VII. STAFF CONCLUSIONS AND RECOMMENDATIONS ON PRIMARY NAAQS

This chapter presents staff conclusions and recommendations for the Administrator to consider in deciding whether to retain, revise, and/or supplement the current primary PM NAAQS. Drawing from the synthesis of information and analyses contained in both the Criteria Document (CD, Chapter 13) and in Chapters IV, V, and VI herein, this chapter begins with staff findings on the overall adequacy of the current primary standards for PM, going on to address each of the major components needed to specify ambient standards: pollutant indicator, averaging time, form, and level. Staff conclusions and recommendations on each of these interrelated components for the current and alternative primary standards are based on considering how both the components of an individual standard and a suite of standards operate together to protect public health with an adequate margin of safety.

In recommending a range of options for the Administrator to consider, the staff notes that the final decision is largely a public health policy judgment. A final decision must draw upon scientific information about health effects and risks, as well as judgments about how to deal with the range of uncertainties that are inherent in the scientific evidence and analyses. The staff's approach to informing these judgments is based on a recognition that the available health effects evidence generally reflects a continuum consisting of levels at which scientists generally agree that health effects are likely through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the Clean Air Act and with how EPA and the courts have historically interpreted the Act. These provisions do not require the Administrator to establish a NAAQS at a zero-risk level but rather at a level that avoids unacceptable risks and, thus, protects public health with an adequate margin of safety.

In addition, the staff notes that especially where considerable uncertainty exists with regard to appropriate policy choices based on the scientific information and analyses, it is appropriate to consider the risk management implications of alternative approaches that represent scientifically sound options. For example, if the Administrator concludes that the current standards should be revised to provide greater health protection, it is appropriate to consider whether it would be more effective and efficient to do so by tightening the current

PM_{10} standards or by establishing new $PM_{2.5}$ standards. Thus, staff has considered risk management implications together with the scientific evidence in assessing whether alternative approaches to establishing PM standards would provide both the requisite level of protection and an effective and efficient basis for pollution control strategies that will result in the attainment and maintenance of adequate public health protection.

A. Adequacy of the Current Primary Standards for Particulate Matter

As discussed in Chapter II, the Clean Air Act calls for periodic review of the criteria and the NAAQS. The overarching issue in such reviews is whether revision of the existing standards is appropriate to reflect advances in scientific knowledge. The information presented in the Criteria Document and this Staff Paper is intended to provide a scientifically sound and policy-relevant basis, in accordance with sections 108 and 109 of the Clean Air Act, for the Administrator to reach conclusions with respect to whether the existing standards should be revised and, if so, what revised or new standards, are appropriate. The concluding section of the integrative summary of health effects information in the PM Criteria Document provides the following cogent summary of the science with respect to this issue for the current review of the PM standards:

> "The evidence for PM-related effects from epidemiologic studies is fairly strong, with most studies showing increases in mortality, hospital admissions, respiratory symptoms, and pulmonary function decrements associated with several PM indices. These epidemiologic findings cannot be wholly attributed to inappropriate or incorrect statistical methods, misspecification of concentration-effect models, biases in study design or implementation, measurement errors in health endpoint, pollution exposure, weather, or other variables, nor confounding of PM effects with effects of other factors. While the results of the epidemiology studies should be interpreted cautiously, they nonetheless provide ample reason to be concerned that there are detectable health effects attributable to PM at levels below the current NAAQS" (CD, p 13-92).

This finding from the review of the scientific criteria clearly calls into question the adequacy of the current NAAQS. The extensive PM epidemiologic database provides evidence of serious health effects (e.g., mortality, exacerbation of chronic disease, increased hospital admissions) in susceptible population groups (e.g., the elderly older adults with

chronic cardiopulmonary disease). Although the increase in individual relative risk is small for the most serious outcomes, it is likely significant from an overall public health perspective, because of the large number of individuals in susceptible population groups that are exposed to ambient PM (CD, p 1-21). While the lack of demonstrated mechanisms that explain the range of epidemiologic findings is an important caution which limits conclusions as to causality, qualitative information from laboratory studies of the effects of particle components at high concentrations and dosimetry considerations suggest that the kinds of effects observed in community studies (e.g., respiratory- and cardiovascular-related responses) are at least plausibly related to particulate matter. Indeed, the CD points to the consistency of the results of the epidemiologic studies from a large number of different locations and the coherent nature of the observed effects as being suggestive of a likely causal role of ambient PM in contributing to the reported effects. Given the evidence that such effects may occur at levels below the current standards, as well as the nature and potential magnitude of the public health risks involved, the staff believes that revision of the current standards is clearly appropriate. Thus, the principal recommendation of this staff assessment is that the current standards should be revised.

The remainder of this chapter focuses on developing a range of alternative standards for the Administrator to consider in determining what revised or new standards are appropriate to protect public health. In formulating alternative approaches to establishing adequately protective, effective, and efficient PM standards, staff concurs with the important conclusion from the CD that fine and coarse fractions of PM_{10} should be considered as two separate pollutants (CD, p 13-93). As discussed in Section V.F., the staff assessment finds sufficient evidence to support establishment of separate standards relating to these two fractions of PM_{10}. On the other hand, the staff also notes the larger body of epidemiologic evidence and air quality information related to undifferentiated PM_{10} .

Therefore, staff concludes that it is reasonable to consider two alternative approaches for revising the standards: 1) adopt more protective standards using PM_{10} as the sole indicator combining fine and coarse fractions; and 2) develop separate standards for fine and coarse fractions of PM_{10} using appropriate indicators for each fraction. Conceptually, the first

approach is precautionary and gives significant weight to recent findings using PM_{10} as a surrogate for both fine and coarse fraction particles, with less consideration of the evidence that suggests that the current standards provide adequate protection for coarse fraction particles. Because the PM_{10} monitoring network is in place, it also would result in more immediate implementation of revised standards. The second approach is based on the view that in the long run, more effective and efficient protection can be provided by separately targeting appropriate levels of controls to fine and coarse particles. Because of the need to develop and install additional monitors, this approach would provide additional time to consider significant new scientific information before any such standards were actually implemented.

The relative merit of these two alternative approaches are considered in the next section, which also summarize staff conclusions and recommendations regarding indicators for thoracic particles, fine particles, and coarse fraction particles. Subsequent sections focus on identifying alternative averaging times, forms, and levels for the recommended approach.

B. Alternative PM Indicators and Risk Management Implications

1. PM_{10} as Surrogate Indicator for Fine and Coarse Fraction Particles

The most recent summary of scientific information in the CD and outlined in Chapters IV and V continues to support past staff and CASAC recommendations regarding selecting size specific-indicators for PM standards. More specifically, the staff believes that the following conclusions reached in the 1987 assessment remain valid:

1) Health risks posed by inhaled particles are influenced both by the penetration and deposition of particles in the various regions of the respiratory tract and by the biological responses to these deposited materials.

2) The risks of adverse health effects associated with deposition of ambient fine and coarse fraction 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.

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

4) The size specific indicator(s) should represent those particles capable of penetrating to the thoracic region, including both the tracheobronchial and alveolar regions.

Based upon the above considerations as well as the available information on human dosimetry of particles, in the previous review the staff and CASAC recommended a size specific indicator that included particles less than or equal to a nominal 10 µm cut point, termed PM_{10}. The recent information on human particle dosimetry contained in the CD provides no basis for changing 10 µm as the appropriate dividing line for particles capable of penetrating to the thoracic regions. The recent epidemiologic literature also provides some evidence that thoracic particles can be somewhat more closely linked to effects than can the "super coarse" (> 10 µm) fraction of TSP (e.g. Dockery et al., 1993). The CD concludes that "recent analyses have substantiated the previous selection of PM_{10} as an indicator of particle-related health effects" (CD, p. 13-93).

In selecting the most appropriate indicator(s) for the PM standards, the staff believes that consideration should be given to protecting public health through the use of standards that are as effective and efficient as possible. An effective set of standards would capture all of the most harmful constituents of PM_{10} and target them such that an appropriate level of control occurs for the harmful components. Conceptually, a broad based PM indicator such as TSP set at a stringent enough level can provide effective protection for the most harmful components. However, because such a standard would set unnecessarily stringent controls on extrathoracic constituents unlikely to be most harmful, it would not be an efficient standard. As staff concluded in the previous review, a PM_{10} indicator provides more efficient as well as more effective health protection than would TSP (U.S. EPA, 1982b). In the present review, it is important to make use of the current state of knowledge to select an indicator(s) that not only captures all of the most harmful components (i.e., an effective indicator), but also places

greater emphasis for control on those constituents or fractions that are most likely to result in the largest risk reduction (i.e., an efficient indicator).

Therefore, consideration of the available evidence regarding the components of PM_{10} most likely responsible for the observed health effects categories at various levels is critical to maximizing the effectiveness and efficiency of health protection strategies. The indicator is used to target and monitor health protection strategies, and the choice is key to overall health protection provided by the PM NAAQS. Given these concerns and the expanded information, the staff believes it is appropriate to reexamine the question of whether the PM_{10} indicator should undergo additional refinement to reflect new scientific understandings of fine and coarse fraction particles as separate pollutants.

The staff assessment of the progress made through implementing the current PM_{10} standards is instructive in this regard (Section IV.D). Figure IV-4 and Table IV-5 summarize how the States and EPA characterize the major sources of PM_{10} and the extent of progress to date. In essence, the lessons learned from past TSP and PM_{10} programs can be summarized as follows:

- PM_{10} is generally viewed as a local rather than a regional problem. This is clearly appropriate in most Western areas with the highest PM_{10} levels. However, even in the eastern U.S., where high regional levels of transported fine particles make significant, but not dominant, contributions to PM_{10} mass, programs tend to focus on control of local sources, in part because of the difficulty in developing multi-jurisdictional strategies. This means that abatement programs will generally focus on the most readily available local sources of primary particles, leaving secondary or regional options as a last resort.

- In areas where local fine particle sources are overwhelmingly dominant, for example in areas with high woodsmoke contributions (e.g., Klamath Falls, OR), PM_{10} controls have led to significant reductions in fine particles. Historically, TSP-based local programs have also resulted in significant reductions in local primary fine particle emissions from coal combustion and industrial sources (e.g., New York City, Pittsburgh, PA).

- In areas where fugitive sources of crustal materials are clearly dominant (e.g., Coachcella Valley, CA), PM_{10} programs focus on measures that reduce road dust, construction, and related sources. These programs have had limited success to date.

Local sources of precursor gases contributing to fine particles generally are not addressed.

- In areas dominated by local point source complexes (industrial emissions), both coarse and fine controls are applied, and sources sometimes may trade reductions between the two on a mass basis. Where source complexes are located in a zone of high transported fine particles, the transported component is treated as background, increasing the need for local controls; this likely results in greater relative control for coarse particles than fine.

- In Western areas having "mixed" contributions, including significant local secondary particle formation, three areas (SCAB[1]; Provo, UT; Denver, CO) have begun to require controls of gaseous precursors (SO_x, NO_x) in addition to fugitive dust and other controls.

- Any reductions in fine particles related to regional sulfur oxides emissions that have taken place to date are not related to implementation of the PM_{10} or TSP standards, but the SO_2 NAAQS and other mandated requirements of the CAA, such as the acid rain program.

This experience is a useful guide for a qualitative examination of the potential effectiveness and efficiency of alternative revised protective standards using PM_{10} as the sole surrogate for the harmful components of PM. To provide a basis for such examination, Table VII-1 presents a set of increasingly more protective alternative PM_{10} standards drawn from the staff analysis of potential PM_{10} effects "cutpoints" developed in Appendix E for the risk assessment. These alternatives do not reflect staff recommendations, but are examples presented for the purpose of the present assessment of the PM_{10} indicator. The table indicates the regional distribution of the percentage of counties (meeting a 50% data completeness criteria) that would not attain the listed alternatives. The table also notes the characteristic regional contribution of coarse fraction particles to PM_{10} mass, which, like total mass, is generally highest in the West.

Looking first at annual PM_{10} standards alone, the table suggests that a moderate reduction from the current level (to 40 $\mu g/m^3$) would result in few controls in eastern areas,

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[1] South Coast Air Basin of California.

but would approach the combined effect of the current 24-hour and annual standards in the West. A more substantial reduction in an annual standard to 30 µg/m^3 would affect about half of the Western areas and also begin to prompt additional controls in the East. By comparison, a revised 24-hour PM_{10} standard of 100 µg/m^3 (alone or in combination with a 40 µg/m^3 annual) would have effects similar to a 30 µg/m^3 annual standard alone in the East, but affect still more (approximately 55 to over 75%) Western areas. Based on the implementation experience outlined above, the eastern areas would likely develop control programs to achieve such standards with an initial focus on local sources of PM_{10}, which would tend to result in a proportionally greater reduction for coarse

TABLE VII-1. PERCENTAGE OF COUNTIES NOT MEETING ALTERNATIVE PM_{10} STANDARDS*

	Level of Alternative Standards**	All	SW	NW	CE	SE	NE
County Total		482	60	80	68	99	175
Annual	50	2.3	13.	3.8	0	0	0
	40	7.3	22	15	7.4	1.0	2.3
	30	29	45	48	26	16	23
24-hr	150	12	27	34	8.8	2.0	3.4
	100	35	55	76	32	25	16
	50	97	97	98	90	100	98
Combined Standards	50/150	12	26	34	8.8	2.0	3.4
	40/100	35	55	76	32	25	16
	30/50	97	97	98	90	100	98

	Level of Alternative Standards**	All	SW	NW	CE	SE	NE
Coarse/PM_{10}* **	--	0.44	0.55	0.60	0.37	0.44	0.37

* Based on 1991-1993 data, using 50% data completeness criteria and the Appendix K missing data adjustment to account for less than every day sampling frequencies. See staff analyses (Fitz-Simons et al., 1996).

** Based on current 1-expected-exceedance form of the 24-hour PM_{10} NAAQS and current expected annual average of annual PM_{10} NAAQS, at the highest monitor for each standard.

*** Regional median ratio of coarse fraction mass to PM_{10} mass all seasons, based on available data from few sites (SAI, 1996).

fraction particles than fine. Without a more detailed assessment beyond the scope of this paper, it is not clear whether or how much PM_{10} standards set at these levels would also prompt more balanced reductions in fine and coarse fraction particles in the East. In the West, however, widespread nonattainment resulting from such PM_{10} standards would clearly prompt much more coarse particle control, based on the prevailing high coarse fraction content of PM_{10}.

This analysis suggests that, nationwide, progressively reducing the level of the PM_{10} standards alone to the middle levels in the table would place relatively more emphasis on additional controls for coarse fraction particles than for fine. On a regional basis, relatively less impetus for additional control would be placed on the East, which has the highest regional concentrations of fine particles, than on the West, which has the highest localized concentrations of coarse fraction particles. Clearly, PM_{10} standard levels somewhere in the range below the middle levels shown in Table VII-1 would also result in relatively more control of fine particles in the East. Such standards would inevitably increase the number of areas needing to address coarse fraction particles in the West.

One view of the risk management implications of the recent epidemiology holds that a single PM_{10} indicator is most appropriate because more studies have used PM_{10} and it would

therefore be more prudent to prompt proportional reductions in the major components of PM_{10}. Even accepting such a view, however, our analysis indicates that reduced PM_{10} standards would not result in proportional reductions in fine and coarse fraction particles in the very areas from which most of the epidemiological results are derived (see cover figure). Selecting levels that would achieve such proportional reductions in the East through a PM_{10} indicator alone would still result in significantly disproportional coarse particle control in the West[2]. In essence, the above analysis is consistent with the admonition in the CD that more effective PM_{10} programs can be achieved by establishing separate targets for fine and coarse fraction particles (CD, 13-94).

From this analysis, then, a decision to provide increased health protection through standards indexed by undifferentiated PM_{10} alone would have to be based on two additional premises: 1) fine and coarse fraction particles are likely to produce similar health effects at equivalent concentrations, i.e. be of relatively comparable toxicity; and 2) control strategies for fine and coarse fraction particles would produce roughly equivalent reductions in exposure in sensitive populations shown to be at increased risk of PM effects. Yet, the staff analyses of the available information as summarized in Section V.F provides little support for either premise. While the relative toxicity of fine and coarse fraction particles is not clearly established, both physical and chemical toxicologic considerations suggest that fine particles are likely to be more toxic for several, although not necessarily all, of the relevant effects categories than are coarse fraction particles (Section V.F). Based on the direct comparisons in epidemiological studies and on exposure considerations, the staff further concludes that - - whatever the relative toxicity of fine and coarse fraction particles - - control of sources of ambient fine particles is likely to be more effective in reducing exposure to sensitive subpopulations than is control of sources of ambient coarse fraction particles.

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[2]The acid rain program should result in some additional regional SO_x reductions in the East. However, much of the improvement has already been realized with more gradual reductions over the next 15 years due to the banking and trading components. The existence of such a program, however, provides no justification for establishing inappropriate PM NAAQS targets, nor for the potential over control of coarse fraction particles, particularly in the West.

Given the available evidence, a uniform reduction in the levels of the PM_{10} standards could provide effective health protection from the effects of the most harmful components of PM_{10}, but only at concentrations that appear to be unnecessarily stringent with respect to coarse fraction particles. Limited, but important epidemiological evidence as well as mechanistic considerations suggest that coarse fraction particles are linked to effects in areas that exceed the current PM_{10} standards (CD, p. 13-51). Given the lack of evidence with respect to coarse particle effects at concentrations at or below the level of the current PM_{10} standards, however, little justification exists for proportional, much less disproportional, reductions in coarse fraction particles beyond those afforded by the current standards. By contrast, a number of epidemiological studies have used fine particles as an indicator. The available evidence comparing the two fractions suggests that fine particles are a better surrogate for those components of PM_{10} that are associated with adverse effects at levels below the current standard (sectionV.F). For these reasons, staff concludes that a single PM_{10} indicator would not provide the most effective and efficient protection from the health effects of particulate matter. Instead, the data available in this review suggest that the most effective and efficient approach would be to control PM_{10} through separate standards for fine and coarse fraction particles.

2. Alternative Surrogate Indicators for Fine and Coarse Fraction Particles

The large number of recent community epidemiologic studies and improvements in human exposure and air quality presented in the CD and outlined in Chapters IV and V above have greatly expanded the information regarding associations between contemporary community air pollution containing particles and morbidity and mortality in sensitive subpopulations as compared to the previous review. Even with the presence of other pollutants in the communities studied, PM is independently associated with the observed health effects. While earlier studies mainly relied on BS, TSP, and sulfates as particle indicators, the recent work has added a much larger body of quantitative and qualitative information on PM_{10}, with a lesser but still substantial number of community studies that provide specific information on fine particles, including sulfate and acid aerosol components, and to a still lesser extent, coarse fraction particles (CD, p 1-21).

The CD concludes that the indices most consistently associated with health endpoints are thoracic (PM_{10} or PM_{15}) and fine particle indicators. Less consistent relationships have been observed for TSP and the coarse fraction of PM_{10} (CD, p 1-21). Based on an examination of relevant information in the CD on fine and coarse fraction particles (Section V.F), the staff concludes that the weight of the available evidence allowing direct comparisons suggests that ambient coarse fraction particles are either less potent or a poorer surrogate for community effects of air pollution than are fine particles. This assessment finds that the limited evidence suggestive of independent coarse particle effects was found in areas that significantly exceed the current standards, while reported associations with fine particles frequently occur at levels well below the current standards.

The staff concurs with the CD recommendation that "it would be appropriate to consider fine and coarse mode particles as separate subclasses of pollutants" (CD, p 13-94). The staff also concludes that sufficient information exists to do so. The analysis in the preceding section indicates that establishing distinct targets for fine and coarse fraction particles would provide more effective and efficient health protection strategies for PM. Therefore, the staff recommends that separate standards be established for the fine and coarse fractions of PM_{10}. The discussion below outlines staff conclusions and recommendations for selecting indicators for such standards.

a. Surrogate Indicators for the Fine Fraction of PM_{10}

Although fine mode particles consist of several distinct chemical classes (Table IV-2), they share a number of important characteristics related to size and formation mechanisms. The CD concludes that none of these subclasses can be specifically implicated as the sole or even primary cause of specific morbidity and mortality effects (CD, p. 13-93). In essence, fine particle mass is a surrogate for whatever components appear to be causing the mortality and morbidity effects in community air pollution.

In examining the potential effectiveness of fine particles as a surrogate, it is useful to consider the results of various analyses of air pollution and mortality in Philadelphia as discussed in Section V.E (Moolgavkar et al., 1995; Wyzga and Lipfert, 1995; Samet et al., 1995, 1996a; Cifuentes and Lave, 1996). The CD evaluation of these multiple investigations

concludes that for this single city example, it appears most difficult to separate independent effects of PM (as TSP) and SO_2, concluding that the relationship between these pollutants and mortality may be inherently non-linear (CD, p 13-57). Several clearly hypothetical explanations have been advanced to explain these results. The following qualitative assessment of several speculative, but plausible hypotheses (in italics), outlines the potential implications of these alternatives for the effectiveness of fine particle control as a surrogate:

- *The complex relationship is a statistical artifact and only one of the pollutants is causally related*. *If the pollutant is PM,* then fine particle control would clearly be beneficial. *If the pollutant is SO_2,* which occurs at moderate levels in Philadelphia, reductions in local and transported SO_2 precursor control prompted by a fine particle standard would reduce health risk.[3]

- *The relationship is real and due to increased penetration of an SO_2 complex carried on carbonaceous or other non-acidic particles*. Then local controls of primary fine particle combustion sources would likely reduce risks, because reducing the aggregate particle surface area (by reducing fine mass) is more likely to reduce dose than SO_2 reductions.

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

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

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

Although the above examples of alternative consequences of the use of fine particles as a surrogate are limited to PM and SO_2 interactions, some of these outcomes would extend to PM interactions with other pollutants as well. Given the large surface area of aqueous droplet

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

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

The above examples also illustrate why, based on current information, it is more appropriate to control fine particles as a group, as opposed to singling out particular classes. The qualitative literature has found various effects of high concentrations of fine sulfuric acid, ammonium sulfates and nitrate, carbonaceous materials, and transition metals, alone or in some cases, in combination with gases (CD, Chapter 11; Section V.C). Community studies have found significant associations between fine particles or PM_{10} and health in areas with significant mass contribution of these fine components, including sulfates (6 cities), wood smoke (Santa Clara), nitrates (Los Angeles and Utah Valley), secondary organics (Los Angeles), and acid sulfate aerosols (24 City Study). As noted above, it is not possible to rule out any one of these components as contributing to fine particle effects.

The most substantial laboratory and epidemiologic data for any single class of fine particles exists for sulfates and associated acids. The data for acids, which are more difficult to measure, is less consistent than for sulfates. For example, the recent 24 City Study data suggest that regionally high exposures to acids in modest sized communities in the “sulfate belt” are associated with bronchitis and decreased lung function in children (Dockery et al., 1996; Raizenne et al., 1996). Yet relatively strong correlations exist between acids, sulfates, and fine particles, making it difficult to single out any factor with confidence (CD, p 13-93).

Indeed, the staff considers sulfates useful as an indicator of fine particles for assessing the health effects literature. This literature suggests that reductions of regional sulfates as part of a fine particle standard control program would likely reduce mortality and morbidity risks for the large segments of the sensitive population who reside in the East. It would be inappropriate, however, to extend this finding to establishing a separate sulfate standard, alone or in combination with fine particle standards. A sulfate standard, even if understood as an indicator of all fine particles as suggested by Lippmann and Thurston (1996), would be less likely to lead to controls of the other potentially harmful components of fine particles.

A number of monitoring approaches have been used as indicators for fine particles (Appendix B). All of them have inherent strengths and weakness (CD, pp. 1-6 to 7). In selecting an indicator for a fine particle NAAQS, the staff places great weight on providing consistency with the largest segment of the epidemiologic data, and to a lesser extent, on making use of the existing fine particle data in the U.S. Staff have submitted their recommendations regarding the most appropriate monitoring approach for a fine particle standard to the CASAC Technical Subcommittee for Fine Particle Monitoring[4]. The staff rejected the use of filter based optical approaches because they are more sensitive to variations in carbon and require mass calibration (CD, p 1-6). Although direct optical (e.g., nephelometry) and other continuous methods can offer significant advantages and are often well correlated with gravimetric mass measurements, under some circumstances they are less well linked, in part because of losses of semi-volatile components (CD, p 1-6). Further development of such approaches for routine use is an important need. Because most of the quantitative epidemiological data for fine particles and PM_{10} were based on gravimetrically determined mass, staff recommends that this measurement principle be adopted for fine particle standards. Although some loss of nitrate and other semi-volatile mass can occur with such methods, gravimetric approaches are most directly related to the available epidemiology, and they can be used to provide composition information helpful for developing control

[4]The Subcommittee met to review these recommendations as well as specifications for a possible Federal Reference Method and Monitoring Guidance at a public meeting on March 1, 1996.

strategies. Again, improved continuous approaches that could be used as equivalent methods for fine particles are an important development need.

Staff also recommend the use of a sharp 2.5 µm cutpoint for a fine particle indicator. As discussed in Chapter IV and Appendix A, the minimum particle diameter between the fine and coarse modes lies between 1 and 3 µm, and the scientific data support a cut point to delineate fine particles in this range. Because of the potential overlap of fine and coarse particle mass in this intermodal region, specific cut points are only an approximation of fine mode particles. Thus, the decision within this size range is largely a policy judgement. The staff recommendation for a 2.5 µm cutpoint is based on considerations of consistency with health data, the limited potential for intrusion of coarse fraction particles into the fine fraction, and availability of monitoring technology. Therefore, the staff recommends using $PM_{2.5}$ as the fine particle indicator. The definition will be further specified in the Federal Reference Method and equivalency program.

$PM_{2.5}$ encompasses all of the potential agents of concern in the fine fraction, including most sulfates, acids, fine particle metals, organics, and ultrafine particles and includes most of the aggregate surface area and particle number in the entire PM distribution. $PM_{2.5}$ has been used directly in health studies as described in the CD and Chapter V. Although a number of studies have used $PM_{2.1}$, in most locations there should be little difference in mass. The more widespread use of $PM_{2.5}$ measurement technologies since the 1970s has resulted in the generation of relatively more data for this cutpoint than for other cutpoints for fine fraction particles.

$PM_{2.5}$ does have some potential for intrusion of the “tail” of the coarse mode during episodes of fugitive dust concentrations (See Appendix A). Staff recommends a sharp inlet for the FRM to minimize this potential intrusion of coarse mode particles. Such intrusions into $PM_{2.5}$ measurements is not anticipated to be significant in most situations; nevertheless, if subsequent data reveal problems in this regard, this issue can and should be addressed on a case-by-case basis in the monitoring and implementation programs. Because the purpose of a $PM_{2.5}$ standard is to direct controls toward sources of fine mode particles, it would be appropriate to develop analytical procedures for identifying those cases where a $PM_{2.5}$ standard

violation would not have occurred in the absence of coarse mode particle intrusion.[5] Consideration should be given to a policy similar to the natural events policy (See Chapter IV) for addressing such cases.

Some commentors have recommended use of a smaller cutpoint at 1 µm (PM_1) to further reduce coarse particle intrusion. PM_1 has not been used in health studies, although in most cases mass should be similar as for cutpoints of 2.1 or 2.5. While this indicator could reduce intrusion of fugitive dust, it might also omit portions of hygroscopic acid sulfates in high humidity episodes. PM_1 sampling technologies have been developed; however, the PM_1 samplers have not been widely field-tested to date. Of some concern is the theoretical possibility that different flow velocities for the smaller cut might increase the loss of semivolatile materials relative to a larger cut. Thus, the staff recommends the use of $PM_{2.5}$ as the fine particle cutpoint.

b. Surrogate Indicators for the Coarse Fraction of PM_{10}

The CD and staff assessment finds that epidemiologic information, dosimetry and toxicology support the need for a particle indicator that addresses the health effects of coarse fraction particles smaller than nominal 10 µm. Coarse fraction particles deposit in both the tracheobronchial and alveolar region. Although the role of coarse fraction particles in much of the recent epidemiological results is unclear, studies where coarse fraction particles are the dominant fraction of PM_{10} suggest that the major short-term effects include aggravation of asthma and increased upper respiratory illness. Such effects are supported by dosimetric considerations (CD, p 13-51). Children, who spend more time in outdoor activities, may encounter higher exposures and doses of coarse fraction particles than other potentially sensitive populations. Long-term deposition of insoluble coarse fraction particles in the alveolar region may have the potential for enhanced toxicity, in part because clearance from this region of the lung is significantly slower than from the tracheobronchial region. Qualitative support for this concern is found in autopsy studies of animals and humans exposed

[5] Analytical procedures could involve measurements of chemical components related to local coarse mode particles as a basis for developing a coarse mode intrusion estimate. Lundgren et al. (1996) have submitted a paper suggesting one such approach.

to various ambient crustal dusts at or slightly above ambient levels typical in the Western U.S. (Section V.C).

In selecting an indicator for coarse fraction particles, it is important to note that the existing ambient data base for coarse fraction particles ($PM_{10-2.5}$) is smaller than that for fine particles, and that the only studies of clear quantitative relevance have used undifferentiated PM_{10}. However, it is possible to consider PM_{10} itself as a useful surrogate for coarse fraction particles, when used in conjunction with $PM_{2.5}$ standards. As noted above, in many areas with high fugitive dust, this is already the case with respect to control strategies. Because coarse fraction particles in such areas contribute significantly more mass than smaller particles, risk managers have incentives to focus reduction measures on particle sources that contribute the most by mass. The monitoring network already in place for PM_{10} is large. Therefore, if a fine particle indicator were chosen, the staff would recommend retention of PM_{10} as the indicator to protect against the risks of coarse fraction particles.

3. Staff Conclusions and Recommendations for Particle Indicators

Based on the above assessments and the scientific information in the CD, the staff draws the following conclusions and recommendations:

1) Ambient particles capable of penetrating to the thoracic region represent the greatest risk to health. Previous staff and CASAC recommendations for 10 µm as the appropriate cut point for such particles remain valid. In examining alternative approaches to increasing the protection afforded by PM_{10} standards, the staff finds that reducing the levels of the current standards would not provide the most effective and efficient protection from the health effects of particulate matter.

2) The recent health evidence, the fundamental differences between fine and coarse fraction particles, and implementation experience with PM_{10} have, however, prompted the staff to consider separate standards for the fine and coarse fractions of PM_{10}.

3) The staff finds that the available information is sufficient to support separate indicators for these pollutant classes. While it is difficult to distinguish the effects of fine or coarse fraction particles from those of PM_{10}, consideration of comparisons between fine and coarse fraction particles suggests that fine particles are a better surrogate for

those particle components linked to mortality and morbidity effects at levels below the current standards. Coarse fraction particles are most clearly linked with certain effects at levels above those allowed by the current standards.

4) In selecting an indicator for fine particles, staff recommends use of a 2.5 µm cut point for fine particle mass. Adoption of sulfate or other chemical class indicators is not advisable during this review. In selecting an indicator for coarse fraction particles, the staff recommends use of PM_{10} .

C. Alternative $PM_{2.5}$ Standards for Control of Fine Fraction Particles

1. Averaging Time

The current primary PM NAAQS include both a 24-hour standard, with no more than one expected exceedance, and an annual standard with an expected arithmetic mean form. These standards were intended jointly to protect the public against the health effects associated with both short-term and long-term exposures to PM based on epidemiological and other health studies available at the conclusion of the last review. The recent health effects information includes reported associations with both short-term (from less than 1 day to up to 5 days) and long-term (from generally a year to several years) measures to PM. This information, summarized in Chapter V, provides increased support for consideration of both short-term and long-term standards, as discussed below.

a. Short-term $PM_{2.5}$ Standard

The current 24-hour averaging time is consistent with the majority of the results from community epidemiological studies, which have reported associations of 24-hour concentrations of PM_{10}, fine particles, and TSP with an array of health effects. Nevertheless, because some such studies have found a stronger association with a multiple day average (Pope et al., 1992; Ostro et al., 1995; Pope and Dockery et al., 1992), the staff considered whether a multiple day averaging time would be more appropriate. The above results are also consistent with the existence of a lagged single exposure effect of PM, which may not be due to multiple day exposures. Moreover, some studies have found health effects to be associated with same day or previous day PM concentrations. For example, such associations are shown by mortality studies in Los Angeles, CA; Birmingham, AL; St. Louis, MO; Toronto, Canada;

Santiago, Chile; Athens, Greece; and London, England. Further, most hospital admissions studies show associations with same day concentrations. In any case, a 24-hour standard can effectively protect against episodes lasting for several days while also protecting sensitive individuals who may experience effects after a single day of exposure. Thus, the staff concludes that the complexity in adopting a multiple day averaging time, e.g. 3 to 5 days, would not provide more effective protection than a 24-hour average.

The staff has also considered the evidence regarding effects associated with PM exposures of durations less than 24 hours. Some investigators prior to the 1987 review (Lawther et al., 1970) speculated that the observed health effects might be largely due to short-term peaks on the order of an hour. Controlled human and animal exposures to specific components of fine particles, such as acid aerosols, also suggest that some effects, such as bronchoconstriction, can occur after exposures of minutes to hours. Some epidemiological studies of exposures to acid aerosols have also found changes in respiratory symptoms in children using averaging times less than a 24-hour period (e.g., 12 hours). However, the majority of effects have been associated with daily or longer exposure to PM. Moreover, limitations in current mass monitoring devices make shorter durations less practical at present. A 24-hour average can be expected to provide significant protection from potential effects associated with short duration peaks in most urban atmospheres. Thus, although some study results may be suggestive of short duration effects, the staff does not believe that the reported results provide a satisfactory quantitative basis for setting a general particle standard with an averaging time of less than 24 hours. The staff believes that additional research is needed to examine short duration exposures.

The staff recommends that consideration be given to retaining the current 24-hour averaging time as a means of controlling short-term ambient $PM_{2.5}$ concentrations, especially peak concentrations, and thus providing protection from health effects associated with short-term (from less than 1-day to up to 5-day) exposures to $PM_{2.5}$.

b. <u>Long-term $PM_{2.5}$ Standard</u>

As summarized in Chapter V, community epidemiological studies have reported associations of annual concentrations of $PM_{2.5}$, sulfates, PM_{10}, and TSP with an array of health

effects, notably increased mortality (Dockery et al., 1993, Pope et al., 1995), respiratory symptoms and illness (e.g., bronchitis and cough in children), and reduced lung function. The relative risks associated with such exposures, although highly uncertain, appear to be larger than those associated with short-term exposures. Based on the available epidemiology and consideration of relevant toxicologic and dosimetric information, staff concludes that significant, and potentially independent, health consequences are associated with long-term PM exposures (CD, p 13-34)[6].

The staff notes that some health endpoints may better reflect the cumulative effects of PM exposures over a number of years (CD, p. 1-13). In such cases, an expected annual average standard would provide effective protection against long-term exposures to PM that exceed several years. Requiring a much longer averaging time would complicate and unnecessarily delay control strategies and attainment decisions.

In addition, an annual standard would have the effect of controlling air quality across the entire yearly distribution of 24-hour $PM_{2.5}$ concentrations to varying degrees, although such a standard would not as effectively limit peak 24-hour concentrations as would a 24-hour standard. Thus, an annual standard could also provide protection from health effects associated with short-term exposures to $PM_{2.5}$.

Based on the above considerations, the staff recommends consideration be given to retaining an annual averaging time as a means of controlling both long- and short-term ambient $PM_{2.5}$ concentrations, and thus providing protection from health effects associated with both long- and short-term exposures to $PM_{2.5}$.

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[6]The seasonality of wintertime smoke and summertime regional acid sulfate and ozone suggest that an intermediate averaging time might also be appropriate in future reviews. Annual effects associated with acids, such as those observed by Dockery et al (1996) and Raizenne et al (1996) might be interpreted as the result of repeated seasonally high exposures.

2. Form -- General Approaches

a. 24-Hour $PM_{2.5}$ Standard

As part of the last review, the 24-hour standard was changed from a deterministic form, in which the standard was not to be exceeded more than once per year, to a statistical form. The statistical form selected permits no more than one expected-exceedance, averaged over 3 years. The basis for this change in the form of the standard was that a statistical form can offer a more stable target for control programs and, with reasonably complete data, is less sensitive to truly unusual meteorological conditions than the deterministic form (U.S. EPA, 1982b). The staff continues to believe that this rationale is sound, but could be extended to consider alternatives that have been developed in conjunction with the ongoing review of the ozone standard. These general approaches to defining the form of a 24-hour standard include multiple exceedances and concentration percentile forms, as discussed more specifically in the next section in conjunction with the level of alternative standards.

One additional approach that is also being considered for the ozone standard is some form of averaging across multiple monitors. In a previous review of the PM NAAQS, staff recommended consideration of a multiple monitor spatial average form in its earlier recommendations for a secondary fine particle standard (EPA, 1982b). Such a form would better focus risk management activities on reductions in area or regionwide fine particle concentrations. Because the health effects information (as well as the risk assessment in Chapter VI) is keyed to fluctuations in areawide fine particle concentrations, such a form would also be more directly related to reduction in population risk. Such an approach would not have to require multiple monitors in all areas, assuming location criteria specified sites representative of areawide population exposures. If such an approach were adopted, consideration should be given to the extent to which peak localized exposures might result in unacceptable individual risk. Limits on localized peak exposures might be provided through the 24-hour PM_{10} NAAQS, if retained, which is applied at each monitor individually. Appropriately located PM_{10} monitors would likely limit not only coarse fraction particle levels but also fine particle levels that result from highly localized emission sources.

b. Annual $PM_{2.5}$ Standard

As part of the last review, the annual standard was changed from a geometric mean to an expected arithmetic mean of the daily measurements. This change in the form of the standard was based on an arithmetic mean being 1) more directly related to dose, which is associated with observed health effects, 2) more sensitive to repeated short-term peaks, and 3) more consistent with other annual NAAQS (U.S. EPA, 1982b). The staff continues to believe that this rationale is sound and, thus, recommends that an expected arithmetic average form be adopted for an annual $PM_{2.5}$ standard. Further, as discussed above for a 24-hour standard, staff recommends consideration be given to adopting a spatial averaging approach for an annual $PM_{2.5}$ standard.

3. Level and Specific Forms

In developing an approach to formulating recommendations on appropriate ranges of levels and specific forms for 24-hour and annual $PM_{2.5}$ standards, staff has taken into account the following considerations:

1) Recent new epidemiological studies are noteworthy in their scope and efforts to account for potential confounding and other uncertainties (e.g., characterization of exposure). However, each individual study has inherent and methodological limitations and interpretation of these findings is the subject of ongoing debate within the scientific community. Thus, the staff views its assessment of each individual study in the context of the overall body of epidemiological evidence (with mechanistic support from toxicological and dosimetry studies) and the consistency and coherence of results across studies and effects.

2) As noted in the last review, it continues to be the case that even the best epidemiological studies have inherent limitations. Further, the available studies do not provide clear evidence of population thresholds of response. Thus, the staff recognizes that attempting to identify “lowest observed effects levels” and adding margins of safety below such levels is not an appropriate approach in this case. Instead, the staff has attempted to assess the nature of health effects and risks, and the associated uncertainties, along a continuum of exposures using the full range of available health

and exposure data from studies identified in the CD as being appropriate for quantitative assessments.

3) Relative to other single pollutants for which NAAQS have been set, establishing appropriate ranges of levels for $PM_{2.5}$ standards involves unusually large uncertainties. While recent studies help to reduce the uncertainties that were present in the last review, they do not change this basic observation relative to other NAAQS. To better address these uncertainties over time, the staff believes that research should continue into the more difficult problem of identifying and assessing potential health effects that may be associated with specific chemical and physical characteristics within the fine and coarse fractions of thoracic particles. However, even without any additional chemical-specific evidence, the staff believes that the large uncertainties inherent in setting $PM_{2.5}$ standards do not preclude our identifying appropriate ranges of policy alternatives from which specific standards can be selected to effectively and efficiently protect public health with an adequate margin of safety.

Taking these considerations into account, the staff's approach to formulating recommendations on appropriate ranges of standard levels and forms for the recommended $PM_{2.5}$ indicator and averaging times is based on: 1) quantitative results from studies showing statistically significant associations between ambient concentrations of fine fraction particles and health effects; 2) information on U.S. air quality distributions and estimated background levels of $PM_{2.5}$; 3) examinations of the quantitative concentration-response relationships suggested by specific epidemiological studies identified in the CD as appropriate for quantitative assessment purposes; 4) quantitative risk analyses that provide estimates of risk associated with air quality under "as is" conditions and attainment of current and alternative new $PM_{2.5}$ standards; and 5) quantitative and qualitative consideration of the sensitivity of the risk estimates to key assumptions and inherent uncertainties in these analyses that affect the margins of safety associated with ranges of standard levels. This approach recognizes that final decisions about appropriate PM standard levels and forms must draw not only on scientific information about health effects and risks, but also on policy judgments about avoiding unacceptable risk from a public health perspective, addressing the uncertainties

inherent in the evidence and assessments, and establishing health protective standards that serve as a meaningful guide to action in developing strategies to reduce unacceptable health risks associated with anthropogenic contributions to ambient $PM_{2.5}$ levels.

These staff assessments and considerations are discussed below for both 24-hour and annual $PM_{2.5}$ standards. The following discussions are based on information in the CD and in Chapters IV, V, and VI, and associated appendices, of this Staff Paper.

a. 24-Hour $PM_{2.5}$ Standard

Several key observations discussed below frame the staff's thinking in defining a range of 24-hour $PM_{2.5}$ levels and specific forms for the Administrator to consider in selecting an appropriate standard that protects public health with an adequate margin of safety from adverse health effects associated with ambient levels of $PM_{2.5}$.

- Staff notes, based on consideration of the body of evidence as a whole as discussed throughout this Staff Paper, that $PM_{2.5}$ concentrations occurring in areas that attain the current PM_{10} standards are likely to be associated with increased risks of mortality, hospital admissions, and respiratory symptoms in various sensitive subgroups.

As a result, staff concludes that an appropriate range of 24-hour $PM_{2.5}$ levels should result in reductions in health risks relative to the risks associated with the current PM_{10} standards. Results estimated for the highest 24-hour $PM_{2.5}$ level considered in the quantitative risk assessment done for two example cities, 65 $\mu g/m^3$, suggest that this level would result in some reductions in risks relative to the current standard, with the amount of reductions likely to vary from city to city.

As would be expected from these risk results, a $PM_{2.5}$ level of 65 $\mu g/m^3$ is below the $PM_{2.5}$ level that corresponds, based on a national average ratio, to the current PM_{10} standard level of 150 $\mu g/m^3$ (i.e., a $PM_{2.5}$ level of approximately 75 $\mu g/m^3$). Staff notes that the use of a national average ratio does not take into account the highly regional nature of the ratio between $PM_{2.5}$ and PM_{10}. In some Eastern areas, a $PM_{2.5}$ level as high as about 100 $\mu g/m^3$ could correspond to the current 24-hour PM_{10} standard level, whereas in some Western areas the corresponding $PM_{2.5}$ level could be as low as about 50 $\mu g/m^3$. Thus, there is no "equivalent" level that applies nationally based on information on ratios between $PM_{2.5}$ and

PM_{10}. Alternatively, "equivalence" with the current NAAQS could be considered on the basis of determining the $PM_{2.5}$ standard level that would result in approximately the same number of counties that would not be in attainment. Consistent with the information provided in Table VII-1 for alternative PM_{10} standards, Table VII-2 presents the predicted total and regional distribution of the percentage of counties that would not attain the listed alternative $PM_{2.5}$ standards defined in terms of the current forms.[7] By comparison with Table VII-1, it can be seen that, based on the 1991-1993 PM_{10} data used to develop the two tables, a $PM_{2.5}$ level of greater than 75 µg/m^3 but well less than 100 µg/m^3 is predicted to result in approximately the same number of nonattainment counties as for the current 24-hour and annual NAAQS combined.

Based on the above discussion, although there is no clear point at which "equivalence" with the current NAAQS would be achieved, in staff's judgment consideration should be given to a $PM_{2.5}$ standard set below a level reflecting any type of approximate equivalence with the current NAAQS. Thus, staff recommends consideration be given to bounding the upper end of the range below 75 µg/m^3, at approximately 65 µg/m^3.

- Epidemiological studies reporting statistically significant associations were conducted in areas in which the mean 24-hour $PM_{2.5}$ concentrations ranged from approximately 16 to 30 µg/m^3 for mortality studies, with hospital admissions and respiratory symptoms studies falling within this range (Table VI-2).

Staff notes that these concentrations are relevant to considering a range of a standard, in that these studies are generally interpreted as providing risk estimates for which there is greatest confidence around the mean of the air quality data. However, as discussed in section V.E, there are significant uncertainties in any given study due to model specification, exposure misclassification, confounding, and other issues. Thus, staff believes that no one $PM_{2.5}$

[7] The predicted comparison of counties not meeting alternative $PM_{2.5}$ standards in Table VII-2 is derived from an analysis that estimates $PM_{2.5}$ air quality from the much larger PM_{10} data base in AIRS (Fitz-Simons et al., 1996). As such, these estimates are highly uncertain and are presented here for rough comparative purposes only.

TABLE VII-2. PREDICTED PERCENTAGE OF COUNTIES NOT MEETING ALTERNATIVE $PM_{2.5}$ STANDARDS*

	Level of Alternative Standards**	All	SW	NW	CE	SE	NE
County Total		482	60	80	68	99	175
Annual	25	2.5	5.0	3.8	4.4	0	1.7
	20	8.7	15	8.8	15	4.0	6.9
	15	36	27	28	48	26	43
	10	84	52	65	93	95	94
24-hr	100	6.8	13	24	4.4	1.0	1.1
	75	15	28	41	15	2.0	6.3
	65	23	38	59	21	8.1	10
	50	42	58	78	35	38	25
	25	98	97	98	96	100	98
Combined Standards	25/75	15	28	41	16	2.0	6.3
	20/65	24	38	59	24	10	11
	15/50	56.	58	78	56	50	50

* These estimates are based on a methodology that uses the PM_{10} data in AIRS, together with more limited information on $PM_{2.5}/PM_{10}$ relationships, to predict which monitors might exceed a given $PM_{2.5}$ alternative standard. Such estimates are highly uncertain and should be interpreted with caution. More speifically, the estimates are based on 1991-1993 data, using a 50% data completeness criteria, and applying the Appendix K missing data adjustment to account for less than every day sampling frequenciew. See staff analyses (Fitz-Simons et al., 1996) which discusses methodology for calculating estimated $PM_{2.5}$ values.

** Based on current 1-expected-exceedance form of the 24-hour PM_{10} NAAQS and current expected annual average of annual PM_{10} NAAQS, at the highest monitor for each standard.

concentration derived from any particular study should appropriately serve as the basis for the level of a standard.

- Results from the quantitative risk assessment presented in section VI.C suggest a pattern of a continuum of decreasing risk with lower levels of alternative $PM_{2.5}$ standards, extending over and likely below the range of 65 to 25 µg/m^3 $PM_{2.5}$ included in the risk analyses.

Based on the limited risk analyses for two example cities, using base case assumptions, a 24-hour $PM_{2.5}$ standard of 25 µg/m^3 is estimated to reduce PM-related risks associated with short-term exposures for the effects considered by roughly 70% - 85%, relative to risks associated with attaining the current standards. Alternatively, at a 24-hour $PM_{2.5}$ level of 65 µg/m^3, risks are estimated to be reduced by roughly 10% and 40% for the Philadelphia and Los Angeles study areas, respectively. Putting these risk estimates into a broader perspective, these PM-related risk reductions translate into much smaller reductions relative to the total incidence of such effects from any cause. Relative to total incidence, a $PM_{2.5}$ standard of 25 µg/m^3 may reduce total mortality risk by roughly 1% to 2%, total hospital admissions by roughly 1% to 5%, and respiratory symptoms in children by roughly 15% - 25%. Alternatively, at a level of 65 µg/m^3, total mortality risk may be reduced by roughly 1% or less, total hospital admissions by roughly 2% to less than 1%, and respiratory symptoms in children by roughly 2% to 13%.

In terms of total incidence of effects upon attainment of alternative $PM_{2.5}$ standards, mortality incidence associated with short-term PM exposures is estimated to range from roughly 300 to 400 events per year for the Philadelphia (population 1.6 million) and Los Angeles (population 3.6 million) study areas, respectively, with a $PM_{2.5}$ standard of 65 µg/m^3. At a level of 25 µg/m^3, mortality incidence is estimated to be roughly on the order of 100 events per year in each study area. Estimated incidences of hospital admissions for respiratory and cardiac causes are up to 70% greater than those of mortality events. Respiratory symptom incidence is judged to be considerably more uncertain than estimates for the other effects, with roughly 10 to over 20 thousand events per year in the Philadelphia and Los Angeles study areas, respectively, at a level of 65 µg/m^3, and from roughly 3 to 6 thousand events per year,

respectively, at a level of 25 µg/m^3. Thus, under base case assumptions, rough estimates of incidences are appreciably lower, but not eliminated in going from a $PM_{2.5}$ standard of 65 to 25 µg/m^3.

Staff emphasizes that these estimates are based on only two cities, include significant uncertainties, and are sensitive to a number of assumptions that have been considered in the integrated uncertainty analyses discussed in Chapter VI. Thus, policy judgments that are based in part on a consideration of such results should also take into account these uncertainties, critical assumptions, and the public health implications of the estimated incidence rates.

- Sensitivity analyses designed to address alternative assumptions in the risk analyses presented in section VI.C. suggest that estimated risks are sensitive to a number of assumptions, including in particular assumptions about the shape of concentration-response relationships and the ranges of air quality to which they are applied. The examination of concentration-response relationships that helped to frame the sensitivity and integrated uncertainty analyses provides information useful in identifying an appropriate $PM_{2.5}$ range for consideration.

For several alternative assumptions examined in the sensitivity and integrated uncertainty analyses, relatively small to moderately large differences in estimated risks were predicted across the range of alternative assumptions considered. In examining relevant concentration-response relationships using a variety of approaches, staff identified alternative cutpoints for the lower end of the range of air quality over which it may be appropriate to calculate increased risk from the studies. From the short-term $PM_{2.5}$ studies, staff identified concentrations of 10, 18, and 30 µg/m^3 as potential cutpoints reflecting increased uncertainties in this lower range of observed concentrations and inherent limitations in the data to detect any potential effects thresholds that may be present within that range. Relative to base case risk estimates, which do not assume any effects threshold or cutpoint within the range of the data, mortality risks estimated from the integrated uncertainty analysis are lower by as much as a factor of 2 across the range of alternative assumptions considered. Thus, alternative assumptions, most notably about the shape of the concentration-response relationship, can have

significant impacts in lowering the estimated total PM-related risk for "as is" air quality as well as for attainment of the current NAAQS and alternative $PM_{2.5}$ standard cases.

- Several epidemiological studies reporting statistically significant effects include ranges of air quality that may approach estimates of background levels in some locations.

To serve as a meaningful guide to action in developing strategies to reduce unacceptable health risks associated with anthropogenic contributions to ambient $PM_{2.5}$ levels, staff believes that a standard should be set at a level sufficiently above estimated background levels. As discussed in Chapter IV, while estimated annual average $PM_{2.5}$ background levels range from approximately 2 to 5 $\mu g/m^3$ in the East and 1 to 4 $\mu g/m^3$ in the West, maximum annual 24-hour fine particle concentrations of 15 to 20 $\mu g/m^3$ are possible from background sources particularly in Eastern areas. Further, staff notes that on a daily basis exceptional natural events such as forest fires can result in even higher background concentrations, but such excursions are dealt with through the natural events policy in implementing the standards.

In taking into account the above observations, staff believes that the lower end of a range of $PM_{2.5}$ levels for the Administrator to consider in selecting an appropriate standard level should be less than 25 $\mu g/m^3$ but greater than 15 to 20 $\mu g/m^3$. While at 25 $\mu g/m^3$ significant reductions in risk may result, mortality studies show significant associations even when the observed means of 24-hour $PM_{2.5}$ concentrations in each of the study locations are approximately at or below 20 $\mu g/m^3$. Further, an assessment of concentration-response relationships below these levels suggested consideration of possible thresholds at concentrations of 18 and 10 $\mu g/m^3$. On the other hand, staff believes an appropriate standard should be sufficiently above estimated background levels so as to meaningfully facilitate the design and implementation of realistic air quality management strategies. Further, staff is mindful that the Act does not require that NAAQS be set at a zero-risk level, but rather at a level that avoids unacceptable risks and, thus, protects public health with an adequate margin of safety.

- With regard to specific alternative forms of 24-hour $PM_{2.5}$ standards, staff analyses of predicted $PM_{2.5}$ concentrations provide an illustrative comparison of the impact in terms of the number of counties that would not attain alternative forms for an example standard level (Table VII-3).

Table VII-3 compares the predicted impact of alternative exceedance-based forms (ranging from 1 to 5 exceedances per year) and concentration percentile forms (including the average n^{th} concentration percentile, with n ranging from the 95th to the 99th percentile) for an example 24-hour $PM_{2.5}$ standard level held constant at 50 µg/m^3 (in conjunction with an annual $PM_{2.5}$ standard set at 15 µg/m^3).[8] As can be seen from the table, the form of the standard can result in significant differences in the number of areas that would not attain a given standard, such that the degree of health protection provided by a standard is a function of both the level and form of the standard.

TABLE VII-3. PREDICTED COMPARISON OF ALTERNATIVE FORMS FOR A 24-HOUR $PM_{2.5}$ STANDARD
(For counties meeting a 15 µg/m^3 annual $PM_{2.5}$ standard)

Alternative Forms of Standard	Number of Counties Projected to Meet 24-hour Standard of 50 g/m³	Number of Counties Not Projected to Meet 24-hour Standard of 50 g/m³
1 Exceedance	210	99
2 Exceedance	229	80
3 Exceedance	268	41
4 Exceedance	274	35
5 Exceedance	280	29
Avg 99th percentile	277	32
Avg 98th percentile	292	17
Avg 95th percentile	303	6

[8] As for Table VII-2, these staff estimates are based on predicting $PM_{2.5}$ concentrations based on the available PM_{10} data base, and are highly uncertain. See staff analyses in Fitz-Simons et al. (1996).

NOTE: Of the 482 counties with at least 50% data completeness per quarter 1991-93, 309 meet the PM2.5 annual standard, and 173 do not. Exceedance forms include the Appendix K missing data adjustment to account for less than every day sampling frequencies. See staff analyses in Fitz-Simons et al. (1996).

In weighing all these factors and considerations outlined above, staff offers the following conclusions and recommendations:

1) The lower end of the range of consideration for a new 24-hour $PM_{2.5}$ standard should be 20 µg/m^3. Considering a standard at this level would place significant weight on the consistency and coherence of the body of evidence as a whole, and on the results of quantitative analyses of concentration-response information and risks, even in light of inherent uncertainties in the analyses and alternative interpretations possible for each study considered independently. The staff believes that a 24-hour $PM_{2.5}$ standard set at this level, while not likely to be risk-free, would be precautionary in nature in protecting against a full range of short-term effects associated with the identified sensitive subgroups of the population. A standard set at this level would give less weight to concerns that the relied-upon studies may not have completely controlled for all potential confounding variables nor fully accounted for all limitations in the exposure data. Staff notes that this level is at the upper end of the range of uncertainty for peak 24-hour $PM_{2.5}$ background concentrations.

2) The upper end of the range of consideration for a new 24-hour $PM_{2.5}$ standard should be approximately 65 µg/m^3. A standard set at or near this level would give significant weight to both the qualitative and quantitative uncertainties inherent in the most recent epidemiological studies, and, conversely, little weight to the quantitative assessments of the evidence and associated risks. Such a standard would likely provide increased protection relative to the current standard.

3) In selecting a level for a 24-hour $PM_{2.5}$ standard within this range, the staff suggests that the Administrator also take into account the degree and nature of protection that would be afforded by a new annual $PM_{2.5}$ standard. The joint protection provided by a suite of standards that includes both 24-hour and annual $PM_{2.5}$ standards may be an

important consideration in selecting the levels for each standard. One possible policy approach would be to view an annual $PM_{2.5}$ standard, as discussed below, as serving as the target for control programs designed to effectively lower the entire distribution of $PM_{2.5}$ concentrations, thus protecting not only against long-term effects but also short-term effects as well. With this approach, the 24-hour $PM_{2.5}$ standard could be set so as to protect against the occurrence of peak 24-hour concentrations that would likely not be controlled in areas attaining a new annual $PM_{2.5}$ standard. Thus, in conjunction with an annual $PM_{2.5}$ standard, the Administrator may judge that the 24-hour standard should be set so as to limit only those peak 24-hour concentrations that are likely to persist upon attainment of the annual standard.

4) In selecting a form for a 24-hour $PM_{2.5}$ standard within the range of alternative forms analyzed, the staff suggests that the Administrator give primary consideration to a concentration percentile form. Concentration percentile forms are more stable and better take into account differences in sampling frequencies than the single (i.e., the current form) and multiple exceedance forms. Further, consideration should be given to the relative health protection provided by alternative forms at a given level, considering the relative impact of alternative forms on the number of counties affected by a particular form, and, thus, the number of areas likely to experience reduced risks to public health as a result of attaining a given standard level and form.

b. <u>Annual $PM_{2.5}$ Standard</u>

Similar to the approach outlined above for a 24-hour standard, the following observations frame the staff's thinking in defining a range of annual $PM_{2.5}$ levels:

- Staff notes that annual $PM_{2.5}$ concentrations occurring in some areas that attain the current PM_{10} standards are likely to be associated with increased risk of mortality beyond that associated with short-term mortality effects, as well as possibly increases in doctor-diagnosed cases of acute bronchitis in children.

- Further, as discussed above in the section on averaging times, an annual standard would have the effect of controlling air quality across the entire yearly distribution of 24-hour $PM_{2.5}$ concentrations to varying degrees, such that an annual standard set an appropriate level could also provide protection from health effects associated with short-term exposures to $PM_{2.5}$.

Based on the above considerations, the staff recommends consideration be given to use of an annual averaging time as a means of controlling both long- and short-term ambient $PM_{2.5}$ concentrations, and thus providing protection from health effects associated with both long- and short-term exposures to $PM_{2.5}$.

By comparing information in Tables VII-1 and VII-2, it can be seen that for the 1991-1993 data presented in the two tables, an annual $PM_{2.5}$ level of 25 µg/m^3 is estimated to result in approximately the same number of nonattainment counties as the current PM_{10} NAAQS. In staff's judgment consideration should be given to an annual $PM_{2.5}$ standard set below a level reflecting approximate equivalence with the current annual NAAQS. Thus, staff recommends consideration be given to bounding the upper end of the range below 25 µg/m^3, at approximately 20 µg/m^3.

Alternatively, in viewing an annual standard as creating a target for control programs designed to effectively lower the entire distribution of $PM_{2.5}$ concentrations, staff concludes that an appropriate range of annual $PM_{2.5}$ levels for such a standard should result in reductions in health risks relative to the risks associated with the combination of current 24-hour and annual PM_{10} standards. Under this approach, a comparison of Tables VII-1 and VII-2 suggests that an annual $PM_{2.5}$ standard level of less than 20 µg/m^3 would be needed to result in the same number of predicted nonattainment counties as for the combination of current 24-hour and annual PM_{10} NAAQS.

- Based on the long-term mortality study used in the quantitative risk assessment (Pope et al., 1995), a statistically significant association was observed across 151 cities in which the annual $PM_{2.5}$ concentrations ranged from approximately 9 to 34 µg/m^3 (Table VI-2); a somewhat similar range is estimated from the long-term studies of lung function decrements and doctor-diagnosed bronchitis in children (Table V-13).

Staff notes that these concentrations are relevant to considering a range for an annual standard, although, as discussed in Chapter VI and Appendix E, staff recognizes that uncertainty in the concentration-response relationships increase at the lower end of the range of data due in part to inherent limitations in discerning any potential effects threshold that may actually be present. In examining the concentration-response relationships for long-term mortality from the Pope et al. (1995) study, as well as from the more uncertain Dockery et al.

(1993) study, possible concentration cutpoints at which effects threshold may potentially exist were identified (Chapter VI and Appendix E). The lowest such cutpoint was 12.5 μg/m^3, based on inherent limitations of the data for discerning effects thresholds, and a cutpoint of 15 μg/m^3 was identified based on visual inspection of the data. The minimum mean concentrations in these two studies were 18 μg/m^3.

- The body of evidence from long-term exposure studies, together with results from the quantitative risk assessment presented in section VI.C, suggests a pattern of a continuum of decreasing risk with lower levels of alternative annual $PM_{2.5}$ standards, likely extending below the range of concentrations included in the analyses, 15 and 20 μg/m^3 $PM_{2.5}$ annual average.

Based on these limited analyses for two example cities, and applying only base case assumptions, the analyses estimate that an annual $PM_{2.5}$ standard of 15 μg/m^3 may reduce PM-related risks for mortality associated with long-term exposures by roughly 30 and 60% relative to risks associated with attaining the current NAAQS for Philadelphia and Los Angeles study areas, respectively. Alternatively, at a $PM_{2.5}$ level of 20 μg/m^3, reduction in risks associated with long-term exposure in Los Angeles county are estimated at 30%; staff notes that this level does not result in any estimated risk reduction in Philadelphia county because the current annual mean in Philadelphia is below this level. Putting these risk estimates into a broader perspective, these PM-related risk reductions translate into much smaller reductions relative to the total incidence of such effects from any cause. Relative to total incidence, an annual $PM_{2.5}$ standard of 15 μg/m^3 may reduce total mortality risk associated with long-term exposures by roughly 1and 5% for the Philadelphia and Los Angeles study areas, respectively. Alternatively, at a level of 20 μg/m^3, total mortality risk for Los Angeles county may be reduced by roughly 2%.

In terms of total incidence of effects upon attainment of alternative annual $PM_{2.5}$ standards, mortality incidence associated with long-term exposures to PM is estimated to range from roughly less than 1000 to about 1500 events per year for the Philadelphia and Los Angeles study areas, respectively, with an annual $PM_{2.5}$ standard of 20 μg/m^3, to roughly on the order of half as many events per year for each study location at a level of 15 μg/m^3. Thus,

under base case assumptions, rough estimates of incidences are appreciably lower, but not eliminated, in going from an annual $PM_{2.5}$ standard of 20 to 15 µg/m^3.

Staff again emphasizes that these estimates are based on only two cities, include significant uncertainties, and are sensitive to a number of assumptions that can not be fully addressed by additional analysis of available data. Thus, policy judgments that are based in part on a consideration of such results should also take into account these uncertainties, inherent limitations in available data and analyses, and the public health implications of the estimated incidence rates.

- Sensitivity analyses designed to address alternative assumptions in the risk analyses presented in section VI.C. suggest that estimated long-term risks are sensitive to a number of assumptions, including in particular assumptions about the shape of concentration-response relationships and the ranges of air quality to which they are applied and historical air quality information used in the analysis. The examination of concentration-response relationships and historical air quality that helped to frame these particular sensitivity analyses provides information useful in identifying an appropriate $PM_{2.5}$ range for consideration.

Based on an analysis of long-term mortality using the alternative cutpoints discussed in Chapter VI, staff notes that estimated risk for Philadelphia County is roughly 50% lower than the base case estimate if a 12.5 µg/m^3 cutpoint is applied. Similarly, applying a cutpoint of 15 µg/m^3 reduces estimated long-term mortality risk by over 75%, while applying a cutpoint of 18 µg/m^3 results in an estimate of no long-term mortality risk for “as is” air quality in Philadelphia County. Further, by assuming higher historical $PM_{2.5}$ concentrations than were reported in the Pope et al. (1995) study, estimated risk would be significantly lower than the base case estimate (Appendix F). Thus, alternative assumptions about the shape of the long-term PM concentration-response relationships and historical air quality can have very significant impacts on the estimated risk reductions associated with attaining alternative $PM_{2.5}$ standards.

In taking into account the above observations, staff believes that the lower end of a range of $PM_{2.5}$ levels for the Administrator to consider in selecting an appropriate annual standard level should be consistent with the lowest cutpoint for a possible threshold derived from an examination of the long-term mortality concentration-response relationships, 12.5

$\mu g/m^3$. Staff believes that such an annual level is sufficiently above estimated annual $PM_{2.5}$ background levels as to serve as a meaningful standard to facilitate the design and implementation of realistic air quality management strategies. Further, as noted above, staff is mindful that the Act does not require that NAAQS be set at a zero-risk level, but rather at a level that avoids unacceptable risks and, thus, protects public health with an adequate margin of safety.

In weighing all these factors and considerations outlined above, staff offers the following conclusions and recommendations:

1) The lower end of the range of consideration for a new annual $PM_{2.5}$ standard should be 12.5 $\mu g/m^3$. Considering a standard at this level would place significant weight on the consistency and coherence of the body of evidence as a whole, and on the results of quantitative analyses of concentration-response information and risks, even in light of inherent uncertainties in the analyses and alternative interpretations possible for the relevant studies. The staff believes that an annual $PM_{2.5}$ standard set at this level, while not likely to be risk-free, would be precautionary in nature in protecting against long-term mortality effects and other long-term morbidity effects such as lung function decrements and doctor-diagnosed bronchitis in children. A standard set at this level would give less weight to concerns that the relied-upon studies may not have completely controlled for all potential confounding variables nor fully accounted for all limitations in the exposure data.

2) The upper end of the range of consideration for a new annual $PM_{2.5}$ standard should be 20 $\mu g/m^3$. A standard set at or near this level would give significant weight to both the qualitative and quantitative uncertainties inherent in the long-term epidemiological studies, and, conversely, little weight to the quantitative assessments of the evidence and associated risks. Such a standard would likely provide some increased protection relative to the current annual standard.

3) As discussed above, in selecting a level for an annual $PM_{2.5}$ standard within this range, in conjunction with a 24-hour $PM_{2.5}$ standard, staff suggests that the Administrator take into account the joint protection likely to be afforded by both standards. In an

approach that viewed the annual $PM_{2.5}$ standard as the primary target for control programs designed to effectively lower the entire distribution of $PM_{2.5}$ concentrations, the Administrator may choose to consider an annual standard from the lower end of this range. Correspondingly a 24-hour $PM_{2.5}$ standard could be set so as to protect against the occurrence of peak 24-hour concentrations that would likely not be controlled by areas attaining a new annual $PM_{2.5}$ standard. For example, an annual $PM_{2.5}$ standard at 15 $\mu g/m^3$ may be expected to result in substantially reduced 24-hour levels, potentially limiting the second highest 24-hour levels to less than about 50 $\mu g/m^3$ in approximately 90% of the areas, thus adding to the protection against short-term effects afforded by a 24-hour standard (SAI, 1996).

D. <u>Alternative PM_{10} Standards for Control of Coarse Fraction Particles</u>

1. Averaging Time

If fine particle standards are adopted, the major function of the PM_{10} standard would be to protect against the known and anticipated effects associated with coarse fraction particles in the size range of 2.5 to 10 µm. As noted above, coarse fraction particles are plausibly associated with certain effects from both long and short-term exposures. Some epidemiologic evidence suggests increased asthma and upper respiratory infections may be associated with daily increases in PM_{10} that was dominated by coarse fraction particles (Gordian et al, 1996), while another study suggests smaller relative risks of bronchitis symptoms after daily episodes of very high fugitive dust (Hefflin et al, 1994). Both studies reported multiple exceedences of the current 24-hour NAAQS with PM_{10} peaks exceeding 900 $\mu g/m^3$. The potential build up of insoluble coarse fraction particles in the lung after long-term exposures to high levels should also be considered.

These studies show an important characteristic of significant coarse particle events. In a number of Western areas, multiple exceedences occur in relation to high winds increasing emissions from naturally occurring or human-disturbed surfaces. In the Gordian et al. (1996) study, the worst levels occurred in relation to a volcanic eruption. In a number of cases, such excursions are exempted from control by the natural events policy. In some areas, variations in annual rainfall or windspeed cause year-to-year changes in dust emissions, making

implementation and assessment of control strategies more difficult. It is therefore appropriate to consider which combination of averaging time and form might provide a more robust target for practical coarse particle controls. In this regard, basing control on an annual standard alone or in combination with a 24-hour standard with multiple exceedences may provide adequate protection from potential long- and short-term effects of coarse fraction particles.

2. Level and form for alternative averaging times

a. Annual PM_{10} Standard

The nature of the more limited information for coarse fraction particles means the approach for selecting a level of the standard should be less like the recommended approach for fine particles, and more related to the approach taken in the last review for PM_{10}. In that approach, evidence from limited quantitative studies was used to select a range, with support from the qualitative literature used to support decisions within the range (EPA, 1982b, 1986).

The major quantitative basis for the level of the current annual PM_{10} standard was a study of children by Ware et al. (1986), conducted as part of the Harvard Six City series. This study has been supplemented in the recent literature by a follow-up long-term cohort study of acute bronchitis in children (Dockery et al., 1989). This study found somewhat better associations with PM_{15} than with $PM_{2.5}$ over the entire cohort, but a direct comparison with coarse fraction particles was not presented. However, still more recent studies found bronchitis symptoms in a larger cross sectional comparison to be unrelated to somewhat lower coarse particle concentrations than found in some of the six cities (Dockery et al, 1996). It is possible, but not conclusive, that coarse fraction particles, in combination with fine particles, may have influenced the observed effects, at least at the levels in the three most polluted cities in the study. From an exposure/deposition perspective, it is possible that cumulative deposition of coarse fraction particles could be elevated in children, who are more prone to be active outdoors than sensitive adult populations. Based on the original study by Ware et al. (1986), in the last review, staff recommended consideration that the lower bound of the range for the annual standard be set at 40 $\mu g/m^3$ (EPA, 1986).

Qualitative evidence of other long-term coarse particle effects, most notably from long-term buildup of silica containing materials, supports the need for a long-term standard, but does not provide evidence of effects below this range (CD, p 13-79). Staff concludes that the qualitative evidence with respect to biological aerosols (13-79) also supports the need to limit coarse materials, but should not form the major basis for a national standard. The nature and distribution of such materials, which vary from endemic fungi (e.g. valley fever) to pollens larger than 10 µm are not appropriately addressed by traditional air pollution control programs.

A PM_{10} standard in the range of 40 to 50 µg/m^3 (current level) would also provide substantial protection against the effects of 24-hour exposures associated with asthma and upper respiratory infections. The national mean ratio for the second highest 24-hour concentration in a year to the annual mean is 2.41 (SAI, 1996). This indicates that the mean second highest 24-hour concentrations associated with such a range (about 95 to 120 µg/m^3) would be well below the current standard. Peak levels at the worst sites could still exceed the level of the current 24-hour standard. Additional information on the relative short-term protection afforded by the current annual standard is summarized in the discussion below.

Staff recommends that consideration be given to adopting an annual PM_{10} standard in the range of 40 to 50 µg/m^3 to protect against the long- and short-term effects of coarse fraction particles. Such a standard would provide a more robust target for coarse particle controls that would be less sensitive to episodic natural events.

b. <u>24-Hour PM_{10} Standard</u>

Consideration should also be given to a 24-hour standard for coarse fraction particles as measured by PM_{10} . The level of the current 24-hour PM_{10} standard (150 µg/m^3) was based in large measure on the London mortality and morbidity studies (EPA, 1982b). As noted above, staff believes that fine particles are a better surrogate for such effects. The main quantitative basis for a short-term standard is provided by the two fugitive dust studies referenced above. Because these studies reported multiple large exceedences of the current 24-hour standard they suggest no need to lower the level of the standard below 150 µg/m^3.

If a 24-hour PM_{10} standard is retained in conjunction with a fine particle standard, consideration should be given to maintaining the current level and revising the PM_{10} standard to a more robust form. Such forms would be less sensitive to naturally occurring episodes. Staff have conducted analyses of several alternative forms for a PM_{10} standard, similar to the analyses for alternative forms for a $PM_{2.5}$ standard as discussed above. Table VII-4 compares the impact of alternative exceedance-based forms (ranging from 1 to 5 exceedances per year) and concentration percentile forms (including the average n^{th} concentration percentile, with n ranging from the 95th to the 99th percentile) for an example 24-hour PM_{10} standard level held constant at 150 $\mu g/m^3$ (in conjunction with an annual PM_{10} standard set at 50 $\mu g/m^3$). As can be seen from the table, the analysis suggests that a 50 $\mu g/m^3$ annual standard would limit 24-hour exceedences in all but nine of the sites to 5 or less (i.e., only nine sites would not attain a standard with a 5-exceedance form). Staff is examining alternative analytical approaches to provide additional insight into the relative protection afforded by these forms.

Because of the episodic nature of coarse particle excursions, the staff recommends that if a 24-hour standard is adopted, consideration should be given to one of the alternative more robust forms presented in Table VII-4, with or without an accompanying annual PM_{10} standard.

3. Summary of Coarse Fraction (PM_{10}) Standard Conclusions and Recommendations

Staff conclusions and recommendations are as follows:

1) As an indicator for coarse fraction particles, in conjunction with a $PM_{2.5}$ standard, the basis and purpose for the PM_{10} standards have been altered.

2) Staff recommends consideration of an annual PM_{10} standard in the range of 40 to 50 $\mu g/m^3$ to protect against both the short- and long-term effects of coarse fraction particles. An annual standard would provide a robust target for effective coarse particle control and monitoring strategies.

3) Consideration should also be given to a 24-hour PM_{10} standard of 150 $\mu g/m^3$ with a revised, more robust form selected from the range of alternatives presented in Table VII-4. Additional analyses of these forms are needed before more definitive recommendations can be made.

TABLE VII-4. COMPARISON OF ALTERNATIVE FORMS FOR A 24-HOUR PM_{10} STANDARD
(For counties meeting a 50 µg/m^3 annual PM_{10} standard)

Alternative Forms of Standard	Number of Counties Projected to Meet 24-hour Standard of 150 g/m³	Number of Counties Not Projected to Meet 24-hour Standard of 150 g/m³
1 Exceedance	425	46
2 Exceedance	433	38
3 Exceedance	451	20
4 Exceedance	455	16
5 Exceedance	462	9
Avg 99th percentile	455	16
Avg 98th percentile	467	4
Avg 95th percentile	471	0

NOTE: Of the 482 counties with at least 50% data completeness per quarter 1991-93, 471 meet the PM_{10} annual standard, and 11 do not. Exceedance forms include the Appendix K missing data adjustment to account for less than every day sampling frequencies. See staff analyses in Fitz-Simons et al. (1996).

E. Summary of Key Uncertainties and Research Recommendations

Staff believes it is important to emphasize the unusually large uncertainties associated with establishing standards for PM relative to other single component pollutants for which NAAQS have been set. The CD and this Staff Paper note throughout a number of unanswered questions and uncertainties that remain in the scientific evidence and analyses as well as the importance of ongoing research to address these issues. Prior to summarizing staff

recommendations on the primary PM NAAQS in the next section, this section summarizes key uncertainties and related staff research recommendations.

1) One of the most notable aspects of the available information on PM is the lack of demonstrated mechanisms that would explain the mortality and morbidity effects associated with PM at ambient levels reported in the epidemiological literature. The absence of such mechanistic information limits judgments about causality of effects and appropriate concentration-response models to apply in quantitatively estimating risks. Building on promising preliminary findings from ongoing research involving more representative animal models and particle mixes and levels, staff believes there is an urgent need to expand ongoing research on the mechanisms by which PM, alone and in combination with other air pollutants, may cause health effects at levels below the current NAAQS.

2) Uncertainties and possible biases introduced by measurement error in the outdoor monitors, including both the error in the measurements themselves and the error introduced by using central monitors to estimate population exposure, contributes to difficulties in interpreting the epidemiological evidence. To address these concerns, additional research into improved continuous sampling and analyses methods, together with the use of a research-oriented ambient monitoring network and personal monitors to better characterize relationships between personal exposure and outdoor/indoor air quality, is needed for PM components as well as for other criteria pollutants. For example, monitoring techniques that allow new epidemiological studies to address not only size fractionation and improved measurements of semi-volatile particles but also particle number and surface area will be important to isolate key components of fine and coarse fraction particles. Further, examination of potential exposure to ultrafine particles near highways and other possible sources, for example, is important to determine the extent to which these materials persist long enough to present significant exposure to sensitive population groups.

3) Inherent in epidemiological studies such as those cited in this review is the question as to whether or to what extent the observed effects attributed to PM exposures are

confounded by other pollutants commonly occurring in community air, such as SO_2, ozone, NO_2, and CO. In particular, a number of authors conducting reanalyses of mortality studies within a given city, most notably for Philadelphia, have demonstrated that it may not be possible to separate individual effects of multiple pollutants when those pollutants are highly correlated within a given area. Based on its assessment of available information regarding potential confounding within and across a number of areas with differing combinations of pollutants, as recommended in the HEI reanalysis report, the CD concludes that in general the reported PM effects associations are valid and not likely to be seriously confounded by copollutants. Nevertheless, additional research and analyses are important to better characterize the extent to which PM-related effects may be modified by the presence of other copollutants in the ambient air.

4) Although staff has concluded that it is more likely than not that fine fraction particles play a significant role in the reported health effects associations, identification of specific components and/or physical properties of fine particles which are associated with the reported effects is very important for both future reviews of the standards and in development of efficient and effective control strategies for reducing health risks. Epidemiological and toxicological research is needed to isolate key components (e.g., nitrates, sulfates, organics, metals, ultra fine particles) and/or characteristics of fine particles, as well as to identify the nature and extent of subpopulations most susceptible to the adverse effects associated with such components and/or characteristics. Such research is critical in addressing uncertainties in estimating risk reductions likely to be achieved by alternative fine particle standards and new implementation strategies.

5) Uncertainties in the shape of concentration-response relationships, most specifically whether linear or threshold models are more appropriate, significantly affects the confidence with which risks and risk reductions can be estimated. Mechanistic and epidemiological research highlighted above would likely help reduce such uncertainties.

6) Unaddressed confounders and methodological uncertainties inherent in epidemiological studies of long-term PM exposures limit interpretations and conclusions that can be drawn with regard to associations between PM and chronic health effects. Additional research

and analysis are needed to reduce the uncertainties related to the appropriate exposure periods and historical air quality to consider in evaluating such studies, and to better address life-style and other potentially important cofactors.

7) An important aspect in characterizing the nature of the mortality risk associated with short- and long-term exposures to PM, from a public health perspective, is the extent to which lifespans are being shortened. Available epidemiological evidence provides a very limited basis for testing hypotheses as to whether and to what extent lifespans are shortened by only a few days or by years. More research is needed to quantitatively characterize the degree of prematurity of deaths associated with exposures to PM.

8) The characterization of annual and daily background concentrations likely to occur across the U.S. contains significant uncertainties. Additional air quality monitoring and analyses that improve these background characterizations would help to reduce the uncertainties in estimating health risks relevant to standard setting, i.e., those risks associated with exposures to PM in excess of background levels.

9) Despite long-standing staff recommendations for a comprehensive examination of the effects associated with exposures to coarse fraction particles, there continues to be a lack of animal, clinical, and community studies in this area. Such research would potentially provide both qualitative and quantitative information that could allow for the establishment of a coarse fraction particle standard rather than continued reliance on a PM_{10} standard as the means to control exposures to coarse fraction particles.

F. Summary of Staff Recommendations on Primary PM NAAQS

The major staff recommendations and supporting conclusions from sections VII.A-D are briefly summarized below:

1) The current PM standards should be revised. As the Criteria Document concludes, current evidence provides ample reason to be concerned that there are detectable health effects attributable to PM at levels below the current NAAQS. Given the nature and potential magnitude of the public health risks involved, staff believes revision of the current standards is clearly appropriate. The health effects reported, ranging from premature mortality to various measures of morbidity, including increased hospital

admissions, aggravation of existing respiratory disease, including asthma, and decreased lung function, include effects that are clearly adverse to public health.

2) Ambient particles capable of penetrating to the thoracic region, including both the fine and coarse fractions of PM_{10} , should continue to be the focus of PM standards. Staff concludes that these thoracic particles represent the greatest risk to health, and that the previous recommendations for 10 µm as the appropriate cutpoint for such particles remain valid.

3) The fine and coarse fractions of PM_{10} should be considered as two separate pollutants based on the recent health evidence, the fundamental differences between fine and coarse fraction particles, and implementation experience with PM_{10}. The staff concludes that the available information is sufficient to support separate indicators for these separate pollutants. Further, while it is difficult to distinguish the effects of fine or coarse fraction particles from those of PM_{10} , consideration of comparisons between fine and coarse fractions suggests that fine fraction particles are a better surrogate for those particle components linked to mortality and morbidity effects at levels below the current standards. In contrast, coarse fraction particles are more likely linked with certain effects at levels above those allowed by the current PM_{10} standards. In examining alternative approaches to increasing the protection afforded by PM_{10} standards, the staff concludes that reducing the levels of the current PM_{10} standards would not provide the most effective and efficient protection from these health effects.

4) A 2.5 µm cutpoint (i.e., $PM_{2.5}$) should be used as the indicator for fine fraction particles, and the current PM_{10} indicator should now be used as the indicator for the coarse fraction particles. A $PM_{2.5}$ indicator for fine fraction particles is specifically recommended based primarily on consistency with the health effects literature and the suitability and availability of ambient monitors. The recommendation for PM_{10} as the indicator for coarse fraction particles is based on the very limited data base and monitoring capabilities directly for coarse fraction particles, as well as the applicability of the existing PM_{10} monitoring network. Further, staff concludes that use of sulfate or other chemical class indicators is not advisable on the basis of this review.

5) Staff recommends that new $PM_{2.5}$ standards be established for two averaging times.

a) Annual and 24-hour $PM_{2.5}$ standards should be established as the most appropriate standards to address health effects associated with both short-term (from less than 1 day up to 5 days) and long-term (from months to years) exposures to fine fraction particles.

b) Staff recommends consideration of more robust forms for a 24-hour standards (especially concentration percentile forms), averaged over three years. In addition, staff recommends consideration be given to using the average of multiple monitors representative of population exposure as part of the form of the annual and/or 24-hour standards. Staff also recommends the retention of the current expected arithmetic average form of the annual standard.

c) Staff recommends that the Administrator consider selecting the level of a new 24-hour $PM_{2.5}$ standard from the range of 20 $\mu g/m^3$ to approximately 65 $\mu g/m^3$, and the level of a new annual $PM_{2.5}$ standard from the range of 12.5 $\mu g/m^3$ to approximately 20 $\mu g/m^3$. These recommended ranges are based primarily on quantitative results from epidemiological studies, examinations of concentration-response relationships suggested by these studies, quantitative risk assessment, including consideration of the sensitivity of the risk estimates to key assumptions and inherent uncertainties in the underlying data and analytic approaches, and relevant policy considerations based on air quality analyses. In recommending these ranges, staff is mindful that the Clean Air Act does not require that NAAQS be set at zero-risk levels, but rather at level that avoid unacceptable risks to public health, thus protecting public health with an adequate margin of safety. Further, in selecting specific levels for $PM_{2.5}$ standards, staff recommends that the Administrator consider the joint protection afforded by both the 24-hour and annual standards. The recommended approach is to view an annual $PM_{2.5}$ standard as the primary target for control programs designed to effectively lower the entire distribution of $PM_{2.5}$ concentrations, with a corresponding 24-hour $PM_{2.5}$ standard set so as to protect

against the occurrence of peak 24-hour concentrations that would likely not be controlled by areas attaining such a new annual $PM_{2.5}$ standard.

6) Staff recommends that an annual PM_{10} standard be retained, alone or in combination with a 24-hour PM_{10} standard.

a) Staff recommends that the Administrator consider selecting the level of an annual PM_{10} standard from the range of 40 $\mu g/m^3$ to 50 $\mu g/m^3$, with an expected arithmetic mean form. Such a standard would reflect the range considered in the last review, and would protect against the principal effects of concern, including effects associated with both short- and long-term exposures to PM such as aggravation of asthma, upper respiratory infections, and bronchitis in children, as well as the long-term build-up of insoluble coarse fraction particles in the lung.

b) Further, if a 24-hour PM_{10} standard is retained, staff recommends retention of the current level of 150 $\mu g/m^3$, but with a revised, more robust form to better address the episodic nature of coarse particle excursions.