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OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

September 10, 2010

EPA-CASAC-10-015

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 – Second External Review Draft* (June 2010)

Dear Administrator Jackson:

The Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel met on July 26 – 27, 2010 and on August 25, 2010 in a public teleconference to review the *Policy Assessment for the Review of the PM NAAQS - Second External Review Draft* (June 2010). This letter highlights CASAC's main comments on this document, followed by consensus responses to the charge questions and comments of individual Panel members.

This review of the *Second Draft Policy Assessment* completes the first cycle through the revised suite of NAAQS review documents and thus represents a major milestone. CASAC commends EPA staff for developing an ordered and transparent basis for decision-making throughout the NAAQS review process from the *Integrated Science Assessment* (ISA) to the *Quantitative Health Risk Assessment* and *Urban Focused Visibility Assessment* and then to the *Policy Assessment*. The *Second Draft Policy Assessment* was notably responsive to CASAC's comments on the first draft. At CASAC's request, the current draft sets out the underlying decision-making algorithms, greatly enhancing the transparency and readability of the document. EPA's approach to reviewing the standard is explicitly articulated throughout the document, as are the key decision-making points and the evidence considered. CASAC's major concerns, as expressed in our letter of May 17, 2010, have been addressed. EPA staff are to be congratulated for building on CASAC's suggestions and developing an assessment that provides a scientifically sound basis for making decisions on the primary and secondary PM standards.

Primary Standards for Fine Particles

CASAC supports the EPA staff's conclusion in the *Second Draft Policy Assessment* that "currently available information clearly calls into question the adequacy of the current standards". For $PM_{2.5}$, the current 24-hour primary standard is 35 μg/m^3 and the annual standard is 15 μg/m^3. EPA staff also conclude that consideration should be given to alternative annual $PM_{2.5}$ standard levels in the range of 13 – 11 μg/m^3, in conjunction with retaining the current 24-hour $PM_{2.5}$

standard level of 35 µg/m^3, and that consideration could also be given to an alternative 24-hour $PM_{2.5}$ standard level of 30 µg/m^3 in conjunction with an annual standard level of 11µg/m^3. CASAC concludes that the levels under consideration are supported by the epidemiological and toxicological evidence, as well as by the risk and air quality information compiled in the *Integrated Science Assessment* (December 2009), *Quantitative Health Risk Assessment for Particular Matter* (June 2010) and summarized in the *Second Draft Policy Assessment.* Although there is increasing uncertainty at lower levels, there is no evidence of a threshold (i.e., a level below which there is no risk for adverse health effects). In addition, these combinations of annual/daily levels may not be adequately inclusive. It was not clear why, for example, a daily standard of 30 µg/m^3 should only be considered in combination with an annual level of 11 µg/m^3. The rationale for the 24-hour/annual combinations proposed for the Administrator's consideration (and the exclusion of other combinations within the ranges contemplated) should be more clearly explained.

Primary Standard for Thoracic Coarse Particles

CASAC recommends that the primary standard for PM_{10} should be revised downwards. While current evidence is limited, it is sufficient to call into question the level of protection afforded by the current standard (a 24-hour standard of 150 µg/m^3).

CASAC supports the EPA staff conclusion that it is appropriate to change the PM_{10} standard to a 98th percentile form because of its higher rate of identifying areas in nonattainment while reducing the rate of misclassification. We do not agree that the available scientific evidence strongly supports the proposed upper bound standard level of 85 µg/m^3. The *Second Draft Policy Assessment* demonstrates that a 98th percentile level of 85 µg/m^3 would be less stringent as compared to the current standard, protecting a smaller fraction of the population. In fact, on a population basis, results in the *Second Draft Policy Assessment* demonstrate that a 98th percentile level between 75 and 80 µg/m^3 is comparable in the degree of protection afforded to the current PM_{10} standard. The change in form will lead to changes in levels of stringency across the country, a topic needing further exploration. While recognizing scientific uncertainties, CASAC supports a lower level to provide enhanced protection, somewhere in the range of 75 – 65 µg/m^3. We recognize that the Administrator will need to apply the Clean Air Act's requirement for a "margin of safety" in a context of uncertainty with respect to the health effects of thoracic coarse particles.

The *Second Draft Policy Assessment* concludes that PM_{10} should continue to be the indicator for thoracic coarse particles. While it would be preferable to use an indicator that reflects the coarse PM directly linked to health risks ($PM_{10-2.5}$), CASAC recognizes that there is not yet sufficient data to permit a change in the indicator from PM_{10} to one that directly measures thoracic coarse particles. To improve EPA's scientific basis for the next NAAQS review, we recommend the deployment of a network of $PM_{10-2.5}$ sampling systems so that future studies will be able to expand the evidence base on this indicator and facilitate assessment of whether $PM_{10-2.5}$ should be used as an appropriate indicator for thoracic coarse particles. In concluding this letter, we elaborate further on the urgency of research on certain aspects of PM and health.

Secondary Standard for PM-Related Visibility Impairment

CASAC supports the EPA staff conclusion that "currently available information clearly calls into question the adequacy of the current standards and that consideration should be given to revising the suite of standards to provide increased public welfare protection." The current secondary standards are identical to the current primary standards for fine and thoracic coarse particles. The detailed estimates of hourly PM light extinction under current conditions (and for assumed scenarios of meeting current standards) clearly demonstrate that current standards do not protect against levels of visual air quality which have been judged to be unacceptable in all of the available urban visibility preference studies. EPA staff's approach for translating and presenting the technical evidence and assessment results is logically conceived and clearly presented. The 20-30 deciview range of levels chosen by EPA staff as "Candidate Protection Levels" is adequately supported by the evidence presented.

While the evidence shows that the current standard does not adequately protect visibility, the choice of indicator for such protection was a subject of considerable discussion among CASAC panelists. The *Second Draft Policy Assessment* discusses three potential indicators: a $PM_{2.5}$ Mass Indicator, a Speciated $PM_{2.5}$ Mass-calculated Light Extinction Indicator, and a Directly Measured $PM_{2.5}$ Light Extinction Indicator. Overwhelmingly, CASAC would prefer the direct measurement of light extinction, the property of the atmosphere that most directly relates to visibility effects. It has the advantage of relating directly to the demonstrated harmful welfare effect of ambient PM on human visual perception. However, in discussing the Directly Measured $PM_{2.5}$ Light Extinction Indicator with EPA staff, we learned that the time required to develop an official Federal Reference Method (FRM) for this indicator would postpone its implementation for years. Given the time lag associated with implementing the Directly Measured Indicator, CASAC agrees with EPA staff's preference for a Speciated $PM_{2.5}$ Mass-calculated Light Extinction Indicator. Its reliance on procedures that have already been implemented in the Chemical Speciation Network (CSN) and routinely collected continuous $PM_{2.5}$ data suggest that it could be implemented much sooner than a directly measured indicator.

Areas for Future Research

The *Second Draft Policy Assessment* has identified scientific issues that will need to be addressed in order to improve EPA's scientific basis for promulgating PM standards in the future. As stated in our letter of May 17, 2010, CASAC urges the Agency to reinvigorate research that might lead to new indicators that may be more directly linked to the health and welfare effects associated with ambient concentrations of PM. CASAC also suggests the ongoing collection of more comprehensive PM monitoring data, including expanding the range of sizes to provide information in the ultrafine particle range, and adding measurements of numbers, chemistry, species, and related emissions characteristics of particles. CASAC strongly urges EPA to pursue research to develop a Federal Reference Method for a Directly Measured $PM_{2.5}$ Light Extinction Indicator and to develop baseline light extinction data so that it will be available for the next 5 year review cycle. CASAC is available to provide advice on priorities for PM-related research.

Thank you for the opportunity to comment on the *Second Draft Policy Assessment*. We look forward to receiving your response.

Sincerely,

/Signed/

Dr. Jonathan M. Samet, Chair
Clean Air Scientific Advisory Committee

NOTICE

This report has been written as part of the activities of the EPA's Clean Air Scientific Advisory Committee (CASAC), a federal advisory committee independently chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. CASAC provides balanced, expert assessment of scientific matters related to issues and problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies within the Executive Branch of the federal government. In addition, any mention of trade names or commercial products does not constitute a recommendation for use. CASAC reports are posted on the EPA Web site at: http://www.epa.gov/casac.

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

<u>Primary Standards for Fine Particles</u>

1. **Current Approach (Section 2.1.3)**:
    a. **What are CASAC's views on the staff's approach to translating the available epidemiological evidence, risk information, and air quality information into the basis for reaching conclusions on the adequacy of the current standards and on alternative standards for consideration?**

CASAC agrees with the approach as described in Section 2.1.3 and appreciates the clarity with which the approach is detailed. The overview of the approach presented in Figure 2-1 is well-organized, logical, and clear. CASAC agrees that it is appropriate to return to the strategy used in 1997 that considers the annual and the short-term standards together, with the annual standard as the controlling standard, and the short-term standard supplementing the protection afforded by the annual standard. CASAC commends the expansion of the discussion on evidence of risk across life stages as well as of specific susceptibility risk factors and the use of empirical evidence and risk assessment findings together. CASAC considers it appropriate to place the greatest emphasis on health effects judged to be causal or likely causal in the analysis presented in the ISA. Finally, the statement that the data "call into question" the adequacy of the current standard could be more forcefully stated by concluding that the current standard is not protective.

   b. **Has staff appropriately applied this approach in reviewing the adequacy of the current standards (Section 2.2) and potential alternative standards (Section 2.3)?**

The staff has carefully followed this approach in reviewing the adequacy of the current standards and in considering potential alternative standards. The outline of the text of Section 2.3 follows the outline presented in the overview of the approach given in Figure 2-1.

2. **Form of the Annual Standard (Section 2.3.3.1):**
    a. **What are CASAC's views on the additional analyses conducted to characterize the potential for disproportionate impacts on susceptible populations, including low income groups and minorities associated with spatial averaging allowed by the current annual standard?**
    b. **In light of these analyses, what are CASAC's views on staff's conclusion that the form of the annual standard should be revised to eliminate spatial averaging?**

CASAC found the additional analyses provided in the 2nd draft PA to be helpful in understanding how spatial averaging differs relative to the highest average value from a single community site. This latter approach helps to ensure adequate protection of populations living in lower socioeconomic areas and contributes an additional margin of safety for other populations. Although much of the epidemiological research has been conducted using community-wide averages, several key studies reference the nearest measurement site, so that some risk estimates are not necessarily biased by the averaging process. Further, the number of such studies is likely to expand in the future. CASAC concludes that it is reasonable for EPA to eliminate the spatial averaging in the new $PM_{2.5}$ annual average standard.

3. **Alternative Levels (Section 2.3.4): What are CASAC's views on the following:**
   a. **The insights that can be gained into potential alternative standard levels by considering:**
      i. **Confidence bounds on concentration-response relationships?**

CASAC commends the progress made in attempting to use confidence bounds in considering alternative levels of the standard, but also finds unresolved complexities. First, staff apparently made a comprehensive effort to identify relevant studies for which bounds were reported on concentration-response (C-R) relationships; this should be explicitly stated. Second, the statement made in reference to what these bounds do not indicate ("these analyses do not provide evidence of a concentration below which the confidence interval becomes notably wider and uncertainty in a C-R relationship substantially increases" [p.2-57]) is contradictory to what they, in fact, do indicate. The confidence bounds widen at lower concentrations because there are fewer data at such concentrations, as acknowledged by staff. This widening is of interest in characterizing precision of estimates as one source of uncertainty. Third, CASAC does not agree with the conclusion that these bounds cannot be used in considering alternative levels of the PM NAAQS, even with the limited C-R functions shown. EPA Staff should be encouraged to integrate the information available on relevant C-R confidence bounds with that on study concentration distributions in arriving at a range of levels for consideration.

For the future, findings of epidemiological studies might be used in several ways in considering a range of levels for a NAAQS. It would be preferable to have information on the concentrations that were most influential in generating the health effect estimates in individual studies. Less ideal, but still useful, would be information on the distribution of concentrations experienced by participants in the studies. For time-series studies, because of the similar number of events (e.g., deaths) per day, this is likely to be the same as the PM concentration distribution; the situation is more complex for cohort studies in which exposures of individuals change over time. Least preferable is using PM concentration distribution metrics, such as those used by EPA Staff in arriving at a range of levels for consideration. An attempt should be made, to the extent possible, to integrate this latter approach with aspects of the first two approaches, realizing that the reported study findings and data needed to accomplish this goal may not be readily available, and that interactions with investigators may be needed.

      ii. **Different statistical metrics that characterize air quality distributions from multi-city epidemiological studies?**

The *Second Draft Policy Assessment* provides two alternatives, referred to as the composite monitor and the maximum monitor. On the top of page 2-61, the text appears to be stating that, for the same air quality domain, the composite monitor concentrations are less than those based on the maximum monitor approach, and an argument is made that an approach based on composite monitors has a "margin of safety" compared to the maximum monitor perspective. However, a judgment is made that data should be selected from the epidemiological studies for which the C-R relationships are "strongest," and that concentrations not more than one standard deviation below the long-term mean concentration should be used. The judgment, while not unreasonable, is not explained.

It is not clear why the lower bound to be considered is a range from the 10th to 25th percentiles, as opposed to, say, the 10th percentile alone. In Figure 2-7, for long-term exposure studies, in the upper panel, the 10th percentile annual mean concentrations range from approximately 9 to 11 $\mu g/m^3$. The population-weighted values are 10 to 13 $\mu g/m^3$. In both cases, the upper bounds of these ranges are for the high site, and the lower bounds are for the composite monitor.

In summary, this section of the report lacks clarity and focus on the key consideration of identifying ambient concentrations at which adverse effects are observed, in anticipation of supporting a range of concentrations that take into account the statutory mandate to provide an adequate margin of safety.

b. Potential alternative annual standard levels based on composite monitor distributions versus maximum monitor distributions?

The composite monitor approach is preferable because of its stability, and for the additional margin of safety it provides. The NAAQS should provide health protection for both long-term and short-term health effects. It is not clear, for example, as to why the 24-hour level should be at least 2.5 times higher than the annual standard. Such a statement seems to be independent of consideration of health effects. A statement is made on page 2-73, lines 26-27 that "based on this consideration" consideration should be given to retaining the 35 $\mu g/m^3$ 24-hr level in conjunction with annual standards of 13 to 11 $\mu g/m^3$. Setting aside the math problem here (e.g., 11*2.5 = 27.5, not 35), the rationale for the 2.5 times factor appears arbitrary and not based on health considerations.

c. Use of risk information in informing staff conclusions on alternative annual and 24-hour standard levels, including approaches used to assess overall confidence and potential bias in the risk estimates?

The risk information provides valuable insights, and should be used in drawing conclusions. However, there is not symmetry between the evidence-based section and the risk-based section. . The "evidence-based" section reaches the conclusion that alternative levels to be considered should be 11 to 13 $\mu g/m^3$ for the annual standard and 35 ug/m^3 for the 24-hour standard, and also a combination of 11/30 $\mu g/m^3$ for the annual/24-hour levels. However, the risk-based analysis does not systematically evaluate these combinations, omitting the 11/35 $\mu g/m^3$ and 11/30 $\mu g/m^3$ combinations. Furthermore, the text implies that a 10/35 ug/m^3 case was analyzed, but no results were reported. This difference between the ranges from the two sections reflects in part the scenarios considered in the risk assessment. While the Administrator's consideration should not be limited to those combinations that were analyzed quantitatively, the final policy assessment should be systematic and emphatic about providing conclusions regarding combinations of annual and daily levels that were not analyzed quantitatively but that are recommended for consideration.

The results of the risk assessments are presented mainly in terms of percentage risk reduction compared to the current standard, in Figures 2-11 and 2-12 for long-term and short-term effects, respectively. While this is useful information, it is not directly relevant to the setting of a NAAQS, given the goal of a NAAQS--to protect public health with an adequate margin of safety. Additionally, the information on risk reduction might be better presented as the absolute numbers of deaths avoided rather than the percentage reduction under the various scenarios. The text should be rewritten to better reflect the utility and relevance of the information on reduction of disease burden for determining the NAAQS.

This section should not only focus on the best estimate of risk, but the confidence intervals and non-quantified sources of bias, such as the role of socio-economic status (SES). See also Page 2-35, lines 10-12, which indicates that sensitivity analysis of model specification used in the risk assessment produce risk estimates that are a factor of 2 to 3 higher than the core risk estimates.

d. Staff's conclusion that alternative annual standard levels in the range of 13 to 11 $\mu g/m^3$ are most strongly supported by the available evidence and risk-based information?

The rationale for the conclusion was well developed, but could use further justification, particularly in regard to the pairing of the 24-hour and annual standards. The risk assessment did not explore all the combinations considered in the *Policy Assessment*. While CASAC agrees with the range of 13 to 11 ug/m^3, it finds less justification for the pairings proposed.

e. Staff's approach of focusing on peak-to-mean ratios to inform the level of a 24-hour standard that would provide supplemental protection to a generally controlling annual standard?

The peak-to-mean ratio merits consideration in providing insight as to whether the annual or 24-hour standard would be controlling in a particular area. It is not relevant to informing the actual level to be selected for the 24-hour standard.

f. Staff's conclusion that consideration should be given to retaining the current 24-hour standard level of 35 $\mu g/m^3$ in conjunction with annual standard levels in the range of 13 to 11 $\mu g/m^3$, and that consideration could also be given to an alternative 24-hour standard level of 30 $\mu g/m^3$ particularly in conjunction with an annual standard level of 11 $\mu g/m^3$?

The conclusions are reasonable in relation to the criteria established by the Clean Air Act (CAA), and those developed by the OAQPS Staff that have been endorsed by CASAC. The choices within these options will need to be based on the Administrator's interpretation of the CAA's requirement for an adequate margin-of-safety. In other words, in the absence of thresholds in the dose-response relationships for the health outcomes of concern, how much public health impact resulting from exposure to ambient air $PM_{2.5}$ is acceptable under the CAA.

The least protective option (35-13 $\mu g/m^3$) would provide significant additional public health benefits in most of the U.S., in comparison to the current limits (35-15 $\mu g/m^3$). The most protective option (30-11 $\mu g/m^3$) would provide significant additional public health benefits to a larger part of the U.S. population in comparison to the current limits (35-15 $\mu g/m^3$) and any of the intermediate options, but would not prevent at least some adverse health effects among the most susceptible segments of the population, given our current understanding of dose-response relationships.

4. **Key Uncertainties and Areas for Future Research and Data Collection (Section 2.5): What are CASAC's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?**

The key uncertainties and areas for future research and data collection are well summarized in Section 2.5. The acknowledgement (at the top of page 2-87) that "Much of this research may depend on the availability of increased monitoring data" is apt and appreciated. The opportunities for epidemiological research to effectively address the knowledge gaps on the effects, and concentration-response relationships, of PM components and source-related mixtures cannot be achieved without additional monitoring data to provide PM speciation and better temporal and spatial resolution. Only the EPA can provide the impetus and support for such an enhancement in air quality monitoring.

The research needs to address uncertainties in health outcomes, exposure durations of concern, and susceptible populations that are also very nicely outlined are well targeted, and can be effectively studied in human populations. Such studies, to be most productive, will need the enhanced monitoring data, as recognized by EPA staff.

This section, as written, has more to do with future research priorities than with uncertainties that influence impending decisions on revisions to the $PM_{2.5}$ NAAQS. The section outlines a very broad and ambitious research agenda. It would help to begin this section with a prioritized review of key uncertainties in order to help establish priorities among the suggested research topics. Obviously the key uncertainty is the range of concentrations that are causing the observed health effects in the epidemiological studies, and the degree of certainty in effects at the lower concentrations along the C-R relationship. This uncertainty has necessitated using the distributional measures of concentrations from the epidemiology studies in attempting to make the link between the epidemiological findings and consideration of alternative concentrations for the PM NAAQS. While this uncertainty is reflected in two (p.2-88 and 2-90) of the many recommendations for future research that C-R functions include confidence bounds, this uncertainty should be highlighted. We urge careful attention to priorities in relation to future revisions of the PM NAAQS, rather than a lengthy list of research topics.

CASAC finds the list to be appropriate, but also suggests consideration of the following:

- Generating time-activity data to support probabilistic scenario-based exposure models, such as additional activity diary data to incorporate into the Consolidated Human Activity Database (CHAD).
- Characterizing indoor exposures to PM of ambient origin. For example, the penetration of ambient $PM_{2.5}$ and PM_{10} into indoor microenvironments (home, work, school, restaurant, bar, vehicle) should be better characterized, particularly taking into account differences in penetration with respect to particle size and composition. Given the greater amount of time we spend in indoor vs. outdoor environments, the need for these data is compelling.

- Addressing the bidirectional linkages between climate change and concentration, size distribution and composition of PM in the PM_{10}, $PM_{2.5}$, and ultrafine particle (UFP) fractions. This would include assessing the relative effects of climate cooling due to aerosols (e.g., sulfate) vs. climate warming due to elemental carbon. Effects of increased wildfires, windblown dust and pollen seasonality are also of interest.
- Continuing support of toxicological research in terms of chemical components, sources and subfractions (to include UFP). Toxicological studies will address biological plausibility and give insights as to possible mechanisms. Although C-R relationships are a challenge to extrapolate from animal to human, animal studies do provide an effective means to conduct controlled and well-characterized exposure scenarios to examine C-R relationships.

Primary Standard for Coarse Particles

5. Current Approach (sections 3.1.4, 3.2, 3.3):

a. What are CASAC's views on the approach to translating the available evidence and air quality information into the basis for reviewing the coarse particle standard?

CASAC finds the second draft superior to the first draft reviewed earlier; it demonstrates considerable progress and responsiveness to CASAC's suggestions. The document is grounded on explicit data and clearly stated arguments. EPA staff has done its best to take the available evidence relating to exposure and health effects and to use them as the basis for reviewing the coarse particle standard.

There are inherent deficiencies which persist because of lack of data. Concentrations of the coarse particle fraction--particles between 2.5 and 10 microns—are usually estimated by subtraction and not measured directly. Moreover, given the limited data on coarse particles, much of the evidence on health effects comes from interpreting studies using PM_{10} and assessing the extent to which the health effects observed relate to the entire size range collected [including $PM_{2.5}$] or to only the coarse particle fraction.

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standard (section 3.2) and potential alternative standards (section 3.3)?

CASAC responds affirmatively to this question. The staff have noted the limitations of the data and used them in light of these limitations to address the question of whether current standards are adequate. CASAC also finds that staff has adequately discussed alternative standards and the consequences of applying them.

In toto, Chapter 3 reads well and is much improved. EPA staff has done its best to describe an evidence-based approach for applying the limited amount of health effects evidence and air quality information in different US regions as a basis for reviewing the adequacy of the current coarse particle standard.

6. **Adequacy of the Current PM_{10} Standard (section 3.2): What are CASAC's views on the alternative approaches presented for considering the evidence and its uncertainties as they relate to the adequacy of the current standard?**

The general consensus of CASAC is that consideration should be given to revising the current 24-hour PM_{10} standard. The rationale for this recommendation emerges from the judgment that the current data, while limited, is sufficient to call into question the level of protection afforded the American people by the current standard. The opinion hinges on the strength of associations in multi-city studies and positive trends in single city studies linking PM_{10} exposure and health endpoints, and moreover that these health effects can occur below the current standard. This approach gives significant weight to studies that have generally reported that $PM_{10-2.5}$ effect estimates remain positive when evaluated in co-pollutant models. Likewise controlled human exposure $PM_{10-2.5}$ studies showing decreases in heart rate variability and increases in markers of pulmonary inflammation are deemed adequate to support the plausibility of the associations reported in epidemiologic studies.

7. **Indicator (Section 3.3.1): What are CASAC's views on the approach taken to considering standard indicator and on staff's conclusion that PM_{10} remains an appropriate indicator in this review?**

The majority of CASAC determined that there was insufficient evidence currently available to support a change in the indicator from PM_{10} to $PM_{10-2.5}$. However, CASAC vigorously recommends the implementation of plans for the deployment of a network of $PM_{10-2.5}$ sampling systems so that future epidemiological studies will be able to more thoroughly explore the use of $PM_{10-2.5}$ as a more appropriate indicator for thoracic coarse particles.

If a PM_{10} indicator is retained, the Agency should consider limiting the Federal Reference Method to include only low volume PM_{10} samplers, as high volume PM_{10} samplers do not produce comparable results.

8. **Form (Section 3.3.3): What are CASAC's views on the approach taken to considering the form of the standard and on staff's conclusion that revising the form to a 98^{th} percentile form would be appropriate for a 24-hour PM_{10} standard meant to protect against exposures to thoracic coarse particles?**

CASAC felt strongly that it is appropriate to change the statistical form of the PM_{10} standard to a 98^{th} percentile form. Published work has shown that the percentile form has greater power to identify non-attainment and a smaller probability of misclassification relative to the expected exceedance form of the standard. This change in form will lead to changes in levels of stringency across the country, a topic needing further exploration.

9. **Level (Section 3.3.4): What are CASAC's views on the following:**
    a. **The approach taken by staff to identify potential alternative PM_{10} standard levels, in conjunction with a 98^{th} percentile form, including the weight placed on different studies?**

b. **Staff's conclusion that the evidence most strongly supports standard levels around 85 µg/m³?**
c. **The alternative approach to considering the evidence that could support standard levels as low as 65 µg/m³?**

CASAC concurs that the approach in identifying potential alternative PM_{10} standard levels are appropriate, with the discussion regarding the weight placed on different studies clearly and cogently presented. CASAC also considered that the proposed alternative standard levels of 85 and 65 ug/m³ (based on consideration of 98th percentile PM_{10} concentration) could be justified.

CASAC, however, does not agree that scientific evidence most strongly supports an upper bound standard level of 85 µg/m³. As stated in the *Second Draft Policy Assessment*, scientific evidence supports the adoption of a standard at least as stringent as the current standard of 150 µg/m³ based on one expected exceedance. Table A3 suggests that a 98th percentile level of 85µg/m³ is less stringent as compared to the current standard, protecting a smaller fraction of the population. Results instead point to a 98th percentile level between 75 and 80 µg/m³ as comparable to the current standard. CASAC further notes that setting new 24-hour PM_{10} standard levels should also consider the impact of corresponding changes in $PM_{2.5}$ standards, which will likely result in lower 24-hour $PM_{2.5}$ concentrations and lower measured PM_{10} values. Thus, proportionately more coarse particle mass could be airborne at the standard level. Absent corresponding reduction in the PM_{10} standard, these lower $PM_{2.5}$ concentrations would lessen the level of protection provided by the PM_{10} standard for exposure to $PM_{10-2.5}$

The *Second Draft Policy Assessment* does not adequately convey the possible rationale for selecting the lower end of the proposed range of levels. Therefore, the considerations that might lead to selecting a PM_{10} standard level more stringent than afforded by the current standard should be more clearly elaborated. These considerations focus on margin of safety, particularly as it relates to the impact and weight given to suggestive findings of causality, to findings of positive but statistically insignificant results, and to exposure measurement error and other sources of uncertainty.

10. Key Uncertainties and Areas for Future Research and Data Collection (Section 3.5): What are CASAC's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

See comments on Chapter 2.

The key distinction for this chapter is the need to seriously focus on $PM_{10-2.5}$ for both mass and composition. CASAC looks forward to the planned implementation of monitors that measure $PM_{10-2.5}$, rather than PM_{10}. There is a critical need for national monitoring data on $PM_{10-2.5}$ in order to provide a basis for epidemiological studies that focus on this size fraction. Furthermore, there is a need for speciated data to support health effects research. Spatial and temporal variability in coarse particle mass and composition need to be characterized. In addition, the national monitoring data will support a baseline for ambient air quality in order to compare with health effects data in order to assess whether there is a need for a more stringent standard.

The research areas described in the draft Section 3.5 are reasonable, but there needs to be strong emphasis on the critical need for coarse PM data, in order that the NAAQS can move beyond PM_{10} as an indicator for thoracic coarse PM in a future NAAQS revision.

Another question to be considered is regarding what size cut-points are most appropriate, and also regarding what specific components are of most interest or concern with respect to health effects.

There is a need for continuous monitoring of coarse PM (and of $PM_{2.5}$) in order to support health effects studies and to be able to assess alternative forms of possible future standards.

Other challenges for future research: (a) it may be difficult to get useful data from rodent inhalation studies since they can breathe particles only up to about 2 to 3 microns into their lung airways; (b) getting good chemical characterization of the particles will be a problem, since there are primary biological materials of potential interest in the thoracic coarse size range.

Prioritization of the research topics is needed, such as via a separate meeting or workshop.

Secondary Standard for PM-related Visibility

11. Current Approach (Section 4.1.3):

a. **What are CASAC's views regarding our approach for translating technical evidence and assessment results into the basis for assessing current fine particle standards and considering alternative standards to provide protection against PM-related visibility impairment?**

The translation of technical evidence and assessment results as a basis for reviewing and revising the current secondary fine particle standard is logically conceived, clearly presented, and responsive to previous CASAC recommendations. The combined evidence-based and impact-based assessments effectively contrast and integrate the various combinations of metrics for protecting urban visibility. While this approach is inherently complex, it is clearly explained in the text and concisely summarized in Figure 4-1. The various tables and graphics in Chapter 4 and its associated appendices are helpful in communicating the inherent complexity that results from the evaluation of so many possible combinations of indicators, averaging times, levels and forms.

b. **Has staff appropriately applied this approach in reviewing the adequacy of the current standard (Section 4.2) and potential alternative standards (Section 4.3)?**

The detailed estimates of hourly PM light extinction under current conditions and for "what if" scenarios of just meeting current standards clearly indicate that the current $PM_{2.5}$ standards do not protect against levels of visual air quality which have been judged to be unacceptable in all of the available urban visibility preference studies. The levels are too high, the averaging times are too long, and the $PM_{2.5}$ mass indicator could be improved to correspond more closely to the light scattering and absorption properties of suspended particles in the ambient air.

While not discussed in detail in the *Second Draft Policy Assessment*, direct measurements of light extinction are the preferable indicator for an alternate standard to make an accurate assessment of the PM effect on urban visibility. These measurements would provide timely and easy-to-understand results to address the protection of the public welfare from PM impacts, but without a Federal Reference Method (FRM) adopted or in the development process – these data are not currently available for most urban areas. Additional discussion of the timeline and process anticipated by EPA to advance direct measurement of light extinction monitoring methods to FRM status would be helpful.

Given this limitation, the detailed estimates of PM light extinction employed for 15 urban areas in the UFVA, and used to evaluate alternative new indicators including hourly $PM_{2.5}$ mass and "speciated $PM_{2.5}$ mass-calculated light extinction" in the *Second Draft Policy Assessment* are appropriate for the initial promulgation and first generation of regulatory air quality analysis and planning; similar to the process for the Regional Haze Rule. The speciated $PM_{2.5}$ mass-calculated light extinction indicator produces hourly extinction values quite similar to those resulting from more complex calculations, and it could be an appropriate indicator for a revised secondary standard, if employed on an interim basis until methods for direct light extinction measurements can be developed and deployed.

While the stated intent of the *Second Draft Policy Assessment* is "to provide as broad an array of options as is supportable by the available information", the CASAC recommends providing additional and more focused discussion of the policy implications that may be associated with selecting and implementing specific combinations of indicators, levels and forms from within this broad array of options. Some discussion should also be provided to indicate that reductions in light scattering aerosols could decrease light extinction but increase radiative forcing, while reductions in light absorbing aerosols would decrease both light extinction and radiative forcing. The contributions of anthropogenic controllable "Short-Lived-Climate-Forcers" that contribute significantly to urban visibility impairment would also be worthy of some attention in the analysis of policy implications.

12. Nature of the Indicator (Section 4.3. 1): What are CASAC's views on the following:

- **a. Staff's consideration of the three indicators identified in this section and our conclusions on the appropriateness of these indicators for consideration in this review?**
- **b. The development and evaluation of a new approach that is based on using speciated $PM_{2.5}$ mass and relative humidity to calculate $PM_{2.5}$ light extinction by means of the IMPROVE algorithm?**
- **c. The assessment approach and results comparing the PM components that contribute to the hours selected in the top percentiles for $PM_{2.5}$ mass and PM_{10} light extinction?**

As noted in past comments, CASAC strongly prefers directly measuring light extinction to using estimates based on mass measurements (e.g., the other options provided in the *Second Draft Policy Assessment*). In their recent review, the Ambient Air Monitoring and Methods Subcommittee (AAMMS) noted that there are commercial instruments available that provide light extinction measurements directly, and promising additional technologies may soon become available. The AAMMS also encouraged the EPA to begin the process of developing performance standards for PM light extinction measurements. However, a FRM for light extinction measurement does not yet exist, and as EPA does not view it as practical to develop an FRM in time for this rule making, CASAC recognizes that alternative approaches need to be considered.

A current weakness of the *Second Draft Policy Assessment* is that it does not explicitly state the reasons that EPA does not currently recommend using a direct measurement of light extinction. It also does not provide any indication that the proposed mass-based indicators are intended for use on an interim basis, to be replaced with direct light extinction-based measurements as those methods are developed, tested and deployed. If staff consider it impractical to develop performance standards for an FRM in time for this round of rule making, this should be clearly stated and a schedule for developing such performance standards and evaluating candidate instruments should be specified well in advance of the next PM NAAQS review.

Assuming it is currently impractical to develop a FRM for direct measurements of PM light extinction in a sufficiently timely manner, CASAC agrees that for this rule making, a method to estimate extinction based on measurements from continuous $PM_{2.5}$ monitors, preferably adjusted by $PM_{2.5}$ speciation and relative humidity (RH) data, is appropriate. The "speciated $PM_{2.5}$ mass-calculated light extinction" method described in the *Second Draft Policy Assessment* appears to be a reasonable approach for estimating hourly light extinction. For purposes of "near real time" visibility tracking, CASAC recommends considering a simpler calculation in which historical, rather than concurrent, monthly or seasonal speciation averages would be used to estimate speciation for combining with real-time continuous $PM_{2.5}$ and RH data, even though the most recent speciation data would be used for developing plans for improving visibility. CASAC also recommends that the Agency consider developing the monthly or seasonal speciation estimates on a regional basis as well as on a site-specific basis, as this would allow light extinction estimates at all (>700) sites with continuous $PM_{2.5}$ data, rather than just the relatively few sites with collocated continuous $PM_{2.5}$ and speciation monitors.

13. Alternative Levels and Forms (Section 4.3.3): What are Panel views on the following:

- **a. The performance assessment which focused on the Candidate Protection Levels of 64, 112, 191 Mm^{-1} for $PM_{2.5}$ light extinction and speciated $PM_{2.5}$ mass-calculated light extinction, and alternative levels of 10, 20, and 30 $\mu g/m^3$ for $PM_{2.5}$ mass concentration?**

These are appropriate CPL and $PM_{2.5}$ levels. The CPL values were based on all visibility preference data that are available and bound the study results as represented by the 50% acceptability criteria. However, the presentation could be improved by expanding some of the tables to include 10 and 40 dv values, in that at 10 dv, no viewer found the scene to be unacceptable, and at 40 dv, virtually all viewers found all scenes to be unacceptable. What would these dv levels correspond to in the context of $PM_{2.5}$ and the various percentile levels?

- **b. Use of three-year averaged 90^{th} and 95^{th} percentiles in conjunction with a 1-hour daily maximum form and use of three-year averaged 98^{th} percentile in conjunction with the all daylight hours form?**

While these levels may be appropriate, they are not well justified. A cursory argument was made that the $90–95^{th}$ percentiles in conjunction with the 1-hour daily maximum identified similar days and hours of non-compliance, as did the 98^{th} percentile in conjunction with all daylight hours, and this correspondence was a sufficient basis to pick these two approaches. It would be informative to compare all, or at that least the same, percentiles for both all days and the daily hourly daily maximum. These analyses should be informative as to whether one approach is preferred. Whether different sources might be identified, depending on use of daily average or maximum values has not been adequately addressed. For example, a significantly extended episode of low visibility might be attributed to a single source, such as a large wildfire or prescribed fire, which would result in the all hour, all day approach targeting only one large emission episode that occurred for only one or a few time periods. For wintertime episodes in many cities of multi-day poor urban visibility conditions, the events can cross the end of the calendar year, tracking the highest daily hour for each day to form a full 3-year distribution of values (i.e., N = ~1,095) for which the compliance value is then compared to the percentile level selected by EPA.

c. Insights to be drawn by comparing the PM components for hours included among the 10% highest for a 1-hour daily maximum form with the hours included among the 2% highest for an all daylight hours form, for the various indicators considered (Appendix C)?

See comments above. These two approaches appear to be similar; however, it would be helpful to quantify the similarities as opposed to relying only on a qualitative discussion. A scatter plot might be useful for the 14 sites that provides the average fractional contribution of a species in relation to the time metric used. Additionally, comparisons should be shown for the specific days found in non-compliance by metric.

14. Key Uncertainties and Areas for Future Research and Data Collection (Section 4.5): What are CASAC's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

The major areas of research and data collection needed to address key uncertainties related to a visibility-based secondary standard are nicely captured in Section 4.5 of the *Second Draft Policy Assessment*. The section appropriately identifies two major areas of need, one related to visibility preference, and one related to methods of measurement.

In the first category, preference studies, the details noted by EPA all identify a strong need for additional urban visibility preference studies conducted using consistent methodology. The range of 50% acceptability values discussed as possible standards are based on just four studies (Figure 4-2), which, given the large spread in values, provide only limited confidence that the benchmark candidate protection levels cover the appropriate range of preference values. Studies using a range of urban scenes (including, but not limited to, iconic scenes – "valued scenic elements" such as those in the Washington DC study), should also be considered.

In the second category related to methods of measurement, CASAC supports the proposal to conduct studies in several cities, pairing direct monitoring of light extinction with enhanced monitoring of PM size and composition distributions (i.e., continuous PM speciation monitoring). Additional work should also be conducted to understand the contribution of $PM_{10-2.5}$ in southwestern areas other than Phoenix, to address the lack of information for scattering associated with this fraction of PM_{10} as is noted on page 4-30.

Underlying this overall discussion is a clear need for better particle size – composition distribution information (i.e., particle composition distributions as a function of particle size). These data gaps are addressed in different ways in the discussion of future research needs elsewhere in the Second Draft Policy Assessment (Sections 2.5 and 3.5). Moreover, the development of continuous monitoring methods for specific PM components addressed in Section 2.5 is equally applicable here. Improved understanding of size-dependent PM composition would also help address the questions related to the role of scattering and absorbing aerosols in climate forcing that are raised in Section 5.2.4.

Finally, a number of research and data collection topics overlap between the secondary PM NAAQS, and the $PM_{2.5}$ and PM_{10} primary PM NAAQS. For example, the fraction of combustion-related primary carbon PM species can be an important indicator of harmful health effects, visibility impairment and climate forcing.

With these characteristics, research to jointly quantify and reduce these primary PM carbon species from combustion sources would advance the information available to the Administrator for her judgment about the necessary level of protection to be provided by the future PM NAAQS, to be assessed in the next review cycle.

CASAC suggests that EPA look for additional opportunities to align health and welfare improvement strategies simultaneously for common indicators, such that the next reviews of the PM and other NAAQS have not only the analyses of the effects of PM and other NAAQS indicators on health and welfare, but also include metrics useful for measuring progress toward attainment.

Appendix A: Compendium of Individual Comments
CASAC Particulate Matter Review Panel on
Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards (Second External Review Draft, June 2010)

Dr. Lowell Ashbaugh

These comments are directed toward Chapters Four and Five of the Policy Assessment. I was very pleased with this draft. EPA staff has done an excellent job of responding to CASAC comments and has produced a very readable and informative document. I have a few minor editorial comments that I will enumerate below, but first I have a few more general comments.

On pages 4-32/4-33 an unstated advantage of direct measurement of light extinction is the immediate response obtained. In contrast the process of collecting filters, analyzing them, and performing the data validation necessary to calculate reconstructed light extinction takes a significant amount of time. Direct measurement of light extinction could provide immediate feedback to planning agencies and could be used for alerts and behavior modification, if necessary. Furthermore, the increased analytical sensitivity achieved by sampling for longer periods makes speciated $PM_{2.5}$ calculated light extinction better for longer term averaging than for short term applications. This concept is particularly important in the ten-step simplified approach outlined on pages 4-34/4-35. The inherent uncertainties in the speciated measurements used in this method might be significantly enhanced with this method. It would be important to perform a critical analysis of these uncertainties prior to using it.

The findings of the WACAP study described briefly on page 5-21 are important in identifying that the source of airborne contaminants is nearby emissions and not those transported from Eastern Europe or Asia. This should be highlighted to avoid using scarce resources on projects that assume long-range transport is more important.

Page	Line	Comment
4-31	20	Change “wide spread” to “widespread”
4-36	15	insert “of” between “because” and “the differing”
4-38	25	add a space between “$PM_{2.5}$” and “mass”
4-39	9	remove the comma after “document”
4-40	9	add a space between “daylight” and “1-hour”
4-46	6	should this be “4 of the 14…”?
5-2	17	remove the comma after “1997”
5-5	3	remove the comma
5-9	7	change “effects” to “affects”
5-9	8	remove the comma after “thus”
5-9	33	change “are” to “is”
5-13	1	change “are” to “is”
5-13	14	add “comes” at the beginning of the line
5-16	3-4	move “to” inside the numbered items (i.e. “are (1) to identify…and (2) to qualitatively

Charge questions

Chapter 4 (Secondary Standard for PM-related Visibility)

11. Current Approach (section 4.1.3):

a. What are the Panel's views regarding our approach for translating technical evidence and assessment results into the basis for assessing current fine particle standards and considering alternative standards to provide protection against PM-related visibility impairment?

The approach is sound – it follows a logical step-by-step process and is explained very well. Figure 4-1 provides an excellent road map of the approach.

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standard (section 4.2) and potential alternative standards (section 4.3)?

Yes, the approach is applied well. Staff has taken a complex process and simplified in very well into a readable document. I made a few comments above on section 4.3 regarding the advantages of direct light extinction measurement for fast response, and the suitability of speciated $PM_{2.5}$ calculated light extinction for longer term averages. In particular, the ten-step simplified approach for calculating hourly extinction is subject to high uncertainties that should be analyzed prior to attempting to implement it.

12. Nature of the Indicator (section 4.3. 1): What are the Panel's views on the following:

a. Staff's consideration of the three indicators identified in this section and our conclusions on the appropriateness of these indicators for consideration in this review?

Staff has provided an excellent discussion of the merits of the three indicators. I would only add that the direct light extinction measurement can be accomplished immediately and could provide important feedback for encouraging behavior and emission adjustments that could curtail widespread air pollution events as they unfold.

b. The development and evaluation of a new approach that is based on using speciated PM2.5 mass and relative humidity to calculate PM2.5 light extinction by means of the IMPROVE algorithm?

This approach is good when applied to longer term averages, but I have reservations about its use for short term (hourly) applications. The inherent uncertainties in the measurements may be magnified significantly in the short term. This needs to be carefully evaluated prior to using it.

c. The assessment approach and results comparing the PM components that contribute to the hours selected in the top percentiles for PM2.5 mass and PM10 light extinction?

This approach and assessment are well thought out and are presented well.

13. Alternative Levels and Forms (section 4.3.3): What are Panel views on the following:

a. The performance assessment which focused on the Candidate Protection Levels of 64, 112, 191 Mm^{-1} for PM2.5 light extinction and speciated PM2.5 mass-calculated light extinction, and alternative levels of 10, 20, and 30 $\mu g/m^3$ for PM2.5 mass concentration?

The logic behind this selection of Candidate Protection Levels is explained well; staff has done a commendable job of explaining the performance of the Alternative Standards. Table 4-5 is a clear representation of how the CPLs would perform in the 14 urban areas examined.

b. Use of three-year averaged 90th and 95th percentiles in conjunction with a 1-hour daily maximum form and use of three-year averaged 98th percentile in conjunction with the all daylight hours form?

The use of these percentiles and forms is explained well. Staff has done an excellent job of describing the steps used to get to this selection.

c. Insights to be drawn by comparing the PM components for hours included among the 10% highest for a 1-hour daily maximum form with the hours included among the 2% highest for an all daylight hours form, for the various indicators considered (Appendix C)?

This display of results is very informative. My primary complaint is that the labels on the graphs are difficult to read because of the formatting necessary to fit them all on the page. The staff discussion explains the plots well; I had no problem following it.

14. Key Uncertainties and Areas for Future Research and Data Collection (section 4.5):

What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

Staff responded very well to the panel's request for a section on future research needs. I am especially pleased to see a discussion of the need for additional visibility preference studies to assess (or try to reduce) the differences in response between people in different urban areas. The call for a pilot light extinction monitoring program is also highly important.

Mr. Ed Avol

General Comments

The second draft of the Policy Assessment for PM is a marked improvement over the earlier version. The discussions contained within are more focused, more targeted, and by virtue of the presentation, more convincing. Staff has generally been very responsive to comments provided on the first draft Policy Assessment.

In the course of presentation, there is repeated reference to “currently available scientific and technical information” as the basis for making informed judgments. This is entirely appropriate, but if there is not an assessment of missing gaps and data needs desired for the next review cycle (along with a subsequent commitment to devoting resources and energy to closing those gaps), progress will be slow in achieving the necessary or desired threshold of sufficient information on which to make additional informed and improved judgments. That is why Sections 2.5 and 3.5 (“Key Uncertainties and Areas for Future Research and Data Collection”) are such welcome and thoughtful additions, for which staff should be duly commended. This is a key element of encouraging substantive improvements in future review cycles, and should be a part of every subsequent pollutant review.

That is not to say that the current draft could not still be improved. There are still occasions in the text where there is a tendency to lapse into presentation of data, rather than referral to data presented in the ISA or RA documents. There are several sentences, paragraphs, and sections that meander a bit, and could be tightened up. The overall document could still be edited and reduced in length. That said, however, the formulation, approach, and presentations have significantly and positively evolved, and this general approach should be conceptually preserved for future policy assessments for other pollutants.

Specific Comments

P1-12, lines 6-9 – The statement (and/or the thinking behind the statement) is not well-expressed here. I would propose that the purpose for reviewing the emerging evidence on ultrafine particles is not to regulate PM2.5 “…or categories of fine particle sources…”, but rather to identify whether there is a basis for promulgating a health-protective standard for ultra-fine particles, which have a different constellation of sources, control strategies, exposure pathways, and health outcomes than PM2.5.

Pg 2-50, line32-34 – This question and answer seems like a circular argument. The fact that most studies utilize the annual and 24hr averaging times as the metric of analysis should not be seen as justification for having them. Rather, they are a reflection of the fact that they are the de facto “standard” metrics or “currency of the realm”.

Pg 2-52, line1-3 – This apparent inconsistency raises a possible question as to whether there is a lag effect of PM, with exposure leading to hospitalization in the winter, increased fragility or susceptibility, and increased risk of death several months later in the warm season, when PM is nearly as elevated.

Pg2-86, lines 19-21 – If this is not the appropriate forum for discussion (and it arguably is not), then what is the appropriate forum to discuss/present the research recommendations needed to meet standards implementation and strategy development? This would seem to be a valuable discussion that should be held. Moreover, it should be tied closely to the review cycle of pollutants, in order to motivate continuing improvements in regulation and public health protection.

Pg 3-8, Figure 3-1 – This figure seems incomplete, with the several boxes at the bottom missing. Shouldn't there be pathways and boxes for alternative and retained indicator, averaging time, form, and level options, respectively (so two possibilities for each element of the standard), and shouldn't that lead to a retention of or alternatives to the current standard? The flow chart for review of the PM2.5 standard (Figure 2-1, Pg 2-12) is depicted in a similar but slightly different from, but shouldn't these two figures be conceptually identical?

Minor Comments (typos, etc)

The inherent writing style involves systematic (and arguably excessive) use of compound, complex, and sometime convoluted sentences throughout the document. Sentences fewer than three or more lines are rare. This often makes it difficult for readers to follow and understand the discussion. Multiple ideas are often conveyed within one meandering statement. Improved efforts should be made to be clear, concise, and brief.

Pg ix, definition of FEV1 – this is not the change in FEV1 (which would be "delta' FEV1), but rather the volume of air exhaled in the first second of exhalation.

Pg xi, definition of PMx – 7th line should read "…diameter are collected with an efficiency that decreases…"

Pg 1-10, line 26 – replace "…we considered…" with "staff considered…"

Pg 1-11, line 6 – replace "…we revised…" with "…staff revised…"

Pg 1-11, lines 14-15 – were there really two second drafts of the REA? Don't you mean two drafts of the REA?

Pg 2-3, lines 1-5 – Something is grammatically awkward or incorrect here. I suggest re-wording to read: "This conclusion was based on a key observation: most of the aggregated annual risk …"

Pg 1-11, line 21 – replace "…we will…" to "…staff will…".

Pg 1-11, line 25 – replace "We plan to release the final…" with "Plans call for release of the final…"

Pg 2-3, line 2 – insert comma after "…risk assessment…"

Pg 2-7 lines 23,27,34,… - This document begins in the third person ("staff' determines or "staff' found this or that…), then gradually switches over to the first person (Our, we, …). My personal opinion is that the third person is more appropriate, but consistency of presentation is another issue.

Pg 2-16, line 34 – Here, CVD is defined as cerebrovascular disease, but in the List of Acronyms at the start of the document, CVD is listed as cardiovascular disease.

Pg 2-22, line 29 – Delete "These studies also…", or complete the thought.

Pg. 2-45, line 14 – Based on current understanding (and the referenced text in the ISA), it's the particle size, NOT the greater surface area, of UFPs that increases the potential to cross cell membranes and epithelial barriers. The current sentence in the text here should be changed to correct this.

Pg 2-69 footnote 52, line 4 – should read "in fact", not "if fact"

Pg 3-27, lines 1-4 – The discussion in the section refers to "Western", "East", and "Southwest", but the referred-to figure (Figure 3-4) is identified in terms of "Mediterranean", "Dry", "Dry Continental", etc. The footnote on p3-26 explaining the designations identifies the Figure groupings by yet another way - specific states (e.g., "The Mediterranean region includes CA, OR, WA.") So, there are three slightly different designations in the same discussion about overlapping (but not the same) areas (e.g., "Mediterranean" seems to include both Southwest (CA) and Northwest (OR, WA) entries). If the inclusion of specific areas varies by definition in each of these three treatments, what are we to infer from the apparent variations between regions shown in the figure?

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<u>Panel Charge Questions for the Primary Standards</u>

1. Current Approach for Fine PM – Staff has generally done an excellent job in summarizing the available evidence and reviewing the adequacy of current and potential alternative standards.
2. Form of the Annual Fine PM Standard – The issue of susceptible populations remains a challenging issue that cannot be minimized or ignored. Spatial averaging has the potential for reducing the importance of the potentially higher exposures encountered where susceptible populations may reside. Accordingly, in consideration of "allowing an adequate margin of safety", this approach should not be used.
3. Alternate Level for Fine PM – Presentation was appropriate and adequate.
4. Key Uncertainties for Fine PM – Staff should be commended for an excellent job in developing this section. A prioritized listing of needs would be a next level of improvement, but the relative and varying perception of priorities may make this a challenging undertaking.
5. Current Approach for Coarse PM – Generally well done and convincing.
6. Adequacy of the Current PM10 Standard – Reasonable and logical approach with presentation of objective criteria and evidence on which to base current determinations.
7. Indicator of Coarse PM – The presentation seemed reasonable, in view of the available evidence.

8. Form of the Coarse PM Standard – Seems reasonable.
9. Level of the Coarse PM Standard – Generally well-constructed presentation and discussion; Some questions remain as to why staff presented information in the 65-85ug/m3 range, but recommended the higher end of the range. Where and how does an "adequate margin of safety" for public health enter into this recommendation?
10. Key Uncertainties for coarse PM – Excellent compilation of research needs to be addressed in the next/current cycle of research. As in the case of PM2.5 recommendations, prioritization might be useful to apply/maximize the use of limited resources.

Dr. Joseph D. Brain

Overall Assessment

The June 2010 draft of the PA for PM demonstrates considerable progress. EPA staff took seriously CASAC's suggestions and this current version is much improved. Major concerns of CASAC have been addressed. The nature of the recommendations are clear, and the advice of EPA staff is clearly grounded on data and clearly stated arguments.

Answers to Charge Question 5: Current Approach for Coarse PM

Current Approach (sections 3.1.4, 3.2, 3.3):

a. What are the Panel's views on the approach to translating the available evidence and air quality information into the basis for reviewing the coarse particle standard?

The panel finds the second draft superior to the first draft discussed earlier. EPA staff has done its best to take the available evidence relating to exposure and health effects and to use them as the basis for reviewing the coarse particle standard. There are inherent deficiencies which persist. The coarse particle fraction--particles between 2.5 and 10□--can only be estimated by subtraction. Course particles are not measured directly. Moreover, the health effects studies suffer from an adjacent defect. We can only look at PM10 studies and try to estimate the extent to which the health effects observed relate to the entire size range collected or to only that fraction of coarse particles.

In toto, Chapter 3 reads well and is much improved. EPA staff has done its best to describe an evidence-based approach for applying the limited amount of health effects evidence and air quality information in different US regions into a basis for reviewing the adequacy of the current coarse particle standard.

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standard (section 3.2) and potential alternative standards (section 3.3)?

We believe that the answer to this question is yes. Given some deficiencies in data for both the exposure and health outcome side, the EPA staff has carefully delineated the limitations of the data available to them. They have done their best to use these data and to address the question of whether current standards are adequate. They also do an excellent job of discussing possible alternative standards and the implications of applying them.

A New Concern Not Currently Adequately Addressed:

Page 3-1. This chapter focuses on "thoracic coarse particles," which it defines as those particles with an aerodynamic mass median diameter between 10 microns and 2.5 microns. To what extent are the risks associated with particles in this size range confined to the thorax? Particularly, during quiet breathing (primarily via the nose), there will be considerable deposition of these particles in the nose. What impact do they have on nasal inflammation and injury? Do such particles interact with exposure to allergens? There is increasing evidence that some metals and even nanoparticles can be transported from the nose through epithelial and olfactory sensory neurons, through the olfactory bulb, to the brain. To what extent should we also worry about the impact of these particles on the nose and the CNS? It's a little late to bring this up, but this aspect should at least be acknowledged, if not in this document, at least in future versions. It should be on our radar screen.

Minor Comments

Page ES1, Third Paragraph, Line 11. Ordinarily, one would give the lower end of the range first. Why not change this to "11-13 µg/m3."

Page ES2, Four Lines from Bottom. There seems to be a missing verb. Shouldn't this line read "…there is sufficient information…"?

Page ix (List of Abbreviations), Line 11. Delete the words "change in."

Page 2-32, Line 14. I'm not sure what staff means by the word "peakiness." It is sometimes used in relation to waveforms, particularly in relation to speech, but I don't know what it means in this context. I'm also unclear as to what they mean in Line 15 by "rollback approach." This is the first sentence of this paragraph, and is thus an important topic sentence. It should be rewritten and clarified.

Adjacent Concerns

Discussions of the PM standard as well as this second draft of the PA raise long term generic issues. While not conveniently address is this document, I believe that CASAC should begin thinking about these issues and make suggestions to solve them. We recognize that the time for implementation may be decades. Two topics come to mind:

1. ***PM Sampling Strategy***

The panel suggests a more rational design of exposure assessment. This would involve thinking of the ideal size cuts to address size ranges of interest. What should be the cutpoints? Where and how should these devices be deployed? The goals would be a far more rational and useful design of exposure assessment, and one which would be coupled to the next generation of health outcome studies. A long term process is needed in order for the next generation of sampling devices to be developed, calibrated, and deployed.

There is also a continuing cry for a more thoughtful assessment of particle composition. There is increasing evidence that the extent of particle toxicity relates to the composition and solubility of the particles. There is also concern about the most appropriate metric. Should standards really be mass-based or should they reflect numbers or surface area of particles? The composition issue is particularly relevant to discussions of coarse particles. How do we make the distinction between those derived from fossil fuel combustion and resuspended crustal dust? There is consensus that resuspended crustal dust is less toxic than combustion products. There are clear regulatory implications as well. It's hard to regulate dust storms, but easier and more appropriate to regulate stationary and mobile sources.

2. ***Renewal of the Clean Air Act (CAA)***

Pages 1-2 and 1-3 lucidly discuss the requirements of the Clean Air Act. The first CAA was passed in 1963, and it was then amended in 1966 and 1970. The next major revision was in 1990. CASAC should contribute to the process of renewing and refining the Clean Air Act. We have discussed inherent problems. We have discussed repeatedly some of the inherent problems with the current version of the Clean Air Act. Some of the requirements simply cannot be met. Particularly for PM, we cannot protect all citizens, particularly the most vulnerable ones, and protect them with an adequate margin of safety. We need to craft language which maximizes public health but is also consistent with what we know about health outcomes and PM exposure. We have not yet identified a threshold – an assumption inherent in the current Clean Air Act.

We should also discuss whether regulating individual pollutants makes sense. To what extent should mixtures be regulated? What about new chemicals known to be toxic? These and other problems should be comprehensively addressed. Perhaps this is too big a job for CASAC, given its continuing responsibilities and the increased pace of activity in relation to criteria pollutants. But we should advocate for such a process, and suggest mechanisms to achieve it.

Dr. Wayne Cascio

General Comments:

The EPA staff has responded to the comments of CASAC and markedly improved the Policy Assessment. The text is more focused and the rationale for the conclusions reached is now better justified. The text remains long but much easier to read. There remain many typographical errors that will undoubtedly identified in proof, but I would like to point out one reference that appears to be in error. The reference Zanobetti A, Schwartz J. (2009) on 3-50 the correct citation is 117:898-903. Epub 2009 Feb 13, rather than 117:1-40, 2008.

Chapter 2 (Primary Standards for Fine Particles)

1. Current Approach (section 2.1.3):
a. What are the Panel's views on the staff's approach to translating the available epidemiological evidence, risk information, and air quality information into the basis for reaching conclusions on the adequacy of the current standards and on alternative standards for consideration?

Comment: The approach is systematic, logical and explained clearly. Figure 2-1 is very useful in conveying the details of the approach.

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standards (section 2.2) and potential alternative standards (section 2.3)?

Comment: The staff has been consistent in their application of the approach described in section 2.1.3 and illustrated in Figure 2.1.3. The EPA staff has struck a good balance between the evidence-based and risk-based considerations and associated uncertainties to determine the adequacy of the current standards.

2. Form of the Annual Standard (section 2.3.3.1):
a. What are the Panel's views on the additional analyses conducted to characterize the potential for disproportionate impacts on susceptible populations, including low income groups and minorities associated with spatial averaging allowed by the current annual standard?

Comment: Some individuals with specific medical conditions, and children represent susceptible populations whose pathophysiologic response to PM exposure is enhanced. Individuals of low social position who reside disproportionately in areas of higher exposure might also share a greater susceptibility to the impact of PM exposure. The additional analyses provided characterizing the potential for disproportionate impact on such a population allowed by spatial averaging is appropriate.

b. In light of these analyses, what are the Panel's views on staff's conclusion that the form of the annual standard should be revised to eliminate spatial averaging?

Comment: Based on the requirement to protect susceptible individuals it is appropriate to eliminate spatial averaging.

3. Alternative Levels (section 2.3.4): What are the Panel's views on the following?
a. The insights that can be gained into potential alternative standard levels by considering: i. Confidence bounds on concentration-response relationships?

Comment: Figure 2-3 is useful in conveying the confidence bounds on $PM_{2.5}$ C-R relationship. The figure would benefit from putting two panels on one page and the third panel on a second page. The size of the images and associated text are too small to easily understand the message.

ii. Different statistical metrics that characterize air quality distributions from multicity epidemiological studies?

Comment: Appropriate.

b. Potential alternative annual standard levels based on composite monitor distributions versus maximum monitor distributions?

Comment: The composite monitor distributions appear to be quite robust and stable when compared to the maximum monitor distributions, and therefore is preferred.

c. Use of risk information in informing staff conclusions on alternative annual and 24- hour standard levels, including approaches used to assess overall confidence and potential bias in the risk estimates?

Comment: The risk information particularly Figures 2-11 and 2-12 is described clearly and is utilized appropriately by the EPA staff to draw reasonable conclusions about the alternatives for the annual and 24-hour standard levels.

d. Staff's conclusion that alternative annual standard levels in the range of 13 to 11 μg/m3 are most strongly supported by the available evidence and risk-based information?

Comment: An alternative annual standard level in the range of 13 to 11 $\mu g/m^3$ is supported by the available evidence and risk assessment. While a threshold does not appear to exist at lower concentrations the uncertainties do explode and limit confidence of the magnitude of the health effect at lower concentrations.

e. Staff's approach of focusing on peak-to-mean ratios to inform the level of a 24-hour standard that would provide supplemental protection to a generally controlling annual standard?

Comment: This is a reasonable approach.

f. Staff's conclusion that consideration should be given to retaining the current 24-hour standard level of 35 μg/m3 in conjunction with annual standard levels in the range of 13 to 11

μg/m3, and that consideration could also be given to an alternative 24-hour standard level of 30 μg/m3 particularly in conjunction with an annual standard level of 11 μg/m3?

Comment: Reducing the annual standard from 15 to 13 $\mu g/m^3$ is predicted to provide a significant public health benefit. Reducing the 24-hours standard from 35 to 30 μg/m3 is also predicted to provide significant public health benefit. The 30/11 option would provide the greatest protection to the largest number of people in the U.S., yet even this option will probably not offer optimal protection the most at risk populations, e.g. those with greater susceptibility to the effects of PM.

4. Key Uncertainties and Areas for Future Research and Data Collection (section 2.5): What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

Comment: The Key uncertainties and areas for future research and data collection presented in section 2.5 are quite comprehensive and informative. Gaps in knowledge needed to eliminate uncertainties and improve risk assessment are identified in a wide range of areas including components and sources, ultrafine PM, co-pollutant exposures, exposure related factors, health effects, C-R relationships, and duration of exposure, susceptible populations, genetic and epigenetic susceptibility, and social position. Moreover to answer the numerous questions related to the various issues described above, improvements are needed in data collection and monitoring methods as described on page 2-89. To answer all of the policy related questions will require a vast amount of resources and time. For this reason the EPA, the NIEHS and other relevant federal agencies should work collaboratively to establish priorities to determine which questions would provide the most cost-effective additions to our knowledge to inform policy relevant questions and disease mechanisms needed and address this important public health issue.

Chapter 3 (Primary Standard for Coarse Particles)

General comment: In reviewing the recently up-dated Chapter 3 it is agreed that EPA staff provided significant revisions in the 2nd draft Policy Assessment to the discussions of the current and potential alternative standards. The addition of Figures 3-2 and 3-3 that summarize the epidemiological evidence and air quality data relevant to the adequacy of the current standard add considerably to understanding the rationale for EPA's conclusions.

The discussion of potential alternative standard levels reads well and staff conclusions are well justified. The discussion was improved by adding Figures 3-5 and 3-6 that summarized the epidemiological evidence and air quality data related to PM_{10} and $PM_{10-2.5}$.

5. Current Approach (sections 3.1.4, 3.2, 3.3):
a. What are the Panel's views on the approach to translating the available evidence and air quality information into the basis for reviewing the coarse particle standard?

Comment: The approach as outlined in Figure 3-1 provides a concise and logical approach to translating the available evidence and air quality information into the review of the adequacy of the current standard. The approach is logical and relies on accumulated evidence linking $PM_{10-2.5}$ to adverse health effects. However, in contrast to the abundant evidence for $PM_{2.5}$, the authors had to contend with several serious limitations. These include limited epidemiological data specifically related to $PM_{10-2.5}$ and very limited toxicological data in animal models, regional and spatial characteristics that complicate the generalization of exposures over a city or region, and a surrogate measure of $PM_{10-2.5}$, i.e. PM_{10} that contains $PM_{2.5}$. Nevertheless, the authors provide an excellent review of the evidence, and the value of that evidence in informing the risk for overall mortality and cardiovascular and respiratory effects.

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standard (section 3.2) and potential alternative standards (section 3.3)?

Comment: The EPA staff has utilized the approach described successfully.

6. Adequacy of the Current PM10 Standard (section 3.2): What are the Panel's views on the alternative approaches presented for considering the evidence and its uncertainties as they relate to the adequacy of the current standard?

Comment: It appears clear in reviewing the current literature and epidemiological studies that the present standard is not sufficient to protect health. While uncertainties remain for many different reasons, the overall judgment is that the alternatives are likely to provide increased protection of human health.

7. Indicator (section 3.3.1): What are the Panel's views on the approach taken to considering standard indicator and on staff's conclusion that PM10 remains an appropriate indicator in this review?

Comment: Given the availability of the health data, the associated health risk, and the present monitoring system, PM_{10} is the only reasonable indicator for coarse PM at the present time.

8. Form (section 3.3.3): What are the Panel's views on the approach taken to considering the form of the standard and on staff's conclusion that revising the form to a 98th percentile form would be appropriate for a 24-hour PM10 standard meant to protect against exposures to thoracic coarse particles?

Comment: Based on the discussion provide by the EPA staff the 98^{th} percentile method appears to be the optimal form for the 24-hour standard.

9. Level (section 3.3.4): What are the Panel's views on the following:
a. The approach taken by staff to identify potential alternative PM10 standard levels, in conjunction with a 98th percentile form, including the weight placed on different studies?

Comment: Appropriate. This concentration-based standard will be better matched to the health effects, will better compensate for missing data and as described on page 3-31 is predicted to give "proportionally greater weight to days when concentrations are well above the level of the stand than to days when the concentrations are just above the level of the standard."

b. Staff's conclusion that the evidence most strongly supports standard levels around 85 µg/m3?

Comment: A standard around 85 µg/m3 is easily supported by the evidence and will generally provide equal protection to the current standard with some enhance improvement in some urban areas. Yet, such a standard will fail to protect a significant number of individuals as indicated by the studies of Zanobetti and Schwartz (2009) and Peng et al. (2008) where significant health impacts were measured with PM_{10} 98^{th} percentile concentration was 78 µg/m^3 and 68 µg/m^3 respectively. It is reasonable to consider a standard below 85 µg/m^3.

c. The alternative approach to considering the evidence that could support standard levels as low as 65 µg/m3?

Comment: The available evidence provides a justification for a 24-hour standard to lower values if positive but non-statistically significant associations are judged important, but justification near or below 65 µg/m^3 is weak. New data from future studies will be necessary to resolve uncertainties in the vicinity of 65 µg/m^3 and at lower concentrations. Solutions might come in the form of more direct measures of $PM_{10\text{-}2.5}$ and chemical characterization of the PM, and influence of co-pollutants.

10. Key Uncertainties and Areas for Future Research and Data Collection (section 3.5): What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

Comment: Over the last several years, sufficient evidence has emerged regarding the adverse health effects of coarse PM, yet in contrast to fine PM the knowledge base regarding coarse PM or $PM_{10\text{-}2.5}$ is limited, and many significant gaps are present in our understanding the C-R of its health effects. The key uncertainties presented in section 3.5 provide a broad overview of the areas of information that are needed to fill these knowledge gaps and develop and justify more effective control strategies. Understanding sources and components of $PM_{10\text{-}2.5}$, and modification of effects by co-pollutants is essential, and defining the concentration-response relationships accurately is extraordinarily important. Establishing the differential effects of PM mass on the various organ systems (heart, blood vessels, lungs, central nervous system, hematopoietic and immunity), reproduction and fetal development is key to understanding the contribution the overall risks. Also consideration should be given to attaining a better understanding of the spatial distribution and constituents of coarse PM and how they relate to local environments and human activity, such as traffic, industry or agriculture.

Dr. Christopher Frey

Charge Question 3: What are the Panel's views on the following:

Confidence bounds: The report seems to argue that there is not an adequate basis to consider concentration-response (C-R) confidence bounds quantitatively when developing or assessing potential alternative standard levels. However, as shown in Tables 2-2 and 2-3, 95 percent confidence intervals are estimated for the health effects endpoints for long-term IHD mortality and short-term CV mortality and hospital admissions.

What is not entirely clear to the reader is what is meant by "evidence-based considerations" and why this is different than "risk-based considerations." The risk assessment is based also on evidence, so the distinction is not clear.

On page 2-57 it is stated that there are epidemiological studies that report 95% confidence intervals for the effect estimates. A statement is made, that is a bit unclear, as follows (lines 25-27): "these analyses do not provide evidence of a concentration below which the confidence interval becomes notably wider and uncertainty in a C-R relationship substantially increases." Perhaps this statement is attempting to convey first the notion that the reported CIs are applicable to the range of ambient concentrations observed in the epidemiological study, and that EPA is making a judgment that the CI's should not be extrapolated to other values of ambient concentration. Second, the idea seems to be that if the C-R relationship would be applied to ambient concentrations that were not the basis of the specific epidemiological study, that the confidence intervals would widen. These assumptions could be stated more clearly.

The next sentence is even more unclear (p 2-57, lines 27-30). What is an "unacceptable degree of uncertainty"? What is a "continuing C-R relationship"? The notion that "the possibility that an effects threshold may exist becomes more likely" is likewise unclear. Since the intended meaning is unclear, it is not possible to propose an alternative wording.

A key point is that there are few PM2.5 studies for which confidence bounds are reported for C-R functions. On page 2-58, lines 4-7 a purpose for the estimation of the CIs is given with an implication perhaps that somehow these CI's are not relevant. It is not surprising, of course, that the CI's would widen as ambient concentration decreases into a range for which there are fewer ambient data. A point not discussed, however, is whether the confidence intervals widen such that the effects estimates are not statistically significant. Even if not statistically significant, is there an indication of an effect at the central tendency of the C-R relationship? Furthermore, there should be some discussion not only of the lower bound of the CI, but also of the upper bound. This would be consistent with the statutory mandate that the standard allow an "adequate margin of safety" that are "requisite to protect the public health."

The Schartz et al. 2008 Figure 2 would be useful.

Different statistical metrics: The assessment provides two alternatives referred to as the composite monitor and the maximum monitor. On the top of page 2-61, the text is a bit unclear but appears to be stating that, for the same air quality domain, the composite monitor concentrations are less than those based on the maximum monitor approach. An argument is made that an approach based on composite monitors has a "margin of safety" compared to the maximum monitor perspective. An implication is that if the maximum monitor approach is used, then data from epidemiological studies should be selected that are based on significant lower annual average concentrations. However, a judgment is made that data should be selected from the epidemiological studies for which the C-R relationships are "strongest." A judgment is made that concentrations not more than one standard deviation below the long-term mean concentration should be used. Although it is reasonable to make some kind of judgment such as this, the judgment should be explained. For example, it is not clear as to why one standard deviation was chosen, and not, say, 1.65 standard deviations, 1.96 standard deviations, and so on. For example, the information given in Table 2-4 implies that there are both author reported and EPA analyzed air quality data well below the "Mean-1SD"

Figures 2-7 through 2-8 provide useful information regarding the frequency distribution of annual mean concentrations. The lower panel of each figure is a bit unclear, but seems to be a population weighted version of the same air quality data. However, the sample sizes in the lower panels appear to be different than those in the upper panel, which should be explained.

The text is somewhat confusing to the reader. For example, it is not clear as to why the lower bound to be considered is a range from the 10th to 25th percentiles, as opposed to, say, the 10th percentile alone. In figure 2-7, for long-term exposure studies, the upper panel, the 10th percentile annual mean concentrations range from approximately 9 to 11 ug/m3. The population weighted values are 10 to 13 ug/m3. In both cases, the upper bounds of these ranges are for the high site, and the lower bounds are for the composite monitor.
It is not clear to the reader that a standard deviation is any more or less arbitrary than a specific percentile of a frequency distribution, contrary to the text on page 2-65, lines 20-23.

A key point is made on page 2-68, lines 7-16, which seems to need more discussion, and needs to be discussed in the previous section regarding confidence intervals on the C-R relationships. A key point to make clearly is regarding what is the lowest long-term ambient concentration and the lowest short-term ambient concentration at which statistically significant effects are observed, and, furthermore, what are the lowest long-term and short-term concentrations at which positive, even if not statistically significant, effects are observed.

The discussion of sensitive groups is very important. However, this material would seem to e more appropriate fit in the section on confidence intervals.

In general, this section of the report is somewhat confusing to the reader, because the key consideration should be to select ambient concentrations at which adverse effects are observed, taking into account the statutory mandate to provide an adequate margin of safety. Much of this text seems to focus on what range of air quality data were the basis of the epidemiological study, but without an adequate tie-in to whether there are health effects associated with such concentrations. For example, page 2-72, paragraph of lines 6 to 14, the basic argument here is unclear. What is the "evidence" to support these numbers? Is the idea simply that the levels should not be chosen to be lower than approximately the 10th percentile of ambient concentrations observed in the epi studies? If so, then the text of this section could be shortened considerably.

If the maximum monitor approach is ultimately deemed to be less useful, then perhaps it need not be included in the document.

b. Potential alternative annual standard levels based on composite monitor distributions versus maximum monitor distributions:

First, it is not at all clear as to why the annual standard should be "generally controlling." The NAAQS should provide health protection for both long-term and short-term health effects. It is not clear, for example, as to why the 24-hour level should be at least 2.5 times higher than the annual standard. Such a statement seems to be independent of consideration of health effects. A statement is made on page 2-73, lines 26-27 that "based on this consideration" consideration should be given to retaining the 35 ug/m3 24-hr level in conjunction with annual standards of 13 to 11 ug/m3. Setting aside the math problem here (e.g., 11*2.5 = 27.5, not 35), the rationale here does not appear to be based on health effects, and thus appears not to be valid.

While it is useful to have insight as to what combinations of annual and 24 hour levels would lead to the annual standard being controlling in a given area, it is not clear why the policy objective should be set both levels such that the annual standard is generally controlling.

c. Use of risk information in informing staff conclusions on alternative annual and 24-hour standard levels, including approaches used to assess overall confidence and potential bias in the risk estimates?

There is a disconnect between the evidence-based section and the risk-based section that is confusing to the reader. The "evidence-based" section reaches the conclusion that alternative levels to be considered should be 11 to 13 ug/m3 for the annual standard and 35 ug/m3 for the 24-hour standard, and also a combination of 11/30 for the annual/24-hour levels. However, the risk-based analysis does not systematically evaluate these combinations, omitting the 11/35 and 11/30 combinations. Furthermore, the text implies that a 10/35 case was analyzed, but no results are reported.

The results of the risk assessments are presented mainly in terms of percentage risk reduction compared to the current standard, in Figures 2-11 and 2-12 for long-term and short-term effects, respectively. While this is useful information, it is not relevant to the setting of a NAAQS. The goal of NAAQS is not to achieve relative risk reduction, but to protect public health with an adequate margin of safety. Thus, the risk characterization should be based on absolute rather than relative numbers (e.g., number of premature deaths estimated under each scenario). Therefore, much of the text needs to be revised.

This section should not only focus on the best estimate of risk, but the confidence intervals and non-quantified sources of bias, such as SES. See also Page 2-35, lines10-12, which indicates that sensitivity analysis of model specification used in the the risk assessment produce risk estimates that are a factor of 2 to 3 higher than the core risk estimates.

In cases where the 24-hour level would be controlling, it may be the case that there is less confidence in the risk characterization for the annual level. However, this in and of itself is not a reason as to why the 24-hour standard should not be controlling in such cases. A key policy question is whether having a 24-hour level be controlling in these cases protects public health with an adequate margin of safety.

d. Staff's conclusion that alternative annual standard levels in the range of 13 to 11 μg/m3 are most strongly supported by the available evidence and risk-based information?

Section 2.3.4.3 concludes that is appropriate to set levels so that the annual standard is generally controlling. However, it is not clear to the reader as to how this conclusion was reached.

A conclusion is made that alternative annual standards ranging from 13 to 11 ug/m3 are appropriate to consider. For internal consistency, a reason should be given as to why a level of 14 ug/m3 is not appropriate to consider. A level of 14/35 was considered in the risk assessment. Thus, the reader may wonder why this is set aside in the staff conclusions.

A conclusion is made to the effect that consideration should be given to retaining the 24-hour level of 35 ug/m3 or to having a 30 ug/m3 level "particularly" in combination with an annual level of 11 ug/m3. It is not clear as to how this conclusion was reached, or why other combinations such as 13/30, 12/30, or 11/25 would not also be useful to consider.

The assessment is weakened by not having a quantitative risk assessment result for the 11/35 and 11/30 levels, or possibly for other combinations as noted above.

There should be discussion of potential sources of biases in the risk characterization, such as the role of differences in distributions of low SES groups represented in the epidemiological studies versus in the urban populations being analyzed.

e. Staff's approach of focusing on peak-to-mean ratios to inform the level of a 24-hour standard that would provide supplemental protection to a generally controlling annual standard?

The key consideration should be the health effects evidence, rather than the peak-to-mean ratios. The ratios are useful in providing insight as to whether the annual or 24-hour standard would be controlling in a particular area, but it is not clear as to why the annual standard should be generally controlling.

f. Staff's conclusion that consideration should be given to retaining the current 24-hour standard level of 35 μg/m3 in conjunction with annual standard levels in the range of 13 to 11 μg/m3, and that consideration could also be given to an alternative 24-hour standard level of 30 μg/m3 particularly in conjunction with an annual standard level of 11 μg/m3?

This point is addressed above.

Charge Question 4: Key Uncertainties and Areas for Future Research and Data Collection (section 2.5): What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

Response: The material presented here is generally reasonable. It would be nice to have all of this information to support future assessments.

A few additional points to mention are:

- Need for activity data to support probabilistic scenario-based exposure models, such as additional activity diary data to incorporate into the Consolidated Human Activity Database (CHAD)
- Characterization of indoor exposures to PM of ambient origin. For example, the penetration of ambient PM2.5 and PM10 into indoor microenvironments (home, work, school, restaurant, bar, vehicle) should be better characterized, particularly taking into account differences in penetration with respect to particle size and composition.
- How might climate change affect the size distribution and composition of PM in the PM10, PM2.5, and UFP ranges?

What is lacking in this section is an idea of priorities. What is outlined here is a very broad and ambitious research agenda. It would help to start this section with a prioritized review of key uncertainties, in order to help establish priorities among the suggested research topics.

Charge Question 10: Key Uncertainties and Areas for Future Research and Data Collection (section 3.5): What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

Response:

See comments on Chapter 2.

The key distinction for this chapter is the need to seriously focus on PM10-2.5 for both mass and composition. The CASAC looks forward to the planned implementation of monitors that measure PM10-2.5, rather than PM10. There is a critical need for national monitoring data on PM10-2.5 in order to provide a basis for epidemiological studies that focus on this size fraction. Furthermore, there is a need for speciated data to support health effects estimates. Spatial and temporal variability in coarse particle mass and composition need to be characterized. In addition, the national monitoring data will support a baseline for ambient air quality in order to compare with health effects data in order to assess whether there is a need for a standard.

The research areas described in the draft Section 3.5 are reasonable, but there needs to be strong emphasis on the critical need for coarse PM data, in order that the NAAQS can move beyond PM10 as an indicator for coarse PM in a future revision.

Another question to be considered is regarding what size cut-points are appropriate, and also regarding what specific components are of most interest or concern with respect to health effects.

There is a need for continuous monitoring of coarse PM (and of PM2.5) in order to support health effects studies and to be able to assess alternative forms of possible future standards.

Other challenges for future research: (a) it may be difficult to get useful data from rodent studies since they can breathe particles only up to about 4 to 5 microns; (b) getting good chemical characterization of the particles will be a problem, since there are primary biological materials.

Prioritization is needed, such as via a separate meeting or workshop.

Dr. Joseph J. Helble

The Second Draft Policy Assessment is much more concise and readable than was the earlier draft. Text has been removed and replaced with appropriate references to the ISA and other documents, and there is little overlap between sections. The length and clarity of this document are now, in my view, appropriate for this Policy Assessment.

Charge Question 12: Nature of the Indicator (section 4.3. 1): What are the Panel's views on the following:

a. Staff's consideration of the three indicators identified in this section and our conclusions on the appropriateness of these indicators for consideration in this review?

The three indicators – mass, direct measurement of extinction, and calculated extinction based on speciation and size data – are the three relevant indicators. Given the dependence of extinction on particle composition, the conclusions regarding the relative inadequacy of a PM mass-only standard are appropriate. Direct measurement of extinction is, of course, a direct measurement and relevant, and the reasonable match of the calculations based on speciated PM mass suggests that this latter indicator is also appropriate.

b. The development and evaluation of a new approach that is based on using speciated PM2.5 mass and relative humidity to calculate PM2.5 light extinction by means of the IMPROVE algorithm?

Appropriate, as noted above. As discussed in the research needs section of the PA, better understanding of speciated PM2.5 mass distributions is needed.

c. The assessment approach and results comparing the PM components that contribute to the hours selected in the top percentiles for PM2.5 mass and PM10 light extinction?

The assessment approach, looking at contributions to PM mass v. contributions to PM light extinction under different scenarios, is appropriate, as are the conclusions extacted from the study. My only comment is that the figures in Appendix 4C are difficult to read, the text used to describe each part isn't particularly clear, and it appears that the captions of the relevant figures may be mislabeled (for example, in each figure, it seems that extinction is presented in parts a and d, *not* a and b – PA text is correct, figure caption is not)

Charge Question 14: Key Uncertainties and Areas for Future Research and Data Collection (section 4.5): What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

The major areas of research and data collection needed to address key uncertainties related to a visibility-based secondary standard are nicely captured in Section 4.5 of the PA. The section appropriately identifies two major areas of need, one related to visibility preference, and one related to methods of measurement.

In the first category, preference studies, the details noted by EPA all identify a strong need for additional urban visibility preference studies conducted using consistent methodology. The range of 50% acceptability values discussed as possible standards are based on just four studies (Figure 4-2), which, given the large spread in values, provide only limited confidence that the benchmark candidate protection levels cover the appropriate range of preference values. Studies using a range of urban scenes (including, but not limited to, iconic scenes – "valued scenic elements" such as those in the Washington DC study), should also be considered.

In the second category related to methods of measurement, I support the proposal to conduct studies in several cities, pairing direct monitoring of light extinction with enhanced monitoring of PM size and composition distributions (i.e. continuous PM speciation monitoring). Additional work should also be conducted to understand the contribution of $PM_{10-2.5}$ in southwestern areas other than Phoenix, to address the lack of information for scattering associated with this fraction of PM10 as is noted on page 4-30.

Underlying this overall discussion is a clear need for better particle size – composition distribution information (i.e. particle composition distributions as a function of particle size). It is addressed in different ways in the discussions of future research needs elsewhere in the PA (Sections 2.5 and 3.5), and the development of continuous monitoring methods for specific PM components addressed in Section 2.5 is equally applicable here. Improved understanding of size-dependent PM composition would also help address some of the questions related to the role of scattering and absorbing aerosols in climate forcing that are raised in PA Section 5.2.4.

Minor ed. Comments:

p. 2-89, line 16, missing “to” between “models” and “expand” ?

p. 4-13, line 25: “effects” is vague. Degradation would be a clearer term here.

p. 4-19, line 16,) needed after “screen”

p. 4-33, line 33, delete “, and simplicity” since the text is already describing “a simpler approach”

p. 4-35, line 15, first word, change “show” to “shown”

p. 4-36, line 15, insert of between “because” and “the differing”

p. 4-39, line 9, delete second period at end of sentence

p. 4-41, line 3, change “areas” to “area”

p 4-46, line 2 delete apostrophe

p. 4-51, line 19, insert “data” between “component” and “to calculate”

p. 5-5, line 3, delete comma

p. 5-15, line 32, “review” ? – wouldn’t “policy assessment” be correct here?

Dr. Rogene Henderson

Answer to charge questions assigned to me:

1. Current Approach (section 2.1.3):
a. What are the Panel's views on the staff's approach to translating the available epidemiological evidence, risk information, and air quality information into the basis for reaching conclusions on the adequacy of the current standards and on alternative standards for consideration?

The Panel agrees with the approach as described in section 2.1.3 and appreciates the clarity with which the approach was described. The overview of the approach presented in Figure 2-1 is well-organized and clear. The Panel agrees that it is appropriate to go back to the approach used in 1997 to consider the annual and 24 hr standards together, with the annual standard as the controlling standard and the short-term standard intended to supplement the protection afforded by the annual standard. The Panel supports the Agency's consideration of evidence-based and risk-based information as well as the uncertainties associated with both types of information. The Panel considers it appropriate to place the greatest emphasis on health effects judged to be causal or likely causal in the analysis presented in the ISA.

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standards (section 2.2) and potential alternative standards (section 2.3)?

The staff has followed this approach in reviewing the adequacy of the current standards and in considering potential alternative standards. The outline of the text of section 2.3 follows the outline presented in the overview of the approach given in Figure 2-1.

6. Adequacy of the Current PM10 Standard (section 3.2): What are the Panel's views on the alternative approaches presented for considering the evidence and its uncertainties as they relate to the adequacy of the current standard?

Section 3.2 is exceptionally well written. It includes a discussion of the studies that are most significant for the question for the adequacy of the current standard. At the end, the authors offer two different approaches to analysis of the studies. The information on the new studies related to coarse particles indicated differences in the robustness of the responses that left the answer to the question of adequacy of the current standard uncertain. Therefore it was helpful to have the descriptions of two approaches to analysis of the data, as given at the end of the section.

Rogene Henderson
July 15, 2010

General comment on 2nd draft PA:

I think this is a much-improved draft PA; the Agency has been responsive to the previous comments of CASAC.

Answers to other charge questions:

Chapter 2 (Primary Standards for Fine Particles)

1. Current Approach (section 2.1.3):
a. What are the Panel's views on the staff's approach to translating the available epidemiological evidence, risk information, and air quality information into the basis for reaching conclusions on the adequacy of the current standards and on alternative standards for consideration?
Good approach.
b. Has staff appropriately applied this approach in reviewing the adequacy of the current standards (section 2.2) and potential alternative standards (section 2.3)?
Yes.

2. Form of the Annual Standard (section 2.3.3.1):
a. What are the Panel's views on the additional analyses conducted to characterize the potential for disproportionate impacts on susceptible populations, including low income groups and minorities associated with spatial averaging allowed by the current annual standard?
Well done
b. In light of these analyses, what are the Panel's views on staff's conclusion that the form of the annual standard should be revised to eliminate spatial averaging?
Agree.

3. Alternative Levels (section 2.3.4): What are the Panel's views on the following:
a. The insights that can be gained into potential alternative standard levels by considering:
i. Confidence bounds on concentration-response relationships?
ii. Different statistical metrics that characterize air quality distributions from multi-city epidemiological studies?
I agree with the discussion of these topics in the text.
b. Potential alternative annual standard levels based on composite monitor distributions versus maximum monitor distributions?
I agree with the policy to focus on alternative levels that are just somewhat below the long-term mean concentrations reported in the epidemiological studies using the composite monitor distributions.
c. Use of risk information in informing staff conclusions on alternative annual and 24hour standard levels, including approaches used to assess overall confidence and potential bias in the risk estimates?
This was well done.
d. Staff's conclusion that alternative annual standard levels in the range of 13 to 11 µg/m3 are most strongly supported by the available evidence and risk-based information? I agree.
e. Staff's approach of focusing on peak-to-mean ratios to inform the level of a 24-hour standard that would provide supplemental protection to a generally controlling annual standard?
I agree.

f. Staff's conclusion that consideration should be given to retaining the current 24-hour standard level of 35 µg/m3 in conjunction with annual standard levels in the range of 13 to 11 µg/m3, and that consideration could also be given to an alternative 24-hour
standard level of 30 µg/m3 particularly in conjunction with an annual standard level of 11 µg/m3?
Agree.

4. Key Uncertainties and Areas for Future Research and Data Collection (section 2.5):
What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?
I have nothing to add.

Chapter 3 (Primary Standard for Coarse Particles)

5. Current Approach (sections 3.1.4, 3.2, 3.3):
a. What are the Panel's views on the approach to translating the available evidence and air quality information into the basis for reviewing the coarse particle standard?
I agree with the approach.
b. Has staff appropriately applied this approach in reviewing the adequacy of the current standard (section 3.2) and potential alternative standards (section 3.3)?
Yes.

6. Adequacy of the Current PM10 Standard (section 3.2): What are the Panel's views on the alternative approaches presented for considering the evidence and its uncertainties as they relate to the adequacy of the current standard?
I liked the presentation of the two approaches for consideration of the data.

7. Indicator (section 3.3.1): What are the Panel's views on the approach taken to considering standard indicator and on staff's conclusion that PM10 remains an appropriate indicator in this review?
I agree with the staff conclusions.

8. Form (section 3.3.3): What are the Panel's views on the approach taken to considering the form of the standard and on staff's conclusion that revising the form to a 98th percentile form would be appropriate for a 24-hour PM10 standard meant to protect against exposures to thoracic coarse particles?
I agree.

9. Level (section 3.3.4): What are the Panel's views on the following:
a. The approach taken by staff to identify potential alternative PM10 standard levels, in conjunction with a 98th percentile form, including the weight placed on different studies? OK.
b. Staff's conclusion that the evidence most strongly supports standard levels around 85 µg/m3?
I agree.
c. The alternative approach to considering the evidence that could support standard levels as low as 65 µg/m3?

I do not agree with this low a level because it places more weight on studies in which results were positive but not statistically significant.

10. Key Uncertainties and Areas for Future Research and Data Collection (section 3.5): What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?
I have nothing to add to this section.

Dr. Morton Lippmann

The 2nd Draft PM PA is a great improvement over the first. OAQPS Staff was very responsive to the CASAC comments and recommendations on the first draft, and deserves to be commended for producing a clearly readable exposition of the scientific basis for its conclusions, as well as clearly stated rationales for its recommendations.

I could only generate a relatively small number of specific suggestions for edits and/or changes for Chapters 2 and 3, which are enumerated below.

Page Line Comment

2-23 10 change "found" to "continued to find".
2-23 17 insert a comma after "studies" and insert "the increased" before "risk".
2-32 14 insert a definition of "peakiness". Does it have a specific meaning in the context of this document? If so, what is it?
2-34 23,25 change "which" to "that".
2-36 2 add to end of sentence: "but give greater weight to eastern and Midwestern populations."
2-43 18 insert "and toxicological" after "epidemiological".
2-44 20 insert "and humidity" after "concentrations".
2-45 8 insert "collective" before "surface".
2-45 21 change "i.e.," to "within the".
2-86 21 add to end of sentence: ", and will be the subject of a future document".
2-87 27 change " Exposure-related Factors." to "Factors Influencing Exposures".
2-89 1 change "Children" to "Age", and add "and older adults" after "children" at end of the line.

Charge Questions:

Chapter 2 (Primary Standards for Fine Particles)

1. Current Approach (Section 2.1.3):
a. What are the Panel's views on the staff's approach to translating the available epidemiological evidence, risk information, and air quality information into the basis for reaching conclusions on the adequacy of the current standards and on alternative standards for consideration?
The approach is sound.

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standards (section 2.2) and potential alternative standards (section 2.3)?
Yes.

2. Form of the Annual Standard (Section 2.3.3.1):
a. **What are the Panel's views on the additional analyses conducted to characterize the**

potential for disproportionate impacts on susceptible populations, including low income groups and minorities associated with spatial averaging allowed by the current annual standard?
They were well conceived and well articulated.

b. In light of these analyses, what are the Panel's views on staff's conclusion that the form of the annual standard should be revised to eliminate spatial averaging?
The conclusion was well justified.

3. Alternative Levels (Section 2.3.4): What are the Panel's views on the following:
a). The insights that can be gained into potential alternative standard levels by considering:
i. Confidence bounds on concentration-response relationships?
Useful, and an appropriate choice.

ii. Different statistical metrics that characterize air quality distributions from multi-city epidemiological studies?
Useful, and highly appropriate for the purpose.

b). Potential alternative annual standard levels based on composite monitor distributions versus maximum monitor distributions?
The composite monitor approach is preferable because of its stability.

c). Use of risk information in informing staff conclusions on alternative annual and 24-hour standard levels, including approaches used to assess overall confidence and potential bias in the risk estimates?
The risk information provides valuable insights, and should be used in drawing conclusions.

d**). Staff's conclusion that alternative annual standard levels in the range of 13 to 11 μg/m^3 are most strongly supported by the available evidence and risk-based information?**
The rationale for the conclusion was well developed, and well justified.

e). Staff's approach of focusing on peak-to-mean ratios to inform the level of a 24-hour standard that would provide supplemental protection to a generally controlling annual standard?
The approach is sound.

f). Staff's conclusion that consideration should be given to retaining the current 24-hour standard level of 35 μg/m3 in conjunction with annual standard levels in the range of 13 to 11 μg/m3, and that consideration could also be given to an alternative 24-hour standard level of 30 μg/m3 particularly in conjunction with an annual standard level of 11 μg/m3?
The conclusions are reasonable in relation to the criteria established by the Clean Air Act (CAA), and those developed by the OAQPS Staff that have been endorsed by CASAC.

The choices within these options will need to be based on the Administrators interpretation of the CAA's requirement for a margin-of-safety. In other words, in the absence of response thresholds, how much public health impact resulting from exposure to ambient air $PM_{2.5}$ is acceptable under the CAA.

The least protective option (35-13) would provide significant additional public health benefits in most of the U.S., in comparison to the current limits (35-15), and these benefits would be greatest in the more humid parts of the U.S. The most protective option (30-11) would provide significant additional public health benefits to a larger part of the U.S. population in comparison to the current limits (35-15) and any of the intermediate options, but would not prevent at least some adverse health effects among the most susceptible segments of the population.

The decision to be made on the selection among the alternative levels for the $PM_{2.5}$ NAAQS will need to be made judiciously, with acknowledgment of its public health consequences. As compared to the previous round for PM, it is no longer justifiable to rely on residual uncertainties as a basis for confronting the need for a significant advance in public health protection.

4. Key Uncertainties and Areas for Future Research and Data Collection (Section 2.5): What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

The key uncertainties and areas for future research and data collection are well summarized in Section 2.5. The acknowledgement (at the top of page 2-87) that "Much of this research may depend on the availability of increased monitoring data" is apt and appreciated. The opportunities for epidemiological research to effectively address the knowledge gaps on the effects, and concentration-response relationships, of PM components and source-related mixtures cannot be achieved without additional monitoring data to provide PM speciation and better temporal and spatial resolution. Only EPA can provide the impetus and support for such an enhancement in air quality monitoring.

The research needs to address uncertainties in health outcomes, exposure durations of concern, and susceptible populations that are also very nicely outlined are well targeted, and can be effectively studied in human populations. Such studies, to be most productive, will need the enhanced monitoring data that EPA has recognized as being needed, and that only EPA can provide.

Chapter 3 (Primary Standard for Coarse Particles)

5. Current Approach (sections 3.1.4, 3.2, 3.3):

a. **What are the Panel's views on the approach to translating the available evidence and air quality information into the basis for reviewing the coarse particle standard?**

The Staff has done a good job of describing a suitable, evidence-based, approach for translating the limited amount of relevant health effects evidence and air quality information in different U.S. regions into a basis for reviewing the adequacy of the current coarse particle standard.

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standard (section 3.2) and potential alternative standards (section 3.3)?

Yes.

6. Adequacy of the Current PM10 Standard (section 3.2): What are the Panel's views on the alternative approaches presented for considering the evidence and its uncertainties as they relate to the adequacy of the current standard?

They remind us of the reliance on uncertainties used by the previous Administrator as an excuse to discount the increasing evidence that exposures to thoracic coarse PM increases health risks.

7. Indicator (section 3.3.1): What are the Panel's views on the approach taken to considering standard indicator and on staff's conclusion that PM10 remains an appropriate indicator in this review?
The document makes a good case for retaining PM_{10} as an indicator for this round of review.

8. Form (section 3.3.3): What are the Panel's views on the approach taken to considering the form of the standard and on staff's conclusion that revising the form to a 98th percentile form would be appropriate for a 24-hour PM10 standard meant to protect against exposures to thoracic coarse particles?
The document makes a good case for using the 98^{th}% form for this round of review**.**

9. Level (section 3.3.4): What are the Panel's views on the following:

a. The approach taken by staff to identify potential alternative PM10 standard levels, in conjunction with a 98th percentile form, including the weight placed on different studies?
The approach outlined is a very reasonable one, and appropriate weights were given to the available studies.

b. **Staff's conclusion that the evidence most strongly supports standard levels around 85 µg/m3.**
This conclusion is <u>not</u> appropriate, insofar as it is based on an average equivalence of PM_{10} at 150 *u*g/m^3 for the 4^{th} highest concentration in 3 years, and 85 *u*g/m^3 for the 98^{th} $\%^{ile}$. Because of the well-documented differences in "peakiness" and the ratios of $PM_{2.5}$ to PM_{10} in different parts of the U.S., there will be a less protective limit for parts of the U.S. The absence of data on the adequacy of the present PM_{10} NAAQS to protect against the adverse effects of $PM_{10-2.5}$ does not provide a basis for relaxing the thoracic coarse PM NAAQS for parts of the U.S.

c. **The alternative approach to considering the evidence that could support standard levels as low as 65 µg/m3?**
The presentation of the evidence, as summarized in the text beginning on line 33 of page 3-42 is convincing, at least to this CASAC Panel reviewer, that a PM_{10} level below 85 *u*g/m^3 is warranted, and a range of 75 to 65 *u*g/m^3 should be recommended for consideration.

10. (Section 3.5): Key Uncertainties and Areas for Future Research and Data Collection What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?
The brief statement of the key uncertainties and areas for future research and data collection in Section 3.5 is very much on target, with one exception. That one is: "Animal toxicological studies of long-term exposures (i.e., months to years) to $PM_{10-2.5}$ would be useful", as stated on page 3-46, lines 37 & 38. However, inhalation exposures are not feasible in rodents because nearly all particles <2*u*m would deposit in the nasal airways, and not penetrate into the lung parenchyma, and those few that did would not have much deposition in the tracheobronchial airways. Exposure studies in animals by other routes of administration would have severe limitations in terms of interpretation and risk assessment.

Dr. William Malm

The current draft PM PA is much improved over the first. EPA staff was for the most part responsive to CASAC recommendations. However, a few significant issues remain as outlined below.

11. Current Approach (section 4.1.3):
a. What are the Panel's views regarding our approach for translating technical evidence and assessment results into the basis for assessing current fine particle standards and considering alternative standards to provide protection against PM-related visibility impairment?

The combined evidence- and impact-based review nicely contrasts various approaches and metrics for protecting urban visibility. The three indicators; $PM_{2.5}$ extinction, reconstructed extinction, and mass concentration, pretty much cover the currently available metrics that could be used to set a standard. Averaging times are considered, as are various percentile levels for both extinction and mass concentration. The various metrics are compared to VAQ acceptability studies that were carried out in four urban areas.

Detailed analysis was only presented for a subset of percentile levels and 1-hr daily maximum levels versus maximums for all days. It is clear that contrasting and comparing all combinations would be overwhelming; however, the selection of a 90^{th} percentile for 1-hr maximum and a 98^{th} percentile criteria for all daylight hours is not well justified, other than the two approaches yield similar results. It would be helpful to develop an easily understood statistic for each comparison, and then extend the contrasts and comparisons to more combinations of the percentile levels, metric forms, and maximum selections.

The EPA is to be commended for taking the VAQ acceptability studies and applying the logit digit model to the results in such a way as to more directly intercompare the four studies and estimate various visibility acceptability levels. It would be of interest to further expand the analysis, using existing data, to see if there is a visibility index that represents visibility conditions independent of the type of scene being viewed, such that preference levels for all studies, when plotted against this index, would all yield the same response curve. If such an index could be identified, the currently available studies could be used to assess visibility levels in any urban area or setting, using this index. The relationship of this index to dv or extinction will necessarily be nonlinear; however, this approach would allow representative extinction levels to be examined for a variety of urban areas and/or landscape/urbanscape features.

In any case, I think the approach taken very clearly shows the limitations of using the current $PM_{2.5}$ standards to protect against visibility impairment judged to be unacceptable by available VAQ acceptability studies.

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standard (section 4.2) and potential alternative standards (section 4.3)?

For the most part they have.

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

a. Staff's consideration of the three indicators identified in this section and our conclusions on the appropriateness of these indicators for consideration in this review?

The three indicators, mass, reconstructed extinction, and measured extinction, are appropriate indicators. However, it would be of interest to further expand the analysis, using existing photos and preference data, to see if there is a visibility index that represents visibility conditions independent of the type of scene being viewed, such that preference levels for all studies, when plotted against this index, would all yield the same response curve. If such an index could be identified, the current available studies could be used to assess visibility levels in any urban area or setting. The relationship to dv or extinction will necessarily be nonlinear; however, this approach would allow representative extinction levels to be examined for a variety of urban areas and/or landscape/urbanscape features.

b. The development and evaluation of a new approach that is based on using speciated PM2.5 mass and relative humidity to calculate PM2.5 light extinction by means of the IMPROVE algorithm?

It has been demonstrated in many studies that it is possible to reconstruct extinction from speciated mass data if the relative humidity is known. The EPA has further demonstrated that, in most cases, applying monthly average speciated mass data to hourly mass measurements and applying the IMPROVE algorithm results in a similar estimate of hourly extinction values as would have been obtained by using the hourly speciated data directly.

c. The assessment approach and results comparing the PM components that contribute to the hours selected in the top percentiles for PM2.5 mass and PM10 light extinction?

See comments in 11a and 13a. A quantitative statistical index, representative of the good or not so good comparison between approaches, should be developed.

13. Alternative Levels and Forms (section 4.3.3): What are Panel views on the following:
a. The performance assessment which focused on the Candidate Protection Levels of 64, 112, 191 Mm-1 for PM2.5 light extinction and speciated PM2.5 mass-calculated light extinction, and alternative levels of 10, 20, and 30 µg/m3 for PM2.5 mass concentration?

These are appropriate CPL and $PM_{2.5}$ levels. The CPL values were based on all visibility preference data that are available and bound the study results as represented by the 50% acceptability criteria. However, I think it would be worth it, but not necessarily essential, to expand some of the tables to include 10 and 40 dv values, in that at 10 dv, not anybody found the scene to be unacceptable, and at 40 dv, virtually everybody found the all scenes to be unacceptable. What would these dv levels correspond to in the context of $PM_{2.5}$ and the various percentile levels?

b. Use of three-year averaged 90th and 95th percentiles in conjunction with a 1-hour daily maximum form and use of three-year averaged 98th percentile in conjunction with the all daylight hours form?

These levels may very well be appropriate; however, I don't think they were well justified. It seems that the cursory argument was that the 90–95th percentiles in conjunction with the 1-hr daily maximum identified similar days and hours of violation, as did the 98th percentile in conjunction with all daylight hours, and this correspondence was reason enough to pick these two approaches. I think it would be informative to do all, or at that least the same, percentiles for both all days and daily max hr, contrast and compare the approaches, and then try to develop a self consistent argument of why one approach would be better than another. It doesn't seem that this was done. The question of the implications of which sources might be identified as problematic as a function of all hours all days versus daily max hr has still not been adequately addressed. It was pointed out that the all hour, all day in some cases selected out multiple hours on the same day. It seems that a significantly extended episode of low visibility might be attributed to a single source, such as a large wildfire or prescribed fire, which would result in the all hour, all day approach targeting only one large emission episode that occurred for only one or a few time periods.

c. Insights to be drawn by comparing the PM components for hours included among the 10% highest for a 1-hour daily maximum form with the hours included among the 2% highest for an all daylight hours form, for the various indicators considered (Appendix C)?

See comments above. These two approaches appear to be similar; however, it would be helpful to quantify the similarities as opposed to a qualitative discussion. Maybe a scatter plot for the 14 sites of the average fractional contribution of a species as a function of the various approaches and some way of showing which days are selected in the context of all other days would be useful—some way of gaining insight into the kinds of visibility episodes that get selected.

14. Key Uncertainties and Areas for Future Research and Data Collection (section 4.5): What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

Under "Visibility Preference". I repeat my comments under 11a. It would be of interest to further expand the analysis, using existing data, to see if there is a visibility index that represents visibility conditions independent of the type of scene being viewed, such that preference levels for all studies, when plotted against this index, would all yield the same response curve. If such an index could be identified, the current available studies could be used to assess visibility levels in any urban area and setting, using this index. The relationship of this index to dv or extinction will necessarily be nonlinear; however, this approach would allow representative extinction levels to be examined for a variety of urban areas and/or landscape/urbanscape features.

Under "Urban Visibility Conditions". There isn't any discussion of the role that clouds or atmospheric conditions might play in peoples' visibility preferences as a function of PM. Visibility conditions associated with sky color and clouds could very well be significant normalizing features, making many or most urban settings similar. Any new visibility effects assessments should include a variety of atmospheric conditions other than clear skies, as was used in the current studies.

Some specific comments:

Page 4.5: *"The 2005 Staff Paper noted that a standard set at any specific PM2.5 concentration would necessarily result in visual ranges that vary somewhat in urban areas across the country, reflecting the variability in the correlations between PM2.5 concentrations and light extinction."* More than just correlations – the slope of the line between $PM_{2.5}$ and visual range will also vary.

Page 4.13, line18: One could use a more up to date f(RH) curve in conjunction with the IMPROVE algorithm and "improve" the equation significantly.

Line 35: The "refinements" in the IMPROVE algorithm reflect more than just the aging of organic aerosols. Might want to discuss the change in Roc and size distribution shifts of both OC and inorganic carbon as a function of aging.

Page 4.17, line 17: *"These combine to make early morning the most likely time for peak urban visibility impacts."* Probably sun angle is as important as or more important than the atmospheric variables mentioned. Include discussion of sun angle effects – forward/back scatter, illuminated and shadowed scenes, etc.

Page 4.18, 1st paragraph: See comments under 11a. Here is where you could have a discussion of scene-specific indices that characterize observers' response functions. For example, such variables as modulation depth, JNCs, average contrast, and so forth. Then relate these variables to the modulation transfer function of the atmosphere and, ultimately, extinction. This would show how scene characteristics and illumination in conjunction with extinction contribute to preference.

Line 11: Atmospheric mixing characteristics were also held constant. None of the studies addressed non-uniform haze, such as layered hazes.

Page 4.24, lines 10–12: It would be helpful to, at times, point out when real data is being used versus modeled information.

Page 4.35, line 34: *"…we believe…"* There is no room for using words like belief in a scientific document. A belief is not an adequate justification for any decision point! It is also bothersome to read *"…sufficiently similar results…"* – especially in the context of "belief" to justify an analysis approach. Quantify the concept!

Page 4.36: The general discussion around the figures in 4C are difficult to follow primarily because the captions and axes in the figures are so small they cannot be easily read. Figures need to be improved and a clear and complete description of these figures would be helpful before the discussion points.

Page 4.37: *"While perception of change in visibility can occur in less than a minute, meaningful changes to path averaged light extinction occur more slowly and can be well represented by hourly averaging."* This may very well be true, but I think it is conjecture.. I haven't seen any evidence in the literature for making this statement, certainly not in the absolute way that it is stated. I am not sure this argument is adequate justification for a 1-hr averaging time.

Page 4.39, lines 18-28: What are the emission control strategy implications of this discussion? If not here, I would think a discussion of what sources might be preferentially controlled as a function of regulation form and type would be appropriate.

Page 4.40: "*We noticed a close correspondence…*" Here, and throughout the document, there are a number of qualitative statements such as this. What is a close correspondence? Make it quantitative. A close correspondence means different things to different people. Some would say a correlation of 0.5 constitutes a close correspondence, while others might make this judgment only if the correlation was 0.9 or greater.

Page 4.41, lines 1-8: Might do a scatter plot of mass fraction from different approaches using the 14 sites as individual data points.

Page 4.51: *"Additionally, prior to the next PM NAAQS review and as part of the planning for additional preference and valuation survey studies, a literature review of recent social science literature could usefully be conducted to assess the state of knowledge of view exposure mechanisms, and the psychological and behavioral effects associated with viewed stimuli."* Good recommendation! Needs to be done.

Mr. Tom Moore

Thanks to the author team for a great effort on the 2nd draft of the Policy Assessment - much more readable than the 1st draft.

Specific Comments on Section 4:

Page 4-1, lines 11-16: The discussion of the considerations behind "…staff conclusions on a range of alternative secondary standards appropriate…" should note that federal, state, and local air quality management agencies have been analyzing cumulative and individual pollutants' impacts on visibility under the National Environmental Policy Act, the New Source Review, Prevention of Significant Deterioration, Best Available Retrofit Technology, and Regional Haze Rule programs over the past 25 years. While the Administrator's decision must draw upon the factors listed in this paragraph, air quality management to improve visibility by controlling PM to reduce light extinction impacts would utilize well-developed methodologies and control methods – perhaps not as difficult a "...public welfare policy judgment.." as the current text would suggest.

Page 4-3, lines 1-2: Data available in 1997, especially in urban areas, were not based on an existing primary or secondary PM2.5 NAAQS. These data were very limited for the purposes of forecasting improvement "… to some degree…" in urban PM-caused visibility impairment. The 1997 PM2.5 primary NAAQS led to the first effort, funded by EPA and implemented by state and local air agencies to more completely and routinely characterize urban PM2.5 composition across the nation. The expansion of the IMPROVE network in 2000-01 to support the implementation of the Regional Haze Rule led to a much fuller understanding of Class I area impacts from urban sources and regions. The forecasts of PM-caused urban visibility improvements from the 24-hour average PM2.5 secondary NAAQS proposed at 50 µg/m3 in 1996 were highly speculative, and the 24-hour average secondary PM2.5 NAAQS of 65 µg/m3 adopted by EPA in 1997 was even less protective of PM-caused visibility impairment.

Page 4-3, lines 14-17: This sentence is not necessarily true, as the requirements for air quality planning and attainment of the NAAQS are more timely and in statute, while the Regional Haze program is required under a less stringent administrative rule with a long time horizon. If and when secondary PM NAAQS are promulgated to separately protect visibility in [monitored] urban/small town/rural areas, testing of the hypothesis that the Regional Haze program adopted in rule under §169A and 169B of the CAA "…can be more responsive to the factors contributing to regional differences in visibility…" can be done. PM-caused visibility impairment in urban/small town/rural areas is both an effect and a source.

Page 4-3, lines 19-24: While in 1997, "…a regional haze program, in conjunction with secondary standards set identical to the suite of PM2.5 primary standards, would provide appropriate protection for visibility in non-Class I areas." conceptually would provide protection from PM welfare impacts on visibility in the ambient environment, the EPA had little or no urban PM2.5 mass or composition data at the time to make this assertion. The Regional Haze analyses and planning effort since that time suggest that an administrative rule with a 60+-year implementation time frame will not lead to the more timely and necessary reductions in PM causing welfare visibility impacts in urban/small town/rural areas. Instead the Regional Haze program guidance from EPA addresses primarily stationary point sources, and states have accounted for the national mobile source control programs adopted by EPA primarily to attain the various primary NAAQS. The lesson learned from Regional Haze is that if impacts from PM on “non-Class I area” visibility are occurring as EPA’s 2010 PM ISA and UFVA analyses suggest, then a secondary PM NAAQS to protect visibility is now necessary - different in form, averaging time, level, and perhaps indicator from the primary PM NAAQS, along with the requisite analyses to develop emission control plans to complement the Regional Haze program.

Page 4-4, line 2: Replace “local” with “sub-regional”.

Page 4-4, line 3: Replace “City of Denver” with “Colorado Front Range urban areas from Fort Collins to Colorado Springs”.

Page 4-4, lines 5-8: While it is reasonable to assert now that visibility would improve in a “…urban area near a mandatory Class I Federal area … by implementation of the current visibility regulations…” [which include ongoing implementation of stationary point source controls under the NSR, PSD, BART and Regional Haze programs], the urban area-specific nature and causes of PM-caused visibility impairment may not be addressed appropriately and proportionally since we have never had a specifically-visibility-protective PM NAAQS. This sentence also does not belong in the 1997 section, it is an analysis of the current situation.

Page 4-4, line 12: After “…impairment”, add “known at that time”.

Page 4-4, lines 17-18: After “…EPA”, insert “recommended separate and more stringent, but promulgated” before “revised”. Remove “the” and “by making them”.

Page 4-4, line 29: Remove “Denver” – should instead be mentioned in or around line 3 above.

Page 4-10, diagram: This diagram is a helpful depiction of the overall process followed by EPA in preparing the secondary welfare PM NAAQS analysis for visibility impacts.

Page 4-18, line 3: After “…extinction”, insert “by PM” before “…is an…”. In the same sentence, after …that”, remove “by itself does not directly translate into a” and insert “is a direct measure of the public welfare effect, but setting a secondary welfare PM NAAQS for light extinction is not a sufficient measure of the…”.

Page 4-18, line 3: After “Light extinction”, insert “by PM”, then after “…atmospheric property that…”, delete “by itself does not directly translate into a” and replace with “ is a direct measure of the” before “public welfare effect”. Insert a following sentence: “Promulgation of a secondary welfare PM NAAQS for light extinction gives definition to the dimensions of urban visibility impairment effects by defining the measurement method(s) to characterize the indicator, as well as the form, level, and averaging time.”

Page 4-18, line 4: After “…meaningful”, insert “and the public policy effect evaluated by using” before “in the context…”. Delete “in” before “the context”.

Page 4-18: line 6: After “The perception”, insert “of some representative group of individuals” before “of the…”.

Page 4-18, end of line 13: Insert a new sentence, something like: “Further, the “scenic-ness” of a given scene is a setting- and context-based value judgment by an individual. Those individual judgments should be part of a large and representative sample size distribution.

Page 4-21: line 12: After “…which is by far the best of the four studies”, insert “due to the large sample size” and modify the reminder of the sentence to make a list including “least noisy” and “most representative”.

Page 4-29, line 13: After “…air quality conditions.”, continue the sentence by adding “by mass, not species contribution to light extinction”. Future change in species’ magnitudes and/or source mix are not likely to be proportional.

Page 4-31, line 23: Delete “…Chemical Speciation Network (CSN)…” – it does not produce hourly average mass concentrations. It would be more accurate to note the sampling schedule and averaging time for CSN in a separate sentence.

Page 4-38, line 34: The assertion that averaging for 3 years is sufficient “…to provide stability…” is not supported, particularly as NAAQS are changed to more stringent levels. The 3-average is much less than generally accepted climatological averaging periods of 7 to 10 years, nor is the 3-averaging period source-independent. If the long-time formulation of the compliance time period for the various NAAQS over a 3-year period is due to the NAAQS review and air quality planning requirement in the Clean Air Act, it should be stated as such – especially in the Policy Assessment. The effect of climate change and expected future variations in climate will also reduce the “stability” of a 3-year average.

Page 4-39, line 10: After the sentence ending in “… values.”, insert a new sentence: “Such studies were done in the absence of an EPA secondary PM NAAQS set to protect the public from welfare impacts of impaired urban visibility.”

Page 4-47, table starting line 4: Modify the table to remove “Mm-1” from every data cell. Does the coloring apply to more values than are currently “colored in”?

Page 4-49, line 2: After the sentence ending “…Administrator.”, insert a clause to start the next sentence “As there is no explicit protection for this impact at present,” before “we recognize…”.

Page 4-50, after line 12: Add a “(7)” describing what would be expected to be learned and the associated EPA activities to support the gathering and analysis of new knowledge through the promulgation, initial implementation, and the first round of “nonattainment plans” to implement this secondary welfare PM NAAQS for visibility over the 5 years from October 2011 through 2016.

Page 4-52: Noted there are only 17 references for Section 4 of the Policy Assessment, while Section 5 where no action is recommended has 41 – are there more references to add for Section 4?

Dr. Robert Phalen

I. General Comments on P.A. draft 2

a. As expected,the Staff has prepared a lucid and elegant second draft of the P.A.

b. I am struck by the limitations placed on the Staff in framing the P.A., and concerned that readers may believe that several potentially adverse secondary health consequences have been evaluated along with the direct health effects, when they have not. Thus, I recommend adding an explicit informative statement to the P.A., or the cover letter, such as:
"Due to statute, case-law, and policy decisions, it should be noted that this Policy Assessment addresses only the direct adverse health effects of PM mass fractions. Thus, secondary public health effects, such as:(1)the potential health effects of compliance actions on jobs, and the availability of goods and services;(2)the potential health effects at locations that have positive (rather than negative)health associations with PM mass; and (3) the potential health effects of changes in PM mass on other air contaminants (e.g. UFP counts, and airborne acidity), are not considered. In short, the range of potential unintended secondary adverse consequences have not been evaluated in this document. Thus the recommendations herein may, or may not, improve overall public health."

Such a statement would both help readers to understand the current state of evolution of the NAAQS-setting process, and help guide the way for its future improvement. It also states, for those who may not appreciate what the P.A does, and does not, achieve.

c. On pg. 3-14, lines 9 - 13: Strike the sentence,"It is possible that such differences in particle composition could affect particle toxicity,...". Numerous studies have shown that particle composition definitely, not "possibly" affects particle toxicity.

d. On pg. 3-44, line 26: For the sake of transparency add, "from the direct adverse effects of individual criteria air pollutants" after "public health".

II. Charge Question no. 5

a. The approach is o.k.
b. the application of the approach is o.k.

Dr. Kent Pinkerton

The Second External Review Draft of the Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards is a well-written document that brings to focus the most relevant scientific evidence and technical information in determining whether and how to revise the PM standard for the country. The chapters of the Policy Assessment document are well organized to address primary standards for fine particles ($PM_{2.5}$) and thoracic coarse particles ($PM_{10-2.5}$), as well as secondary standards for PM-related visibility impairment and non-visibility welfare effects. This second draft of the policy assessment is greatly improved over the first version. The staff is to be commended for their efforts to address each of the concerns of CASAC in this second version of the policy assessment.

Charge Question #4: Key uncertainties and areas for future research and data collection. What are the Panel's views on the areas for future research and data collection outlined in this section on relative priorities for research in these areas and on any areas that ought to be identified?

This section of the document provides a list of areas for future health-related research, along with some of the key uncertainties, model development and data collection needs, as well as research and data collection efforts that should be pursued in the future. The list is excellent, but dwells predominantly on those areas to provide further epidemiological evidence of PM-related health effects. Although appropriate and highly desirable, future studies should also include toxicological studies to provide defining and confirming evidence for the biological plausibility of PM-related health effects. These studies should be based on the same premise as posed for the future need for epidemiological evidence in terms of components and sources of PM, the influence of particle size as well as co-pollutant interactions with a particular emphasis on ozone.

This section further recommends new research and analyses for exposure related factors which include intra-city and inter-city differences related to various PM components and size fractions, all excellent points. However, future consideration should also be given to particle transport and aging as a potentially important factor to alter particle effects and toxicity as well. Consideration for new research should also encompass the interaction of climate conditions (i.e. climate change and temperature) on PM incidence, concentrations and distribution, including factors leading to desertification (dust formation), increased wildfires and secondary particle formation. An important research consideration is to further evaluate how ultrafine particles contribute to the $PM_{2.5}$ particle size fraction, both temporally and spatially as these particles undergo accumulation and/or aggregation. The recommended future monitoring measurements of the section are briefly stated, but are timely and relevant. Model development to improve models for estimating $PM_{2.5}$ mass and composition are clearly important as a future research priority.

Mr. Rich Poirot

Pre-Meeting Review Comments on 2nd Draft PM Policy Assessment

Generally, I thought the second draft PAD was a substantial improvement on the first draft – logically reasoned, clearly and concisely presented, and responsive to previous CASAC review comments. My pre-meeting comments are primarily focused on Chapter 4 (secondary visibility standards) and also respond to charge question 9 on the proposed range of levels for a PM_{10} primary standard.

"Controlling" Annual $PM_{2.5}$ vs. 24-hour Peaks
I also wanted to confess ignorance and request clarification on the rationale for the proposed need to "pair" the annual and 24-hour $PM_{2.5}$ standards such that the annual standard would remain the "controlling" standard. I don't understand why this is logical or desirable, as it would seem inconsistent with the observations of separate kinds of effects resulting from acute and chronic exposures to $PM_{2.5}$ pollution. It also seems like this has become, is becoming or soon will become a less desirable air quality management approach as progress is made (and continues with CAIR) on reducing the large regional source influences most important for high annual concentrations over large areas. The scatter plot Figure 2-10 (page 2-75) and the Figure 2-9 box/whiskers on the preceding page do seem to indicate that a majority of US sites have 98th percentile 24-hour concentrations which are about 2.5 times their annual means, but that there are a number of sites particularly in the Northwest that have ratios of 3.5 to 1 or higher. Taking a closer look at data from that region, I think many of these sites are in relatively deep mountain valley locations, with strong winter seasonal early morning peaks under stagnation/ inversion conditions. Much of the "peakiness" here is due to wood-smoke, other heating fuel burning and gasoline motor vehicle and diesel exhaust, which not only reach much higher than average concentrations on bad days but see even more extreme short-term hourly morning peaks during rush hour. Are these sources, their associated carbonaceous aerosols, and extreme temporal exposure regimes so benign that control efforts should focus instead on the summer ammonium sulfate that tends to dominate chronic exposures in areas which exceed annual standards but not the current 24-hour standard?

I also think there could be an important conflict here with health messaging and public communication. States and municipalities issue daily air quality forecasts and during pollution events issue air quality alerts, advisories, action days, etc. based on the "Air Quality Index" which is directly linked to the levels of the NAAQS (and for which EPA still hasn't provided official guidance relative to the current 24-hour $PM_{2.5}$ NAAQS of 35). At a minimum this guidance needs to be updated, and it and the short term standard should reflect short-term concentrations at which effects may be expected for sensitive groups – regardless of whether a controlling annual standard is useful for other purposes.

9. Level (section 3.3.4): What are the Panel's views on the following:
a. The approach taken by staff to identify potential alternative PM10 standard levels, in conjunction with a 98th percentile form, including the weight placed on different studies?

Given the limitations in currently available coarse particle epidemiological studies, the absence of statistically significant results in many of the mortality and morbidity studies, and the stated intent to focus more on urban than rural coarse particles by retaining a PM_{10} indicator (tricky, but I think I like it for now): the approach taken to identify a range of levels for a revised PM_{10} standard, using a 98th percentile form, generally appears to be reasonable.

b. Staff's conclusion that the evidence most strongly supports standard levels around 85 µg/m3?

Part of the stated justification for the upper end of the range was the absence of statistically significant positive associations between $PM_{10-2.5}$ and mortality in single-city studies with 98th percentile PM_{10} concentrations below this level. While there is some logic to use this to help determine an upper bound level, it should also be recognized that there were a number of mortality and morbidity studies showing relatively consistent positive, but non-significant results at lower levels, and that there are a number of factors which will tend to push epi results for coarse particles toward the null hypothesis. $PM_{10-2.5}$ is not measured very precisely, especially when compared to $PM_{2.5.}$ The spatial representativeness of $PM_{10-2.5}$ measurements is also very limited, relative to the density of measurements and difficult to associate with large populations. There are also substantial differences between indoor and outdoor concentrations of $PM_{10-2.5}$, as outdoor concentrations don't penetrate indoors very efficiently and as there are also often large, independent indoor sources of coarse particles, further complicating accurate human exposure assessments. All of the above will tend to push results toward null and/or make them difficult to confirm with high statistical confidence in areas with lower ambient air $PM_{10-2.5}$ concentrations. Thus the upper bound of 85 µg/m^3 may not provide much of a margin of safety.

Another part of the justification for the upper end of the range was the stated intent of not weakening the existing PM_{10} standard of 150 µg/m^3 with an "expected exceedance" form, while transitioning to a more stable (and less sample-size dependent) 98th percentile form. I think there is at least a wee bit of logic to this (don't weaken the status quo) argument, as there is no strong evidence for loosening the current standard. However, I don't agree that this logic necessarily leads to a 98th percentile form at 85 µg/m^3. This judgment seems to be primarily supported by the Figure 3-7 (page 3-39) scatter plot comparing expected exceedance design values with 98th percentile design values for the same recent 3-year periods (the large solid symbols, incidentally, make it hard to really see the data here). The fairly broad scatter indicates that there is a lot of variability in the relationship and that there is no single "equivalence point" for comparing the two metrics; at the 150 µg/m^3 level of the current standard, the 98th percentile counterparts range from about 30 to 130 µg/m^3. A regression line (which doesn't appear to fit the data very well) intersects the 150 µg/m^3 expected exceedences level at a 98th percentile level of about 85 µg/m^3 and so this is taken as the point of "equivalence" and used to support the selection of 85 µg/m^3 as the upper bound for a 98th percentile level. It looks to me like there are many more points below this line than above it – that would be afforded less, and in some cases much less protection that they receive under the current standard. From Table 3A-1 in Appendix 3A, it can be noted that the population protected by current 150 µg/m^3 expected exceedance PM_{10} standard is 32,169,000, and that this would be reduced by about 30% to a protected population of 22,736,000 if an "equivalent" 98th percentile level of 85 µg/m^3 were selected. The 98th percentile form in Table 3A-1 that affords protection to a population that comes closest to that afforded by the current standard is 75 µg/m^3 and I think new 98th percentile standards at levels above 75 µg/m^3 should be recognized as weakening the current standard. So again, I think the upper bound is not especially well justified.

c. The alternative approach to considering the evidence that could support standard levels as low as 65 µg/m3?
I think the rationale for this lower bound is reasonable, and might be further strengthened by noting that there may be good reasons for absence of significant results, and that the relative consistency among many studies finding positive but non-significant results is supportive, and by noting that a standard at this level would reduce, but not eliminate the number of sites for which a 98th percentile form would weaken the current standard.
11. Current Approach (section 4.1.3):
a. What are the Panel's views regarding our approach for translating technical evidence and assessment results into the basis for assessing current fine particle standards and considering alternative standards to provide protection against PM-related visibility impairment?

The approach for translating and presenting the technical evidence and assessment results is logically conceived and clearly presented. The various tables and graphics in Chapter 4 and its associated appendices are very helpful in communicating the inherently complex information that unavoidably results from the evaluation of so many optional combinations of indicators, averaging times, levels and forms.

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standard (section 4.2) and potential alternative standards (section 4.3)?

The detailed estimates of hourly PM light extinction under current conditions and for "what if" scenarios of just meeting current standards clearly indicate that these current standards do not protect against levels of visual air quality which have been judged to be unacceptable in all of the available urban visibility preference studies.

Given the limitation that there are not currently available methods for directly measuring the preferred indicator of PM light extinction, the alternative indicators of hourly $PM_{2.5}$ mass or estimated hourly $PM_{2.5}$ light extinction (composition and humidity-adjusted hourly $PM_{2.5}$ mass) are logical choices for a revised secondary standard. Each indicator has advantages and disadvantages compared to the other. In my opinion, the pragmatic advantages that a $PM_{2.5}$ mass indicator might have over the estimated $PM_{2.5}$ extinction indicator are understated. I also think that there may be reasonable approaches to further simplify the estimated extinction approach that would not significantly compromise its benefits as an effective regulatory metric. See answer to 12b below.

12. Nature of the Indicator (section 4.3. 1): What are the Panel's views on the following:
a. Staff's consideration of the three indicators identified in this section and our conclusions on the appropriateness of these indicators for consideration in this review?

Generally, the 3 indicators evaluated are logical options which essentially span a range from directly measured PM extinction (theoretically ideal but currently impractical) to directly measured (dried) $PM_{2.5}$ mass (easy to implement but not directly representative of visibility effects). The "simplified" estimated $PM_{2.5}$ extinction option is a sort of compromise between the two measurement extremes, although I think that other less complex intermediate options could also be considered.

b. The development and evaluation of a new approach that is based on using speciated PM2.5 mass and relative humidity to calculate PM2.5 light extinction by means of the IMPROVE algorithm?

While this is an approach that could be implemented using existing measurements, I think there may be simpler alternatives that would produce similar results and which should be evaluated. Reflecting back on the comparison of hourly $PM_{2.5}$ mass vs. hourly PM light extinction in Table D-1 of the UFVA document, it can be noted that the average correlation (R^2) is 0.70 across all 14 urban areas (excluding St. Louis with its questionable data) – which I'll first argue is not really all that bad, and is way tighter than the relationships between any other primary or secondary pollutant NAAQS indicator and any associated effect. A number of adjustments could improve upon the quality of an hourly $PM_{2.5}$ mass indicator, but each adjustment adds complexity, and the currently proposed adjustments are very complex for a regulatory metric, and would require combining data from continuous $PM_{2.5}$, filter FRM $PM_{2.5}$, speciation $PM_{2.5}$ (3 filters) and relative humidity measurements (and could only be applied at sites where all of the above were measured). In many states, the continuous data are adjusted to be FRM-like prior to submittal to AQS, but that is typically conducted after the end of each calendar quarter. While the need to use FRM filter data might be eliminated by use of continuous FEM instruments, the proposed use of the (concurrent month) speciation data has the added disadvantage of delaying the availability of the estimated extinction estimate until several months after real time. I question whether the added complexity and time delay is justifiable compared to simpler adjustment approaches.

One simpler approach would be to develop (by regression of hourly $PM_{2.5}$ mass and RH vs. the estimated $PM_{2.5}$ light extinction) a generic "aerosol f(RH)" function. This could be done using historical data on a site-specific or regional basis, and calculated on a seasonal, or even monthly basis if need be. The resulting equations could be used to convert continuous FEM $PM_{2.5}$ mass and RH data to estimated $PM_{2.5}$ extinction in near-real time. A slightly more complex variation on this would be to use the historical speciation data – again on a seasonal basis if warranted, on either a site-specific or regional basis, to develop quarterly composition estimates. These would include seasonal estimates of the hygroscopic mass fractions which could be multiplied by the measured mass and enhanced by IMPROVE f(RH) functions. A third variation would be to discard the current RH data and instead use historical hourly RH averages – again on a quarterly or monthly basis and expressed as site-specific or regional averages. Following somewhat the logic of the regional haze rule, the use of climatologically derived RH and f(RH) functions might reproduce actual hourly PM light extinction less perfectly, but might still be a better regulatory metric. Arguably it would be more effective to reduce concentrations of hygroscopic species on months and hours of day when the combinations of pollutant concentration and RH have tended (and will tend) to be highest, rather than the specific month and hour of day when an extreme event occurred.

I'm confident that any of the above approaches would represent a substantial improvement over the use of fine mass alone as an estimator of visibility effects, but the calculations would be simpler and could be done one time, in advance, so that the resultant estimated light extinction could be reported in near-real time, employed as a public communication tool, compared to real-time extinction measurements as they evolve (or as ASOS scattering data become available at higher resolution, which is happening now), etc. If regional average equations worked reasonably well, an advantage would be to allow the extinction estimates to be made at all (> 550) continuous $PM_{2.5}$ sites – not just the (<200) sites with speciation data (and far fewer, I suspect where FRM and CSN – running every 3rd day are collocated with continuous $PM_{2.5}$.

This reminds me to suggest that it could be useful to see a table or map indicating the numbers and locations of Continuous, FRM and Speciation $PM_{2.5}$ sites and indications of where all the above (with the filters running every 3rd day) are collocated (maybe also including continuous PM_{10} if there are many of those out there collocated with $PM_{2.5}$.

c. The assessment approach and results comparing the PM components that contribute to the hours selected in the top percentiles for PM2.5 mass and PM10 light extinction?

The approach and results comparing PM components that contribute to the highest extinction percentiles are logically contrived and clearly presented. As a practical matter, I don't think its likely that states or municipalities will develop vastly different source control strategies based on relatively subtle differences in the regulatory metrics. For example, it's unlikely that a lot of effort would be "wasted" on visibility-inefficient attempts to control fine soil if a $PM_{2.5}$ mass indicator was selected. Nor are there practical options for sub-daily reductions in hygroscopic sulfates and/or nitrates that might be directed toward "the wrong hours" if a mass indicator, or a percentile based on all daylight hours was employed.

13. Alternative Levels and Forms (section 4.3.3): What are Panel views on the following:
a. The performance assessment which focused on the Candidate Protection Levels of 64, 112, 191 Mm-1 for PM2.5 light extinction and speciated PM2.5 mass-calculated light extinction, and alternative levels of 10, 20, and 30 µg/m3 for PM2.5 mass concentration?

These ranges of levels for $PM_{2.5}$ light extinction, estimated extinction and fine mass indicators are logically derived, and the performance assessments for exceeding/ attaining these various candidate protection levels are clearly presented. Various combinations of CPLs and percentiles could be considered which would affect the spatial extent, frequency and severity of non-attainment of a visibility-related secondary standard. Because visibility is so sensitive to impairment by concentrations of fine particles and associated water (i.e. particles as they exist in the ambient air), it should be expected that levels of PM light extinction considered "acceptable" to human observers would be exceeded relatively frequently in many areas and by relatively high margins in some areas. Attaining specific threshold conditions may be especially difficult and require very long-term strategies in areas subject to frequent high humidity, stagnation or inversion conditions, or persistent regional transport influences. Consequently, guidance provided by EPA on the expected pace, or rate of progress toward attaining the secondary standard in the implementation phase is likely to become an important component of the standard's ultimate performance, which would modify the "stringency" of any specific combination of level and form.

As indicated previously, there may be some advantages to using a $PM_{2.5}$ mass indicator (at least on an interim basis until more direct PM light extinction methods can be developed and evaluated). Compared to an extinction indicator, a mass indicator would tend to de-emphasize somewhat the importance of hygroscopic sulfate and nitrate scattering aerosols, which tend to impair visibility (and as Ted points out exert a cooling effect on climate) over relatively large areas, and emphasize the relative importance of more locally produced carbonaceous aerosols which might have both visibility and climate benefits. A mass indicator would also somewhat reduce the differences in stringency between the East and West, and at a given level might be somewhat more feasible to attain in the more humid (and possibly less scenic) East while affording greater protection in the dryer (and more scenic) West. This option might be worth considering if EPA is not able to utilize a "progress-based" approach in implementing a secondary standard.

b. Use of three-year averaged 90th and 95th percentiles in conjunction with a 1-hour daily maximum form and use of three-year averaged 98th percentile in conjunction with the all daylight hours form?

The illustrations provided indicate that the choice between a 90^{th} or 95^{th} percentile with a 1-hour daily maximum form or a higher 98^{th} percentile based on all daylight hours does not really seem to have much effect on the species implicated or the kinds of control strategies that would be most effective. I don't really think the different "susceptible population" exposure arguments make are especially compelling either, and believe a choice between these two functionally similar options could be made for other reasons. For example, the single worst daylight hour is a simpler calculation, although it would also be more susceptible to measurement noise that effects some of the continuous $PM_{2.5}$ mass measurement instruments.

c. Insights to be drawn by comparing the PM components for hours included among the 10% highest for a 1-hour daily maximum form with the hours included among the 2% highest for an all daylight hours form, for the various indicators considered (Appendix C)?

See answer to B above. Note that I've also suggested alternative approaches for estimating hourly extinction that would permit simpler and more timely hourly extinction estimates. Occasionally these simpler estimates could be distorted – for example if a moderate forest fire or fine dust impact was occurring during a period of high humidity and historically projected high sulfate concentration. Use of the single worst hour per day would simplify the task of identifying and correcting such occasional outliers.

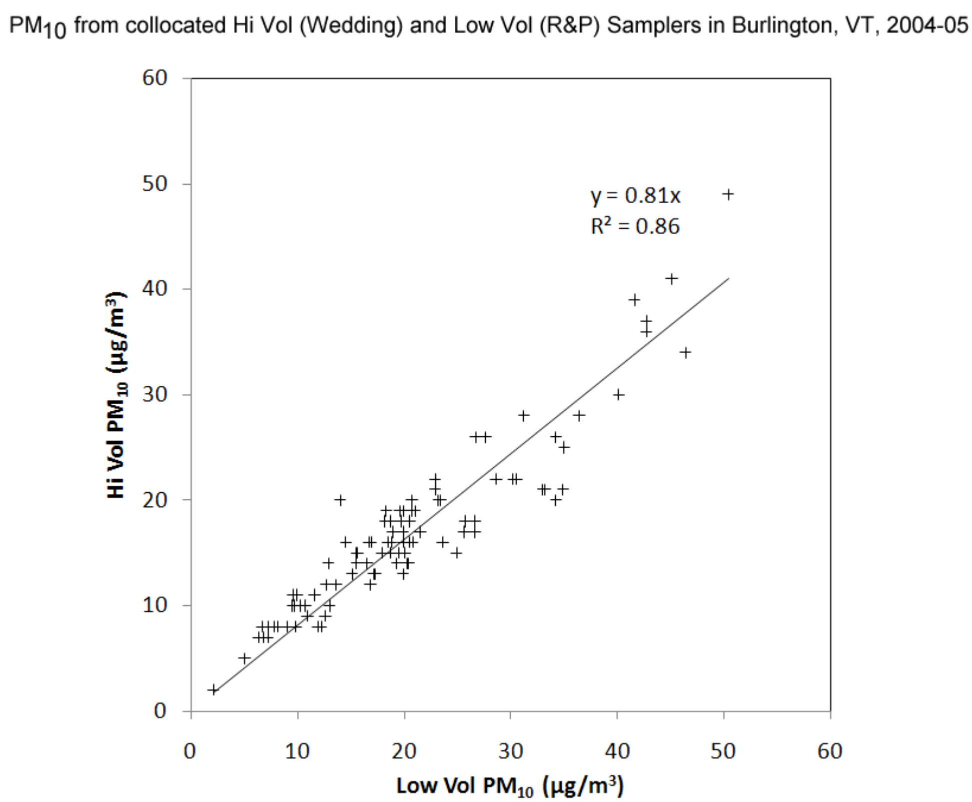
14. Key Uncertainties and Areas for Future Research and Data Collection (section 4.5): What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

Generally, I think this section is very good and identifies several important research needs for the near future. Often however, the best laid plans…never get funded. In this case I think expanded visibility preference studies and establishing a small pilot urban visibility monitoring network (which includes some support for instrument development and evaluation) would be extremely valuable.

Post-meeting Review Comments on Second Draft PM PAD

PM_{10} Indicator for Coarse Particles

This didn't get discussed at the 7/25-26/10 meeting, but I wanted to suggest, belatedly, that in revising the PM_{10} standard, EPA should consider specifying the low volume PM_{10} method as the sole federal reference method (FRM). Currently, both low volume and high volume PM_{10} methods are designated as FRMs, although they have consistently been demonstrated to produce different results in field and laboratory comparisons – with the high volume method typically showing lower concentrations. For an example showing differences of 25% to 35% in an area with very high PM_{10} and coarse mass concentrations, see: Ono, D.M., E. Hardebeck, J. Parker, and B.G. Cox (2000) Systematic Biases in Measured PM_{10} Values with U.S. Environmental Protection Agency-Approved Samplers at Owens Lake, California, *J. Air & Waste Manage. Assoc.* **50**:1144-1156. For an example showing differences of about 20% from an area with relatively low PM_{10} and coarse mass, see the example below from Burlington, VT.



Wind tunnel tests have generally demonstrated similar results and show the hi volume PM_{10} samplers can have cut points significantly less 10 microns, especially under high wind conditions. The recently established FRM for $PM_{10-2.5}$ (by difference) specifies low volume PM_{10} (and $PM_{2.5}$) samplers. If the PM_{10} standard is revised with the intention of providing better protection against coarse particle effects, it would be a timely opportunity limit the FRM to low-volume samplers. This would afford better protection, assure more consistent data across space and time, increase the collection of and assure better consistency with $PM_{10-2.5}$ measurements, and produce samples on Teflon (rather than quartz) filters more conducive to speciation analysis - for PM_{10} and for $PM_{10-2.5}$ (by difference).

Dr. Ted Russell

Overall, this draft of the PM PAD is much improved and lays the foundation for informing the revision of the PM standards, providing both a synopsis of the prior documents and the procedure used to develop suggestions for the revisions. Their conclusions are generally supported by the information in the prior documents and have been responsive to CASAC's prior comments as well. My areas of disagreement/concern are rather specific as discussed below.

My major concern has to do with consideration for the potential of the tightening of the standards to exacerbate climate warming if the appropriate fraction of PM is not preferentially controlled. This concern has to do most with the level at which the secondary standard. Decreasing light scattering aerosols will improve visibility, but increase radiative forcing. It would be better to focus on reducing light absorbing aerosols to both improve visibility and potentially reduce warming (there is uncertainty about the latter). There is also a growing body of evidence that EC is more strongly associated with various health impacts, so in the implementation, focusing on EC controls would be a win-win.

Chapter 3

7. Indicator (section 3.3.1): What are the Panel's views on the approach taken to considering standard indicator and on staff's conclusion that PM10 remains an appropriate indicator in this review?: As noted previously, I view the use of PM10 as a reasonable choice as laid out by the PAD.

8. Form (section 3.3.3): What are the Panel's views on the approach taken to considering the form of the standard and on staff's conclusion that revising the form to a 98th percentile form would be appropriate for a 24-hour PM10 standard meant to protect against exposures to thoracic coarse particles? Using a multiyear average of a percentile (e.g., 98^{th} in this case) is reasonable and consistent with other pollutants. I may differ with others in that I prefer a multiyear average of the 98^{th}%ile as opposed to the 98^{th} %ile of a multiyear distribution, both for consistency with other pollutant standards (particularly for PM2.5) and for stability for planning purposes.

9. Level (section 3.3.4): What are the Panel's views on the following:
a. The approach taken by staff to identify potential alternative PM10 standard levels, in conjunction with a 98th percentile form, including the weight placed on different studies?
b. Staff's conclusion that the evidence most strongly supports standard levels around 85 µg/m3?
c. The alternative approach to considering the evidence that could support standard levels as low as 65 µg/m3?
The approach used by staff in determining an appropriate level is consistent with the approach used for other pollutants and PM2.5, and is based on the relevant health studies. If the 24-hr PM2.5 standard is tightened, however, this would argue for tightening of the 24-hr PM10 standard beyond the "around 85" (or below 65 if one is persuaded that the standard should be effectively tightened) currently proposed to maintain the appropriate level of $PM_{10-2.5}$ allowed. (That is, the approach

might be posed as taking the 24 hr PM2.5 and adding 50 (or 30, if you want to go with the tighter level). Their reasoning for considering a level as low as 65 is viable, and they note that while studies tended to have a decrease in statistically significant positive results at the lower levels, a bulk of the studies (but not all) still found positive associations. Another reason to explore levels below 85 is that some areas that meet an 85 98th %ile can have levels above the 150 current standard, so this would effectively loosen the standard.

Chapter 4.

12. Nature of the Indicator (section 4.3. 1): What are the Panel's views on the following:
a. Staff's consideration of the three indicators identified in this section and our conclusions on the appropriateness of these indicators for consideration in this review?
b. The development and evaluation of a new approach that is based on using speciated PM2.5 mass and relative humidity to calculate PM2.5 light extinction by means of the IMPROVE algorithm?
c. The assessment approach and results comparing the PM components that contribute to the hours selected in the top percentiles for PM2.5 mass and PM10 light extinction?

Staff has laid out three potential indicators:

1. PM2.5 mass
2. Directly measured PM2.5 light extinction
3. Mass-calculated light extinction

First, if the secondary effect of interest is PM impacts on visibility, the indicator should include all components of PM that impact visibility unless reasoned otherwise. If we are going to directly measure light extinction, there are good reasons to limit the measurements to just those particles less than PM2.5, driven largely by instrumental concerns, and supported by the more widespread impacts of fine PM versus coarse. If there are no instrumental limitations, the inclusion of PM-coarse on visibility should be included or argued away with sound reasoning.

Each of the three has potential benefits, strengths and weaknesses. The PM2.5 mass indicator is the easiest to implement, but as shown both here and the UVFA it is not necessarily a good indicator of light extinction. What is not shown is that the relationships developed for each city will also vary with time, adding further uncertainty in using PM2.5 mass as an indicator for visibility degradation. The use of a mass indicator would not necessarily lead to selecting strategies that are selected to improve visibility the desired amount. Given the problems with this indicator, and the advantages of the other two, it should be ruled out. EPA does not provide a strong argument for its consideration. Further, a reasoned argument for not including PM coarse impacts should be given. Appendix 4 provides some evaluation of the use of a PM2.5 mass indicator, but does not address concerns about the extent of control that would be needed to provide the desired light extinction.

Measuring light extinction directly has the benefit that you are truly measuring the quantity of concern. Technologies exist currently, and others are being tested and further developed, to provide such information, and such information can augment our understanding of atmospheric dynamics of the pollutants that impact health and visibility. On the other hand, those instruments do not provide information, directly, on the species leading to visibility degradation.

A PM2.5 Speciated Mass Calculated Light Extinction Indicator has the advantage of giving results that are likely close to the actual light extinction due to PM2.5 aerosol and relies on current measurements. On the other hand, the performance of the proposed approach has not been tested against direct measurements (currently, it has been model-to-model evaluation) and there have been a variety of simplifications added to simplify the procedure. A particular concern is that concentrations of constituents of PM2.5 correlate with RH and aerosol water content (e.g., nitrate, and components of organic carbon). At present, there are only 24-hour average measurements of those constituents, so the likely periods where visibility is most degraded (where RH is high), will also have higher nitrate and OC that would not be captured in a daily (or longer) average composition. Further, both those constituents can be lost in some continuous and/or integrated measurements, adding further uncertainty to correctly calculating the actual visibility reduction at the time of the peak hourly extinction. Until continuous measurements of the components of PM2.5 are employed, this issue is going to plague this approach. Thus, while much better than just using PM2.5 mass, this approach can lead to incorrect estimates of visibility degradation, and we currently do not know the extent of this problem. One issue that arises with choice of this indicator as other than a bridging approach (to bridge between now and the time direct measurements can be used) is that if this were to be the indicator of choice, it might as well include PM-coarse. A driving reason to just consider just PM2.5 impacts on visibility is instrumental if this is not being used to bridge the gap.

As an aside, the limit of 90% RH has an added benefit beyond instrumental considerations, that being f(RH) in the extinction calculation goes up dramatically with RH beyond 90%, and at 90% it is about 4. Above 3.3, it biases the controls to sulfate and nitrate and away from EC on a per mass basis (my climate-related concerns).

As a note, Appendix 4 provides critical support for the arguments laid out in support of the three indicators. However, it is a very difficult read, and it would help if they could identify the major questions being addressed and provide more succinct responses with the appropriate foundation. At present, they provide too many graphs and tables without targeted summary graphs and tables. Also, on 4b-22, there is an error in that a slope of 1.07 does not indicate a bias of 7% unless the intercept is zero. (Otherwise, LA and NY would have negative biases, which are impossible.) Further, you should not change scales in the graphs when asking for people to use them for comparison. Having a series of stacked, colored bar charts is not a very good way to provide a quantitative understanding of relationships. Other figures/tables can be more informative in this case.

13. Alternative Levels and Forms (section 4.3.3): What are Panel views on the following:
a. The performance assessment which focused on the Candidate Protection Levels of 64, 112, 191 Mm-1 for PM2.5 light extinction and speciated PM2.5 mass-calculated light extinction, and alternative levels of 10, 20, and 30 µg/m3 for PM2.5 mass concentration?
b. Use of three-year averaged 90th and 95th percentiles in conjunction with a 1-hour daily maximum form and use of three-year averaged 98th percentile in conjunction with the all daylight hours form?

c. Insights to be drawn by comparing the PM components for hours included among the 10% highest for a 1-hour daily maximum form with the hours included among the 2% highest for an all daylight hours form, for the various indicators considered (Appendix C)?

a) I might recommend not including three significant digits in the CPLs if the final direction chosen goes that way. In terms of level, given my climate-concerns, I would tend towards the less stringent end of the spectrum unless there are some safeguards as to going after the warming components first.

Q14: Uncertainties and Areas for Future Research and Data Collection: They have captured some of the key research areas and uncertainties (e.g., visibility preference studies). However, as part of the light extinction measurement/monitoring program, instrument development should be added. Another key uncertainty in terms of setting a visibility standard is assessing the impact of such a standard on potential climate forcing. This would be a somewhat involved study looking at potential regional climate changes from reducing specific components of PM, and it is recognized that this would be pushing present modeling approaches. A general concern of mine is that the potential adverse consequences of reducing components of PM2.5 that would lead to warming have not been adequately wrapped in to the considerations of the current review. Warming will have both health and welfare implications. While I agree that there are significant uncertainties in the climate responses, the likely outcomes should influence the choice of a standard (thus my tendency to a less tight secondary standard unless something is done to focus on the warming components).

Dr. Frank Speizer

General Comment: Staff should be congratulated on an excellent job of incorporating suggestions from CASAC as well as streamlining the PA. The addition of an Executive summary and the format used within the text should go a long way as a model for the future. Most of my comments below (in bold) represent minor "tweeking" of the text and might be considered alternative semantics. There are a few places where they might bear discussion of emphasis.

Charge to the Panel in Reviewing the Second Draft PM Policy Assessment
Chapter 2 (Primary Standards for Fine Particles)
1. Current Approach (section 2.1.3)*:*
a. What are the Panel's views on the staff's approach to translating the available epidemiological evidence, risk information, and air quality information into the basis for reaching conclusions on the adequacy of the current standards and on alternative standards for consideration?

Section 2.1.3 provides a logical and thorough discussion of the approach to be applied. Although I previously questioned the usefulness of imbedding rhetorical questions in the text (see beginning of section 2.2) I am now convinced that this is helpful since it better focuses the discussion within each section and provides a logical sequence to the discussion.
I applaud the staff for expanding the discussion on evidence of life stages of risk as well as specific susceptibility risk factors and the introduction of the use of combined empirical data and risk assessment.
With regard to the adequacy of the current standard, it may only be a matter of semantics, but I would suggest that the statement at the bottom of page 2.30 is not quite strong enough. The data presented more than adequately indicate that that the current standard is not as protective with a margin of safety and thus to indicate that the data "call into question" the adequacy could have be more forcefully indicated to say that the current standard is simply not protective. That is what the rest of the paragraph says. Ditto the consideration of the risk assessment data and as indicated bottom of page 2.43.

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standards (section 2.2) and potential alternative standards (section 2.3)?
Yes

2. Form of the Annual Standard (section 2.3.3.1):
a. What are the Panel's views on the additional analyses conducted to characterize the potential for disproportionate impacts on susceptible populations, including low income groups and minorities associated with spatial averaging allowed by the current annual standard?

Good job in raising the logic of the issue and why it would be inappropriate to continue to rely on spatial averaging

b. In light of these analyses, what are the Panel's views on staff's conclusion that the form of the annual standard should be revised to eliminate spatial averaging?

Top of page 2.54: Although this is an attempt to correct a deficiency with regard to identifying the problem of highest values apparently being recorded in area of lowest social class and potentially minority population, it is not clear that the wording solves the problem. "…measurements made at the monitoring site that represents "community-wide air quality" recording the highest PM2.5 concentration". I think a footnote is need to define "community-wide air quality" For example, what if there is a pocket of folks living in a highly impacted area but they are small enough that they would not be considered "community-wide" These might be the only blacks living in a 1 mile radius in a 10 mile radius town and thus would not be considered "community wide".

3. Alternative Levels (section 2.3.4): *What are the Panel's views on the following:*
a. The insights that can be gained into potential alternative standard levels by considering:
i. Confidence bounds on concentration-response relationships?

It would appear that Staff is not confident enough in the existing data to use the widening of confidence bounds as a measure of where uncertainty becomes important. However, in their evaluation of the data it seems clear that until one reaches about 12ug/m3 for the annual average the confidence bounds are relatively tight and thus, I would have thought that Staff could have used this number as a "benchmark" with which to assess other alternatives with more confidence than expressed.

ii. Different statistical metrics that characterize air quality distributions from multicity epidemiological studies?

The arguments given for using the composite monitor and the maximum monitor distributions are well presented. The arbitrary selection of 1 SD below the max mean is logical and consistent with the data in terms of keeping uncertainty at a minimum, however, it is clear that much of the uncertainty below that level relates to lack of data rather than increased variability. Thus, the more conservative alternative of assessing between 25-10 percentile should not be off the table.

b. Potential alternative annual standard levels based on composite monitor distributions versus maximum monitor distributions?

The differences between these two alternative seem to me minimal and more semantic in interpretation than actually change the concluding numbers.

c. Use of risk information in informing staff conclusions on alternative annual and 24-hour standard levels, including approaches used to assess overall confidence and potential bias in the risk estimates?

Provides additional confidence that the conclusion are not wildly different comparing risks.

d. Staff's conclusion that alternative annual standard levels in the range of 13 to 11 µg/m3 are most strongly supported by the available evidence and risk-based information?

Agreed.

e. Staff's approach of focusing on peak-to-mean ratios to inform the level of a 24-hour standard that would provide supplemental protection to a generally controlling annual standard?

This appears to be an important consideration and is appropriate. However, it is not clear that it is adequately dealt with in discussion, since the discussion seems to focus on two not necessarily matched alternatives. (Eg. 13-11ug/m3 with a 24 hour of 35; and 11ug/m3 with a 24 hour of 30). There should be a whole range in between, and figure 2-10 suggests that Northwest is truly out of bounds with either. Does this suggest that the peak-to- mean doesn't work?

f. Staff's conclusion that consideration should be given to retaining the current 24-hour standard level of 35 µg/m3 in conjunction with annual standard levels in the range of 13 to 11 µg/m3, and that consideration could also be given to an alternative 24-hour standard level of 30 µg/m3 particularly in conjunction with an annual standard level of 11 µg/m3?

See above.

4. Key Uncertainties and Areas for Future Research and Data Collection (section 2.5):
What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

The list of key areas of research is comprehensive and covers the main areas to be considered. Although mentioned I would have like to have seen a more full discussion of potential for changes in effects associated with time over the life course of populations. With regard to relative priorities, I believe, wisely, Staff has avoided ranking the various research need. However, it may be worth a discussion by CASAC and Staff as to whether one or two of the categories might be emphasized. For example, have we reach the stage where the focus should be on components of PM and or co-pollutants over and above further data in other categories? By taking these two arenas on can we incorporate many of the other suggested areas both to reduce uncertainty and improve understanding?

Chapter 3 (Primary Standard for Coarse Particles)
***5. Current Approach (sections 3.1.4, 3.2, 3.3)**:*
a. What are the Panel's views on the approach to translating the available evidence and air quality information into the basis for reviewing the coarse particle standard?

Unfortunately, the approach seems to indicate that studies of PM10-2.5 which are few in number and interpreted only as suggestive for cardiovascular and respiratory disease. At least a summary of how the PM10 studies are to be included, to bolster the logic of retaining PM10 as a surrogate for course particles, with all the appropriate caveats, should be included. (To try to understand this better I went back to the on-line version of the Final ISA (Dec 2009) and found that figure referred to as 6.2 on page 6.66 is not printed appropriately. This is unfortunate as it represents the IHD data and should be more impressive than figure 6.3 which is CHF).

b. Has staff appropriately applied this approach in reviewing the adequacy of the current standard (section 3.2) and potential alternative standards (section 3.3)?

In contrast to the above introduction, the PM10 data are presented, which would seem appropriate.

6. Adequacy of the Current PM10 Standard (section 3.2): *What are the Panel's views on the alternative approaches presented for considering the evidence and its uncertainties as they relate to the adequacy of the current standard?*

Although the conclusion seems to be right, not contained in this section is the logic of why PM10 effects (since there are only suggestive effects for PM10-2.5) translate to a range of potential concerns below the current standard for PM10. All of the discussion seems to focus on the few positive PM10-2.5 studies.

7. Indicator (section 3.3.1): *What are the Panel's views on the approach taken to considering standard indicator and on staff's conclusion that PM10 remains an appropriate indicator in this review?*

From middle of page 3.27 to end of section I think the logic is well presented and supported by the data.

8. Form (section 3.3.3): *What are the Panel's views on the approach taken to considering the form of the standard and on staff's conclusion that revising the form to a 98th percentile form would be appropriate for a 24-hour PM10 standard meant to protect against exposures to thoracic coarse particles?*

See below, as Staff seems to want to consider these two questions together.

9. Level (section 3.3.4): *What are the Panel's views on the following:*
a. The approach taken by staff to identify potential alternative PM10 standard levels, in conjunction with a 98th percentile form, including the weight placed on different studies?

Appropriately, more weight is given to the multi-city studies over the single city studies. Although it is not clear that the impact of which studies are chosen to consider in setting an upper bound of 85 ug/m3 is really any better supported than any other number. The 98th percentile value of 87 seems to keep all sites below the level where effects are seen with PM10-25, but there are so few studies I certainly do not have a lot of confidence in these numbers. Table 3.2 offers some confidence but not much that there really are differences between 150 and 87, particularly at the higher sites. I think the specific level for consideration will need to be discussed and better logic provided.

b. Staff's conclusion that the evidence most strongly supports standard levels around 85 µg/m3?

See above.

c. The alternative approach to considering the evidence that could support standard levels as low as 65 µg/m3?

See above.

10. Key Uncertainties and Areas for Future Research and Data Collection (section 3.5):

What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?

All of the usual suspects are mentioned. The emphasis need to be simply put on more data, with uniform or standardized measures of PM10-2.5.

Dr. Helen H. Suh

2. Form of the Annual Standard (section 2.3.3.1):
a. What are the Panel's views on the additional analyses conducted to characterize the potential for disproportionate impacts on susceptible populations, including low income groups and minorities associated with spatial averaging allowed by the current annual standard?

b. In light of these analyses, what are the Panel's views on staff's conclusion that the form of the annual standard should be revised to eliminate spatial averaging?

The additional analyses and their explanation seem appropriate and provide additional justification in favor of the elimination of spatial averaging. The elimination of spatial averaging makes sense and is appropriate.

9. Level (section 3.3.4): *What are the Panel's views on the following:*
a. The approach taken by staff to identify potential alternative PM10 standard levels, in conjunction with a 98th percentile form, including the weight placed on different studies?

b. Staff's conclusion that the evidence most strongly supports standard levels around 85 µg/m3?

c. The alternative approach to considering the evidence that could support standard levels as low as 65 µg/m3?

The approach and considerations in identifying potential alternative PM_{10} standard levels is appropriate. The discussion regarding the weight on different studies was clearly and cogently presented. However, even with the various study weighting options, it is not clear from the epidemiological study results that a PM_{10} standard level of 85 ug/m^3 protects public health with a sufficient margin of safety from the impacts of coarse particle exposures. The case seems stronger in support of standard level of 65 ug/m^3.

Dr. Sverre Vedal

3. Alternative Levels (section 2.3.4): *What are the Panel's views on the following:*

a. The insights that can be gained into potential alternative standard levels by considering:

i. Confidence bounds on concentration-response relationships?
It was good to see progress made in attempting to use these bounds in focusing on levels of the standard. There are some issues, however. First, it appears that a comprehensive effort was made to identify relevant studies reporting bounds on C-R relationships; this should be stated. Second, it seems that what is stated regarding what these bounds do not indicate ("these analyses do not provide evidence of a concentration below which the confidence interval becomes notably wider and uncertainty in a C-R relationship substantially increases" [p.2-57]) is exactly what they in fact do indicate. It is important to understand not only that the widening of the confidence bounds at lower concentrations is partly due to there being less data at those concentrations (as acknowledged by staff), but that this is itself a source of uncertainty about which we are interested. This does not make these bounds less useful, but in fact provides the information that we want to glean from them. Third, I do not agree with the conclusion that these bounds cannot be used to inform us about alternative levels of the PM NAAQS, even with the limited C-R functions shown. Staff should be encouraged to integrate the information available on relevant C-R confidence bounds with that on study concentration distributions in arriving at a range of levels for consideration.

There are several ways in which one might use findings from epidemiological studies to arrive at a suggested range of levels for consideration. Most ideal would be information on the concentrations that were most influential in generating the health effect estimate in individual studies. Less ideal, but still useful, would be information on the distribution of concentrations in the population sample employed in individual studies. For time series studies, because of the similar number of events (e.g., deaths) per day, this is likely to be the same as the PM concentration distribution; this is probably not the case for cohort studies. Least ideal is using PM concentration distribution metrics, such as those used by staff in arriving at a range of levels for consideration. An attempt should be made, as much as possible, to integrate this latter approach with aspects of the first two approaches, realizing that the reported study findings needed to accomplish this may not be readily available.

ii. Different statistical metrics that characterize air quality distributions from multicity epidemiological studies?
Obviously there is a relationship between these distributions and the confidence bounds on the C-R functions, but the relationship is complex. It must be realized that this approach (use of air quality distributions) is not the ideal one, but one that is utilized here because of perceived inadequacies in the use of C-R bounds for this purpose. Selection of concentrations "just somewhat below" the long-term mean concentrations in epidemiological studies is obviously arbitrary, as is use of concentrations "substantially below" these means. Selection of 1SD below the mean is also as arbitrary as any of the proposed percentiles (25^{th} or 10^{th} percentile, for example). Also, I don't understand why 1 SD is "a more comparable statistical measure across studies" (p.2-65, line 21) than are percentiles. Consideration of alternative percentiles provides for intuitive sensitivity analyses.

b. Potential alternative annual standard levels based on composite monitor distributions versus maximum monitor distributions?

This choice is intended to provide for some margin of safety in an indirect way, recognizing that standards use metrics based on maximum concentration distributions. Again, it would be preferable to use the C-R functions themselves for this purpose. I don't understand why using the composite vs. maximum monitor distributions is more robust when all of these data should be available. I'm not sure that defending the use of composite vs. maximal on the basis that the former were what were used in the epidemiology studies is much of an argument, as opposed to arguing in favor of the latter because that corresponds more with the form of the standard.

c. Use of risk information in informing staff conclusions on alternative annual and 24hour standard levels, including approaches used to assess overall confidence and potential bias in the risk estimates?
No comments to make at this point.

d. Staff's conclusion that alternative annual standard levels in the range of 13 to 11 $\mu g/m^3$ are most strongly supported by the available evidence and risk-based information?
The concentration distribution approach to linking epidemiological findings and proposed revisions to the PM NAAQS has focused attention on concentrations as low as 11 and 10 mcg/m3, which are below those supported by the Panel earlier. Also, as I anticipated, endpoints characterized in the ISA as having a "suggestive" causal link with exposure, once incorporated into this analysis, end up influencing the concentrations of interest in considering the standard. I do not think this is appropriate.

e. Staff's approach of focusing on peak-to-mean ratios to inform the level of a 24-hour standard that would provide supplemental protection to a generally controlling annual standard?
The argument that 35 mcg/m3 is a reasonable 24-hr standard because it is at least 2.5 times greater than the suggested annual standards (13 to 11 mcg/m3; p.2-73) does not seem to be relevant. The 24-hr standard should be based on health considerations, not observed concentrations. Arguing that considering an annual standard of 11 mcg/m3 (with a 24-hr standard of 30) retains the annual standard as the controlling standard is no argument at all (p.2-74). Obviously a lower annual standard, whatever it is, will retain its role as the controlling standard. Again, the 24-hr standard should be based on health considerations, not observed concentrations or observed ratios.

f. Staff's conclusion that consideration should be given to retaining the current 24-hour standard level of 35 $\mu g/m^3$ in conjunction with annual standard levels in the range of 13 to 11 $\mu g/m^3$, and that consideration could also be given to an alternative 24-hour standard level of 30 $\mu g/m^3$ particularly in conjunction with an annual standard level of 11 $\mu g/m^3$?
As noted above (section e.), the latter conclusion is based on a strange argument.

g. *Additional points*:
1. The risk assessment only went down to an annual concentration of 12 mcg/m3. The Panel did not recommend doing a risk assessment for lower concentrations.

2. I believe (but could be wrong) that the Panel recommended the hybrid rollback approach to estimated risk reduction and remaining risk rather than the two extreme alternative approaches of proportional (used here) or locally-focused rollbacks.

4. Key Uncertainties and Areas for Future Research and Data Collection (section 2.5):
What are the Panel's views on the areas for future research and data collection outlined in this section, on relative priorities for research in these areas, and on any other areas that ought to be identified?
This section, as written, has more to do with future research priorities than with uncertainties that influence decisions on revisions to the PM2.5 NAAQS. What is outlined here is a very broad and ambitious research agenda. It would help to begin this section with a prioritized review of key uncertainties in order to help establish priorities among the suggested research topics. Obviously the key uncertainty is that regarding the concentrations that are most responsible for the observed health effects in the epidemiological studies, and the degree of certainty in effects at the lower concentrations along the C-R relationship. This uncertainty has necessitated the less than ideal use of the distributional measures of concentrations from the epidemiology studies in attempting to make the link between the epidemiological findings and PM NAAQS levels to consider. While this uncertainty is reflected in two (p.2-88 and 2-90) of a long list of recommendations for future research that C-R functions include confidence bounds, this uncertainty should be highlighted. This further motivates the more general point that there should be some prioritizing of research recommendations that are most critical for future revisions to the PM NAAQS, rather than simply the itemization presented here.

With respect to the recommendations listed, these are reasonable and would provide useful information for the NAAQS setting process.