proposed PM standards in a letter to the Administrator (Henderson, 2006, p. 2), noting that members of the CASAC PM Panel were generally pleased that the proposed 24-hour $PM_{2.5}$ primary standard was within the range that had previously been recommended by most members. Further, the Panel recognized that the proposed choice of the high end of the recommended range was a policy judgment. A number of commenters, including many States and Tribes, who supported the proposed level generally placed great weight on the recommendation of CASAC.

Many more commenters expressed disagreement with the proposed level. As noted above, these commenters generally fell into two distinct groups that expressed sharply divergent views on their interpretations of the science (in some cases taking into consideration "new" science not included in the Criteria Document), on the appropriate policy response based on the science, and on how the quantitative risk assessment should factor into a decision on the standard level.

In interpreting the available scientific information, including consideration of "new" science, and advocating a policy response based on the science, one group of commenters focused strongly on the uncertainties they saw in the scientific evidence as a basis for concluding that no change to the current level of the 24-hour $PM_{2.5}$ standard was warranted. This group included virtually all commenters representing industry associations and businesses. In commenting on the proposed level, these commenters most generally relied on the same arguments presented above in section II.B.2 as to why they believed it was inappropriate for EPA to make any revisions to the suite of primary $PM_{2.5}$ standards. That is, they asserted that the health effects of concern associated with short-term exposure to $PM_{2.5}$ have not changed significantly since 1997; that the uncertainties in the underlying time-series epidemiologic studies are as great or greater than in 1997; that the estimated risk upon attainment of the current $PM_{2.5}$ standards is lower now than it was when the $PM_{2.5}$ standards were set in 1997; and that "new" science not included in the Criteria Document continues to increase uncertainty about possible health risks associated with exposure to $PM_{2.5}$. These general comments are addressed above in section II.B.2.

In more specific comments, UARG and other commenters in this group called into question EPA's rationale for the proposed level of 35 $\mu g/m^3$. In so doing, these commenters primarily relied on an examination of this rationale included in an attachment to UARG's comments as the basis for concluding that the available studies do not support EPA's view of the overall pattern of statistically significant associations in studies of short-term exposure to $PM_{2.5}$ across a wide range of 98th percentile $PM_{2.5}$ values. This examination of such studies concluded that there is no consistent pattern of associations at levels up to (and above) the 65 $\mu g/m^3$ 98th percentile level of the current standard. This examination was based on an individual consultant's ranking of a set of short-term exposure studies by what is characterized as the "overall significance" of each study's results. A number of studies were included in this examination that EPA did not include in looking at the pattern of associations.

In considering the approach used in this examination, EPA concludes that the categorical rankings were inappropriately defined in a very restrictive way that overly emphasized certain studies based on selection criteria that favored multi-pollutant models and alternative model specifications, which had the effect of dismissing statistically significant results in some studies. This conclusion reflects EPA's consideration of these issues as presented above in section II.B.2. As noted there, EPA believes in the importance of a comprehensive evaluation that considers and weighs a variety of evidence, including biological plausibility of associations between the various pollutants and health outcomes, and focuses on the stability of the size of the effect estimates in time-series studies using both single- and multi-pollutant models, rather than just looking at statistical significance in a large number of alternative models and using it simplistically to delineate between real and suspect associations. In addition, the examination included several studies that, for a variety of reasons, EPA does not believe are appropriate for such an analysis. The inclusion of such studies, many of which had low statistical power, served to dilute the pattern of associations seen in studies considered by EPA as providing a more appropriate basis for this type of examination.

Further, even if this examination were to be accepted at face value, it still would support a distinction between the patterns of associations above and below the proposed level, in that over half of the cited studies with 98th percentile values above 35 $\mu g/m^3$ were characterized as being of overall or mixed significance, and more than half of the cited studies with 98th percentile values below 35 $\mu g/m^3$ were characterized as having no overall significant association. After fully considering this examination of patterns of study results, the Administrator believes that the observations of patterns of study results presented earlier in this section remain valid.[42]

The other group of commenters, including many medical groups, numerous physicians and academic researchers, many public health organizations, some States, and a large number of individual commenters, viewed the epidemiologic evidence and other health studies as strong and robust and expressed the belief that a much stronger policy response is warranted, generally consistent with a standard level at or below 25 $\mu g/m^3$. Some of these commenters generally expressed the view that the level of the standard should be set below the lowest level observed in any of the studies that report any statistically significant association. Some also expressed the view that important uncertainties inherently present in the evidence warrant a highly precautionary policy response, particularly in view of the serious nature of the health effects at issue, and should be addressed by selecting a standard level that incorporates a large margin of safety.

More specifically, American Lung Association *et al.* and other commenters noted three studies included in the Criteria Document with 98th percentile values below 35 $\mu g/m^3$, including a mortality study in Phoenix (Mar *et al.*, 2000; reanalyzed in Mar *et al.*, 2003) with a 98th percentile value of 32 $\mu g/m^3$, a study of emergency department visits in Montreal (Delfino *et al.*, 1997) with a 98th percentile value of 31 $\mu g/m^3$, and a study of increase in myocardial infarction in Boston (Peters *et al.*, 2001) with a 98th percentile value of 28 $\mu g/m^3$. Further, these commenters expressed the view that EPA's proposed approach to selecting a level of the 24-hour $PM_{2.5}$ standard is fundamentally flawed because it "relies unreasonably on point estimates of statistical significance at various concentrations, rather than on trends, and because it completely fails to consider issues of statistical power" (American Lung Association *et al.*, p. 57). In addition, these commenters found EPA's justification for the proposed level to be "simply irrational" in that it "essentially fabricates uncertainty" as a basis for avoiding setting a standard that

[42] The EPA's consideration of this examination is discussed more fully in the Response to Comments document.

the evidence "clearly indicates is necessary" (*Id.*).

In considering these comments, the Administrator first notes that he generally agrees with CASAC's view that selecting a level within the range of 30 to 35 $\mu g/m^3$ is a public health policy judgment and that the science does not dictate the selection of any specific level within this range. The Administrator also believes that this policy judgment should take into consideration the important uncertainties that remain in issues that are central to interpreting these types of time-series epidemiologic studies. While the Administrator believes that progress has been made since the last review in addressing key uncertainties, as discussed above in section II.B.2, EPA and the scientific community, including CASAC and the National Research Council (NRC), recognize that important uncertainties remain that warrant further research (*e.g.*, see NRC, 2004). Thus, the Administrator does not agree that the Agency is "fabricating" uncertainties that do not exist. More specifically, in considering the studies cited in these comments as a basis for a standard level below 35 $\mu g/m^3$, the Administrator continues to believe that it is necessary to consider not only the results of these studies and the inherent uncertainties in such studies, but also the pattern of results from other studies with similar air quality values. In so doing, EPA notes that the statistically significant results in Peters *et al.* (2001) were uniquely associated with 1 to 2 hour lag times, but not with 24-hour average $PM_{2.5}$ concentrations, such that it would provide a very tenuous basis for the level of a 24-hour average national standard. While the studies in Phoenix and Montreal do provide some evidence of statistically significant associations within the range of 30 to 35 $\mu g/m^3$, several other studies within this range of air quality that generally have somewhat greater statistical power and narrower confidence ranges do not provide such evidence. In making the public health policy judgment inherent in selecting a standard level, the Administrator believes that it is necessary to weigh the evidence and related uncertainties against the requirement that the standard is to be neither more nor less stringent than necessary to protect public health with an adequate margin of safety. See *NRDC v. EPA*, 902 F. 2d 962, 971 (D.C. Cir. 1990) (in considering level of a NAAQS, EPA is required to take into account all of the relevant studies in the record and rationally determine what weight to give each study); *API v. Costle*, 665 F. 2d 1176, 1187 (DC Cir. 1981) (same). In so doing, the Administrator does not agree that this evidence presented by American Lung Association *et al.* warrants a level below 35 $\mu g/m^3$.

These commenters also identified several "new" studies in support of their arguments for a lower level. As noted above, as in past NAAQS reviews, EPA is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review, and will consider the newly published studies for purposes of decision making in the next PM NAAQS review. Nonetheless, in provisionally evaluating commenters' arguments (see Response to Comments document), EPA notes that its provisional assessment of "new" science found that such studies did not materially change the conclusions in the Criteria Document.

With regard to the other studies, EPA notes that neither the Vancouver nor the Atlanta studies found statistically significant associations with $PM_{2.5}$, and that the Atlanta and California studies were conducted in areas with 98th percentile $PM_{2.5}$ values well above the proposed level. Thus, EPA concludes that, taken at face value, these studies would provide no basis for the commenters' claim that they would require a lower standard level than one based on the science included in the Criteria Document.

With regard to considering how the quantitative risk assessment should factor into a decision on the standard level, EPA notes that both groups of commenters generally consider the risk assessment in their comments on the standard level, but they reach diametrically opposed conclusions as to what standard level is supported by the assessment. The general views of both groups on the implications of the risk assessment are presented above in section II.B.2, with one group arguing that it supports a decision not to revise either of the current $PM_{2.5}$ standards, and the other group arguing that it supports a decision to revise both $PM_{2.5}$ standards. More specifically, some of the medical/environmental health commenters consider the magnitude of risk estimated to remain upon meeting the proposed 24-hour standard as a strong reason to select a lower level. These commenters generally assert that the risks are likely even higher than EPA's primary estimates, in part because EPA incorporated a surrogate threshold of 10 $\mu g/m^3$ even though there is no clear evidence of a threshold in the relevant time-series studies. On the other hand, the industry/business commenters generally assert that the risks are likely lower than EPA's primary estimates, in part because EPA did not base its primary estimates on an assessment that included all statistical model results presented in the studies. Having considered comments based on the quantitative risk assessment from both groups of commenters, the Administrator finds no basis to change the position on the risk assessment that was taken at the time of proposal. That is, as discussed above, while the Administrator recognizes that the risk assessment rests on a more extensive body of data and is more comprehensive in scope than the assessment conducted in the last review, he is mindful that significant uncertainties continue to underlie the resulting quantitative risk estimates. Further, in the Administrator's view, as noted above in this section, this risk assessment, which is based on studies that do not resolve the issue of a threshold, has important limitations as a basis for standard setting in this review, since if no threshold is assumed the assessment necessarily predicts that ever lower standards result in ever lower risks. This has the effect of masking the increasing uncertainty that exists as lower levels are considered, even when a range of assumed thresholds are considered. As a result, the Administrator judges that the quantitative risk assessment does not provide an appropriate basis for selecting the level of the 24-hour $PM_{2.5}$ standard.

After carefully taking the above comments and considerations into account, the Administrator has decided to set the level of the primary 24-hour $PM_{2.5}$ standard at 35 $\mu g/m^3$. In the Administrator's judgment, based on the currently available evidence, a standard set at this level will protect public health with an adequate margin of safety from serious health effects including premature mortality and hospital admissions for cardiorespiratory causes that are likely causally associated with short-term exposure to $PM_{2.5}$. A standard set at a higher level would not likely result in improvements in air quality in areas across the country in which short-term exposure to $PM_{2.5}$ can reasonably be expected to be associated with serious health effects. A standard set at a lower level would only result in significant further public health protection if, in fact, there is a continuum of health risks down to the lower end of the ranges of air quality observed in the key epidemiologic studies and if the reported associations are, in fact, causally related to $PM_{2.5}$ at

those lower levels. Based on the pattern of results observed in the available evidence, the Administrator is not prepared to make those assumptions. Taking into account the uncertainties that remain in interpreting the available epidemiologic studies, the likelihood of obtaining benefits to public health decreases at lower levels while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to reduce risks to public health increases. On balance, the Administrator does not believe that a lower standard is necessary to provide the requisite degree of public health protection. This judgment by the Administrator appropriately considers the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

2. Annual $PM_{2.5}$ Standard

Based on the approach discussed above at the beginning of section II.F, at the time of proposal the Administrator relied upon evidence from the long-term exposure $PM_{2.5}$ studies as the principal basis for selecting the proposed level of the annual standard. In considering these studies as a basis for the level of an annual standard, the Administrator agreed with the evidence-based focus in the Staff Paper of looking at the long-term mean $PM_{2.5}$ concentrations across the cities included in such long-term studies. In so doing, the Administrator recognized that these studies, like the short-term exposure studies, provide no evidence of clear effect thresholds or lowest-observed-effects levels. Thus, in focusing on the cross-city long-term mean concentrations in these studies, the Administrator was seeking to establish a standard level that will require improvements in air quality in areas in which long-term exposure to $PM_{2.5}$ can reasonably be expected to be associated with serious health effects.

Based on the characterization and assessment of the long-term $PM_{2.5}$ exposure studies presented in the Criteria Document and Staff Paper, in the proposal the Administrator recognized the importance of the validation efforts and reanalyses that have been done since the last review of the original Six Cities and ACS mortality studies. These new assessments provide evidence of generally robust associations and provide a basis for greater confidence in the reported associations than in the last review, for example, in the extent to which they have made progress in understanding the importance of issues related to co-pollutant confounding and the specification of statistical models. Consistent with the information available in the last review, these two key long-term exposure mortality studies reported long-term mean $PM_{2.5}$ concentrations across all the cities included in the studies of 18 and 21 $\mu g/m^3$, respectively. The Administrator also particularly recognized the importance of the extended ACS mortality study, published since the last review, which provides new evidence of mortality related to lung cancer and further substantiates the statistically significant associations with cardiorespiratory-related mortality observed in the original studies.[43] The Administrator noted that the statistically significant associations reported in the extended ACS study, in a large number of cities across the U.S., provide evidence of effects at a lower long-term mean $PM_{2.5}$ concentration (17.7 $\mu g/m^3$) than had been observed in the original study, although the relative risk estimates are somewhat smaller in magnitude than those reported in the original study. The assessment in the Criteria Document of these mortality studies, taking into account study design, the strength of the study (in terms of statistical significance and precision of result), and the robustness of results, concluded that it would be appropriate to give the greatest weight to the reanalyses of the Six Cities and ACS studies, and in particular to the results of the extended ACS study (EPA, 2004a, p. 9–33) in weighing the evidence of mortality effects associated with long-term exposure to $PM_{2.5}$. Consistent with that assessment, the Administrator placed greatest weight on these studies as a basis for selecting the proposed level of the annual $PM_{2.5}$ standard.

In addition to these mortality studies, the Administrator also recognized the availability of relevant morbidity studies providing evidence of respiratory morbidity, including decreased lung function growth, in children with long-term exposure to $PM_{2.5}$. Studies conducted in the U.S. and Canada include the 24-Cities study considered in the last review and more recent studies of cohorts of children in southern California, in which the long-term mean $PM_{2.5}$ concentrations in all the cities included in the studies are approximately 14.5 and 15 $\mu g/m^3$, respectively. As discussed in section II.A. of the proposal (71 FR at 2632), in the 24 Cities study, statistically significant associations were reported between long-term fine particle exposures and lung function measures at a single point in time, whereas positive but generally not statistically significant associations were reported with prevalence of several respiratory conditions. As interpreted in the last review, the results from the 24-Cities study are uncertain as to the extent to which the association extends below a long-term mean $PM_{2.5}$ concentration of approximately 15 $\mu g/m^3$. The more recent Southern California children's cohort study provides evidence of important respiratory morbidity effects in children, including evidence for a new measure of morbidity, decreased growth in lung function. Reports from this study suggest that long-term $PM_{2.5}$ exposure is associated with decreases in lung function growth, as measured over a four-year follow-up period, although statistically significant associations are not consistently reported. The Administrator recognized that these are important new findings, indicating that long-term $PM_{2.5}$ exposure may be associated with respiratory morbidity in children. However, the Administrator also observed that this is the only study reporting decreased lung function growth, conducted in just one area of the country, such that further study of this health endpoint in other areas of the country would be needed to increase confidence in the reported associations. Thus, the Administrator provisionally concluded that this study provides an uncertain basis for establishing the level of a national standard (*Id.* at 2651).

The Administrator generally agreed that, as discussed in the Staff Paper (EPA, 2005, p. 5–22), it was appropriate to consider a level for an annual $PM_{2.5}$ standard that is below the averages of the long-term $PM_{2.5}$ concentrations across the cities in the key long-term exposure mortality studies, recognizing that the evidence of an association in any such study is strongest at and around the long-term average where the data in the study are most concentrated. The Administrator was mindful that considering what standard is requisite to protect public health with an adequate margin of safety requires public health policy judgments that neither overstate nor understate the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. The Administrator provisionally concluded that these key mortality studies, together

[43] In the extended ACS study, significant lung cancer associations were found for those with high school education or less, but not for those with better than a high school education. When data are combined for all education levels, a significant association is found.

with the morbidity studies, provide a basis for considering a standard level no higher than 15 $\mu g/m^3$. This level is somewhat below the long-term mean concentrations in the key mortality studies and consistent with the interpretation of the evidence from the morbidity studies discussed above. Further, in the Administrator's provisional view, these studies did not provide an appropriate basis for selecting a level lower than the current standard of 15 $\mu g/m^3$.

In considering the extent to which the quantitative risk assessment can help to inform these judgments with regard to the annual $PM_{2.5}$ standard, the Administrator again recognized that risk estimates based on simulating the attainment of standards set at lower levels, as expected, continue to suggest some additional reductions in risk at the lower standard levels considered in the assessment, and that these estimates largely depend upon assumptions made about the lowest level at which reported associations will likely persist and remain causal in nature. Thus, the Administrator was again hesitant to use such risk estimates as a basis for proposing a lower annual standard level than 15 $\mu g/m^3$, the level that is based directly on the evidence in the studies themselves, as discussed above.

Taking the above considerations into account, the Administrator proposed to retain the level of the primary annual $PM_{2.5}$ standard at 15 $\mu g/m^3$. In the Administrator's judgment at that time, based on the currently available evidence, a standard set at this level would be requisite to protect public health with an adequate margin of safety from serious health effects, including premature mortality and respiratory morbidity that are likely causally associated with long-term exposure to $PM_{2.5}$. This judgment by the Administrator appropriately considered the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognized that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

At the time of proposal, the Administrator recognized that the CASAC Panel did not endorse retaining the annual standard at the current level of 15 $\mu g/m^3$ (Henderson, 2005a, p. 7). In weighing the recommendation of the CASAC Panel, the Administrator carefully considered CASAC's stated rationale. In discussing its recommendation (Henderson, 2005a), the CASAC Panel first noted that changes to either the annual or 24-hour $PM_{2.5}$ standard, or both, could be recommended. The Panel then gave three reasons for placing more emphasis on lowering the 24-hour standard than the annual standard: (1) The vast majority of studies indicating effects of short-term $PM_{2.5}$ exposure were carried out in settings in which $PM_{2.5}$ concentrations were largely below the current 24-hour standard level of 65 $\mu g/m^3$; (2) the amount of evidence on short-term exposure effects, at least as reflected by the number of reported studies, is greater than for long-term exposure effects; and (3) toxicologic findings are largely related to the effects of short-term, rather than long-term, exposures. In not endorsing the option presented in the Staff Paper of retaining the level of the current annual standard in conjunction with lowering the 24-hour standard, the CASAC Panel observed that some cities have relatively high annual $PM_{2.5}$ concentrations without much day-to-day variation and that such cities would only rarely exceed a 24-hour standard, even if it were set at a level below the current standard. In such a city, attaining a 24-hour standard would likely have minimal if any effect on the long-term mean $PM_{2.5}$ concentration and consequently would be less likely to reduce health effects associated with long-term exposures. These observations indicate the desirability of lowering the level of the annual $PM_{2.5}$ standard as well as that of the 24-hour standard, so as to ensure that revisions to the standards achieve appropriate reductions in long-term exposures. Based on these considerations and taking into account the results of the risk assessment, most CASAC Panel members favored setting an annual standard in the range of 14 to 13 $\mu g/m^3$, along with lowering the 24-hour standard (Henderson, 2005a, p. 7).

In considering these views, the Administrator noted that the appropriateness of setting an annual standard that would lower annual $PM_{2.5}$ concentrations in cities across the country depends upon a policy judgment as to what annual level is required to protect public health with an adequate margin of safety from long-term exposures to $PM_{2.5}$ in light of the available evidence. In considering the evidence of effects associated with long-term $PM_{2.5}$ exposure as a basis for selecting an adequately health protective annual standard, as discussed above, the Administrator provisionally concluded that the evidence did not provide a basis for requiring annual levels below 15 $\mu g/m^3$. Thus, the Administrator agreed conceptually with the CASAC Panel that any particular 24-hour standard may not result in reductions in the level of long-term exposures to $PM_{2.5}$ in all areas with relatively higher than typical annual $PM_{2.5}$ concentrations and lower than typical ratios of peak-to-mean values (71 FR 2652). Further, the Administrator agreed that this general advice supported relying on the annual standard, and not the 24-hour standard, to achieve the appropriate level of protection from long-term exposures to $PM_{2.5}$. However, the Administrator did not believe that this advice necessarily translated into a reason for setting the annual $PM_{2.5}$ standard at a level below the current level of 15 $\mu g/m^3$. As discussed above, the Administrator believed that the principal basis for selecting the appropriate level of an annual standard should be the evidence provided by the long-term studies, in conjunction with judgments concerning whether and over what range of concentrations the reported associations are likely causal, without reliance on the risk assessment, and that this evidence reasonably supported retaining the current level of the annual standard (*Id.*).

Reflecting the great importance that EPA places on the advice of CASAC, the Administrator solicited broad public comment on the range of 15 down to 13 $\mu g/m^3$ the low end of the range recommended by CASAC for the level of the annual $PM_{2.5}$ standard, and on the reasoning that formed the basis for that recommendation. The Administrator recognized that a decision to select a standard in this range below 15 $\mu g/m^3$ would place greater weight on the strength of the associations reported in the key epidemiologic mortality and morbidity long-term exposure studies down to the lower part of the range of $PM_{2.5}$ concentrations observed across all the cities included in these studies. Such a standard could also reflect greater reliance on the results of the quantitative risk assessment that suggested increased reductions in risk associated with meeting an annual standard at such lower levels (*Id.*).

At the time of proposal, the Administrator also recognized that sharply divergent views on the appropriate level of this standard had been presented to EPA as part of the NAAQS review process, and solicited comments on a wider range of levels, down to 12 $\mu g/m^3$ on alternative views of the appropriate interpretation of the epidemiologic evidence and related uncertainties, and on relevant research that would improve our understanding of key issues and analytic approaches to

better inform policy judgments in the future. As was the case with the 24-hour $PM_{2.5}$ standard, the same sharply divergent views were again expressed by the two distinct groups of commenters identified above in section II.B.2, as discussed below.

In considering comments received on the proposal, the Administrator first notes that CASAC requested that EPA reconsider its proposed decision on the level of the annual $PM_{2.5}$ standard and set the level within the range that CASAC had previously recommended, 13 to 14 $\mu g/m^3$ (Henderson, 2006, p. 1).[44] In so doing, CASAC reiterated and elaborated on the scientific basis for its earlier recommendation (Henderson, 2006, pp. 3–4), which included consideration of the Agency's risk assessment (as "the primary means of determining the effects on risk of changes in the 24-hour and annual $PM_{2.5}$ standards in concert") as well as the observations that "a lower daily $PM_{2.5}$ concentration limit alone cannot be relied on to provide protection against the adverse effects of higher annual average concentrations," that "there is evidence that effects of long-term $PM_{2.5}$ concentrations occur at or below the level of the current standard," and that "short-term effects of $PM_{2.5}$ persist in cities with annual $PM_{2.5}$ concentrations below the current standard" down to approximately 13 $\mu g/m^3$ (*e.g.*, Burnett and Goldberg, 2003; Mar *et al.*, 2003; and Lipsett *et al.*, 1997). The CASAC concluded:

> In summary, the epidemiologic evidence, supported by emerging mechanistic understanding, indicates adverse effects of $PM_{2.5}$ at current annual average levels below 15 $\mu g/m^3$. The PM Panel realized the uncertainties involved in setting an appropriate, health-protective level for the annual standard, but noted that the uncertainties would increase rapidly below the level of 13 $\mu g/m^3$. That is the basis for the PM Panel recommendation of a level at 13–14 $\mu g/m^3$ (Henderson, 2006, p. 4).

In response to CASAC's request for reconsideration, the Administrator has carefully considered its stated views and the scientific basis for the range it recommended. As an initial matter, the Administrator notes that CASAC's recommendation to lower the level of the annual standard was based in large measure on the results of the Agency's risk assessment, which examined changes in both the 24-hour and annual standard levels in concert. In considering this information qualitatively, as discussed above in section II.B, the Administrator believes that the estimates of risks likely to remain upon attainment of the current suite of $PM_{2.5}$ standards are indicative of risks that can reasonably be judged to be important from a public health perspective, and thus support revision of the current suite of standards. In addressing what revisions to the current suite of $PM_{2.5}$ standards are appropriate, the Administrator has determined that the evidence of health effects associated with short-term exposure to $PM_{2.5}$ is such that it is appropriate to lower the level of the 24-hour $PM_{2.5}$ standard (as discussed in section II.F.1 above). However, as discussed more fully above, the Administrator also believes that this risk assessment has important limitations as a basis for setting a standard level in this review, in part because the available studies do not resolve questions related to potential effect thresholds and because of other important uncertainties noted above in section II.A.3. As a result, the Administrator judges that the quantitative risk assessment does not provide an appropriate basis for selecting the level of either the 24-hour or the annual $PM_{2.5}$ standard. Thus, the Administrator more heavily weighs the implications of the uncertainties associated with the Agency's quantitative risk assessment than CASAC apparently does, and disagrees with CASAC that the risk assessment results appropriately serve as a primary basis for a decision on the level of the annual $PM_{2.5}$ standard.

The CASAC also considered the evidence from specific short-term exposure studies as part of the basis for its recommendation for a lower annual standard level, pointing to studies indicating that effects from short-term exposure of $PM_{2.5}$ persist in cities with annual $PM_{2.5}$ concentrations below the current standard. While the Administrator does not disagree with CASAC's factual statements regarding the findings of the studies of short-term exposure effects, he believes that, based on the evidence available in this review, it is more appropriate to consider the short-term exposure studies as a basis for the level of the 24-hour standard and to consider the long-term exposure studies as a basis for the level of the annual standard. The Administrator recognizes that the Agency used available short-term exposure studies as the primary basis for setting the level of a "generally controlling" annual standard in the last review, with the purpose that the annual standard would provide protection against both short-term exposures and long-term exposures, but notes that such a public health policy choice was made primarily because the short-term exposure studies were judged to be the strongest evidence available at that time and the evidence from long-term exposure studies was judged to be too limited to serve as other than a secondary consideration in setting the level of the annual standard. See 62 FR 38675 n. 41 and 38676. In this review, however, the bodies of evidence for both short- and long-term exposures have been substantially extended and strengthened, such that each $PM_{2.5}$ standard can appropriately be evaluated based on the most directly relevant body of scientific studies, and can be focused on providing protection from the health risks evaluated in that body of scientific studies. The Administrator continues to believe, consistent with the evidence-based approach presented in the Staff Paper, that using evidence of effects associated with periods of exposure that are most closely matched to the averaging time of each standard is the most appropriate public health policy approach to evaluating the scientific evidence in selecting the level of each standard, with each standard designed to provide protection from the health risks associated with exposures reflecting that averaging time. Thus, the Administrator believes that the 24-hour standard should be set so as to provide an appropriate degree of protection from health effects associated with short-term exposures to $PM_{2.5}$, and the annual standard should be set so as to provide an appropriate degree of protection from health effects associated with long-term exposures to $PM_{2.5}$. In determining the level of each standard, the Administrator believes it is appropriate to rely on the short-term studies for purposes of determining the level of the 24-hour standard, and the long-term studies for purposes of determining the level of the annual standard.[45] Therefore, the Administrator does not believe that evidence from short-term exposure studies is an appropriate basis for selecting any different level of the annual standard in this review than that selected based on the long-term exposure evidence. The EPA has instead

[44] Two PM Panel members did not agree with the views of the majority, expressing the view that there was an adequate scientific basis to choose an annual $PM_{2.5}$ standard level within the range of 12 to 15 $\mu g/m^3$ and that the choice of a specific level within that range was a policy decision (Henderson, 2006, p. 6).

[45] This is consistent with the approach taken in the Staff Paper, sections 5.3.4.1 and 5.3.5.1, for evaluating the evidence-based considerations related to setting the standards. The CASAC's letter of June 6, 2005 states that the Second Draft of the Staff Paper was "Scientifically well-reasoned," with the exception of a section not relevant to the fine PM (Henderson, 2005a, pp. 1–2). The CASAC's general view thus includes this evidence-based approach presented in the Staff Paper.

evaluated these short-term exposure studies in the context of determining the appropriate level for the 24-hour standard.

Finally, CASAC also expressed the view that there is evidence that effects of long-term $PM_{2.5}$ concentrations occur at or below the level of the current standard. While the Administrator agrees that any such evidence would be directly relevant to his decision on the level of the annual $PM_{2.5}$ standard, CASAC did not provide any specific information as to what studies it felt provided such evidence nor the considerations that played a role in its interpretation of the studies, including its assessment of the uncertainties inherent in any such studies.[46] As discussed below, the Administrator has considered the available studies of long-term exposure to $PM_{2.5}$, together with the uncertainties inherent in that body of evidence, to reach his final decision on the level of the annual standard. However, since CASAC did not provide any more specific statements as to its assessment of such mortality or morbidity studies, the Administrator cannot determine in what ways his judgments about that evidence may differ from CASAC's views.[47] Lacking such specific statements to support CASAC's view that there is evidence that effects of long-term $PM_{2.5}$ concentrations occur at or below the level of the current standard, the Administrator cannot discern a clear line of scientific reasoning that would preclude the current level of 15 $\mu g/m^3$ from being a reasonable policy choice based on the most relevant available evidence on the health effects of long-term exposures to $PM_{2.5}$.

As noted above, EPA received other comments on the proposal from two distinct groups of commenters. One group that included virtually all commenters representing industry associations and businesses agreed with the Agency's proposed decision not to revise the level of the annual $PM_{2.5}$ standard. The other group of commenters included many medical groups, numerous physicians and academic researchers, many public health organizations, many States, and a large number of individual commenters. They strongly disagreed with the Agency's proposed decision and argued that EPA should lower the level of the annual $PM_{2.5}$ standard. While some of these commenters felt that the level should be set within the range recommended by CASAC, most such commenters advocated a level of 12 $\mu g/m^3$. These commenters largely based their views on the same general considerations put forward by CASAC as a basis for its recommendation to lower the level of the annual $PM_{2.5}$ standard. To the extent that these commenters, like CASAC, relied upon the Agency's risk assessment or the evidence from short-term exposure studies as a basis for their views, their comments are addressed above. Comments that address how specific long-term $PM_{2.5}$ exposure studies should be considered as a basis for the level of the annual $PM_{2.5}$ standard are addressed below.

A few commenters offered detailed comments on the key long-term exposure $PM_{2.5}$ mortality studies discussed in the proposal, including the original analyses and reanalyses of the ACS and Six Cities cohorts and the extended ACS cohort study. In general, some medical/public health/researcher/State commenters expressed the view that EPA has downplayed the results of these studies to the extent that they provide evidence of effects below the level of the current standard. For example, American Lung Association *et al.* and Schwartz (2006) asserted that the ACS cohort study and the HEI reanalysis provide direct evidence of premature mortality associated with annual exposures below 15 $\mu g/m^3$ based on plots of the concentration-response function between long-term exposure to $PM_{2.5}$ and risk of dying across 50 U.S. metropolitan areas that show no substantial deviation from linear, non-threshold relationships down through levels well below 15 $\mu g/m^3$. These commenters did not, however, discuss the uncertainties inherent in this type of epidemiologic study or the implications of these uncertainties on their interpretation of the results.

In contrast, some industry/business commenters (*e.g.*, Pillsbury *et al.*; Annapolis Center; UARG) emphasized that uncertainties remain in interpreting these studies with regard to issues such as potential confounding by co-pollutants, especially SO_2, modeling to address spatial correlations in the data, and effect modification by education level or socioeconomic status. In addition, some industry/business commenters raised additional questions about the appropriate interpretation of these key studies in light of other studies, which EPA did not rely on, that provided either mixed or no evidence of $PM_{2.5}$-mortality associations, and in light of their view that the studies that EPA relied on report implausibly large effect estimates.

In considering these commenters' sharply divergent assessments of the key mortality studies, the Administrator continues to believe that these studies provide strong evidence of an association between long-term exposure to $PM_{2.5}$ and mortality. However, the Administrator believes that the remaining uncertainties weigh against reaching the conclusion that the level of the annual $PM_{2.5}$ standard should be lowered on the basis of these studies. In reaching this conclusion, the Administrator notes that even though the long-term average $PM_{2.5}$ concentration across the cities in the extended ACS study (17.7 $\mu g/m^3$) is lower than in the original study (21 $\mu g/m^3$), the level of the current standard is still appreciably below the long-term average of the extended ACS study and that of the Six Cities study (18 $\mu g/m^3$). In commenting on alternative approaches to interpreting the study results as a basis for setting a standard level, American Lung Association *et al.* expressed the view that the level of the standard should more appropriately be based on the concentration that is one standard deviation below the cross-city long-term average in each relevant long-term exposure study. In considering such an approach, the Administrator notes that while that approach would by definition lead to a more precautionary standard, there is no basis for concluding that it is a more scientifically defensible approach or that it is more appropriate in this case where a number of key uncertainties in the evidence remain to be addressed in future research, and where the basic decision is a judgment by the Administrator as to what level is neither more nor less stringent than is necessary to protect public health with an adequate margin of safety. The Administrator continues to believe that it is reasonable to base the decision on the standard level on long-term average $PM_{2.5}$ concentrations in the key long-term exposure studies, because the evidence of an association in any such study is strongest at and around the long-term average where the data in the study are most concentrated (71 FR 2651).

Both groups of commenters also identified several "new" mortality studies not included in the Criteria Document in support of their various views. As noted above in Section I.C, as in past NAAQS reviews, EPA is basing

[46] The EPA does not believe that CASAC based this statement on the evidence it cites concerning effects associated with the long-term means of the short-term studies. These studies address effects from short-term exposures, and do not address effects from long-term exposures.

[47] The CASAC did express the view that although the "new" scientific literature that was not included in the Criteria Document appears to support its findings, that literature was not needed to support its recommendation of a lower annual standard level (Henderson, 2006, p. 6).

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the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review, and will consider the newly published studies for purposes of decision making in the next PM NAAQS review. Nonetheless, in provisionally evaluating commenters' arguments (see Response to Comments document), EPA notes that its provisional assessment of "new" science found that such studies did not materially change the conclusions in the Criteria Document.

Some commenters who supported a lower annual standard level also asserted that EPA failed to adequately consider long-term exposure $PM_{2.5}$ morbidity studies, especially studies of effects in children. For example, the Children's Health Protection Advisory Committee and other commenters noted that studies by Raziennne *et al.* [1996] and Gauderman *et al.* (2002, 2004) showed effects on children's lung function at long-term cross-city average $PM_{2.5}$ concentrations of 14.5 $\mu g/m^3$ and 15 $\mu g/m^3$, respectively. The proposal notice included a careful discussion of the 24-Cities study (Razienne *et al.*, 1996) and the earlier Southern California children's health study (Gauderman *et al.*, 2000, 2002), studies which were included in the Criteria Document,[48] and explained the basis for the Administrator's provisional conclusion that these studies provide an uncertain basis for establishing the level of a national standard (71 FR 2651). These commenters offered no information that would change the Administrator's judgment with regard to these studies.[49] In addition, the Children's Health Advisory Committee also cited several studies of "traffic-related" pollution (van Vliet *et al.*, 1997; Brunekreef *et al.*, 1997; Kim *et al.*, 2004[50]) as showing associations between fine particles and adverse respiratory outcomes, including asthma in children who live near major roadways, with mean annual average fine particle concentrations near and below 15 $\mu g/m^3$.

In considering these comments, EPA first notes that studies of traffic-related pollution generally do not disentangle potential effects of fine particles from those of other traffic-related pollutants, and thus provide an uncertain basis for establishing the level of a $PM_{2.5}$ standard. Further, two of the studies cited by this commenter are "new" studies not included in the Criteria Document. As discussed above in section I.C, EPA is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review, and will consider the newly published studies for purposes of decision making in the next PM NAAQS review.

The CARB and some other commenters who supported a lower annual standard level discussed the rationale used by the CARB in deciding to set the State's annual $PM_{2.5}$ standard at a level of 12 $\mu g/m^3$. Some of these commenters also pointed to the World Health Organization's annual $PM_{2.5}$ guideline value of 10 $\mu g/m^3$ in support of their view that the scientific evidence supports an annual $PM_{2.5}$ standard in the U.S. at a level no higher than 12 $\mu g/m^3$. In considering these comments, the Administrator notes that his decision is constrained by the provision of the CAA that requires that the NAAQS be requisite to protect public health with an adequate margin of safety. This requires that his judgment is to be based on an interpretation of the evidence that neither overstates nor understates the strength and limitations of the evidence, or the appropriate inferences to be drawn from the evidence. This is not the same legal framework that governs the standards set by the State of California or the guidelines established by a working group of scientists within the World Health Organization.[51] Thus, the Administrator does not agree that the California standard or the WHO guideline provide an appropriate basis for setting the level of the annual $PM_{2.5}$ NAAQS in the U.S.

The Administrator further stresses, as explained at proposal, that he is placing the greatest weight in determining the level of the annual standard on the long-term means of the levels associated with mortality effects in the two key long-term studies in the record, the ACS and Six Cities studies (71 FR at 2651). The ACS and Six Cities studies are the two key long-term studies in this review, taking into account both "study design, strength of the study (in terms of statistical significance and precision of result), and the consistency and robustness of results" (71 FR 2651), and also the comprehensive reanalyses of these studies, which involved replication, validation, and sensitivity analyses. These reanalyses replicated the original results and confirmed the associations noted in the original studies (EPA 2005, p. 3–17). The Administrator has taken into account all the relevant studies but in evaluating the strengths and weaknesses of the various studies has determined that the greatest weight should be placed on these key studies, as compared to other studies, in determining the level of the annual standard. As discussed above, the level of the current annual standard is appropriate as it is appreciably below the long-term average of these key studies. This standard is also basically at the same level as the long-term average in the two morbidity studies, the 24 Cities study and the Southern California children's cohort study. These morbidity studies provide an uncertain basis for setting the level of the national standard, and, therefore, in the judgment of the Administrator do not warrant setting a lower level for the annual standard than the level warranted based on the key mortality studies.[52]

After carefully taking the above comments and considerations into account, the Administrator has decided to retain the level of the primary annual $PM_{2.5}$ standard at 15 $\mu g/m^3$. In the Administrator's judgment, based on the currently available evidence, a standard set at this level would be requisite to protect public health with an adequate margin of safety from serious health effects including premature mortality and respiratory morbidity that are likely causally associated with long-term exposure to $PM_{2.5}$. A standard set at a lower level would only result in significant further public health protection if, in fact, there is a continuum of health risks in areas with long-term average $PM_{2.5}$ concentrations that are well below the cross-city long-term average concentrations observed in

[48] The Gauderman *et al.* [2004] study cited by these commenters is a "new" study, and EPA's provisional consideration of this study is discussed in the Response to Comments document.

[49] The Administrator notes that CASAC's letter of March 21, 2006 did not note any objection to his views on these morbidity studies as discussed in the proposal, or provide any reason to reconsider such views [Henderson, 2006].

[50] Kim *et al.* (2004) is a "new" study and EPA's provisional consideration of this study is discussed in the Response to Comments document.

[51] For example, the California statute does not refer to setting a standard that is "requisite" to protect, as that term is used in the CAA, and California, unlike EPA, may take economic impacts into consideration in setting air quality standards. In addition, as with the WHO guidelines, the standards appear to be more in the nature of goals as compared to binding requirements that must be met.

[52] The EPA is not required to base the level of the standard on either the highest or lowest level from any one study. Rather, the Administrator must "make an informed judgment based on available evidence." *American Petroleum Inst* v. *Costle*, 665 F. 2d at 1187; *NRDC* v. *EPA*, 902 F. 2d at 971. Such an informed judgment can result in higher levels than shown in some of the studies in the record. See, e.g. *NRDC v. EPA*, 902 F. 2d at 971 (upholding 1987 PM_{10} annual standard selected from "near the middle of the 'range of interest' "); *API* v. *Costle*, 665 F. 2d at 1187 (upholding 1979 hourly standard for ozone selected at level higher than a number of studies in the record).

the key epidemiologic studies and if the reported associations are, in fact, causally related to $PM_{2.5}$ at those lower levels. Based on the available evidence, the Administrator is not prepared to make these assumptions. As was the case in considering the 24-hour $PM_{2.5}$ standard, taking into account the uncertainties that remain in interpreting the available long-term exposure epidemiologic studies, the likelihood of obtaining benefits to public health decreases with a standard set below the current level, while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to reduce risks to public health increases. On balance, the Administrator does not believe that a lower standard is needed to protect public health with an adequate margin of safety. This judgment by the Administrator appropriately considers the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

G. Final Decisions on Primary $PM_{2.5}$ Standards

For the reasons discussed above, and taking into account the information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, including its request to reconsider parts of the proposal, and public comments received on the proposal, the Administrator is revising the current primary $PM_{2.5}$ standards. The suite of standards as revised will provide increased protection from the health risks associated with exposure to $PM_{2.5}$, and in the judgment of the Administrator will be requisite to protect public health with an adequate margin of safety.

Specifically, the Administrator is making the following revisions:

(1) The level of the primary 24-hour $PM_{2.5}$ standard is revised to 35 $\mu g/m^3$.

(2) The form of the primary annual $PM_{2.5}$ standard is revised with regard to the criteria for spatial averaging, such that averaging across monitoring sites is allowed if the annual mean concentration at each monitoring site is within 10 percent of the spatially averaged annual mean, and the daily values for each monitoring site pair yield a correlation coefficient of at least 0.9 for each calendar quarter. Data handling conventions for the revised standards are specified in revisions to Appendix N, as discussed below in section V, and minor revisions to the reference method for monitoring PM as $PM_{2.5}$ are specified in Appendix L, as discussed below in section VI.

In a related rule on ambient air monitoring regulations (40 CFR Parts 53 and 58) published elsewhere in today's **Federal Register**, EPA is revising the requirements for reference and equivalent method determinations for fine particle monitors, monitoring network descriptions and periodic assessments, quality assurance, and data certification.

Issues related to the implementation of revised $PM_{2.5}$ standards are discussed below in section VII. The EPA plans to propose related revisions to the Air Quality Index for $PM_{2.5}$ at a later date.

III. Rationale for Final Decisions on Primary PM_{10} Standards

A. Introduction

1. Overview

This section presents the Administrator's final decisions on the review of the primary NAAQS for PM_{10}. The rationale for the final decisions on the primary PM_{10} NAAQS includes consideration of: (1) Evidence of health effects related to short- and long-term exposures to thoracic coarse particles; (2) insights gained from a quantitative risk assessment prepared by EPA; and (3) specific conclusions regarding the need for revisions to the current standards and the elements of standards for thoracic coarse particles (*i.e.*, indicator, averaging time, form, and level) that, taken together, would be requisite to protect public health with an adequate margin of safety.

In developing this rationale, EPA has taken into account the information available from a growing, but still limited, body of evidence on health effects associated with thoracic coarse particles from studies that use $PM_{10-2.5}$ as a measure of thoracic coarse particles. The EPA has drawn upon an integrative synthesis of the body of evidence on associations between exposure to ambient thoracic coarse particles and a range of health endpoints (EPA, 2004a, Chapter 9), focusing on those health endpoints for which the Criteria Document concludes that the associations are suggestive of possible causal relationships. In its policy assessment of the evidence judged to be most relevant to making decisions on elements of the standards, EPA has placed greater weight on U.S. and Canadian epidemiologic studies using thoracic coarse particle measurements, since studies conducted in other countries may well reflect different demographic and air pollution characteristics.

While there is little question that particles in the thoracic coarse particle size range can present a risk of adverse effects to the most sensitive regions of the respiratory tract at sufficient exposure levels, the characterization of health effects attributable to various levels of exposure to ambient thoracic coarse particles is subject to uncertainties that are markedly greater than is the case for fine particles. As summarized below, however, there is a growing body of evidence available since the last review of the PM NAAQS, with important new information coming from epidemiologic, toxicologic, and dosimetric studies. Moreover, the newly available research studies have undergone intensive scrutiny through multiple layers of peer review and extended opportunities for public review and comment. While important uncertainties remain, the review of the health effects information has been extensive and deliberate. In the judgment of the Administrator, this intensive evaluation of the scientific evidence provides an adequate basis for making final regulatory decisions at this time.

In addition, this review has already provided important input to EPA's research and monitoring plans for improving our future understanding of the relationships between exposures to ambient thoracic coarse particles and health effects. As discussed in the proposal, the epidemiological evidence available in this review is almost entirely based on measurements of undifferentiated $PM_{10-2.5}$ mass, without regard to the composition of thoracic coarse particles. Yet both fundamental toxicological considerations and the limited data available on this issue strongly suggest that the health effects could vary significantly depending upon the composition of the ambient coarse particle mix. The goal of the Agency's research and monitoring programs going forward is to provide scientific advances that will enable future PM NAAQS reviews to make more informed decisions that will provide more effective and efficient protection against the effects of those coarse particles and related source emissions that prove to be of concern to public health.

The health effects information and human risk assessment were summarized in sections III.A and III.B of the proposal and are only briefly outlined in subsections III.A.2 and 3 below. Subsequent sections provide a more complete discussion of the Administrator's rationale, in light of key

issues raised in public comments, for his decision to retain the current 24-hour primary PM_{10} standard and to revoke the current annual PM_{10} standard. Specifically, these sections present a more complete discussion of the Administrator's rationale regarding the need to maintain protection against the health effects of coarse particles (section III.B) as well as the rationale for the decisions regarding specific elements of the primary PM_{10} standards including indicator (section III.C); and averaging time, level and form (section III.D).

2. Overview of Health Effects Evidence

The first PM NAAQS (36 FR 8186) used an indicator based solely on a preexisting monitor for total suspended particles (TSP) that was not designed to focus on particles of greatest risk to health. In preparing for the initial review of those standards, EPA placed a major emphasis on developing a new indicator that considered the significant amount of evidence on particle size, composition, and relative risk of effects from penetration and deposition to the major regions of the respiratory tract (Miller *et al.*, 1979). The development and assessment of these lines of evidence in the PM Criteria Document and PM Staff Paper published between 1979 and 1986 culminated in revised standards for PM that used PM_{10} as the indicator (52 FR 24634). The major conclusion from that review, which remained unchanged in the 1997 review, was that ambient particles smaller than or equal to 10 μm in aerodynamic diameter are capable of penetrating to the deeper "thoracic"[53] regions of the respiratory tract and present the greatest concern to health (61 FR 65648). While considerable advances have been made, the available evidence in this review continues to support the basic conclusions reached in the 1987 and 1997 reviews regarding penetration and deposition of fine and thoracic coarse particles. As discussed in the Criteria Document, both fine and thoracic coarse particles penetrate to and deposit in the alveolar and tracheobronchial regions. For a range of typical ambient size distributions, the total deposition of thoracic coarse particles to the alveolar region can be comparable to or even larger than that for fine particles. For areas with appreciable coarse particle concentrations, thoracic coarse particles would tend to dominate particle deposition to the tracheobronchial region for mouth breathers (EPA, 2004a, p. 6–16). Deposition of particles to the tracheobronchial region is of particular concern with respect to aggravation of asthma.

In the last review, little new toxicologic evidence was available on potential effects of thoracic coarse particles and there were few epidemiologic studies that had included direct measurements of thoracic coarse particles. Evidence of associations between health outcomes and PM_{10} that were conducted in areas where PM_{10} was predominantly composed of thoracic coarse particles was an important part of EPA's basis for reaching conclusions about the requisite level of protection from coarse particles provided by the final standards. The new studies available in this review include epidemiologic studies that have reported associations with health effects using direct measurements of $PM_{10-2.5}$, as well as new dosimetric and toxicologic studies.

Section III.A of the proposal further outlines key information contained in the Criteria Document (Chapters 6–9) and the Staff Paper (Chapter 3) on known or potential effects associated with exposure to thoracic coarse particles and their major constituents. The information highlighted there includes:

(1) New information available on potential mechanisms for health effects associated with exposure to thoracic coarse particles or their constituents.

(2) The nature of the effects that have been associated with short-term exposures to ambient thoracic coarse particles, particularly in urban and industrial settings, including aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions), increased respiratory symptoms in children, and premature mortality.

(3) An integrative assessment of the evidence on health effects related to thoracic coarse particles, with an emphasis on the key issues raised in assessing the available community-based epidemiologic studies, including alternative interpretations of the evidence, both for individual studies and the evidence as a whole.

(4) Subpopulations that appear to be sensitive to effects from exposure to thoracic coarse particles, specifically including individuals with preexisting lung diseases such as asthma, and children and older adults.

(5) Conclusions, based on the magnitude of these subpopulations and risks identified in health studies conducted in urban and industrial areas, that exposure to ambient thoracic coarse particles can have an important public health impact.

The summary of the health effects evidence related to ambient coarse particles in the proposal will not be repeated here. The EPA emphasizes that the final decisions on these standards take into account the more comprehensive and detailed discussions of the scientific information on these issues contained in the Criteria Document and Staff Paper, which were reviewed by the CASAC and the public. For reasons summarized in section I.C above, EPA is not relying on studies published after completion of the Criteria Document as a basis for reaching final decisions on these standards.

3. Overview of Quantitative Risk Assessment

The general overview and discussion of key components of the risk assessment used to develop risk estimates for $PM_{2.5}$ presented in section II.A above is also applicable to the assessment done for $PM_{10-2.5}$ in this review. However, the scope of the risk assessment for $PM_{10-2.5}$ is much more limited than that for $PM_{2.5}$, reflecting the much more limited body of epidemiologic evidence and air quality information available for $PM_{10-2.5}$. As discussed in chapter 4 of the Staff Paper, the $PM_{10-2.5}$ risk assessment includes risk estimates for just three urban areas for two categories of health endpoints related to short-term exposure to $PM_{10-2.5}$: hospital admissions for cardiovascular and respiratory causes, and respiratory symptoms.

Estimates of hospital admissions attributable to short-term exposure to $PM_{10-2.5}$ have been developed for Detroit (cardiovascular and respiratory admissions) and Seattle (respiratory admissions), and estimates of respiratory symptoms have been developed for St. Louis.[54] While one of the goals of the $PM_{10-2.5}$ risk assessment was to provide estimates of the risk reductions associated with just meeting alternative $PM_{10-2.5}$ standards, the nature and magnitude of the uncertainties and concerns associated with this portion of the risk assessment weigh against use of these risk estimates as a basis for recommending specific standard levels (EPA, 2005, p. 5–69).

[53] The "thoracic" regions of the respiratory tract are located in the chest (thorax) and are comprised of the tracheo-bronchial region with connecting airways and the alveolar, or gas-exchange region of the lung. For ease of communication, "thoracic" particles penetrating to these regions are often called "inhalable" particles.

[54] Quantitative risk estimates associated with recent air quality levels for these three cities are presented in Figures 4–11 and 4–12 of the Staff Paper.

These uncertainties and concerns are summarized in section III.B of the proposal and discussed more fully in the Staff Paper (Chapter 4) and the technical support document (Abt Associates, 2005).

B. Need for Revision of the Current Primary PM_{10} Standards

As presented in the proposal, taking into account both the nature of recent scientific evidence and legal considerations, this review of the primary PM_{10} standards has focused on whether to revise the indicator for thoracic coarse particles, and on the appropriate level, form and averaging time for any revised indicator. The basis for reaching a final decision on the indicator, as well as other facets of the standards, is presented below in sections III.C and III.D. This section provides an overview of the considerations that led to the Administrator's provisional conclusion, at the time of proposal, that it would be appropriate to revise the PM_{10} standards by adopting a new indicator ($PM_{10-2.5}$).[55] The section then presents a summary of public comments concerning whether the available evidence supports retention, revision, or revocation of standards to protect against exposure to thoracic coarse particles. For the reasons discussed below, the Administrator has concluded, consistent with CASAC and Staff Paper recommendations and conclusions drawn at the time of proposal, that continued protection against health effects associated with short-term exposure to thoracic coarse particles is requisite. However, EPA notes that, having considered the issues raised in extensive public comment on the proposal, the Administrator's final decision differs from that in the proposal regarding whether it is appropriate to revise the indicator in order to retain protection from coarse particles. This section, and the subsequent section on indicator, outline the rationale presented at the time of the proposal, and then describe how the Administrator has reached a different conclusion in his final decision.

1. Overview of the Proposal

The initial issue addressed in the current review of the primary PM_{10} standards was whether, in view of the advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the current standards should be revised. The Staff Paper addressed this question by first considering the conclusions reached in the last review, the subsequent litigation of that decision, and the nature of the new information available in this review.

In 1997, in conjunction with establishing new $PM_{2.5}$ standards, EPA concluded that continued protection against potential effects associated with thoracic coarse particles in the size range of 2.5 to 10 μm was warranted based on particle dosimetry, toxicologic information, and limited epidemiologic evidence from studies that measured PM_{10} in areas where coarse particles were likely to dominate the distribution (62 FR 38677). This information indicated that thoracic coarse particles can deposit in those regions of the lung of most concern (*i.e.*, the tracheobronchial and alveolar regions, which together make up the thoracic region),[56] and that they can be expected to aggravate effects in individuals with asthma and contribute to increased upper respiratory illness (62 FR 38666–8).

Further, EPA decided that the new function of PM_{10} standard(s) would be to provide such protection against effects associated with particles in the narrower size range between 2.5 to 10 μm. Although some consideration had been given to a more narrowly defined indicator that did not include fine particles (*e.g.*, $PM_{10-2.5}$), EPA decided that it was more appropriate to continue to use PM_{10} as the indicator for standards to control thoracic coarse particles. This decision was based in part on the recognition that the only studies of clear quantitative relevance to health effects most likely associated with thoracic coarse particles used PM_{10} in areas where the coarse fraction was the dominant fraction of PM_{10}, namely two studies conducted in areas that substantially exceeded the 24-hour PM_{10} standard (62 FR 38679). The decision also reflected the fact that there were only very limited ambient air quality data then available specifically on thoracic coarse particles (*i.e.* $PM_{10-2.5}$), in contrast to the extensive monitoring network already in place for PM_{10}. In essence, EPA concluded at that time that it was appropriate to continue to control thoracic coarse particles, but that the only information available upon which to base such standards was indexed in terms of PM_{10}.

In subsequent litigation regarding the 1997 PM NAAQS revisions, however, the U.S. Court of Appeals (D.C. Circuit) held in part that EPA had not provided a reasonable explanation justifying use of PM_{10} as an indicator for thoracic coarse particles. *ATA I*, 175 F.3d at 1054–55. Although the court found "ample support" (*id.* at 1054) for EPA's decision to regulate thoracic coarse particles, it vacated the 1997 revised PM_{10} standards. The result of subsequent EPA actions, discussed above in section I.C, is that the 1987 PM_{10} standards remain in place (65 FR 80776, 80777, Dec. 22, 2000) and the present review is consequently of those 1987 standards.

In this review, the Staff Paper focused on the recent information available in the Criteria Document from a growing, but still limited, body of evidence on health effects associated with thoracic coarse particles from studies that use $PM_{10-2.5}$ as the measure of thoracic coarse particles. In addition, there is now much more information available to characterize air quality in terms of $PM_{10-2.5}$ than was available in the last review. In considering this information, the Staff Paper found that the major considerations that formed the basis for EPA's 1997 decision to retain PM_{10} as the indicator for thoracic coarse particles, rather than a more narrowly defined indicator that does not include fine particles, no longer apply. More specifically, staff concluded that the continued use of PM_{10} as an indicator for standards intended to protect against health effects associated with thoracic coarse particles was no longer necessary since the information available in the Criteria Document could support the use of a more directly relevant indicator, $PM_{10-2.5}$. Further, staff concluded that continuing to rely principally on health effects evidence indexed by PM_{10} to determine the appropriate averaging time, form, and level of a standard was no longer necessary or appropriate since a number of more directly relevant studies, indexed by $PM_{10-2.5}$, were available. Thus, the Staff Paper concluded that it was appropriate to revise the current PM_{10} standards in part by revising the indicator for thoracic coarse particles, and by basing any such revised standard principally on the currently available evidence and air quality information indexed by $PM_{10-2.5}$, but also considering evidence from studies using PM_{10} in locations where $PM_{10-2.5}$ was the predominant fraction (EPA, 2005, section 5.4.1). As noted in the introduction to this section,

[55] The Administrator also proposed qualifications to the indicator, and corresponding revisions to the level and form of the 24-hour standard to provide protection that is generally equivalent to that afforded by the PM_{10} standard, and to revoke the annual PM_{10} standard.

[56] EPA further concluded at that time that the risks of adverse health effects associated with deposition of particles in the thoracic region are "markedly greater than for deposition in the extrathoracic (head) region," and that risks from extrathoracic deposition are "sufficiently low that particles which deposit only in that region can safely be excluded from the standard indicator" (62 FR 38666).

having considered public comments on this issue, EPA has reached different conclusions regarding the appropriateness of revising the current indicator in this final decision; this is described in more detail below in section III.C.

Recognizing that dosimetric evidence formed the basis for the initial establishment of the PM_{10} indicator in 1987 and supported the decision in 1997 to retain the PM_{10} indicator, the Staff Paper also considered whether currently available dosimetric evidence continues to support the basic conclusions reached in those reviews of the standards. In particular, consideration was given to available information about patterns of penetration and deposition of thoracic coarse particles in the sensitive thoracic region of the lung and to whether an aerodynamic size of 10 μm remains a reasonable separation point for particles that penetrate and potentially deposit in the thoracic regions. The Staff Paper concluded that while considerable advances have been made in understanding particle dosimetry, the available evidence continues to support those basic conclusions from past reviews. More specifically, both fine particles, indexed by $PM_{2.5}$, and thoracic coarse particles, indexed by $PM_{10-2.5}$, penetrate to and deposit in the thoracic regions. Further, for a range of typical ambient size distributions, the total deposition of thoracic coarse particles to the alveolar region can be comparable to or even larger than that of fine particles (EPA, 2004a, p. 6–16).

Beyond the dosimetric evidence, as noted in past reviews (EPA, 1982, 1996b), toxicologic studies show that the deposition of a variety of particle types in the tracheobronchial region, including resuspended urban dust and coarse-fraction organic materials, has the potential to affect lung function and aggravate respiratory symptoms, especially in asthmatics. Of particular note are limited toxicologic studies that found urban road dust can produce cellular and immunological effects (*e.g.*, Kleinman *et al.*, 1995; Steerenberg *et al.*, 2003).[57] In addition, some very limited *in vitro* toxicologic studies show some evidence that coarse particles may elicit pro-inflammatory effects (EPA, 2004a, section 7.4.4). Further, the Staff Paper assessment of the physicochemical properties and occurrence of ambient coarse particles suggests that both the chemical makeup and the spatial distribution of coarse particles are likely to be more heterogeneous than for fine particles (EPA, 2005, chapter 2). In particular, as discussed below in section III.C, coarse particles in urban areas can contain all of the components found in more rural areas, but can also be contaminated by a number of additional materials, from motor-vehicle-related emissions to metals and transition elements associated with industrial operations. The Staff Paper concluded that the weight of the dosimetric, limited toxicologic, and atmospheric science evidence, taken together, lends support to the plausibility of the $PM_{10-2.5}$-related effects reported in the urban epidemiologic studies discussed below, and provides support for retaining some standard for thoracic coarse particles so as to continue programs to protect public health from such effects (EPA, 2005, p. 5–49).[58]

The available epidemiologic evidence, discussed in section III.A of the proposal, includes studies of associations between short-term exposure to thoracic coarse particles, indexed by $PM_{10-2.5}$, and health endpoints. More specifically, several U.S. and Canadian studies now provide evidence of associations between short-term exposure to $PM_{10-2.5}$ and various morbidity endpoints. Three such studies conducted in Toronto (Burnett *et al.*, 1997), Seattle (Sheppard, 2003), and Detroit (Ito, 2003) report statistically significant associations between short-term $PM_{10-2.5}$ exposure and respiratory- and cardiac-related hospital admissions, and a fourth study (Schwartz and Neas, 2000), conducted in six U.S. cities (Boston, St. Louis, Knoxville, Topeka, Portage, and Steubenville), reports statistically significant associations across these six areas with respiratory symptoms in children. These studies were mostly done in areas in which $PM_{2.5}$, rather than $PM_{10-2.5}$, is the larger fraction of ambient PM_{10}, and they are not representative of areas with relatively high levels of thoracic coarse particles (EPA, 2005, p. 5–49).

In evaluating the epidemiologic evidence from health studies on associations between short-term exposure to $PM_{10-2.5}$ and mortality, the Criteria Document concluded that such evidence was "limited and clearly not as strong" as that for associations with $PM_{2.5}$ or PM_{10} but nonetheless was suggestive of associations with mortality (EPA, 2004a, p. 9–28, 9–32). Statistically significant mortality associations were reported in short-term exposure studies conducted in areas with relatively high $PM_{10-2.5}$ concentrations, including Phoenix (Mar *et al.*, 2003), Coachella Valley, CA (Ostro *et al.*, 2003),[59] and in the initial analysis of data from Steubenville (as part of the Six Cities study, Schwartz *et al.*, 1996; reanalysis, Schwartz, 2003). In a separate reanalysis of the Six Cities study, the $PM_{10-2.5}$ mortality association was not statistically significant for Steubenville (Klemm and Mason, 2003). In areas with lower $PM_{10-2.5}$ concentrations, including the remaining five cities in the Six Cities study, no statistically significant associations were reported with mortality, though most were positive.

The Staff Paper also considered relevant epidemiologic studies indexed by PM_{10} that were conducted in areas where the coarse fraction of PM_{10} is typically much greater than the fine fraction. Such studies include findings of associations between short-term exposure to PM_{10} and hospitalization for cardiovascular diseases in Tucson, AZ (Schwartz, 1997), hospitalization for COPD in Reno/Sparks, NV (Chen *et al.*, 2000), and medical visits for asthma or respiratory diseases in Anchorage, AK (Gordian *et al.*, 1996; Choudhury *et al.*, 1997). In addition, a number of epidemiologic studies have reported significant associations with mortality, respiratory hospital admissions and respiratory symptoms in the Utah Valley area (*e.g.*, Pope, 1989 and 1991; Pope *et al.*, 1992). This group of studies provides additional supportive evidence for associations between short-term exposure to thoracic coarse particles and health effects, particularly morbidity effects, generally in areas not meeting the PM_{10} standards (EPA, 2005, p. 5–50).[60]

In contrast to the findings from the short-term exposure studies discussed above, available epidemiologic studies do not provide evidence that long-term community-level exposure to thoracic coarse particles is associated with mortality or morbidity (EPA, 2005, p. 3–25). More specifically, no association is

[57] The Criteria Document notes that toxicologic studies, in general, use exposure concentrations that are generally much higher than ambient concentrations (EPA, 2004a, p. 9–51).

[58] Eventually, as a result of the data that will be gathered under EPA's new research and monitoring plan, the Agency may be able to further refine its regulation of coarse particles to better target those coarse particles of greatest concern to health.

[59] The Coachella Valley study, like the Seattle study noted above, is subject to additional measurement uncertainties because it used regression techniques to impute $PM_{10-2.5}$ concentrations; this approach fills in missing $PM_{10-2.5}$ data based on relationships developed using data from days when data are available for both PM_{10} and $PM_{2.5}$.

[60] Based on recent air quality data, as well as the summary information provided for PM concentrations used in the studies, the existing PM_{10} standards are not met in any of these study cities except Tucson, AZ. Based on 2002–2004 air quality data, the 98th percentile $PM_{2.5}$ concentrations in three of these areas range from 15 to 25 μg/m^3, while in Utah Valley the concentrations range from 37 to 54 μg/m^3.

found between long-term exposure to thoracic coarse particles and mortality in the reanalyses and extended analysis of the ACS cohort (EPA, 2005, p. 8–306–07). Further, little evidence is available on potential respiratory and cardiovascular morbidity effects of long-term exposure to thoracic coarse particles (EPA, 2005, p. 3–23–24).

The Staff Paper concluded that the available body of health evidence, including dosimetric, toxicologic and epidemiologic study findings, supports retaining a NAAQS that would continue to provide protection against the effects associated with short-term exposure to thoracic coarse particles. However, the substantial uncertainties associated with this limited body of epidemiologic evidence on health effects related to exposure to $PM_{10-2.5}$ suggest a high degree of caution in interpreting this evidence, especially at the lower levels of ambient particle concentrations in the morbidity studies discussed above (EPA, 2005, p. 5–50).

Beyond this evidence-based evaluation, the Staff Paper also considered the extent to which $PM_{10-2.5}$-related health risks estimated to occur at current levels of ambient air quality may be judged to be important from a public health perspective, taking into account key uncertainties associated with the estimated risks. Consistent with the approach used to address this issue for $PM_{2.5}$-related health risks, discussed above in section II.A.3, the Staff Paper considered the results of a series of base-case analyses that reflect in part the uncertainty associated with the form of the concentration-response functions drawn from the studies used in the assessment. In this assessment summarized above in section III.A.3, which is much more limited than the risk assessment conducted for $PM_{2.5}$, health risks were estimated for three urban areas (Detroit, Seattle, and St. Louis) by using the reported linear or log-linear concentration-response functions as well as modified functions that incorporate alternative assumed cutpoints as surrogates for potential population thresholds. In considering the risk estimates from this limited assessment, and recognizing the very substantial uncertainties inherent in basing an assessment on such limited information, the Staff Paper concluded that the results for the two areas in the assessment that did not meet the current PM_{10} standards are indicative of risks that can reasonably be judged to be important from a public health perspective, in contrast to the appreciably lower risks estimated for the area that did meet the current standards (EPA, 2005, p. 5–52).

The Staff Paper recognized the substantial uncertainties associated with the limited available epidemiologic evidence and the inherent difficulties in interpreting the evidence for purposes of setting appropriate standards for thoracic coarse particles. Nonetheless, in considering the available evidence, the public health implications of estimated risks associated with current levels of air quality, and the related limitations and uncertainties, the Staff Paper concluded that this information supports (1) revising the current PM_{10} standards in part by revising the indicator for thoracic coarse particles, and (2) consideration of a standard that will continue to provide public health protection from short-term exposure to thoracic coarse particles of concern that have been associated with morbidity effects and possibly mortality at current levels in some urban areas (EPA, 2005, p. 5–52).

In CASAC's review of these Staff Paper recommendations, there was unanimous agreement among CASAC Panel members that "there was a need for a specific primary standard to address particles in the size range of 2.5 to 10 microns" (Henderson, 2005b, p. 4). In making this recommendation, CASAC indicated its agreement with the summary of the scientific data regarding the potential adverse health effects from exposures to thoracic coarse particles in section 5.4 of the Staff Paper upon which the EPA staff recommendations were based.

Unlike the case in the current $PM_{2.5}$ review, neither EPA staff nor CASAC concluded that it was necessary to revise the PM_{10} standards to provide additional health protection against coarse particles beyond that afforded by the current standards. Rather, as noted above, staff and CASAC found that the most recent scientific information suggested it was possible to move to a more direct measurement of thoracic coarse particles via a $PM_{10-2.5}$ indicator, and this was the major basis for recommending revisions to the current 24-hour PM_{10} standard. In considering what level of protection was appropriate, staff and CASAC recommended consideration of a range of levels for alternative 24-hour coarse particle standards, from levels which would be more stringent than the current 24-hour PM_{10} standard to a level that would provide protection that was roughly equivalent to that provided by the current 24-hour PM_{10} standard.

In considering whether the primary PM_{10} standards should be revised at the time of proposal, the Administrator considered the rationale and recommendations provided by the Staff Paper and CASAC, and the public comments received through the time of proposal. The Administrator provisionally concluded that the health evidence, including dosimetric, toxicologic and epidemiologic study findings, supported retaining a standard to provide continued protection against effects associated with short-term exposure to thoracic coarse particles. Further, the Administrator expressed the belief that the new evidence on health effects from studies that use $PM_{10-2.5}$ as a measure of thoracic coarse particles, together with the much more extensive data now available to characterize air quality in terms of $PM_{10-2.5}$, provided an appropriate basis for revising the current PM_{10} standards in part by revising the indicator to focus more narrowly on particles between 2.5 and 10 μm. The Administrator also noted that the need for a standard for thoracic coarse particles had already been upheld based upon evidence of health effects considerably more limited than now available. *ATA I*, 175 F.3d at 1054. Based on these considerations, the Administrator provisionally concluded that the current suite of PM_{10} standards should be revised, and that the revised standard(s) should be set at a level that would ensure an equivalent level of protection to the current suite of standards (71 FR 2665).

2. Comments on the Need for Revision

The vast majority of public comments on coarse particles raised issues related to the proposed revisions to the indicator for thoracic coarse standards, particularly the proposal to adopt a new $PM_{10-2.5}$ indicator that was qualified to focus on particles associated with particular types of emissions sources and to impose stringent monitor site-suitability criteria for NAAQS-comparable monitors. These comments are addressed below in section III.C. Comments more specific to the 24-hour and annual standards (*i.e.*, on averaging time, form, and level) are addressed below in section III.D. This section addresses those comments that, directly or indirectly, addressed the need to continue the kind of protection against coarse particles that is provided by the current PM_{10} standards.

A substantial majority of commenters supported the Administrator's provisional conclusion that it is necessary to maintain a standard to continue protection against the health effects associated with short-term exposure to thoracic coarse particles. Those advocating a coarse particle standard included public health organizations such as the American Lung Association, the American Heart

Association, and the American Cancer Society; environmental groups such as Environmental Defense, Earthjustice and Natural Resources Defense Council; the Children's Health Protection Advisory Committee, which provides the EPA Administrator with advice on children's health issues; all state and local air pollution control agencies commenting on the proposed coarse particle standard; and Tribal groups such as the National Tribal Caucus, the National Tribal Environmental Council, and numerous individual Tribes.

These commenters agreed with EPA that the currently available scientific evidence clearly supports the need to provide continued protection from health effects associated with coarse particle exposure. Citing the Criteria Document and the Staff Paper, those commenters providing a more detailed rationale stressed the availability of epidemiologic, toxicologic and dosimetric studies showing associations between thoracic coarse particles and multiple morbidity and mortality endpoints. Many of these commenters also cited CASAC's recommendation in favor of continued protection. Moreover, some of these commenters pointed to particular studies, such as Ito (2003), Mar *et al.* (2003) and Ostro *et al.* (2003), which they concluded show that coarse particles are associated with hospital admissions or mortality and that coarse particles may even have stronger effects than fine particles in some instances. Several also cited two recent independent reviews (Brunekreef and Forsberg, 2005; WHO, 2005) which considered many of the same scientific studies on the health effects of coarse particles that were included in the Criteria Document as support for separate standards for coarse particles, in addition to standards for fine particles.

In general, this body of commenters opposed revisions that they believed would reduce the level of protection provided by the current PM_{10} standards. For example, the comments of the American Lung Association and five environmental groups stated (American Lung Association *et al.*, p. 81):

> We strongly support the need for a coarse PM standard * * *. However, the coarse particle standard proposed by EPA is an egregious step backwards in protection of human health and welfare compared to the status quo * * *. If EPA feels it lacks adequate data to undertake the change in the coarse PM indicator to a $PM_{10-2.5}$ standard, without reducing current protections * * * then the Agency must retain the existing PM_{10} NAAQS.

Citing the more abundant evidence from studies focusing on short-term exposures, these commenters advocated maintaining a 24-hour standard for thoracic coarse particles, at a minimum. Several of them also recommended an annual standard for thoracic coarse particles to protect against possible long-term effects, despite a significantly more limited body of evidence (for specific comments on averaging time, see section III.D.1 below).

Many of these commenters, while recognizing that the epidemiologic evidence available to support specific coarse particle standards is weaker than that for fine particles, believed that the weight of evidence required revisions that provided a greater degree of protection, on a national basis, than that afforded by the current PM_{10} standards (for specific comments on level, see section III.D.2 below). Some commenters favoring a coarse particle standard supported their arguments by reference to emerging science from new toxicologic and epidemiologic studies that were not included in the Criteria Document. In general, however, these "new" studies were used in support of commenters' concerns about the proposal to qualify the indicator (discussed in section III.C.2 below), and not to support their comments on the need for coarse particle standards.

The EPA generally agrees with these commenters regarding the need to provide continued protection from short-term exposure to coarse particles that may be harmful. The scientific evidence cited by these commenters was generally the same as that discussed in the Criteria Document and the Staff Paper and the commenters' recommendations for retaining a coarse particle standard are broadly consistent with staff and CASAC recommendations on this issue. To the limited extent that some commenters cited "new" scientific studies in support of their arguments in favor of retaining a coarse particle standard, EPA notes that it is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review. Although EPA is not basing its final decisions in this review on such information, the Agency will consider the newly published studies for purposes of decision making in the next PM NAAQS review, as discussed above in section I.C. Nonetheless, in provisionally evaluating commenters' arguments concerning the need for revision to or elimination of the current standards, the Agency notes that its preliminary analysis suggests such studies would not materially change the conclusions in the Criteria Document.

In sharp contrast, a number of commenters, including virtually all of those representing industry associations and businesses, recommended revising the PM_{10} standards by revoking both the 24-hour and annual standards. These groups argued that the current body of scientific evidence is insufficient to justify either retaining the current PM_{10} standards or setting a revised standard for thoracic coarse particles at this time. These commenters included the National Cattlemen's Beef Association, the National Mining Association, the American Farm Bureau Federation, the Alliance of Automobile Manufacturers, the Engine Manufacturers Association, the National Association of Home Builders, and the Coarse Particle Coalition, which includes the National Stone, Sand and Gravel Association, the Industrial Minerals Association, the American Forest and Paper Association, the Portland Cement Association and the National Cotton Council. These commenters stressed the uncertainties, particularly those associated with interpreting the limited number of epidemiologic studies focusing on coarse particle health effects, and stated that EPA had failed to demonstrate that a coarse particle standard is necessary to protect public health. These commenters recommended deferring the decision on the appropriateness of setting a coarse particle standard pending additional monitoring and scientific research on health effects associated with exposure to coarse particles.

These commenters criticized the key epidemiologic studies cited by EPA, referring especially to the alternative interpretations of the evidence presented in the proposal and citing a review and critique of key studies prepared by an academic consultant. They also argued that all coarse particle epidemiologic studies are flawed to the extent that they rely on air quality data from central monitors in exposure assessments. Based on these arguments, the commenters asserted that EPA's risk assessment cannot be used to demonstrate that ambient coarse particles present a significant risk to public health, and therefore EPA cannot maintain the existing PM_{10} NAAQS or establish a revised NAAQS to address coarse particles. Each of these issues is further summarized and discussed below.

In discussing their disagreement with EPA's interpretation of four key epidemiologic studies (Ito, 2003; Burnett *et al.*, 1997; Mar *et al.*, 2003; Ostro *et al.*, 2003), these commenters placed significant weight on the alternative interpretations of these

studies that EPA provided in the proposal to encourage additional public comment (71 FR 2671–72). In particular, they criticized EPA's reliance on the single pollutant models in these and other studies as biased because the models omit $PM_{2.5}$ and gaseous co-pollutants. The commenters argued that when $PM_{2.5}$ or gaseous co-pollutants were added to the underlying models, the effects associated with $PM_{10-2.5}$ lost statistical significance. These commenters also stated that EPA failed to consider and give appropriate weight to a significant number of studies which relied on larger and more powerful data sets, were of longer duration, and assessed $PM_{10-2.5}$ using multi-pollutant models, but did not find any statistically significant associations, including Schwartz *et al.* (1996), Thurston *et al.* (1994), Sheppard (2003), Fairley (2003), and Lipfert *et al.* (2000). They further summarized and attached a "detailed review of the cited studies" prepared by an academic consultant, which they stated reveals numerous deficiencies that undermine the use of these studies to support the proposed coarse particle standard or any alternative standard. Based on all of the above, one commenter claimed that a "fair and sound" assessment of evidence would not conclude coarse particles have effects at ambient concentrations (National Mining Association, p. 14).

The rationale for these commenters' conclusions, however, do not consider important aspects of the rationale for retaining coarse particle protection and are inconsistent with CASAC and other recent reviews of the scientific evidence. As summarized in section III.A of the proposal, the scientific evidence contained in the Criteria Document and Staff Paper, both of which have been reviewed and found acceptable for use in regulatory decision making by CASAC, supports the need for some standard to provide continued protection from coarse particles.[81] The alternative interpretation of the evidence espoused by these commenters essentially argues that it is more reasonable to presume that the positive results from one-pollutant $PM_{10-2.5}$ statistical models is the result of bias associated with omitting co-pollutants, especially $PM_{2.5}$, for which the evidence is much stronger. EPA does not accept this argument for both technical and public health policy reasons. The Criteria Document and Staff Paper explain the rationale for reliance on single pollutant models in these studies, while recognizing the significant uncertainties in the limited number of studies available (EPA, 2004, section 8.4.3; EPA, 2005, p. 3–46). These documents illustrate the results of a number of studies that examined co-pollutants (Figures 8–16 through 8–18 of the Criteria Document), where it can be seen that, in most cases, the inclusion of gaseous co-pollutants does little to change the effects estimate for $PM_{2.5}$, although in some cases it does. Recognizing the additional uncertainties in measuring coarse particles (as discussed below), these documents further note the importance of the relative consistency in the size of effects estimates for coarse particles as well as the pattern of generally positive associations, and the need for considering the results of recent statistically significant associations found in PM_{10} studies where it is reasonable to expect that the coarse fraction dominated the distribution. It would be unwise to presume, in the face of this evidence, that the single pollutant result for coarse particles is generally the result of omitted gases in the model.

EPA also believes that it is inappropriate to presume that coarse particle or PM10 associations in single or multi-pollutant models can be wholly explained by fine particles. In studies where $PM_{2.5}$ and $PM_{10-2.5}$ have similar effect estimates, it is difficult to determine whether one or both contribute to the result (*e.g.* EPA 2004a, p 8–61). The comparison of $PM_{2.5}$ and $PM_{10-2.5}$ is further complicated by the differential measurement error between the two pollutants, which is generally greater for coarse particles (as discussed below). When both pollutants have similar effect estimates, it is difficult to determine whether one or both contribute to the result (*e.g.* EPA, 2004a, p. 8–61). Some studies conducted in urban areas, however, have found significant associations for coarse particles, but not fine particles. The Criteria Document summarizes a case cross-over study (Lin *et al.*, 2002) conducted in Toronto, that found a significant association of $PM_{10-2.5}$ with asthma hospital admissions in children ages 6–12 that was robust to the inclusion of gaseous co-pollutants, but did not report significant associations for $PM_{2.5}$.[82] Three different studies used essentially the same air quality data set to examine coarse and fine particles in Phoenix (Mar *et al.*, 2000, 2003; Clyde, 2000; Smith *et al.*, 2000). All three studies found significant associations between mortality and $PM_{10-2.5}$, but only one found a significant association for $PM_{2.5}$ (EPA, 2004a, p. 8–57 to 66). Ito (2003) found a significant association in Detroit between hospital admissions for ischemic heart disease and exposure to coarse particles, but not fine particles. While all of these studies have limitations, it is difficult to ignore the fact that, despite the differential measurement error associated with coarse particles, a number of these studies find statistically significant associations for coarse particles, but not for fine particles. For these reasons, EPA believes that it would be inappropriate, based on the limited data currently available, to presume that all of the effects associated with coarse particles in single pollutant models are actually the result of confounding by fine particles.

It is also important to note that in the NAAQS reviews that concluded in 1987 and 1997, EPA found that the scientific evidence then available supported the need to continue regulation of thoracic coarse particles through appropriate NAAQS. This evidence included mechanistic considerations developed from particle dosimetry and toxicology, as well as an integrated assessment of particle composition and both community and occupational epidemiologic studies. By 1997, EPA judged the evidence to be strong enough to propose separate standards for fine and coarse particles. While the D.C. Circuit found problems with the indicator for thoracic coarse particles promulgated in 1997, the court upheld EPA's determination that a standard was needed (*ATA I*, 175 F.3d at 1054). In EPA's judgment, the more recent studies included in the 2004 Criteria Document, even with their recognized limitations, serve to add to, not reduce, the concern present in previous reviews over ambient exposures to coarse particles, particularly in urban areas.

The business and industry commenters also suggested that the epidemiologic studies were flawed by the reliance on data from central monitors to estimate community-level exposures to coarse fraction particles. According to these commenters, this would result in an overestimation of

[81] The Response to Comments document contains more detailed responses to the specific issues these commenters raise regarding the interpretation of the epidemiologic evidence, which is important in terms of the use of these studies for supporting a coarse standard [this section of the preamble] as well as their use in deciding upon an appropriate level of protection [section III.D.2 of this preamble].

[82] Unlike more commonly used time series studies, the design used in this study has the advantage of controlling for confounding by having each case serve as its own control. The Criteria Document notes limitations in available measurement information and adjustment for season that may have influenced the relative results for fine and coarse particles (EPA, 2004a, pp. 185–186).

exposure due to the significant spatial variability associated with coarse particle distributions. Such overestimation, in the commenters' view, would invalidate any statistical associations found between ambient data, as measured by the central monitors, and adverse health effects. The National Mining Association (p. 16–17), for example, noted:

> The spatial variability of coarse PM renders even the few, limited, uncertain epidemiological studies that have been cited by EPA invalid, as well as imprecise * * *. Given that the purported associations between PM coarse and health effects is small to begin with, 71 FR at 2659, the logical conclusion should be that the lack of a demonstrable connection between the monitored ambient data and the level of exposure of the subject population is a fatal flaw that precludes reliance on the studies for any connection between PM coarse and health effects.

These commenters also provided supporting information regarding correlations among monitors and an air quality modeling analysis purporting to show that significant quantities of coarse particles cannot travel more than 1 kilometer from sources.[63]

The Criteria Document and Staff Paper contain detailed analyses of the spatial variability of coarse particle concentrations, as well as other issues that generally result in greater exposure measurement error for coarse particles as compared to fine particles (EPA, 2004a, p. 3–52–53, Appendix 3A; EPA, 2005, pp. 2–36–40, 2–70–73). While EPA agrees that coarse particle measurements from central monitors is subject to potentially large measurement error when used to reflect population exposures in epidemiologic studies, the Agency disagrees with the commenters' assessment of the direction of the resulting bias and with their conclusion that any statistically significant associations between centrally monitored air quality concentrations and adverse health effects measured in these studies are invalid as a result. This issue received substantial attention in the Criteria Document (EPA, 2004a, section 8.4.5). The Criteria Document concluded that such measurement errors are more likely to underestimate the strength and the significance of any association between coarse particles and any adverse health effects observed in the study (EPA, 2004a, pp. 5–126, 8–341). While the spatial variation of coarse particle data is larger than for fine particles, the Staff Paper notes that, on a day-to-day basis, coarse particle data from monitor sites within an urban area can be fairly well correlated, even when substantial differences exist in the absolute concentrations between the sites (EPA, 2005, p. 3–41). The signal that drives statistical associations between ambient concentrations and health effects in time-series studies is the day-to-day changes in concentration, not the absolute daily values. To the extent possible, EPA examined both the day-to-day correlations and annual averages in $PM_{10-2.5}$ taken from multiple monitors in key study locations, such as Detroit, Phoenix and Coachella Valley (Ross and Langstaff, 2005).[64]

In reacting to this issue in opposing comments, the California Air Resources Board similarly stated:

> The current scientific consensus suggests that measurement of coarse particles will typically involve greater errors than that of fine particles. However we reject the * * * implication that therefore these studies are not reliable. In fact, the larger measurement error, which is likely to be random, would make it more difficult to find an association with mortality. It is well accepted in the epidemiological literature that such measurement error will tend to obscure a relationship between an exposure and a given health outcome, assuming that such a relationship exists. Therefore, the measurement error argument cannot be used to nullify an effect that has been observed. If anything, it is likely that the real effects are likely to be larger than those that were estimated. (CARB, p. 11)

The EPA agrees with CARB's analysis of the issue. Therefore, for the purposes of determining whether public health protection is warranted in light of the available evidence, EPA believes that it has interpreted the evidence from these epidemiologic studies correctly, and that despite the uncertainties, the evidence of statistically significant relationships between exposure to coarse particles and adverse health effects is sufficiently strong to support continued regulation of coarse particles.

Some commenters opposed to maintaining a coarse particle standard criticized EPA's risk assessment. These commenters stated that current short-term epidemiologic data are insufficient to serve as the basis for a scientifically sound quantitative risk assessment, without which, they claim, EPA lacks sufficient evidence to establish a standard based on those data. According to these commenters, while EPA may exercise its judgment about future risks and set standards that are preventive in nature, as long as an adequate scientific rationale is presented, the Agency does not have the authority to engage in "crystal ball speculation" in the absence of support in the record considered as a whole. (*See e.g.*, Coarse Particle Coalition, p. 8–9, citing *Lead Industries Assoc* v. *EPA*, 647 F. 2d 1130, 1146–7 (DC Cir. 1980), *NRDC* v. *EPA*, 902 F.2d 962, 968, 971 (D.C. Cir. 1990) and *Ethyl Corp.* v. *EPA*, 541 F.2d 1, 13 (D.C. Cir. 1976).) These commenters stated that the NAAQS must address only "significant risk", not any risk, and that EPA has failed to demonstrate that coarse particles pose a significant enough risk to human health to warrant a coarse particle standard.

The EPA disagrees on technical, policy, and legal grounds. For reasons specified in the proposal and summarized above, EPA believes that the available scientific evidence is more than adequate to support a decision to continue regulation of coarse particles under the NAAQS. Although the data are weaker than for fine particles and subject to greater measurement error, in several of the studies where comparisons are possible, the normalized relative risk estimates for coarse particles from the new urban/industrial-area studies that were included in the Criteria Document often fall into a similar range as those for fine particles (EPA, 2004a, p. 8–64; EPA, 2005, pp. 3–13 and 3–20). Furthermore, as summarized above, EPA did produce a risk assessment for thoracic coarse particles, which was reviewed by CASAC and included in the Staff Paper (EPA, 2005, Chapter 4). While the limited number of cities and the significant uncertainties noted in the risk assessment and the proposal limit their quantitative usefulness, EPA staff concluded that the risk assessment results for the two urban areas in the assessment that did not meet the current PM_{10} standards are indicative of risks that can reasonably be judged to be important from a public health perspective.

Furthermore, there is no requirement that EPA develop a "scientifically sound quantitative risk assessment" before adopting or revising a NAAQS (ATA III, 283 F.3d at 374), or that the Agency must demonstrate significant risk before promulgating a NAAQS.[65] EPA's reliance on evidence from peer-

[63] This issue is discussed in more detail in the Response to Comments document.

[64] In Phoenix, for example, two key sites were highly correlated with similar means. In Detroit/Windsor, correlations were moderate to good, but absolute values were significantly higher in Detroit (Ross and Langstaff, 2005).

[65] See *e.g.*, *American Petroleum Inst.* v. *Costle*, 665 F. 2d at 1186–87: "In setting margins of safety the Administrator need not regulate only the known dangers to health, but may "err" on the side of overprotection by setting a fully adequate margin of safety. Of course the Administrator's conclusions must be supported by the record, and he may not engage in sheer guesswork. Where the Administrator bases his conclusion as to an adequate margin of safety on a reasoned analysis and evidence of risk, the court will not reverse."

reviewed scientific studies in this review, as well as its reliance on CASAC's unanimous recommendation that there is a need for a standard for thoracic coarse particles, cannot be considered "crystal ball speculation."

After careful consideration of all of these comments, EPA continues to believe that the health evidence, including dosimetric, toxicologic and epidemiologic study findings, supports retaining a standard to protect against effects associated with short-term exposure to thoracic coarse particles. As noted above and summarized in section III.A of the proposal, there is a growing body of evidence suggesting causal associations between short-term exposure to thoracic coarse particles and morbidity effects, such as respiratory symptoms and hospital admissions for respiratory diseases, and possibly mortality. As summarized in the proposal (71 FR 2659), the available body of evidence also suggests there is a lack of such effects associated with long-term exposure to thoracic coarse particles. Considering the magnitude of the risks identified in health studies, and the size of potentially susceptible subpopulations such as people with preexisting respiratory diseases, including asthma, and children and older adults, EPA concludes that short-term exposure to thoracic coarse particles can have an important public health impact. The health evidence regarding effects of thoracic coarse particles is limited in some respects and still subject to significant uncertainty. The Administrator has concluded that it is a priority to establish a robust research program that will enable future PM NAAQS reviews to make more informed decisions that will provide more targeted protection against the effects only of those coarse particles and related source emissions that prove to be of concern to public health. The Administrator also notes that the need for a standard for thoracic coarse particles has already been upheld based upon evidence of health effects considerably more limited than now available (*ATA I*, 175 F.3d at 1054).

In the judgment of the Administrator, it is appropriate at this time to retain a standard to address the known and potential public health risks associated with exposure to coarse particles. The Administrator's specific decisions regarding the indicator, averaging time, level and form of a standard for thoracic coarse particles are described below.

C. Indicator for Thoracic Coarse Particles

1. Introduction

As outlined above, at the time of proposal the Administrator judged it appropriate, based on an evaluation of the available scientific evidence, to propose a new indicator of thoracic coarse particles defined to include those particles between 2.5 and 10 μm in diameter, or $PM_{10-2.5}$, and qualified to focus on the mix of thoracic coarse particles generally present in urban environments. In making this determination, the Administrator relied heavily on key findings and observations from the Criteria Document and Staff Paper, and on recommendations from CASAC. The Staff Paper made the following general observations about the $PM_{10-2.5}$ indicator:

(1) The most obvious choice for a thoracic coarse particle standard is the size-differentiated, mass-based indicator used in the epidemiologic studies that provide the most direct evidence of such health effects, $PM_{10-2.5}$.

(2) The upper size cut of a $PM_{10-2.5}$ indicator is consistent with dosimetric evidence that continues to reinforce the finding from past reviews that an aerodynamic size of 10 μm is a reasonable separation point for particles that penetrate to and potentially deposit in the thoracic regions of the respiratory tract.

(3) The lower size cut of such an indicator is consistent with the choice of 2.5 μm as a reasonable separation point between fine and coarse fraction particles.

(4) Further, the limited available information is not sufficient to define an indicator for thoracic coarse particles solely in terms of metrics other than size-differentiated mass, such as specific chemical components.

(5) The available epidemiologic evidence for effects of $PM_{10-2.5}$ exposure is quite limited and is inherently characterized by large uncertainties, reflective in part of the more heterogeneous nature of the spatial distribution and chemical composition of thoracic coarse particles and the more limited and generally uncertain measurement methods that have historically been used to characterize their ambient concentrations.

In evaluating relevant information from atmospheric sciences, toxicology, and epidemiology related to thoracic coarse particles, the Staff Paper also noted that there appear to be clear distinctions between (1) the character of the ambient mix of particles generally found in urban areas as compared to that found in non-urban and, more specifically, rural areas, and (2) the nature of the evidence concerning health effects associated with thoracic coarse particles generally found in urban versus rural areas.[55] Based on such information, and on specific initial advice from CASAC (Henderson, 2005a), the Staff Paper considered a more narrowly defined indicator for thoracic coarse particles that would focus on the mix of such particles that is characteristic of the mix generally found in urban areas where thoracic coarse particles are strongly influenced by traffic-related or industrial sources. In so doing, the Staff Paper focused on comparing the potential health effects associated with thoracic coarse particles in urban and rural settings, as discussed below.

The Staff Paper also noted that atmospheric science and monitoring information indicates that exposures to thoracic coarse particles tend to be higher in urban areas than in nearby rural locations. Further, the mix of thoracic coarse particles typically found in urban areas contains a number of contaminants that are not commonly present to the same degree in the mix of natural crustal particles that is typical of rural areas. The elevation of $PM_{10-2.5}$ levels in urban locations as compared to those at nearby rural sites suggests that sources located within urban areas are generally the cause of elevated urban concentrations; conversely, $PM_{10-2.5}$ concentrations in such urban areas are not largely composed of particles blown in from more distant regions (EPA, 2005, sections 2.4.5 and 5.4.2.1). Important sources of thoracic coarse particles in urban areas include dense traffic that suspends significant quantities of dust from paved roads, as well as industrial and combustion sources and construction activities that contribute to ambient coarse particles both directly and through deposition to soils and roads (EPA, 2005, Table 2–2).

[55] In general, EPA believes it is appropriate to draw a distinction between two general types of ambient mixes of coarse particles: "urban" and "non-urban". The first term characterizes the mix in more heavily populated urban areas, where sources such as motor vehicles and industry contribute heavily to ambient coarse particle concentrations and composition. The term "non-urban," on the other hand, encompasses mixes in a variety of other locations outside of urbanized areas, including mixes in rural areas which are likely to be dominated by natural crustal materials (and where urban types of sources are largely absent or, in the case of motor vehicles, are not present to the same degree). It should be noted that some types of sources are present in both urban and non-urban areas. Industrial sources, for example, are found in non-urban areas, though they are more commonly located in urban areas. Similarly, agricultural and mining sources are primarily non-urban sources, but may be found in or near urban areas as well.

The Staff Paper concluded that the mix of thoracic coarse particles in urban areas would likely differ in composition from that in rural areas, being influenced to a relatively greater degree by components from urban mobile and stationary source emissions.

While detailed composition data are more limited for $PM_{10-2.5}$ than for $PM_{2.5}$, available measurements from some areas as well as studies of road dust components do show a significant influence of urban sources on both the composition and mass of thoracic coarse particles generally found in urban areas. Although crustal elements and natural biological materials represent a significant fraction of thoracic coarse particles in urban areas, both their relative quantity and character may be altered by urban sources (EPA, 2005, p. 5–54). Traffic-related activities can also grind and resuspend vegetative materials into forms not as common in more natural areas (Rogge *et al.*, 1993). Studies of urban road dusts find that levels of a variety of components are increased from traffic as well as from other anthropogenic urban sources, including products of incomplete combustion (*e.g.* polycyclic aromatic hydrocarbons) from motor vehicle emissions and other sources, brake and tire wear, rust, salt and biological materials (EPA, 2004a, p. 3D–3). Limited ambient coarse fraction composition data from various comparisons show that metals and sometimes elemental carbon contribute a greater proportion of thoracic coarse particle mass in urban areas than in nearby rural areas. In addition, while large uncertainties exist in emissions inventory data, the Staff Paper observed that major sources of $PM_{10-2.5}$ emissions in the urban counties in which epidemiologic studies have been conducted are paved roads and "other" sources (largely construction), and that such areas also have larger contributions from industrial emissions, whereas unpaved roads and agriculture are the main sources of $PM_{10-2.5}$ emissions outside of urban areas.

In the proposal, EPA also stated that toxicologic studies, although quite limited, support the view that thoracic coarse particles from sources common in urban areas are of greater concern than uncontaminated materials of geologic origin. One major source of thoracic coarse particles in urban areas is paved road dust; the Criteria Document discussed results from a recent toxicologic study in which road tunnel dust particles had greater allergy-related activity than several other particle samples (Steerenberg *et al.*, 2003; EPA, 2004a, pp. 7–136–137). This study supports evidence available in the last review regarding potential effects of road dust particles (EPA, 1996b, p. V–70). In contrast, a number of studies have reported that Mt. St. Helens volcanic ash, an example of uncontaminated natural crustal material of geologic origin, has very little toxicity in animal or *in vitro* toxicologic studies (EPA, 2004a, p. 7–216).

A few toxicologic studies have used ambient thoracic coarse particles from urban/suburban locations ($PM_{10-2.5}$), and the results suggest that effects can be linked with several components of $PM_{10-2.5}$. These *in vitro* toxicologic studies linked thoracic coarse particles with effects including cytotoxicity, oxidant formation, and inflammatory effects (EPA, 2005, sections 3.2 and 5.4.1). While these studies cannot be used for quantitative assessment of morbidity or mortality effects, they suggest that several components (*e.g.*, metals, endotoxin, other materials) may have roles in various health responses but do not suggest a focus on any individual component.

Although largely focused on undifferentiated PM_{10}, the series of epidemiologic observations and toxicologic experiments related to the Utah Valley suggest that directly emitted (fine and coarse) and resuspended (coarse) urban industrial emissions are of concern. Of particular interest are area studies spanning a 13-month period when a major source of PM_{10} in the area, a steel mill, was not operating. Observational studies found that respiratory hospital admissions for children were lower when the plant was shut down (Pope, 1989). More recently, a set of toxicologic and controlled human exposure studies have used particles extracted from filters from ambient PM_{10} monitors from periods when the plant did and did not operate. In both human volunteers and animals, greater lung inflammatory responses were reported with particles collected when the source was operating, as compared to the period when the plant was closed (EPA, 2004a, p. 9–73). In addition, in some studies it was suggested that the metal content of the particles was most closely related to the effects reported (EPA, 2004a, p. 9–74). While peak days in the Utah Valley occur in conditions that enhance fine particle concentrations, over the long run, over half of the PM_{10} was in the coarse fraction. The aggregation of particles collected on the filters during the study period reflects this long-term composition and represent the kinds of industrial components that would be incorporated in road dusts in the area.

The Staff Paper also noted that epidemiologic studies that have examined exposures to thoracic coarse particles generally found in urban environments, together with studies that have taken into account exposures to natural crustal materials typical of rural areas, generally support the view that the mix of thoracic coarse particles generally found in urban areas is of concern to public health, in contrast to natural crustal dusts of geologic origin. With respect to the urban results, several recent studies have shown associations between $PM_{10-2.5}$ and health outcomes in a few sites across the U.S. and Canada. Associations have been reported with morbidity in a few urban areas, some of which had relatively low $PM_{10-2.5}$ concentrations. For mortality, statistically significant associations have been reported only for two urban areas that have notably higher ambient $PM_{10-2.5}$ concentrations. These associations are with short-term exposures to aggregated $PM_{10-2.5}$ mass, and no epidemiologic evidence is available on associations with different components or sources of $PM_{10-2.5}$. However, these studies have all been conducted in urban areas of the U.S., and thus reflect effects associated with the ambient mix of thoracic coarse particles generally present in urban environments, which includes PM from traffic and industrial sources.

The Staff Paper also pointed to other evidence from epidemiologic studies suggesting that mortality and possibly other health effects are not associated with thoracic coarse particles from dust storms or other such wind-related events that result in suspension of natural crustal materials of geologic origin. The clearest example is a study in Spokane, WA, which specifically assessed whether mortality was increased on dust-storm days using case-control analysis methods. The average PM_{10} level was more than 200 $\mu g/m^3$ higher on dust storm days than on control days, and the authors report no evidence of increased mortality on these specific days (Schwartz *et al.*, 1999). One caveat of note is the possibility that people may reduce their exposure to ambient particles on the dustiest days (*e.g.*, Gordian *et al.*, 1996; Ostro *et al.*, 2000). Nevertheless, these studies provide no suggestion of significant health effects from uncontaminated natural crustal materials that would typically form a major fraction of coarse particles in rural areas.

Beyond the urban and rural distinctions discussed above, the Staff Paper also considered the extent to which there is evidence of effects from

exposure to the ambient thoracic coarse particles in communities predominantly influenced by agricultural or mining sources.[57] For example, in the last review, EPA considered health evidence related to long-term silica exposures from mining activities, but found that there was a lack of evidence that such emissions contribute to effects linked with ambient PM exposures (EPA, 1996b, p. V–28). Similarly in this review, there is an absence of evidence related to such community exposures. While crustal and organic dusts generated from agricultural activity can include a variety of biological materials, and some occupational studies discussed in the Criteria Document report effects at occupational exposure levels (EPA, 2004a, Table7B–3, p. 7B–11), such studies do not provide relevant evidence for effects at the much lower levels of community exposure. Further, it is unlikely that such predominantly non-urban sources contribute to the effects reported in the recent urban epidemiologic studies.

The Criteria Document concluded its integrated assessment of the effects of natural crustal materials as follows:

> Certain classes of ambient particles appear to be distinctly less toxic than others and are unlikely to exert human health effects at typical ambient exposure concentrations (or perhaps only under special circumstances). For example, particles of crustal origin, which are predominately in the coarse fraction, are relatively non-toxic under most circumstances, compared to combustion-related particles (such as from coal and oil combustion, wood burning, etc.) However, under some conditions, crustal particles may become sufficiently toxic to cause human health effects. [EPA, 2004a, p. 8–344]

The Staff Paper assessment of the available evidence relevant to the appropriate scope of an indicator for coarse particles can be summarized as follows. Ambient concentrations of thoracic coarse particles generally reflect contributions from local sources, and the limited information available from speciation of thoracic coarse particles and emissions inventory data indicate that the sources of thoracic coarse particles in urban areas generally differ from those found in non-urban areas. As a result, the mix of thoracic coarse particles people are typically exposed to in urban areas can be expected to differ appreciably from the mix typically found in non-urban or rural areas. Ambient $PM_{10-2.5}$ exposure is associated with health effects in studies conducted in urban areas, and the limited available health evidence more strongly implicates the ambient mix of thoracic coarse particles that is dominated by traffic-related and industrial sources than that dominated by uncontaminated soil or geologic sources. The limited evidence does not support either the existence or the lack of causative associations for community exposures to thoracic coarse particles from agricultural or mining industries. Given the apparent differences in composition and in the epidemiologic evidence, the Staff Paper concluded that it is not appropriate to generalize the available evidence of associations with health effects that have been related to thoracic coarse particles generally found in urban areas and apply it to the mix of particles typically found in non-urban or rural areas (EPA, 2005, p. 5–57). The Staff Paper concluded that the available evidence collectively suggests that a more narrowly defined indicator for thoracic coarse particles should be considered that would protect public health against effects that have been linked with the mix of thoracic coarse particles generally present in urban areas. Such an indicator would be principally based on particle size, but also reflect a focus on the mix of thoracic coarse particles that is generally present in urban environments and the sources that principally generate that mix. The Staff Paper recommended consideration of thoracic coarse urban particulate matter ($UPM_{10-2.5}$) as an indicator for a thoracic coarse particle standard, referring to the mix of airborne particles between 2.5 and 10 μm in diameter that are generally present in urban environments, which, as discussed above, are principally comprised of resuspended road dust typical of high traffic-density areas and emissions from industrial sources and construction activities (EPA, 2005, p. 5–54, 5–57–58). The Staff Paper concluded that such an indicator would more likely be an effective indicator for standards to protect against health effects that have been associated with thoracic coarse particles than a more broadly focused $PM_{10-2.5}$ indicator. This indicator would also be consistent with a cautious interpretation of the epidemiologic evidence that does not potentially over-generalize the results of the limited available studies.

In conjunction with this recommendation of an indicator defined in terms of the mix of thoracic coarse particles that are generally present in urban areas, the Staff Paper also discussed the importance of a monitoring network designed to be consistent with the intent of such an indicator and to facilitate implementation of such a standard. It should be noted that EPA has historically used other implementation-related policies, specifically its guidelines regarding the handling of data affected by exceptional or natural events, to address elevations in thoracic coarse particle levels that may occur in urban areas as a result of dust storms or other such events for which the staff-recommended indicator was not intended to apply. The Staff Paper recommended that both new criteria for monitor network design and revised natural/exceptional events policies should work in concert with a revised thoracic coarse particle indicator to ensure the most effective application of a thoracic coarse particle standard.

In its review of the Staff Paper recommendation for a thoracic coarse particle indicator (Henderson, 2005b, p. 4), the CASAC generally agreed that "thoracic coarse particles in urban areas can be expected to differ in composition from those in rural areas;" that "coarse particles in urban or industrial areas are likely to be enriched by anthropogenic pollutants that tend to be inherently more toxic than the windblown crustal material which typically dominates coarse particle mass in arid rural areas;" and that "evidence of associations with health effects related to urban coarse-mode particles would not necessarily apply to non-urban or rural coarse particles." Further, most CASAC Panel members concurred that "the current scarcity of information on the toxicity of rural dusts makes it necessary" for EPA to base its standard for thoracic coarse particles "on the known toxicity of urban-derived coarse particles." While most Panel members concurred with the thoracic coarse particle indicator recommended in the Staff Paper, a few members recommended specifying an unqualified $PM_{10-2.5}$ indicator in conjunction with monitoring network design criteria and natural/exceptional events policies that would emphasize urban influences. In either case, CASAC indicated that the intent of any such indicator should be to "provide protection against those components of $PM_{10-2.5}$ that arise from anthropogenic activities occurring in or near urban and industrial areas."

Based on these considerations, the Administrator proposed to establish a new indicator for thoracic coarse particles in terms of $PM_{10-2.5}$, qualified so as to include any ambient mix of $PM_{10-2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and PM generated

[57] As used in the Staff Paper, the term "mining sources" is intended to include all activities that encompass extraction and/or mechanical handling of natural geologic crustal materials. In the context of this rulemaking, neither mining nor agricultural sources are included in the more general category of "industrial sources."

by industrial sources and construction sources, and to exclude any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources (71 FR 2667–68). Furthermore, EPA proposed that "[a]gricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting this standard" (71 FR 2699). As summarized above in section I.E, the proposed standard also included specific monitor site-suitability requirements which any monitor would have to meet in order to be used for comparison to the NAAQS, including a requirement that such monitors be sited in urbanized areas with a minimum population of 100,000. These requirements were designed to ensure that the monitors were capturing the ambient mix of $PM_{10-2.5}$ dominated by the sources of concern.

Subsequent to the proposal, CASAC provided additional comments to the Administrator on the proposed indicator for thoracic coarse particles. In a letter dated March 21, 2006, the Committee stated that "the PM Panel was pleased to see that the indicator for coarse thoracic particles of concern to public health took into account some of the various approaches that the PM Panel identified for consideration" (Henderson 2006, p. 4). The CASAC reiterated its earlier statement that "the current scarcity of information on the toxicity of rural dusts makes it necessary for the Agency to base its regulations on the known toxicity of urban-derived coarse particles." However, the Committee went on to say that "the CASAC neither foresaw nor endorsed a standard that specifically exempts all agricultural and mining sources, and offers no protection against episodes of urban-industrial $PM_{10-2.5}$ in areas of populations less than 100,000." The Committee recommended the "expansion of our knowledge of the toxicity of rural dusts rather than exempting specific industries (e.g. mining, agriculture)" from control under the standard (*id* at 5).

2. Comments on Indicator for Thoracic Coarse Particles

The EPA received a large number of comments on its proposed decision with regard to the indicator of thoracic coarse particles which overwhelmingly opposed the proposed indicator. Few commenters unconditionally supported EPA's proposal to replace the PM_{10} indicator with a qualified $PM_{10-2.5}$ indicator that would provide targeted protection by including certain ambient mixes of thoracic coarse particles and excluding others. Support for the proposed approach came almost entirely from those industrial sectors whose sources were excluded from the proposed qualified $PM_{10-2.5}$ indicator (*i.e.*, agriculture and mining interests). While these commenters argued that EPA should not maintain any standard for thoracic coarse particles, they conditionally supported the qualified indicator if any standard were to be set. In contrast, all other commenters, including environmental and public health groups, State and local agencies, and industries not excluded from the proposed indicator (*e.g.*, transportation and construction), opposed the proposed qualified indicator. Representatives from a variety of groups who otherwise disagreed on various aspects of the proposed indicator commented on the need for additional research to address the uncertainties in the current body of evidence regarding coarse particles and health effects. In addition, a variety of commenters urged EPA to deploy additional $PM_{10-2.5}$ monitors in both urban and rural areas, consistent with the advice of CASAC, to provide a more robust and complete body of evidence regarding coarse particle effects.

Commenters conditionally supporting the proposal expressed the view that EPA should exclude non-urban windblown dust and soil from the $PM_{10-2.5}$ indicator. According to these commenters, "such particles have been shown to be nontoxic, and the scientific studies show that they are not associated with adverse health effects' (American Farm Bureau Federation, p. 1). Furthermore, these commenters agreed with the proposed exclusion for agricultural and mining sources, stating that "the preponderance of scientific evidence continues to demonstrate that fugitive dust from agricultural and mining operations presents no substantial health or welfare concerns' (National Mining Association, p. 1; see also National Cattlemen's Beef Association, p. 1). These commenters quoted extensively from the Criteria Document and Staff Paper, and made points that were in many cases conceptually similar to the arguments in these documents and in the proposal. These commenters also tended to argue that there is substantial scientific evidence showing an absence of health effects from rural particles.

These commenters cited differences in the composition of the mix of particles in urban areas versus the mix of particles in non-urban areas, which they stated is dominated by wind-blown soil fractions including silicates, primary organic materials including ground plant matter, residential wood smoke, and dust from unpaved roads. Though the coarse particle mix in urban areas also contains significant crustal materials, the commenters stated that it is contaminated by a wide variety of industrial and combustion-related byproducts, such as metals and organic materials (tire and brake wear, vehicle exhaust, industrial emissions, residential fuel combustion). These commenters noted that studies conducted in urban areas have linked health effects specifically to these urban-industrial contaminants. For example, the American Farm Bureau Federation cited the distinction between studies that found health effects related to traffic emissions in urban areas (Pearson *et al.*, 2000; Kramer *et al.*, 2000; and Lin *et al.*, 2002) and a study they suggested found a strong association between cardiovascular mortality and motor vehicle exhaust components, but a negative association between soil and total mortality (Mar *et al.*, 2000).[58] Some of these commenters argued that coarse mode particles, especially crustal coarse mode particles, are unlikely to serve as carriers of urban-area contaminants because they have less surface area, do not adsorb contaminants easily, and have short atmospheric residence times. These commenters conditionally agreed with EPA's proposed goal of focusing regulatory efforts on the sources known to be associated with toxic coarse particles, especially traffic (Coarse Particle Coalition). Some of these commenters cited new studies completed after the close of the Criteria Document as providing additional evidence of associations between traffic-related emissions and adverse health effects (*e.g.* Kim *et al.*, 2004; Ryan *et al.*, 2005; Gershick *et al.*, 2003; McDonald *et al.*, 2004; and Ostro *et al.*, 2006).

These commenters also stated that while urban contaminants may increase the toxicity of coarse particles, studies have demonstrated a lack of adverse effects associated with exposure to coarse particles in non-urban areas (*e.g.*, Buist *et al.* (1983) study of exposure to Mount St. Helens' ash among diabetic children). Furthermore, these commenters argued that studies have found a lack of effects associated with exposure to crustal materials in general. They cited the lack of an association between mortality and dust storms found in Schwartz *et al.* (1999) and also noted that studies such as the 6-city study by Laden *et al.* (2000) have found

[58] Commenters cite the original publication. In the subsequent reanalysis, the investigators report "our original findings remained unchanged" (Mar *et al.* 2003).

that crustal material, in both the fine and coarse fractions, is not associated with increased mortality. Thus, these commenters argued that there is sufficient evidence to show that crustal particulate matter is essentially benign and therefore should be excluded from the coarse particle indicator.

The EPA agrees with these commenters that the strongest available evidence relates to the toxicity of the ambient mix of coarse particles found in urban environments. The limited evidence available from epidemiologic and toxicologic studies indicates exposure to ambient thoracic coarse particulate in urban areas is associated with health effects, and the health evidence more strongly implicates coarse particles from urban types of sources such as resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources than coarse particles from uncontaminated soil or geologic sources. The EPA also agrees that there is far more evidence concerning health effects associated with thoracic coarse particles in urban areas than in non-urban areas. However, EPA disagrees with these commenters that there is sufficient evidence to demonstrate that there are no adverse health effects from community-level exposure to coarse particles in non-urban areas. Rather, the existing evidence is inconclusive with regard to whether or not community-level exposures to thoracic coarse particles are associated with adverse health effects in non-urban areas. However, EPA does agree with these commenters that additional research is needed to clarify this issue and to reduce some of the other uncertainties regarding the effects associated with coarse particles. As discussed above, the EPA is, in fact, expanding both its research and monitoring programs to collect additional evidence on the differences between coarse particles typically found in urban areas and those typically found in rural areas. Specifically, EPA notes that the Agency's National Center for Environmental Research recently issued a Request for Proposals on "Sources, Composition, and Health Effects of Coarse Particulate Matter" which is designed to [1] improve understanding of the type and severity of health outcomes associated with exposure to $PM_{10-2.5}$; (2) improve understanding of subpopulations that may be especially sensitive to $PM_{10-2.5}$ exposures including minority populations, highly exposed groups, and other susceptible groups; (3) characterize and compare the influence of mass, composition, source characteristics and exposure estimates in different locations and differences in health outcomes, including comparisons in rural and urban areas; and [4] characterize the composition and variability of $PM_{10-2.5}$ in towns, cities or metropolitan areas, including comparisons of rural and urban areas. In addition, as described in the final monitoring rule published elsewhere in today's Federal Register, EPA and the states will require measurement of $PM_{10-2.5}$ at 75 new multipollutant monitoring sites around the country. These sites will provide continuous measurements of mass as well as chemical speciation. EPA will locate 55 of these sites in urban areas and 20 in rural areas in order to gather information on the composition and transport of coarse particles in urban and rural areas. In addition, these monitors will employ the latest in speciation technology to advance the science so that future regulation will provide more targeted protection against the effects only of those coarse particles and related source emissions that prove to be of concern to public health.

In addition, EPA disagrees with these commenters that there is sufficient evidence to exclude crustal materials from the coarse particle indicator regardless of the degree of contamination. Although there is some evidence that coarse particles of natural geologic origin are relatively non-toxic in their uncontaminated form, the Criteria Document notes that such particles may become sufficiently "contaminated by toxic trace elements or other components from previously deposited fine PM," to cause health effects (EPA, 2004a, 8–344). Indeed, the urban coarse PM associated with adverse health effects in the studies discussed above was, by mass, predominantly crustal in origin.[69] As noted in the proposal and in the response to these commenters on the need to maintain a coarse particle standard, EPA is aware of the studies that found no effects on mortality at lower coarse particle concentrations, but believes, consistent with the Staff Paper and Criteria Document conclusions, that the evidence is suggestive of a coarse particle effect in urban or industrial areas.[70] The EPA continues to believe that urban sources may significantly alter both the relative quantity and character of crustal and natural biological materials in ambient mixes in urban areas. As noted above in section III.C.1, metals and other contaminants such as elemental carbon tend to appear in higher concentrations in the urban $PM_{10-2.5}$ mix, and vegetative materials are ground and resuspended by traffic-related activities into forms not common outside urban areas.

In contrast to those few commenters who conditionally supported EPA's proposed indicator, the vast majority of commenters opposed one or more aspects of EPA's proposed indicator, including: (1) The basic decision to qualify the indicator to focus on particles associated with certain types of sources and to exclude other ambient mixes; and (2) the particular qualifications applied to the indicator, including the proposed siting requirements for coarse particle monitors suitable for comparison with the NAAQS and the proposed exclusion of agricultural, mining, and other similar sources from control under the standard. This large group of commenters advanced scientific as well as legal and policy arguments against drawing a distinction between particles typical of urban versus non-urban or rural areas. These commenters included public health groups such as the American Lung Association, the American Heart Association, the American Cancer Society, the American Diabetes Association, and the American Public Health Association, and environmental groups such as Earthjustice, Environmental Defense, and the Natural Resources Defense Council. It also included the State and Territorial Air Pollution Program

[69] The American Farm Bureau Federation's summary of the results of Mar *et al.* (2000), offered in support of their arguments about the lack of effect of soil or crustal materials, misses some important elements of the study results. A major finding of the original study as well as the reanalysis (Mar *et al.*, 2003) was an association between $PM_{10-2.5}$ particles and mortality. The analysis in this work that examined sources and components examined contributions to the effects of $PM_{2.5}$, not to $PM_{10-2.5}$. In the opinion of the authors, the factor commenters call motor vehicle exhaust "probably represents the influence of motor vehicle exhaust and resuspended road dust" (Mar *et al.*, 2000, p. 351). The negative association for "soil" in the fine fraction cited by the commenter was apparently related to problems in the $PM_{2.5}$ measurement. When the data were reassessed for the period with an improved sampler, the authors report that the association between soil and mortality was "positive and significant at 0 days lag" (ibid., p. 352).

[70] The Laden *et al.* (2000) study cited by commenters was reanalyzed in Schwartz (2003), with qualitatively similar findings. As in Mar *et al.* (2000, 2003), this study examined the associations of crustal materials in the fine particle fraction, in which they make up such a small fraction of fine mass that one of the six cities had to be excluded from the analysis (Laden *et al.*, 2000, p. 945). While this result does not provide any support for associations between coarse crustal materials and mortality, given the lower concentrations of coarse particles in five of the six cities and the lack of examination of coarse particle composition, the results are inconclusive with respect to the potential effects of higher concentrations of coarse particles.

Administrators and the Association of Local Air Pollution Control Officials (STAPPA/ALAPCO) and numerous individual State and local air pollution control agencies, as well as dozens of Tribes and Tribal organizations such as the National Tribal Caucus, the National Tribal Air Association and its parent organization, the National Tribal Environmental Council. In addition, a number of industry groups expressed opposition to the proposal to qualify the coarse particle indicator; in general, these comments came from groups representing industry categories that were not excluded from the proposed indicator, such as the Engine Manufacturers Association, the Alliance of Automobile Manufacturers, and the National Association of Home Builders. Though these industry commenters primarily argued against setting any coarse particle standard at this time, they stated that if a standard were to be adopted, scientific evidence did not support the proposal to qualify the indicator based on the mix of sources present.

Commenters opposed to a qualified coarse particle indicator advanced numerous scientific arguments to support their position. They criticized EPA's interpretation of key epidemiologic studies, such as Gordian *et al.* (1996), Choudhury *et al.* (1997), Ostro *et al.* (2003), Smith *et al.* (2000) and Mar *et al.* (2003), arguing that these studies linked thoracic coarse particles to adverse health effects in environments where crustal components formed a significant part of the ambient mix of $PM_{10-2.5}$. For example, commenters argued that the study conducted by Ostro *et al.* (2003) in Coachella Valley, which found statistically significant associations between exposure to coarse particles and mortality, provides direct evidence of harm from exposure to rural particles. These commenters also challenged the results of Schwartz *et al.* (1999), attributing the lack of statistically significant mortality results in that study to avoidance behavior (*i.e.*, people may stay inside during dust storms) and noting that the study might have drawn different conclusions if morbidity endpoints had been considered. In support of this argument, they pointed to Hefflin *et al.* (1994), which looked at hospitalizations for bronchitis and sinusitis during dust storms and did find a small increase in these effects in the same area.

In addition, a number of commenters, including States, researchers, environmental and public health groups, and industry commenters, cited studies of particle composition as showing that the coarse PM found in rural areas is commonly contaminated with the same toxic components as particles found in urban areas (*e.g.* Alaska Department of Environmental Conservation; American Lung Association; Engine Manufacturers Association; Veranth). Moreover, these commenters noted that rural dusts may contain additional toxic contaminants such as molds, fungi, endotoxins, pesticides, and carbonaceous compounds including polycyclic aromatic hydrocarbons (PAHs), all of which are associated with rural sources and have been shown to produce toxic effects (citing studies including: Monn and Becker 1999; Soukup and Becker 2001; Horvath *et al.*, 1996; Offenberg and Baker, 2000; Eleftheriadis and Colbeck, 2001). (See American Lung Association *et al.*, pp. 92–100.) In addition, some commenters pointed to studies of the composition of coarse particles in particular locations, such as Owens and Mono Lakes in California, as evidence of the dangerous nature of rural particles. Commenters noted that coarse particles from these areas are contaminated by heavy metals, arsenic, and other toxic contaminants, but would be excluded from the proposed indicator.

Commenters critical of the proposed decision to qualify the coarse particle indicator also stated that EPA had inappropriately relied on the relatively few studies involving exposure to crustal materials, especially the Mt. St. Helens' studies. These commenters expressed the view that EPA should not equate exposure to volcanic ash to exposure to coarse particles emitted from agricultural and mining industries. Commenters noted that volcanic ash lacks many of the organic components typical of rural coarse PM, including pesticides and PAHs. Commenters pointed to specific components of coarse particles emitted by agricultural or mining activities, including endotoxins, pesticides, and metals, that they claim are associated with adverse health effects. These commenters argued that coarse particles in rural and other non-urban areas are not generally "uncontaminated materials of geologic origin" or "uncontaminated natural crustal dusts." They argued that some of the effects noted in epidemiologic studies of thoracic coarse particles, such as Mar *et al.* (2003), occurred in areas dominated by agricultural or mining dusts (Maricopa County Air Quality Department, p. 3–4). Some commenters also stated that EPA had not demonstrated or even claimed that coarse particles associated with agricultural and mining activities are harmless. Citing a long history of occupational studies documenting effects and EPA's statement in the proposal that "in the 1987 review, EPA found that occupational and toxicological studies provided ample cause for concern related to higher levels of thoracic coarse particles' (71 FR 2654), these commenters urged EPA to give greater weight to the results of such studies.

A number of commenters opposing a qualified $PM_{10-2.5}$ indicator referenced "new" epidemiologic and toxicologic studies which were not included in the Criteria Document in support of their arguments in favor of an unqualified $PM_{10-2.5}$ indicator. Specifically, the commenters pointed to recent epidemiologic studies showing statistically significant adverse health effects from exposure to coarse particles of varying composition, such as one study that found an association between exposure to volcanic ash and wheeze and exercise-induced bronchoconstriction [Forbes *et al.*, 2003]. In addition, commenters cited several "new" studies of health effects associated with exposure to coarse particles during Asian dust storms (Chen Y-S *et al.*, 2004; Chen and Yang, 2005; Yang C-Y *et al.*, 2005; Chang *et al.*, 2006). Commenters also pointed to "new" toxicologic studies such as Schins *et al.* (2004), Veranth (2004, 2006), Becker (2005), Labban *et al.* (2004, 2006), and Steerenberg *et al.* (2006), arguing that toxicological studies do not show consistent differences between urban and rural dusts.

In response to these commenters' first point regarding the epidemiologic studies that were included in the Criteria Document, EPA does not agree with the commenters that these epidemiologic studies provide direct evidence of harm from non-urban or rural crustal material. While EPA acknowledges that crustal particles may have dominated the ambient mix in some of the locations in which these studies were done, it is also the case that these areas are all urban, so the crustal materials in the ambient mix typically would be contaminated by metals, road dust, and other combustion byproducts. At the same time, EPA notes that CASAC cited the studies by Ostro *et al.* (2000, 2003) as suggestive of health effects associated with exposure to rural crustal materials: "Little is known about the potential toxicity of rural dusts, although the 2000 and 2003 Coachella Valley, CA studies from Ostro *et al.* showed significant adverse health effects, primarily involving exposures to coarse-mode particles arising from

crustal sources' (Henderson, 2005a, p. 4). Thus while EPA does not agree with these commenters that the epidemiologic studies demonstrate that non-urban or rural crustal particles are harmful, at the same time EPA believes the studies do raise credible concerns and suggest the need to be cautious in interpreting the epidemiologic and other evidence.

The EPA agrees with these commenters that the observations of Hefflin *et al.* (1994) suggest it is possible that the lack of mortality effects on dust storm days observed in Schwartz *et al.* (1999) may be due to avoidance behavior. As noted in the proposal (71 FR 2666), there is a possibility that people may reduce their exposure to ambient particles on the most dusty days. This argues for caution in interpreting the results of Schwartz *et al.* (1999) with regard to the potential health effects associated with exposure to natural crustal material.

The EPA acknowledges the limitations on the scientific evidence identified by these commenters regarding the differences in composition and toxicologic effects of urban and rural thoracic coarse particles. As noted in the Criteria Document and Staff Paper, there is clear evidence of toxicity of certain components of thoracic coarse particles, such as metals and endotoxins, as well as evidence that natural crustal materials of geologic origin, such as Mt. St. Helens volcanic ash, may have very little toxicity. There is largely an absence of evidence regarding the presence or absence of toxicologic effects associated with other types of coarse particles in non-urban areas. However, EPA agrees that thoracic coarse particles in non-urban areas may become contaminated with a wide variety of toxic materials (EPA, 2004a, p. 8–344). Clearly, however, crustal material associated with particular locations, such as the dry lakebeds of Owens and Mono Lakes, can be highly contaminated with metals, salts, and other toxic constituents. The EPA agrees with commenters that the potential toxicity of these components is well recognized; however, such locations tend to be isolated and not representative of other locations.

In response to other comments raised by this group of commenters, EPA continues to find it inappropriate to assume that effects observed in occupational studies should be considered representative of effects that would occur at community exposure levels. However, EPA agrees with commenters that the presence of occupational exposure studies demonstrating adverse effects lends further support to a cautious approach in considering revisions to the standards affording protection from thoracic coarse particles. Finally, to the extent that commenters cited new scientific studies that were not considered in the Criteria Document in support of their arguments against a qualified coarse particle indicator, EPA notes that as discussed above in section I.C, EPA it is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review, and will consider the newly published studies for purposes of decision making in the next PM NAAQS review.

Overall, the scientific evidence supports a conclusion that the risks of adverse health effects associated with thoracic coarse particles typically found in urban or industrial areas warrant targeted protection. Although the limited and inconclusive evidence does not support such a conclusion concerning thoracic coarse particles typically found in non-urban or rural areas, it supports a cautious approach concerning thoracic coarse particles. The EPA agrees with all the commenters who pointed to the need for additional research to strengthen the current body of evidence to reduce some of the uncertainties regarding the health effects associated with coarse particles.

In addition to their criticisms of the scientific basis for EPA's proposed indicator, commenters opposed to a qualified indicator also advanced legal and policy arguments against EPA's proposed approach. In particular, commenters criticized the proposal's provision that "agricultural sources, mining sources, and other similar sources of crustal materials shall not be subject to control in meeting this standard" (71 FR 2699); a large number of commenters expressed the view that the exclusion is flatly illegal, citing CAA section 101 (a) (3) and case law in support. These commenters also pointed to CASAC's March 21, 2006 letter to the Administrator which stated that EPA had misconstrued the finding of the Committee and that the proposed rule—particularly the source-category exclusions—was not consistent with the Committee's recommendations.

These commenters also stated that EPA had failed to demonstrate that its proposed qualified indicator would protect public health with an adequate margin of safety. Pointing again to the relative paucity of data regarding health effects associated with coarse particles of differing compositions, and the almost complete lack of evidence regarding health effects in rural areas, these commenters expressed the view that EPA must demonstrate affirmatively that the coarse particle standards will ensure an absence of adverse effects on sensitive individuals (American Lung Association, p. 82, citing *Lead Industries Ass'n v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980) and *American Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998)), and that in the absence of evidence, or in the face of significant uncertainty, the CAA requirement to provide an adequate margin of safety obligates EPA to regulate all coarse particles equally (*Lead Industries Ass'n v. EPA*, 647 F.2d 1154–55). Some of these commenters pointed to the DC Circuit Court's instruction in ATA III that "[t]he Act requires EPA to promulgate protective primary NAAQS even where * * * the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree'" (*ATA III*, 283 F.3d 355, 369 (quoting PM NAAQS, 62 FR 38653)).

Commenters also argued that, under the CAA, EPA is charged with setting ambient standards that are national in scope and application, and that the proposed qualified indicator fails this test. Citing *Whitman*, 531 U.S. at 473, some of these commenters stated that the proposed qualified indicator is a thinly veiled attempt to establish a coarse particle standard that only applies to urban areas, and that it denies citizens in non-urban areas adequate health protection. Several commenters, including numerous Tribes, argued that the qualified indicator, by virtue of depriving non-urban populations of protection from coarse particles, violated principles of environmental justice and the government's Trust Responsibility to Tribes.

Commenters pointed to other concerns as well, many of them focused on specific aspects of the proposed $PM_{10-2.5}$ indicator. First, some commenters stated that the proposed qualified indicator inadequately describes the substance(s) being regulated. These commenters argued that EPA is attempting to establish a composition-based indicator without being able to define adequately which particular chemical or physical components are associated with adverse health effects. Furthermore, commenters pointed out that the indicator was defined in large part through an implementation strategy—i.e. via the placement of monitors—rather than in scientific terms. The Alliance of Automobile Manufacturers expressed concern that the result would be that two sources of coarse particulate matter with similar composition that presumably produce similar health

impacts would be "given different regulatory treatment based merely on the non-scientific qualifiers established in EPA's indicator" (Alliance of Automobile Manufacturers, p. 9).

In addition, some commenters pointed to a logical paradox inherent in the proposed $PM_{10-2.5}$ indicator, which is defined to include any ambient mix "dominated by" particles from particular types of sources. Commenters noted the potential for the same concentration of "harmful" coarse particles—*i.e.* particles from high-density traffic, industrial sources and construction sources—to be regulated differently in different locations depending on what percentage of the ambient mix it constitutes relative to "crustal" particles. These commenters stated that the coarse particle standard must provide a consistent level of protection from particles of concern, and that use of a 50 percent domination threshold would result in a variable level of protection from particles of concern.

The EPA also received an extremely large number of comments from diverse stakeholder groups—some of whom conditionally supported a qualified indicator—regarding perceived problems with implementing the proposed $PM_{10-2.5}$ indicator. Many commenters pointed out that EPA failed to specify which source types were included in the broad source category descriptions listed in the indicator. They requested further definition of what could be considered an "agricultural source," a "mining source," or "other similar sources of crustal material" (i.e. those sources that would be excluded from control under the proposed standard), and which "industrial" and "construction" sources were included in the indicator. Furthermore, some commenters inquired about the treatment of sources that were neither explicitly included in nor excluded from the proposed indicator, such as residential and commercial sources. In addition, commenters wondered how EPA or the States would make the determination that one set of sources was "dominant," given the scarcity of knowledge about coarse particle emissions and air quality concentrations, and the lack of suitable source attribution techniques.

Commenters also objected to the proposed five-part test for siting NAAQS-comparable monitors, noting that as written, the monitor siting criteria arbitrarily would prohibit monitoring and regulation of coarse particles outside urbanized areas of 100,000 population, regardless of the presence of large or numerous sources of the types of coarse particles of concern or the nature of the ambient mix. Commenters pointed out that the monitor siting criteria, by virtue of their highly prescriptive role in defining where the pollutant can and cannot be measured, in essence define the indicator itself, and artificially narrow its scope such that in many instances, coarse particles of concern would not be covered by the indicator. These commenters argued that by failing to provide protection from coarse particles of concern in non-urban areas even though the composition of those particles may be identical to that of coarse particles found in large urban areas, the qualified indicator, as EPA proposed to implement it, would be under inclusive. Many Tribes and some other commenters raised concerns about the environmental justice implications of the proposal and stated that EPA had violated its Trust Responsibility toward Tribes, because Tribal lands would be virtually excluded from coverage under the proposed monitor siting criteria, regardless of the mix of particles present. Furthermore, numerous commenters stated that the siting criteria would be impossible to implement, so the criteria undermined the proposed standard on a practical level. Commenters particularly objected to the fifth part of the monitor-site suitability test, which as proposed would require an affirmative demonstration that the ambient mix at the site was dominated by sources of concern, even if all of the other four monitor site-suitability criteria were met. Commenters stated that this demonstration would be impossible to execute due to the lack of suitable data and techniques, undermining the siting of any NAAQS-comparable $PM_{10-2.5}$ monitors.

In response to these perceived problems with the proposed qualified indicator, commenters suggested a number of remedies. A few commenters, mostly industry representatives who preferred that no coarse particle standard be set at the current time, stated that if EPA does set a standard, it should be based on a qualified $PM_{10-2.5}$ indicator, but EPA should fix specific problematic aspects of the proposal (e.g. clarify the definition of included vs. excluded industries). Most commenters, including States, Tribes, and environmental and public health groups, urged EPA to adopt an unqualified $PM_{10-2.5}$ indicator to ensure adequate public health protection and to avoid some of their perceived legal and/or policy issues associated with the qualified indicator. A few of these commenters recommended that EPA utilize the Exceptional Events Rule, proposed on March 10, 2006 (71 FR 12592–12610), to exclude violations caused by rural windblown dust. According to these commenters, this would be consistent with historical practice, because in the past the Natural Events Policy has been applied in many instances to exclude data associated with dust storms and other events from consideration under the PM_{10} standard (see New Mexico Air Quality Bureau, p. 10).

Some commenters advocating an unqualified $PM_{10-2.5}$ indicator stated that, given the limitations on the scientific evidence, and in light of some of the other problems identified with the proposed qualified indicator, EPA should consider retaining the current PM_{10} standards to continue protection from coarse particles. They expressed particular concern about the absence of control in the interim period between the issuance of the final PM NAAQS rule (which as proposed would include the revocation of existing PM_{10} standards in almost all locations) and the completion of designations under a new $PM_{10-2.5}$ standard (which would require deployment of a new monitoring network followed by 3 years of data collection). A few of the commenters advocating the retention of the PM_{10} standards suggested that measurements of PM_{10} could be adjusted by subtracting out $PM_{2.5}$ to avoid double regulating the fine fraction, to satisfy a concern voiced by the D.C. Circuit in *ATA I* (*e.g.*, Alliance of Automobile Manufacturers; also some Tribes and States). Some Tribal, State and local commenters suggested that the 24-hour PM_{10} standard be retained permanently in all areas where the $PM_{10-2.5}$ standard did not apply by virtue of the monitoring requirements, which limited NAAQS-comparable monitors to sites that met the five-point site suitability test outlined in the monitoring rule.

While EPA proposed a qualified indicator that attempted to include certain ambient mixes of thoracic coarse particles and exclude others, EPA's evaluation of the large number of adverse comments received on the proposed qualified indicator has led it to the conclusion that significant caution is warranted in considering such revisions to the scope of the indicator affording public health protection from coarse particles. As discussed below, there are two main issues that arise from consideration of a qualified indicator for thoracic coarse particles: (1) The inability to effectively and precisely identify which coarse particles are included in the indicator

and which are not;[71] and (2) the importance of providing some level of protection from exposure to all thoracic coarse particles while targeting protection at those kinds of thoracic coarse particles for which there is more evidence regarding adverse health effects.

As explained earlier in this section, EPA continues to believe that, from a scientific standpoint, it is appropriate to draw a distinction between the character of the ambient mix of thoracic coarse particles generally found in urban areas and that found in non-urban and, more specifically, rural areas, recognizing that the mix of coarse particles in urban areas is influenced to a relatively greater degree by components from urban mobile and stationary source emissions and that the evidence of health effects associated with exposure to these urban types of coarse particles should not be generalized to other types of coarse particles. In the presence of significant, though limited, evidence of effects in urban areas, it remains EPA's view that a targeted indicator that focuses control on areas with ambient mixes of coarse particles known to be associated with adverse health effects will provide the most certain and substantial public health benefits.

However, EPA also recognizes a number of flaws in the proposed qualified indicator, as noted by numerous commenters, most specifically the difficulties inherent in attempting to effectively and precisely identify the ambient mixes of concern. These include: (1) The artificial constraints on the reach of the indicator resulting from the application of quantitative monitor site-suitability criteria such as the requirement that NAAQS-comparable monitors can only be sited in urbanized areas with minimum 100,000 population even if there is an ambient mix of concern around such an area; and (2) the difficulties associated with attempting to determine with any precision which sources "dominate" the ambient mix of coarse particles in different locations.

The quantitative constraints in the monitor site-suitability criteria result in an under-inclusive indicator that fails to include all ambient mixes of concern. Smaller urban and/or industrial areas, for example, would not meet the proposed monitor siting criteria, but might have an ambient mix of concern. Consequently, EPA agrees with commenters that unless the constraints were changed, the proposed indicator would be under-inclusive. The EPA has considered several options to modify the quantitative criteria, including those discussed in the proposal (see Weinstock, 2006). For example, EPA evaluated different possible minimum population thresholds (e.g., 25,000 or 50,000 instead of 100,000) for areas eligible to site NAAQS-comparable monitors, and/or the possibility of adding additional criteria to include areas that do not meet a quantitative population threshold but are dominated by industrial or traffic-oriented sources. Each of these options, however, was found too inflexible to capture all relevant areas or too difficult to implement in practice. Thus, EPA believes that even a more complex set of quantitative criteria would fail to resolve the basic problem inherent in precisely identifying those ambient mixes to include and those to exclude. Based on the data available to us in this review, there still remains a clear risk of failing to capture all ambient mixes of concern, or of capturing ambient mixes that are intended to be excluded from the qualified indicator.

Moreover, as a general matter, the use of a qualified indicator without such objective monitor site-suitability criteria would still present serious problems because it is currently impossible to determine with any precision which sources "dominate" the ambient mix in many different locations. Although it may be easy in certain instances to identify an ambient mix dominated by urban and/or industrial sources, in many cases it would be difficult to determine whether that precise ambient mix presents the types of health risks identified in the epidemiologic and other studies. The EPA is currently unable to identify any set of objective criteria or techniques such as chemical air quality speciation or modeling that could be practically employed to ensure adequate inclusion of all areas with particles of concern, and exclusion of areas without such particles.

The EPA is also aware that the legal concerns raised by commenters with regard to the exemption of agricultural and mining sources from control under the standard, and the specific sections of the Clean Air Act that speak to this issue, would require careful consideration if the proposed qualified indicator were to be adopted. The logical paradox noted by commenters is also a flaw in the qualified indicator that would need to be resolved. It is another example of the lack of precision in the use of such a qualified indicator.

After careful consideration of the concerns raised by commenters and the options available, EPA now agrees with commenters that the proposed qualified indicator is fundamentally flawed, because it cannot effectively and precisely identify the ambient mixes of concern and because modifications to the indicator that could rectify this and other problems highlighted by the commenters have not been identified. At the present time, therefore, EPA believes that there is an inherent risk that a qualified indicator would not include all of the ambient mixes of concern which the indicator is intended to capture.

Furthermore, in light of the significant scientific uncertainty surrounding the health effects associated with different ambient mixes of coarse particles, EPA agrees with commenters that the proposed qualified indicator would be insufficiently protective and further concludes that, given the limitations on the evidence regarding the health risks associated with different ambient mixes, some protection from exposure to thoracic coarse particles is warranted in all areas. The EPA recognizes that additional data will be collected and analyzed that will be useful to inform the next review.

The EPA has already set out the reasons for providing protection from exposure to ambient mixes dominated by the types of thoracic coarse particles found in urban or industrial areas. With respect to other ambient mixes, some commenters have argued that the scientific evidence, including epidemiologic, dosimetric, toxicologic, and occupational studies, demonstrates that non-urban mixes of thoracic coarse particles are harmful, and therefore that EPA should maintain an unqualified indicator. Other commenters argue that the evidence demonstrates that non-urban mixes of thoracic coarse particles are benign and therefore EPA should retain a qualified indicator. The EPA disagrees with both of these views regarding the strength of the evidence. The existing evidence is inconclusive with regard to whether or not community-level exposures to thoracic coarse particles are associated with adverse health effects in non-urban areas. In light of this uncertainty and the need for caution in considering the evidence, and recognizing the large population groups potentially exposed to non-urban thoracic coarse particles and the nature and degree of the health effects at issue, it is the judgment of the Administrator that the proper response to this body of evidence is to provide some protection from thoracic coarse particles in all areas. Congress "specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not

[71] These concerns apply both to defining the qualified indicator and implementing the standard.

yet been uncovered by research and effects whose medical significance is a matter of disagreement * * * Congress' directive to the Administrator to allow an "adequate margin of safety" alone plainly refutes any suggestion that the Administrator is only authorized to set primary air quality standards which are designed to protect against health effects that are known to be clearly harmful." *Lead Industries* v. *EPA*, 647 F.2d at 1154–55; see also *American Petroleum Inst.* v. *Costle*, 665 F.2d at 1186 ("in setting margins of safety the Administrator need not regulate only the known dangers to health").

The Administrator has carefully reviewed the scientific evidence and recommendations contained in the Staff Paper, the advice and recommendations from CASAC, and the public comments received regarding the appropriate indicator for coarse particles. After doing so, the Administrator has decided that it would not be appropriate at this time to revise the indicator for coarse particles by adopting a qualified $PM_{10-2.5}$ indicator, either as proposed or with modifications. At the same time, the Administrator believes it is appropriate to target protection from thoracic coarse particles principally towards those types of coarse particles that have been demonstrated to be associated with significant adverse health effects, specifically urban and industrial ambient mixes of coarse particles.

In general, EPA believes these conclusions regarding the potential health effects associated with thoracic coarse particles, and the conclusion that an unqualified indicator that provides targeted protection is the most appropriate approach for regulating coarse particles, are consistent with views expressed by CASAC. In its June 6, 2005 letter, CASAC expressed the view that it was "important to qualify the $PM_{10-2.5}$ standard by somehow allowing exceptions for regions where the coarse fraction was composed largely of material that was not contaminated by industrial- or motor vehicle traffic-associated sources. Options discussed by members of the Panel for attempting to achieve this approach included limiting the standard to cover "all" urban areas, the judicious siting of monitors with a focus on urban areas, or regulatory exceptions for regions where road dust is not an issue or where rural components dominate the source. *No single option was favored*" (Henderson, 2005a, p. 8, emphasis added). CASAC thus recognized that there were numerous ways to approach the need for targeted protection. In its September 2005 letter responding to the recommendations regarding a qualified $PM_{10-2.5}$ indicator in the final Staff Paper, the PM Panel noted that some members did not favor adoption of a qualified indicator. Moreover, CASAC clearly anticipated the difficulties associated with adopting a qualified $PM_{10-2.5}$ indicator:

> CASAC generally agrees with EPA staff conclusions that thoracic coarse particles in urban areas can be expected to differ in composition from those in rural areas and that evidence of associations with health effects related to urban coarse-mode particles would not necessarily apply to non-urban or rural coarse particles (although it is likely that there will be some overlap of the same contaminants in both areas). Most Panel members concurred that the current scarcity of information on the toxicity of rural dusts makes it necessary for the Agency to base its regulations on the known toxicity of urban-derived coarse particles, and that an urban coarse particle indicator should be specified as $UPM_{10-2.5}$. Other Panel members recommended specifying a national $PM_{10-2.5}$ standard accompanied by monitoring and exceptional-events guidance that emphasized urban influences. Some members also expressed concerns whether EPA would be able to specify a clear definition of "urban" to effectively determine in advance the specific conditions in which the standard would (and would not) apply. It is recognized that, as more information on the toxicity of rural dusts is acquired, the name and/or geographical focus of a coarse-particle indicator may need to be reconsidered* * *. There is a paucity of data currently available on health outcomes related to thoracic coarse particles in rural areas and limited information on the composition and toxicity of rural area coarse particles. (Henderson 2005b, p. 4)

CASAC also commented negatively on the proposed qualified indicator, raising concerns about the quantitative criteria for monitor siting and the source exclusions, as well as flagging the need for more information about health effects in non-urban areas (Henderson, 2006, p.4).

The comments and concerns expressed by CASAC are consistent with the difficulties EPA has encountered in attempting to craft a qualified indicator, and the Committee correctly anticipated these difficulties. Furthermore, CASAC's advice is generally consistent with the ultimate decision by the Administrator not to move to a qualified $PM_{10-2.5}$ indicator at present. The practical difficulties and imprecision associated with a qualified indicator, as well as the substantial scientific uncertainty regarding the health effects associated with different components and mixes of coarse particles, the large population groups potentially exposed to non-urban thoracic coarse particles and the nature and degree of the health effects at issue, have convinced the Administrator that it is inappropriate to adopt a qualified $PM_{10-2.5}$ indicator at this time. In the following section, EPA considers what indicator would most appropriately provide the type of targeted but comprehensive protection judged appropriate based on its review of the scientific evidence.

3. Decision Not To Revise PM_{10} Indicator

For reasons discussed in the previous section, in the view of the Administrator it is not appropriate to revise the PM_{10} indicator by replacing it with a qualified indicator for thoracic coarse particles at this time. Based on the scientific evidence already summarized, the Administrator believes it is necessary to maintain some protection from all ambient mixes of thoracic coarse particles, and also to have that level of protection reflect the varying degree of public health concern presented by the different ambient mixes of thoracic coarse particulate matter. This would mean allowing lower ambient concentrations of thoracic coarse particles in urban areas, where the evidence indicates the public health risks to be significant, and higher levels in non-urban areas where the public health concerns are less certain. The difficulty of the task is compounded because there presently is no means of achieving this objective by linking allowable concentrations to specific coarse particle chemical components. As CASAC noted, "[s]ufficient data are lacking at the present time to set standards [for thoracic coarse particulate matter] based specifically on composition" (Henderson 2005b, p. 5).

Given these objectives and constraints, EPA carefully considered various possibilities regarding the indicator for coarse particles, including adopting an unqualified $PM_{10-2.5}$ indicator, retaining the existing PM_{10} indicator, and/or retaining the PM_{10} indicator with adjustment to avoid double-counting the PM2.5 fraction. These options are discussed below.

a. Unqualified $PM_{10-2.5}$ Indicator. The EPA evaluated whether an unqualified $PM_{10-2.5}$ indicator would satisfy the goals for public health protection described above. However, if such an indicator were utilized as part of a standard with a single unvarying level, it would not reflect the critical difference in evidence regarding the relative public health risks associated with urban and non-urban thoracic coarse particles. If the level were selected to provide appropriate protection against effects associated

with exposure to the ambient mixes typical of urban or industrial areas, the standard would likely be more stringent than necessary to protect against effects associated with exposure to the ambient mixes in non-urban areas. In the judgment of the Administrator, the evidence warrants a lower ambient concentration of ambient coarse particles in urban areas than in non-urban areas, where the coarse particles are typically from different sources and there is less evidence of public health risk. Conversely, if a less stringent level were adopted on the grounds that there is less certainty that the ambient mix in non-urban areas poses a health risk, then the standard would not provide sufficient protection from the ambient mix found in urban or industrial areas. In both instances the standard would not be requisite overall, *i.e.*, "not lower or higher than is necessary," to protect the public health with an adequate margin of safety. *Whitman*, 531 U.S. at 476.

Arguably this dilemma could be resolved by adopting a standard based on a $PM_{10-2.5}$ indicator with a varying level depending on whether the area is urban or non-urban. However, determining appropriate levels for different kinds of ambient mixes is not feasible at this time. The EPA notes that given the variety of sources contributing to $PM_{10-2.5}$ concentrations in different locations, a wide variety of "ambient mixes" are likely to exist, greatly complicating the determination of the appropriate standard level for each location. There is a lack of evidence to support establishing specific quantitative distinctions in level based on variations in coarse particle composition and differential toxicity. In addition, there is insufficient evidence regarding coarse particle composition in different areas to allow for the proper assignment of different standard levels in different locations, and the technical capabilities necessary to make such determinations are currently lacking. Even if EPA tried to assign only two levels, urban and non-urban, the same problems identified earlier with respect to a qualified indicator would apply here, given the inability to effectively and precisely identify different ambient mixes. Therefore, EPA finds that the current state of the science does not provide an adequate basis upon which to establish a $PM_{10-2.5}$ standard with an appropriately varying level. As EPA's new research program produces speciated monitoring data, thereby improving scientific knowledge, revealing more specific and precise information about coarse particle composition and relative toxicity, and about the distribution of ambient coarse particle mixes of varying composition, it will be appropriate in a future review to revisit the option of a $PM_{10-2.5}$ standard with a variable level or a qualified indicator.

b. PM_{10} Indicator. An alternative approach would be to retain PM_{10} as an indicator. The EPA recognizes, as did many commenters, that the D.C. Circuit concluded that EPA's 1997 choice of PM_{10} as the indicator for coarse particles was arbitrary and capricious. *ATA I*, 175 F.3d at 1027, 1054–55. In that case, the court noted the tension between EPA's conclusion that coarse and fine particles are different kinds of particles and pose independent and distinct threats to public health, and its choice to address the public health risks associated with coarse particles indirectly, using an indicator for coarse particles that nonetheless includes both fine and coarse particles. Although EPA adopted PM_{10} as a "surrogate for coarse fraction particles," the court also noted EPA's recognition "that $PM_{10-2.5}$ would have served as a satisfactory coarse particle indicator." With this backdrop, the court evaluated EPA's three bases for selecting PM_{10} as the indicator: (a) That the two epidemiologic studies underlying the standards for coarse particles used PM_{10} rather than $PM_{10-2.5}$ as the indicator; (b) that the PM_{10} standards would work in conjunction with the $PM_{2.5}$ standards "by regulating the portion of particulate pollution not regulated by the $PM_{2.5}$ standards"; and (c) that a nationwide monitoring network for PM_{10} already existed. *Id.* at 1054.

The court rejected the first two arguments for two interrelated reasons. First, use of PM_{10} as the indicator regulates both fine and coarse particles, contrary to EPA's argument that the PM_{10} indicator would work in conjunction with the $PM_{2.5}$ standard to regulate only the coarse particle fraction of PM_{10}. The court concluded: "we cannot discern exactly how a PM_{10} standard, instead of a $PM_{10-2.5}$ standard, will work alongside a $PM_{2.5}$ standard to regulate only the coarse fraction of PM_{10}. EPA provides no explanation to aid us in understanding its decision." *Id.* at 1054. Second, because the PM_{10} indicator regulates both fine and coarse particles, the amount of coarse particles allowed "will depend [quite arbitrarily] on the amount of $PM_{2.5}$ pollution in the air." *Id.* EPA failed to explain why this result was consistent with its argument that a PM_{10} indicator would increase the likelihood that the standard would achieve the desired level of protection from exposure to coarse particles. The resulting combination of $PM_{2.5}$ and PM_{10} standards would lead to double regulation of fine particles and the potential under-regulation of coarse particles, since the amount of allowable coarse particles would always depend on the amount of fine particles in the air. *Id.* The court rejected the third of EPA's arguments, the pragmatic, administrative convenience of using the existing monitoring network, on the grounds that only factors related to public health can be considered in establishing a NAAQS. *Id.* at 1054–55. In sum, the court rejected EPA's adoption of a PM_{10} indicator as arbitrary because of the inadequacy of the reasons provided by the Agency as support for the decision.

Based on the current review of the scientific evidence, EPA feels it is now appropriate to reconsider utilizing PM_{10} as an indicator for coarse particles. Unlike its view in 1997, EPA views $PM_{10-2.5}$ as an unsatisfactory indicator in this review, for the reasons described in the previous subsection. In addition, EPA is not maintaining, as it did in 1997, that a PM_{10} indicator will work in conjunction with the $PM_{2.5}$ standard to regulate coarse particles exclusively, nor is the Agency justifying its choice of the PM_{10} indicator on grounds of administrative convenience. Instead, after careful consideration, it is the view of the Administrator that the PM_{10} indicator will in fact provide the type of targeted protection from thoracic coarse particles which is justified by the emerging body of scientific evidence, that it will do so more effectively and more appropriately than all other indicators evaluated by EPA during the course of this review, and that the inclusion of $PM_{2.5}$ in the PM_{10} indicator does not over-regulate fine particles or under-regulate coarse particles.

To the contrary, the inclusion of $PM_{2.5}$ in the PM_{10} indicator plays two important roles in effectively providing the kind of targeted health protection called for under the current state of the science. Because the PM_{10} indicator includes both coarse PM (PM10–2.5) and fine PM (PM2.5), the concentration of PM10–2.5 allowed by a PM_{10} standard set at a single level declines as the concentration of $PM_{2.5}$ increases. Thus, the level of coarse particles allowed varies depending on the level of fine particles present. At the same time, $PM_{2.5}$ levels tend to be lower in rural areas and higher in urban areas. EPA, 2005, p. 2–54, and Figures 2–23 and 2–24 at pp. 2–52 and 2–53. Thus, to the extent that higher $PM_{2.5}$ levels lead to a lower allowable level of coarse particles in some areas compared to others, this will occur in precisely those locations—

i.e. urban or industrial areas—where the science has shown the strongest evidence of adverse health effects associated with exposure to coarse particles. The EPA's recent Particle Pollution Report (EPA, 2004b, Figure 5, p. 8) provides evidence that annual average concentrations of $PM_{2.5}$ in selected eastern and western urban areas consistently exceed the annual average levels of $PM_{2.5}$ in nearby rural areas. This means that a PM_{10} standard set at a single, unvarying level will permit, on average, lower levels of coarse particles in urban areas, where $PM_{2.5}$ concentrations tend to be higher. The varying levels of coarse particles allowed by a PM_{10} indicator will therefore target protection in urban and industrial areas where the evidence of adverse health effects associated with exposure to coarse particles is strongest. For the same reason, lower levels of $PM_{2.5}$ lead to a higher allowable level of coarse particles in non-urban areas, again an appropriate result given the inconclusive evidence of health risks associated with coarse particles in these areas. The varying amounts of coarse particles that are allowed in urban vs. non-urban areas under the 24-hour PM_{10} standard, based on the varying levels of $PM_{2.5}$ present, appropriately reflect the differences in the strength of evidence regarding coarse particle effects in urban and non-urban areas.[72]

This result is consistent with our current understanding of the strength of the evidence regarding the toxicity of different ambient mixes of thoracic coarse particles in urban and non-urban or rural areas, and also is in accord with our current understanding of the observed toxicity in urban and industrial areas. As noted in both the proposal and the Criteria Document, the observed toxicity of coarse particles in urban and industrial areas comes from the kind of coarse particles found in these environments, for example direct emissions from industrial sources or materials released to road dust from motor vehicles such as brake and tire wear, as well as from the contamination of coarse particles that can occur. This contamination can come from both mobile and stationary sources. In particular, specific components, such as byproducts of incomplete combustion (*e.g.* polycyclic aromatic hydrocarbons) most commonly emitted from motor vehicles and other sources in the form of $PM_{2.5}$, as well as metals and other contaminants emitted from other anthropogenic sources, appear in higher levels in urban areas (EPA, 2004a, p. 8–344; 71 FR 2665). Many of these contaminants in $PM_{10-2.5}$ come originally from fine particles, which may become attached in the atmosphere or be deposited and mixed into coarse materials on the ground. Thus the greater the concentration of $PM_{2.5}$, with higher levels typically found in urban areas, the greater the level of contamination of coarse particles by fine particles. This contamination increases the potential health risk posed by those coarse particles. For that reason, it is logical to allow lower levels of coarse particles when fine particle concentrations are high. In other words, inclusion of $PM_{2.5}$ in the PM_{10} indicator for purposes of coarse particle protection would appropriately reflect the contribution that contaminants emitted in fine particle form can make to the overall health risk posed by coarse particles.

Moreover, due to the contamination of $PM_{10-2.5}$ by $PM_{2.5}$, use of a PM_{10} indicator will not result in inappropriate double regulation of the $PM_{2.5}$ component. To the extent that use of a PM_{10} indicator would result in any reduction in $PM_{2.5}$ concentrations in an area, this would reduce the potential health risk from coarse particles in the area as well. There is no certainty that the contribution of $PM_{2.5}$ to the health risk associated with exposure to contaminated coarse particles would be appropriately addressed through the fine particle standards alone. Thus, to the extent that the inclusion of the $PM_{2.5}$ fraction in the PM_{10} indicator amounts to double regulation of $PM_{2.5}$, its inclusion is non-duplicative and reasonable: it ensures that this risk of contamination of coarse particles by $PM_{2.5}$ is addressed in the suite of fine and coarse PM standards.

Some commenters nonetheless maintained that the court's opinion in *ATA I* bars use of PM_{10} as an indicator for coarse particles, stressing the court's statement that "[i]t is the very presence of a separate $PM_{2.5}$ standard that makes retention of the PM_{10} indicator arbitrary and capricious." 175 F. 3d at 1054. The EPA disagrees that the *ATA I* decision precludes use of a PM_{10} indicator. The court did not hold that it was unlawful *per se* to use PM_{10} as an indicator for thoracic coarse particles. Instead, the court noted two particular problems—the variable level of allowable concentrations of $PM_{10-2.5}$ and double regulation of $PM_{2.5}$—and found that EPA either failed to address these issues, or provided explanations that were inconsistent and unsupported. *Id.* In large part, the court's decision was an important factor in EPA's close evaluation and subsequent proposal of a qualified $PM_{10-2.5}$ indicator as part of this NAAQS review. See EPA, 2005, p. 1–5. However, EPA now believes that a qualified $PM_{10-2.5}$ indicator is inappropriate, and that an unqualified $PM_{10-2.5}$ indicator is more problematic and less effective than a PM_{10} indicator at providing the requisite level of protection from the varying risks associated with thoracic coarse particles. Indeed, for the reasons described above, PM_{10} is an effective indicator for targeting coarse particles because it provides the desired variability in allowable coarse particle concentrations.

Far from being arbitrary and capricious, inclusion of $PM_{2.5}$ serves two important functions: first, it is the mechanism that provides for the variation in allowable $PM_{10-2.5}$ concentrations, targeting lower allowable levels where there is greater public health concern; and second, to the extent that there is "double regulation" of $PM_{2.5}$ by virtue of its inclusion in the PM_{10} indicator (175 F.3d at 1054), regulation of $PM_{2.5}$ via this indicator serves valid, non-duplicative purposes in providing requisite protection from thoracic coarse particles. The EPA also notes that "double regulation" of a pollutant, in the context of multiple NAAQS standards, is neither impermissible nor even unusual. For example, there are both annual and 24-hour standards for $PM_{2.5}$, as well as both primary and secondary standards for $PM_{2.5}$. The key is that the different standards reasonably serve different purposes " they are directed at different effects, or

[72] The EPA recognizes that this relationship is qualitative. That is, the varying coarse particle concentrations allowed under the PM_{10} standard do not precisely correspond to the variable toxicity of thoracic coarse particles in different areas. While currently available information does not allow any more precise adjustment for relative toxicity, EPA believes the standard will generally ensure that the coarse particle levels allowed will be lower in urban areas and higher in non-urban areas. While the allowable levels will vary with location due to differing levels of fine particles, that variability will ultimately be limited by implementation of the $PM_{2.5}$ standards. Areas that do not meet these standards are taking steps to reduce $PM_{2.5}$. Currently, the annual fine particle standard places limits on both the long- and short-term levels of fine particles in a number of cities, particularly in the east and in some California cities. In the long run, this will serve to make the "headroom" allowed for thoracic coarse particles (*i.e.* the allowable PM_{10} level minus the corresponding $PM_{2.5}$ concentration) more uniform among cities. The new 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ will promote this same result. It should cause areas that now meet the annual $PM_{2.5}$ standard, but have high 24-hour $PM_{2.5}$ concentrations, to adopt additional controls, further reducing the variability in the "headroom" for allowable thoracic coarse particle concentrations. In combination with the annual standard, the revised 24-hour $PM_{2.5}$ standard thus will provide for more consistent allowable levels of thoracic coarse particles in cities under the PM_{10} standard.

are not inconsistent when directed at the same effect—as is the case here.

The EPA also recognizes that selection of PM_{10} as the indicator for thoracic coarse particles differs in some degree from the specific advice provided by CASAC to use a qualified $PM_{10-2.5}$ indicator directed at urban or industrial thoracic coarse particles (71 FR 2665). However, EPA believes that the PM_{10} indicator is consistent with the central thrust of CASAC's advice—to utilize an indicator directed at urban types of coarse particulate matter, given the known toxicity of these particles—because it would generally allow lower levels of $PM_{10-2.5}$ in urban areas. The EPA has also explained why it has rejected a qualified $PM_{10-2.5}$ indicator at this time, and notes that CASAC itself considered multiple ways to achieve some degree of targeted protection and voiced strong objections to the qualified $PM_{10-2.5}$ indicator which the Agency proposed (Henderson, 2006, p. 4). The EPA has carefully considered CASAC's views in making its decision, and believes the final decision is consistent with the critical part of CASAC's advice, *i.e.*, to focus the indicator (and standard) on the type of thoracic coarse particles known to be harmful, which are found in urban and/or industrial environments.

c. Unqualified PM_{10} Indicator, with Adjustment to the $PM_{2.5}$ Component. EPA also solicited comment on an approach that would use PM_{10} as an indicator but subtract out the amount of $PM_{2.5}$ in excess of the 24-hour daily standard for $PM_{2.5}$ to avoid the double regulation of $PM_{2.5}$ in the situations where this would have the most regulatory consequence (71 FR 2673). Specifically, this option would retain the indicator, form and level of the 1987 PM_{10} standard, but on days when the measured concentration of PM_{10} exceeds the level of the standard and the measured concentration of $PM_{2.5}$ exceeds the level of the daily $PM_{2.5}$ standard, the amount of $PM_{2.5}$ in excess of the daily $PM_{2.5}$ standard would be subtracted from the total PM_{10}. A few commenters, including certain industry commenters and several local agencies and Tribes, expressed conditional support for pursuing this approach: though they preferred either no coarse particle standard (in the case of industry commenters) or an unqualified $PM_{10-2.5}$ standard applied nationally (in the case of Tribes or local agencies), they suggested that an adjusted PM_{10} indicator would be an acceptable alternative. This alternative, like an unadjusted PM_{10} indicator, would allow variable ambient concentrations of coarse particles. The net result, however, would be that $PM_{10-2.5}$ levels would be allowed to increase relative to the current PM_{10} standard when $PM_{2.5}$ levels are highest. As explained above, this is the opposite result from that desired from a public health perspective. There should be less allowable coarse particulate matter as $PM_{2.5}$ levels increase because these are the conditions under which $PM_{10-2.5}$ tends to become more contaminated and therefore more harmful. Furthermore, it would essentially relax the level of protection afforded by the current 24-hour PM_{10} standard because it would allow higher total PM_{10} levels on days with high $PM_{2.5}$ levels. As explained below in section III.D.2, EPA believes it is important to maintain the current level of protection from health effects associated with exposure to thoracic coarse particles. For both of these reasons, therefore, EPA rejected this approach.

4. Conclusions Regarding Indicator for Thoracic Coarse Particles

After extensive evaluation of the evidence, the alternatives available to the Agency, the advice and recommendations of CASAC, and all of the public comments, EPA concludes that retaining the PM_{10} indicator will be more effective in providing targeted public health protection than all other options available and, based on the current state of the science, is the most appropriate indicator to protect against the health effects associated with exposure to thoracic coarse particles. Thus, in the judgment of the Administrator, it is appropriate to retain PM_{10} as the indicator for coarse particles at this time. The conclusions that led to this decision can be summarized as follows:

(1) All thoracic coarse particulate matter can deposit in the sensitive regions of the lung of most concern, the tracheobronchial and alveolar regions.

(2) It remains appropriate to provide, to the extent possible, targeted protection from thoracic coarse particles that have been demonstrated to be associated with significant adverse health effects. Urban or industrial ambient mixes of coarse particulate matter dominated by high density vehicular, industrial, and construction emissions are of greatest concern, and should be the focus of protection.

(3) The proposed qualified $PM_{10-2.5}$ indicator was beset by numerous problems. Possible modifications to the qualifications considered by EPA failed to resolve these problems, which stem from the basic inability at this time to effectively and precisely identify which ambient mixes are included in the indicator and which are not.

(4) The evidence of health effects associated with non-urban ambient mixes of coarse particles is limited and inconclusive: in general, the evidence does not demonstrate that community-level exposures in non-urban areas are associated with either the existence or absence of adverse health effects.

(5) In light of the entire body of evidence concerning thoracic coarse particles, and given the potentially serious nature of the health risks posed by at least some thoracic coarse particles and the potential size of the population exposed, it is appropriate to provide some protection for all types of thoracic coarse particles, consistent with the requirement of the Act to allow an adequate margin of safety.

With all of the foregoing considerations in mind, the Administrator judges it appropriate not to revise the current PM_{10} indicator at this time. In the view of the Administrator, the PM_{10} indicator provides the type of targeted variation in allowable coarse particle concentrations that is justified by the emerging body of scientific evidence, while providing some protection in all areas. A decision not to revise the PM_{10} indicator reflects an appropriately cautious approach in two respects. First, it ensures inclusion of all ambient mixes of coarse particles of known concern in the indicator; and second, it addresses the potential that additional scientific research may reveal that non-urban or rural ambient mixes of thoracic coarse particles present public health risks that the evidence does not clearly identify at this time. It is EPA's goal that its new research and speciated monitoring program will produce data to determine what effect differences in particle composition may have on health outcomes. Such results have the potential to provide the kind of certainty and specificity required for making future decisions on indicators for thoracic coarse particles that might incorporate qualifications, such as the proposed qualified indicator related to coarse particles from agriculture and mining.

D. Conclusions Regarding Averaging Time, Form, and Level of the Current PM_{10} Standards

1. Averaging Time

In the last review, EPA retained both 24-hour and annual PM_{10} standards to provide protection against the known and potential effects of short- and long-term exposures to thoracic coarse particles (62 FR 38677–79). That

decision was based in part on qualitative considerations related to the expectation that deposition of thoracic coarse particles in the respiratory system could aggravate effects in individuals with asthma. In addition, quantitative support for retaining a 24-hour standard came from limited epidemiologic evidence suggesting that aggravation of asthma and respiratory infection and symptoms may be associated with daily or episodic increases in PM_{10}, where dominated by thoracic coarse particles including fugitive dust. The decision to retain an annual standard as well was generally based on considerations of the plausibility of the potential build-up of insoluble thoracic coarse particles in the lung after long-term exposures to high levels of such particles.

New information available in this review, discussed above, includes several epidemiologic studies that report statistically significant associations between short-term (24-hour) exposure to $PM_{10-2.5}$ and various morbidity effects and mortality. With regard to long-term exposure studies, while one study conducted in southern California reported a link between reduced lung function growth and long-term exposure to $PM_{10-2.5}$ and $PM_{2.5}$, other such studies reported no associations (EPA, 2005, p. 3–19, 3–23–24). Thus, the Criteria Document concluded that the available evidence does not suggest an association with long-term exposure to $PM_{10-2.5}$ (EPA, 2004a, p. 9–79).

Based on these considerations, the Staff Paper concluded that the newly available evidence continues to support a 24-hour averaging time for a standard intended to control thoracic coarse particles, based primarily on evidence suggestive of associations between short-term (24-hour) exposure and morbidity effects and, to a lesser degree, mortality. Noting the absence of evidence judged to be suggestive of an association with long-term exposures, the Staff Paper concluded that there is no quantitative evidence that directly supports an annual standard, while recognizing that it could be appropriate to consider an annual standard to provide a margin of safety against possible effects related to long-term exposure to thoracic coarse particles that future research may reveal. The Staff Paper observed, however, that a 24-hour standard that would reduce 24-hour exposures would also likely reduce long-term average exposures, thus providing some margin of safety against the possibility of health effects associated with long-term exposures (EPA, 2005, p. 5–61). Based on its review of the Staff Paper, CASAC recommended retention of a 24-hour averaging time and agreed that an annual averaging time is not currently warranted for the coarse particle standard (Henderson, 2005b, p.5).

The EPA received relatively few comments regarding the appropriate averaging time of the coarse particle standard. Most of those who did comment generally supported the retention of a 24-hour, but not annual, averaging time, as proposed. A few of the commenters who concurred with EPA's proposal to revoke the annual standard urged reconsideration of the appropriateness of an annual averaging time in the next PM NAAQS review. Several commenters, however, including a few States and several environmental and public health groups, urged EPA to retain an annual standard as well as a 24-hour standard. The American Lung Association, in particular, stated that EPA had inappropriately ignored evidence of long-term morbidity effects in several studies, including Gauderman *et al.* (2000, 2002) and Avol *et al.* (2001), and had also ignored substantial evidence from European studies as well as the recommendations for an annual PM_{10} standard made by a WHO working group. These commenters argued that an annual standard was requisite to protect public health with an adequate margin of safety.

EPA disagrees that it ignored the evidence that is relevant to evaluating the health effects associated with long-term exposure to thoracic coarse particles. The EPA's assessment, both in this review and the previous review, placed greatest weight on studies that measured $PM_{10-2.5}$ or on studies conducted in areas where it is reasonable to expect the PM_{10} measurements to be dominated by coarse particles (EPA, 2005). By contrast, these commenters have placed inappropriate reliance on studies that measured PM_{10}, and were conducted in Southern California cities (Gauderman *et al.*, 2000, 2002) or in European cities where it is not reasonable to assume that PM_{10} associations are dominated by coarse particles.[73] In such cases, it is difficult to draw meaningful conclusions about the relative role of coarse as opposed to fine particles. The WHO panel recommendations for PM_{10} limits cited by commenters also do not provide any independent scientific justification regarding the need for a separate long-term standard for coarse particles.[74]

The long-term exposure studies of mortality and morbidity that permit comparisons of fine and coarse particles continue to suggest that, at current ambient levels in the US, fine particles are associated with health effects and coarse particles are not.[75] The EPA believes that the $PM_{2.5}$ standards it is establishing in today's notice address the major risk suggested in the PM_{10} studies cited by commenters. To the extent that additional concerns may exist with regard to long-term exposures to coarse particles that have not been fully identified by scientific research, the Staff Paper notes that the short-term standard for coarse particles, which is generally controlling, has and will continue, as a practical matter, to limit such long-term exposures.[76]

After reviewing the available evidence, the Administrator concurs with staff and CASAC recommendations and concludes that the evidence continues to support a 24-hour averaging time for a coarse particle standard, based primarily on evidence suggestive of associations between short-term (24-hour) exposure and morbidity effects and, to a lesser degree, mortality. As noted above, a 24-hour standard would in effect also provide protection against any as yet unidentified potential effects of long-term exposure at ambient levels. Further, the Administrator concludes

[73] The only one of these studies (Gauderman *et al.*, 2000) to include measurements of coarse particles found an association between lung function growth for PM_{10}, $PM_{2.5}$, $PM_{10-2.5}$, NO_2, and acids. The authors were unable to cite any single pollutant as responsible for these results, but they chose not to include measures for coarse particles in their follow-up study (Gauderman et al., 2002). As noted in the 1996 PM Staff Paper, the other major study of lung function and long-term air pollution in children found no associations with coarse particles (EPA, 1996, p. 5–67a).

[74] The WHO panel essentially developed their recommendations for PM_{10} standards by deriving a ratio of fine particles to PM_{10} and adjusting their recommended levels for $PM_{2.5}$ to derive an equivalent PM_{10} metric, for areas that do not yet have access to $PM_{2.5}$ monitors (WHO, 2005, p. 8).

[75] See EPA 2004a, pp. 8–306 to 307 ("no statistically significant associations have been reported between long-term exposure to coarse fraction particles and cause-specific mortality"); pp. 8–313 to 314 ("[t]he recent studies suggest that long-term exposure to fine particles is associated with development of chronic respiratory disease and reduced lung function growth; little evidence is available on potential effects of exposure to coarse fraction particles").

[76] The Staff Paper analysis of PM_{10} air quality data indicates that the current 24-hour PM_{10} standard is "controlling" in virtually every area in the US; that is, virtually all areas that violate the PM_{10} standards violate the 24-hour PM_{10} standard. Some of them may violate the annual PM_{10} standard as well, but (depending on the year) few, if any, areas violate the annual PM without violating the 24-hour PM_{10} standard (EPA, 2005, p. 2–31 to 32). A supplemental analysis in the Response to Comments document shows that for 2003–2005, all of the areas that would violate the annual PM_{10} standard also violate the 24-hour standard.

that an annual coarse particle standard is not warranted at this time. Thus, the Administrator is retaining the 24-hour PM_{10} standard and revoking the annual PM_{10} standard.

2. Level and Form of the 24-Hour PM_{10} Standard

This section summarizes the major considerations that led to the proposed decision regarding the appropriate level and form for the 24-hour standard for thoracic coarse particles, summarizes and addresses public comments on the appropriate level of protection to be provided by the standard, and presents the Administrator's final conclusions regarding the level and form of the 24-hour standard. The proposed level and form for the 24-hour standard for thoracic coarse particles were based primarily on an assessment of studies that measured $PM_{10-2.5}$, as well as studies that measured PM_{10} in areas that were dominated by $PM_{10-2.5}$. Now that the Administrator has concluded that it is appropriate to retain PM_{10} as the indicator for thoracic coarse particles, rather than adopting a $PM_{10-2.5}$ indicator as proposed, the Administrator relied on this same body of studies as the principal basis for determining an appropriate level and form for a standard based on the PM_{10} indicator. Therefore, in this section EPA reviews the basis for its conclusions in the proposal, and then discusses how this evidence informs the choice of level and form for the 24-hour PM_{10} standard.

In considering the available evidence as a basis for setting a 24-hour standard for thoracic coarse particles, the Staff Paper focused on relevant U.S. and Canadian epidemiologic studies showing associations between short-term $PM_{10-2.5}$ concentrations and morbidity and mortality effects, as discussed above in section III.A. As an initial matter, the Staff Paper recognized that these individual short-term exposure studies provide no evidence of clear population thresholds, or lowest-observed-effects levels, in terms of 24-hour average concentrations. As a consequence, this body of evidence is difficult to translate directly into a specific 24-hour standard that would protect against the range of effects that have been associated with short-term exposures to coarse particles.

In considering the evidence, the Staff Paper noted the significant uncertainties and the limited nature of the available evidence. In examining the available evidence to identify a basis for a range of standard levels that would be appropriate for consideration, the Staff Paper focused on the upper end of the distributions of daily $PM_{10-2.5}$ concentrations in the relevant studies in terms of the 98th and 99th percentile values.[77]

In looking first at the morbidity studies that report statistically significant associations with respiratory- and cardiac-related hospital admissions in Toronto (Burnett *et al.*, 1997), Seattle (Sheppard, 2003), and Detroit (Ito, 2003), the 98th percentile $PM_{10-2.5}$ values reported in these studies range from approximately 30 to 36 $\mu g/m^3$. To provide some perspective on these $PM_{10-2.5}$ levels, the Staff Paper noted that the level of the 24-hour PM_{10} standard was exceeded on only a few occasions during the time periods of the studies in Detroit and Seattle.[78] In the mortality studies that report statistically significant and generally robust associations with short-term exposures to $PM_{10-2.5}$ in Phoenix (Mar *et al.*, 2003) and Coachella Valley, CA (Ostro *et al.*, 2003), the reported 98th percentile values were approximately 70 and 107 $\mu g/m^3$, respectively. These studies were conducted in areas with air quality levels that did not meet the current PM_{10} standards. In addition, as part of the Six Cities study, Schwartz *et al.* (1996 and reanalysis 2003a) reported a statistically significant association between $PM_{10-2.5}$ and mortality in Steubenville, where the $PM_{10-2.5}$ concentrations were fairly high, with a reported 98th percentile value of 53 $\mu g/m^3$, although in a second reanalysis, the association did not remain statistically significant (Klemm and Mason, 2003). On the other hand, the Staff Paper noted that no statistically significant mortality associations were reported in a number of other studies, including those in the five other cities that were part of the Six Cities study (Boston, St. Louis, Knoxville, Topeka, and Portage), and in Santa Clara County, CA, Detroit, Philadelphia, and Pittsburgh. With the exception of Pittsburgh, these cities had much lower 98th percentile $PM_{10-2.5}$ values, ranging from 18 to 49 $\mu g/m^3$. Thus, in mortality studies that reported statistically significant associations, the reported 98th percentile $PM_{10-2.5}$ values were all above 50 $\mu g/m^3$, and all in areas that exceeded the level of the daily PM_{10} standard, whereas in the mortality studies that reported no statistically significant associations, the reported 98th percentile $PM_{10-2.5}$ values were generally below 50 $\mu g/m^3$.

In examining the air quality data used in the key morbidity and mortality studies considered in the Staff Paper, EPA recognized that the uncertainty related to exposure measurement error associated with using ambient concentrations to represent area-wide population exposure levels can be potentially quite large. For example, in looking specifically at the Detroit study, the Staff Paper noted that the $PM_{10-2.5}$ air quality values were based on air quality monitors located in Windsor, Canada. While the study authors concluded that these monitors were appropriate for use in exploring the association between air quality and hospital admissions in Detroit, a close examination of air quality levels at Detroit and Windsor sites in recent years led to the conclusion that the statistically significant, generally robust association with hospital admissions in Detroit likely reflects population exposures that may be appreciably higher in the central city area, but not necessarily across the broader study area, than would be estimated using data from the Windsor monitors (EPA, 2005, p. 5–64).

The Staff Paper also looked more specifically at the Coachella Valley mortality study (Ostro *et al.*, 2003), in which data were used from a single monitoring site in one city, Indio, within the study area where daily measurements were available. A close examination of air quality levels across the Coachella Valley suggested that while the association of mortality with $PM_{10-2.5}$ measurements made at the Indio site was statistically significant, a portion of the study population would have been expected to experience appreciably lower ambient exposure levels. In contrast to the Detroit study, air quality data used in the mortality study conducted in Coachella Valley appeared to represent concentrations on the high end of $PM_{10-2.5}$ levels for Coachella Valley communities. On the other hand, a close examination of the air quality data used in the other studies discussed above generally showed less disparity between air quality levels at the monitoring sites used in the studies and the broader pattern of air quality levels across the study areas than that described above in the Detroit and Coachella Valley studies.

The Staff Paper noted that this close examination of air quality information generally reinforced the view that exposure measurement error is potentially quite large in studies focusing on thoracic coarse particles. As

[77] This examination of the evidence is based on air quality information and analyses presented in two staff memos which were part of the materials reviewed by CASAC (Ross and Langstaff, 2005; Ross, 2005).

[78] As shown in air quality data trends reports: for Seattle, *1997 Air Quality Annual Report for Washington State*, p. 17, at *http://www.ecy.wa.gov/pubs/97208.pdf*; for Detroit, Michigan's 2003 Annual Air Quality Report, p. 46, at *http://www.deq.state.mi.us/documents/deq-aqd-air-reports-03AQReport.pdf*.

a consequence, the air quality levels reported in these studies as measured by ambient concentrations at monitoring sites within the study areas are not necessarily good surrogates for population exposures that are likely associated with the observed effects in the study areas or that would likely be associated with effects in other urban areas across the country. The Detroit example suggests that population exposures were probably appreciably underestimated in the Detroit morbidity study, such that the observed effects are likely associated with higher $PM_{10-2.5}$ levels than reported. In contrast, the Coachella Valley mortality study provides an example in which $PM_{10-2.5}$ levels to which the study populations were exposed were probably appreciably overestimated, such that the observed effects may well be associated with lower $PM_{10-2.5}$ levels than reported. At relatively low levels of air quality, population exposures implied by these studies as being associated with the observed effects become more uncertain, suggesting a high degree of caution in interpreting the air quality levels from the group of morbidity studies as a basis for identifying a standard level that would protect against the observed effects. See generally EPA, 2005, pp. 5–65–66.

Taking into account this close examination of the air quality data associated with health effects in these studies, the Staff Paper concluded that this evidence suggests that EPA could consider a standard for urban thoracic coarse particles at a $PM_{10-2.5}$ level at least down to 50 $\mu g/m^3$, in conjunction with a 98th percentile form. This view takes into account the conclusion that this evidence is particularly uncertain as to population exposures, especially from the morbidity studies reporting effects at relatively low concentrations, as well as the general lack of evidence of associations from the group of mortality studies with reported concentrations below these levels. *Id.* at p. 5–66.

The Staff Paper also outlined another view that reflected a more cautious or restrained approach to interpreting the limited body of $PM_{10-2.5}$ epidemiologic evidence. This approach would judge that the uncertainties as to population exposures associated with the observed effects in this whole group of studies were too large to permit direct use of the reported effects levels as a basis for setting a specific standard level. Such a judgment would be consistent with concluding that these studies, together with other dosimetric and toxicologic evidence, provide support for retaining standards for thoracic coarse particles at some level to protect against the morbidity and mortality effects observed in the studies, regardless of whether an associated population exposure level can be clearly discerned from the studies.

Based on this more cautious approach, the Staff Paper concluded that it would be reasonable to interpret the available epidemiologic evidence more qualitatively. Considering the available evidence in this way led to the following observations:

(1) The statistically significant mortality associations with short-term exposure to $PM_{10-2.5}$ reported in the Phoenix and Coachella Valley studies were observed in areas that did not meet the current PM_{10} standards.

(2) The statistically significant morbidity associations with short-term exposure to $PM_{10-2.5}$ reported in the Detroit and Seattle studies were observed in areas that exceeded the level of the current 24-hour PM_{10} standard on just a few occasions during the time periods of the studies.

(3) All but one of the statistically significant morbidity and mortality associations with short-term exposure to PM_{10} that were reported in areas in which PM_{10} was dominated by the coarse particle fraction (including Reno/Sparks, NV, Tucson, AZ, Anchorage, AK, and the Utah Valley area) were observed in areas that did not meet the current PM_{10} standards. *Id.* at p. 5–67.

Based on these considerations, the Staff Paper found little basis for concluding that the degree of protection afforded by the current PM_{10} standards in urban areas is greater than warranted, since potential mortality effects have been associated with air quality levels not allowed by the current 24-hour standard, but have not been associated with air quality levels that would generally meet that standard, and morbidity effects have been associated with air quality levels that exceeded the current 24-hour standard only a few times. Further, the Staff Paper found little basis for concluding that a greater degree of protection is warranted in light of the very high degree of uncertainty in the relevant population exposures implied by the morbidity studies. The Staff Paper concluded, therefore, that it is reasonable to interpret the available evidence as supporting consideration of a short-term standard for urban thoracic coarse particles, so as to provide generally "equivalent" protection to that afforded by the current 24-hour PM_{10} standard, recognizing that no one $PM_{10-2.5}$ level will be strictly equivalent to a specific PM_{10} level in all areas (EPA, 2005, p. 5–67). Such a standard would likely provide protection against morbidity effects especially in those urban areas where, unlike several of the study areas, PM_{10} is generally dominated by coarse-fraction rather than fine-fraction particles. Such a standard would also likely provide protection against the more serious, but less certain, coarse-particle-related mortality effects observed in some studies, generally at somewhat higher concentrations.

The Staff Paper went on to consider what level for a 24-hour $PM_{10-2.5}$ standard for urban coarse particles would provide an equivalent level of protection to that afforded by the current 24-hour PM_{10} standard. This consideration of a $PM_{10-2.5}$ standard providing generally "equivalent" protection reflected a judgment that while the epidemiologic evidence supported establishing a short-term standard for urban thoracic coarse particles at such a generally "equivalent" level, the evidence concerning air quality levels of thoracic coarse particles in the studies was not strong enough to provide a basis for changing the level of protection generally afforded by the current PM_{10} standards (EPA, 2005, pp. 5–68–69). The Staff Paper examined various approaches to providing this equivalent level of protection, including establishing a level of 70 $\mu g/m^3$ (98th percentile form) for the qualified $PM_{10-2.5}$ standard (*Id.* at 5–67–68), which is what EPA proposed (71 FR 2671).

CASAC generally supported the Agency's proposed range of 50–70 $\mu g/m^3$ (98th percentile) for the 24-hour $PM_{10-2.5}$ standard. As noted, the upper end of this range was based on EPA's assessment of a level for an urban coarse particle standard that would provide a generally equivalent level of protection to that afforded by the current PM_{10} standards. The lower end of the range was developed in consideration of an approach that would place greater weight on the effects levels reported in several studies with lower ambient coarse particle concentrations. The CASAC Panel noted that "there was general agreement among Panel members that Agency staff had presented a reasonable justification for the ranges of levels proposed" (Henderson 2005b, p. 6).

Relatively few public commenters addressed the issue of whether "general equivalence" was an appropriate goal for the level and form of the proposed coarse particle standard. Some commenters, particularly those industry commenters advocating that no coarse

particle standard be adopted,[79] stated that seeking "equivalence" to the PM_{10} standard was fundamentally flawed because, in their view: (1) The level of the current PM_{10} standard was not based on coarse particle studies; (2) the proposed standard is not equivalent to the PM_{10} standard; and (3) the court had already declared any standard based directly or indirectly on PM_{10} to be invalid. The EPA agrees that the 1987 PM_{10} standards were designed to protect against the health effects of both fine and coarse particles, and based in part on epidemiological studies that variously measured particles both smaller and larger than PM_{10}. However, the arguments regarding the origin of the 1987 standards as well as commenters' claims about the basis for the PM_{10} standards promulgated in 1997[80] are not relevant to the current review. In determining whether to revise the standards in this review, EPA has examined the degree of protection provided by the current 24-hour PM_{10} standard in light of the quantitative evidence from the expanded epidemiological data base that includes studies using direct $PM_{10-2.5}$ measurements as well as studies using PM_{10} measurements in areas where coarse particles dominate the distribution.

Because as discussed in section III.C.3 above, the Administrator has decided that it is appropriate to retain PM_{10} as the indicator for thoracic coarse particles, there can be no uncertainty as to whether the final standard is equivalent to the current standard, making the commenters' second point above moot. With regard to their third point, for reasons outlined in section III.C.3, EPA believes that it has addressed the concerns raised by the court regarding PM_{10} as an indicator, and in any case, the D.C. Circuit did not address the issue of the level of protection from thoracic coarse particles afforded by the 1997 or 1987 24-hour PM_{10} standard.

Other commenters, particularly environmental and public health groups, disagreed with EPA's proposal to seek an "equivalent level of protection" because they believe the scientific evidence mandates a lower level to protect against adverse health effects. These commenters cited studies reviewed in the Staff Paper and noted above, which they claimed showed significant associations between health effects and $PM_{10-2.5}$ concentrations at levels between 30–40 $\mu g/m^3$, and recent decisions by the European Union and the State of California to adopt 24-hour PM_{10} standards of 50 $\mu g/m^3$.

These commenters argued that, even considering EPA's analyses of the uncertainties in the relevant ambient concentration measurements, these studies, particularly those in Atlanta, Seattle, and Toronto and the six-cities study of respiratory symptoms in children (Schwartz and Neas, 2000), demonstrate the need for a more stringent level of protection than that provided by the current standards. These commenters also argued that EPA's approach to determining an equivalent level resulted in less protection than the current standard, even in urban areas. In addition, these commenters pointed to the study review conducted by Brunekreef and Forsberg (2005) and numerous "new" studies published too recently for inclusion in the Criteria Document such as Mar *et al.* (2004), Chen Y *et al.* (2005), and Lin *et al.* (2005), as supportive of lower levels.

As noted above, EPA has conducted a careful assessment of the studies cited by commenters[81] from the Staff Paper assessment but reaches substantially different conclusions about their implications for the level of a 24-hour standard for thoracic coarse particles. Based on that assessment, EPA staff recommended consideration of a range of levels for a 24-hour $PM_{10-2.5}$ standard extending from a level equivalent to the current PM_{10} standard down to a level of 50 $\mu g/m^3$, which is clearly above that suggested by these commenters. CASAC found general agreement that the "staff had presented a reasonable justification" for this range of levels. While EPA strongly agrees that the available scientific evidence supports and requires maintaining the level of protection provided by the current 24-hour PM_{10} standard, the limited extent of epidemiological evidence as well as the unusually large uncertainties in measuring exposures to thoracic coarse particles, particularly at lower levels, argue for the more cautious interpretation advocated by EPA staff and CASAC. Because the Administrator has decided to continue the use of PM_{10} as the indicator for coarse particles, commenters' remaining concerns about whether the proposed levels for $PM_{10-2.5}$ are as protective as current standards are no longer relevant.

For reasons summarized in section II.F above, EPA does not believe that standards adopted by the State of California or, by extension, the European Union, which operates under a different legal and policy structure, provide a relevant guide for establishing U.S. National Ambient Air Quality Standards. While EPA agrees that the assessment of Brunekreef and Forsberg (2005) supports separate regulation of fine and coarse particles, these authors make no recommendations with respect to appropriate levels of protection. To the extent that commenters cited "new" studies in support of their argument for a more stringent standard to protect against health effects associated with exposure to coarse particles, EPA notes that as in past NAAQS reviews, it is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review, and will consider the newly published studies for purposes of decision making in the next PM NAAQS review, as discussed above in section I.C. As evidenced by the uncertainties found in the detailed assessment of key coarse particle studies in the Staff Paper, the kind of assessment and analysis provided by the formal criteria and standards review process is particularly crucial for coarse particle studies that may be relevant to selecting the level of the standard.

After considering the public comments on this issue, EPA continues to believe that the available evidence leads to the conclusion that the degree of protection afforded by the current 24-hour PM_{10} standard is requisite to protect public health with an adequate margin of safety. Having chosen to retain the current indicator for the standard (PM_{10}), and to retain the same degree of protection, it is still necessary to determine the appropriate form and level for the standard. In the context of proposing a standard based on a qualified $PM_{10-2.5}$ indicator, EPA proposed to change the form of the 24-hour standard from a one-expected

[79] As discussed in section III.B.2, these commenters call EPA's interpretation of the key studies discussed in this section into question. EPA's response to the criticisms of use of these studies for standard setting is summarized in section III.B.2 and presented in more detail in the Response to Comments document.

[80] Commenters also suggested that, in promulgating revised PM_{10} standards in 1997, EPA did not consider whether the level of the PM_{10} standards it promulgated was lower than necessary and did not base the levels on coarse particle health effects data. While EPA disagrees with both of these claims—for example, EPA relied on two PM_{10} studies done in areas dominated by coarse particles in selecting the level (62 FR 38679)—this argument is not relevant to this review.

[81] As detailed in the Response to Comment document, EPA had various reasons for not placing primary reliance on the reported air quality results in these studies for selecting a standard level. The Atlanta study (Tolbert *et al.*, 2000), found a significant effect for PM_{10}, but not for coarse particles. Both the Six Cities children's diary study (Schwartz and Neas, 2000) and the Toronto hospital admissions study (Burnett *et al.*, 1997) were conducted for a periods of less than one year, making it difficult to determine what peak value across all seasons in a year might represent exposures of concern.

exceedance form to a 98th percentile form. The 98th percentile form was intended to be consistent with the goal of providing protection equivalent to that afforded by the current 24-hour PM_{10} standard (71 FR at 2671; EPA, 2005, p. 5–68). The few commenters addressing the proposed form supported it, largely because the 98th percentile would provide a more stable statistical basis for making nonattainment determinations. However, some commenters objected to the 98th percentile form because they felt it was inappropriate to allow as many as 21 days over the level of the standard over the course of a three-year period. These commenters argued for a more restrictive form (generally 99th percentile) to ensure the protection of public health with an adequate margin of safety. The EPA notes that the current one-expected-exceedance form of the 24-hour PM_{10} standard allows only three days above the standard over a three-year period.

While EPA generally favors the concentration-based form for short-term standards for reasons noted above, EPA also notes that adopting such a form in this review without changing the level would result in a standard that would not provide the same protection as the current standard, and the level of the standard would have to be adjusted downward to achieve the desired protection. Given the overall decision to provide the same protection as the current standards, the Administrator concludes it is best to retain both the form and the level of the current primary 24-hour PM_{10} standard.

In conclusion, it is EPA's view, as expressed in the Staff Paper and proposal and supported by CASAC and by the available health effects evidence, that the level of protection afforded by the current 24-hour PM_{10} standard of 150 $\mu g/m^3$, one-expected-exceedance form, continues to be appropriate for the types of thoracic coarse particles typically found in urban or industrial areas. As explained above, mortality effects observed in epidemiologic studies for coarse particles are generally associated with exposure levels that exceed the current standards, and morbidity effects are generally associated with exposure levels that exceeded the current standards on only a few occasions. This suggests the level of protection afforded by the current PM_{10} standards is not greater than warranted. Furthermore, the very high degree of uncertainty in the relevant population exposures implied by the morbidity studies suggests there is little basis for concluding at this time that a greater degree of protection is warranted.

Moreover, as explained above in section III.C.3.b, the PM_{10} indicator provides appropriate variation in allowable coarse particle concentrations in different areas based on the relative proportions of $PM_{2.5}$ and $PM_{10-2.5}$ in the ambient mix. In urban areas where $PM_{2.5}$ concentrations tend to be higher, the current 24-hour PM_{10} standard level of 150 $\mu g/m^3$ will result in lower allowable levels of $PM_{10-2.5}$. In non-urban areas, the higher allowable levels of coarse particles provided by the current 24-hour PM_{10} standard will also provide appropriate protection of public health, given the body of evidence discussed above. The EPA therefore believes that the level of protection from coarse particles provided by the current 24-hour PM_{10} standard remains requisite to protect public health with an adequate margin of safety. Revising either the level or the form of this standard would alter the current level of protection and therefore would not be appropriate based on the scientific evidence available at this time.

Therefore, after considering the available scientific evidence, the rationale and recommendations contained in the Staff Paper, the advice and recommendations of CASAC, and the public comments received regarding the appropriate level and form for a 24-hour standard intended to afford requisite protection of public health from effects associated with exposure to coarse particles, the Administrator has determined to retain the current level of 150 $\mu g/m^3$ for the 24-hour PM_{10} standard, and the current one-expected-exceedance form. In the Administrator's judgment, based on the currently available evidence, a standard set at this level remains requisite to protect public health with an adequate margin of safety from the morbidity and possibly mortality effects that have been associated with short-term exposures to thoracic coarse particles in urban or industrial areas, as well as to protect against the potential for risks from exposure to thoracic coarse particles in other areas. The EPA intends to address the considerable uncertainties in the currently available information on thoracic coarse particles as part of the Agency's ongoing PM research program.

E. Final Decisions on Primary PM_{10} Standards

For the reasons discussed above in this section, and taking into account the information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, and public comments received on the proposal, the Administrator is retaining the current primary 24-hour PM_{10} standard at the level of 150 $\mu g/m^3$, which is met when this level is not exceeded more than once per year on average over a three-year period measured at each monitor within an area. The Administrator also is revoking and not replacing the annual PM_{10} standard.

As discussed in more detail in section VI, EPA is promulgating a new reference method (FRM) for measurement of mass concentrations of $PM_{10-2.5}$ in the atmosphere. Although NAAQS for $PM_{10-2.5}$ have not been established by EPA, this new FRM will nevertheless be defined as the standard of reference for measurements of $PM_{10-2.5}$ concentrations in ambient air. This should provide a basis for approving Federal Equivalent Methods (FEMs) and promote the gathering of scientific data to support future reviews of the PM NAAQS. One of the reasons for not finalizing a $PM_{10-2.5}$ standard was the limited body of evidence on health effects associated with thoracic coarse particles from studies that use $PM_{10-2.5}$ measurements of ambient thoracic coarse particle concentrations. If an FRM is available, researchers will likely include $PM_{10-2.5}$ measurements of thoracic coarse particles in health studies either by directly using the FRM or by utilizing approved equivalent methods based on the FRM.

In addition, EPA published elsewhere in today's Federal Register a requirement for a new multi-pollutant monitoring network that takes an integrated approach to air quality measurements. One of the required measurements at these multi-pollutant monitoring stations is $PM_{10-2.5}$. The availability of an FRM, and subsequently approved equivalent methods for $PM_{10-2.5}$, will support State and local agencies' efforts to deploy robust methods at these monitoring stations for the measurement of thoracic coarse particles that do not include fine particles. These multi-pollutant monitoring stations will provide a readily available dataset at approximately 75 urban and rural locations for atmospheric and health researchers to compare particle and gaseous air pollutants.

Finally, the $PM_{10-2.5}$ FRM, by definition, provides a reference measurement. Because it is a filter based system, this method can itself be used to provide speciated data and EPA will be issuing guidance to ensure the use of a consistent national approach for speciated coarse particle monitors as soon as possible. The reference measurement from this instrument is

also important in the development of alternative $PM_{10-2.5}$ speciation samplers. We will be developing dichotomous samplers to meet the requirements of SAFETEA–LU. Appropriate guidance to ensure that the use of a consistent national approach for speciated coarse particle monitors will be issued with this method. As discussed in more detail in the final monitoring rule published elsewhere in today's Federal Register, EPA is requiring the deployment of $PM_{10-2.5}$ speciation samplers at all 75 multi-pollutant monitoring stations. Such speciation monitoring will help States in developing SIPs and will address a key research need for thoracic coarse particles by providing a better understanding of the chemistry of the collected samples.

IV. Rationale for Final Decisions on Secondary PM Standards

This section presents the Administrator's final decisions regarding the review of the current secondary NAAQS for PM. The existing suite of secondary PM standards, which is identical to the suite of primary PM standards, includes annual and 24-hour $PM_{2.5}$ standards and annual and 24-hour PM_{10} standards. The existing suite of secondary standards is intended to address visibility impairment associated with fine particles,[82] and materials damage and soiling related to both fine and coarse particles. The following discussion of the rationale for the final decisions on revising the secondary PM standards focuses on those considerations most influential in the Administrator's decisions, first addressing visibility impairment as it relates to the $PM_{2.5}$ secondary standards and then addressing the other welfare effects as they relate to both the $PM_{2.5}$ and PM_{10} secondary standards. The other welfare effects considered in this review include effects on vegetation and ecosystems, materials damage and soiling, and climate change.[83]

Sections IV.A and IV.B of the proposal (71 FR 2675–2685) provide a detailed summary of key information contained in the Criteria Document (EPA, 2004a, Chapters 4 and 9) and in the Staff Paper (EPA, 2005, Chapters 6 and 7) on the known and potential welfare effects associated with PM, including PM-related visibility impairment and PM-related effects on vegetation and ecosystems, materials damage and soiling, and climate change, respectively. This information is only briefly outlined in subsections IV.A.1 and IV.B.1 below. Subsequent sections provide a more complete discussion of the Administrator's rationale, having considered the evidence in light of public comments and his final decisions on the primary standards for PM, for his decision to revise the current PM secondary standards by making them identical in all respects to the revised suite of primary PM standards.

A. Visibility Impairment

This section presents the rationale for the Administrator's decision to revise the current secondary $PM_{2.5}$ standards to address PM-related visibility impairment by setting secondary standards identical in all respects to the revised $PM_{2.5}$ primary standards. As discussed below, the rationale includes consideration of: (1) The latest scientific information on visibility effects associated with PM; (2) insights gained from assessments of correlations between ambient $PM_{2.5}$ and visibility impairment prepared by EPA staff; and (3) specific conclusions regarding the need for revisions to the current standards (*i.e.*, indicator, averaging time, form, and level) that, taken together, would be requisite to protect the public welfare from adverse effects of $PM_{2.5}$ on visual air quality.

1. Visibility Impairment Related to Ambient PM

Section IV.A.1 of the proposal (71 FR 2675–2678) outlined key information contained in the Criteria Document and Staff Paper relevant to considering visibility impairment that is related to ambient PM. The information highlighted there summarizes:

(1) The nature of visibility impairment, including trends in visual air quality and the characterization of current visibility conditions, with a particular focus on visibility impairment in urban areas.

(2) Direct, quantitative relationships that exist between ambient PM constituents and light extinction, and thus visibility impairment, based in part on analyses of the extensive new data now available on $PM_{2.5}$ concentrations, primarily in urban areas, that explored factors that have historically complicated efforts to address visibility impairment nationally, including regional differences related to levels of primarily fine particles and to relative humidity.

(3) The impacts of urban visibility impairment on public welfare, based in part on valuation studies of benefits associated with improvements in visibility and in part on recognition of a number of programs, standards, and planning efforts to address visibility impairment, in the U.S. and abroad, that illustrate the value that the public places on improved visibility.

(4) Approaches to evaluating public perceptions and attitudes about visibility impairment, including new methods and tools that have been developed to communicate and evaluate public perceptions of varying visual effects associated with alternative levels of visibility impairment relative to varying pollution levels and environmental conditions.

The summary of the evidence on visibility impairment related to ambient fine particles in the proposal will not be repeated here. The EPA emphasizes that the final decisions on the secondary standards take into account the more comprehensive and detailed discussions of the scientific information on visibility impairment contained in the Criteria Document and Staff Paper.

2. Need for Revision of the Current Secondary $PM_{2.5}$ Standards To Protect Visibility

In 1997, EPA decided to address the effects of PM on visibility by setting secondary standards identical to the suite of $PM_{2.5}$ primary standards, in conjunction with the future establishment of a regional haze program under sections 169A and 169B of the Act (62 FR 38679–83). In reaching this decision, EPA first concluded that PM, especially fine particles, impairs visibility in various locations across the country, including multi-state regions, urban areas, and remote Class I Federal areas (e.g., national parks and wilderness areas). The EPA also concluded that addressing visibility impairment solely through setting more stringent national secondary standards would not be an appropriate means to protect the public welfare from adverse impacts of PM on visibility in all parts of the country. As a consequence, EPA determined that an approach that combined national secondary standards with a regional haze program was the most appropriate and effective way to address visibility impairment (EPA 2005, p. 7–2).

As anticipated in the last review, EPA promulgated a regional haze program in 1999 (65 FR 35713). That program requires States to establish goals for improving visibility in Class I areas and

[82] The Administrator recognized in establishing the levels of the secondary standards for $PM_{2.5}$ that these standards would work "in conjunction with implementation of a regional haze program" under Section 169A to provide appropriate national protection against visibility impairment in both urban and non-urban areas (62 FR 38683).

[83] As noted in section I.A above, in establishing secondary standards that are requisite to protect the public welfare from any known or anticipated adverse effects, EPA may not consider the costs of implementing the standards.

to adopt control strategies to achieve these goals. Since strategies to meet these goals are to reflect a coordinated approach among States, multi-state regional planning organizations have been formed and are now developing strategies, to be adopted over the next few years, that will make reasonable progress in meeting these goals.

The initial issue to be addressed in the current review of the secondary PM standards is whether, in view of the information now available, the existing secondary standards should be revised to provide requisite protection from PM-related adverse effects on visual air quality. As discussed in the Criteria Document and Staff Paper, while new research has led to improved understanding of the optical properties of particles and the effects of relative humidity on those properties, it has not changed the fundamental characterization from the last review of the role of PM, and especially fine particles, in visibility impairment. However, extensive new information from visibility and fine particle monitoring networks since the last review has allowed for updated characterizations of visibility trends and current levels in urban areas, as well as Class I areas. As discussed in section IV.A.1.b. of the proposal [71 FR 2676–2677), these new data were a critical component of analyses that better characterized visibility impairment in urban areas and the relationship between visibility and $PM_{2.5}$ concentrations, and led to the finding that $PM_{2.5}$ concentrations can be used as a general surrogate for visibility impairment in urban areas.

Taking into account the most recent monitoring information and analyses, and recognizing that efforts are now underway to address all human-caused visibility impairment in Class I areas through the regional haze program implemented under sections 169A and 169B of the CAA, as discussed above, this review focused on visibility impairment primarily in urban areas. In so doing, given the stronger link between visibility impairment and short-term $PM_{2.5}$ concentrations, EPA gave significant consideration to the question of whether visibility impairment in urban areas allowed by the current 24-hour secondary $PM_{2.5}$ standard can be considered adverse to public welfare.

As discussed in section IV.A.1.c. of the proposal [71 FR 2677–2678), studies in the U.S. and abroad have provided the basis for the establishment of standards and programs to address specific visibility concerns in a number of local areas. These studies (e.g., in Denver, Phoenix, British Columbia) have produced reasonably consistent results in terms of the visual ranges found to be generally acceptable by the participants in the various studies, which spanned from approximately 40 to 60 km in visual range. Standards targeting protection within this range have also been set by the State of Vermont and by California for the Lake Tahoe area, in contrast to the statewide California standard that targets a visual range of approximately 16 km.

In addition to the information available from such programs, photographic representations (simulated images and actual photographs) of visibility impairment are available, as discussed in section IV.A.1.d of the proposal (71 FR 2678), to help inform judgments about the acceptability of varying levels of visual air quality in urban areas across the U.S. In considering these images for Phoenix, Washington, DC, and Chicago (for which $PM_{2.5}$ concentrations are reported), the Staff Paper observed that:

(1) At concentrations at or near the level of the current 24-hour $PM_{2.5}$ standard (65 $\mu g/m^3$), which equates to visual ranges roughly around 10 km (6 miles), scenic views (e.g., mountains, historic monuments), as depicted in these images around and within the urban areas, are significantly obscured from view.

(2) Appreciable improvement in the visual clarity of the scenic views depicted in these images occurs at $PM_{2.5}$ concentrations below 35 to 40 $\mu g/m^3$, which equate to visual ranges generally above 20 km for the urban areas considered (EPA, 2005, p. 7–6).

(3) Visual air quality appears to be good in these images at $PM_{2.5}$ concentrations generally below 20 $\mu g/m^3$, corresponding to visual ranges of approximately 25 to 35 km (EPA, 2005, p. 7–8).

While being mindful of the limitations inherent in using visual representations from a small number of areas as a basis for considering national visibility-based secondary standards, the Staff Paper nonetheless concluded that these observations, together with information from the analyses and other programs discussed above, support revising the current secondary $PM_{2.5}$ standards to improve visual air quality, particularly in urban areas. As discussed below, the Staff Paper recommended the establishment of a new short-term secondary $PM_{2.5}$ standard to provide increased and more targeted protection, primarily in urban areas, from visibility impairment related to fine particles (EPA, 2005, p. 7–12). Based on its review of the Staff Paper, the CASAC advised the Administrator that most CASAC PM Panel members strongly supported the Staff Paper recommendation to establish a new distinct secondary $PM_{2.5}$ standard to protect urban visibility (Henderson, 2005a).[84] Most Panel members considered such a standard to be a reasonable complement to the Regional Haze Rules that protect Class I areas.

In the proposal, the Administrator carefully considered the rationale and recommendations in the Staff Paper, the advice and recommendations from CASAC, and initial public comments on the issue of whether the secondary PM standards should be revised to provide increased PM-related visibility impairment primarily in urban areas. In so doing, the Administrator first recognized that PM-related visibility impairment is principally related to fine particle levels, such that it is appropriate to focus the review on whether the current secondary $PM_{2.5}$ standards should be revised. The Administrator also recognized that perception of visibility impairment is most directly related to instantaneous levels of visual air quality, such that in considering whether the current suite of secondary standards would provide the appropriate degree of protection, he first considered whether the current 24-hour secondary $PM_{2.5}$ standard provides an appropriate level of protection from visibility impairment, principally in urban areas.

In the proposal, the Administrator called attention to the Staff Paper finding that, at concentrations at or near the level of the current 24-hour $PM_{2.5}$ secondary standard (65 $\mu g/m^3$) visual ranges are degraded to a distance of about 10 km (6 miles) and images of scenic views (e.g., mountains, historic monuments, urban skylines) around and within a number of urban areas are significantly obscured from view. Further, the Administrator took note of the various State and local standards and programs that have been established to protect visual air quality beyond the degree of protection that would be afforded by the current 24-hour secondary $PM_{2.5}$ standard. Based on all of the above considerations, the Administrator provisionally concluded that it was appropriate to revise the current 24-hour secondary $PM_{2.5}$ standard to provide an appropriate level of protection from visibility impairment principally in urban areas, in conjunction with the regional haze

[84] A dissenting view was expressed in one Panel member's individual review comments to the effect that any urban visibility standard should be voluntary and locally adopted [Henderson, 2005a].

program for protection of rural air quality in Class I areas.

The majority of commenters who expressed an opinion on the secondary standards, including NESCAUM, STAPPA/ALAPCO, a number of individual States, Tribal associations, and local organizations, and combined comments from various environmental groups supported the position that the secondary $PM_{2.5}$ standards should be revised to increase protection against visibility impairment. A number of these commenters cited the studies and evidence in the PM Staff Paper, as well as the recommendations of CASAC, in support of their views that a more protective standard is warranted. NESCAUM noted that, though monitors in the northeast region do not exceed the current secondary $PM_{2.5}$ standards, their regional haze camera network (CAMNET) routinely documents extremely hazy days obscuring city skylines and views. NESCAUM stated that "this shows that virtually all of $PM_{2.5}$ effects on visibility in the Northeast are occurring below the present secondary standard, justifying EPA's proposal to revise the existing standard to a more stringent level adequately protective of public welfare" (NESCAUM, attachment C, p. C–1) In general, EPA agrees with these commenters that the more recent information on visibility values, photographic evidence, and air quality/visibility relationships supports the need to revise the current secondary $PM_{2.5}$ standards.

Other commenters, including UARG, American Public Power Association, and American Electric Power, opposed a revision to strengthen the secondary $PM_{2.5}$ standards at this time. UARG stated that:

> Because the record does not establish that the risks to public welfare from ambient $PM_{2.5}$ are greater, different in character, or more certain than was understood when the present standards were established, the Agency lacks a basis for revising its conclusion that those standards provide the requisite protection of public welfare. [UARG, p. 36].

UARG questioned the usefulness of the photographic images and urban studies of acceptable visibility highlighted in the proposal for determining appropriate levels of urban visibility. They further noted that, for most areas, the annual $PM_{2.5}$ standard would prevent any exceedances of 65 $\mu g/m^3$.

While, as summarized above, the key optical aspects of the relationship between fine particles and visibility have been established for a long time, EPA strongly disagrees that the more recent visibility-related evidence and analyses presented in the Criteria Document and Staff Paper provide no basis for considering more protective $PM_{2.5}$ standards. As discussed in the Staff Paper, one of the key issues in the last review was whether the differences in humidity between East and West complicated the establishment of a nationally uniform $PM_{2.5}$ secondary standard, even for urban areas (EPA, 2005, p. 7–3). With the substantial addition to the air quality and visibility data made possible by the national urban $PM_{2.5}$ monitoring networks, an analysis conducted for this review found that, in urban areas, visibility levels show far less difference between eastern and western regions on a 24-hour or shorter time basis than implied by the largely non-urban data available in the 1997 review (EPA, 2005, p. 7–5). Of equal importance, more recent studies of visibility values conducted for several urbanized areas have found results generally consistent with an earlier study done for the city of Denver. While such studies are still limited in number and subject to uncertainty, they suggest a remarkable consistency in public reaction to urban visibility impairment caused by fine particles (EPA 2005, p. 6–18 to 23).

Furthermore, staff and CASAC agreed on the utility of photographic evidence in characterizing the nature of particle-induced haze. At the level of the current 24-hour $PM_{2.5}$ standard, the potential subtleties associated with alternative photographic views alluded to by UARG would be obscured by the density of the accompanying haze, which would restrict the distance of the farthest discernable dark objects to only 6 miles and greatly reduce the contrast for objects at significantly shorter distances. Although, as suggested by these commenters, the annual standard serves to limit excursions above the level of the current 24-hour standard, particularly in eastern urban areas, continuation of the current 24-hr $PM_{2.5}$ standard would permit a large number of exceedances of this level especially in some western urban areas, even when the standard is just attained. In summary, contrary to the views of this set of commenters, EPA believes that the combination of new insights from air quality analyses, the standards and studies developed to address urban visibility in several areas, as well as an evaluation of the photographic evidence, supports the need to revise the current secondary $PM_{2.5}$ standards.

Having considered the evidence and analysis of visibility and fine particles in the Criteria Document and Staff Paper, the advice and recommendations of the CASAC, as well as the public comments on this issue, the Administrator concludes that it is appropriate to revise the current secondary $PM_{2.5}$ standards to provide increased protection from visibility impairment in urban areas. Consistent with the considerations and rationale summarized above and in the proposal, the Administrator believes that emphasis should be placed on revisions to the current 24-hour $PM_{2.5}$ standard that would provide an appropriate level of protection against visibility impairment principally in urban areas, in conjunction with the regional haze program for protection of visual air quality in Class I areas.

3. Indicator of PM for Secondary Standard To Address Visibility Impairment

As discussed in the Staff Paper, fine particles contribute to visibility impairment directly in proportion to their concentration in the ambient air. Hygroscopic components of fine particles, in particular sulfates and nitrates, contribute disproportionately to visibility impairment under high humidity conditions. Particles in the coarse mode generally contribute only marginally to visibility impairment in urban areas. In analyzing how well $PM_{2.5}$ concentrations correlate with visibility in urban locations across the U.S. (see EPA, 2005, section 6.2.3), the Staff Paper concluded that the observed correlations are strong enough to support the use of $PM_{2.5}$ as the indicator for such standards. More specifically, clear correlations exist between 24-hour average $PM_{2.5}$ concentrations and reconstructed light extinction, which is directly related to visual range. These correlations are similar in the eastern and western regions of the U.S. Further, these correlations are less influenced by relative humidity and more consistent across regions when $PM_{2.5}$ concentrations are averaged over shorter, daylight time periods (e.g., 4 to 8 hours). Thus, the Staff Paper concluded that it is appropriate to use $PM_{2.5}$ as an indicator for standards to address visibility impairment in urban areas, especially when the indicator is defined for a relatively short period of daylight hours. Based on its review of the Staff Paper, most CASAC Panel members endorsed a $PM_{2.5}$ indicator for a secondary standard to address visibility impairment (Henderson, 2005a, p. 9).

The Administrator provisionally concurred with the EPA staff and CASAC recommendations, and proposed that $PM_{2.5}$ should be retained as the indicator for fine particles as part

of a secondary standard to address visibility protection. No commenters disputed the appropriateness of continuing to use $PM_{2.5}$ as the indicator for fine particle secondary standards to address visibility impairment.

Having considered the scientific information discussed in the proposal and summarized above, as well as the recommendations of the staff and CASAC and the public comments on this issue, the Administrator concludes that $PM_{2.5}$ should be retained as the indicator for fine particles as part of a secondary standard to address visibility protection.

4. Averaging Time of a Secondary $PM_{2.5}$ Standard for Visibility Protection

As discussed in the Staff Paper, averaging times from 24 to 4 hours were considered for a revised standard to address visibility impairment. Within this range, clear and similarly strong correlations were found between visibility and 24-hour average $PM_{2.5}$ concentrations in eastern and western areas, while somewhat stronger correlations were found with $PM_{2.5}$ concentrations averaged over a 4-hour time period. In general, correlations between $PM_{2.5}$ concentrations and light extinction were found to be generally less influenced by relative humidity and more consistent across regions as shorter, sub-daily averaging times, within daylight hours from approximately 10 a.m. to 6 p.m., were considered. The Staff Paper concluded that an averaging time from 4 to 8 hours, generally within this daylight time period, should be considered for a standard to address visibility impairment.

In reaching this conclusion, the Staff Paper recognized that the $PM_{2.5}$ Federal Reference Method (FRM) monitoring network provides 24-hour average concentrations, and, in some cases, on a third- or sixth-day sample schedule, such that implementing a standard with a less-than-24-hour averaging time would necessitate the use of continuous monitors that can provide hourly time resolution. Given that the data used in the Staff Paper analysis discussed above were from commercially available $PM_{2.5}$ continuous monitors, such monitors clearly could provide the hourly data that would be needed for comparison with a potential visibility standard with a less-than-24-hour averaging time.

Most CASAC Panel members supported the Staff Paper recommendation of a sub-daily (4 to 8 daylight hours) averaging time, finding it to be an innovative approach that strengthens the quality of the $PM_{2.5}$ indicator for visibility effects by targeting the driest part of the day (Henderson, 2005a, p. 9). In its advice to the Administrator, CASAC noted an indirect but important benefit to advancing EPA's monitoring program goals that would come from the direct use of hourly data from a network of continuous $PM_{2.5}$ mass monitors.

In considering the Staff Paper recommendation and CASAC's advice, the Administrator provisionally concluded that averaging times from 24 hours to 4 daylight hours would represent a reasonable range of choices for a standard to address urban visibility impairment. A 24-hour averaging time could be selected and applied based on the extensive data base currently available from the existing $PM_{2.5}$ FRM monitoring network, whereas a sub-daily averaging time would necessarily depend upon an expanded network of continuous $PM_{2.5}$ mass monitors. While the Administrator agreed that broader deployment of continuous $PM_{2.5}$ mass monitors is a desirable goal, working toward that goal does not depend upon nor provide an appropriate basis for setting a sub-daily standard. The Administrator believed that it was appropriate to evaluate averaging time in conjunction with reaching decisions on the form and level of a standard. Public comments on these issues, as well as the rationale for the final decisions on averaging time, form, and level of the secondary standards, are presented in the following section.

5. Final Decisions on Secondary $PM_{2.5}$ Standards for Visibility Protection

In considering $PM_{2.5}$ standards that would provide an appropriate level of protection against PM-related impairment of visibility primarily in urban areas, the Administrator took into account the results of the public perception and attitude surveys in the U.S. and Canada, State and local visibility standards within the U.S., and visual inspection of photographic representations of several urban areas across the U.S. summarized in section IV.A.1 of the proposal. In the Administrator's judgment, these sources provide useful but still quite limited information on the range of levels appropriate for consideration in setting a national visibility standard primarily for urban areas, given the generally subjective nature of the public welfare effect involved. In considering alternative forms for such standards, the Administrator took into account the same general factors that were considered in selecting an appropriate form for the 24-hour primary $PM_{2.5}$ standard (as discussed above in section II.E.1), as well as additional information on the percent of areas not likely to meet various alternative $PM_{2.5}$ standards, consistent with CASAC advice to consider such information (Henderson, 2005a, p. 10).

In considering the remaining elements of a secondary $PM_{2.5}$ standard (averaging time, form, and level) for purposes of the proposal, the Administrator looked to the rationale presented in the Staff Paper and to CASAC's advice and recommendations for such a standard. Based on photographic representations of varying levels of visual air quality, public perception studies, and local and State visibility standards, as discussed above, the Staff Paper concluded that 30 to 20 $\mu g/m^3$ $PM_{2.5}$ represents a reasonable range for a national visibility standard primarily for urban areas, based on a sub-daily averaging time. The upper end of this range is below the levels at which the illustrative scenic views are significantly obscured, and the lower end is around the level at which visual air quality generally appears to be good based on observation of the illustrative views. Analyses of 4-hour average $PM_{2.5}$ concentrations indicate that this concentration range can be expected generally to correspond to median visual ranges in urban areas within regions across the U.S. of approximately 25 to 35 km (see EPA, 2005, Figure 7–1).[85] This range of visual range values is bounded above by the visual range targets selected in specific areas where State or local agencies placed particular emphasis on protecting visual air quality.

In considering a reasonable range of forms for a $PM_{2.5}$ standard within this range of levels, the Staff Paper concluded that a concentration-based percentile form is appropriate for the same reasons as those discussed in section II.F.1 above (on the form of the 24-hour primary $PM_{2.5}$ standard). The Staff Paper also concluded that the upper end of the range of concentration percentiles should be consistent with the percentile used for the primary standard, which was proposed to be the 98th percentile, and that the lower end of the range should be the 92nd percentile, which represents the mean of the distribution of the 20 percent most impaired days, as targeted in the regional haze program (EPA, 2005, p. 7–11 to 12).

In its advice to the Administrator, the CASAC Panel recognized that it is difficult to select any specific level and

[85] The Staff Paper notes that a standard set at any specific $PM_{2.5}$ concentration will necessarily result in visual ranges that vary somewhat in urban areas across the country, reflecting the variability in the correlations between $PM_{2.5}$ concentrations and light extinction (EPA, 2005, p. 7–8).

form based on currently available information (Henderson, 2005a, p. 9). Some Panel members felt that the range of levels recommended in the Staff Paper was on the high side, but recognized that developing a more specific (and more protective) level in future reviews would require updated and refined public visibility valuation studies, which CASAC strongly encouraged the Agency to support prior to the next review. With regard to the form of the standard, the recommendations in the final Staff Paper reflected CASAC's advice to consider percentiles in the range of the 92nd to the 98th percentile. Some Panel members recommended considering a percentile within this range in conjunction with a level toward the upper end of the range recommended in the Staff Paper.[85]

Based on the above considerations, for purposes of the proposal the Administrator believed that it was appropriate to first consider the level of protection that would be afforded by the proposed suite of primary $PM_{2.5}$ standards (71 FR 2681). The limited and uncertain evidence currently available for use in evaluating the appropriate level of protection suggested that a cautious approach was warranted in establishing a distinct secondary $PM_{2.5}$ standard to address visibility impairment. While significantly more information is available since the last review concerning the relationship between fine PM levels and visibility across the country, there is still little available information for use in making the relatively subjective value judgment needed in selecting the appropriate degree of protection to be afforded by such a standard. Given this, the Administrator first evaluated the level of protection that the proposed primary $PM_{2.5}$ standards would likely provide, and then determined whether the available evidence warranted adopting a standard with a different level, form, or averaging time.

In comparing the extent to which the proposed suite of primary standards would require areas across the country to improve visual air quality with the extent of increased protection likely to be afforded by a standard based on a sub-daily averaging time, the Administrator looked to an analysis of the predicted percent of areas not likely to meet various alternative secondary and primary $PM_{2.5}$ standards (EPA, 2005, Tables 7A–1 and 5B–1(a)[87]. In so doing, the Administrator observed that the predicted percent of counties with monitors not likely to meet the proposed suite of primary $PM_{2.5}$ standards (i.e., a 24-hour standard set at 35 $\mu g/m^3$, with a 98th percentile form, and an annual standard of 15 $\mu g/m^3$) was actually somewhat greater (27 percent) than the predicted percent of counties with monitors not likely to meet a sub-daily secondary standard with an averaging time of 4 daylight hours, a level toward the upper end of the range recommended in the Staff Paper (e.g., up to 30 $\mu g/m^3$), and a form within the recommended range (e.g., around the 95th percentile) (24 percent). A similar comparison was seen in considering the predicted percentages of the population living in such areas.

Considering the evidence in light of these comparisons, the Administrator provisionally concluded that revising the current secondary 24-hour standard for $PM_{2.5}$ to be identical to the proposed revised primary $PM_{2.5}$ standard and retaining the current annual secondary $PM_{2.5}$ standard was a reasonable policy approach to addressing visibility protection primarily in urban areas. Consistent with CASAC's recommendation, the Administrator also solicited comment on a sub-daily (4- to 8-hour averaging time) secondary $PM_{2.5}$ standard.

In additional comments responding to EPA's proposed revision of the secondary $PM_{2.5}$ standards for visibility protection (71 FR 2675–2781), the CASAC requested that a sub-daily standard to protect visibility be favorably reconsidered (Henderson, 2006, p. 2). As noted above, most of the CASAC Panel recommended a sub-daily standard for $PM_{2.5}$ with a level in the 20 to 30 $\mu g/m^3$ range for a four- to eight-hour (4–8 hr) mid-day time period with a 92nd to 98th percentile form. The CASAC members noted three cautions regarding the Agency's proposed reliance on a secondary $PM_{2.5}$ standard identical to the proposed 24-hour primary $PM_{2.5}$ standard (*Id.* at pp. 5–6):

(1) They noted that the $PM_{2.5}$ mass measurement is a better indicator of visibility impairment during daylight hours, when humidities are low; the sub-daily standard more clearly matches the nature of visibility impairment, whose adverse effects are most evident during the daylight hours; using a 24-hour standard as a proxy introduces error and uncertainty in protecting visibility; and sub-daily standards are used for other NAAQS and should be the focus for visibility.

(2) They noted that CASAC and its monitoring subcommittees have repeatedly commended EPA's initiatives promoting the introduction of continuous and near-continuous PM monitoring, and that expanded deployment of continuous $PM_{2.5}$ monitors is consistent with setting a sub-daily standard to protect visibility.

(3) They cautioned that the analysis showing a similarity between percentages of counties not likely to meet what they considered to be a lenient 4- to 8-hour secondary standard and a secondary standard identical to the proposed 24-hour primary standard is a numerical coincidence that is not indicative of any fundamental relationship between visibility and health.

The CASAC Panel further stated that "visual air quality is substantially impaired at $PM_{2.5}$ concentrations of 35 $\mu g/m^3$" and that "it is not reasonable to have the visibility standard tied to the health standard, which may change in ways that make it even less appropriate for visibility concerns." (*Id.* at p. 6.)

Many of the public commenters who supported a more stringent visibility standard also supported the more specific EPA staff and CASAC recommendations and urged EPA to adopt a sub-daily (4- to 8-hour averaging time) $PM_{2.5}$ standard to address visibility impairment, within the range of 20 to 30 $\mu g/m^3$ and with a form within the range of the 92nd to 98th percentile. In general, these commenters based their recommendations on the same studies, analyses, and considerations presented in the Staff Paper and in section IV.A of the proposal.[88]

EPA agrees with several of the key technical points made in CASAC's original recommendations and their request for reconsideration. The Administrator recognizes that there is a significant body of data and information indicating that a sub-daily standard has

[85] Some CASAC Panel members also recommended that such a standard be implemented in conjunction with an "exceptional events" policy so as to avoid having non-compliance with the standard be driven by natural source influences such as dust storms and wild fires (Henderson, 2005a).

[87] The information in these Tables is based on analysis of 2001–2003 air quality data, including 562 counties with FRM monitors that met specific data completeness criteria for developing predicted percentages of counties not likely to meet the suite of primary $PM_{2.5}$ standards and 168 counties with continuous $PM_{2.5}$ monitors that met less restrictive data completeness criteria for developing predicted percentages for a 4-hour secondary $PM_{2.5}$ standard.

[88] The American Lung Association *et al.* disagreed with the Administrator's view that the secondary standards should be focused primarily on providing protection in urban areas, with protection of Class I areas provided by the Regional Haze Rule. These commenters suggested that EPA should not rely on the regional haze program and must set national standards to protect all areas. As discussed in the Response to Comments document, EPA believes that this issue was settled in *ATA I* (See 175 F.3d at 1055–1057.)

strong technical merit. The fine particle/visibility relationship is most consistent across regions for shorter averaging times during the daylight hours, when humidity tends to be lowest. The EPA also agrees that visibility impairment has the greatest impact on public welfare during the daylight hours, but notes that daylight is not limited to a four to eight hour period.

The Administrator believes, however, that it is appropriate to consider the protection the revised suite of primary $PM_{2.5}$ standards would provide against adverse effects on public welfare. The analysis summarized above found that the relative protection provided by the proposed primary standards was equivalent or more protective than several of the 4-hour secondary standard alternatives in the range recommended by the Staff Paper and CASAC. Given the limitations in the underlying studies and the subjective nature of the judgment required, the Administrator continues to believe that caution is warranted in establishing a distinct secondary standard for visibility impairment. Contrary to commenters who recommended a distinct standard providing greater protection, in this case, the Administrator does not believe that these studies warrant adopting a secondary standard that would provide either more or less protection against visibility impairment in urban areas than would be provided by secondary standards set equal to the proposed primary $PM_{2.5}$ standards. While EPA agrees that the use of 24-hour and annual averages will result in more variability in visibility across urban areas, as the Staff Paper notes, any $PM_{2.5}$ secondary standard would result in some variability in protection in different locations (EPA, 2005, p. 7–8).

While, as noted above and in the proposal, the Administrator agrees with CASAC's point that broader deployment of continuous $PM_{2.5}$ mass monitors is a desirable goal, working toward that goal does not depend upon nor provide an appropriate basis for setting a sub-daily standard. Moreover, pursuant to CASAC recommendations, EPA is today issuing modifications to the $PM_{2.5}$ reference and equivalent methods that will encourage the certification and deployment of more continuous monitors (in a separate document published in today's Federal Register). With respect to the third CASAC comment summarized above, EPA agrees that the result of the analysis showing a similarity in the percentages of counties not likely to meet the revised 24-hour primary $PM_{2.5}$ standard or a sub-daily standard set toward the upper end of the range of protectiveness recommended by CASAC is not indicative of any fundamental relationship between visibility and public health. However, EPA does not believe that this coincidental similarity weighs against considering making the secondary standard identical to the revised primary standard.

Having considered the evidence, the advice of CASAC, and public comments, the Administrator believes that revising the current secondary $PM_{2.5}$ standards to be identical to the revised suite of primary $PM_{2.5}$ standards adopted in today's notice is a reasonable policy approach to addressing visibility impairment primarily in urban areas. The current annual and revised 24-hour secondary $PM_{2.5}$ standards will result in improvements in visual air quality in as many or more urban areas across the country as would the alternative approach of setting a sub-daily standard consistent with the upper portion of the ranges recommended by CASAC. This approach recognizes the substantial limitations in the available hourly air quality data and in available studies of public perception and attitudes with regard to the acceptability of various degrees of visibility impairment in urban areas across the country. Given these limitations, the Administrator believes that a distinct secondary standard with a different averaging time, level, or form is not warranted at this time, because the available evidence does not support a decision to achieve a level of protection different from that provided by the revised suite of primary standards, and because no further change in averaging time, level, or form appears needed to achieve a comparable level of protection. A decision in this review to make secondary standards equivalent in all respects to the primary standards, as revised, does not limit the ability of the Agency to establish a distinct secondary standard in the future if and when the underlying evidence indicates that it is appropriate. Further, the Administrator notes that continuing to advance the use of continuous $PM_{2.5}$ monitors is not dependant on establishing a sub-daily secondary $PM_{2.5}$ standard.

The Administrator believes that any secondary NAAQS for visibility protection should be considered in conjunction with the regional haze program as a means of achieving appropriate levels of protection against PM-related visibility impairment in urban, non-urban, and Class I areas across the country. Programs implemented to meet the national primary standards can be expected to improve visual air quality not just in urban areas but in surrounding non-urban areas as well; similarly, programs now being developed to address the requirements of the regional haze rule established for protection of visual air quality in Class I areas can be expected to improve visual air quality in surrounding areas as well. The Administrator further believes that the development of local programs continues to be an effective and appropriate approach to provide additional protection for unique scenic resources in and around certain urban areas that are highly valued by people living in those areas.

Based on all of the considerations discussed above, the Administrator concludes that it is appropriate to revise the current secondary $PM_{2.5}$ standards to be identical in all respects to the revised suite of primary $PM_{2.5}$ standards adopted in today's notice to provide an appropriate level of visibility protection primarily in urban areas.

B. Other PM-Related Welfare Effects

In considering the currently available evidence on non-visibility PM-related welfare effects, the Staff Paper noted that there was much information linking ambient PM to potentially adverse effects on vegetation and ecosystems and on materials damage and soiling, and on characterizing the role of atmospheric particles in climatic and radiative processes. However, given the evaluation of this information in the Criteria Document and Staff Paper, which highlighted the substantial limitations in the evidence, especially the lack of evidence linking various effects to specific levels of ambient PM, the Administrator provisionally concluded in the proposal that the available evidence did not provide a sufficient basis for establishing distinct secondary standards for PM based on any of these effects alone.

In the proposal, the Administrator also addressed the question whether reductions in PM likely to result from the current secondary PM standards, or from the range of revised primary PM standards, would provide appropriate protection against any of these PM-related welfare effects. As discussed below, these considerations included the latest scientific information characterizing the nature of these non-visibility PM-related effects and judgments as to whether revision of the current secondary standards is appropriate based on that information.

1. Evidence of Non-Visibility Welfare Effects Related to PM

Particulate matter contributes to adverse effects on a number of welfare effects categories other than visibility impairment, including vegetation and

ecosystems, soiling and materials damage, and climate. These welfare effects result predominantly from exposure to excess amounts of specific chemical species, regardless of their source or predominant form (particle, gas, or liquid). Reflecting this fact, the Criteria Document concluded that regardless of size fraction, particles containing nitrates and sulfates have the greatest potential for widespread environmental significance. The nature of these welfare effects is discussed in the Criteria Document (Chapters 4 and 9) and Staff Paper (Chapter 6) and summarized in section IV.B.1 of the proposal. The information highlighted there includes:

(1) PM-related effects on vegetation, specifically those associated with excess levels of particulate nitrate and sulfate in acidifying deposition to foliage, leading to accelerated weathering of leaf cuticular surfaces; increased permeability of leaf surfaces to toxic materials, water, and disease agents; increased leaching of nutrients from foliage; and altered reproductive processes—all which serve to weaken trees so that they are more susceptible to other stresses (e.g., extreme weather, pests, pathogens).

(2) PM-related effects on ecosystems, specifically those resulting from the nutrient or acidifying characteristics of deposited PM on both terrestrial and aquatic ecosystems, which contribute to adverse impacts on essential ecological attributes such as species shifts, loss of diversity, impacts to threatened and endangered species and alteration of native fire cycles.

(3) Characterization of ecosystem exposure to PM deposition, specifically the currently available deposition monitoring network and the lack of sufficient long-term monitoring of ecosystem response needed for PM-related ecological risk assessment.

(4) The critical loads concept and its applicability as an assessment tool in the context of the PM secondary NAAQS review.

(5) PM-related effects on materials, specifically the physical damage caused mainly by deposited particulate nitrates and sulfates and the impaired aesthetic qualities due to soiling caused mainly by particles consisting primarily of carbonaceous compounds.

(6) PM-related effects on climate, specifically through scattering and absorption of radiation by ambient particles, as well as effects on the radiative properties of clouds through changes in the number and size distribution of cloud droplets, and by altering the amount of ultraviolet solar radiation (especially UV–B) penetrating through the atmosphere to ground level.

2. Need for Revision of the Current Secondary PM Standards To Address Other PM-Related Welfare Effects

At the time of proposal, in considering the currently available evidence on each type of PM-related welfare effects discussed above, the Administrator noted that there was much information linking the sulfur- and nitrogen-containing components of ambient PM to potentially adverse effects on ecosystems and vegetation, as well as links between PM and its constituents and materials damage and soiling, as well as climatic and radiative processes. However, after reviewing the extent of relevant studies and other information available since the 1997 review of the PM standards, which highlighted the substantial limitations in the evidence, especially with regard to the lack of evidence linking various effects to specific levels of ambient PM, the Administrator concurred with conclusions reached in the Staff Paper and by CASAC (Henderson, 2005a) that the available data do not provide a sufficient basis for establishing distinct secondary PM standards based on any of these non-visibility PM-related welfare effects.

While recognizing that PM-related impacts on vegetation and ecosystems and PM-related soiling and materials damage are associated with chemical components in both fine and coarse-fraction PM, the Administrator provisionally concluded that sufficient information was not available at this time to consider either an ecologically based indicator or an indicator based distinctly on soiling and materials damage, in terms of specific chemical components of PM. Further, consistent with the rationale and recommendations in the Staff Paper, the Administrator agreed that it was appropriate to continue control of ambient fine and coarse-fraction particles, especially long-term deposition of particles such as particulate nitrates and sulfates that contribute to adverse impacts on vegetation and ecosystems and/or to materials damage and soiling. The Administrator also agreed with the Staff Paper that the available information did not provide a sufficient basis for the development of distinct secondary standards to protect against such effects beyond the protection likely to be afforded by the proposed suite of primary PM standards. In considering those proposed standards in combination, including the proposed more protective 24-hour standard for $PM_{2.5}$ and the proposed 24-hour standard for $PM_{10-2.5}$, which was intended to provide an equivalent degree of protection to the current PM_{10} standards in areas where the proposed $PM_{10-2.5}$ indicator would apply (which tend to be more densely populated areas where materials damage would be of greater concern), the Administrator believed that this proposed suite of standards would afford at least the degree of protection as that afforded by the current secondary PM standards.

Finally, the Administrator believed that such standards should be considered in conjunction with the protection afforded by other programs intended to address various aspects of air pollution effects on ecosystems and vegetation, such as the acid deposition program and other regional approaches to reducing pollutants linked to nitrate or acidic deposition. Based on these considerations, and taking into account the information and recommendations discussed above, the Administrator proposed to revise the current secondary $PM_{2.5}$ and PM_{10} standards to address these other welfare effects by making them identical in all respects to the proposed suite of primary $PM_{2.5}$ and $PM_{10-2.5}$ standards.

In response to the proposal, in addition to their recommendation for a $PM_{2.5}$ secondary standard, CASAC recommended (Henderson, 2006, p. 4) "that a secondary $PM_{10-2.5}$ standard be set at the same level as the primary PM coarse standard to protect against the various irritant, soiling and nuisance welfare or environmental effects of coarse particles. Since these effects are not uniquely related to urban sources or receptors, the standard should not be limited to urban areas." Only limited public comments were received on this aspect of the proposal.

In general, public comments relating to secondary standards and other welfare effects focused on issues related to the current secondary PM_{10} standards. Most of these commenters, including the groups who objected to the use of a qualified indicator for the primary thoracic coarse particle standard, argued that current levels of PM dust contribute or potentially contribute to nuisance, soiling, and irritant impacts on personal comfort and well being, especially in non-urban areas. The same commenters agreed with CASAC that, in the absence of a demonstration to the contrary, EPA is not justified in eliminating or reducing the level of protection to rural areas that is provided by the current suite of secondary standards. Most of these commenters recommended that EPA either retain the current PM_{10} secondary standard or replace it with a $PM_{10-2.5}$

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standard set identical to the proposed primary standard without the proposed qualifications that limited application of the standard to urban areas.

A few commenters argued against retaining any secondary standard for coarse particles. Many of these same commenters argued that if EPA did set a secondary $PM_{10-2.5}$ standard, it should be set equal to the primary $PM_{10-2.5}$ standard because there was insufficient evidence to support adoption of a distinct secondary standard for $PM_{10-2.5}$ at this time. Furthermore, these commenters noted that in the proposal, EPA had correctly excluded from both primary and secondary standards "any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources" because these particles are nontoxic and generally settle quickly.

In reaching a final decision on the need to revise the PM secondary standards regarding these non-visibility related welfare effects, the Administrator has taken into account several key factors, including: (1) The latest scientific information on non-visibility welfare effects associated with PM, as previously described; (2) the post-proposal recommendations of CASAC, (3) comments received during the public comment period, and (4) the final decisions reached in today's notice on the primary standards for fine and coarse particles, as well as the decision presented above on secondary $PM_{2.5}$ standards to protect against visibility impairment. The Administrator notes that extending today's decision not to revise the current 24-hour primary PM_{10} standard to the secondary standard would be consistent with the recommendations of CASAC and would address the issues raised by the first group of commenters summarized above. Consistent with the assessment of the evidence in the Staff Paper and the CASAC recommendations, the Administrator disagrees with those who assert that no secondary standard is needed to protect against the welfare effects associated with coarse particles.

On the other hand, the Administrator does not believe that distinct secondary standards for fine or coarse particles are warranted for any of the effects considered in this section. The available evidence is not sufficient to support the selection of an ecologically based indicator or an indicator based distinctly on materials damage, soiling, irritant or nuisance effects, or other effects of PM. However, the Administrator recognizes that it is appropriate to continue control of ambient fine and coarse particles, especially long-term deposition of particles such as particulate nitrates and sulfates that contribute to the total input of nitrogen and sulfur to ecosystems that has been shown to adversely affect sensitive aquatic and terrestrial ecosystems, and/or particles that contribute to materials damage and soiling. The Administrator notes that setting the secondary PM standards identical to the revised suite of primary standards directionally improves the level of protection afforded vegetation, ecosystems, and materials. In addition, the Administrator continues to believe that the secondary NAAQS should be considered in conjunction with the protection afforded by other programs intended to address various aspects of air pollution effects on ecosystems and vegetation, such as the acid deposition program and other regional approaches to reducing pollutants linked to nitrate or acidic deposition.

Based on the above considerations, the Administrator concludes that it is appropriate to address the other welfare effects summarized in this section by revising the current suite of $PM_{2.5}$ secondary standards, making them identical in all respects to the suite of primary $PM_{2.5}$ standards, while retaining the current 24-hour PM_{10} secondary standard and revoking the current annual PM_{10} secondary standard. For the reasons noted in section III.D.1 above, the 24-hour PM_{10} standard will provide adequate protection against the known and potential effects related to long-term PM_{10} concentrations.

C. Final Decisions on Secondary PM Standards

For the reasons discussed above, and taking into account the information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, and public comments received on the proposal, the Administrator is revising the current secondary PM standards by making them identical in all respects to the suite of primary PM standards, as revised by today's action. In the Administrator's judgment, these standards, in conjunction with the regional haze program, will provide appropriate protection to address PM-related welfare effects, including visibility impairment, effects on vegetation and ecosystems, materials damage and soiling, and effects on climate change.

V. Interpretation of the NAAQS for PM

This section presents EPA's final decisions regarding the revision, addition, and/or revocation of appendices to 40 CFR Part 50 on interpreting the primary and secondary NAAQS for PM.

A. Amendments to Appendix N—Interpretation of the National Ambient Air Quality Standards for $PM_{2.5}$

The EPA proposed to revise the data handling procedures in appendix N to 40 CFR Part 50 for the annual and 24-hour $PM_{2.5}$ standards (71 FR 2685–2686). The proposed amendments to appendix N detailed the computations necessary for determining when the proposed primary and secondary $PM_{2.5}$ NAAQS were met. The proposed amendments also addressed data reporting, monitoring considerations, and rounding conventions. Key elements of the proposed revisions to appendix N were presented in section V of the preamble to the proposed rule and are summarized below, together with EPA's final decisions on revisions to appendix N.

1. General

As proposed, EPA is adding several new definitions to section 1.0 and using these definitions throughout the appendix, most notably ones for "design values." Also, the 24-hour sampling timeframe has been clarified as representing "local *standard* (word inserted) time." This revision reflects EPA's previous intent as well as majority practice, and also avoids ambiguity since local *clock* time varies according to daylight savings periods. No opposing comments were received on these changes.

2. $PM_{2.5}$ Monitoring and Data Reporting Considerations

As proposed, two new sections are being added to appendix N to more specifically stipulate and highlight monitoring and data considerations (71 FR 2685). New section 2.0 includes statistical requirements for spatial averaging (which is part of the form of the annual standard for $PM_{2.5}$). As discussed in section II.F.2 above, EPA is tightening two of the constraints on the use of spatial averaging to provide an adequate margin of safety to susceptible subpopulations by reflecting enhanced knowledge of typical monitor relationships in metropolitan areas.

New section 3.0 to appendix N codifies aspects of raw data reporting and raw data time interval aggregation including specifications of number of decimal places. Previously, these reporting instructions resided only in associated guidance documents. Section 3.0 also notes the process for assimilating monitored concentration data from collocated instruments into a