PA LETTER DRAFT of 4-30-10

EPA-CASAC …
The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: CASAC Review of *Policy Assessment for the Review of the PM NAAQS - First External Review Draft* (March 2010)

Dear Administrator Jackson,

The Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel teleconferenced on April 8, 2010 and April 9, 2010 to review the *Policy Assessment for the Review of the PM NAAQS - First External Review Draft* (March 2010). This letter highlights CASAC's main comments on the *Policy Assessment,* followed by our consensus responses to the charge questions and comments from individual Panel members. Before addressing specific issues associated with the *Policy Assessment*, we offer some general thoughts below for your consideration.

General Comments

In 2006, EPA revised the primary and secondary NAAQS for PM to provide increased protection of public health and welfare, setting the 24-h $PM_{2.5}$ standard at 35μg/m^3 and retaining the annual standard at 15μg/m^3. In the *Policy Assessment* released earlier this year, EPA is considering revisions to these primary standards, using $PM_{2.5}$ as the indicator for fine particles, and either $PM_{10-2.5}$ (as measured), or the combination (difference) of $PM_{2.5}$ and PM_{10} as the indicator for thoracic coarse particles. EPA has also, for the first time, proposed consideration of a secondary PM standard that would be based on a different indicator – PM light extinction – than the mass-based indicators which have traditionally been used for the primary PM standards. The CASAC applauds this initiative and encourages the Agency to move aggressively forward toward developing the next generation of indicators for primary PM standards as well. At this juncture, it is appropriate to consider the evolution of PM indicators and look ahead to developing the next generation of indicators.

EPA has a history of continuously improving indicators for primary PM NAAQS as new evidence becomes available. Since the first standard for airborne PM, Total Suspended Particles (TSP), was promulgated in 1971, the EPA has implemented PM NAAQS with progressively more specific indicators from both the pollution source and biological perspectives. In 1987, PM penetrating into the thorax (PM_{10}) replaced total suspended particulate matter (TSP), and in 1997, fine PM ($PM_{2.5}$), which differs substantially in chemical composition from the coarse particle fraction within PM_{10} and which penetrates the gas exchange region of the lung, was adopted to supplement the protection provided by the PM_{10} standard.

$PM_{2.5}$ has been a useful surrogate index since it was adopted in the 1997 PM NAAQS promulgation, but may become an increasingly inadequate index of health risk as the mass concentration limits are reduced to the levels being contemplated in the current *Policy Assessment*. PM_{10} is a non-specific indicator of the respiratory system risks associated with $PM_{10-2.5}$, as widely acknowledged in the Panel's discussions of the *Integrated Science Assessment* (ISA), *Quantitative Health Risk Assessment*, and *Policy Assessment* documents. Neither index is directly related to health risks associated with ultra-fine particles (UFP). While research evidence on PM and health has evolved, we urge the Agency to undertake additional efforts to leverage the gains made thus far. Now is the time to look ahead to the next review cycle and reinvigorate support for the development of evidence that might lead to newer indicators that may correlate better with the health effects associated with ambient air concentrations of particulate matter (PM) and more comprehensive PM monitoring data, including expanding the range of sizes, measurements of numbers, chemistry, and species of particles. There is an inherent circularity in the cycle from research to policy formulation whereby researchers use the monitoring data that are gathered primarily for regulatory purposes with available indicators, and, in turn, expand the scientific basis for regulation. If EPA initiates efforts with air pollution researchers now to create a more robust monitoring platform for research, the Agency will be better positioned to make the transition to the "next generation" of indicators of PM-related health risks.

Draft Policy Assessment (March 2010)

Overall, the first draft *Policy Assessment* provides a solid start as EPA completes further analyses and deliberations related to thoracic coarse particles and visibility-related effects. As the first instance of moving through the sequence from an *Integrated Science Assessment* (ISA) through a *Policy Assessment*, the documents and the underlying flow of evidence and analytic findings provide an ordered and transparent basis for decision-making. CASAC was unanimous in recommending that the document be condensed and carefully edited to remove redundancy. While the document needs to be self-contained, the text should quote only the most critical evidence and rely more extensively on citations to the ISA and *Risk Assessment.* CASAC also suggests that the underlying decision-making algorithm that flows through the major questions posed in the text be made more explicit. (Text, and perhaps a figure, could be provided in Chapter 1, or at the start of Chapters 2-5.)

Primary Standards

The *Policy Assessment* recommends consideration of NAAQS that cover both fine particles, using $PM_{2.5}$ as the indicator, and thoracic coarse particles, using either $PM_{10-2.5}$ or the combination of $PM_{2.5}$ and PM_{10}. At the present time, CASAC agrees that these indicators are the best available given scientific knowledge to date. The evidence presented in the *Integrated Science Assessment, Quantitative Health Risk Assessment* and *Policy Assessment* shows that health effects have been observed in areas that meet current standards for $PM_{2.5}$. Thus, CASAC supports EPA's conclusion that consideration should be given to revising the current $PM_{2.5}$ primary standards to provide increased public health protection. Since the last NAAQS review, findings from additional epidemiological studies support the association between $PM_{10-2.5}$ and cardiovascular and respiratory morbidity and mortality. While the precision of the associations between health effects for the association with $PM_{10-2.5}$ exposure does not match that for $PM_{2.5}$, CASAC also agrees with EPA's conclusion that there is sufficient evidence to consider an adjustment of the PM_{10} standard.

The choice of indicator is driven by findings of epidemiological studies that have drawn on monitoring data for PM_{10} and $PM_{2.5}$ as exposure measures, as well as biological and source-related considerations. For the fine particle standard, the *Policy Assessment* draws heavily on the analyses in the *Quantitative Health Risk Assessment for Particulate Matter*, which are based on the assumption of a linear no-threshold model for risk. The *Risk Assessment* covers the evidence supporting this model, drawing on the findings of the ISA, particularly the finding of associations of PM indicators with morbidity and mortality at concentrations measured in the United States. In commenting on the *Second External Review Draft* of the *Quantitative Health Risk Assessment,* CASAC recommended that EPA develop criteria for setting the lower bound for the scenarios considered in the risk analysis. That same issue emerges with the *Policy Assessment* as lower bounds are considered for the range for the annual and 24-hr $PM_{2.5}$ standards. The approach could be statistically based, using interquartile range, standard deviation, or lower-bound confidence interval, or based in broader consideration of uncertainty. In fact, selection of the lower bound of the inter-quartile range may not be sufficiently health protective and further consideration should be given to using the 10th percentile as a level at which associations have been observed. The criterion by which a lower bound concentration is chosen becomes central in decision-making under a no-threshold model, since any suite of NAAQS above policy-relevant background leaves residual morbidity and premature mortality.

Secondary Standard

With respect to EPA's consideration of a secondary PM standard, CASAC supports the recommendations for secondary PM standards to protect public welfare as presented in the first draft *Policy Assessment*. The focus on protecting visibility is appropriate given the advanced scientific understanding of the direct effects of PM on visual air quality, as set out in the *Integrated Science Assessment*. The *Policy Assessment* establishes that the current secondary PM standards are inadequate to protect visibility, as their levels are too high, their averaging times are too long, and their mass-based indicators exhibit excessive spatial variability in relation to PM effects on visual air quality.

CASAC supports the proposed "PM light extinction" indicator, as it represents an actual and measurable consequence of particles in the ambient air and it relates directly to the demonstrated harmful welfare effect of ambient PM on human visual perception. PM light extinction also captures the physical and chemical properties of ambient aerosols and associated meteorological conditions. The *Policy Assessment* also proposes an optional $PM_{2.5}$ mass indicator, which the Panel finds to be a less direct measure of light extinction, but an adequate indicator for a secondary PM standard, especially if the mass scattering/absorption efficiencies are adjusted on seasonal, site-specific and/or regional basis to reflect differences in aerosol composition and relative humidity. Moreover, a mass based standard could be considered on an interim basis while methods to measure the preferred PM light extinction indicator are being developed, tested and deployed.

At most locations, a majority of PM light extinction is caused by fine particles, while coarse particles also pose measurement problems for instruments measuring light scattering or adsorption. For these reasons, an initial focus on $PM_{2.5}$ light extinction may be appropriate. However, coarse particle visibility effects can be very important at some locations, and a variety of

approaches could be employed to measure or estimate coarse particle effects, regardless of whether light extinction or mass-based indicators are employed (see responses to questions 14, 17 and individual panelist comments for more detail).

CASAC supports the use of a one-hour averaging time for a secondary visibility standard, as this time span reflects the nearly instantaneous nature of human perception of visual air quality, which itself can change rapidly over the course of a day. An hourly averaging time would also be well within the instrumental response capabilities of currently available light extinction monitoring instruments, although if a $PM_{2.5}$ mass indicator were used, a somewhat longer averaging time may be necessary to accommodate the larger response variability of some continuous $PM_{2.5}$ monitors. The current focus on daytime visibility is also appropriate, given the fact that nighttime visibility, while important, has a complex relationship with PM and other factors such as light pollution, for which scientific understanding is less advanced than for daylight conditions.

The *Policy Assessment* presents a large number of optional combinations of levels and forms, including levels for PM light extinction in the range of 20 to 30 deciviews, with forms ranging between the 90^{th} and 98^{th} percentiles, which would be calculated based on either the single worst hour in a day (with 90^{th} or 95^{th} percentile) or based on all daylight hours (with 95^{th} or 98^{th} percentile). These many options are further complicated by consideration of $PM_{2.5}$ mass as a possible alternative indicator. While the range of options proposed appears reasonable, the PM Panel recommends that the next draft of the *Policy Assessment* provide more detailed illustrations of the similarities and differences in the many optional combinations, to provide a more informed view of the policy implications of these options. Specifically, it would be useful to describe the levels of visibility protection and/or $PM_{2.5}$ mass concentration, the PM species, the sources and event types that would be most affected, and the temporal and spatial variations in these factors that would result from different combinations of optional indicators, levels and forms.

In addition to its principal focus on visibility protection, the *Policy Assessment* also includes very brief discussions of effects of PM on climate, ecosystems and materials. CASAC concurs with the *Policy Assessment's* conclusions that while these effects are important, and should be the focus of future research efforts, there is not currently a strong technical basis to support revisions of the current standards to protect against these other welfare effects. Because different PM components that affect visibility can have differential (cooling or warming) effects on climate, CASAC recommends revising the discussion of climate effects to better inform policy makers that reducing certain aerosol components could lead to increased radiative forcing and regional climate warming while having a beneficial effect on visibility.

Finally, CASAC reiterates its expectation that the revised *Policy Assessment* will be accompanied by a delineation of key changes from the first draft. This will enhance the efficiency and targeting of our review, and will provide a transparent record of the basis for these changes. As always, we appreciate the opportunity to provide advice on this important subject and look forward to continuing our dialogue with the Agency on PM.

CASAC Responses to Charge Questions on the First Draft Policy Assessment for the Review of the Particulate Matter NAAQS

Overarching Questions (related to Chapters 2, 3, 4, 5)

1. **Organizational Structure**

   a. **Does the Panel find the introductory and background material, including that pertaining to previous reviews of the PM standards and the current review, to be clearly communicated and appropriately characterized?**

   The introductory and background material in the *Policy Assessment for the Review of the Particulate Matter NAAQS* (PA), including the summary of previous reviews, is appropriate and clearly communicated; however, the discussion could be condensed or summarized, thereby improving clarity.

   b. **To what extent does the Panel find that the questions posed appropriately reflect the important policy-relevant issues for this review? Are there additional policy-relevant questions that should be addressed?**

   The questions posed in the PA reflect important policy-relevant issues relevant to this consideration of the PM NAAQS. As discussed in our letter to the Administrator, we recommend the Agency begin to consider the evidence needed to continue the refinement of the PM indicator for such variables as chemical composition and optimal size ranges.

   c. **What are the Panel's views regarding the level of detail used to address these policy-relevant questions? Please comment on the extent to which the discussions are appropriately focused in addressing the questions.**

   The level of detail is excessive. It should be cut back to provide succinct summaries of the information extracted from the *Integrated Science Assessment* (ISA) and *Quantitative Health Risk Assessment* (RA) documents. An Executive Summary would be very helpful, and could be based on the summaries offered throughout the *PA*.

2. **Technical Content**

   a. **Do the discussions accurately reflect and clearly communicate the currently available health and welfare effects evidence, including important uncertainties, as characterized in the final ISA?**

   Yes, the *PA* captures the currently available health and welfare evidence, as well as important uncertainties as characterized in the final ISA; however, much of the evidence could be summarized and referenced to the ISA, making the *PA* a more "reader friendly" document. The *PA* satisfactorily captures the range of proven and possible health effects literature that has expanded since previous PM reviews.

   The discussion of the welfare effects on visibility accurately reflects the currently available scientific evidence. The rationale for selecting the 1-hour averaging time is particularly clear and convincing. The summary of the differences between nighttime visibility and daytime visibility, and the basis for considering the human impact of short-term visibility vs. all daylight hours, is clearly stated.

b. **Do the discussions accurately reflect and clearly communicate policy-relevant information from the human health risk and visibility assessments, including important uncertainties, as characterized in the second draft REAs?**

Yes, the *PA* captures the policy-relevant information and important uncertainties as characterized in the second draft RA. However, more of the evidence could be summarized and referenced to the RA. The policy-relevant information for the visibility assessment is clearly communicated, particularly the discussion of the nighttime visibility effects and the rationale for selecting the 1-hour averaging time over all daylight hours.

Review of the Primary Standards for Fine Particles (Chapter 2)

3. **Approach (section 2.1.3): Various approaches are described for translating different air quality metrics from epidemiological studies into the basis for reaching preliminary staff conclusions on the adequacy of the current $PM_{2.5}$ standards and on alternative standards for consideration. What are the Panel's views regarding the appropriate weight to place on these various approaches; should specific approaches be afforded more or less weight? Are there additional approaches that should be considered?**

The selection of both evidence- and risk-based approaches is sound, as is the consideration of the utility of both annual and 24-hour concentration limits, and of various pairings of the two in exploring the degree of public health protection offered under possible NAAQS. The balance between evidence- and risk-based approaches is appropriate.

Charge question #3 also pertains to approaches used to translate different air quality metrics from epidemiological studies into the basis for identifying concentration ranges (levels) relevant to assessing the adequacy of the current $PM_{2.5}$ standards and to suggesting alternative standards for consideration. These approaches included using concentrations somewhat below the aggregate mean, at one standard deviation below the mean, and at the lowest quartile of the interquartile range. A more direct approach would use confidence bounds on the concentration-response relationships, such as those found in time-series studies. Attention could then be focused on the region where these bounds and other sources of uncertainty indicate an unacceptable degree of uncertainty about the concentration-response relationship. The less direct approaches used in the PA instead make use of the concentrations observed in the epidemiological studies without consideration of the estimates of effect. The confidence bounds along a concentration-response relationship and distributional measures of concentrations are intrinsically related, since the estimated exposure-response relationship is most certain in a concentration range where most of the data reside. We recommend that EPA consider using confidence bounds on the concentration-response relationships, where they are available, rather than the distributional measures of concentrations.

4. **Adequacy of current suite of $PM_{2.5}$ standards (section 2.2):**

What are the Panel's views on the following:

a. **The appropriateness and characterization of the sets of long- and short-term $PM_{2.5}$ exposure studies highlighted? (section 2.2.1)**

- **Are there specific studies that should be given more or less emphasis?**

The PA features appropriate studies and they are given appropriate emphasis. The discussion would be enhanced if there were an added indicator in Figure 2.1 to specify which of the studies were multicity vs. single-city studies. This would visually emphasize that more confidence should be given to the multicity studies (since the confidence intervals would be tighter) and provide justification for preferentially relying on multi-city studies. The Krewski et al. (2009) study receives greater emphasis in comparison to the other highlighted studies of annual mortality, however, because the study population was a relatively high SES group of volunteers, the estimates from the study may underestimate the risk for the US population in general. The PA should acknowledge this potential underestimation, and present the findings of this study in the context of the other US cohort studies.

- **Are there additional studies that should be focused on?**

Yes, the section concludes that older adults and children along with those with pre-existing cardiopulmonary diseases should be considered as part of the susceptible population. In addition, CASAC suggests that additional groups (as identified in the ISA) should be mentioned, including diabetics, and people with specific genetic polymorphisms that were reported in the ISA.

- **Does the Panel generally support placing greater weight on multi-city vs. single-city short-term exposure studies?**

Yes, see above in response to the first bullet.

- **Does the Panel agree with the characterizations of $PM_{2.5}$ air quality at which associations have been observed?**

Yes, the presentation of results indicating $PM_{2.5}$ effects below the current 24 hour and annual standard is appropriately summarized from multiple studies, adds to the observations previously made, and supports the conclusion about the inadequacy of the current two primary PM standards, However, the selection of the lower bound of the inter-quartile range may not be sufficiently health protective. Further consideration should be given to using the 10th percentile as a level for assessing various scenarios of levels for the PM NAAQS.

b. **The focus on persons with lower socioeconomic status as a susceptible population in addition to consideration of newly available evidence for susceptible populations identified in previous reviews (e.g., children, older adults, persons with pre-existing cardiac and respiratory disease)? (section 2.2.1)**

The data presented fully justifies consideration of lower socioeconomic status (SES) people as a susceptible group. This consideration would build from the integration of recent findings in the ISA that expand the identification of susceptible groups.

c. **The preliminary staff conclusion that the estimated risks remaining upon simulation of just meeting the current suite of standards can reasonably be judged to be important from a public health perspective? (section 2.2.2)**

A substantial body of empirical evidence is summarized indicating that significant health effects are reported at or just below the current 24 hour and annual standards, justifying the conclusion in the PA that the observed effects are important from a public health perspective. Thus, the discussion of estimated public health risks remaining if ambient air quality levels were to just meet the current standard is valuable and should contribute to the deliberations made by the Administrator in setting a PM NAAQS to protect the public with an adequate margin of safety.

d. **The relative roles of the annual and 24-hour standards in providing public health protection as informed by the quantitative risk assessment, specifically in focusing on simulation of estimated risks remaining upon just meeting the current suite of standards? (section 2.2.2)**

The approach used to characterize the relative contributions of the annual and 24-hour concentrations is clearly presented. The PA clearly explains why greater confidence can be placed on the roll-back estimates when the annual standard estimates are controlling, as compared to when the 24-hour values are controlling. The link to the characteristics of the data available is made clear. As CASAC wrote in discussing the RA, we would have preferred that EPA use Total Cardiovascular Mortality for both comparisons, although the conclusions would not likely change substantially. The RA and PA do explain their use of ischemic heart disease (IHD) mortality.

e. **The integration of evidence-based and risk-based considerations to inform the preliminary staff conclusion that the available information clearly calls into question the adequacy of the current suite of $PM_{2.5}$ standards and provides strong support for giving consideration to revising the current standards to provide increased public health protection? (section 2.2.3)**

With regard to the integration of evidence-based and risk-based considerations, CASAC concurs with EPA's conclusion that the new data strengthens the evidence available on associations previously considered in the last round of the assessment of the $PM_{2.5}$ standard. CASAC also agrees that there are significant public health consequences at the current levels of the standard that justify consideration of lowering the $PM_{2.5}$ NAAQS further. More text might be provided to describe specifically the uncertainties that have been addressed by the new evidence since the last review.

5. **Indicator (section 2.3.1):**

What are the Panel's views on the following:

a. **The preliminary staff conclusion that it is reasonable to retain $PM_{2.5}$ as an indicator for fine particles?**

This conclusion is reasonable for this round of the PM NAAQS review. There was insufficient peer-reviewed literature to support any other indicator at this time. However, it is essential that EPA continue to develop the ambient air quality database so that the suite of PM indicators considered in epidemiological studies can be expanded. Population-based studies will be needed to begin to assess more refined PM indicators, including chemical speciation of fine particles and measurements of ultrafine particles (UFP), that may more directly reflect the risk of $PM_{2.5}$ to human health.

b. **The preliminary staff conclusion that the currently available information is too limited to support a distinct PM standard for ultrafine particles?**

This conclusion was unavoidable in that there was insufficient peer-reviewed literature on ultrafine particle (UFP) exposures and exposure-response relationships to support a UFP indicator at this time. As for fine PM (above), EPA needs to implement a network of UFP monitors to support broader research on associations between UFP exposures and health.

c. **The preliminary staff conclusion that the currently available information is not sufficient to support consideration of a separate indicator for a specific $PM_{2.5}$ component or for the mix of fine particles from any specific source category, and that data are too limited to consider eliminating any component or source category from the mix of fine particles included in the $PM_{2.5}$ mass-based indicator?**

See answer to 5.a. above.

6. **Averaging Times (section 2.3.2):**

What are the Panel's views on the following:

a. **The preliminary staff conclusion that it is reasonable to retain annual and 24-hour averaging times?**

This conclusion is reasonable in view of the current limited evidence pointing towards other averaging times.

b. **The preliminary staff conclusions that the currently available evidence is too limited to support additional averaging times to address sub-daily exposures or seasonal exposures?**

This conclusion is reasonable. To the extent that EPA supplements or replaces 24-hour fine PM samplers with continuous monitors, it may become possible to conduct studies that demonstrate that other averaging times for acute responses may be more appropriate than 24-hour averages, for at least some effects.

7. **Forms (section 2.3.3):**

What are the Panel's views on the utility of additional analyses to inform consideration of eliminating provisions included in the current form of the annual standard that allow for spatial averaging across monitors, specifically with regard to the potential for disproportionate impacts on susceptible populations with lower socioeconomic status?

Given stronger evidence showing that persons with lower SES levels are a susceptible group for PM-related health risks, CASAC recommends that the provisions that allow for spatial averaging across monitors be eliminated for the reasons cited in the PA. Moreover, it should be recognized that monitors are located specifically to reflect exposures to surrounding populations, which may vary spatially.

Given this recommendation and its basis, additional analyses are not needed to inform a decision about spatial averaging. Should EPA decide that additional analyses are warranted, however, a description of the aims, methods, and the decision criteria to applythese analyses are needed to assess their utility. CASAC notes the need for additional analyses and models to assess local heterogeneity in PM concentrations, both in terms of assessing population exposure, especially for low SES populations, and as a guide in future monitor siting decisions.

8. **Levels (sections 2.3.4, 2.3.5, and 2.3.6):**

What are the Panel's views on the following:

a. **The preliminary staff conclusions regarding alternative standard levels that are appropriate for consideration, and the rationale upon which those conclusions are based?**

CASAC believes that the document provides a clear and appropriate rationale for using the annual $PM_{2.5}$ standard as the controlling standard and the 24-h standard to provide additional protection. As discussed in more detail in our response to Charge Question 3, the text could be clarified substantially, specifically with regard to the rationale used to select the two sets of alternate standards considered in the PA. This explanation should include the rationale behind the use of a lower bound [whether it be the lower end of the IQR (25%) or the 10^{th} percentile] to define annual $PM_{2.5}$ standards and the relation of the alternative standards to policy-relevant background levels.

b. **The insights that can be gained from the quantitative risk assessment to inform our understanding of the roles that the annual and 24-hour standards play in providing public health protection, specifically in focusing on simulations of estimated risks remaining upon just meeting alternative suites of standards? (sections 2.3.4.2 and 2.3.5.2)**

CASAC supports the use of the quantitative risk assessment to illustrate the impact of alternative standards on health risk. The value of the risk assessment to this process would be increased substantially if the discussion was clarified and condensed.

c. **The policy implications of the uncertainties associated with estimating risks, including potential underestimation of risk, in reaching conclusions regarding standards that would provide public health protection with an adequate margin of safety?**

CASAC recommends that the impacts of model choices on long- and short-term risk estimates should be expanded to assess whether and how estimated risks would differ if: (1) comparisons were made to the LML (as compared to the PRB); and (2) alternative concentration-response (C-R) functions were selected. The selection of C-R functions is relevant to margin of safety considerations. For example, use of C-R functions from Krewski et al. (2009) may underestimate risks for lower SES groups.

d. **A policy approach for identifying a suite of standard levels in which the annual standard would be the "generally controlling" standard to provide protection for both long- and short-term $PM_{2.5}$ exposures, in conjunction with a 24-hour standard set to provide supplemental protection against days with high peak concentrations**

associated with localized "hotspots" and risk arising from seasonal emission that might not be controlled by a national annual standard? (section 2.3.6)

The policy approach for identifying the suite of standard levels was clearly described.

e. **Additional considerations that could inform our conclusions related to alternative suites of fine particle standards?**

CASAC identified a few areas for further consideration, including potential alternative lower bounds for estimating risk, margin of safety issues (as described above) with regard to the impacts on estimated risks of model choices, particle speciation and size (e.g., coarse and ultra-fine).

Review of the Primary Standard for Thoracic Coarse Particles (Chapter 3)

9. **Adequacy of the current 24-hour PM_{10} standard (Sect. 3.2):**

What are the Panel's views on the following:

a. **The preliminary staff conclusion that the available scientific evidence supports maintaining a standard that provides protection against health effects associated with exposure to thoracic coarse particles?**

CASAC concurs that the evidence since the last review is stronger in linking adverse health effects to the thoracic course fraction. One complexity is the finding that after taking into account the component of the PM_{10} that is made up of $PM_{2.5}$, urban thoracic coarse particles appear to be more toxic than rural PM_{10} for which $PM_{2.5}$ is a smaller fraction of the total. Thus, no single measure of thoracic coarse fraction can be applied uniformly across all sites.

b. **The various approaches described for translating the evidence and related uncertainties into the basis for conclusions on the adequacy of the current PM_{10} standard?**

The PA describes the uncertainty coming from having insufficient $PM_{10-2.5}$ monitors and limited geographic coverage, particularly for the purpose of comparing the thoracic coarse fraction in rural and urban areas. See the answer to question 13. Further insight could be gained by using the data from all locations with co-located PM samplers so that $PM_{10-2.5}$ could be calculated as PM_{10} concentration minus $PM_{2.5}$ concentration.

c. **The adequacy of the public health protection afforded by the current PM_{10} standard against exposures to thoracic coarse particles?**

The relatively toxicity of the total PM_{10} fraction depends on several factors. The proportion of the PM_{10} that is in fact $PM_{2.5}$ is different between urban and rural sites. In addition, although the limited evidence is only suggestive, there are independent differential potential health effects of the $PM_{10-2.5}$ portion of PM_{10} in both urban and rural areas that can be separated from the health impact of $PM_{2.5}$. Since such effects have been reported in both urban and rural areas at concentrations below the current standard, it is clear that the current PM_{10} standard is not adequate to protect the public health. It is also the case that there is no evidence to guide the choice between PM_{10} or $PM_{10-2.5}$ that would be appropriate as a standard for both urban and rural regions as a

single national standard. Since there are insufficient spatial $PM_{10-2.5}$ measurements at this time, CASAC suggests that we continue with the PM_{10} measure as the indicator, but encourage EPA to work on a national monitoring scheme for a range of particles including both smaller and larger fractions.

10. **Indicator (sections 3.3.1, 3.3.2, and 3.3.3):**

What are the Panel's views on the following:

a. **The preliminary staff conclusion that it is appropriate to maintain a standard that provides protection against all thoracic coarse particles, regardless of their source of origin or composition?**

This conclusion is justifiable at this time, in view of the evidence from the PM ISA showing that coarse thoracic PM exposures are associated with acute respiratory system responses that are not accounted for by fine PM. However, it is important to recognize that there is a lack of data on the influence of coarse thoracic PM composition. While it is reasonable to not consider chemical composition in the current round of review of a coarse thoracic NAAQS, it is essential that a suitable database for $PM_{10-2.5}$ concentrations and composition be developed over the next several years so that a more satisfactory judgment on the need for composition-specific can be made in the next review cycle.

b. **The appropriateness of maintaining an indicator that allows lower $PM_{10-2.5}$ concentrations in urban areas than non-urban areas?**

Because $PM_{2.5}$ concentrations are generally higher in urban areas than rural areas, particles in this size range constitute a greater proportion of PM_{10} in such areas.. In view of the evidence that there is a greater proportion of road dust, incinerator effluents, and other coarse PM that contain known toxicants in urban areas than in windblown soil dusts in rural areas, it is appropriate to maintain a coarse thoracic PM indicator that allows lower concentrations in urban areas than non-urban areas. In this review cycle, PM_{10} can serve as a prudent index of coarse thoracic PM. However, as noted (in 10.a. above) chemical speciation of $PM_{10-2.5}$ may provide a more robust basis for future coarse thoracic PM NAAQS.

c. **The appropriateness of either a PM_{10} or $PM_{10-2.5}$ indicator for a standard meant to protect against exposures to thoracic coarse particles?**

While a $PM_{10-2.5}$ indicator for a standard meant to protect against exposures to thoracic coarse particles would be preferable, a PM_{10} indicator is an acceptable substitute in this round of review.

11. **Averaging Time (section 3.3.4):**
What are the Panel's views on the preliminary staff conclusions that the currently available evidence supports maintaining a 24-hour standard to protect against health effects associated with short-term exposures to thoracic coarse particles, and does not support consideration of a long-term thoracic coarse particle standard?

This conclusion is reasonable.

12. **Form (section 3.3.6):**
What are the Panel's views on the preliminary staff conclusion that it is appropriate to consider a 98th percentile form for a revised 24-hour standard meant to protect against short-term exposures to thoracic coarse particles?

CASAC finds the 98th percentile approach to be appropriate, but some members questioned the approach used to calculate the 98th percentile, noting that in the absence of additional information, a 98th-percentile calculation from the multi-year distribution of values was more defensible than a year-by-year calculation over three successive years.

13. **Level (section 3.3.7):**
What are the Panel's views on the appropriateness of considering 98th percentile, 24-hour PM_{10} or $PM_{10-2.5}$ concentrations in epidemiological study locations for identifying a range of potential alternative standard levels for consideration, recognizing the more limited air quality information available for $PM_{10-2.5}$?

This portion of the PA provided only a promissory note that additional analyses would be done, dependent upon the conclusions as to whether CASAC would recommend staying with PM_{10} or moving to $PM_{10-2.5}$ as the indicator for coarse thoracic particles. The proposal to use PM_{10} for alternative levels parallels what was done with $PM_{2.5}$ and seems appropriate. Because of the potential lack of sufficient spatial data available for $PM_{10-2.5}$, it is not clear that similar analyses can be accomplished. However, there may be sufficient data coming from locations with co-located $PM_{2.5}$ and PM_{10} monitors, so that by subtraction an estimate of $PM_{10-2.5}$ could be made. It would be valuable to conduct some additional analyses if there is a smaller subset with sufficient data to carry out such estimates of $PM_{10-2.5}$. In addition there may be data to make direct comparisons of the estimated levels with directly measured $PM_{10-2.5}$ in selected sites for purposes of testing the sensitivity of the subtraction estimates. This comparison would serve the purpose of demonstrating relative differences (or lack thereof) of the different indicators.

Review of the Secondary $PM_{2.5}$ Standards for Visibility-Related Effects (Chapter 4)

14. Adequacy **(section 4.2): What are the Panel's views on the preliminary staff conclusion that the currently available information clearly calls into question the adequacy of the current suite of $PM_{2.5}$ standards to provide public welfare protection from unacceptable levels of visibility impairment, primarily in urban areas, and supports consideration of alternative standards to provide appropriate protection?**

CASAC agrees that the PA clearly describes how the form and level of the current PM standard are inadequate to protect the public from unacceptable levels of visibility impairment. Specifically, the levels of the current $PM_{2.5}$ and PM_{10} standards are too high, and their averaging times are too long, to guard against levels of visual air quality considered adverse over the short (hour or less) time periods during which changes in visual air quality are perceptible. The current mass-based indicators are also not ideal, and could be made much more directly responsive to visibility effects by using a PM light extinction indicator. Although an alternative $PM_{2.5}$ mass indicator applied over shorter daylight hourly averaging times and at

lower levels is not ideal to protect visibility, it would represent a substantial improvement over the current 24-hour and annual means.

The relationship between the maximum daily 1-hour 90th percentile and the all daylight hours 98th percentile is clearly and convincingly presented. The reasoning for excluding hours with relative humidity above 90% is also readily understood. The box-and-whisker plots of PM light extinction clearly show that rolling back the $PM_{2.5}$ concentrations to meet the current standards would not protect visibility in most locations, regardless of which candidate protection level (CPL) or percentile form is considered. It appears from Figure 4-3 that Phoenix (along with Tacoma) would also not exceed the least restrictive CPL more than 2% of the time. If so, Phoenix should also be mentioned on line 17 of page 4-26.

The summary in section 4.2.2 is very clear in describing why the current PM standards are not protective of visibility. An addition that could strengthen the chapter in future drafts would be to show – with data examples – how high a 1-hour $PM_{2.5}$ mass concentration or a 1-hour PM light extinction level could be on (a) day(s) when the 24-hour $PM_{2.5}$ mass concentration does not exceed the current 35 $\mu g/m^3$ standard. In addition, some photographic illustrations using actual photos or Winhaze images would be helpful to show what visual air quality looks like at levels of the current standards (and at the higher 1-hour levels that are possible without exceeding the 24-hour average standards).

15. **Indicator (section 4.3.1): What are the Panel's views on the following:**

   a. **The appropriateness of considering PM light extinction and $PM_{2.5}$ mass as indicators for a distinct secondary PM standard for visibility protection, and the relative advantages and disadvantages associated with each indicator?**
   b. **The appropriateness of considering the contribution of coarse particles with respect to a potential PM light extinction indicator?**

The majority of CASAC members agreed that it would be preferable to use PM light extinction as the indicator since it is directly related to visibility and can be directly measured. Light extinction is a fundamental physical property of the ambient aerosol and thus, it represents a very appropriate indicator for a secondary visibility standard. While PM light extinction is much preferred, $PM_{2.5}$ mass (with appropriate averaging time, level and form) could also be an adequate indicator for PM visibility effects, and may be more reflective of other possible welfare outcomes.

Since a continuous $PM_{2.5}$ mass monitoring network is already in operation and robust methods for widespread PM light extinction measurements will take several years to develop, evaluate and deploy, the Agency might consider a phased approach in which a standard is set based on PM light extinction, with compliance measurements initially made using Federal Equivalent Method $PM_{2.5}$ mass as a surrogate for light extinction, until such time as a more direct PM light extinction network is in place. To facilitate a better agreement between mass and extinction some consideration should be given to adjusting the mass scattering efficiencies that relate mass to extinction in such a way as to reflect spatial and seasonal variability in the relative composition of ambient aerosols and regional differences in relative humidity. Setting a standard to any specific level of $PM_{2.5}$ mass

concentration would still allow a wide range of visibility effects at different times and locations and would provide much less efficient protection than could be attained with a light extinction indicator. CASAC still encourages the Agency to develop suitable methods for measuring PM light extinction, and to evaluate these methods in a small pilot field network.

The bulk of the light extinction at a majority of locations is driven by fine particles ($PM_{2.5}$). There are significant problems with the measurement of both light scattering and light absorption from larger particle sizes. Consequently, it is appropriate to focus initially on measurement of $PM_{2.5}$ light extinction or its components. Another approach that would improve the quality of measurements of extinction from both fine and coarse particles would be to deploy a system that periodically switches between $PM_{2.5}$ and PM_{10} inlets for the same measurement device (nephelometer or aethalometer). A third approach would be to limit light extinction measurements to instruments with $PM_{2.5}$ inlets (which would also reduce instrumental maintenance requirements), and estimate coarse particle extinction from continuous $PM_{10-2.5}$ mass measurements, based on the difference method.

16. **Averaging times (section 4.3.2): What are the Panel's views on the following:**

a. **The preliminary staff conclusion that consideration should be given to a 1-hour averaging time?**

CASAC concurs that a one-hour averaging time is most appropriate for a secondary standard to protect visibility, since PM effects on visibility can vary widely and rapidly over the course of a day, and such changes are almost instantaneously perceptible to human observers. An hourly averaging time is also well within the instrumental response times of the various currently available and developing optical monitoring methods. If a $PM_{2.5}$ mass indicator is used, the Agency may wish to consider somewhat longer averaging times - 2 to 4 hours - to assure a more stable instrumental response, although obtaining reliable hourly data from currently available continuous $PM_{2.5}$ monitors should be both feasible and a highly desirable objective for a variety of other applications.

b. **The advantages and disadvantages of focusing on a 1-hour daily maximum or each 1-hour average concentration during all daylight hours?**

As noted in the second draft Urban-Focused Visibility Assessment (UFVA), there is relatively little difference in the levels of visibility protection that would be provided by a PM light extinction standard based on considering the single worst daylight hour in a day combined with a relatively low 90^{th} percentile form and one based on considering all daylight hours combined with a higher 98^{th} percentile form. It is likely that these two approaches may tend to emphasize different kinds of visibility events and source influences, and in its recent review of the UFVA, CASAC requested that the Agency prepare additional analyses to better illustrate and evaluate what these differences may be. We expect that the results of these analyses will be helpful to Staff in recommending the best approach and to CASAC in commenting on it more objectively.

While it may be that the single worst daylight hour is judged to be a better approach, CASAC did not think that the stated rationale of protecting the most "sensitive" or "susceptible" individuals who may only have a short period of outdoor time each day to

view scenery was an especially strong basis for this selection. We suggest that a different justification needs to be provided if this approach is considered superior to one based on all daylight hours. In addition, CASAC recognizes that there are other complexities associated with evaluating and protecting nighttime visibility – such as the combined influence of PM and light pollution. The PA should make clear that the current focus on daytime visibility is not because nighttime visibility is unimportant, but rather because the scientific understanding of PM visibility effects under daylight conditions is currently much more advanced than for nighttime effects.

17. **Levels and Forms (section 4.3.3): What are the Panel's views on the following:**

c. **The preliminary staff conclusions regarding ranges of options with varying levels and forms in combination with different indicators (light extinction and $PM_{2.5}$ mass-based indicators) and averaging times (1-hour daily maximum or each 1-hour average concentration during all daylight hours)?**

There is general agreement that the standard should be based on 1-hour averaging time. Furthermore, CASAC found that a standard based on extinction is preferable to a mass-based standard. However, because of potential issues in implementing monitoring for light extinction, a mass-based indicator may be acceptable, at least on an interim basis, given the right averaging time and percentile level. However, the consensus of the committee was that not enough information is provided in the first draft PA to clearly evaluate the differences in protection associated with the various combinations of levels, percentiles, and 1 hr worst visibility vs. all daylight hours. The PA more specifically does not address how the protection afforded by these various combinations would be further modified by the choice of an extinction vs. a mass indicator. For the limited comparisons illustrated in the PA, CASAC agreed that 20 to 30 deciviews was an appropriate range of levels for a PM light extinction indicator, but concludes that the upper bound of 40 – 60 $\mu g/m^3$ was unreasonably high for a $PM_{2.5}$ mass indicator and that a range more along the lines of 15-35 $\mu g/m^3$ should be evaluated in future drafts.

In considering the implications of using a mass vs. an extinction indicator, it is critical to understand what level of average or median mass concentration corresponds to a given level of extinction as a function of atmospheric characteristics in representative eastern and western cities. A given level of visibility protection will correspond to differing mass concentrations around the country, while a given level of $PM_{2.5}$ mass will correspond to differences in associated visibility protection. More detailed comparisons should be included in the PA to better illustrate the differences in visibility protection as the degree of protection varies with mass concentration and species composition. Regional and seasonal variation in protection should also be explored.

While it has been demonstrated that a 90^{th} percentile form combined with the worst daylight hour each day would generally result in similar average levels of visibility protection as the 98^{th} percentile based on all daylight hours, these two options may tend to focus on different kinds of visibility impairing events, PM species compositions and emissions sources. The *PA* should provide clearer illustrations of the differences (or

similarities) between these approaches, and how they might be further modified if a $PM_{2.5}$ mass indicator is selected rather than the preferred light extinction indicator.

d. **Additional approaches that could help inform our consideration of alternative levels and forms?**

The 90% RH screen may not be needed if a $PM_{2.5}$ indicator is used. Some consideration should be given to using a nephelometer that cycles between a $PM_{2.5}$ and a PM_{10} inlet. This approach would allow for the very accurate measurement of $PM_{2.5}$ scattering with a reasonable estimate of coarse particle scattering. The same approach could be used for a continuous mass or light absorption monitoring system.

As indicated in previous comments on the UFVA, a "progress-based" attainment test rather than the traditional "threshold-based" attainment test would be preferable from a scientific perspective. While the Agency has indicated this is not an option in the standard-setting process, this approach could and should be considered in the implementation phase (where, for example, the Agency could provide guidance on what would be considered reasonable rates of progress). Possibly an example of how this approach might work could be provided in the next draft PA.

It would be helpful if the next draft of the PA included a section identifying and prioritizing key near-term monitoring and research needs to support refinements and revisions to secondary PM standards in the future. This could include establishing a small pilot urban visibility network to field-test and evaluate alternative PM light extinction measurement methods, additional visibility preference studies to better define levels (and/or frequencies) of visual air quality considered acceptable over a wider range of locations and viewing conditions, and chemically speciated measurements of fine particles to support the linkage between PM mass and visibility impairment.

18. **Climate (section 5.2): What are the Panel's views on the preliminary staff conclusion that there is insufficient information to base a standard on climate impacts associated with current ambient PM concentrations?**

CASAC agrees that the preliminary staff conclusions on the climate impact of aerosols are correct – there is insufficient evidence on which to base a national standard. However, the causal relationship is established, and the risk of aerosol impact on climate is high so further research on a regional basis is urgently required. This need should be strongly voiced in the PA, and research should be undertaken sooner rather than later. If possible, research should be designed and begun now to be included in future assessments of the NAAQS.

While there may be insufficient information to base a secondary standard on potential climate change, CASAC emphasizes that policy makers should be better informed that reducing certain aerosol components could lead to increased radiative forcing and regional climate warming while having a beneficial effect on visibility. There is abundant information demonstrating that aerosols that scatter visible light (e.g., nitrates and sulfates) are cooling, and can lead to increased/longer lived/more reflective cloud formation. The REA (based largely on other assessments) demonstrates that light scattering aerosols lead to a net decrease in radiative

forcing, and while the uncertainty is significant, it suggests that the effect may be quite large. Further, there is sufficient evidence that light absorbing aerosols (e.g., black carbon) can lead to warming. To go forward with a secondary standard based on reducing light extinction, the PA needs to more directly weigh the potential that regional warming could accompany improved visibility if light scattering aerosols are preferentially targeted. There also may be significant regional heterogeneity to controls that would address a visibility-based secondary standard which should be addressed. For example, the areas that currently have lower PM concentrations may benefit most from maintaining or improving visibility, but the areas with regionally high sulfate levels (and reduced visibility) would likely benefit most from the reduced radiative forcing. At a minimum, EPA needs to address how a secondary standard might impact regional radiative forcing and climate, assess the uncertainties, and provide a reasoned analysis weighing the two issues. Also, on Page 5-11, lines 10-11 and lines 31-32, it is noted that "aerosols that are warming are co-emitted with aerosols that are cooling." While this statement is correct in some instances, it does not accurately represent the aerosols with these competing effects. Most of the warming aerosols in the US are emitted by biomass burning and internal engine combustion. Much of the cooling aerosol is formed in the atmosphere by oxidation of SO_2 or VOCs. Thus, a set of controls to control warming PM would not necessarily have that much impact on cooling PM and vice versa. These statements should be modified accordingly.

Finally putative difficulties in relating PM to climate effects are laid out in sections 5.2.3 and 5.2.4 (pages 5-11 to 5-13) and again in section 5.3.4 (page 5-24). However, these apply to all other potential effects of PM, and it is not appropriate to emphasize them here, as if they were uniquely related to climate. For example, other PM-effects relationships would be improved by using chemically-speciated mass measurements; other relationships are expected to vary locally and regionally; others have offsetting positive and negative effects (warming vs. cooling, radiation attenuation vs. radiation scattering); others are confounded by effects at a distance from sources, by the difficulty of distinguishing anthropogenic from natural constituents (PRB issues should be explicitly mentioned here - section 5.2.4); by spatial and temporal heterogeneity; etc. In addition, many of the caveats in section 5.3.4 are equally true of nitrogen oxides, sulfur oxides, and ozone, but have not presented insurmountable obstacles to revising NAAQS for those contaminants.

19. **Ecological effects (section 5.3): What are the Panel's views on the preliminary staff conclusion that data are insufficient to support establishing a distinct standard for ambient PM based on ecosystem effects not addressed in the ongoing NOx/SOx secondary NAAQS review?**

CASAC agrees with the conclusions of the PA that the published literature is insufficient to support a national standard for PM effects on ecosystem services. The best established effects are related to particles containing nitrogen and sulfur, which are no longer considered in this assessment of particulate matter. CASAC considers that some causal relationships are known, but that sensitivities are not well characterized. Further research should be advocated, including progress toward a monitoring network that will yield time resolved information on chemically speciated particulate mass that is likely to be most closely related to ecosystem endpoints.

The references in the PA to welfare valuation associated with end use, taken from the ozone assessment documents, and to ecosystem services as specific and individual endpoints, taken from the Millennium Ecological Assessment, may prove useful in structuring this research.

CASAC recommends incorporation of text into Section 5.3 that is similar to that in the current draft of Section 5.4, regarding the importance of maintaining an appropriate degree of control of both fine and coarse particles to address ecosystem effects attributed to them, even in the current absence of sufficient information to develop a standard.

20. **Material effects (section 5.4): What are the Panel's views on the preliminary staff conclusion that no new evidence calls into question the adequacy of the protection afforded by the current suite of PM standards, and that there continues to be support for retaining an appropriate degree of control for both fine and coarse particles to provide protection against materials damage and soiling?**

CASAC agrees with the conclusions of the *PA* that the published literature, including literature published since the last review, is insufficient either to call into question the current level of the standard or to support any specific national standard for PM effects on materials. However, causal relationships are well established, particularly with regard to soiling of buildings and monuments. CASAC believes this end point is particularly amenable to demonstration of relationships between PM mass (particularly chemically speciated mass) and levels of soiling, because the non- linear effects that characterize ecosystem endpoints may be less significant. Soiling effects of PM on materials may be linked to atmospheric burdens simply through an appropriate deposition velocity for specific components.

We believe it is important to retain the text in the current draft of Section 5.4 regarding the importance of maintaining an appropriate degree of control of both fine and coarse particles to address materials damage and soiling attributed to them, even in the absence of sufficient information to develop a new standard.

Compendium of Preliminary Individual Comments on Particulate Matter Policy Assessment (March 2010)

Comments from Dr. Lowell Ashbaugh

Question 2a:

> Do the discussions accurately reflect and clearly communicate the currently available health and welfare effects evidence, including important uncertainties, as characterized in the final ISA?

I believe the discussions of the health effects evidence accurately reflect the currently available evidence, but I'll focus more on the welfare effects and leave it to the other reviewers to provide more detail on the health effects evidence.

The discussion of the welfare effects on visibility is quite complete and it accurately reflects the currently available science. The rationale for selecting the 1-hour averaging time is particularly clear and convincing. The summary of the differences between nighttime visibility and daytime visibility, and the reasoning for human impact of short-term visibility vs. all daylight hours is clearly stated.

The term 'deciview' is introduced on page 4-18, but it is not defined. A simple description of its relationship to extinction, along with guidance on how to understand it, would be useful. For example, it would help to explain that a one deciview change is just noticeable, and that higher values correspond to reduced visibility.

The discussion of the CPL values and how they were arrived at is very good. It is particularly useful to point out that the greater uncertainty, represented by the more scattered data points, for the Denver and British Columbia results may arise from the use of actual photos taken under varying conditions, while the better fit of the Phoenix results could be due to the use of WinHaze to alter the same photograph to display different visibility conditions.

The distinction between the Washington, DC results and the results from western cities is accurately and clearly described. The results presented by Smith (2009) on a new study at Washington, DC are not discussed here, though, and probably should receive some attention. Although I believe there are good reasons to discard the results for the PA, they should be mentioned.

Question 2b:

> Do the discussions accurately reflect and clearly communicate policy-relevant information from the human health risk and visibility assessments, including important uncertainties, as characterized in the second draft REAs?

The policy-relevant information for the visibility assessment is clearly communicated. I particularly like the discussion of the nighttime visibility effects and the rationale for selecting the 1-hour standard over all daylight hours. The selection of CPLs is described well and the justification for selecting them is consistent with the evidence presented. The only caveat I would make is that the results of the Smith (2009) study presented at the April 2009 CASAC meeting should be discussed. The results of that study provide an opportunity to explain uncertainties in visibility studies and why these results should not be included in the final assessment.

Question 14:

Adequacy (section 4.2): What are the Panel's views on the preliminary staff conclusion that the currently available information clearly calls into question the adequacy of the current suite of PM2.5 standards to provide public welfare protection from unacceptable levels of visibility impairment, primarily in urban areas, and supports consideration of alternative standards to provide appropriate protection?

The PA clearly describes how the form and level of the current PM standard is not adequate to provide public welfare protection from unacceptable levels of visibility impairment. The relationship between the maximum daily 1-hour 90^{th} percentile and the all daylight hours 98^{th} percentile is clear and convincing. The reasoning for excluding hours with relative humidity above 90% is also clear. The box-and-whisker plots of PM light extinction are clear evidence that the current levels of PM standards are not protective of visibility, particularly combined with the estimated light extinction if PM levels are rolled back to just meet the current standard. It appears from Figure 4-3 that Phoenix (along with Tacoma) would also not exceed the least restrictive CPL more than 2% of the time. If so, it should be included in line 17 of page 4-26.

The summary in section 4.2.2 is very clear in describing why the current PM standards are not protective of visibility.

Question 15:

Indicator (section 4.3.1): What are the Panel's views on the following:

a. The appropriateness of considering PM light extinction and $PM_{2.5}$ mass as indicators for a distinct secondary PM standard for visibility protection, and the relative advantages and disadvantages associated with each indicator?
b. The appropriateness of considering the contribution of coarse particles with respect to a potential PM light extinction indicator?

The issues associated with selecting PM light extinction as a standard are described well. The limitations of using 24-hour $PM_{2.5}$ mass to predict 1-hour visibility impacts could be better described. In particular, the discussion of visibility impacts clearly points out that short-term visibility is most clearly representative of the welfare effects of visibility. PM mass, though, is not currently measured on a 1-hour time scale, so it is not able to adequately represent visibility impacts. Figure 4.3-1 shows the relationship between 24-hour visibility and 1-hour light extinction. The uncertainty associated with this relationship could be discussed in more detail to illustrate the shortcomings of $PM_{2.5}$ mass as an indicator of short-term visibility.

It's appropriate to consider the contribution of coarse particles with respect to a potential light extinction indicator. Although coarse particles are not a significant contributor in some parts of the country, they are significant in other parts – notably the southwestern U.S. It's important that EPA acknowledge these differences by including coarse particles in the indicator.

Question 16:

Averaging times (section 4.3.2): What are the Panel's views on the following:

a. The preliminary staff conclusion that consideration should be given to a 1-hour averaging time?
b. The advantages and disadvantages of focusing on a 1-hour daily maximum or each 1-hour average concentration during all daylight hours?

The discussion of visibility effects on welfare presents clear and convincing evidence that a 1-hour averaging time is appropriate for a visibility indicator. The assessment points out that a significant fraction of the population is exposed to visibility conditions for only brief periods during the day, and their welfare is affected by these brief exposures. The relationship between the 1-hour daily maximum and 1-hour average daylight visibility indicators is clearly explained and the protective benefits of using the 1-hour maximum indicator is justified in the PA.

Question 17:

Levels and Forms (section 4.3.3): What are the Panel's views on the following:

a. The preliminary staff conclusions regarding ranges of options with varying levels and forms in combination with different indicators (light extinction and PM2.5 mass-based indicators) and averaging times (1-hour daily maximum or each 1-hour average concentration during all daylight hours)?
b. Additional approaches that could help inform our consideration of alternative levels and forms?

The staff conclusions regarding the levels and forms of the light extinction indicator are related well to the evidence presented earlier in the PA. The difficulty in relating PM levels to light extinction is also described well, and the selection of alternative $PM_{2.5}$ mass concentration levels is well justified. In the discussion on page 4-34 it is not clear why the 98^{th} percentile form is not considered. A brief comment on why it is not included would be helpful. I infer from the discussion that EPA staff considers it too restrictive, but this could be explained more explicitly.

The discussion of the maximum daily 1-hour indicator versus the average daylight 1-hour visibility is well done. I like the characterization of people who have infrequent access to daytime visibility as a susceptible population, and the explanation that the 1-hour daily maximum indicator would be also protective of people who have access to visibility throughout the day is effective.

The box-and-whisker plots and the tables showing the effect of "just meeting" the alternative standards are very effective in conveying the anticipated results. The use of color-coding in Figure 4.3-2 is very helpful in comparing the alternative standards. The blue shading in the table of Appendix A is too light; it should be darker to more effectively highlight those conditions.

Review of the Secondary Standards for Other Welfare-related Effects (Chapter 5)

Question 18:

Climate (section 5.2): What are the Panel's views on the preliminary staff conclusion that there is insufficient information to base a standard on climate impacts associated with current ambient PM concentrations?

The preliminary staff conclusions on the climate impact of aerosols are accurate – there is insufficient evidence on which to base a national standard. The risk of aerosol impact on climate is high, though, so this issue needs further development. It's important to state that research into the effects of aerosols on climate is needed and should be undertaken sooner rather than later. If possible, research should be designed and begun now to be included in future assessments of the NAAQS.

Question 19:

> **Ecological effects (section 5.3):** What are the Panel's views on the preliminary staff conclusion that data are insufficient to support establishing a distinct standard for ambient PM based on ecosystem effects not addressed in the ongoing NOx/SOx secondary NAAQS review?

The preliminary staff conclusion is appropriate for ecological effects. While acknowledging that ecological effects occur, it is not possible at this time to establish a PM level that would be protective of ecosystems.

Question 20:

> **Material effects (section 5.4):** What are the Panel's views on the preliminary staff conclusion that no new evidence calls into question the adequacy of the protection afforded by the current suite of PM standards, and that there continues to be support for retaining an appropriate degree of control for both fine and coarse particles to provide protection against materials damage and soiling?

This preliminary staff conclusion is also appropriate. The wording of this conclusion could be applied to the climate effects and the ecological effects sections. In particular, a version of the following sentence from the materials effects section could be applied to the other two sections: "However, in the absence of information that provides a basis for establishing a different level of control, observations continue to support retaining an appropriate degree of control on both fine and coarse particles to help address materials damage and soiling associated with PM."

Comments from Mr. Ed Avol

General Comments: The objectives of the Policy Assessment (PA) document are laudatory – to provide the Administrator with a review of the policy implications arising from the conclusions drawn from the ISA and RA. The PA has all of the elements to make a persuasive and compelling presentation of the assembled data. However, in my opinion, the current PA is too repetitive, too wordy, and devotes too many pages to re-visiting previous discussions presented in the ISA and RA documents, rather than summarizing the findings and moving on to the policy implications.

An inordinate amount of space is afforded to the 2004 AQCD, with regular discussion of what was presented and/or concluded in the 2004 review document. The ISA and RA presented the relevant science and evaluated it in the context of risk estimates and levels of uncertainty; what are the policy implications of these findings? The current document should focus on what the cumulative information, through the current review, tells us now about PM exposure, effects, levels, and susceptibility, so that an informed judgment can be made at this point in time. It may be interesting to compare what was known several years ago with what is known now, but that is not the central issue at hand. As a result of this approach, this Policy Assessment document is much too long, making it frustrating to read. This style of presentation results in weakening the impact of the document, and masking its key messages. I personally found it very difficult to wade through, even though I realize it contains important information that will be critical to the Administrator's determinations. This needs to dramatically improve in the next draft, in order to make this document accessible and worthwhile.

Specific Comments:
P2-2, line 19 to P2-9, line 8 (sections 2.1.1 and 2.1.2) – This is historically interesting, helps to lay the groundwork for how EPA got to where it is with the fine particle standard…and is arguably completely irrelevant to the current document and discussion. The issue for the current policy document is interpretation of the *currently* available information for re-examining the *current* standard. Details about *previous* cycles of review and their outcomes could be placed in an appendix, but do not centrally address the focused theme of this document – the basis for review of the current standard.

P2-9, lines24 & 25 – "…the annual and 24-hour standards taken together, rather than to consider each standard separately…" But didn't the RA clearly demonstrate that the annual standard was "controlling" (i.e., set at a given annual level, it effectively achieved a number of 24-hour standards being considered in conjunction with it?

P2-10 through2-13 – all this preparatory introduction about what is going to be discussed is unnecessary meandering (in my opinion); the document should be a focused application of the data presented in the ISA and RA, presented clearly and then clearly summarized; these pages could (and should) be distilled down to a paragraph or two. The Policy document should be brief, focused, and clear; this document has the potential to become that, but isn't there yet.

P2-10, line 9 – Declaring a focus on US and Canadian studies side-steps the issue that careful and well-performed science (or poorly-performed science, for that matter) can be performed in other countries, just as they can be performed in the US and Canada.

P2-10, lines 26 & 27 – This conclusion line is not needed here; first present the information and then summarize the document's position in a succinct integrative final chapter or section.

P2-13, lines 30 to 35 – not necessary, can be deleted without impacting presentation.

P2-14, lines 11 to 18 – not necessary, can be deleted without impacting presentation.

P2-17, lines 25 to 34 – The text is slipping into a listing and re-discussion of studies and findings, which was done quite well in the ISA and re-visited in the RA. This document should be a crafted, directed summary, rather than a re-listing of the studies…so I think this section could be edited to a line or two. The policy-relevant comment is in lines 25 through 27 ("…locations with the largest reductions in PM2.5 saw the largest improvements in reduced mortality rates, while those with the smallest decreases in PM2.5 concentrations saw the smallest improvements in reduced mortality rates…"); the rest is repetitive carryover from the ISA. Figure 2.1 (which is on an un-numbered page that might be P2-23) could be refered to and used as the basis for comments about what was reported in the ISA…without going through and talking about several of the studies in the text.

P2-19, lines 9-17 – Here, again, I think the point has been made and re-listing ISA references does not add to the presentation; I think these can be deleted. The current presentation seems to have slipped back into a review and listing of the body of evidence that supports a given conclusion (which was already done in the ISA), rather than presenting the conclusions brought forward from the ISA and RA and presenting a discussion that begins with those ISA and RA conclusions being carried forward.

P2-24, lines33 to 35 – The notion of a summary is great and much-appreciated, but this is too wordy and meandering. Delete lines 33 to 35 and get to the point!

P2-25, lines 1 and 2 – same as previous comment, delete this and get to the point.

P2-25, line26 to p2-26, line 2 – this is yet another example of unnecessary meandering and re-opening an issue that does not need to be re-visited in this document. Earlier versions of ISAs, and the PM ISA, discussed and evolved towards a functional and useful definition of susceptibility, and this document should begin from that point, not re-visit what the evolution was.

P2-26, line 29 – change the word "factors" to "observations".

P2-27, lines 8 to 11 – Is this consistent with the previous comment (P2-10, line9) that the focus would be on US and Canadian studies (a focus with which I respectfully disagree)?

P2-43, line 4 – replace the phrase "peak shaving" with a more accurate one that describes the approach.

P2-44, lines 3 to 7 – This statement about the importance of annual average $PM_{2.5}$ concentrations on interpreting risk results for both short and long-term exposures is a key observation that should be highlighted, bolded, underlines, or otherwise clearly identified.

P2-45, line 9 and line 21 – The comments about lung cancer here (when the argument was previously made about basing the presentation on "causal" levels of determination) raises the issue of staff confidence and belief in the strength of association between $PM_{2.5}$ long-term exposure and lung cancer. What is the determination on this matter that Staff wants to transmit to the Administrator?

P2-45, line 11 to 14 – Does this comment about 10 of the 15 study areas having "…design values which result in the current 24-hour standard controlling…" contradict the previous one (p2-44, lines 3-7), which asserted that annual averages were controlling for both short and long-term exposures? Together with a later comment (p2-49, lines 27 to 29, "…This pattern is generally characteristic of the larger set of urban areas across the US that do not meet the current suite of standards…"), this leaves the reader somewhat confused –which standard is controlling? What is the policy implication?

P2-51, line 27 on to P2-52, line 33 – This discussion of the representativeness of the study areas seems out of place here, 50+ pages into the discussion…Shouldn't this be established early in the presentation so that the credibility of all that follows is increased?

P2-52, line 34 to p2-55, line 3 – This seems like an obvious and unnecessary comment – Does Staff really think that someone might conclude that these 15 areas in the presentation are the ONLY 15 areas in the country for which this discussion is relevant?

P2-52, line 4 to p2-55, line10 – This question and response seems unnecessary and out of place here. The purpose of the NAAQS review is to periodically assess the current information relevant to the current standard and make a judgment about the adequacy of the standard to protect the public health. The determination as to whether there are "risks remaining upon simulation of the current suite of standards…" will be addressed when the body of information is presented and the Administrator makes that determination.

P2-54, lines 24 to 28 – This is yet another example of meandering monologue – rephrase this to present the conclusion clearly and succinctly – the data suggest that level of the current $PM_{2.5}$ standard needs to be re-considered.

P2-57, lines 6 & 7 – Change this line to read, "These techniques, while widely used in aerosol research, have not yet been widely used in health effects studies*, or systematically deployed for extensive time periods in local or regional air monitoring networks*."

P2-57, lines 23 to 28 – Unnecessary and can be deleted…

P2-58, lines 25 to 29 – This is certainly true and potentially a self-fulfilling prophecy (in that there will never be national-level ultra-fine data until and unless there is directed interest to support the collection of such data). Could an appendix of "Research Needs To Advance Future Reviews" be added?

P2-62 – The presentation has slid back to a review of data, which has already been done in the ISA (where it rightfully belongs, not here).

P2-64, lines 24 to 34 – This is a useful summary comment. Based on the history of PM research (from mass-based assessments to particle size, constituent, and biological toxicity) and the PM NAAQS (gradually moving to smaller size fractions), it seems reasonable to anticipate that a component of PM might be the biological actor of interest. With the STN network and large-scale chemical characterization studies, we are on the cusp of perhaps collecting the information needed to identify the important chemical constituents of biological significance. This could and should be added to the "Research Needs" list.

(The same generic comments apply for most of the next 50+ pages– too wordy, unnecessary detail, substantial editing needed!)

P2-107, section 2.4 – This is a well-constructed, focused presentation and should serve as the template for the previous 100 pages. These comments could be supported by references to the ISA or RA, but the specific supporting materials do not need to be here to make a convincing presentation (and to the authors' credit, the supporting materials do not appear here).

P2-109, Section 2.5 – Key Uncertainties – This section can and should be a focused, terse, and brief presentation…a few pages at most, possibly only a page or less. It is somewhat surprising that in this first draft, given the excellent discussion in the RA, there is only a title and placeholder here…

Chapter 3, Thoracic Particles – The presentation scheme is analogous to the previous chapter, and in doing so, suffers from the same generic shortfalls (too much detail, too much repetition, only a placeholder for the uncertainty discussion, etc).

Chapters 4 and 5 – defer to my visibility colleagues on these sections…

Specific Charge Question Assignments:

Question 4: Adequacy of current suite of $PM_{2.5}$ standards (section 2.2):

What are the Panel's views on the following:

c. The appropriateness and characterization of the sets of long- and short-term $PM_{2.5}$ exposure studies highlighted? (Section 2.2.1). Too-long-winded a discussion but studies are the appropriate ones.

- *Are there specific studies that should be given more or less emphasis?* No, and the studies' discussion should be referenced to ISA and RA, not re-visited in the manner and extent here.
- *Are there additional studies that should be focused on?* No.
- *Does the Panel generally support placing greater weight on multi-city vs. single-city short-term exposure studies?* Favor multi-city studies to better substantiate findings and make findings that much more representative.

- *Does the Panel agree with the characterizations of $PM_{2.5}$ air quality at which associations have been observed?* Yes.

d. *The focus on persons with lower socioeconomic status as a susceptible population in addition to consideration of newly available evidence for susceptible populations identified in previous reviews (e.g., children, older adults, persons with pre-existing cardiac and respiratory disease)? (section 2.2.1).* This is appropriate and could arguably be included in those with compromised health, because lower SES carries with it a host of related increased risks (access to health care, poor diet, increased smoking rates, increased exposure (roadway proximity of residences and occupational exposures), increased violence and stress, etc).

e. *The preliminary staff conclusion that the estimated risks remaining upon simulation of just meeting the current suite of standards can reasonably be judged to be important from a public health perspective? (section 2.2.2).* Based on the referenced health risk estimates, this is a logical conclusion.

f. *The relative roles of the annual and 24-hour standards in providing public health protection as informed by the quantitative risk assessment, specifically in focusing on simulation of estimated risks remaining upon just meeting the current suite of standards? (section 2.2.2).* Agreed and acceptable.

g. *The integration of evidence-based and risk-based considerations to inform the preliminary staff conclusion that the available information clearly calls into question the adequacy of the current suite of $PM_{2.5}$ standards and provides strong support for giving consideration to revising the current standards to provide increased public health protection? (section 2.2.3).* Agreed and acceptable, but raises a policy issue as to whether PM speciation is potentially more informative rather than total mass.

Question 8: Levels (sections 2.3.4, 2.3.5, and 2.3.6):

What are the Panel's views on the following:

h. *The preliminary staff conclusions regarding alternative standard levels that are appropriate for consideration, and the rationale upon which those conclusions are based?* The conclusions are fine – appropriate for the foundational arguments made. The presentation, however, is too wordy, too long, too repetitious, and in need of substantial editing.

i. *The insights that can be gained from the quantitative risk assessment to inform our understanding of the roles that the annual and 24-hour standards play in providing public health protection, specifically in focusing on simulations of estimated risks remaining upon just meeting alternative suites of standards? (sections 2.3.4.2 and 2.3.5.2)* Useful and warranted. Presentation-wise, the figures and the summaries, with reference to the RA, would have been sufficient to make the point.

j. *The policy implications of the uncertainties associated with estimating risks, including potential underestimation of risk, in reaching conclusions regarding standards that would provide public health protection with an adequate margin of safety?* My preference would have been for a clearer and concise section directly discussing uncertainty here, rather than comments about "increased variability" scattered throughout.

k. *A policy approach for identifying a suite of standard levels in which the annual standard would be the "generally controlling" standard to provide protection for both long- and short-term $PM_{2.5}$ exposures, in conjunction with a 24-hour standard set to provide supplemental protection against days with high peak concentrations associated with localized "hotspots" and risk arising from seasonal emission that might not be controlled by a national annual standard? (section 2.3.6)* The question itself is indicative of the systematic problem permeating the document – lack of clear, succinct and focused presentation.

l. *Additional considerations that could inform our conclusions related to alternative suites of fine particle standards?* Clarity, focus, and brevity....

Question 12: Form (section 3.3.6):
What are the Panel's views on the preliminary staff conclusion that it is appropriate to consider a 98^{th} percentile form for a revised 24-hour standard meant to protect against short-term exposures to thoracic coarse particles? The argument for utilizing a concentration-based approach rather than an exceedance-based approach is compelling, and the presentation is terse but clear.

Typos:
P2-1, line 16 – missing a period.

P2-43, line32 – change "references" to "reference'.

P2-51, line 23 – insert the word "to" after "…24-hour standard is controlling due…"

Comments from Dr. Joe Brain

Overarching Questions (related to Chapters 2, 3, 4, 5)

1. Organizational Structure

a. Does the Panel find the introductory and background material, including that pertaining to previous reviews of the PM standards and the current review, to be clearly communicated and appropriately characterized?

The panel views the Policy Assessment (PA) document as critically important to the overall process of standard setting. It is the culmination of a deliberate process leading from the ISA to the REA, and ultimately to an informed decision by the Administrator. In toto, the panel approves of the current versions of the ISA and the REA, and feels that key ideas from them now appear in the PA. In particular, the panel feels that the discussion of previous reviews of the PM standards is adequate, appropriate, and clearly communicated.

b. To what extent does the Panel find that the questions posed appropriately reflect the important policy-relevant issues for this review? Are there additional policy-relevant questions that should be addressed?

The panel feels that the questions posed (questions 2-20) are pertinent to an overall assessment of the evidence for the regulation of PM. The questions – and the answers – focus on policy-relevant issues. Other than minor aspects addressed by answers to other charge questions, the panel feels that there are no major additional questions that should be addressed.

c. What are the Panel's views regarding the level of detail used to address these policy-relevant questions? Please comment on the extent to which the discussions are appropriately focused in addressing the questions.

The panel was divided regarding the level of detail present in the current PA. Some thought the scope of the present PA was appropriate. It may be necessary to include the considerable detail which characterizes the current document.
However, a substantial minority felt that an ideal policy assessment should be far shorter and more focused. Key staff and the administrator can turn to the REA and the ISA as necessary. The Policy Assessment could be one third its current length and be a brief summary of the evidence and how that relates to alternative PM levels. Moreover, a concise description of how the form of the standard is important would also be useful.

2. Technical Content

a. Do the discussions accurately reflect and clearly communicate the currently available health and welfare effects evidence, including important uncertainties, as characterized in the final ISA?

The panel welcomes the expansion of material relating to health and welfare effects. The range of proven and possible health effects has been expanded since previous PM reviews. We welcome a discussion of how PM affects visibility and is involved in climate change. We

believe these topics are important, and we applaud the authors' attempt to concisely inform the Administrator regarding the importance of these relevant outcomes.

b. Do the discussions accurately reflect and clearly communicate policy-relevant information from the human health risk and visibility assessments, including important uncertainties, as characterized in the second draft REAs?

The panel believes that the current PA discussion does clearly communicate information relating to human health risks and visibility. There is a good discussion of uncertainties and how these uncertainties impact quantitative risk assessments.
As noted earlier, some panel members thought that the PA would be more effective if it were shorter. More of the evidence contained in it could be summarized and references to the REA or ISA – as appropriate – could be included to compensate for some of the missing or truncated detail.

Comments from Dr. Wayne Cascio

Charge Questions 4 and 9

4. Adequacy of current suite of $PM_{2.5}$ standards (section 2.2):

What are the Panel's views on the following?

a. The appropriateness and characterization of the sets of long- and short-term $PM_{2.5}$ exposure studies highlighted? (Section 2.2.1). Are there specific studies that should be given more or less emphasis? Are there additional studies that should be focused on? Does the Panel generally support placing greater weight on multi-city vs. single-city short-term exposure studies? Does the Panel agree with the characterizations of $PM_{2.5}$ air quality at which associations have been observed?

Comment: EPA staff in authoring the Policy Assessment has achieved an appropriate and balanced emphasis between the strengths and weaknesses of the studies, and weighing their relative contribution to the assessment. There are no additional studies that need to be introduced from the ISA in support of the Policy Assessment. Multi-city studies do merit greater emphasis (or weight) for the purpose of establishing the association between $PM_{2.5}$ exposure and health effects. Table 2-1 provides an informative overview summary of the causality determinations for $PM_{2.5}$. While the present ISA does not specifically address long-term neurocognitive effects of $PM_{2.5}$, it is likely to be a factor to be evaluated in the next ISA. As such it might be worthwhile placing such an outcome in the Table. One could use "Central Nervous System Effects" as is already present in the Short-term category and indicating that the causal determination is "inadequate". Figure 2-1 provides an informative summary of the effect estimates and air quality distributions for long-term exposure studies. An added designation that would be useful would be to identify each study as single- or multi-city study and note the number of cities included in the multi-city studies. The value of multi-city studies is emphasized in the ISA, RA and PA therefore it would be useful to see the specific number. Have the region of the country present in the table as has already been done is useful.

b. The focus on persons with lower socioeconomic status as a susceptible population in addition to consideration of newly available evidence for susceptible populations identified in previous reviews (e.g., children, older adults, persons with pre-existing cardiac and respiratory disease)? (Section 2.2.1)

Comment: The identification of individuals having a lower socioeconomic status as a susceptible population is appropriate. Two noticeable omissions are the absence of a description of the association with certain gene polymorphisms associated with enzymes modulating oxidant stress, and diabetes. While more data needs to be obtained to better establish the magnitude of these risks and define the mechanism accounting for the increased risks, there appears to sufficient evidence (Chapters 4, 6 and 8) in the ISA to comment in the PA.

c. The preliminary staff conclusion that the estimated risks remaining upon simulation of just meeting the current suite of standards can reasonably be judged to be important from a public health perspective? (Section 2.2.2)

Comment: The conclusion that simulations of just meeting the current suite of standards demonstrates persist risk to the health of the public is justified and important. Yet, it must be noted that these estimates of excess risk are extrapolated to $PM_{2.5}$ levels for which there are only limited real world data

and higher degrees of uncertainly. Consequently, the rationale for further adjusting the PM standard rests with assuring a margin of safety.

d. The relative roles of the annual and 24-hour standards in providing public health protection as informed by the quantitative risk assessment, specifically in focusing on simulation of estimated risks remaining upon just meeting the current suite of standards? (Section 2.2.2)

Comment: Comparisons of short-term and long-term cardiovascular risk based are challenging based on Tables 2-2 and 2-3 that describe different health effects end-points, incidence of ischemic heart disease mortality in Table 2-2 and total cardiovascular mortality in Table 2-3. Providing total cardiovascular mortality in both tables or in the text would allow a more direct comparison of the relative roles of the annual and 24-hour standard.

e. Does the current suite of $PM_{2.5}$ standards provide adequate protection of public health? (Section 2.2.3) EPA staff in the PA has provided a logical approach and justification of the conclusion that the current $PM_{2.5}$ standard is insufficient to protect health and should be revised.

Comment: Taken in total the data presented in the ISA and summarized in the PA provide strong justification for reconsidering the current $PM_{2.5}$ standard. Convincing evidence continues to be present indicating that serious cardiovascular and respiratory health effects and adverse heath outcomes occur at the level of the current standard, and that a lower standard will result in greater protection of health.

9. Adequacy of the current 24-hour PM standard (section 3.2):
What are the Panel's views on the following?
a. The preliminary staff conclusion that the available scientific evidence supports maintaining a standard that provides protection against health effects associated with exposure to thoracic coarse particles?

Comment: While data from epidemiological studies are suggestive of short-term cardiovascular, respiratory and mortality effects, at the present time significant uncertainties exist with respect to the health impact of coarse PM ($PM_{10-2.5}$). Limitations exist with respect to exposure assessment, and non-human studies addressing biological plausibility. Since the last review new information has generally supported an association but an important multi-city Canadian study did not find association between $PM_{10-2.5}$ statistically significant, thus emphasizing the persistent uncertainty of the impact of this PM fraction. On page 3-12 (L. 26-28) it is stated that "Considered as a whole, the ISA notes that epidemiologic studies that have evaluated thoracic coarse particles have reported consistent, positive associations between $PM_{10-2.5}$ and mortality (US EPA, 2009a, section 6.5.2.3)". It should further be stated, "…, yet, in many cases the associations did not achieve statistical significance."

b. The various approaches described for translating the evidence and related uncertainties into the basis for conclusions on the adequacy of the current PM_{10} standard?

Comment: Evidence appearing since the last review shows that mortality is increased even in some cities where the current PM_{10} standard is met. This suggests that the PM_{10} standard should be reconsidered. Issues related to the uncertainty of air quality estimates in the epidemiological studies reporting the health effects of $PM_{10-2.5}$ remain, as does the limitation of few studies addressing confounding by co-pollutants. For these reasons in contrast to $PM_{2.5}$ significant uncertainties persist regarding association between $PM_{10-2.5}$ and overall mortality as well as cause specific mortality.

c. The adequacy of the public health protection afforded by the current PM10 standard against exposures to thoracic coarse particles?

Comment: Since the last review additional epidemiological studies support the association between $PM_{10-2.5}$ and cardiovascular and respiratory morbidity and mortality. While the precision of the associations between health effects for the association with $PM_{10-2.5}$ exposure does not match that for $PM_{2.5}$ there is sufficient evidence to consider an adjustment of the PM_{10} standard. Because evidence is presented in the ISA that shows that health effects have been observed in areas that meet current standards there is reason to expect that a downward adjustment of the standard will benefit the health of the public. Importantly, these associations at lower than the current standard levels are preserved even in two-pollutant models. And there is limited but supportive evidence from human exposure studies and non-human toxicological studies. While the available evidence continues to be less robust than the $PM_{2.5}$ by the limitations noted, one can argue that the standard should be lowered to provide a greater margin of protection.

Comments from Dr. Chris Frey

Initial comments on the draft PA – Frey, 3/26/11

- It is unusual that C-R estimates based on the low end of a plausible range of values would be used. In public health applications, it is more typical to user upper bound estimates of dose-response relationships in order to be protective of public health. Thus, one could argue that EPA has biased the risk characterization to be very low and, therefore, is on a path that will not be adequately protective of public health.
- P 2-73: The draft PA seems to say that the form of the standard will not be assessed until the 2nd draft of the PA. This would seem to effectively disengage CASAC from being able to comment on a fully specified alternative standard that takes into account indicator, level, averaging time, and form. All of these must be considered jointly in order to assess a regulatory alternative.
- The PA is very very long. While it may be useful to provide background for people who have not read the ISA or the REA, the text is simply too verbose. Avoid being so tentative with statements. Avoid passive phrases such as "we note that…". The text will have more impact over all if things are said just once and not repeated. While it is useful to summarize material from the ISA and REA, there does not need to be an extensive verbose discussion of these. The interested reader can access these documents for more detail.
- the summary paragraphs at the end of each major section are very useful. These summary paragraphs should be the basis of creating an executive summary or synthesis chapter, that would enable a reader to get the main points without having to labor through hundreds of pages of material.
- The objective in evaluating alternative standards should not be risk reduction but rather seeking a standard that is protective of public health with an adequate margin of safety. (e.g., page 2-87)
- P 2-97 – should also take into account that sensitivity analysis of the C-R functions generally lead to higher effects estimates that the core estimates. Furthermore, the assessment does not adequately take into account that the C-R functions are likely to be underestimated for reasons not quantified, such as exposure error.
- Section 2 does not seem to deal with the number of adverse effects cases associated with each alternative standard. This is necessary to consider in order to satisfy the legal objective/statutory mandate for the NAAQS.

Comments from Dr. David Grantz

Overall, this Policy Assessment is well laid out and presented. It moves smoothly and clearly through the relevant issues and provides abundant information on each. There is some repetitive introductory text which might be condensed. The amount of information presented is large, and may be excessive since it has been already carried through the ISA and one or both of the Risk Assessments. What needs to be highlighted in the Policy Assessment are staff conclusions, their implications, and the type of information on which they are based.

Question 14. Adequacy. The PA does a nice job of demonstrating that, for a visibility endpoint, the current standard is not protective of public welfare. In the text describing Fig. 4-3 it should be noted that Pheonix as well as Tacoma would meet the candidate level 98% of the time.

Question 15. Indicator. The PA adequately presents the advantages of a visibility-based indicator. It also, however, demonstrates that a mass-based PM 2.5 indicator would work almost as well (subject to modest additional spatial variability in achieved visibility).

There are advantages to retaining a mass-based indicator for the Secondary Standard:

1. Choosing a visibility-based indicator would be analogous to choosing one of the several health endpoints as the indicator for the Primary Standard. In either case, this inappropriately diminishes the importance of other endpoints, whether or not there is sufficient evidence to use them in the current review cycle.
2. Mass is more conducive to future development of concentration-effects relationships for other endpoints. Research should be advocated in the PA to develop appropriate deposition velocities for PM to link atmospheric concentrations to loads on ecosystems and materials, and to develop relationships between loading and diverse effects. A similar advantage of the mass approach holds for effects on cloud nucleation (climate) and radiation scattering (penetration into plant canopies).
3. Nothing is sacrificed with respect to visibility protection if the level of the mass-based standard is derived from known physical relationships between visibility and PM2.5 mass (accepting some variability) and the human preference data (also with considerable regional variability).

A goal to be advocated in the PA is movement towards a chemically speciated, mass-based standard. This appears to be equally true for the Primary and Secondary standards. The PA should endorse further research on relationships between chemically speciated mass and various endpoints, and further proliferation of monitoring networks to support such a standard in the future. There is insufficient information to consider such an indicator during this review cycle.

Because the coarse PM fraction contributes significantly to visibility impairment in some locations, it is appropriate to consider a visibility-based standard for coarse PM mass.

Question 16. Averaging time. A visibility-based criterion is reasonably based on a worst one hour averaging time, since the PA demonstrates that visibility is essentially instantaneously perceived.

It is not appropriate to apply the concept of a "sensitive sub-population" to individuals who only go outside occasionally (page 4-15; line 22). It is equally reasonable to postulate that people who spend their whole day outside are exposed to repeated instantaneous updates regarding poor visibility, and that they are the true "sensitive sub-population".

Any standard based on a one hour averaging time will require a new monitoring protocol. This could be for visibility, or it could be used to push towards a real-time (continuous) mass measurement network. The latter would be useful for more purposes, has been advocated previously by CASAC, and therefore should be given serious consideration at this time.

While visibility and corresponding mass levels could be assessed during daylight hours, the standard could apply at all hours if a mass indicator were selected. This could have potential benefits, for example in control of "dumping" of PM emissions at night when visibility is not monitored.

Question 17. Levels and Forms. The options are well laid out, in the PA and Appendix A. These are presented relative to the Candidate Protection Levels, based on the visibility preference studies. The underlying data regarding visibility preferences are somewhat weak, as appropriately noted in the PA, and further research will be required to determine whether there is real regional variability or these relationships can be collapsed into a population mean.

It is appropriate to consider a <100% form, allowing some hours of exceedance. This is more to stabilize the statistic than, as stated in the current draft PA, because this is appropriate for an aesthetic standard. A relatively high percentile form, with a correspondingly lower level, would support the significance of the chosen level by seeking to minimize its exceedance.

It is appropriate to consider a screen at 90% RH, to remove non-PM associated visibility impairments.

Question 18. Climate. The PA appropriately concludes that there is insufficient information to proceed toward a national standard for PM effects on climate. However, the causal relationship is established, and further research on a regional basis is urgently required. This should be advocated in the PA.

A number of putative difficulties in relating PM to climate effects are laid out in sections 5.2.3 and 5.2.4 (pages 5-11 to 5-13) and again in section 5.3.4 (page 5-24). However, these apply to all other potential effects of PM, and it is not appropriate to emphasize them here as if they were uniquely related to climate. For example, other PM-effects relationships would be improved by using chemically-speciated mass measurements; other relationships are expected to vary locally and regionally; others have offsetting positive and negative effects (warming vs.cooling, radiation attenuation vs. radiation scattering); others are confounded by effects at a distance from sources, by the difficulty of distinguishing anthropogenic from natural constituents (PRB issues should be

explicitly mentioned here (section 5.2.4); by spatial and temporal heterogeneity; etc. In addition, many of the caveats in section 5.3.4 are equally true of N, S and ozone, but have not prevented those effects from being used in evaluation of the NAAQS for those contaminants.

Question 19. Ecological Effects. The PA appropriately concludes that there is insufficient information to proceed toward a national standard for PM effects on ecosystem services. However, causal relationships are known, and further research should be an Agency priority. This should be advocated in the PA, incorporating the desirability of chemically speciated mass determinations.

The framing of the discussion (section 5.3.1) in terms of the end use of the product, taken from the ozone documents, and in terms of ecosystem services, following the Millennium Assessment, is very good. Structuring future research in terms of effects on individual ecosystem services may lead to these effects becoming useful in development of a NAAQS for PM.

Question 20. Materials. The PA appropriately concludes that there is insufficient information to proceed toward a national standard for PM effects on materials. However, causal relationships are well established. Further research should be advocated in the PA, though other potential welfare effects may be more significant. Soiling effects on materials may, however, be the most straightforward to relate to atmospheric PM, since the linkage is only through deposition velocity for specific components.

Two editorial comments

1. On page 5-16, line 36, it should be added that plant genotype also determines uptake of metals and organics.
2. On page 5-19, line 32, I assume this is “peroxisomal” rather than “peroxidomal”.?

Comments from Dr. Joseph Helble

Charge Question 3: Approach (section 2.1.3)

The discussion in section 2.1.3 is very general, and not particularly well-addressed by charge question 3. The text in this section, while clearly written, is longer than necessary for making the general points that 24 hour and annual standards should be considered together, since controls directed towards one will affect the other, but that the Agency feels that "more consistent risk reductions are likely to be accomplished through strategies aimed at meeting an annual standard" (p 2-11). This is clear. The balance of the section (p. 2-12 and 2-13) is an overview of the approach taken in the rest of the document to developing potential standards. My recollection is that this was addressed adequately in the RA; a one paragraph summary with a reference back to the RA would be better here.

Small point, but one that arose earlier and persists: the scientific rationale for focusing on studies conducted primarily in the U.S. and Canada (p 2-10, line 9) is not clear, and not addressed in the PA.

Charge Question 7: Forms (section 2.3.3)

The question addresses the appropriateness of allowing spatial averaging in determining compliance with the annual standard. The discussion both in this section and elsewhere in the PA indicates that EPA is moving away from the use of spatial averaging in this context.

The utility of spatial averaging depends upon the heterogeneity or "spikiness" of the PM concentration distribution relative to the local population distribution. It will therefore strongly depend upon monitor placement, with respect to population density, source location, and local airflow patterns. EPA notes in the PA that it will address these questions through "additional analysis" (section 2.3.4.1) that will be addressed in the 2nd draft PA. Some description and discussion of the planned "additional analysis" would be helpful, as it was not addressed here, nor in the RA.

Further, this is one area where detailed modeling of PM concentration distributions could be helpful in assessing local heterogeneity of PM concentrations, both in terms of assessing population exposure and as a guide in future monitor siting decisions.

Additional Comment

In the footnote on p 1-5, is this backwards? The wording is not clear, but particles with $dp > d_{50}$ are those captured with *higher* efficiency than those at d_{50}. *Smaller* particles (particles with $dp < d_{50}$) are collected with *lower* efficiency.

Comments from Dr. Rogene Henderson

Charge Questions 1 and 2, Organizational structure and technical content: I found the organizational structure to be helpful in following the logic of the conclusions of the staff. The technical content was excellent. I especially liked the summary paragraphs. It would be helpful to reduce the amount of verbiage by referring back to the ISA or the RA more often, rather than repeating the content of those documents.

Charge Question 8. Levels: Based on the lack of ability to detect a threshold level for adverse health effects in epidemiology studies, and the need to protect sensitive sub populations with a margin of safety, we are beginning to arrive at risk estimates that drive our estimates of health-protective levels down almost to background levels. I think this must be discussed in the PA document. As a science advisory body, it is not our place to make policy recommendations as to where to draw the line. However, the Agency should discuss the criteria they will use to determine where to draw the line. This is their policy choice, but it would be wise to have their choice informed by discussions from CASAC..

Charge Question 9. Coarse Particles
a. I agree with the staff conclusion that the available scientific evidence supports maintaining standard for coarse particles.
b. I agree with the staff approaches to considering the adequacy of the current PM 10 standard.

Charge Question 8: Levels for Coarse Particle Standards
I agree with the described approach.

Comments from Dr. Mort Lippmann

Review of March 2010 Draft of the Policy Assessment for the Primary PM NAAQS
M. Lippmann

Major Comment and Concern:

On the basis of the scientific evidence and risk assessment, the OAQPS Staff has recommended that a revised $PM_{2.5}$ annual NAAQS in the range of 13 – 12 ug/m^3 is needed to provide better public health protection, and furthermore that consideration should also be given to a $PM_{2.5}$ annual NAAQS in the range of 11 – 10 ug/m^3. I find that these options were well considered, and scientifically justifiable on the basis of the analyses cited in the PM PA draft. Their implementation would be consistent with the Administrator's obligations under the Clean Air Act with respect to setting NAAQS that would protect the public health.

However, I also believe that 2nd draft of the PM PA needs to more explicitly address the policy implications of the selection of a concentration limit that, even at 13 ug/m^3 is considerably more stringent than the current limit of 15 ug/m^3. Promulgation of this concentration limit would require: a broad array of new controls on emissions of $PM_{2.5}$ and its precursors; would result in much more non-attainment over long periods of time; and would only be achievable in a time frame measured in years in most urban areas in the eastern and Midwestern States and California. For the even lower alternate concentration limits (12 -10 ug/m^3), the requisite controls on emissions of fossil fuel combustion effluents would require huge capital investments in new power plants and/or in alternate energy sources. These considerations lead me to conclude it is now time to begin the transition to alternate indicators that better target the health-risks that have been associated with $PM_{2.5}$ mass concentration. I come to this conclusion on the basis that:

1. There is a rapidly growing body of scientific evidence, much of it cited in the PM ISA, that indicates that $PM_{2.5}$-associated cardiovascular mortality and morbidity risk coefficients vary widely across the US, as does the $PM_{2.5}$ chemical composition.
2. The establishment and maintenance of a chemical speciation network (CSN) over the past decade has made it possible for well-targeted epidemiological studies to demonstrate that the urban areas with the highest health-based risks are those most heavily exposed to $PM_{2.5}$ components originating from the combustion of coal and residual oil, as well as the pollutants associated with motor vehicle traffic. Thus, emission controls focused on reductions of effluents from these source categories are highly likely to reduce $PM_{2.5}$-associated health risks more than emission reductions from other source categories or for $PM_{2.5}$ as a whole.
3. Unfortunately, the current limitations of the CSN, in terms of temporal and spatial coverage, have greatly limited the opportunities for epidemiologists to establish associations between $PM_{2.5}$-components and source categories and health effects. Having data for only every third or sixth day severely limits the ability to study acute responses and their lag structure, while having only one or a few sampling sites in an urban area severely limits studies of both the acute and chronic effects of components and source-related mixtures that are not uniformly distributed an urban area.
4. Moving toward the designation of better-targeted indicators for primary PM NAAQS is not a new strategy. In 1987, PM penetrating into the thorax (PM10) replaced total suspended particulate matter (TSP), and in 1997, fine PM ($PM_{2.5}$), which differs substantially from the

coarse particle fraction within PM_{10}, and which penetrates in the gas exchange region of the lung, was adopted to supplement the protection provided by PM_{10}.

5. While the scientific evidence to support a designation of one or more new indicators of $PM_{2.5}$–related health risks is inadequate for this PM NAAQS review round, EPA needs to initiate actions to ensure that an adequate scientific basis will exist within the next 4 to 5 years for the designation of better and more efficient indices of $PM_{2.5}$–related health risks for the next round of PM NAAQS review.
6. The most urgent need for data to support new indicators of health risks is to enhance the temporal and spatial coverage of the CSN network for $PM_{2.5}$, and if possible, for PM_{10} or $PM_{10-2.5}$, and ultrafine PM as well. An expanded CSN network can be supplemented by arranging for the creation and maintenance of an archive for daily FRN Teflon filters that can be made available for epidemiological studies focused on the health effects of inhaled trace metals and black carbon. The archived filters could support retrospective as well as prospective studies.

General Comments:

1. The OAQPS Staff have done an excellent job in summarizing the most relevant findings reported in the PM ISA and REA, and translating them into a suitable policy framework to facilitate and enable rational and defensible decisions by the Administrator on the promulgation of the next suite of primary PM NAAQS.
2. The OAQPS Staff warrants commendation for its straightforward and well-reasoned interpretations of the health effects evidence and risk estimates for $PM_{2.5}$, and their implications to the choice of the most suitable indicators, forms, levels for further consideration, and monitoring site data, as well as the optimal combinations of 24h and annual limits for public health protection. They point to the need for selection of a much more stringent annual limit, which will result in exceedances in most US urban areas.
3. Chapter 2 of the PA document, while comprehensive in terms of the issues that needed to be addressed, has not yet been sufficiently edited to remove the redundancies. In too many places, there are repetitions of the same words, phrases, and whole sentences (e.g., in the introductory paragraphs, discussion of the long-term exposure-related evidence and risk estimates, the discussion of the short-term exposure-related evidence and risk estimates, and the options for suites of long- and short-term exposure limits). These common issues and themes should be presented only once in full, and cited or summarized briefly, where they apply, in the later sections.
4. The content of this first draft of Chapter 3 on a NAAQS for PM_{10} or $PM_{10-2.5}$, represents a place holder, and contains only boiler-plate wording adapted from the more complete Chapter 2 that deals with $PM_{2.5}$ NAAQS. Critical comments on Chapter 3 will have to wait until we have a chance to see the second draft.

Specific Comments:

Page Line Comment

2-33 Fig. 2-1 Separate listings of mortality effects from those of other effects
2-25 17 change “fine particles at least as” to “$PM_{2.5}$ NAAQS as, or more”
2-25 23 insert “the extensive” before “interindividual”
2-25 24 insert “likely to be” before “at”
2-26 25 change “to” to “for”

2-26 29 insert "of outdoor origin" after "PM"
2-27 18 change "which" to "that"
2-31 14 insert "chemical composition, which varies" after "along"
2-36 17 change "This reduction was" to " Reductions were"
2-37 19 The ACS and 6-cities based risk estimates were not similar to and 6-cities or those of the other cited studies
2-41 16 The entry for the brackets is missing
2-43 32 change "references" to "reference"
2-48 23 change "effected" to "affected"
2-59 7 change "larger particle sizes" to "$PM_{2.5}$ particle mass"
2-60 33 insert "metals," before "sulfate" for consistency with other text entries
2-74 32 "MCAPS" has not been defined in the text
2-76 30 change "which" to "that"
2-85 35 What city, other than New York, should be cited within the bracket?
2-86 3 correct the 3.2% entry

Overarching Questions (related to Chapters 2, 3, 4, 5)

Question 1: Organizational Structure

a. Does the Panel find the introductory and background material, including that pertaining to previous reviews of the PM standards and the current review, to be clearly communicated and appropriately characterized?

Yes

b. To what extent does the Panel find that the questions posed appropriately reflect the important policy-relevant issues for this review?

Yes, but not all of the policy-relevant issues.

Are there additional policy-relevant questions that should be addressed?

Yes. Specifically, the mismatch between associations between $PM_{2.5}$ mass concentrations and adverse health effects, and the public health need to control exposures to $PM_{2.5}$ components that account for the effects. As the $PM_{2.5}$ level approaches background concentrations, the $PM_{2.5}$ indicator becomes much less defensible.

c. What are the Panel's views regarding the level of detail used to address these policy-relevant questions? Please comment on the extent to which the discussions are appropriately focused in addressing the questions.

The level of detail is excessive. It should be cut back to provide succinct summaries of the information extracted from the ISA and REA documents.

Question 2: Technical Content

a. Do the discussions accurately reflect and clearly communicate the currently available health and welfare effects evidence, including important uncertainties, as characterized in the final ISA?

Yes.

b. Do the discussions accurately reflect and clearly communicate policy-relevant information from the human health risk and visibility assessments, including important uncertainties, as characterized in the second draft REAs?

Yes.

Review of the Primary Standards for Fine Particles (Chapter 2)

Question 3: Approach (section 2.1.3): Various approaches are described for translating different air quality metrics from epidemiological studies into the basis for reaching preliminary staff conclusions on the adequacy of the current $PM_{2.5}$ standards and on alternative standards for consideration.

What are the Panel's views regarding the appropriate weight to place on these various approaches; should specific approaches be afforded more or less weight? Are there additional approaches that should be considered?

The selection of both evidence- and risk-based approaches is sound, as is the consideration of the utility of both annual and 24 hour concentration limits, and of their combinations in providing public health protection.

Question 4: Adequacy of current suite of $PM_{2.5}$ standards (section 2.2):

What are the Panel's views on the following:

a. The appropriateness and characterization of the sets of long- and short-term $PM_{2.5}$ exposure studies highlighted? (section 2.2.1)

The highlighted data sets are appropriate selections.

- Are there specific studies that should be given more or less emphasis?

The Krewski et al. (2009) study is overemphasized in relation to the other highlighted studies of annual mortality in that it relies on a higher SES population than the others and thereby underestimates responses for the US population as a whole.

- Are there additional studies that should be focused on?

The 6-cities study, having a more representative population, should be given greater emphasis, at least for Eastern and Midwestern populations, where the coefficients of response are greater than for Western populations. If the question refers to additional studies to be highlighted, the answer is no.

- Does the Panel generally support placing greater weight on multi-city vs. single-city short-term exposure studies?

Yes.

- Does the Panel agree with the characterizations of $PM_{2.5}$ air quality at which associations have been observed?

Yes, but the selection of the lower bound of the inter-quartile range may not be sufficiently health protective. Further consideration should be given to using the 10th percentile as a level at which associations have been observed.

b. The focus on persons with lower socioeconomic status as a susceptible population in addition to consideration of newly available evidence for susceptible populations identified in previous reviews (e.g., children, older adults, persons with pre-existing cardiac and respiratory disease)? (section 2.2.1)

This was appropriate.

c. The preliminary staff conclusion that the estimated risks remaining upon simulation of just meeting the current suite of standards can reasonably be judged to be important from a public health perspective? (section 2.2.2)

This was appropriate.

d. The relative roles of the annual and 24-hour standards in providing public health protection as informed by the quantitative risk assessment, specifically in focusing on simulation of estimated risks remaining upon just meeting the current suite of standards? (section 2.2.2)

This was appropriate.

e. The integration of evidence-based and risk-based considerations to inform the preliminary staff conclusion that the available information clearly calls into question the adequacy of the current suite of $PM_{2.5}$ standards and provides strong support for giving consideration to revising the current standards to provide increased public health protection? (section 2.2.3)

This was appropriate.

Question 5: Indicator (section 2.3.1):

What are the Panel's views on the following:

a. The preliminary staff conclusion that it is reasonable to retain $PM_{2.5}$ as an indicator for fine particles?

It was reasonable only because there was insufficient peer-reviewed literature to support any other indicator at this time. However, it is essential that EPA develop the database, over the next four years, to support the identification of one or more indicators that are better suited to represent the risks of exposure to $PM_{2.5}$, especially of its components that, based on emerging evidence, represent the greatest risks to public health.

b. The preliminary staff conclusion that the currently available information is too limited to support a distinct PM standard for ultrafine particles?

This conclusion was unavoidable in that there was insufficient peer-reviewed literature to support a UFP indicator at this time.

c. The preliminary staff conclusion that the currently available information is not sufficient to support consideration of a separate indicator for a specific $PM_{2.5}$

component or for the mix of fine particles from any specific source category, and that data are too limited to consider eliminating any component or source category from the mix of fine particles included in the $PM_{2.5}$ mass-based indicator?

See answer to 5.a. above.

Question 6: Averaging Times (section 2.3.2):

What are the Panel's views on the following:

a. The preliminary staff conclusion that it is reasonable to retain annual and 24- hour averaging times?

It was appropriate.

b. The preliminary staff conclusions that the currently available evidence is too limited to support additional averaging times to address sub-daily exposures or seasonal exposures?

It was appropriate.

Question 7: Forms (section 2.3.3):

What are the Panel's views on the utility of additional analyses to inform consideration of eliminating provisions included in the current form of the annual standard that allow for spatial averaging across monitors, specifically with regard to the potential for disproportionate impacts on susceptible populations with lower socioeconomic status?

Such analyses are warranted.

Question 8: Levels (sections 2.3.4, 2.3.5, and 2.3.6):

What are the Panel's views on the following:

a. The preliminary staff conclusions regarding alternative standard levels that are appropriate for consideration, and the rationale upon which those conclusions are based?

They were appropriate.

b. The insights that can be gained from the quantitative risk assessment to inform our understanding of the roles that the annual and 24-hour standards play in providing public health protection, specifically in focusing on simulations of estimated risks remaining upon just meeting alternative suites of standards? (sections 2.3.4.2 and 2.3.5.2)

The insights gained were useful and informative.

c. The policy implications of the uncertainties associated with estimating risks, including potential underestimation of risk, in reaching conclusions regarding standards that would provide public health protection with an adequate margin of safety?

Uncertainties need to be defined as well as current information allows. On the other hand, using uncertainty as an excuse for choosing a minimally stringent level is not consistent with having an adequate margin of safety.

d. A policy approach for identifying a suite of standard levels in which the annual standard would be the "generally controlling" standard to provide protection for both long- and short-term $PM_{2.5}$ exposures, in conjunction with a 24-hour standard set to provide supplemental protection against days with high peak concentrations associated with

localized "hotspots" and risk arising from seasonal emission that might not be controlled by a national annual standard? (section 2.3.6)

This approach is most appropriate.

e. Additional considerations that could inform our conclusions related to alternative suites of fine particle standards?

The alternatives that were selected were very reasonable choices.

Review of the Primary Standard for Thoracic Coarse Particles (Chapter 3)

Question 9: Adequacy of the current 24-hour PM_{10} standard (Sect. 3.2):

What are the Panel's views on the following:

a. The preliminary staff conclusion that the available scientific evidence supports maintaining a standard that provides protection against health effects associated with exposure to thoracic coarse particles?

This preliminary conclusion was warranted.

b. The various approaches described for translating the evidence and related uncertainties into the basis for conclusions on the adequacy of the current PM_{10} standard?

The various approaches that were described were appropriate.

c. The adequacy of the public health protection afforded by the current PM_{10} standard against exposures to thoracic coarse particles?

The adequacy is uncertain in view of the very limited database. While it is reasonable to maintain the current PM_{10} NAAQS in this round, it is essential that a suitable database for $PM_{10-2.5}$ concentrations be developed over the next four years so that a more satisfactory judgment can be made in the next review cycle,

Question 10: Indicator (sections 3.3.1, 3.3.2, and 3.3.3):

What are the Panel's views on the following:

a. The preliminary staff conclusion that it is appropriate to maintain a standard that provides protection against all thoracic coarse particles, regardless of their source of origin or composition?

This conclusion is justifiable at this time in view of the absence of data on the influence of coarse thoracic PM composition. While it is reasonable to not consider chemical composition in the current round of review of a coarse thoracic NAAQS, it is essential that a suitable database for $PM_{10-2.5}$ concentrations and composition be developed over the next four years so that a more satisfactory judgment can be made in the next review cycle,

b. The appropriateness of maintaining an indicator that allows lower $PM_{10-2.5}$ concentrations in urban areas than non-urban areas?

On the basis that $PM_{2.5}$ is higher in urban areas than rural areas, it will constitute a greater proportion of PM_{10} in urban areas. Therefore, one can expect that for the same PM_{10} concentration, that the concentration of $PM_{10-2.5}$ will be lower in

urban areas. Thus, it is appropriate to maintain an indicator that allows lower $PM_{10-2.5}$ concentrations in urban areas than non-urban areas.

c. The appropriateness of either a PM_{10} or $PM_{10-2.5}$ indicator for a standard meant to protect against exposures to thoracic coarse particles?

While a $PM_{10-2.5}$ indicator for a standard meant to protect against exposures to thoracic coarse particles would be preferable, a PM_{10} indicator would be an acceptable substitute in this round of review.

Question 11: Averaging Time (section 3.3.4):
What are the Panel's views on the preliminary staff conclusions that the currently available evidence supports maintaining a 24-hour standard to protect against health effects associated with short-term exposures to thoracic coarse particles, and does not support consideration of a long-term thoracic coarse particle standard?

We agree.

Question 12: Form (section 3.3.6):
What are the Panel's views on the preliminary staff conclusion that it is appropriate to consider a 98^{th} percentile form for a revised 24-hour standard meant to protect against short-term exposures to thoracic coarse particles?

We agree.

Question 13: Level (section 3.3.7): What are the Panel's views on the appropriateness of considering 98^{th} percentile, 24-hour PM_{10} or $PM_{10-2.5}$ concentrations in epidemiological study locations for identifying a range of potential alternative standard levels for consideration, recognizing the more limited air quality information available for $PM_{10-2.5}$?

We consider it to be appropriate.

Comments from Dr. Phil Hopke

Question 5: Indicator (section 2.3.1):

What are the Panel's views on the following:

a. The preliminary staff conclusion that it is reasonable to retain $PM_{2.5}$ as an indicator for fine particles?

b. The preliminary staff conclusion that the currently available information is too limited to support a distinct PM standard for ultrafine particles?

c. The preliminary staff conclusion that the currently available information is not sufficient to support consideration of a separate indicator for a specific $PM_{2.5}$ component or for the mix of fine particles from any specific source category, and that data are too limited to consider eliminating any component or source category from the mix of fine particles included in the $PM_{2.5}$ mass-based indicator?

These all represent self-fulfilling prophecies. Given the very limited number of measurements of PM1 or UFP, there is clearly no basis for extensive epidemiology and thus, no basis for an indicator. If we drop PM10 and move to a coarse particle indicator as the companion standard to PM2.5, it would really make more sense based on the nature of the atmospheric aerosol and the sources that would need to be controlled to provide attainment of one or both sized standards to switch from 2.5 μm to 1 μm (or possibly 1.5 μm) as a better separation point and eliminate most of the tail from coarse particle sources penetrating into the fine particle indicator.

In spite of significant toxicological evidence of the role of UFP through the work of two PM centers, the Agency has been unwilling to deploy adequate UFP monitors to provide the data needed for epidemiology. Thus, although it seems reasonable to assume some level of toxicity associated with these particles beyond that which is directly related to their mass, there is no basis for setting an effective number based standard. At the moment, there seems to be no indication that monitoring will be initiated in time for the data and epidemiological results to be available in the next round of review. There is clearly a major disconnect between the laboratory results and activities in the field that would permit an informed basis for deciding if an UFP standard were needed.

We measure limited composition data, but with varying relationships to observed health effects. There may be some "toxic" metals (Ni) in the PM, but we have no significant data on organic components and particularly on reactive organic components. There will need to be an expanded, but targeted monitoring based on clearly defined hypotheses to develop initial composition – health effects links to begin to serious consider component specific

A bigger issue with respect to the indicator is the measurement method since PM mass is operationally defined. PM mass is defined by the sampling system, filter, and post-sample treatment process. This results in a precise result with totally unknown accuracy. We now have continuous monitors that can provide a better measure of the actual airborne particle mass. These measurements are almost uniformly higher than the corresponding FRM mass. It would be useful to consider changing the FRM to a more direct, time resolved system that better reflects the actual airborne mass concentrations.

Question 6: Averaging Times (section 2.3.2):

What are the Panel's views on the following:

a. The preliminary staff conclusion that it is reasonable to retain annual and 24- hour averaging times?

b. The preliminary staff conclusions that the currently available evidence is too limited to support additional averaging times to address sub-daily exposures or seasonal exposures?

Again, we have only started to collect a reasonable amount of more highly time resolved particle mass data. However, there may not be sufficiently well time marked health data to begin to look at whether shorter, higher exposures (peaks) are more important than the 24 hour average value that are now available for health effects models. There are a few hints of short, high exposures inducing acute cardiac effects, but clearly we need far more data and analyses to permit the exploration of time intervals less than 24 hours. Thus, for the moment, we are stuck, but there should be more emphasis on using continuous monitors and not forcing them to reproduce the known negative bias in mass measurements inherent in the FRM values.

Question 7: Forms (section 2.3.3):

What are the Panel's views on the utility of additional analyses to inform consideration of eliminating provisions included in the current form of the annual standard that allow for spatial averaging across monitors, specifically with regard to the potential for disproportionate impacts on susceptible populations with lower socioeconomic status?

Monitors are to be placed to provide population exposure rather than exploring "hot spots." Thus, it does not make sense to average values across an area since that provides an uneven level of protection to the populations that live in high versus low areas.

There should be consideration of looking at three years data together rather than on a year by year basis. The idea of averaging the 98^{th} percentile values determined for each of the three year period does not make a lot of statistical sense. We should be looking at the complete distribution of values measured in that three year period (assuming an adequate number of samples in each period) to determine the 98^{th} percentile value.

Question 8: Levels (sections 2.3.4, 2.3.5, and 2.3.6):

What are the Panel's views on the following:

a. The preliminary staff conclusions regarding alternative standard levels that are appropriate for consideration, and the rationale upon which those conclusions are based?

b. The insights that can be gained from the quantitative risk assessment to inform our understanding of the roles that the annual and 24-hour standards play in providing public health protection, specifically in focusing on simulations of estimated risks remaining upon just meeting alternative suites of standards? (sections 2.3.4.2 and 2.3.5.2)

c. The policy implications of the uncertainties associated with estimating risks, including potential underestimation of risk, in reaching conclusions regarding standards that would provide public health protection with an adequate margin of safety?

d. A policy approach for identifying a suite of standard levels in which the annual standard would be the "generally controlling" standard to provide protection for both long- and short-term $PM_{2.5}$ exposures, in conjunction with a 24-hour standard set to provide supplemental protection against days with high peak concentrations associated with localized "hotspots" and risk arising from seasonal emission that might not be controlled by a national annual standard? (section 2.3.6)

e. Additional considerations that could inform our conclusions related to alternative suites of fine particle standards?

As noted above, the level cannot be separated from the measurement scheme since PM mass is NOT a fundamental property of the aerosol as defined by the standard. The PM mass would be a fundamental property IF it included the particle-bound water. Thus, we have an operational definition of "mass" that is known to have a significant negative bias resulting from the loss of semivolatile species (nitrate and SVOC). It would be better to make it clear that there is such an interdependency and move toward more accurate measurement technologies.
I find the evidence adequate to lower the levels somewhat (13 to 12 $\mu g/m^3$ and 35 to 30 $\mu g/m^3$) but I do not believe there is a strong basis from going below these values. Again an additional measure of protection would be afforded by moving to monitoring methods that do not have the known negative bias inherent in the current FRM approach.

Review of the Primary Standard for Thoracic Coarse Particles (Chapter 3)

Question 9: Adequacy of the current 24-hour PM_{10} standard (Sect. 3.2):

What are the Panel's views on the following:

a. The preliminary staff conclusion that the available scientific evidence supports maintaining a standard that provides protection against health effects associated with exposure to thoracic coarse particles?
b. The various approaches described for translating the evidence and related uncertainties into the basis for conclusions on the adequacy of the current PM_{10} standard?

c. The adequacy of the public health protection afforded by the current PM_{10} standard against exposures to thoracic coarse particles?

There is certainly adequate evidence to suggest the need for a standard to protect health against coarse particles. However, it is clear that PM10 is not adequate given the wide variation in the PM2.5 to PM10 ratio.

Question 10: Indicator (sections 3.3.1, 3.3.2, and 3.3.3):

What are the Panel's views on the following:

a. The preliminary staff conclusion that it is appropriate to maintain a standard that provides protection against all thoracic coarse particles, regardless of their source of origin or composition?

b. The appropriateness of maintaining an indicator that allows lower $PM_{10-2.5}$ concentrations in urban areas than non-urban areas?

c. The appropriateness of either a PM_{10} or $PM_{10-2.5}$ indicator for a standard meant to protect against exposures to thoracic coarse particles?

The arguments in favor of retaining PM10 as the indicator are unpersuasive. It makes much more sense to measure coarse particles directly. There is currently a disparity in the level of protection afforded by the present standard depending on the nature of the fine to coarse ratio in any given location. It does not appear to me that there is significantly less information on PM coarse now as there was on PM2.5 in 1996 when we moved ahead with the new indicator. Thus, it is time to move to a direct indicator of coarse PM. We have as much basis to set a PM coarse standard as we did to set the initial PM2.5 standard and it is time to move away from a corrupted measure like PM10.

Question 11: Averaging Time (section 3.3.4):

What are the Panel's views on the preliminary staff conclusions that the currently available evidence supports maintaining a 24-hour standard to protect against health effects associated with short-term exposures to thoracic coarse particles, and does not support consideration of a long-term thoracic coarse particle standard?

Same arguments as made above regarding short term averaging periods can be made for the coarse particle indicator. We have no basis for looking at anything else and we need to initiate adequate measurements of PM coarse on a continuous basis so that we can actually have the data to ascertain the adequacy of the various possible averaging times.

Question 12: Form (section 3.3.6):

What are the Panel's views on the preliminary staff conclusion that it is appropriate to consider a 98^{th} percentile form for a revised 24-hour standard meant to protect against short-term exposures to thoracic coarse particles?

I suggest the same approach as noted above with respect to the form of the PM2.5 standard.

21. **Level (section 3.3.7):**

What are the Panel's views on the appropriateness of considering 98^{th} percentile, 24-hour PM_{10} or $PM_{10-2.5}$ concentrations in epidemiological study locations for identifying a range of potential alternative standard levels for consideration, recognizing the more limited air quality information available for $PM_{10-2.5}$?

There are no specific ranges discussed. At this point, it would make sense to do what was done with PM2.5 and set a standard based on the smaller end of the range of PM10-PM2.5 differences to provide a first estimate on the standard. Such a value will be similar to the protection offered by the PM10 standard, but will apply uniformly.

Review of the Secondary $PM_{2.5}$ Standards for Visibility-Related Effects (Chapter 4)

Question 14: Adequacy (section 4.2):

What are the Panel's views on the preliminary staff conclusion that the currently available information clearly calls into question the adequacy of the current suite of $PM_{2.5}$ standards to provide public welfare protection from unacceptable levels of visibility impairment, primarily

in urban areas, and supports consideration of alternative standards to provide appropriate protection?

I thought there was adequate justification for a visibility secondary standard in the last round and there remains a strong justification for setting such a standard particularly one based directly on measured light extinction. There is strong public perception that environmental quality has degraded rather than improved as the data clearly demonstrate. Thus, visibility provides a graphic illustration of improved air quality and is a useful part of the improvement of the public welfare.

Question 15: Indicator (section 4.3.1):

What are the Panel's views on the following:

a. The appropriateness of considering PM light extinction and $PM_{2.5}$ mass as indicators for a distinct secondary PM standard for visibility protection, and the relative advantages and disadvantages associated with each indicator?
b. The appropriateness of considering the contribution of coarse particles with respect to a potential PM light extinction indicator?

As indicated in the discussion of PM coarse, it is best to have an indicator that can be directly measured. Light extinction is a fundamental physical property of the ambient aerosol and thus, it represents a very appropriate indicator for a secondary visibility standard. The bulk of the extinction in the vast majority of locations is driven by fine particles (PM2.5). There are significant problems with the measurement of the light extinction from all particle sizes. Thus, the initial secondary standard should use light extinction by PM2.5 particles as the indicator. It could be possible to extend the size up to 4 to 5 μm without extensive increasing the measurement difficulty and that could provide some additional measure of protection to those locations that are more prone to high coarse particle mass concentrations.

Question 16: Averaging times (section 4.3.2):

What are the Panel's views on the following:

a. The preliminary staff conclusion that consideration should be given to a 1-hour averaging time?

b. The advantages and disadvantages of focusing on a 1-hour daily maximum or each 1-hour average concentration during all daylight hours?

At this point, there is no really sound scientific basis for picking an averaging time. An hour is a reasonable starting point.

Question 17: Levels and Forms (section 4.3.3):

What are the Panel's views on the following:

a. The preliminary staff conclusions regarding ranges of options with varying levels and forms in combination with different indicators (light extinction and $PM_{2.5}$ mass-based indicators) and averaging times (1-hour daily maximum or each 1-hour average concentration during all daylight hours)?
b. Additional approaches that could help inform our consideration of alternative levels and forms?

The range of proposed levels is overly large. There is no point in an alternative standard unless it is going to be significantly different from the primary standard. Thus, the level should be set within the lower third of the proposed range.

Review of the Secondary Standards for Other Welfare-related Effects (Chapter 5)

Question 18: Climate (section 5.2):

What are the Panel's views on the preliminary staff conclusion that there is insufficient information to base a standard on climate impacts associated with current ambient PM concentrations?

There are both cooling and warming effects of particles as well as the indirect effects related to cloud formation and brightening. At this point there are far too great uncertainties in the climate system and the role of particles to propose a standard with a strong scientific foundation.

Question 19: Ecological effects (section 5.3):

What are the Panel's views on the preliminary staff conclusion that data are insufficient to support establishing a distinct standard for ambient PM based on ecosystem effects not addressed in the ongoing NOx/SOx secondary NAAQS review?

In reviewing the PA and the ISA, there does not seem to be adequate information available to conclude that there is need for a separate standard to provide ecosystem protection. Thus, the staff conclusion appears justified.

Question 20: Material effects (section 5.4):

What are the Panel's views on the preliminary staff conclusion that no new evidence calls into question the adequacy of the protection afforded by the current suite of PM standards, and that there continues to be support for retaining an appropriate degree of control for both fine and coarse particles to provide protection against materials damage and soiling?

Neither the ISA nor the PA provides evidence to support the consideration of an alternative or new secondary standard to protect against materials degradation.

Other Comments
On page 4-11, it says "The amount of light extinction contributed by PM depends on the particle size distribution and composition, as well as its concentration." However, particle shape also matters. Not all particles are spherical.

Please do not use "particulate" when you mean "particle"

Comments from Dr. Robert Phalen

Regarding sections 2.3.1 (Indicator) and 2.3.2 (Averaging Times). I have a few comments.

1. Both sections are well-written and adequately thorough in describing the many uncertainties in relation to the indicator and averaging times for PM2.5.
2. It is clear that additional research is required before specific components, and/or specific co-pollutant interactions, can be targeted for health-related policy assessments. For the present time, PM2.5 is the only feasible default indicator for health-effect considerations. Sadly, this will place some U.S. regions at a disadvantage in protecting public health using a mass-based indicator (PM2.5).
3. Similarly, as the available health-associated data are robust for 24 hour and annual averaging times, the conclusion to retain these averaging times is appropriate.
4. The lucid discussions of the limitations and uncertainties associated with the indicator and averaging times, will be very helpful for stimulating the needed research. The EPA staff has provided useful guidance in this respect.
5. As a minor editing suggestion, I would consider eliminating the word "strong" on line 6, pg. 2-70, as it conflicts with the lucid discussion of the limitations and uncertainties previously presented. This is not a strong suggestion, but it should be considered.

Comments from Mr. Rich Poirot

Overall, Chapter 4 of the PA represents an excellent first draft presentation of justifications and policy options for setting secondary PM standards to protect visual air quality. While there are advantages to using an optical indicator (PM light extinction) and to using the single worst daylight hour for a regulatory metric, I think there are also certain advantages to using a $PM_{2.5}$ mass indicator, and/or to considering effects in all daylight hours, and that plusses and minuses associated with these various alternatives could be presented in a somewhat more balanced way.

14. Adequacy (section 4.2): What are the Panel's views on the preliminary staff conclusion that the currently available information clearly calls into question the adequacy of the current suite of $PM_{2.5}$ standards to provide public welfare protection from unacceptable levels of visibility impairment, primarily in urban areas, and supports consideration of alternative standards to provide appropriate protection?

The PA does a good job of demonstrating that current PM standards (for which 24-hour $PM_{2.5}$ is most relevant) are not adequate for protecting visibility in most, if not all sections of the country. Specifically, the levels of current $PM_{2.5}$ and PM_{10} standards are too high and their averaging times are too long to guard against levels of visual air quality considered adverse, over the short (hour or less) time periods over which changes in visual air quality are perceptible. The current mass-based indicators are also not ideal and could be made much more directly responsive to visibility effects by using a PM light extinction indicator. An optional $PM_{2.5}$ mass indicator, applied over shorter daylight hourly averaging times and at lower levels would be adequate, and would represent a substantial improvement over the current 24-hour and annual means.

A possible addition which might strengthen the chapter in future drafts would be to show – with data examples – how extreme a 1-hour $PM_{2.5}$ mass concentration or 1-hour PM light extinction level could be on (a) day(s) when the 24-hour $PM_{2.5}$ mass concentration does not exceed the current 35 $\mu g/m^3$ standard. In addition, you might include some photographic illustrations – using actual haze cam photos or Winhaze images showing what visual air quality looks like at levels of the current standards (and at the higher 1-hour levels that are possible without exceeding the 24-hour average standards).

15. Indicator (section 4.3.1): What are the Panel's views on the following:

a. **The appropriateness of considering PM light extinction and $PM_{2.5}$ mass as indicators for a distinct secondary PM standard for visibility protection, and the relative advantages and disadvantages associated with each indicator?**

The PA does a good job of demonstrating the appropriateness and benefits of a PM light extinction indicator, while showing that a (daylight only, hourly) $PM_{2.5}$ mass-based indicator would also be adequate, and a substantial improvement over the status quo. To a certain extent, arguments for use of a light extinction indicator can be strengthened by emphasizing the shortcomings of a $PM_{2.5}$ mass-based indicator. However, I think the PA could provide a somewhat more balanced view of some of the advantages and disadvantages of both alternative indicators.

A PM light extinction indicator has the major obvious advantage that the indicator would essentially **be** the effect. PM light extinction is an actual and measurable characteristic of particles in the atmosphere, which can be directly related on the one hand to the size and composition

(including aerosol water) of airborne particles which cause it, and on the other hand to the levels of visual air quality considered unacceptable by human observers. There are however also disadvantages to a PM light extinction indicator (and advantages to a $PM_{2.5}$ mass indicator) that could be presented more clearly in the PA.

A disadvantage of a PM light extinction indicator is that there is currently no monitoring network in place to assess compliance, nor have standard methods been developed which have been deployed in anything other than research-grade applications. At a minimum, at least 2 separate instruments (nephelometer and aethalometer) would be required using currently available technology, and these will function best if coarse particles are excluded. Thus the measured indicator would actually be $PM_{2.5}$ light extinction, although this could be enhanced where need be with measurements of and estimates of extinction from continuous $PM_{10\text{-}2.5}$ mass (requiring two additional instruments). Accurate RH measurements will also be more important for this indicator.

Conversely, there is already a large network of continuous $PM_{2.5}$ instruments in place that could be used immediately to assess compliance with an hourly $PM_{2.5}$ mass indicator, and the quality of that data – and its utility for assessing human health or other public welfare effects – could be substantially enhanced by forcing closer scrutiny of the accuracy and precision on an hourly basis. A $PM_{2.5}$ mass indicator would allow somewhat higher extinction in the more humid (and generally less scenic) East, and provide relatively better protection in the less humid (and generally more scenic) West – which is not necessarily a disadvantage. It would also tend to place relatively more emphasis on organic carbon and elemental carbon aerosols, which are more negatively associated with other public welfare (soiling and climate) effects, and which are also generally more influenced by local emissions than are the sulfate and nitrate compounds which are emphasized by the PM light extinction indicator.

b. **The appropriateness of considering the contribution of coarse particles with respect to a potential PM light extinction indicator?**

Since coarse particles make relatively minor contributions to light extinction at most locations, and also present both measurement uncertainties as well as increased measurement maintenance needs, it may be reasonable to either:

- Exclude coarse particles from the regulatory metric (either re-name it "$PM_{2.5}$ light extinction" or keep the same name but exclude coarse particles from monitoring requirements) or,
- Add (either on an all-site basis, or at sites where PM_{10}:$PM_{2.5}$ > X) continuous mass measurements of $PM_{10\text{-}2.5}$ by the difference method, estimating the associated PM light extinction increment by multiplying by 0.6 m^2/g as in the IMPROVE formula.
- Conceptually a similar treatment of $PM_{10\text{-}2.5}$ effects could be added to a $PM_{2.5}$ mass indicator, where the revised mass indicator might be something like $PM_{2.5}$ + 0.1 x $PM_{10\text{-}2.5}$.

16. Averaging times (section 4.3.2): What are the Panel's views on the following:

a. **The preliminary staff conclusion that consideration should be given to a 1-hour averaging time?**

The one-hour averaging time (during daylight hours) is appropriate, given the nearly instantaneous nature of perceived impairment of visual air quality. At the same time, I think somewhat longer averaging times (of say 4 daylight hours) could also be justified for several reasons, including:

- To minimize the influence of measurement errors – which could be important if multiple monitors are used for an optical indicator, and also because some of the continuous $PM_{2.5}$ monitors produce "noisy" data over short 1-hour averaging times.
- To minimize the influence of short-term, localized meteorological extremes – such as the concurrence of high RH, low wind speed and low mixing heights on cold, clear winter mornings.
- To intentionally focus on visibility-impairing events which last for more than a few hours, and are arguably more objectionable, and effect more people, than events of short duration.
- To follow the reasoning used and precedents set in locations like Denver and Phoenix where visibility standards have been established, and based on 4-hour averages in both cases.

b. **The advantages and disadvantages of focusing on a 1-hour daily maximum or each 1-hour average concentration during all daylight hours?**

I much prefer a metric based on using all available daylight hours (combined with a higher percentile like 98th) over one based on only the single worst daylight hour (combined with a low percentile like 90th) for several reasons:

- I think "sensitive" or "susceptible" are poor choices of terms for those who care so much about viewing scenery that they chose to work in windowless indoor environments, stay inside during lunch, and (returning home from their 8-hour shifts) further choose not to go outside or look out their windows during the other 2 to 6 hours of daylight that would be available, during 10 to 14-hour days in different seasons at a mid-latitude location in the US. Do they also stay inside and away from windows on weekends, holidays and vacations? I doubt these are the folks who indicate that only the very clearest levels are acceptable in the urban visibility preference studies.
- There's an implied, but illogical assumption that the single worst hour will coincide with the one hour when the poor "shut-ins" are let outside, but that often won't occur. At best, you're disregarding their views on either the to-work or from-work halves of their commutes. What if they work "9 to 5" (as many do), but the worst hour comes at 6 to 7 AM (or PM) or 7 to 8 AM or PM (as it often will), or in mid morning or mid afternoon, or what if they work the second or third shift? By considering only the single worst hour, you are specifically not affording protection to all the non-shut-ins for most of the day, and providing no protection at all for that fraction of the shut-ins whose hour outside doesn't coincide with the worst hour of the day.
- It puts the maximum possible emphasis on uncontrollable natural meteorological influences, including the convergence of maximum RH, minimum wind speed and lowest mixing height (along with whatever weather influences a 90% RH screen might miss) in the hour just after sunrise.
- This early morning met effect will be most extreme in mountain valley locations in winter, but these coldest, calmest winter days often offer the best visibility later in the day when the inversion burns off (or at slightly higher elevations just above the inversion), so benefits of the extreme pollution controls needed to reduce pollutant concentrations at winter dawn, are likely to be spatially and temporally limited.
- There are not really any viable 1-hour control strategies – especially for the hygroscopic SO_4 and NO_3 species which are emphasized by the PM extinction indicator. Conversely, when only the single worst hour B_{ext} is considered, there will be the most minimal knowledge of the pollutants and sources responsible.

- By emphasizing early morning RH and hygroscopic species, it tends to emphasize East/West differences and deemphasize the importance of organic carbon and elemental carbon aerosols, which have other welfare effects such as on soiling and climate.
- For a PM light extinction indicator, measurements might include nephelometer and aethalometer (preferably with $PM_{2.5}$ heads), plus an RH sensor, and could conceivably also include continuous PM_{10} and $PM_{2.5}$ mass at some locations to estimate coarse mass extinction. That's a lot of things that can potentially go wrong, for which a single worst hour/day measurement will be much more sensitive to measurement errors or failures in any of the above than if a more robust metric based on all daylight hours were considered.
- It seems especially illogical when combined with a low percentile: "even a single bad hour will ruin my day, but I don't mind a bit until it happens more than 37 days a year."

17. Levels and Forms (section 4.3.3): What are the Panel's views on the following:

a. **The preliminary staff conclusions regarding ranges of options with varying levels and forms in combination with different indicators (light extinction and $PM_{2.5}$ mass-based indicators) and averaging times (1-hour daily maximum or each 1-hour average concentration during all daylight hours)?**

I think the ranges of options combining various levels, forms, indicators and averaging times are reasonable, with focus on mid-range combinations while considering modest upper and lower bounds. For the $PM_{2.5}$ mass indicator, I think the upper bound concentration levels considered (40 $\mu g/m^3$ and 60 $\mu g/m^3$) are rather unreasonably high and could be replaced in future drafts with smaller 5 $\mu g/m^3$ increment calculations within the range of 15 to 35 $\mu g/m^3$. As indicated previously, I much prefer consideration of all daylight hours, rather than focusing on the single worst hour, and would like to see a full set of calculations based on that metric for both the optical and fine mass indicators included in the next draft. Along similar lines, the PA indicates (p. 4-44, lines 18, 19) an intended focus on the more lenient 90^{th} and 95^{th} percentiles – which I think should specifically pertain only to the single worst hour/day indicator. Higher percentiles (95 to 98^{th}) would be appropriate if all daylight hours are considered. I suggest rewording this to "… 90^{th} or 95^{th} percentile forms is appropriate if based on the single worst daylight hour, while consideration of the 95^{th} or 98^{th} percentiles is more appropriate if based on all daylight hours."

Would it be possible to show estimates of what attaining the various hourly optical or $PM_{2.5}$-based secondary standards would do to (or mean in terms of) changes in annual and 24-hour average $PM_{2.5}$ levels in the test cities? Along similar lines, would it be possible to show the "incremental % reductions" in $PM_{2.5}$ that would be needed to, or associated with efforts to meet the various optical or $PM_{2.5}$-based secondary standards after the current and proposed new primary $PM_{2.5}$ standards were first attained?

I've become confused about the differences that would result if PM light extinction levels or $PM_{2.5}$ concentrations were rolled back to just meet standards based on single worst hour compared to using all hours (and a higher percentile). At any given level of PM light extinction or $PM_{2.5}$ mass, it would seem like rollback to attainment would produce similar results, since once the worst hour is "fixed", the second worst hour takes precedence, and then the third, etc. until all hours above threshold are reduced – in which case, the single worst hour approach becomes very similar to the all hours approach. Can this be explored/explained in more detail?

b. **Additional approaches that could help inform our consideration of alternative levels and forms?**

As indicated above under Q 16a, I think a 4-hour averaging could be considered and justified, especially if the occasionally noisy $PM_{2.5}$ indicator is used. I think the need for a 90 % RH screen becomes less urgent, and might possibly be dropped if a $PM_{2.5}$ indicator is used (see other comments on p. 4-44 below). It is definitely needed if an optical indicator is used, and consideration needs to be given to whether an hour would be eliminated if the average RH exceeds 90%, or if any or many (1-minute) RH levels within the hour exceed 90%.

Because of measurement issues with coarse particle extinction, consideration might be given to using (and measuring) $PM_{2.5}$ light extinction as an indicator. Alternatively, measurements of continuous $PM_{10-2.5}$ mass (by the difference method), combined with an assumed extinction efficiency of say 0.6 m^2/g could be used to supplement $PM_{2.5}$ light extinction measurements – either at all sites or at sites with relatively high coarse particle concentrations. Conceptually, coarse mass by difference could also be used to enhance a $PM_{2.5}$ mass indicator, using a relationship of something like $PM_{2.5} + 0.1 \times PM_{10-2.5}$ (assumes a generic $PM_{2.5}$ extinction efficiency of about 6 m^2/gram – which would represent ammonium sulfate or nitrate at 66% RH – or a mix of these and organic matter at somewhat higher RH).

PM light extinction is an actual and measurable characteristic of particles in the atmosphere, which can be directly related to the levels of visual air quality considered unacceptable by human observers and to the size and composition (including aerosol water) of airborne particles which cause it. Given this, a level of a secondary standard could be selected, even in the absence of – or in advance of a monitoring network to determine compliance. Along similar lines, a PM (or $PM_{2.5}$) light extinction standard could be set, and $PM_{2.5}$ mass measurements specified as an FEM to determine compliance – until such time as an appropriate PM light extinction measurement network can be established.

As indicated in previous comments on the UFVA, a "progress-based" attainment test rather than the traditional "threshold-based" attainment test would be preferable from a scientific perspective. While the Agency has indicated this is not an option in the standard-setting process, it is something that could and should be considered in the implementation phase (where, for example, the Agency could provide guidance on what would be considered reasonable rates of progress). Possibly an illustrative example of how this might work could be provided in the next draft PA.

I think it would be appropriate if the next draft of the PA included a section identifying and prioritizing key near-term monitoring and research needs. This could include things like establishing a small pilot urban visibility network to field-test and evaluate alternative PM light extinction measurement methods, and should also include recommendations for additional visibility preference studies to better define levels (and/or frequencies) of visual air quality considered acceptable over a wider range of locations and viewing conditions, to support refinements and revisions to secondary PM standards in the future.

<u>Other Comments on Chapter 4</u>

P 4-5 line 23: You could add "most" at the end of the line.

P 4-5 lines 34-35: You could add "(all but one)" after "most CASAC Panel members".

P 4-15 lines 15-31: As indicated above, I'm not a fan of the single worst hour approach, and think it's a stretch to claim its needed to protect the most "sensitive" individuals…since they are neither sensitive, nor does it protect them most of the time.

P 4-16, lines 15-23: This is generally true, but especially during the winter. In warmer months (when people spend more time outdoors), RH still peaks at dawn, but morning rush hour occurs several hours later, nocturnal inversions are weaker, SO_2 plumes aloft don't mix down until mid morning, and secondary formation rates for sulfates and organics typically peak in mid-afternoon.

P 4-20 line 17: The "24.3 dv" level cited for the 50^{th} percentile acceptability response in Phoenix is different from the "24.15 dv" 50% level for Phoenix in Table 4-1.

P 4-21 lines 16-31: You might also add something like "It should also be noted that the current version of the Winhaze model does not include clouds in the base photos. The visibility of clouds and their contrast with the background sky would be sensitive to changes in light extinction, even in urban city scenes which otherwise lack distant objects in the background."

P 4-22 line 13: You could add "and Eastern urban scenes with more distant vistas or with background clouds" after "…Western urban scenes."

P 4-29 lines 9-13: As previously indicated, I think the argument to protect the "sensitive" shut-ins is not the strongest. Better arguments are the instantaneous nature of the perceived visibility effect, and you might also add an illustration, based on data, showing how high a one-hour PM light extinction (or $PM_{2.5}$ mass concentration) could be on a day when the current 35 $\mu g/m^3$ secondary $PM_{2.5}$ standard is not exceeded.

P 4-30 lines 21-32: Maybe you could set this point up a bit by zooming in from the concept of light extinction to PM light extinction (excluding Rayleigh and NO_2) – which I assume would be the preferred indicator. Then you might consider but exclude the very small fraction of PM extinction from ultra-coarse particles (> 10 μm) – not because they contribute nothing, but because their contribution is so minor. Then make the point that $PM_{10-2.5}$ particles also usually contribute very little (and their extinction effect is more difficult to measure), but can occasionally be important. This might lead to an optional approach in which "PM light extinction" could be the indicator, measured as "$PM_{2.5}$ light extinction" in most areas, but with supplemental methods to estimate $PM_{10-2.5}$ extinction in areas where coarse particles are important.

P 4-30 line 23: Change "many" to "may".

P 4-30 line 34: I think "one to two years" may be optimistic, and would constitute "rushing" with all of its various associated pitfalls.

P 4-31 line 2: Use of the term "promulgation/implementation" implies that the two things need to be concurrent, but I don't think they need to be so. Conceivably, a PM light extinction standard could be promulgated, with an implementation period delayed until a future time period (perhaps to allow a reasonable time frame to develop, test and deploy appropriate monitoring methods).

P 4-31 line 14: No space needed in "widespread".

P 4-31 line 17: Add something like: "24-hour chemical composition data and" between "produce" and "hourly", or otherwise correct this sentence.

P 4-31 line 19: Delete "produces".

P 4-33 lines 1-4: Presumably the frequency of visibility-impairing "weather" is very small, but not zero, when RH is less than 90%.. It might be informative to know that there may still be some weather influence and that 90% RH is a reasonable compromise, which eliminates most of the weather events.

P 4-33, line 28: I think 60 $\mu g/m^3$ is a very extreme upper bound, and that its nearly impossible to have PM extinction < 191 Mm^{-1} with $PM_{2.5}$ as high as 60 $\mu g/m^3$ (and extinction of 191 Mm^{-1} with $PM_{2.5}$ of 40 $\mu g/m^3$ would be relatively rare as well) . In the entire IMPROVE network for the 5-year period from 2000 through 2004, there were 73,410 samples with reconstructed PM extinction of less than 191 Mm^{-1}. None of these had $PM_{2.5}$ mass concentrations as high as 60 $\mu g/m^3$, and only 2 samples and 9 samples (of 73,410) with reconstructed extinction < 191 Mm^{-1} had fine mass concentrations above 50 and 40 $\mu g/m^3$ respectively.

P 4-35, lines 8-9: As indicated before, I don't buy the logic that a focus on the worst one hour is needed to protect the "susceptible" shut-ins. For this to be true, the single hour of poorest visibility would need to correspond to all the shut-ins' hour outside.

P 4-36 line 4: Remove "could" or the "s" from "affords". Also, I'm not sure that providing a uniform degree of visibility protection nationwide is such a great advantage. You could add to the end of this sentence ", although efforts to attain it would require substantially greater pollution control efforts in the humid East, where scenic vistas are typically more limited. By comparison, an "equally stringent" nationally uniform $PM_{2.5}$ mass indicator would allow somewhat higher levels of visibility impairment in the East, but would provide somewhat better visibility protection in dryer, and typically more scenic, Western urban areas."

P 4-38: I don't understand why, for Tacoma and Phoenix, there are changes from column a to b (90^{th} to 95^{th} percentiles) when both are below the 191 Mm^{-1} threshold?

P 4-41: This table - with the color-coding - is very helpful! Possibly future versions might focus on a more realistic range of say 35 to 15 $\mu g/m^3$, with smaller (5 $\mu g/m^3$) increments between bins. Would there be a way to estimate the changes in and remaining concentrations of in 24-hr average $PM_{2.5}$ mass that would result if these hourly levels (or the hourly B_{ext} levels in Table 4.3-1) were obtained? It will be a lot more work, but you should include all the same calculations based on the 98^{th} percentile using all daylight hours. Without these you will be stuck with illustrations that only apply to your (questionably justified) worst 1 hour metric.

P 4-42, lines 11-13: Although presumably there would be substantial overlap between the worst 10% fine mass days (hours) and the worst 10% B_{ext} days (hours). Could this be explored?

P 4-43, line 21: Is there an intent to specifically emphasize "urban areas", or could this be rephrased to "primarily in those rural, suburban and urban areas which are not protected by the 1999 Regional Haze Rule".

P 4-44 lines 18, 19: By focusing on the 90^{th} or 95^{th} percentile, it sounds like you've already made the (questionable) decision to use the single worst daylight hour. Otherwise, you could change this to "… 90^{th} or 95^{th} percentile forms is appropriate if based on the single worst daylight hour, while consideration of the 95^{th} or 98^{th} percentiles is more appropriate if based on all daylight hours."

P 4-44, line 19: Conceptually, a 90% RH screen could be used for the same weather-screening reasons if a $PM_{2.5}$ mass, rather than a PM light extinction indicator was used. As a practical matter, it may be less critical for a mass indicator for several reasons. Higher RH will tend to "push" hours into the high percentile light extinction bins, but not so for high PM mass hours. In fact any weather (rain, fog) concurrent with high RH is likely to push high PM hours toward lower PM percentiles. Also, with a $PM_{2.5}$ mass indicator, there's no chance of requiring reductions in very low pollution concentrations that happen to concur with extremely high RH conditions, or of having any public perception, however misguided, that EPA is trying to regulate the weather. There is also no benefit from or need to specifically exclude higher RH conditions from (dried) $PM_{2.5}$ mass measurements, nor would errors in the RH sensor measurements have large influences on whether the "right" or "wrong" hours were excluded or included from the regulatory metrics.

P 4-44 lines 29-30: I assume this is a typo and that you meant to say "focus on a level of 20 $\mu g/m^3$as well as levels down to 10 $\mu g/m^3$ and up to 30 $\mu g/m^3$".

Comments from Dr. Armistead Russell

Question 7: Forms (section 2.3.3):

What are the Panel's views on the utility of additional analyses to inform consideration of eliminating provisions included in the current form of the annual standard that allow for spatial averaging across monitors, specifically with regard to the potential for disproportionate impacts on susceptible populations with lower socioeconomic status?

Response: I am not sure that there was sufficient justification for spatial averaging in the past, and do not see that there is much reason to continue the practice. It is likely that a monitor with elevated levels is being impacted with fresh emissions, and unless that monitor is directly adjacent to the source(s), there are areas with even higher levels. Further, those elevated levels may be due to a source whose emissions are more harmful than the regional background PM more evenly distributed across a city. Allowing spatial averaging could lead to a specific area being significantly and consistently adversely impacted beyond the region as a whole.

Question 10: Indicator (sections 3.3.1, 3.3.2, and 3.3.3):

What are the Panel's views on the following:

a. The preliminary staff conclusion that it is appropriate to maintain a standard that provides protection against all thoracic coarse particles, regardless of their source of origin or composition?

Agree.

b. The appropriateness of maintaining an indicator that allows lower $PM_{10-2.5}$ concentrations in urban areas than non-urban areas?

See below.

c. The appropriateness of either a PM_{10} or $PM_{10-2.5}$ indicator for a standard meant to protect against exposures to thoracic coarse particles?

Response: While the association of the observed health effects with larger particles is viewed as being only suggestive of a causal relationship, sufficient information is available to continue to have a standard that includes particles above 2.5 um. While certain sources may primarily emit particles that are found in the coarse size range (2.5-10 um), the tail of the size distribution of those emissions contains PM in the sub-2.5 um range, and those particles presumably contribute to the observed health effects in studies using either PM_{10} or $PM_{10-2.5}$. Using a PM10-2.5 indicator would allow dismissing how this tail contributes. Further, as discussed in the PAD, using a PM10 standard would address the (rather small amount of) evidence that urban coarse particles appear to have greater health impacts than wind blown dust. The epidemiology can support either range, and controls aimed at controlling PM10 (beyond those used to reduce PM2.5) would reduce levels of PM10-2.5 and vice versa. Given the above, a PM10 standard would appear to be preferred. Question (b) should be rephrased as to allowing higher PM concentrations in non-urban areas.

Question 11: Averaging Time (section 3.3.4):

What are the Panel's views on the preliminary staff conclusions that the currently available evidence supports maintaining a 24-hour standard to protect against health effects associated with short-term exposures to thoracic coarse particles, and does not support consideration of a long-term thoracic coarse particle standard?

Response: Agree.

Question 18: Climate (section 5.2): What are the Panel's views on the preliminary staff conclusion that there is insufficient information to base a standard on climate impacts associated with current ambient PM concentrations?

Response: While there may be insufficient information to base a secondary standard on potential climate change, the current discussion does not adequately inform policy makers as to the potential that a standard limiting light extinction would do more harm than good. There is sufficient information demonstrating that some aerosols lead to cooling, in particular aerosols that scatter visible light and can lead to increased/longer lived/more reflective cloud formation. The REA (based largely on other assessments) demonstrates that light scattering aerosols lead to a net decrease in radiative forcing, and while the uncertainty is significant, it suggests that the effect may be quite large. Further, there is sufficient evidence that light absorbing aerosols can lead to warming. To go forward with a secondary standard based on reducing light extinction, the PAD needs to more directly weigh the potential dis-benefits of regional warming with improved visibility unless light absorbing aerosols are preferentially targeted. There may be significant regional heterogeneity to controls that would address a visibility-based secondary standard which should be addressed. For example, it is the areas that have the lower PM concentrations that may benefit most from maintaining/improving visibility, but the areas with regionally high sulfate levels likely benefit most from the reduced radiative forcing. At a minimum, EPA staff needs to address how a secondary standard might impact regional radiative forcing and climate, assess the uncertainties, and provide a reasoned analysis weighing the two issues. Also, on Page 5-11, lines 10-11 and lines 31-31, it is noted that "aerosols that are warming are co-emitted with aerosols that are cooling." While this is true to some degree in some cases, it skews one's perception of the actual case. Most of the warming aerosols in the US are emitted by biomass burning and internal engine combustion. Much of the cooling aerosol is formed in the atmosphere by oxidation of SO2 or VOCs. Thus, a set of controls to control warming PM would not necessarily have that much impact on cooling PM and vice versa. These statements should be modified.

Question 20: Material effects (section 5.4): What are the Panel's views on the preliminary staff conclusion that no new evidence calls into question the adequacy of the protection afforded by the current suite of PM standards, and that there continues to be support for retaining an appropriate degree of control for both fine and coarse particles to provide protection against materials damage and soiling?

Response: Agree.

Minor:

P 5-22, l 13. Replace “impossible” with “difficult”

Comments from Dr. Frank Speizer

Date: March 26, 2010

Charge Question 3: Approach (Section 2.1.3)
Page 2.10-2.12: With regard to the weight given to the various approaches Staff appears to indicate that the lower level of the interquartile range for both the long term and short term empirical evidence should be considered, in spite of indicating no threshold. This may be absolutely the correct approach, but some further discussion as to why this decision was made might be warranted. Indicate why not the 90^{th} or 95^{th} %tile level. What does "notably wider" mean in discussing confidence intervals? How much wider? At what point do they cross zero?
Page 2.12-13: In discussing the use of the risk estimates Staff indicates that the uncertainties are taken into account by considering the sensitivity of the "core" risk. May need to define "core" risk more explicitly. In addition it is not clear how the two separate approaches are to be combined and whether the weighting of one over the other will dominate or be the determining factor. If I read it one way I might conclude that the evidence based values will be used and the risk assessment is simply a test of the sensitivity of reaching a conclusion. Alternatively (and most likely) somehow the use of the total information will be used to reach a judgment.

Charge Question 4: Adequacy of current suite of $PM_{2.5}$ standards (Section 2.2)

a. Appropriateness and characterization of sets of studies. It would appear that the specific studies chosen are appropriate and there are none other that need to be added. However, Figure 3.1 seems not to be adequately discussed in terms of the presentation of differences in weights to be put on any given set of studies. (There are also some specific questions about the way the figure is presented). Clearly the nature of the confidence intervals indicated in the figure provide as estimate of both the nature and size of each study. A more explicit indication on the figure as to which were single city vs multicity studies would be helpful. This would provide further evidence of why relying on the multicity studies seems justified. Specifically with regard to the figure and characterizing the PM exposure there are some questions raised by what is in the figure. For example for a number of the studies the Lower IQR value matches the lower bound of the Range. How does this occur?
b. Page 2.34 The question of susceptible groups seems to conclude with the standard group of older adults and children along with pre existing cardiopulmonary diseases. The paragraph justifying lower SES is appropriate. However, no mention is made of diabetics (perhaps much of the data is post ISA, but not all). This is an important group, the data are at least as firm as some other groups, and it is a growing issue in the face of the obesity epidemic. I would therefore suggest a brief discussion of the risk data and it be added to the list.
c. Use of risk assessment, judge correct. Page 2.34, line 14: Minor point—top of page 2.37, line 1: Not sure where the conclusion that the WHI represented a "healthier cohort population" comes from. If I had noted it in the ISA I would have objected. These women were selected as post menopausal and thus were aged ~45+. In the ACS cohort I believe the lower bound age was 35 and the cohort was probably of a generally higher social class, and in Six Cities it was a random sample of households and generally younger (and probably healthier). Before getting to the question of risk based consideration the several pages leading up to page 2.42 provide substantial evidence that the various studies

considered demonstrate empirically that significant and substantial health effects have been reported by multiple investigators at or just below the current standards. It would seem that the conclusion that the current standards are inadequate to protect the public and should be so stated before making the obvious concluding sentence on page 2.42, starting on line 5. In fact, it is an interesting contrast that one could take the position that since the current standards fail to protect the public and since there are not a lot of studies that show effects below the current standard levels, the very reason for doing the risk assessment is to help the administrator find an appropriate level that includes a margin of safety (rather than simply trying to add the risk assessment information to the empirical data to come to some "combined judgment" I admit this may just be semantics but because risk assessment carries the implication of uncertainty it would seem better to put it into this context.

d. The argument used for justifying the relative contributions of the annual and 24 hour concentrations is logically presented and clearly stated by summarizing the results of table 2.2. and text on page 2.45. As we indicated in discussing the RA, although the conclusions would not have changed, we understood why IHD mortality was used but would have preferred Staff using Total Cardiovascular mortality. The problem is further complicated by trying to compare directly the results as presented in table 2.3 with table 2.2 where the contrast is between the annual and the 24 hour. Since table 2.2 is IHD results and table 2.3 is cardiovascular and the magnitudes of effect are ~3-10 times larger for IHD the tables do not appear to be directly comparable. The argument as to why there is greater confidence in the roll back estimates from where the annual standard is controlling than where the 24 hour is controlling is straight forward and clearly related to the differences in the volume of data for each scenario from which to make the estimates. (The argument presented on page 2.52 for the use of the 15 urban study areas for estimating the contrast between annual and 24 hour values is persuasive and provides the relative limitations of the sites as a fair assessment.)

e. With regard to the integration of the evidence presented in section 2.2.3, Staff is correct in asserting that "newly available information strengthens the associations between …" We also agree that there are significant public health consequences at the current levels of the standard that justify consideration of lower standards in the further. However, what is not is this section is the fact that this is not different from the conclusions of the previous review, but only strengthened by additional data obtained in the last five years. Remember it was the Administrator that when outside the recommendation of both CASAC and Staff the during the last review. Further without specifying the nature of the uncertainties that were reduced since the last review (page 2.54, line 30) the text does a disservice to the previous conlusions that the standards should have been lowered. What are the specific uncertainties that have been lowered? What are the mechanisms that were not known 5 years ago that are better articulated now? It is true that there are a greater suite of health effects, however, they do not meet a higher degree of certainty and thus add little to the quantitative argument available at the last round. (One cannot avoid the obvious conclusion that the Administrator in the last round simply ignored the available scientific data.)

Charge Question 5—Indicator

a. With regard to maintaining $PM_{2.5}$ Staff's argument that the data have expanded over the last several years is correct. They are also correct in indicating that in spite of there

being significant advance in being able to better characterize both in terms of size, number (and perhaps chemistry) these latter measures have generally not be applied sufficiently in health based research to be able to change the indicator (at least for the fine fraction from the current one. Of $PM_{2.5}$.

b. With regard to Ultrafines (UFP) the data are certainly suggestive of health effects. Staff rightfully points out (Page 2.58, Paragraph beginning line 25) there is currently no network of UFP samplers and thus only limited site-specific data sets. These data, however, are compelling and point to the need for the establishment of a network of samplers under some federal guidelines to position EPA to be more effective in making judgments on future particle standards.

c. With regard to speciation and sources perhaps the most important summary statement is that on Page 2.64, sentence beginning line 17, "…evidence not sufficient to support eliminating any component or source from the mix…" However, the suggestion that could find a specific component that might be eliminated is probably a wrong way to conceive of the problem. PM is obviously a summary measure of a mixture of both complex air chemistry and source components. The likelihood of being able to identify or eliminate one of those components is small. More important is the use of this complex chemistry to more accurately identify and label sources that need to be better controlled. Thus far the data point most specifically to oil burning and traffic pollution sources, and less conclusively to wood burning. This obviously is important information for considerations beyond the Standard to the implementation phase. Rather than simply indicating that the work to date does not justify expanding the Indicator to be more specific in terms of speciation, a more positive statement of the sources could be made.

Charge Question 6--Averaging times

a. Agree with Staff's position that the annual and 24 hour average need to both be retained as the standards.

b. Also agree that that there is insufficient information to consider a shorter than 24 hour average or a seasonal average at this time. However, there is mounting clinical evidence that short term exposures (substantially less than 24 hours) are associated with reversible cardiovascular changes. The degree that these changes either from acute or repeated exposures trigger significant adverse events or result in more sustained adverse effects is as present highly suggestive, They certainly point to the need to consider from a policy perspective related to susceptible groups how the 24 hours standard should be modeled to protect the population with a margin of safety. Are there additional analyses that could be done to inform the Administrator on the distributions of the frequencies at which any specific level of exposure for , say up to 2 hours, would occur at specific levels of the 24 hour standard?

Charge Question 7—Form

The argument that there may be difference in the protective effects of a given standard based upon spatial averaging vs 'community-wide air quality" recording the highest value only is sufficiently well presented to justify further analyses.

Charge Question 8—Level

a-c. The rationale presented regarding alternative standard levels is well presented, although it is not clear how Staff intends will eventually focus of the which of the two very logical alternatives (range 13-10ug/m3, 30-35ug/m3 vs. 11-10ug/m3, 30-25ug/m3) will become the focus of discussion in the second draft. Perhaps it would be useful for CASAC to weigh in more heavily on these alternatives. (Obviously, the latter provides a greater degree of safety and is more consistent with an "adequate margin of safety"

d. Clearly the idea that the alternative annual standard will shift the distribution of 24 hour measures is well presented. However, it is also well presented that "hot spots" would remain and it may be these very hot spots that put the most vulnerable parts of the population at greatest risk. Thus, it becomes appropriate to continue to also regulate 24 hour levels, and thus logical to consider and maintain an alternative 24 hour standard.

e. Other considerations. Because one national standard may not deal effectively with the seasonal or spatial variations that might occur (nor the potential localization of susceptible sub-populations at greater risk) it would seem more logical to consider more conservative levels for the standards. Are there additional analyses that could be undertaken to provide more quantitative estimates of the magnitude of the populations that would be left at risk for any given suite of standards? This might be one of the topics to be covered in the second draft of the PA.

Charge Question 9 –Adequacy of current 24 hour PM_{10} standard.

a. Maintaining a Course Fraction particle standard. If anything the evidence since the last review is stronger, although still only suggestive that there are significant adverse health effects associated with the thoracic course fraction. It would appear that uncertainty issues remaining relate mostly to either lack or sufficient numbers of monitors from which to make appropriate statistical associations and adequacy of spatial estimates of exposure, potential for co-pollutant effects (mostly separating the effects of fine particles from course particles) or difficulties in technically being able to carry out toxicological studies of enough variety to provide a foundation for the potential mechanisms (different from those that have already been confirmed for PM2.5). Clearly the public health concern remains high (potentially related more to morbidity effects rather than mortality as evidenced by the relation to hospitalization and emergency room associations). Thus, in spite of the uncertainties maintaining a thoracic course particle standard is warranted. Further to the degree that the associations reported are at least as significant as in the last round of review, and I believe they are even more suggestive, strengthening the standard can also be defended.

Charge Question 10 Indicator.

a-b. Appropriateness of maintaining a standard that protects against particles regardless of source of origin and composition. The answer to this question seems obvious. The issue is that the potential fraction of total course fraction that is combustion generated vs. dust generated may or may not be important. The wind blown dust studies that show impacts at far distances are suggestive that irrespective of source and thus potential toxicity (from what we currently know) may not make as much difference. Therefore accepting that some fraction of the PM10 may be related to the amount of combustion source (read PM2.5) and thus a portion of the toxicity noted does not negate the importance of reducing total particles. Staff seems to be arguing that being able to reduce PM10 from any source will work to the benefit of both urban and rural sources. I think I agree with this, but it still would be worth while a full discussion at CASAC.

c. With regard to which measure (PM10 or PM10-2.5) is appropriate, I believe we will need to discuss this fully. We cannot leave the question open to the Administrator to decide. Therefore what we need is some estimates of exposure fractions with which to make a tentative judgment of what the alternatives would predict.

Charge Question 11—Averaging time.

Staff concludes that the 24 hour average provides the best estimate of exposure to course fraction and is the exposure value with the most data suggesting an association. I would agree. It probably make the most biological sense and the suggestion that control of accumulated repeated 24 hour exposures would reduce the potential for longer term averaging time effects is reasonable.

Charge Question 12. Form.

Concur with the use of the 98^{th} percentile form averaged over 3 years.

Charge Question 13—Level

We currently have a promissory note that Staff will conduct some analyses of alternative levels of the 24 hour standard for PM10 and PM10-2.5. More specific criteria of a "stopping point" are needed. Will the lower bound be at 140,120, 100ug/m3 for PM10, and if so on what basis? For PM10-2.5 will it be at 75%, 60%, 50%, 40%, lower(?) of PM10 and on what basis? (If it were at all possible to see some of these analyses before the Draft 2 it would be useful to include in our discussion.) by indicating that the focus will be on the upper end of the distributions of daily PM will Staff will need to take into consideration the differences between total PM urban and rural and may have to run two sets of analyses to compare differences.

Comments from Dr. Helen Suh

The first draft Policy Assessment is a good start at presenting and discussing the policy-relevant issues in the review of the PM NAAQS. It is comprehensive in its inclusion of relevant evidence and risk based information. The summaries (e.g., sections 2.3.6, 2.4, 3.2.2, 3.4) were particularly notable, as they were generally succinct and thoughtful, clearly and cogently presenting the staff conclusions. Other sections of the Assessment, however, suffered from too much detail, seemingly recounting much of information presented in the ISA and REA. This rehashing of information obscured the key policy related issues and brought a lack of focus and clarity to the document. Further distillation and tightening of the document is needed. While not yet written, the sections on "Key Uncertainties and Needs for Further Research" (for both $PM_{2.5}$ and $PM_{10-2.5}$) are welcomed and important. These sections should certainly include discussions of PM composition, with respect to whether particulate mass is the appropriate indicator. Finally, at its current length, the document would benefit from a chapter either at the beginning or end of the Assessment that summarizes staff conclusions for both the primary and secondary standards.

18. **Forms (section 2.3.3):** *What are the Panel's views on the utility of additional analyses to inform consideration of eliminating provisions included in the current form of the annual standard that allow for spatial averaging across monitors, specifically with regard to the potential for disproportionate impacts on susceptible populations with lower socioeconomic status?*

The rationale to conduct additional analyses to assess whether spatial averaging provisions should be eliminated is sensible and appropriate. Further, the consideration of alternate forms for the annual $PM_{2.5}$ standard, specifically the highest community monitor level, is appropriate. However, the process by which such considerations (and from this the appropriate standard form) will be made is unclear and should be clearly set forth in the second PA. In particular, the second PA should describe how likely regional and temporal variation in the comparisons and the relationship between highest monitor levels and low SES populations was considered.

19. **Levels (sections 2.3.4, 2.3.5, and 2.3.6):** *What are the Panel's views on the following:*

d. The preliminary staff conclusions regarding alternative standard levels that are appropriate for consideration, and the rationale upon which those conclusions are based?

The alternate standard levels to be considered and their rationale are appropriate.

e. The insights that can be gained from the quantitative risk assessment to inform our understanding of the roles that the annual and 24-hour standards play in providing public health protection, specifically in focusing on simulations of estimated risks remaining upon just meeting alternative suites of standards? (sections 2.3.4.2 and 2.3.5.2)

The quantitative risk assessment is a useful and illustrative tool to illustrate the impact of alternative standards on health risk. The usefulness of the risk assessment to this process would be increased if the discussion of the risk assessment results were condensed even further to focus on the major points.

f. The policy implications of the uncertainties associated with estimating risks, including potential underestimation of risk, in reaching conclusions regarding standards that would provide public health protection with an adequate margin of safety?

As noted in discussions and comments from the March 2010 meeting, the impacts of model choices on long- and short-term risk estimates should be expanded (perhaps on page 2-43, paragraph beginning on line 9), as this information is central to determinations of margin of safety. As an example, the potential under- (and/or over-) estimation of long-term mortality risks from reliance on C-R functions from Krewski et al. (2009) should be discussed.

g. A policy approach for identifying a suite of standard levels in which the annual standard would be the "generally controlling" standard to provide protection for both long- and short-term $PM_{2.5}$ exposures, in conjunction with a 24-hour standard set to provide supplemental protection against days with high peak concentrations associated with localized "hotspots" and risk arising from seasonal emission that might not be controlled by a national annual standard? (section 2.3.6)

The policy approach for identifying the suite of standard levels was well written and clear.

h. Additional considerations that could inform our conclusions related to alternative suites of fine particle standards?

With regard to a margin of safety, it may be important to include a statement in the risk assessment consideration of results (page 2-104) regarding the potential implications of model choices regarding under- or over-estimation of risks.

Review of the Primary Standard for Thoracic Coarse Particles (Chapter 3)

[As a general note, the chapter on thoracic coarse particle seems to be less formed and more preliminary than corresponding sections for $PM_{2.5}$.]

6. Form (section 3.3.6): *What are the Panel's views on the preliminary staff conclusion that it is appropriate to consider a 98^{th} percentile form for a revised 24-hour standard meant to protect against short-term exposures to thoracic coarse particles?*

This conclusion seems appropriate for practical reasons. However, it is not clear that the logic used to support a 98^{th} percentile form for NO_2 and $PM_{2.5}$ pertains to thoracic coarse particles given that the high end of the PM_{10} concentration distribution may reflect higher contributions of $PM_{2.5}$ and not $PM_{10-2.5}$ in many parts of the US. Although perhaps this issue can not be addressed, this uncertainty should probably be mentioned.

Comments from Dr. Sverre Vedal

EPA (OAQPS) PM Policy Assessment, 1st draft 2010
Sverre Vedal draft comments - Apr 4, 2010

Charge Question 1: Organizational structure.

a. Intro and Background.

These are well-organized and informative for both naïve and informed readers.

b. Questions posed.

All questions are appropriate - I can't think of additional ones that would be useful.

c. Level of detail and focus.

The balance between too little and too much detail is good, in general. There is repetitiveness as parallel arguments are followed through in dealing with long-term and short-term exposure risks, but I think this is largely unavoidable. The historical review in the coarse PM section (3-26 through 3-30) is perhaps too extensive.

Charge Question 2: Technical content.

a. ISA evidence and uncertainties.

The PA adequately and faithfully summarizes the relevant points from the ISA. I still maintain a minority opinion that the link between long-term exposure and cardiovascular disease is appropriately classified as causal but that with total mortality should be classified as likely causal (p. 2-16, table 2-1). Regardless, the PA is faithful to the last version of the ISA, which has the links with both cardiovascular and total mortality classified as causal.

The section on susceptibility is somewhat poorly focused, including a discussion of lung function deficits in adulthood (p. 2-27) of limited relevance. Also, studies of a single stratum of the population (e.g., post-menopausal women, p. 2-28) that are unable to compare risk across different strata provide little evidence of enhanced subgroup susceptibility. The bottom line, however, is appropriate (p.2-29).

b. Risk assessment policy relevant information and uncertainties.

As in by review of the RA, I take issue with the statement that the magnitude of both long-term and short-term risk depends primarily on annual-average $PM_{2.5}$ concentrations (p. 2-44, line 4 and p. 2-48). I know this is intended to refer to short-term effects being driven by concentrations in the middle part of the distribution, but the statement as stands is not strictly correct.

Charge Question 3: Fine PM primary standard approaches (Section 2.1.3).

1. Approach.

EPA staff is using evidence- and risk-based approaches, as before, to guide consideration of the adequacy of the current standards and the choice of alternative standards. Both have their roles and are appropriate to use for these purposes.

There is asymmetry in the way EPA staff uses evidence from long-term and short-term exposure studies in assessing protection afforded by the annual and 25-hour standards: evidence from long-term exposure studies is used only in assessing protection afforded by the annual standard (p. 2-10, line 18), whereas evidence from short-term exposure studies is used in assessing

protection afforded by both the annual and 24-hour standards (p. 2-11, line 10). Is there a rationale for also considering the evidence from long-term studies in assessing the 24-hour standard? It has been argued that it is the cumulative effect of repeated daily PM concentration increases that is responsible for the chronic effect of PM exposure observed in long-term exposure studies (Brook RD, Rajagopalan S. Air pollution and cardiovascular events. N Engl J Med 2007;356:2104-5). It is therefore possible that chronic effects could be better controlled through the 24-hour standard than the annual standard.

2. The relative weighting.

I agree with using both the annual and 24-hr standard together in providing protection against PM effects. The balance between evidence- and risk-based approaches is fine.

3. Additional approaches?

None to suggest at this time.

Charge Question 8: $PM_{2.5}$ level.

a. Conclusions on alternative standard levels and rationale.

I find the use of the 1SD below the mean or at the lower IQR to define annual mean concentrations of concern to be less appealing that the use of "somewhat below the long-term mean" concentrations, although either is somewhat arbitrary. I know that we are to limit ourselves here to scientific considerations and ignore issues of feasibility and cost-benefit, but as ever lower standards are being considered, this becomes more difficult.

b. Insights from the quantitative RA on annual and 24-hour standards, especially simulations of remaining risks with alternative standards (sections 2.3.4.2 and 2.3.5.2).

The quantitative RA results are very important. The information presented is very dense, for example, in detailing and contrasting effects in individual cities – but, I think this is preferable to being vague. The two scenarios used for alternative 24-hour standards (13/30 and 12/25) may provide most of the information needed, but additional options may be helpful unless it can be justified that they aren't.

c. Policy implications of the uncertainties in estimating risks.

Use of the LML rather than PRB as the lower level for estimating risk is appropriate, in my opinion.

d. Approach with annual standard "generally controlling" standard for both long- and short-term $PM_{2.5}$exposures (section 2.3.6).

I believe the arguments made in favor of the annual standard as the controlling standard are well laid out and ultimately persuasive.

e. Additional considerations related to alternative standards?

It isn't clear how the selected studies were chosen to be included in Fig. 2-4 (p. 2-91).

Charge Question 13: $PM_{10-2.5}$ level. Appropriateness of 98th %ile, 24-hour PM_{10} or $PM_{10-2.5}$ in epi study locations for identifying range of standards, in light of limited monitoring data for $PM_{10-2.5}$ (Section 3.37)?

I am disposed to emphasizing the specific $PM_{10-2.5}$ indicator/measure in assessing level rather than PM_{10}. I find that the extent to which PM_{10} reflects $PM_{2.5}$ (ie, more so in urban areas) may make it insurmountably problematic in using it for reviewing evidence and deliberating on the level of a standard to protect against effects of $PM_{10-2.5}$. I remain open to attempts to accomplish that, however.