studies of particulate matter published since closure on the 1982 criteria document and included in the CD addendum and not summarized individually in Tables 3-1 or 3-2. It is intended to support discussions in Sections III and IV of this paper. The tables follow the organization of the criteria document and begin with studies of mortality (Table A-1) associated with short-term exposures and are followed by and a tabular summary of mortality (Table A-2) and morbidity (Table A-3) associated with long term exposures.

TABLE A-1. EPIDEMIOLOGICAL STUDIES (1982-1986) ON SHORT-TERM CHANGES IN MORTALITY AND EXPOSURE TO PARTICLES

Data Base	Observed Effects/Comments	Study
Daily fluctuations in total London mortality and pollution during 14 winters (1958 - 1972) over a period when PM (BS) and SO_2 levels declined by 80% and 50%, respectively.	Regression coefficients averaged over 14 individual winters; 25.1% change in mortality per mg/m^3 BS vs. 1.2 % per mg/m^3 SO_2. Stratified quartile analysis also indicates association primarily with BS but pollutant collinearity cannot be eliminated. Subset of highest pollution days shows mortality increases with BS across range; with SO_2 only >700 $\mu g/m^3$. Data corrected for temperature, humidity, day of week, annual, seasonal trends. Possible over-control for temperature. Linear and quadratic models using all BS data fit equally well. Below 300 $\mu g/m^3$, smoke explains <0.2% of mortality variation in quadratic model, ≈ 10% in linear model. Authors hypothesize threshold and that quadratic model more plausible. Higher smoke coefficients in later, less polluted years possibly explained by statistical model, surrogate behavior.	Mazumdar et al., 1982
Reanalysis of above data.	Significant effect of BS on mortality deviations for days of BS < 150 $\mu g/m^3$ in 9 of 12 winters, and in 5 of 6 later winters with no BS levels > 500 $\mu g/m^3$ In first 6 winters, BS significantly associated with mortality on days with BS > 150 $\mu g/m^3$; not for later years (with very few observations). Temperature, humidity controlled; SO_2 not included. Lower coefficients with higher BS as in above study.	Ostro, 1984
Report detailing reanalysis of above data. Mortality data stratified by cause.	Multiple time series analysis of detrended data controlled for autocorrelation. Effect of temperature significant, greatest with 2-day lag. BS and SO_2 predict mortality equally well. Log-linear relation holds for all years - no evident threshold or lag for pollution effect. Strongest associations with pollution and temperature cycles of 7-21 days; shorter cycles had small effect. Pollutants more important than temperature in predicting overall and respiratory deaths; temperature more important in cardiovascular mortality. Use of log pollution levels not comparable with other analyses. PM and SO_2 effects were not separated.	Shumway et al., 1983
Unpublished reanalysis of above data.	Autoregression models to control for time series effects (e.g., day of week, epidemics), weather. Accounting for temperature, humidity enhances significance of pollution in explaining mortality. BS consistently associated with mortality with or without SO_2 included down to levels < 150-200 $\mu g/m^3$; higher slopes in later years and at lower levels. SO_2 significant only in 2 years with high levels. Diagnostic plots, regression results suggest concave mortality/BS relationship.	Schwartz and Marcus, 1986

TABLE A-1. EPIDEMIOLOGICAL STUDIES ON (1982-1986) SHORT-TERM CHANGES IN MORTALITY AND EXPOSURE TO PARTICLE (cont'd)

Data Base	Observed Effects/Comments	Study
Daily fluctuations in mortality and pollution during 5 winters (1972-1977) in Pittsburgh, Pa., characterized by variations in PM (CoH) and SO_2 across 3 monitoring sites.	Significant association between total and heart disease mortality and PM, not SO_2, at high pollution site (CoHs ≈ 1.25). Non-significant, inconsistent associations at other sites. Seasonal trends, day-of-week, weather controlled. Data filtered to account for autocorrelation. Possible over-control for temperature. Only same-day effects considered.	Mazumdar and Sussman, 1983
Daily fluctuations in mortality (sum of circulatory, respiratory, cancer). CoH, SO_2, and airport visibility during 14 years in N.Y.C. (1963-1976) over a period when SO_2 levels declined by ≈ 75% and CoH declined slightly.	Preliminary time series analysis, controlling for non-linear time trends, found significant associations with PM indicators, SO_2, temperature. Elevated CoH levels typical of period associated with 1.2-2% increase in daily mortality. Lower end of range corresponds to coefficients reported by Schimmel (1978) in prior analysis of same data. SO_2 associated with 0.3-1.5% increase in mortality. On days of regional visibility deterioration, visibility derived extinction coefficient (surrogate for fine particles) accounted for ~ 1% increase in mortality. SO_2 and PM declined at different rates in NYC such that effects of pollutants less confounded than in other studies. Unlike Schimmel (1978), SO_2 significantly correlated with mortality. CoH and SO_2 measured at only 1 site; mortality estimates somewhat sensitive to location of visibility reading (3 airports).	Ozkaynak and Spengler, 1985 Ozkaynak et al., 1986
Daily fluctuations in total mortality, SO_2 and BS during 8 years in Athens (1975-1982) over a period when SO_2 and BS levels declined by ≈ 75%. 5 monitoring sites with considerable variation in BS, but not SO_2 levels.	Unlike other studies, significant association between mortality and SO_2, but not smoke, after controlling for temperature, secular, seasonal, monthly, weekly variations and their interactions. Regression coefficient for SO_2 unaltered after sequential removal of days with values in excess of 500 down to 150 μg/m^3. Authors inferred threshold slightly below 150 μg/m^3 SO_2. Temporal trends controlled by subtracting expected mortality from 1956-1958 may introduce bias. Reliability of smoke measurements unclear.	Hatzakis et al., 1986

TABLE A-2. EPIDEMIOLOGICAL STUDIES (1982-1986) OF EFFECTS ON MORTALITY DUE TO LONG-TERM EXPOSURES TO PARTICLES

Date Base	Results/Comment	Study
Age-and sex-specific 1969-1970 mortality in 112 U.S. SMSAs related to annual TSP, SO_4 (and ozone for subset of 69 SMSAs based on 1975 levels)	Attempts to improve Lave and Seskin (1978) model with additional variables (diet, drinking water, residential heating fuels, migration, SMSA growth) and to evaluate collinearity in pollutant levels. As variables added, pollution lost significance. TSP and SO_4 coefficients unstable (elasticities between zero and ~ 6%); neither significant in joint regression. TSP coefficient more often significant across data sets, typically ~ 0.7 deaths/year/100,000 per $\mu g/m^3$. Sulfate coefficent less robust, more often non-significant. O_3 coefficient fairly stable, when significant ~ 1.3. Effects of individual pollutants difficult to separate.	Lipfert, 1984
1980 U.S. mortality in U.S. SMSAs along with annual average fine particle (FP; < 2.5 μm), inhalable particle (IP < 15 μm), TSP, and SO_4 from central monitors.	Regression analysis with control variables for % elderly, race, population density, college education, poverty (not smoking). TSP and IP coefficients most often not significant. Mean SO_4 or FP most consistent predictors of mortality. Preliminary analysis, more complex models await testing.	Ozkaynak & Spengler, 1985
1968-1972 mortality among 45-54 year old whites in U.S. counties and aggregated in Public Use Samples (PUS). TSP, SO_2, NO_2 values derived from 1974-1976 data.	Regression analysis with 17 socio-economic (SES) and 4 weather control variables (no control for smoking, occupational exposure). Inconsistent associations; SO_2 most often significant, TSP and NO_2 mostly negative coefficients. Interpretation of results limited by use of retrospective exposure estimates, geographic aggregations by groups of counties, possible overcontrol of SES.	Selvin et al., 1985
Asthma and bronchitis mortality during 1963-1983 in Japanese industrial city (Yokkaichi) over a period when SO_x levels, dominated by petroleum emissions, increased up to 1967 and declined after 1970 (50% reduction by 1973; 75% by 1982). Levels of NO_2, TSP, oxidants consistently low; only data from 1974-1982 presented. Comparisons with clean, control areas.	Asthma mortality for persons $\geq$ 60 years old rose (in 1967) and fell (after 1971) significantly with SO_x levels. Significant increase in mortality due to bronchitis in persons $\geq$ 60; after 1967, continued increase following SO_x declines in 1971; then decreased from 1976 on, 5 years after pollution reductions. Measurements of SO_x using lead peroxide methods limits quantification of acid sulfate versus SO_2 effects.	Imai et al., 1986
1969-1973 mortality among 45-74 year olds in England and Wales. Smoke and SO_2 data from 1971 and estimated historical pollution exposure based on coal consumption rates.	Unlike comparable analyses of data from 1948-1964, no association between pollution and mortality except between SO_2 and chronic bronchitis, hypertensive disease and all causes of death in females. Positive SO_2 results inconsistent with other studies. Suggests declining effect of pollution on mortality since mid-1950's. No account for occupational exposure, migration. BS readings not calibrated to local mass readings; limits reliability.	Chinn et al., 1981

TABLE A-3. EPIDEMIOLOGICAL STUDIES (1982-1986) ON MORBIDITY EFFECTS OF LONG-TERM EXPOSURES TO PARTICLES

Population/Exposure	Results/Comment	Study
Parental questionnaire and lung function tests for ≈ 3500 2nd-4th graders in 4 sections of Hamilton, Ontario during 1979-1982. Within-city gradients in PM levels; multiple TSP and size-selective particle monitors.	No significant association between cough or episodes of bronchitis and pollution indices after adjusting for maternal smoking, SES, gas stove use. Peak flow and MEF_{75}, an index of small airway function, significantly associated with "fine" particles. No association between FEV and PM. Possible biases in Cascade impactor readings, modest gradients, limit conclusions (likely included much larger particles).	Pengelly et al., 1986
≈ 700 men and women (15-64 years) examined between 1965 and 1984 in 3 year interval, living in 2 areas of contasting pollution levels in the Netherlands: Vlaardingen Annual means / Vlagtwedde (24-hr. max) BS SO_2 / BS SO_2 1965 40(185) 200(1030) / "very low" 1974 40(165) 85(362) / "low" 16(158) 1984 37(124) 45(124) / 14(105) 15(117)	After 1st 4 follow-ups (9 years), significantly greater (≈ 60%) decline over time of vital capacity and FEV_1 in Vlaardingen compared with rural area. Preliminary results indicate that over 15 years, difference in FEV_1 decline not significant--mainly due to lower FEV values than expected in last 2 exams in rural area. Prevalence of chronic phlegm and breathlessness always greater in Vlaardingen but much smaller differences in later exams (1976-1984) when symptom prevalence increased in rural town (consistent with lung function changes)--possibly due to short episodes (5-10 days) of peak pollution observed in rural area (24 hr. SO_2 ≈ 50-80 μg/m^3) during last 2 exams. More thorough data analyses and further testing expected.	van der Lende et al., 1986
≈ 22,000 children (6-11 years old) from 19 geographic regions in 6 European countries in 1975. Numerous pollution monitors using different measurement methods - collocated monitors used to standardize readings. Range for adjusted annual Black Smoke 5-57 μg/m^3; annual SO_2 19-326 μg/m^3.	Across countries no significant differences in respiratory symptoms related to smoke or SO_2. When systematic differences in health between countries accounted for, strong associations in Italy and Ireland between smoke and wheezing, breathlessness, cough, and non-specific chronic lung disease. Annual levels in both those countries between ≈ 7-38 μg/m^3 (winter means 24-54 μg/m^3). No smoke effects in other countries. Significant SO_2 effects in some countries. Limited application to current U.S. PM exposures given sampling differences, lack of calibration.	CEC, 1983

TABLE A-3. EPIDEMIOLOGICAL STUDIES ON (1982-1986) MORBIDITY EFFECTS OF LONG-TERM EXPOSURES TO PARTICLES (cont'd)

Population/Exposure	Results/Comment	Study
Children < 4 years from residential areas of contrasting SO_2 and dustfall levels reporting to a clinic in Duisburg, W. Germany	Clear distinction in incidence of croup and obstructive bronchitis between high and low pollution areas ($SO_2 \leq 300$ μg/m^3 >, dustfall ≤ 0.35 g/m^2·day >). Other factors (e.g., infections, distance to clinic, degree of crowding) accounted for but effects of SO_2 and PM cannot be separated. Limited application to assessing effects of U.S. particles.	Muhling et al., 1985
3,088 residents (aged 19-70 years) of Cracow, Poland, surveyed in 1968 and 1973, living in high pollution area in city center (mean suspended particle concentration = 118 μg/m^3, SO_2 = 114 μg/m^3) versus those in other areas (mean SP = 109 μg/m^3, SO_2 = 53 μg/m^3).	Air pollution by itself not a significant predictor of bronchitis. However, effects of occupational exposure to hazards (i.e., chemicals, irritating gases, high temperature and humidity) on prevalence of bronchitis, chronic cough/phlegm, reduced FEV much greater in men living in high pollution areas. Among men with persistent cough/phlegm, more frequent exacerbations of symptoms in high pollution areas. Little effect of pollution on women. Attempts to test interactions among multiple variables suggest marked pollution effects only in combination with other factors. PM measurements not directly applicable to U.S. levels. Cannot separate PM from SO_2.	Wojtyniak et al., 1986

APPENDIX B. ESTIMATION OF PM_{10} LEVELS ASSOCIATED WITH KEY STEUBENVILLE ALERTS

This appendix details the calculations involved in converting TSP measurements from the Steubenville alert studies into PM_{10} units. Two of the four Steubenville alert studies from Dockery et al. (1982) were used in deriving the "possible" and "no significant effects noted" levels in Table 4-1. These were the Spring and Fall 1980 studies. The peak 24-hour TSP levels measured in these studies were, respectively 220 $\mu g/m^3$ and 160 $\mu g/m^3$. Relevant information on TSP and other particle size fraction ratios in Steubenville is summarized in the report of Spengler et al. (1986). PM_{10}/TSP ratios were available only for 1984-85, whereas PM_{15}/TSP ratios, as measured by dichotomous samplers, were available for portions of the actual alert periods in Steubenville. Therefore, the general approach taken was to estimate a range of PM_{10}/DC_{15} ratios (where DC_{15} is PM_{15} as measured by dichotomous sample) expected for Steubenville and then multiply this by the DC_{15}/TSP ratio observed during the relevant alert period to estimate the PM_{10}/TSP ratio for the period, i.e.,

$$\underset{\text{(estimated, 1979-85 data)}}{PM_{10}/DC_{15}} \times \underset{\text{(observed for alert)}}{DC_{15}/TSP} = \underset{\text{(estimated for alert)}}{PM_{10}/TSP} \qquad \text{(B-1)}$$

The range of PM_{10}/DC_{15} ratios was estimated by using 1984-85 measurements of PM_{10}/TSP and PM_{10}/IP_{15} ratios (where IP_{15} is PM_{15} as measured by size selective high volume sampler) together with measurements of IP_{15}/DC_{15} and TSP/DC_{15} made the 1979-84 period. The two approaches can be written as:

$$\underset{\text{(measured 84-85)}}{PM_{10}/IP_{15}} \times \underset{\text{(measured 79-84)}}{IP_{15}/DC_{15}} = \underset{\text{(estimated)}}{PM_{10}/DC_{15}} \qquad \text{(B-2)}$$

and;

$$\underset{\text{(measured 84-85)}}{PM_{10}/TSP} \times \underset{\text{(measured 79-84)}}{TSP/DC_{15}} = \underset{\text{(estimated).}}{PM_{10}/DC_{15}} \qquad \text{(B-3)}$$

The median PM_{10}/IP_{15} ratio for Steubenville in 1984 is 0.76 (Table V-6, Spengler et al., 1986). The median IP_{15}/DC_{15} ratio for 1980-84 (5-yr average) in Steubenville is 1/0.82 or 1.22 (Table V-5, Spengler et al., 1986). The PM_{10}/DC_{15} estimated from equation B-2 is, therefore:

$$0.76 \times 1.22 = 0.93.$$

A somewhat lower figure (0.87) can be obtained by using the 1985 PM_{10}/IP_{15} ratio while a comparable to somewhat higher estimate can be derived from using the IP_{15}/DC_{15} ratio from 1980 (the year in which the episodes occurred) in place of the longer term value. Given the absence of clear trends in the ratios, the longer term estimate is preferred in this case. Given the uncertainties in the estimates a rounded PM_{10}/DC_{15} ratio of 0.9 is derived from this procedure.

Similarly, a lower bound estimate for PM_{10}/DC_{15} can be derived from equation B-3. The median 1984 PM_{10}/TSP ratio for Steubenville is 0.5 while that for 1985 is 0.51 (Table V-6, Spengler et al., 1986). The median TSP/DC_{15} ratio for 1979-84 (6 yr. average) is 1/0.66 or 1.5. From equation A-3, the PM_{10}/DC_{15} ratio is 0.76, which rounds to 0.8. From the above calculations, therefore, the range of estimated median PM_{10}/DC_{15} ratios for Steubenville is 0.8 to 0.9.

The PM_{10}/TSP ratios for specific alert periods can be estimated using these average ratios calculated above (0.8 to 0.9) together with specific PM_{15}/TSP measurements made during the alert studies. In the spring 1980 study, the peak TSP level of 220 $\mu g/m^3$ occurred on or about April 21 (Figure 1, Dockery et al., 1982). Although no particle ratios were available on that day, the DC_{15}/TSP ratios for the higher concentrations days occurring just before and after that date are approximately 0.8 (Figure IV-6, Spengler et al., 1986). Thus, by equation B-1, the range of estimated PM_{10}/TSP ratios for that alert period are:

(0.8 to 0.9) x 0.8 = 0.64 to 0.72.

To estimate the lower bound of the "possible" effects range, the lower PM_{10}/TSP ratio (0.64) is used and the estimated PM_{10} level is 220 μg/m^3 x 0.64 = 140 μg/m^3. Although not useful for deriving a lower bound, the upper bound estimate would yield 220 μg/m^3 x 0.72 = 160 μg/m^3. These upper and lower estimates bound the original lower bound (150 μg/m^3) of the range proposed for a 24-hour PM_{10} standard in 1984.

In the Fall 1980 study, in which significant effects were not observed, the peak TSP concentration of 160 μg/m^3 was reported during the baseline measurement period on or about October 17 (Figure 1, Dockery et al., 1982). Corollary measures indicate somewhat higher concentrations (200 μg/m^3 as TSP) on this date as well as on a subsequent date (about October 29) (Figure IV-7, Spengler et al., 1986). DC_{15}/TSP ratios for this study period were typically in the vicinity of 0.5 for most of the study period. Thus, the range of estimated PM_{10}/TSP ratios from equation B-1 is:

(0.8 to 0.9) x 0.5 = 0.4 to 0.45.

The range of estimated peak PM_{10} levels asociated with this study period is therefore:

(160 to 200 μg/m^3) x (0.4 to 0.45) = 65 to 90 μg/m^3.

APPENDIX C

CASAC Closure Letter

SAB-CASAC-87-010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 16, 1986

OFFICE OF
THE ADMINISTRATOR

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

SAB-CASAC-87-010

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 ug/m^3) BS levels, and hence the mortality data are not readily useful for establishing a lower bound for 24-hour PM_{10} NAAQS, 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 ug/m^3, in comparison to cities with 20-30 ug/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 ug/m^3 for 24-hour standard, and 50-65 ug/m^3 for annual standard.

Since then, EPA staff have proposed updated ranges of interest for both the 24-hour standard (140-250 ug/m^3), and the annual standard (40-65 ug/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 ug/m^3 compared to 150 ug/m^3.

REFERENCES

Bailey, M. R.; Fry, F. A.; James, A. C. (1982) The long-term clearance kinetics of insoluble particles from the human lung. Ann. Occup. Hyg. 26: 273-290.

Bates, D. V.; Sizto, R. (1986) A study of hospital admissions and air pollutants in southern Ontario. In: Lee, S. D.; Schneider, T.; Grant, L. D.; Verkerk, P., eds. Aerosols: research, risk assessment, control strategies, proceedings of the 2nd US-Dutch international symposium; May 1985; Williamsburg, VA. Chelsea, MI: Lewis Publishers, Inc.; pp. 753-766.

Bates, D. V.; Sizto, R. V. (1983) Relationships between air pollutant levels and hospital admissions in southern Ontario. Can. J. Public Health 74: 117-122.

Bohning, D. E.; Atkins, H. L.; Cohn, S. H. (1982) Long-term particle clearance in man: normal and impaired. Ann. Occup. Hyg. 26: 259-271.

Bouhuys, A. G.; Beck, G. J.; Schoenberg, J. B. (1978) Do present levels of air pollution outdoors affect respiratory health? Nature 276: 466-471.

Brunekreef, B. (1986) Personal communication to John Bachmann, Ambient Standards Branch. October 15, 1986.

CEC [Commission of the European Communities] (1983) Report on the EC epidemiology survey on the relationship between air pollution and respiratory health in primary school children. Brussels, Belgium: Environmental Research Programme.

Chann, T.L.; Lippmann, M. (1980). Experimental measurements and empirical modeling of the regional deposition of inhaled particles in humans. Am. Ind. Hyg. Assoc. 41: 399-409.

Chinn, S.; Florey, C. du V.; Baldwin, I.G.,; Gorgol, M. (1981) The relation of mortality in England and Wales 1969-73 to measurements of air pollution. J. Epidemiol. Commun. Health 35: 174-179.

Committee on Public Works, U.S. Senate (1974) A Legislative History of the Clean Air Amendments. Volume 1. Serial No. 93-18. U.S. Government Printing Office, Washington, D.C. Prepared by the Environmental Policy Division of the Congressional Research Service of the Library of Congress.

Dassen, W.; Brunekreef, B.; Hoek, G.; Hofschreuder, P.; Staatsen, B.; deGrout, H.; Schouten, E.; Biersteker, K. (1986). Decline in children's pulmonary function during an air pollution episode. J. Air. Poll. Control Assoc. 36:1223-1227.

D.C. Cir. (1980) Lead Industries Association, Inc. v. EPA, F.2d, 14 ERC 1906 (D.C. Cir.) Cert. Denied 49 U.S.L.W. 3428 December 8, 1980.

D.C. Cir (1981) American Petroleum Institute v. Costle, Nos. 79.1104 et. al. (D.C. Cir.) September 3, 1981.

Dockery, D. W.; Ware, J. H.; Ferris, B. G., Jr.; Speizer, F. E.; Cook, N. R.; Herman, S. M. (1982) Change in pulmonary function in children associated with air pollution episodes. J. Air Pollut. Control Assoc. 32: 937-942.

Emmet, P.C.; Aitken, R.J.; Hannan, W.J. (1982). Measurements of the total and regional deposition of inhaled particles in the human respiratory tract. J. Aerosol Sci. 13: 549-560.

Ferris, B. G., Jr.; Mahoney, J. R.; Patterson, R. M.; First, M. W. (1973) Air quality, Berlin, New Hampshire, March 1966 to December 1967. Am. Rev. Respir. Dis. 108: 77-84.

Ferris, B. G., Jr.; Chen, H.; Puleo, S.; Murphy, R. L. H., Jr. (1976) Chronic non-specific respiratory disease in Berlin, New Hampshire, 1967-1973. A further follow-up study. Am. Rev. Respir. Dis. 113: 475-485.

Ferris, B.G., Jr.; Dockery, D.W.; Ware, J.H.; Speizer, F.E.; Spiro, R. III (1983) The Six-City study: examples of problems in analysis of the data. Environ. Health Perspect. 52: 115-123.

Ferris, B.G., Jr.; Speizer, F.E.; Ware, J.H.; Spengler, J.D.; Dockery, D. W. (1986) The Harvard six cities study. In: Lee, S.D.; Schneider, T.; Grant, L.D.; Verkerk, P.J., eds. Aerosols, research, risk assessment and control strategies. Proceedings of the second U.S.-Dutch international symposium: aerosols; May 1985; Williamsburg, VA; Chelsea, MI; Lewis Publishers, Inc.; pp. 721-730.

Garrard, C. S.; Levandowski, R. A.; Gerrity, T. R.; Yeates, D. B.; Klein, E. (1985) The effects of acute respiratory virus infection upon tracheal mucous transport. Arch. Environ. Health. 40: 322-325.

Gerrity, T. R.; Garrard, C. S.; Yeates, D. B. (1983) A mathematical model of particle retention in the air-spaces of human lungs. Br. J. Ind. Med. 40: 121-130.

Hatzakis, A.; Katsouyanni, K.; Kalandidi, A.; Day, N.; Trichopoulos, D. (1986) Short-term effects of air pollution on mortality in Athens. Int. J. Epidemiol. 15: 73-81.

Hausman, J.A.; Ostro, B.D.; Wise, D.A. (1984) Air pollution and lost work. Cambridge, MA: National Bureau of Economic Research; NBER Working paper no. 1263.

Heyder, J.; Gebhart, J.; Stahlhofen, W.; Stuck, B. (1982) Biological variability of particle deposition in the human respiratory tract during controlled and spontaneous mouth-breathing. In: Walton, W. H.; Critchlow, A.; Coppock, S. M., eds. Inhaled particles V: proceedings of an international symposium organized by the British Occupational Hygiene Society; September 1980; Cardiff, United Kingdom. Ann. Occup. Hyg. 26: 137-147.

Imai, M.; Yoshida, K.; Kitabatake, M. (1986) Mortality from asthma and chronic bronchitis associated with changes in sulfur oxides air pollution. Arch. Environ. Health 41: 29-35.

ISO [International Standards Organization] (1981) Size-definitions for particle sampling. Am. Ind. Hyg. Assoc. I. 42:64-68a.

Lawther, P.J. (1986) Letter to John Bachmann, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, N.C. August 22, 1986.

Lawther, P. J.; Waller, R. E.; Henderson, M. (1970) Air pollution and exacerbations of bronchitis. Thorax 25: 525-539.

Lebowitz, M. D.; Bendheim, P.; Cristea, G.; Markovitz, D.; Misiaszek, J.; Staniec, M.; Van Wyck, D. (1974) The effect of air pollution and weather on lung function in exercising children and adolescents. Am. Rev. Respir. Dis. 109: 262-273.

Levandowski, R. A.; Gerrity, T. R.; Garrard, C. S. (1985) Modifications of lung clearance mechanisms by acute influenza A infection. J. Lab. Clin. Med. 106: 428-432.

Lipfert, F. W. (1984) Air pollution and mortality: specification searches using SMSA-based data. J. Environ. Econ. Manage. 11: 208-243.

Lippmann, M. (1986) CASAC Review and Closure on the OAQPS Particulate Matter Staff Paper Addendum. Letter to Lee M. Thomas. December 16, 1986.

Lunn, J. E.; Knowelden, J.; Handyside, A. J. (1967) Patterns of respiratory illness in Sheffield infant schoolchildren. Br. J. Prev. Soc. Med. 21: 7-16.

Marcus, A.; Schwartz, J. (1986). Statistical Reanalyses of Data Relating Mortality to Air Pollution During 14 London Winters. Memorandum to Bruce Jordan, Chief, Ambient Standards Branch and Lès Grant, Director, Environmental Criteria and Assessment Office, U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711

Martin, A. E. (1964) Mortality and morbidity statistics and air pollution. Proc. R. Soc. Med. 57: 969-975.

Martin, A. E.; Bradley, W. H. (1960) Mortality, fog and atmospheric pollution--An investigation during the winter of 1958-59. Mon. Bull. Minist. Health Public Health Lab. Serv. 19: 56-72.

Mazumdar, S.; Sussman, N. (1981) Relationships of air pollution to health: Results from the Pittsburgh Study. Presented at: 74th annual meeting; of the Air Pollution Control Association; June, Philadelphia, PA. Pittsburgh, PA; Air Pollution Control Association.

Mazumdar, S.; Sussman, N. (1983) Relationships of air pollution to health: results from the Pittsburgh study. Arch. Environ. Health 38: 17-24.

Mazumdar, S.; Schimmel, H.; Higgins, I. T. T. (1982) Relation of daily mortality to air pollution: an analysis of 14 London winters, 1958/59-1971/72. Arch. Environ. Health 37: 213-220.

Mazumdar, S.; Schimmel H.; Higgins, I.T.T. (1983) Response to letter to the Editor. Arch. Env. Health 38: 123-126.

McDonnell, W.F.; Horstman, D.H.; Hazucha, M.J.; Seal, E., Jr.; Haak, E.D., Salaam, S.; House, D.E. (1983) Pulmonary effects of ozone exosure during exercise: dose-response characteristics. J. Appl. Physiol. 54: 1345-1352.

Miller, F. J.; Grady, M. A.; Martonen, T. B. (1984) Coarse mode aerosol behavior in man: theory and experiment. In: Liu, B. Y. H.; Piu, D. Y. H.; Fissan, H., eds. Aerosols: science, technology, and industrial applications of airborne particles. New York, NY: Elsevier Science Pub. Co.; pp. 999-1002.

Miller, F. J.; Martonen, T. B.; Menache, M. G.; Spektor, D. M.; Lippmann, M. (1986) Influence of breathing mode and activity level on the regional deposition of inhaled particles and implications for regulatory standards. Cambridge, United Kingdom: Inhaled particles VI: accepted for publication.

Miller, F. J.; Gardner, D. E.; Graham, J. A.; Lee, R. E., Jr.; Wilson, W. E.; Bachmann, J. D. (1979) Size considerations for establishing a standard for inhalable particles. J. Air Pollut. Control Assoc. 29: 612-615.

Muhling, P.; Bory, J.; Haupt, H. (1985) Einfluss der Luftbelastung auf Atemwegserkrankungen. Untersuchungen bei Saeuglingen und Kleinkindern [The influence of air pollution on respiratory diseases: studies of babies and infants]. Staub Reinhalt. Luft 45: 35-38.

Ostro, B. D. (1983) The effects of air pollution on work loss and morbidity. J. Environ. Econ. Manag. 10: 371-382.

Ostro, B. (1984) A search for a threshold in the relationship of air pollution to mortality: a reanalysis of data on London winters. EHP Environ. Health Perspect. 58: 397-399.

Ostro, B. (1986). Letter to Les Grant, Environmental Criteria and Assessment Office. August 15, 1986.

Ostro, B. D. (1987) Air pollution and morbidity revisited: a specification test. J. Environ. Econ. Manage.: in press.

Ozkaynak, H.; Spengler, J. D.; Garsd, A.; Thruston, G.D. (1986) Assessment of population health risks resulting from exposures to airborne particles. In: Lee, S.D.; Schneider, T.; Grant, L.D.; Verkerk, P.J., eds. Aerosols: research, risk assessment and control strategies, proceedings of the Second U. S.-Dutch international symposium on aerosols; May 1985; Williamsburg, VA. Chelsea, MI: Lewis Publishers, Inc.; pp. 1067-1080.

Ozkaynak, H.; Spengler, J. D. (1985) Analysis of health effects resulting from population exposures to acid precipitation precursors. EHP Environ. Health Perspect. 63: 45-55.

Pace, T.G. (1983) The Use of TSP Data to Estimate PM_{10} Concentrations. Monitoring and Data Analysis Division. Technical Memorandum to John Bachmann, Strategies and Air Standards Division, Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, N.C.

Pace, T.G. (1986) Review of IP Network PM_{10} Data. Air Management Technology Branch. Memorandum to Bruce Jordan, Chief, Ambient Standards Branch, Office of Air Quality Planning and Standards, Research Triangle Park, N.C.

Pace, T.G.; Frank, N.H. (1984) Procedures for Estimating Probability of Non-attainment of a PM_{10} NAAQS Using Total Suspended Particulate or Inhalable Particulate Data (Draft). Monitoring and Data Analysis Division, Office of Air Quality Planning and Standards, Research Triangle Park, N.C. 27711

Pengelly, L. D.; Goldsmith, C. H.; Kerigan, A. T.; Furlong, W.; Toplack, S. A. (1986) The Hamilton study: effect of particle size on respiratory health in children. In: Lee, S. D.; Schneider, T.; Grant L. D.; Verkerk, P., eds. Aerosols: research, risk assessment, control strategies, proceedings of the 2nd US-Dutch international symposium; May 1985; Williamsburg, VA. Chelsea, MI: Lewis Publishers, Inc.; pp. 753-766.

Perry, G. B.; Chai, H.; Dickey, D. W.; Jones, R. H.; Kinsman, R. A.; Morrill, C. G.; Spector, S. L.; Weiser, R. C. (1983) Effects of particulate air pollution on asthmatics. Am. J. Public Health 73: 50-56.

Phalen, R. F.; Oldham, M. J.; Beaucage, C. B.; Crocker, T. T.; Mortensen, J. D. (1985) Postnatal enlargement of human tracheobronchial airways and implications for particle deposition. Anat. Rec. 212: 368-380.

Philipson, K.; Falk, R.; Camner, P. (1985) Long-term clearance in humans studied with teflon particles labeled with chromium-51. Exp. Lung Res. 9: 31-42.

Pollack, A.K.; Hudischewskj, A.B.; Thrall, A.D. (1985) An Examination of 1982-1983 Particulate Matter Ratios and Their Use in the Estimation of PM_{10} NAAQS Attainment Status. Systems Application, Inc., San Rafael, CA. U.S. EPA, Office of Air Quality Planning and Standards, Research Triangle Park, N.C., EPA-450/4-85-010.

Portney, P.R.; Mullahy, J. (1986) Urban air quality and acute respiratory illness. J. Urban Econ. 20: 21-38.

Rodes, C.E.; Rahme, K.A.; Purdue, L.J. (1981) Particle Collection Criteria for 10 Micron Samplers. U.S. Environmental Protection Agency, Environmental Monitoring Systems Laboratory, Research Triangle Park, N.C. 27711

Roth, H.D.; Wyzga, R.E.; Hayter, A.J. (1986) Methods and Problems in Estimating Health Risks from Particulates In Aerosols (S.D. Lee, T. Schneider, L.D. Grant, P.J. Verkerk, eds). Lewis Publishers, Chelsea, MI, pp. 837-957.

Saric, M.; Fugas, M.; Hrustic, O. (1981) Effects of urban air pollution on school age children. Arch. Environ. Health 36: 101-108.

Schimmel, H. (1978) Evidence for possible acute health effects of ambient air pollution from time series analysis: methodological questions and some new results based on New York City daily mortality, 1963-1976. Bull N.Y. Acad. 54: 1052-1108.

Schimmel, H.; Murawski, T.J. (1976) The relation of air pollution to mortality. J. Occup. Med. 18: 316-333.

Schwartz, J.; Marcus, A. (1986). Statistical reanalysis of data relating mortality to air pollution during London winters 1958-1972. U.S. EPA, Office of Policy Planning and Evaluation, Office of Air Quality Planning and Standards, Research Triangle Park, N.C. 27711.

Selvin, S.; Merrill, D.; Wong, L.; Sacks, S. T. (1984) Ecological regression analysis and the study of the influence of air quality on mortality. EHP Environ. Health Perspect. 54: 333-340.

Shumway, R. H.; Tai, R. Y.; Tai, L. P.; Pawitan, Y. (1983) Statistical analysis of daily London mortality and associated weather and pollution effects. Sacramento, CA: California Air Resources Board; contract no. A1-154-33.

Spengler, J. D.; Thurston, G. D. (1983) Mass and elemental composition of fine and coarse particles in six U.S. cities. J. Air Pollut. Control Assoc. 33: 1162-1171.

Spengler, J.D.; Briggs, S.L.K.; Ozkaynak, H. (1986) Relationships Between TSP Measurements and Size-Fractionated Particle Mass Measurements in Six Cities Participating in the Harvard Air Pollution Health Study. Prepared for Office of Air Quality Planning and Standards, Office of Policy Analysis, U.S. Environmental Protection Agency, December 5, 1986.

Stebbings, J. H., Jr.; Fogleman, D. G. (1979) Identifying a susceptible subgroup: effects of the Pittsburgh air pollution episode upon school children. Am. J. Epidemiol. 110: 27-40.

Svartengren, M.; Hassler, E.; Philipson, K.; Camner, P. (1986) Spirometric data and penetration of particles to the alveoli. Br. J. Indus. Med. 43: 188-191.

Svartengren, M. (1986) Lung deposition and clearance of particles in healthy persons and patients with bronchiectasis. Stockholm, Sweden.

Swift, D. L.; Proctor, D. F. (1982) Human respiratory deposition of particles during oronasal breathing. Atmos. Environ. 16: 2279-2282.

U. S. Environmental Protection Agency. (1982a) Review of the National Ambient Air Quality Standards for Particulate Matter: Assessment of Scientific and Technical Information (OAQPS staff paper). Research Triangle Park, NC. Office of Air Quality Planning and Standards, EPA report no. EPA-450/5-82-001. Available from: NTIS, Springfield, VA; PB82-177874.

U. S. Environmental Protection Agency. (1982b) Air Quality Criteria for Particulate Matter and Sulfur Oxides: Research Triangle Park, NC: Environmental Criteria and Assessment Office, EPA report no. EPA-600/8-82-029cF. Available from: NTIS, Springfield, VA; PB84-156801/REB.

van der Lende, R.; Schouten, J.P.; Rijcken, B.; van der Meulen, A. (1986) Longitudinal epidemiologic studies on effects of air pollution in the Netherlands. In: Lee, S.D.; Schneider, T.; Grant, L.D.; Verkerk, P.J., eds. Aerosols: research, risk assessment and control strategies, proceedings of the second U.S.-Dutch international symposium; May, 1985; Williamsburg, VA. Chelsea, MI. Lewis Publishers, Inc.; pp. 731-742.

van der Meulen A. (1986) The relationship between PM_{10} and thoracic particle sampling. J. Air Pollut. Control Assoc. 35: 383-387.

Ware, J. H.; Thibodeau, L. A.; Speizer, F. E.; Colome, S.; Ferris, B. G., Jr. (1981) Assessment of the health effects of atmospheric sulfur oxides and particulate matter: Evidence from observational studies. Environ. Health Perspect. 41: 255-276.

Ware, J. H.; Ferris, B. G., Jr.; Dockery, D. W.; Spengler, J. D.; Stram, D. O; Speizer, F. E. (1986) Effects of ambient sulfur oxides and suspended particles on respiratory health of preadolescent children. Am. Rev. Respir. Dis. 133: 834-842.

Wojtyniak, B.; Krzyzanowski, M.; Jedrychowski, W. (1984) Importance of urban air pollution in chronic respiratory problems = Die Bedeutung staedtischer Luftverunreinigung fuer chronische Atemwegsbeschwerden. Z. Erkr. Atmungsorgane 163: 274-284.

TECHNICAL REPORT DATA

(Please read Instructions on the reverse before completing)

1. REPORT NO.	2.	3. RECIPIENT'S ACCESSION NO.
EPA 450/05 86-012		

4. TITLE AND SUBTITLE	5. REPORT DATE
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~~	December 1986
	6. PERFORMING ORGANIZATION CODE
7. AUTHOR(S)	8. PERFORMING ORGANIZATION REPORT NO.
9. PERFORMING ORGANIZATION NAME AND ADDRESS Office of Air and Radiation Office of Air Quality Planning and Standards U.S. Environmental Protection Agency Research Triangle Park, North Carolina 27711	10. PROGRAM ELEMENT NO. 11. CONTRACT/GRANT NO.
12. SPONSORING AGENCY NAME AND ADDRESS	13. TYPE OF REPORT AND PERIOD COVERED Final 14. SPONSORING AGENCY CODE

15. SUPPLEMENTARY NOTES

16. ABSTRACT

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. This assessment is intended to help bridge the gap between the scientific review contained in the EPA criteria document addendum 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 major recommendations of this addendum include the following:

1. 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 less than or equal to a nominal 10 um, termed PM_{10}.
2. Based on an updated staff assessment of the short-term epidemiological data, the range of 24-hour PM_{10} levels of interest is 140 to 250 ug/m^3.
3. Based on an updated staff assessment of the long-term epidemiological data, the range of annual PM_{10} levels of interest is 40 to 65 ug/m^3.
4. When selecting final standard levels, consideration should be given to the combined protection afforded by the 24-hour and annual standards taken together.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
Particulate Matter Aerosols Air Pollution Sulfur Oxides	Air Quality Standards	

18. DISTRIBUTION STATEMENT	19. SECURITY CLASS (This Report)	21. NO. OF PAGES
Release to public	Unclassified	100
	20. SECURITY CLASS (This page)	22. PRICE

EPA Form 2220-1 (Rev. 4-77) PREVIOUS EDITION IS OBSOLETE