Compendium of Preliminary Pre-Meeting 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 3
Mr. Ed Avol 6
Dr. Joseph D. Brain 10
Dr. Wayne Cascio 13
Dr. Joseph J. Helble 19
Dr. Rogene Henderson 22
Dr. Morton Lippmann 26
Dr. William Malm 31
Mr. Tom Moore 36
Dr. Robert Phalen 38
Dr. Ted Russell 39
Dr. Frank Speizer 43
Dr. Helen H. Suh 47
Dr. Sverre Vedal 49

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 $PM_{2.5}$ mass and relative humidity to calculate $PM_{2.5}$ 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 $PM_{2.5}$ mass and PM_{10} 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 $PM_{2.5}$ 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?

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?

<u>Minor Comments (typos, etc)</u>
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?

****

<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 10μ--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 prefered.

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 μg/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 PM_{10} 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 PM_{10} 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 PM_{10} standard meant to protect

against exposures to thoracic coarse particles?

Comment: Based on the discussion provide by the EPA staff the 98th 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 PM_{10} 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} 98th 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 $PM_{10-2.5}$ 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 $PM_{10-2.5}$ 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 $PM_{10-2.5}$, 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. 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*
> *$PM_{2.5}$ mass and relative humidity to calculate $PM_{2.5}$ 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 $PM_{2.5}$ mass and PM_{10} 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 $\mu g/m^3$ 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 PM_{10} 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 coarse thoracic 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 PM_{10} 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 PM_{10} standard meant to protect against exposures to thoracic coarse particles?
The document makes a good case for using the 98th% 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 PM_{10} 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 4th highest concentration in 3 years, and 85 *u*g/m^3 for the 98th %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 coarse thoracic 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 90th percentile for 1-hr maximum and a 98th 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 $PM_{2.5}$ mass and relative humidity to calculate $PM_{2.5}$ 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 $PM_{2.5}$ mass and PM_{10} 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 $PM_{2.5}$ 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, 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 $PM_{2.5}$ concentration would necessarily result in visual ranges that vary somewhat in urban areas across the country, reflecting the variability in the correlations between $PM_{2.5}$ concentrations and light extinction."* 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.

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.

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. 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 PM_{10} 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 PM_{10} standard meant to protect against exposures to thoracic coarse particles?
Using a multiyear average of a percentile (e.g., 98th in this case) is reasonable and consistent with other pollutants. I may differ with others in that I prefer a multiyear average of the 98th%ile as opposed to the 98th %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 PM_{10} 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/m^3?
c. The alternative approach to considering the evidence that could support standard levels as low as 65 µg/m^3?
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 $PM_{2.5}$ 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?

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 $PM_{2.5}$ 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?
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 PM_{10} 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 PM_{10} 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 98_{th} percentile form would be appropriate for a 24-hour PM_{10} 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 PM_{10} standard levels, in conjunction with a 98_{th} 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 $\mu g/m^3$?

See above.
c. The alternative approach to considering the evidence that could support standard levels as low as 65 $\mu g/m^3$?

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 PM_{10} 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. However, comments and interpretations relating to the use of these bounds seem inadequate and confused. First, it is not known how comprehensive an effort was made to identify studies reporting bounds on C-R relationships. There are likely some that have not been included. 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), and that this is itself a source of uncertainty. This does not make these bounds less useful, but in fact provides exactly that 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.

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 (25th or 10th 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.

How are the within-city and between-city pollutant distributions handled in WHI (Fig 2-7)? Have staff limited this to only between-city distributions?

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 must 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 24-hour 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 has more to do with future research priorities than with uncertainties that influence decisions on revisions to the PM NAAQS. Obviously the key uncertainty is that regarding the concentrations that are most responsible for the observed health effects in the epidemiological studies. This uncertainty has necessitated use of inadequate surrogate measures (see comments to section 2.3.4) to make the link between the epidemiological findings and proposed revisions to the NAAQS. One recommendation is that C-R functions include confidence bounds, and I support that as information that would get at this key uncertainty.