UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

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August 31, 2016

EPA-CASAC-16-003

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: CASAC Review of the EPA's *Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016)*

Dear Administrator McCarthy:

The Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Panel held teleconference meetings on May 23, 2016, and August 9, 2016, to peer review the EPA's *Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016)*, hereafter referred to as the Draft IRP. The Chartered CASAC approved the report on August 9, 2016. The CASAC's consensus responses to the agency's charge questions and the individual review comments from members of the CASAC Particulate Matter Panel are enclosed.

Overall the CASAC finds the Draft IRP to be well written, well organized, and the topics are clearly presented. There are several recommendations for strengthening and improving the document highlighted below and detailed in the consensus responses. With the recommended revisions, the Draft IRP should serve its intended purpose in presenting the review plan, schedule, and process as well as the key policy-relevant science issues that will guide the agency's review of the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM).

The introduction chapter clearly and effectively provides the necessary introductory information and outline for the document. It would be helpful to include brief background information on the goals and major outcomes of the planning workshop, and clear and consistent definitions of "sensitive groups" or "at-risk populations" (that can then be carried through all documents), and additional detail on the decisions made regarding the consideration of coarse particles ($PM_{10-2.5}$) from the previous NAAQS reviews.

The discussion of the key policy-relevant science issues and the decisions made in the previous NAAQS review as well as the policy-relevant questions that will guide the current review are appropriate and generally complete. It would be useful to summarize the key "future research" items identified in September 10, 2010 CASAC review of the *Policy Assessment for the Review of the PM NAAQS – Second External Review Draft (June 2010)* and to discuss briefly what the EPA has done to address

them. Although the existing PM monitoring network is driven by the $PM_{2.5}$ NAAQS, there are other PM metrics, such as particle number concentration and $PM_{10-2.5}$, that should be considered. The CASAC encourages the EPA to seek scientific input (early in the review process) on PM monitoring technical issues from the CASAC Air Monitoring and Methods Subcommittee. These issues could include policy-relevant PM monitoring issues for both the primary ($PM_{2.5}$ and other particle indicators) and the secondary (e.g., visibility) NAAQS, as well as the performance of PM "sensors". The CASAC also recommends including a summary of what is known regarding natural versus anthropogenic concentrations of PM.

The chapter discussing the Integrated Science Assessment (ISA) does a good job describing the scope and clearly outlines where emphases will be placed in the current review, highlighting areas of uncertainty determined during the previous review. The scope of the ISA is sufficiently broad to capture the pertinent literature for review. The CASAC recommends inclusion of specific information about the study quality evaluation process and evaluation criteria that will be used in the ISA, acknowledging the limitations and difficulties involved. The CASAC encourages the EPA to make the planned ISA as succinct and focused as possible emphasizing new evidence relevant to standards that has become available since the prior review.

Additionally, the CASAC encourages the EPA to include discussion of the following areas in the ISA:

- evaluation and summary of health effects across temporal windows of exposure;
- the potential importance of exposures during critical windows of susceptibility;
- discussion of cancer risk;
- the modification of PM-associated health effects by PM composition; and
- uncertainties in emission profiles.

The EPA clearly and adequately describes the scope and issues relevant to the Health Risk and Exposure Assessment (HREA) Planning Document. The CASAC recommends that the EPA specify the criteria that will be used in the HREA Planning Document to determine whether development of a new HREA is justified, particularly for the exposure assessment. The CASAC encourages the EPA to consider expansion of the geographic scope of the HREA to the entire continental United States, which can be facilitated by use of high quality modeled estimates of $PM_{2.5}$ at all census tract centroids in its assessments. The CASAC encourages the EPA to consider more representative exposure metrics, including use of modeled PM at the census tract-level and exposure estimates from stochastic population-based models rather than relying only on data from fixed site monitors.

The chapter on Welfare Risk and Exposure Assessment (WREA) does not adequately address welfare effects. In general, greater discussion of welfare impacts (beyond effects on visibility acceptance) is needed. As there are very few studies in the literature measuring the welfare impacts of changes in visibility, ecosystem effects and other undesirable consequences, the chapter should outline processes to identify potentially affected populations and approaches to measuring the welfare impacts for these affected populations. This can assist the agency in considering the potential impacts of policy changes, and can potentially stimulate research to estimate the welfare impacts that will enhance future evaluations and updates. The chapter does not cover all forms of PM deposition (which includes dry particle, dry gas, wet, frozen or cloud). The secondary standard for PM should address all these sources of deposition. The CASAC also recommends further discussion of other indicators (such as PM mass) in addition to light extinction for the secondary standard.

The general process for the policy assessment (PA) and rule-making of the NAAQS review is clearly and succinctly described. The EPA is urged to develop a schedule to ensure that if an REA is developed, it is available to inform the PA and to allow time for review by the CASAC of more than one draft of the PA.

The CASAC received a public comment urging it to provide you with advice on any adverse economic impacts associated with attaining a possible revised PM standard. As indicated in the June 26, 2014 CASAC letter to you regarding the Ozone 2nd Draft Policy Assessment, the CASAC is aware that cost and implementation issues are not relevant or allowable considerations in setting or revising a NAAQS (Whitman vs. American Trucking Association, Inc., 2001). Therefore, these issues will not be taken into consideration during the CASAC's review of the scientific and technical documents (IRP, ISA, HREA, WREA, and PA) that will support the setting or revision of the PM NAAQS. The CASAC reiterates that, separate from the standard-setting process, it would be receptive to providing advice on possible adverse effects associated with implementation of existing NAAQS, upon request by the EPA. In response to such a request, the SAB Staff Office would form an ad hoc CASAC panel to obtain the full expertise necessary to conduct a review of EPA documents or analyses of any "adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards" (42 U.S. Code § 7409).

The CASAC appreciates the opportunity to provide advice on the Draft IRP and looks forward to the agency's response.

Sincerely,

/Signed/

Dr. Ana Diez Roux, Chair
Clean Air Scientific Advisory Committee

Enclosures

NOTICE

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

U.S. Environmental Protection Agency
Clean Air Scientific Advisory Committee
Particulate Matter Review Panel

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Consensus Responses to Charge Questions on the EPA's
Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter
(External Review Draft – April 2016)

Overall Organization and Clarity and Chapter 1 – Introduction

To what extent does the Panel find that the draft IRP is clearly organized and that it appropriately communicates the plan for the current review of the PM NAAQS and the key scientific and policy issues that will guide the review?

Overall the sections on legislative requirements (1.1), overview of the NAAQS review process (1.2), history of reviews of the PM NAAQS (1.3), general scope of the current review (1.4) and anticipated schedule for the current review (1.5) are clearly and concisely articulated and provide the necessary introductory information and outline for the remainder of the document.

A brief description of the goals and major outcomes of the planning workshop, held February 9-11, 2015, in Research Triangle Park, North Carolina, could be incorporated into Chapter 1. This would provide important background information on the key scientific and policy issues that were considered in the development of the Draft IRP.

It would also be helpful to provide definitions and examples for *sensitive group*s and *at-risk populations* early in the document, prior to their use in this chapter (i.e., pp. 1-3, 1-13) and in subsequent chapters. In this regard, how susceptibility and vulnerability relate to sensitive groups and at-risk populations could be incorporated in these definitions and examples and explained in more detail later in the document. This will be important when determining the adequate margin of safety. In Section 1.1 (Legislative Requirements), more emphasis should be placed on sensitive groups and at- risk populations in regards to the adequate margin of safety (e.g., p. 1-3).

In the history section (1.3), background on the determination of coarse PM standards could be expanded. Section 1.3 should acknowledge the previous consideration of a 24-hour NAAQS for the $PM_{10-2.5}$ indicator at 70 $\mu g/m^3$ (U.S. EPA, 2006). A 1999 decision from the U.S. Court of Appeals for the D.C. Circuit directed the EPA to ensure that regulations for coarse particles did not duplicate those of fine particles. In response to this decision, the EPA proposed a 24-hour $PM_{10-2.5}$ NAAQS. Although the Administrator decided to use PM_{10} as an indicator for $PM_{10-2.5}$, the history section should provide greater detail on the decisions made regarding the consideration of $PM_{10-2.5}$.

In addition, it would be important to consider shorter-term (i.e., <24-hour average) exposures and responses (in addition to size fractions and chemical components expressed on Page 1-15, Lines 14-19), as more information is being published owing to the use of personal and *in-situ* continuous monitors.

Chapter 2 – Key Policy-Relevant Issues in the Current Review

To what extent does the Panel find that Chapter 2 clearly articulates the decisions made in the last review of the primary (sections 2.1.1, 2.1.2) and secondary (sections 2.2.1, 2.2.2) PM standards, and the rationales supporting those decisions?

The discussion of the key policy-relevant science issues and the decisions made by the Administrator in the last review seem appropriate and reasonably complete. In particular, the chapter does a good job of highlighting the key scientific uncertainties from the last review.

To what extent does the Panel find that the policy-relevant questions presented in sections 2.1.3 (primary) and 2.2.3 (secondary) appropriately characterize the key scientific and policy issues for consideration in the current review? Are there additional issues that should be considered?

The policy-relevant questions in these sections seem appropriate and reasonably complete. It would be appropriate to bring forward the key "future research" items identified in the last review, and to summarize what EPA has done to address them. The September 2010 CASAC letter lists several topics relevant to the current review related to the adequacy of the current indicators and alternative indicators, including discussions of alternative or additional PM indicators such as ultra-fine PM and other PM size ranges (including $PM_{10-2.5}$), improved spatial and temporal resolution to better support exposure assessments, size-dependent chemical composition, potential linkages between climate change and PM concentration in different size fractions, and direct measurements of light extinction. See Dr. Frey's individual comments for more detail.

Section 2.3 - PM Ambient Monitoring

Although there were no charge questions for Section 2.3, the CASAC agrees that it is appropriate to include a discussion of the adequacy of the current PM monitoring network during the review process to inform consideration of alternative PM indicators or forms (e.g., sub-daily averages) for both the primary and secondary PM NAAQS. To be consistent with the rest of Chapter 2, Section 2.3 should pose some policy-relevant monitoring and exposure assessment questions to help focus this section better. The existing PM monitoring networks for both health and welfare (visibility) are adequately described. The monitor counts presented are for calendar year 2014; it would be helpful in the final IRP to update this with 2015 information.

Section 2.3.2 notes that the EPA may wish to request that the CASAC Air Monitoring and Methods Subcommittee (AMMS) be convened to provide formal scientific input regarding PM monitoring technical issues. Given the various monitoring issues identified in this section of the draft IRP, it seems prudent to proceed with this request. Possible technical issues to seek input on include: evaluation of the availability and performance of low-cost PM sensors, evaluation and advice regarding the interpretation of PM measurements from the myriad of instruments that have been used in the regulatory monitoring networks and in research studies, and policy-relevant PM monitoring issues for both the health ($PM_{2.5}$ and other particle indicators) and the welfare (visibility) NAAQS.

Chapter 3 – Science Assessment

To what extent does Chapter 3 clearly and adequately describe the scope, specific issues to be considered, and organization of the ISA?

Generally the chapter does an excellent job of describing the scope of the Integrated Science Assessment (ISA), and clearly outlines where emphases will be placed in the current review, highlighting areas of

uncertainty determined during the previous review. The organization of Chapter 3 is logical, however, there are some redundancies with Chapter 2.

What are the panel's views on the overall scope of the ISA? Does the planned scope ensure that the EPA will capture the scientific literature most pertinent to the ISA's focus, which is answering the question, "Is there an independent effect of PM on health and welfare at relevant ambient concentrations?"

The scope of the ISA is sufficiently broad to capture the pertinent literature for review, but there are a few exceptions to this general statement.

With respect to ecological effects (pp. 3-5, lines 16-26), the EPA may wish to reconsider removing nitrogen (N) and sulfur (S) from consideration in the PM ISA on the basis that they are adequately addressed by the NOx and SOx ISAs. First, N and S constitute major fractions of $PM_{2.5}$ and they are not linearly related to their primary precursors that are regulated by the NO_2 and SO_2 NAAQS, respectively. There is likely to be more information available for the PM ISA than was reviewed for the recent NOx and SOx ISAs. In addition, NH_3 is a large source of N that is not adequately addressed by the NOx and SOx ISAs. Finally, there is ample precedent for further controlling NOx and SOx to attain a PM NAAQS beyond that necessary to attain the NO_2 and SO_2 NAAQS (U.S. EPA, 1999, 2005).

The impact of recent revelations of uncertainties in emission profiles, especially for diesel exhaust PM, is not identified as a potentially relevant issue. Allegations that the emissions from some vehicles have not been appropriately reported by the manufacturers or adequately characterized in emissions assessments may be relevant to the ISA.

Health effects associated with exposure to PM near roadways should be given more emphasis. Consideration of on-road (e.g., commuting) exposures, which are increasingly recognized to result in health-relevant exposures, would also seem appropriate. Another recently recognized source of important PM exposure, including ultrafine particles, is large airports.

Considerable recent research has explored how PM composition alters the association between $PM_{2.5}$ and adverse health effects. A synthesis of the findings addressing this issue and degree of coherence across these findings should be included. Studies specifically involving PM components, as well as geographic and seasonal differences in effect estimates, can provide insights into this question. Comparisons of PM-related effects during times of high versus low photochemistry also can provide insights, enabling a better understanding of the influence of secondary PM. It is appropriate, as proposed, to focus the evaluation of the PM component studies on studies that also include PM mass. However, there may be a limited number of studies that provide key information on this question and do not include PM mass. The CASAC suggests that such studies not be excluded *a priori*.

The distinction of effects of short-term exposure studies ("i.e., exposures ranging from hours to days to weeks") that primarily rely on temporal variation in exposure from effects of long-term exposure studies ("i.e., exposures ranging from months to years") that rely on spatial variability of exposure is, in general, appropriate. Conceptually, however, exposures that vary seasonally over months may reflect temporal variation with high relevance for some outcomes, for example trimester-specific gestational effects of exposure. To the extent possible, harmonization of evaluation of effects across temporal windows of exposure would be helpful. It would also be wise to emphasize potential importance of exposures during

critical windows of susceptibility, especially *in utero* and early-life exposures, for contributing to disease later in the life course.

It is unclear whether the restriction of studies of exposures below 2 mg/m^3 precludes inclusion of studies that would help strengthen causal inference based on an evaluation of concentration-response or dose-response relationships. For example, it is unclear whether studies of effects of occupational exposures to diesel exhaust PM components of the PM mixture would be included. To the extent recent studies attempting to examine the integrated exposure-response relationship across a range extending to secondhand or personal tobacco smoke exposure is relevant to the ISA, the 2 mg/m^3 restriction should be loosened. A related issue is the restriction of toxicological studies to those below 2 mg/m^3 PM, which could preclude assessment of dose-response relationships and reduce the ability to identify effects in animal studies.

Since the previous PM NAAQS review, the International Agency for Research on Cancer (IARC) has designated outdoor particulate matter as a Group 1 carcinogen. The Draft IRP notes that IARC only determines if PM can cause cancer at any inhaled concentration, whereas the agency NAAQS review will examine the evidence that PM causes cancer at relevant ambient concentrations. The CASAC supports the agency's proposed approach to examine cancer as an important outcome in relation to relevant ambient PM concentrations and encourages the agency to consider historical exposures in addition to concurrent exposures. It is not clear why evaluation of the risk of cancer will not include studies that use PM filter extracts ("because they may not mimic what is bioavailable in vivo"), or on studies of individual PM components ("due to the inability to compare effects to the current mass-based PM indicator").

The evaluation of study quality was found to be somewhat vague, and the document would benefit from additional detail and clarification. The IRP describes a "uniform approach" to study quality, but this is not well supported in the text. It is important to be transparent about the process and criteria used in the study quality assessment, and how the quality ratings will be used. For example, it is not clear whether every study will be given some kind of quality rating, who will do the quality assessments, or whether poor quality studies will be rejected from consideration. The studies that will be reviewed for the ISA cross scientific disciplines and include a wide variety of approaches and outcomes. This limits the ability to establish standard quality ratings, as is done in some systematic reviews and meta-analyses. We recommend that the IRP include specific information about the quality assessment process and criteria to be used, acknowledging the limitations and difficulties involved.

More explanation needs to be provided about how the causality ratings are assigned during the development of the ISA. These are judgments based on the weight of evidence, and this should be explicitly acknowledged. It would be helpful to describe the process used by the EPA to assign the levels of causality, as well as the criteria used. It may be useful to point out that initial determinations of causality in the draft ISA will be part of the CASAC review and available for public comment before finalizing the ISA.

What are the panel's views on the approaches outlined in Chapter 3 to streamline the discussion in some sections of the ISA? What are the panel's views on EPA's plans to produce an assessment that is concise and forms an adequate scientific foundation for subsequent steps of the NAAQS review process?

The evolution from Criteria Documents to the ISA, in an effort to shorten and focus the review of existing scientific knowledge, has improved the readability and usefulness of the NAAQS reviews. This approach should continue, with less emphasis on describing every study and even more emphasis on integration and comparisons across studies and disciplines. However, a concise and adequate representation of the scientific foundation that includes all relevant new findings for a PM NAAQS is easier said than done.

Chapters 4 – Human Health Risk and Exposure Assessment

To what extent does Chapter 4 clearly and adequately describe the scope and specific issues, including the identification of the most important uncertainties, to be considered in developing the HREA Planning Document for this review?

Chapter 4 clearly and adequately describes the scope and specific issues relevant to developing the HREA Planning Document. The CASAC has comments on two topics for the EPA to address or reconsider: the criteria for developing a HREA and the geographic scope of the health risk assessment.

The criteria that the HREA Planning Document will use to determine whether the development of a HREA is justified should be clearly specified. The justification criteria for the risk and exposure assessment sections should be defined separately. In particular, the EPA is encouraged to clearly define the scope and purpose of the exposure assessment. An exposure assessment is a valuable tool for showing what proportion of the population is exposed to unusually high levels of PM over the short and long term, how those people may differ in terms of demographics, and what factors lead to their higher exposures. Along with these justifications the CASAC encourages prioritization of tasks, clarification of how the information developed from the assessments will be used, and clear definition of the criteria for determining which new assessments will be deemed "appropriate" or "adequate".

The CASAC encourages the EPA to consider expanding the geographic scope of the health risk assessment to the entire continental United States. Given the current state of the art for air pollution risk assessment, the CASAC believes that the assessment could be nationwide.

Is there additional information that should be considered or are there additional issues that should be addressed in considering the potential for risk and/or exposure analyses in the current review?

The CASAC has a few suggestions:

- Since the last review there has been considerable advancement in PM exposure modeling, meaning that high quality modeled estimates of $PM_{2.5}$ at all census tract centroids can be used in the assessments. (See suggested references in Dr. Lianne Sheppard's individual comments). Thus the EPA may want to use modeled PM rather than relying only on monitored PM in the HREA. This would allow a more comprehensive geographic scope and inclusion of rural areas in the risk assessment.
- Monitor siting may be important for consideration in the HREA. It is certainly relevant to epidemiologic inference and thus to estimates that will be part of the risk assessment.
- The CASAC suggests adding a conceptual diagram to portray the key data and approaches and make clear how the exposure and risk assessment analyses are distinct from the approaches

described in the other IRP chapters. A conceptual diagram could also provide insight into how an integrated approach for addressing uncertainty would be implemented across the proposed analyses.

- The question of whether exposure modeling (i.e., using APEX) constitutes a more sensitive indicator of PM-mediated population risks than stationary ambient sites is still unresolved. One plausible perspective is to view exposure models as potential alternative exposure metrics, similar to composite or single-site ambient monitoring.

Comments on variability and uncertainty:

- Expanding the spatial and temporal scope of the analysis may help increase the understanding of the impacts of variability and uncertainty on exposure and risk over time.
- The Consolidated Human Activity Database (CHAD) may be the best dataset currently available, but it is based on old data (pre-2000) that may not accurately portray current activity patterns. The relevance of the CHAD dataset for current activity patterns is a source of uncertainty.
- The characterization of the shape of concentration-response (C-R) functions, especially at low PM concentrations, is a particularly critical factor of uncertainty.
- Many of the sources of variability seem to be presented as static snapshots of factors that may explain between-city heterogeneity in risk. The CASAC suggests that the EPA consider a process for including changing patterns such as ongoing and predicted demographic trends related to baseline comorbidities. The information about accelerated aging patterns and socio-economic changes, may be better able to capture true population risk.

Chapter 5 – Welfare-Related Risk and Exposure Assessments

To what extent does Chapter 5 clearly and adequately describe the scope and specific issues, including the identification of the most important uncertainties, to be considered in developing the WREA Planning Document for this review?

The chapter does not adequately describe welfare effects. For the most part, the chapter does a good job of explaining the current state of the knowledge of technical aspects of air pollution, ambient air quality and uncertainties with respect to exposure. However, not all forms of PM deposition are covered. Total deposition includes dry particle, dry gas, wet, frozen or cloud. It makes sense for the secondary standard for PM to address these sources of deposition. The deposition of mercury on the environment can lead to devastating ecosystem and health effects.

There is no discussion of pathways of exposure and the consequent welfare effects of exposure and uncertainties beyond the technical discussion of potential first-round deposition. The analyses could benefit from discussion of what the potential welfare effects will be, how the policy will reduce adverse welfare impacts, the potential extent of impacts, and uncertainties associated with the impacts.

Although visibility is deemed to be acceptable at the 50% level, this does not mean that there are not welfare losses to the 50% of individuals below the 50^{th} percentile. There is also a difference between acceptable and desired (or preferred levels), and there can still be welfare losses to individuals above the 50^{th} percentile who prefer an unencumbered view.

It is not clear that the acceptability studies have purged all health considerations from individuals' responses and this uncertainty should be addressed in the proposed reanalysis; this should at least documented if not quantitatively addressed.

Is there additional information that should be considered or additional issues that should be addressed in considering the potential for quantitative analyses for welfare effects in the current review?

With respect to visibility acceptability, where quantitative analyses have been performed, there are some additional considerations:

- For existing studies too much concern, perhaps, has been placed on the accuracy of specific images, from a technical perspective, for eliciting subject's perceptions of visibility. If the goal is to have subjects evaluate acceptability of visibility conditions (or changes in visibility conditions), the images are stimuli to accompany verbal descriptions and a consistent format is needed for presenting images of different visibility conditions. In a survey, there is a balancing of what technical experts might think is best practice for their field and what is best practice in the survey design to assist subjects in providing unbiased responses.
- The issue of national representativeness is perhaps the biggest issue with the existing studies and there are alternatives to assess representativeness and to weight the data for analyses that are not discussed. Please refer to individual comments from Mr. Richard Poirot for additional details.
- Nonlinearity of view perception should be addressed in the reanalysis of the acceptability study data.
- Reanalysis should include baseline visibility conditions from which acceptability was based in the reanalysis of these data.
- Careful consideration should be given early in the review process to the specific measurements and data processing techniques that might be used to determine compliance with alternative secondary PM standards.

Chapter 6 – Policy Assessment and Rulemaking

To what extent does Chapter 6 clearly summarize the general process for the policy assessment and rulemaking phases of this review?

Chapter 6 clearly and succinctly summarizes the general process for the policy assessment (PA) and rule-making of the NAAQS review. This chapter notes that the Risk and Exposure Assessment will be used to inform this process "if available". The agency is urged to develop a schedule to ensure that if an REA is developed, it is available to inform the Policy Assessment. The CASAC also urges the EPA to plan for the contingency that more than one draft of the Policy Assessment can be reviewed; the complexity of the PM issue may require more than one review of this important document.

References

U.S.EPA, 1999. 40 CFR Part 51 - Regional haze regulations: Final rule. Federal Register, 64, 35714-35774.

U.S.EPA, 2005. 40 CFR Parts 51, 72, et.al. Rule to reduce interstate transport of fine particulate matter and ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NOX SIP call; Final Rule.

U.S.EPA, 2006. National ambient air quality standards for particulate matter: Proposed rule. Federal Register, 71, 2620-2708.

Appendix A

Individual Comments by CASAC Particulate Matter Panel Members on the EPA's *Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016)*

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Dr. John Adgate **A-4**
Mr. George A. Allen **A-5**
Dr. John Balmes **A-7**
Dr. Kevin J. Boyle **A-8**
Dr. Judith Chow **A-10**
Dr. Douglas W. Dockery **A-15**
Mr. Henry (Dirk) Felton **A-18**
Dr. Mark W. Frampton **A-24**
Dr. H. Christopher Frey **A-26**
Dr. Terry Gordon **A-29**
Dr. Jack Harkema **A-30**
Dr. Joel Kaufman **A-31**
Dr. Patrick Kinney **A-32**
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Dr. David B. Peden **A-37**
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Dr. Jeremy Sarnat **A-43**
Dr. James J. Schauer **A-45**
Dr. Elizabeth (Lianne) A. Sheppard **A-46**
Dr. Barbara Turpin **A-48**
Dr. Sverre Vedal **A-50**
Dr. Ronald E. Wyzga **A-52**

Dr. Peter Adams

Comments on Chapter 2 (Key Policy-Relevant Issues in the Current Review)

To what extent does the Panel find that Chapter 2 clearly articulates the decisions made in the last review of the primary (sections 2.1.1, 2.1.2) and secondary (sections 2.2.1, 2.2.2) PM standards, and the rationales supporting those decisions?

I was not involved in the last review, but it appears that, in general, Chapter 2 is a clearly written and informative summary of that process.

On p. 2-19, there is a paragraph (lines 3-15) arguing that a "number of uncertainties in the scientific information" existed and that "that there was 12 insufficient information available to base a national ambient standard on climate impacts 13 associated with ambient concentrations of PM or its constituents".

This surprises me. The actual physical mechanisms (scattering, absorption, and cloud activation) by which particles affect climate are well established. Uncertainties in estimates of radiative forcing do not appear to me to be larger than uncertainties in concentration-response functions. The statement is probably an accurate summary of justifications offered in the last review and the Administrator's decision process, so there is no need to revise. However, I wonder if it isn't more accurate to say that health effects have an immediacy and urgency that make them different than climate considerations.

To what extent does the Panel find that the policy-relevant questions presented in sections 2.1.3 (primary) and 2.2.3 (secondary) appropriately characterize the key scientific and policy issues for consideration in the current review? Are there additional issues that should be considered?

In general, I find that the policy-relevant questions presented are appropriate and reasonably thorough.

It seems to me that the question about alternative indicators on p. 2-17,

> "Do the available health effects evidence and air quality information provide support for 11 consideration of indicators for fine and thoracic coarse particles in addition to, or in place of, 12 PM2.5 and PM10, respectively? Does the evidence support an alternative approach for 13 defining particle pollution, including in terms of other size fractions, specific components, 14 source-related mixtures, or specific environments?"

could be moved up a tier because the answer to this would support or call into question the adequacy of current standards. However, this concern is partly addressed on p. 2-16, which includes a question about "other indicator of PM" being associated with health effects at PM levels meeting current standards.

There is a useful summary of existing monitor networks, but it seems that there should be a policy-relevant question related to the adequacy of the current monitoring networks. There are a number of appropriate questions about whether or not existing evidence indicates health effects that need addressing beyond the existing NAAQS. However, we are obviously limited in what we can say based

on existing monitors and exposure assessment. A question about "to what extent are existing monitoring networks adequate for epidemiological studies that would inform the appropriate indicators, averaging times, forms, and levels of the NAAQS?" Perhaps this issue has been omitted because it falls under the purview of another committee?

Other comments:

The discussion of how "adequate margin of safety" (in Chapter 1) has been and may be applied in the context of setting the NAAQS is a useful one.

Section 2.3 provides a useful, and reasonably thorough, discussion of existing monitoring networks for the NAAQS indicators (PM10 and PM2.5) as well as some other indicators. The section on "Additional PM Metrics", however, could be supplemented in some ways. In particular, I feel that the discussion of particle count measurements could include additional details such as the number of sites near roadways and elsewhere, technology deployed, time periods covered, etc.

Given evidence that living near major roadways is associated with negative health effects, EPA's move to establish monitor networks near roadways is a good one. Although PM2.5 measurements are likely useful, the document notes that "particle counts are one of several measurements identified as being a secondary priority". Most data I have seen indicate the following: PM2.5 is only modestly elevated near roadways, other pollution indicators including particle number are more strongly elevated, vehicles emit a large number of ultrafine particles that do not contribute much to PM mass levels. Given this, it seems that near roadway monitors should place a primary, not secondary, priority on measures besides PM mass.

Dr. John Adgate

Comments on Chapter 4 (Health Risk and Exposure Assessment)

I have reviewed the document with particular focus on Chapter 4.

To what extent does Chapter 4 clearly and adequately describe the scope and specific issues, including the identification of the most important uncertainties, to be considered in developing the HREA Planning Document for this review?

The description of the proposed approach for the HREA is for the most part clear and reasonable. It identifies the major uncertainties, and to the extent feasible in a draft plan, is comprehensive in its approach and description of key uncertainties.

Chapter 4 could be strengthened if it had a conceptual diagram similar to those in Chapters 2 and 3 that pull together the key data and approaches and make clear how the exposure and risk assessment analyses are distinct from the approaches described in those other chapters. It would also provide insight into how an integrated approach for addressing uncertainty would be implemented across the proposed analyses.

Is there additional information that should be considered or are there additional issues that should be addressed in considering the potential for risk and/or exposure analyses in the current review?

At this time, I am not aware of additional information that should be considered, but given the uncertainties identified in Chapter 4, considering expanding the analysis beyond the 15 cities used in the 2010 HREA is an approach that should be considered. Expanding the spatial and temporal scope of the analysis may help increase our understanding of the impacts of variability and uncertainty on exposure and risk over time. If the decision is made to not expand the temporal or spatial scale of the analysis, then the reasons for this limitation and implications for exposure and risk estimation discussed and justified.

Mr. George A. Allen

Comments on Chapter 2

General Comments:

Chapter 2 generally provides appropriate descriptions and information.

Charge Questions:

To what extent does the Panel find that Chapter 2 clearly articulates the decisions made in the last review of the primary (sections 2.1.1, 2.1.2) and secondary (sections 2.2.1, 2.2.2) PM standards, and the rationales supporting those decisions?

Overall, this section clearly communicates the decisions from the last review of the primary (health) and secondary (welfare) PM standards. The agency's rationales behind the various aspects of those decisions is clearly presented. The discussion of revisions to the spatial averaging component of the form in the last review (to not allow it) on page 2-6 is very useful, as is the discussion on page 2-7 about the 24-hour standard's role as a back-stop ("supplemental protection") for areas with important (e.g., large) local or seasonal (example: woodsmoke from residential space heating) sources. The agency's approach in the last review to setting an annual standard when there is "no discernible population level threshold" for health effects is clearly explained (page 2-8); it is quite possible that a similar situation may play out in this review.

To what extent does the Panel find that the policy-relevant questions presented in sections 2.1.3 (primary) and 2.2.3 (secondary) appropriately characterize the key scientific and policy issues for consideration in the current review? Are there additional issues that should be considered?

The policy-relevant questions in these sections seem appropriate and reasonably complete.

Other comments on Chapter 2.

Section 2.3, PM Ambient Monitoring

Section 2.3 summarizes the ambient monitoring network for PM of various size ranges as well as chemical speciation and "Additional PM Metrics" such as particle number concentration (aka UFP). The monitor counts here are for calendar year 2014; it would be helpful in the final IRP to update this with CY-2015 information.

The discussion of the existing continuous PM2.5 monitoring network on page 2-32 lines 1 to 9 is important, in part because any consideration of a sub-daily PM NAAQS form would require continuous monitors that generate data with sufficient quality for comparison to the NAAQS. The reference to FEMs being used for comparison with the NAAQS here is unclear; not all FEMs currently in operation meet the data quality requirements for that purpose. This topic is clearly explained on page 2-34, lines 12-19 however.

Section 2.3.3 discusses PM monitoring issues for consideration in the current PM NAAQS review. Of all the criteria pollutants, PM is the most difficult to measure with adequate accuracy and precision at levels near the current NAAQs. In addition to the FEM data quality issues noted above, there may be additional PM measurement method issues that could become more important if standards were revised to lower concentrations. This issue may be appropriate to include in the ISA discussion of ambient PM monitoring and methods.

Dr. John Balmes

Comments on Chapter 3 (Science Assessment):

To what extent does Chapter 3 clearly and adequately describe the scope, specific issues to be considered, and organization of the ISA?

Overall, I think that Chapter 3 is well-conceived and well-written.

What are the panel's views on the overall scope of the ISA? Does the planned scope ensure that the EPA will capture the scientific literature most pertinent to the ISA's focus, which is answering the question, "Is there an independent effect of PM on health and welfare at relevant ambient concentrations?"

The planned scope of the ISA is sufficiently broad to ensure that the EPA will capture the scientific literature necessary to address the effect of PM on health and welfare. My major concern is that the proposed scope may be overly broad and ambitious. I applauded the agency's move to more focused ISAs in lieu of encyclopedic Criteria Documents. That said, in my view the SOx ISA was not as well focused as it could have been. I fear that given the much greater size of the literature on PM an even less well-focused ISA will result. I urge the agency to remain committed to integration and synthesis in the preparation of the PM ISA.

What are the panel's views on the approaches outlined in Chapter 3 to streamline the discussion in some sections of the ISA? What are the panel's views on EPA's plans to produce an assessment that is concise and forms an adequate scientific foundation for subsequent steps of the NAAQS review process?

As my comments above make clear, I am 100% in support of efforts to streamline discussion and produce an adequate, but concise foundation for the PM NAAQS review process.

Dr. Kevin J. Boyle

Overall organization and clarity: To what extent does the Panel find that the draft IRP is clearly organized and that it appropriately communicates the plan for the current review of the PM NAAQS and the key scientific and policy issues that will guide the review?

Overall, I felt the presentation was understandable, but there is a lot of repetition in the document that may not be necessary. In such a short document I think you can build on what has already been stated with a reference and focus on the main theme of the topics in later sections. However, if the assumption is that some readers may focus and only read individual chapters or sections, then the current presentation with redundancy may be most appropriate.

Chapter 5 (Welfare Risk and Exposure Assessment):

To what extent does Chapter 5 clearly and adequately describe the scope and specific issues, including the identification of the most important uncertainties, to be considered in developing the WREA Planning Document for this review?

Yes, that chapter does a good job of explaining the current state of the knowledge of technical material and uncertainties.

There is little to no discussion of welfare effects of exposure and risks beyond the technical discussion of potential first-round pathways of exposure. The analyses could benefit with discussion of what the potential welfare effects with be and potential extent of impacts.

Just because visibility is deemed acceptable at the 50% level does not mean that there are not welfare losses to the 50% of individuals below the 50^{th} percentile. There is also a difference between acceptable and desired (or preferred levels), and there can still be welfare losses to individuals above the 50^{th} percentile, but who prefer and unencumbered view.

I am not convinced that the acceptability studies have purged all health considerations from individual's responses and this uncertainty should be addressed in the proposed reanalysis; at least documented if not quantitatively addressed.

Is there additional information that should be considered or additional issues that should be addressed in considering the potential for quantitative analyses for welfare effects in the current review?

With respect to visibility acceptability, where quantitative analyses have been performed there are some additional considerations.

- For existing studies too much concern, perhaps, has been placed on the use of specific images for eliciting subject's perceptions of visibility. If the goal is to have subjects identify a specific environmental condition, then this may be needed, but to evaluate changes, all that may be needed is consistent images across changes evaluated.

- The issue of national representativeness is perhaps the biggest issue with the existing studies and there are alternatives to assess representativeness and to weight the data for analyses that are not discussed.

- Nonlinearity of view perception should be addressed in the reanalysis of the acceptability study data.

- Reanalysis should include baseline visibility conditions from which acceptability was based in the reanalysis of these data.

- I thought improve monitoring sites were largely outside of urban areas. This should be discussed if these monitoring data are going to continue to be the basis of the analyses.

Dr. Judith Chow

Overall Organization and Clarity

To what extent does the Panel find that the draft IRP is clearly organized and that it appropriately communicates the plan for the current review of the PM NAAQS and the key scientific and policy issues that will guide the review?

Chapter 1 provides a good overview of the IRP purpose, methodology, regulatory basis, and past history. Section 1.3 should acknowledge the previous consideration of a 24-hour NAAQS for the $PM_{10-2.5}$ indicator at 70 $\mu g/m^3$ (U.S.EPA, 2006). In response to a 1999 U.S. Court of Appeals for the D.C. Circuit decision directing the EPA to ensure regulations for coarse particles didn't duplicate those of fine particles, a 24-hour $PM_{10-2.5}$ NAAQS was proposed by the EPA. Although the Administrator decided to use PM_{10} as an indicator for $PM_{10-2.5}$, lessons learned from the 2006 draft proposal that intended to exclude agricultural practice and mining operations may warrant the revisit. Specifically, the condition in the 2006 proposal that "… the proposed $PM_{10-2.5}$ indicator is qualified so as to include any ambient mix of $PM_{10-2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and excludes any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources." should be reconsidered.

It would be important to consider shorter-term (i.e., <24-hour average) exposures and responses (in addition to size fractions and chemical components expressed on Page 1-15, Lines 14-19), as more information is being published owing to the use of personal and *in-situ* continuous monitors. The overall organization of the subsequent chapters and sub-sections seems adequate.

Chapter 2: Key Policy-Relevant Issues in the Current Review

To what extent does the Panel find that Chapter 2 clearly articulates the decisions made in the last review of the primary (sections 2.1.1, 2.1.2) and secondary (sections 2.2.1, 2.2.2) PM standards, and the rationales supporting those decisions?

Section 2.1 provides a good summary of the actions taken and the uncertainties considered in the prior reviews.

- Figure 2-1 (Page 2-14) identifies several of the areas for which the literature will be searched for new evidence of adverse health relationships (e.g., $PM_{10-2.5}$, UFP, PM chemistry, <24-hour averages, or alternative NAAQS levels and forms). Although uncertainties in exposure and risk estimates are mentioned in the "Exposure-/Risk-Based Considerations" box in Figure 2-1, there needs to be recognition that most of the past and current relationships are based on PM monitoring at urban- and neighborhood-scale locations (U.S.EPA, 1997). There is growing evidence that these measurements may underestimate exposure, especially near roadways and in areas of lower socioeconomic status. Therefore, exposure errors need to be addressed. $PM_{10-2.5}$ should be added as part of the "Indicator" box in Figure 2-1 in addition to $PM_{2.5}$ and $PM_{10.}$

- Page 2-24, Line 10. The 24-hour $PM_{2.5}$ visibility index of 30 deciview (dv) should be translated to light-extinction of 191 Mm^{-1} or visual range of 19 km to give sense of the distance related to 30 dv. This is poor visibility, and an approach needs to be outlined to set a reasonable limit.
- Section 2.3 makes some important observations about near-road and continuous monitors that need to be considered in the health analysis and for future networks.
- Turner et al. (2015) is cited on Page 2-35 in Lines 17-21 as a useful evaluation of $PM_{10-2.5}$ methods at two sites, which it is. Given the prior descriptions of locations with collocated FEMs, FRMs, CSN, and IMPROVE samplers for $PM_{2.5}$ and PM_{10}, it would seem that a broader analysis of $PM_{10-2.5}$ comparability is possible by mining the existing data base. Some additional chemical (e.g., elemental) analyses of archived filters might be in order.

To what extent does the Panel find that the policy-relevant questions presented in sections 2.1.3 (primary) and 2.2.3 (secondary) appropriately characterize the key scientific and policy issues for consideration in the current review? Are there additional issues that should be considered?

- The questions listed on Pages 2-15 to 2-17 seem well-posed and comprehensive. Several are posed as Yes/No answers (e.g., "Is new information available to improve understanding of PM exposures…" the obvious answer is "Yes," as it is to other Yes/No questions). Same Yes/No comment applies to questions on Pages 2-27 to 2-28. The "To what extent…" phrasing is a better approach." It would be worthwhile to number these questions so that they can be referred to more easily.
- Page 2-15, Lines 17-23. It should also include <24-hour average effects, as indicated in Figure 2-1 and is implicit in answering the 7th bullet on Page 2-16 regarding "effect modification" and the 2nd bullet of the policy-relevant question on Page 2-17 addressing "averaging time".

Additional Comments

- Kelly et al. (2012A, 2012B) on Page 2-24, Lines 24-25 is not included in the reference list at the end of Chapter 2.
- Footnote on Page 2-22 should be revised as "The IMPROVE algorithm (Pitchford et al., 2007) uses major PM chemical composition measurements and relative humidity…" (similar changes should be made on Footnote "119" on Page 5-5.)

Chapter 3: Science Assessment

To what extent does Chapter 3 clearly and adequately describe the scope, specific issues to be considered, and organization of the ISA?

Chapter 3 does an adequate job, however, there are some redundancies with Chapter 2. For example:

- Page 3-12, Lines 33-35. Does this refer to questions in addition to those in Chapter 2? If so, why not include them in Chapter 2?
- Page 3-14, Lines 3-16. Wouldn't it be better to combine these questions with those in Chapter 2? Several are closely related, although the wording is different. Some of these are better expressed than the Yes/No versions in Chapter 2.

What are the panel's views on the overall scope of the ISA? Does the planned scope ensure that the EPA will capture the scientific literature most pertinent to the ISA's focus, which is answering the question, "Is there an independent effect of PM on health and welfare at relevant ambient concentrations?"

The overall scope seems adequate, with the following minor comments:

- The separation of $PM_{2.5}$ and $PM_{10-2.5}$ effects on Page 3-3 (Lines 13-14) is a good approach.
- The seven issues on Page 3-3, Lines 26-30 to Page 3-4, Lines 1-3 seem complete.
- The answers to the questions posed on Page 3-4, Lines 26-30 are obviously "Yes". The meaning of the parenthetical on "i.e., an independent effect" is unclear. Better questions might be:
    1. How does new information (since the last review) more specifically relate PM exposure to health and welfare effects?
    2. What additional or replacement PM indicators, averaging times, levels, and statistical forms are best related to public health and welfare?
- Footnote "77" on Page 3-5 should include PM composition as well as the other properties.
- Page 3-5, Line 8. The "e.g." implies a mass concentration related to three size fractions. Does this mean only studies that include all three of these sizes will be considered? Why would studies looking at specific PM components be excluded, as implied by this statement?
- With respect to ecological effects (Page 3-5, Lines 16-26), this reviewer disagrees with removing N and S from the PM consideration and is not convinced that these are adequately addressed by NO_x and SO_x ISAs. First, N and S constitute major fractions of $PM_{2.5}$ and they are not linearly related to their primary precursors which are regulated by the NO_2 and SO_2 NAAQS, respectively. The same issue is discussed in Section 5.3.2 (Page 5-10, Lines 21-24 and Page 5-11, Lines 1-2) that restated current reviews only deal with ecological risk assessment associated with organics and metals. Second, there is likely to be more information available for the PM ISA than was reviewed for these recent NO_2 and SO_2 NAAQS. Third, NH_3 is a large source of N that is not adequately addressed by the non-PM NAAQS. There is ample precedent for further controlling NO_x and SO_x to attain PM NAAQS beyond that necessary to attain the NO_2 and SO_2 NAAQS (U.S.EPA, 1999, 2005).
- Page 3-6, Lines 8-15. Short-lived climate forcing by PM is well treated in EPA's recent Report to Congress (U.S.EPA, 2012), that should be noted.
- Figure 3-1 (Page 3-9) refers to a non-existent "Figure III" in the first box (i.e., Literature Search and Study Selection), which seems to refer to U.S. EPA (2015). Visibility should be added as an explicit effect in the second box (i.e., Evaluation of Individual Study Quality).
- Page 3-18, Lines 13-21. Differences between assumed and real-world emission factors need to be addressed. There is growing evidence that current emission models/factors underestimate real-world emissions. Recognition of intermittent emitters such as wildfires is good. Other intermittent PM irritants include dust storms and bioaerosol (e.g., allergen) outbreaks. Rather than singling out source apportionment uncertainties (without recognizing uncertainties in emission models/factors), this topic might emphasize reconciling differences between bottom up (emission model) and top down (receptor model) estimates.
- Page 3-18, Lines 22-27. Knowledge about limiting precursors (e.g., NH_3 vs. HNO_3) and pollutant inter-relationships (e.g., SO_2 reductions freeing up NH_3 for reaction with HNO_3) should be considered. Secondary organic PM is emerging as a large unknown as primary and secondary inorganic aerosol levels decrease and its recognition here is appropriate.

- Page 3-18, Lines 37- 40. For PM concentrations, “background” is an ambiguous term. “Natural”, “trans-U.S. boundary”, “unmanageable”, or similar terms would be more specific to source types that would be excluded from U.S. regulation.
- Page 3-19, Line 22. With respect to available techniques for human exposure, “represent” or “simulate” might be better than “replicate”, as replicate implies a higher degree of precision than will be attainable.
- Page 3-19, Lines 33-37 to Page 3-20, Lines 1-2. PM siting criteria specifies urban-scale or neighborhood-scale zones of representation, terms which are more specific than “centralized” monitors. Assessing exposure error, especially for people who spend time near sources (e.g., roadways) will be an important part of this evaluation.
- Page 3-22, Lines 12-14. It might be time to introduce more precise terms than “short- and long-term” exposure. There is growing evidence of immediate (within or after an hour or two) effects on heart-rate or asthma, as well as within a few days or over many years.
- Page 3-23, Lines 6-8. It is not appropriate to reject *a priori* inclusion of studies relating to specific PM compounds or their solubility on PM filter extracts. The rationale of an “…inability to compare effects to the current mass-based standard.” can be applied to many of the other topics treated in this section, and if it is not valid elsewhere, it is not valid here.
- Page 3-25, Lines 8-36 to Page 3-26, Lines 1-15. A focus on life-stages and susceptible populations should be an important component of this assessment, as indicated in this section.
- P. 3-27, Lines 8-17. In addition to sulfate and nitrate, the carbonaceous component, including both organic and elemental carbon, is also important to evaluate visibility effects. This will become more so (even in the eastern U.S.) as sulfate decreases.

What are the panel’s views on the approaches outlined in Chapter 3 to streamline the discussion in some sections of the ISA? What are the panel’s views on EPA’s plans to produce an assessment that is concise and forms an adequate scientific foundation for subsequent steps of the NAAQS review process?

Expression of a concise and adequate scientific foundation that includes all relevant new findings is easier said than done. The intentions are good, but we’ll need to see how it works out. It seems that there is sufficient review and revision in the process to iterate the document toward this goal.

Chapter 4: Health Risk and Exposure Assessment

To what extent does Chapter 4 clearly and adequately describe the scope and specific issues, including the identification of the most important uncertainties, to be considered in developing the HREA Planning Document for this review?

- There is much redundancy with Chapter 3.
- In Chapter 1, REA is used instead of HREA; consistent terminology should be used. To what extent is the information in the PM ISA to be repeated in REA (Figure 1-1 on Page 1-4)?
- A flow diagram showing the specific ISA outputs (e.g., C-R functions) to be used as HREA inputs would be useful. The emphasis on uncertainty identification, quantification, and evaluation is good.
- Coarse particles, $PM_{10-2.5}$ (defined on Page vii) is called thoracic coarse (Page 4-2, Line 9) and defined as “inhalable coarse” on the Factsheet in the EPA website; consistent terminology is needed.

Chapter 5: Welfare Risk and Exposure Assessment

To what extent does Chapter 5 clearly and adequately describe *the scope and specific issues, including the identification of the most important uncertainties, to be considered in developing the WREA Planning Document for this review?*

Information in Chapter 5 presents lots of redundancy with Chapters 2 and 3.

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Dr. Douglas W. Dockery

Overall, I strongly support the Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter. Synthesizing the evidence across disciplines, that is, considering experimental and observational data together to examine effects on broad classes of health outcomes is a very positive approach. I have some additional thoughts elaborating on parts of the Integrated Review Plan which I have tried to link to specific sections by page and line.

Alternative PM Metrics (Page 3-3, lines 12-21)

We should keep in mind that $PM_{2.5}$ was a metric defined by the sampling technology available in the 1980's. It may not be the optimal size cut for defining health effects. In addition, particle mass may not be the optimal measure. However, $PM_{2.5}$ was a very substantial improvement over prior particle measures such as BS, TSP, and even PM_{10}. Moreover, it has been a very robust and consistent indicator of health effects over the last three decades and over hundreds (thousands?) of health effects studies. Clearly, we need to examine alternate measures of particle exposure, but as suggested these alternate measures need to be referenced and directly compared to $PM_{2.5}$. Without such direct comparisons, studies of alternate measures of particulate air pollution health effects are not informative.

Synthesis (Page 3-7, Assessment Approach)

It is refreshing to see that studies would be selected based on the additional information they provide beyond what was known in the last review. Support the approach of examining experimental (toxicologic) and observational (epidemiologic) studies simultaneously while examining broad classes of health outcomes. Indeed, there are likely to be common pathways across the various health outcomes (respiratory, cardiovascular, neurologic, etc.) Ultimately, it would be useful to examine the evidence for pathways rather than by clinical disease, although I do not think we are ready to make that jump.

Avoiding characterization of studies by a checklist is a major advance.

It is also refreshing to see that statistical significance is not mentioned as a defining characteristic of an informative study. As Geoffrey Rose said regarding tests of significance in his seminal paper on causation vs association fifty years ago,

> "No formal tests of significance can answer those questions. Such tests can, and should remind us of the effects that the play of chance can create, and they will instruct us in the likely magnitude of those effects. Beyond that they contribute nothing to the 'proof' of our hypothesis."

Multiple Pollutants (Page 3-14, line 31)

Disaggregating the independent effects of the mix of gaseous and particulate air pollutants continues to be a challenge. Traditional statistical methods to examine correlated pollutants have not been very informative. However, new statistical methods such as mediation analyses have been applied in recent studies and offer new insights.

Short-term Effects (Page 3-20, line 11-16)

The first wave of studies of the acute effects of PM was dependent on the availability of daily rather than every sixth day monitoring. This allowed examination of daily health surveillance and clinical data. PM measurements are now routinely available by hour or even minutes. However, the utility of these sub-daily measurements is limited by the lack of health, clinical or physiologic data on a sub-daily basis. For clinical outcomes it has been almost impossible to define the onset of an event at a scale less than a day. Indeed, using calendar day has been shown to produce misalignment, exposure misclassification, and loss of statistical power. Continuous personal monitoring of physiologic parameters such as heart rate, heart rate variability, dysrhythmias, or blood glucose levels offers some hope of understanding sub-daily effects. However, short-term PM measures will have limited value in epidemiologic studies until continuous or frequent (e.g., hourly) physiologic measures are available for study participants.

Spatial Resolution (Page 3-20, lines 17-25)

The advances in PM epidemiology since the last review are largely due to significant improvements in improved resolution of the spatial distribution of PM. The informative studies are estimating exposures within in addition to between communities. The use of GIS methods to locate subjects' residence has significantly improved our ability to estimate long-term average subject-specific PM exposures. This in turn has led to more statistically powerful epidemiologic studies, and I would argue larger effect estimates. These advances have used a range of geospatial methods to estimate exposure including:

- Geospatial interpolation and smoothing between monitors
- Satellite aerosol optical depth measure at increasing resolution
- Networks of short-term monitoring at strategic locations within a community
- Chemical transport models
- Land-use regression models
- GPS linked personal or vehicular monitors

Each of these approaches provides information on the macro- (10's km) and micro-scale (100's meters) spatial distribution of PM across communities. Each approach has its weaknesses. Indeed, in some sense each of the estimates are wrong, but each are informative. Current PM epidemiologic studies which have used integrated estimates of subject-specific average PM exposure based on these multiple approaches are now common, and are providing the most informative exposure-response functions.

Cutting-edge studies are combining the multiple sources of data to produce time-varying within community (i.e. spatial fine resolution) estimates of exposure. Indeed, the promise of individual personal monitors is that they will allow continuous mapping of the hour-by-hour variation of PM outdoor exposures.

Cancer (page 3-22, line 23)

Since the last PM review, IARC has designated outdoor particulate matter as a Group 1 carcinogen. This is a major change in the assessment of the available epidemiologic and toxicologic literature, and no doubt will be an important consideration in this review. The Draft Integrated Review Plan notes that IARC determines only if PM can cause cancer at any inhaled concentration, while the Integrated Review will examine the evidence that PM causes cancer at relevant ambient concentrations. If the exposure – cancer response is assumed to be linear, with no threshold, there will have to be an extended discussion of acceptable cancer risk.

In addition, IARC also has identified diesel engine exhaust as a Group I carcinogen. This designation would suggest that the Integrated Review will have to have to consider a specific designation for diesel particulate matter.

Welfare Effects (Page 3-26, line 16)

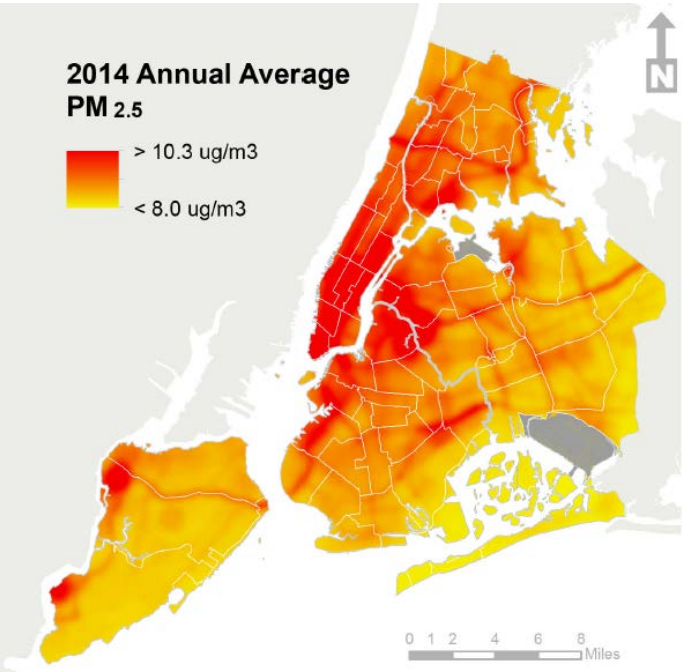
While the Clean Air Act separates primary (health) and secondary (welfare) effects of air pollution, there is increasing evidence of links between traditional welfare indicators such as visibility and health. A growing number of papers are showing that living in “green” communities is associated with indices of health. We would expect that similar measures such as improved visibility would also be linked to improved health. While it is likely beyond the current available body of literature, we should expect continuing blurring of the lines between “welfare” and “health” measures.

Mr. Henry (Dirk) Felton

Comments on Chapter 2

Section 2.1.3 Pg 2-16: Is new information available to improve our understanding of PM exposures, and how those exposures relate to the ambient concentrations often used as exposure surrogates in epidemiologic studies?

It is often difficult to ascertain the representativeness of regulatory monitors due to the limited number of monitors in most urban areas and the requirement for community scale siting which avoids placing monitors near sources. In NYC there is a program that provides an accurate assessment of the variability of PM-2.5 across the metro area. The New York City Community Air Survey (NYCCAS) is an on-going monitoring and modeling program that provides PM-2.5 and other pollutant concentrations by neighborhood and by gradient maps for the NYC metro area.[1] The study design incorporates portable and regulatory monitors at over 100 locations and the study provides a very good measure of the intra-urban variability in pollutant concentrations. Additionally, since the study has been underway since 2008, data show trends and response to pollutant control strategies employed within the city.



Section 2.1.3 Pg 2-17 Do the available health effects evidence, air quality information, and exposure/risk information provide support for considering averaging times in addition to, or in place of, the current 24-hour and annual averaging times?

This comment could fit into several sections in the IRP. I propose a new averaging time for the PM NAAQS that accounts for regularly occurring elevated sub-daily PM exposure. Urban areas typically

[1] New York City Community Air Survey, Neighborhood Air Quality 2008-2014. NYCDOH and Queens College, April, 2016, https://www1.nyc.gov/site/doh/data/data-publications/air-quality-nyc-community-air-survey.page

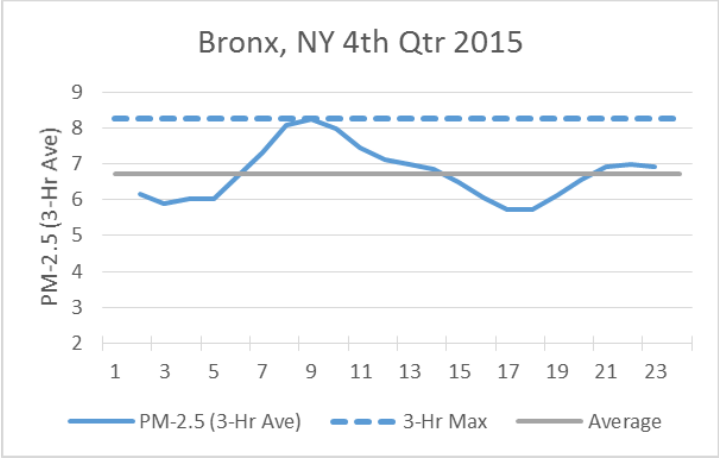
have sources such as traffic, industry or biomass related space heating that cause elevated PM-2.5 for several hours each day. The public is exposed to these sources because the sources and the population are primarily active during the day and evening hours.

The averaging time for the existing 24-Hr PM NAAQS time masks these elevated hours by including overnight hours between midnight and early morning in the 24-Hr average value. Overnight hours are typically lower in PM-2.5 concentration than daytime hours in urban areas and are less relevant for exposure.

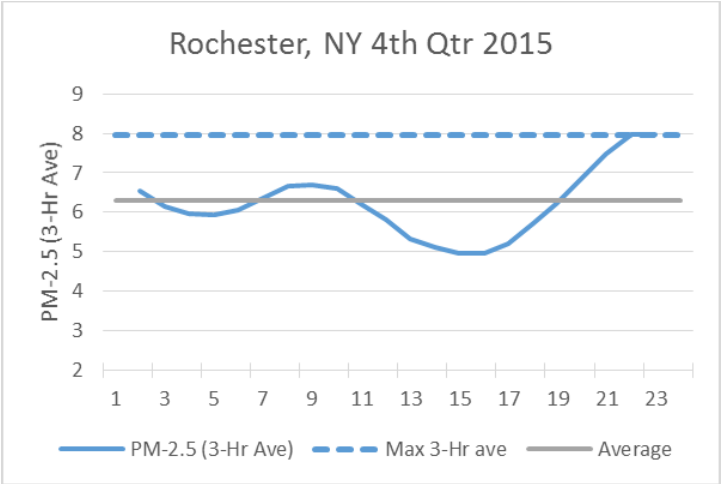
I propose to use a quarterly diurnal average of PM-2.5 values that are then smoothed by a center 3-Hr rolling average. The NAAQS could then be set at the maximum 3-hr diurnal average for the quarter. PM-2.5 FEMs at urban NCore sites can provide the 1-hr data used to calculate the quarterly diurnal rolling averages.

This averaging time makes the NAAQS more stringent in urban/source areas that are effected by the same local sources every day. These local sources including traffic, industry and biomass combustion have the potential for relief through local control strategies. In rural areas, where there is no significant difference between the 3-hr diurnal maximum and the 24-hr average, the NAAQS would not be more stringent. In these areas, PM-2.5 is often due to long range transport and there are no effective local control strategies.

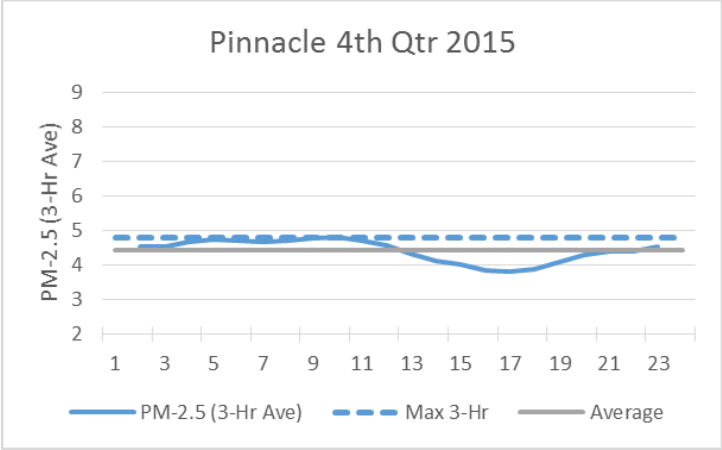
This averaging time provides for regulation of sub-daily PM exposures but it has the stability of a longer term average. Non-repetitive PM sources and noisy 1-hr FEM data will not materially affect the quarterly diurnal average. The plots below provide a 4th Quarter 2015 example for a traffic impacted site in the Bronx, NYC, for a wood smoke impacted urban site in Rochester, NY and for a rural site in NY. In the Bronx and in Rochester where there are significant local sources, the maximum 3-hr diurnal average is 23% and 26% higher than the 24-hr average respectively. At the rural site, the max 3-hr diurnal average is 8% higher than the average.



Local Traffic Exposure: Maximum 3-Hr Diurnal average at 9:00 am



Local Biomass Combustion Exposure: Maximum 3-Hr Diurnal average at 10:00 pm



No local Exposure: no significant Maximum 3-Hr Diurnal average

Section 2.2.3 Pg 2-28 Does the available evidence and/or quantitative analyses suggest that PM-induced visibility impairment or other PM-related welfare effects could occur with ambient concentrations of PM that meet the current standards? If so, could these effects be of sufficient magnitude and/or frequency such that they might reasonably be judged to be adverse to public welfare?

The NYSDEC operates telephone hotlines and a website that are available 24-hours a day to accept complaints from the public regarding any environmental issue. New York State residents have not made any inquiries about degraded urban visibility. This is despite the fact that there is a camera network specifically designed to examine urban and rural visibility at sites in the Northeast from Baltimore to NYC to Moosehorn, Maine.[2] The website updates images every 15 minutes and provides comparisons to ideal views as well as images from good and bad days. There is no evidence that the public welfare is being impacted by the lack of a visibility based secondary PM standard.

[2] Camnet:www.hazecam.net

Comments on Chapter 3 (Science Assessment):

Section 3.4.4 Pg 3-18 What are the strengths and limitations of existing and new measurement methods and approaches (including low cost sensors and remote sensing) for both advancing science and providing routine measurements of particulate matter?

The IRP should specify how issues with each PM monitoring method will be addressed in the upcoming review.

TSP Pb FRM: The High volume method uses a peak roof sampler that makes the sample collection efficiency dependent on wind direction. This method should be improved to make sure that collection efficiency is adequate for the purpose and is insensitive to wind direction.

PM-2.5 FRM: The low volume method does not retain a consistent portion of the volatile fraction of PM. This inconsistency is due to evaporation during and after the sampling period and prior to sample refrigeration. The resulting data are not as representative of what people are breathing as it should be. If the filter method is going to be used into the future, the sample filter should be maintained at a dew point lower than ambient during sampling and the filter should be refrigerated at the conclusion of sampling. If the PM-2.5 FRM included more of the volatile fraction of PM, the resulting data would be better able to assess human exposure near sources that include mobile sources and biomass combustion.

PM-2.5 FEM: The criteria for approving PM-2.5 FEMs were never adequate to insure that FEM data would be similar enough to PM-2.5 FRM data. The method designation criteria required winter and summer test data to be averaged together which negated seasonal bias and the requirement to average triplicate sampler results masked noisy instrument data. Inadequate FEM approvals have resulted in a deployed FEM network that cannot be reliable compared to FRMs or to the NAAQS. There are monitoring agencies that are now faced with FRM data on a 1/3 schedule that meet the NAAQS and FRM data with FEM data filled in on day 2 and 3 that exceed the standard. This is an untenable situation for monitoring and planning agencies across the country.

PM-2.5 CSN: The CSN program was originally intended to be an urban focused long-term trends network to provide data necessary for the development of PM control programs and for health studies that examine the effects of the components of PM-2.5. The EPA never specified that the CSN sampling characteristics match that of the FRM and the program suffered because the retention of specific species did not match the retention of those species on the FRM. The CSN sampling characteristics were modified further so that the EC and OC fractions matched the EC and OC results from the IMPROVE program. The addition of the visibility objective was detrimental to the original program objectives. The CSN data continue to be less valuable because the PM-2.5 component concentrations do not match those retained in the FRM. Mass balance calculations of the CSN components do not match the mass determined on the FRM. This makes it difficult to use CSN data in health studies that attempt to determine which components of PM-2.5 are responsible for health effects. This issue is of particular concern for volatile components of PM-2.5 which are prevalent in urban source regions such as the near road environment.

Section 3.4.9 Pg 3-26 Have recent studies characterized whether certain lifestages or populations experience differential exposures to PM mass, PM components or PM sources, which may contribute to them being at increased risk?

The IRP includes PM deposition in the consideration of welfare effects but not in the consideration of health effects. This separation negates the health impacts from the exposure of air toxics originating from deposited PM on soils in urban and near source areas. This exposure pathway will differentially impact children playing in backyards and in playgrounds as well as the population that consumes vegetables grown in soils that have been contaminated by deposited PM.

Comments on Chapter 4 (Human Health Risk and Exposure Assessment):

Section 4.3.1 Pg 4-14, "the lack of a national monitoring network for ultrafine particles, are likely to continue to challenge our ability to conduct a quantitative assessment for ultrafine particles in the current review", "we will consider in the HREA Planning Document the degree to which these ambient concentrations could be adequately characterized using available data from the national monitoring networks (or other datasets in the case of ultrafine particles) to support the HREA."

The availability of ultrafine particle number (UFP) data has improved since the last review of the PM NAAQS. Most monitoring agencies that operate UFP monitors use the TSI 3783 which is a water based condensation particle counter that was designed for long-term deployment at ambient monitoring stations. The EPA has provided AQS method codes for this instrument and a few agencies have uploaded UFP data to the database. There are UFP datasets available from a variety of monitoring locations including the ones listed below:

Boise, Idaho - Near road
Los Angeles MATES IV - Study locations
San Francisco - Community Scale and Near road
Queens, NY – Community Scale Urban NCore
Buffalo NY - Near road
Pinnacle State Park NY - Rural NCore
Tampa FL - Near road
Baltimore, MD - Near road

Comments on Chapter 5 (Welfare Risk and Exposure Assessment):

To what extent does Chapter 5 clearly and adequately describe the scope and specific issues, including the identification of the most important uncertainties, to be considered in developing the WREA Planning Document for this review?

Prioritizing the welfare effects of ambient PM should be given more attention in this section. Urban visibility should not be ranked highly as mentioned in my comment on section two. The welfare effects of climate change should be given serious consideration. It may be better to focus on the direct effects of aerosols since they are more straightforward than the secondary effects.

Is there additional information that should be considered or additional issues that should be addressed in considering the potential for quantitative analyses for welfare effects in the current review?

In many states, there are ecosystems that are impacted by deposition of PM including compounds such as mercury, zinc, copper and cadmium. The presence of some of these compounds have led to stringent restrictions on the consumption of fish and other species. The resulting welfare effects include impacts to wildlife, economic value and personal comfort and well-being. These welfare effects should be given a high priority in the IRP. The impacted areas in many states are located where there are no potential sources of toxic compounds other than atmospheric deposition. This eliminates much of the uncertainty regarding the origin of the compounds.

Section 3.4.10 Pg 3-26 "In regards to effects of PM on ecosystem components (e.g. plants, soils, wildlife, nutrient cycling), both direct and indirect effects of PM deposition will be considered."

I am including references that address Mercury deposition in case they have not already been collected for this review.

Harris et al, (2007) Whole-ecosystem study shows rapid fish-mercury response to changes in mercury deposition, 16586–16591 Proceedings of the National Academy of Sciences, vol. 104, no. 42.

J. G. Wiener et al, (2006) Mercury in Soils, Lakes, and Fish in Voyageurs National Park (Minnesota): Importance of Atmospheric Deposition and Ecosystem Factors, Environ. Sci. Technol., 40, 6261-6268.

C Hammerschmidt et al, (2006) Methylmercury in Freshwater Fish Linked to Atmospheric Mercury Deposition, Environ. Sci. Technol., 40, 7764-7770.

Charles T. Driscoll et al, (2013) Mercury as a Global Pollutant: Sources, Pathways, and Effects, Environ. Sci. Technol., 47, 4967-4983.

Dr. Mark W. Frampton

General comments:

Overall, the draft IRP represents a clear, thorough description of the approach to be taken in the PM NAAQS review process. It includes a thorough review of the relevant legislation and outcomes of the previous PM NAAQS reviews. It identifies the key remaining uncertainties at the time of the previous review, and describes a comprehensive approach for re-evaluating the primary and secondary PM NAAQS.

Below are my comments in response to the key questions on Chapter 3, followed by specific comments on the Chapter.

Comments on Chapter 3 (Science Assessment)

To what extent does Chapter 3 clearly and adequately describe the scope, specific issues to be considered, and organization of the ISA?

Generally the chapter does an excellent job of describing the scope of the ISA, and clearly outlines where emphases will be placed in the current review, highlighting areas of uncertainty determined during the previous review. The organization is logical and workable.

What are the panel's views on the overall scope of the ISA? Does the planned scope ensure that the EPA will capture the scientific literature most pertinent to the ISA's focus, which is answering the question, "Is there an independent effect of PM on health and welfare at relevant ambient concentrations?"

The scope of the ISA is sufficiently broad to capture the pertinent literature for review.

What are the panel's views on the approaches outlined in Chapter 3 to streamline the discussion in some sections of the ISA? What are the panel's views on EPA's plans to produce an assessment that is concise and forms an adequate scientific foundation for subsequent steps of the NAAQS review process?

The evolution from Criteria Documents to the ISA, in an effort to shorten and focus the review, has improved the readability and usefulness of the NAAQS reviews. This approach should continue, with less emphasis on describing every study and even more emphasis on integration and comparisons across studies and disciplines.

Specific comments:

P. 3-7 line 9: "The PM ISA will conclude with a chapter that examines studies for evidence of differential exposure and risk for PM-related health effects to draw conclusions…". The meaning here is not clear, especially "differential exposure". Suggest rewording this sentence with a better description of what this final chapter is about. And it is not clear whether this is actually meant to be the final chapter. The 2009 ISA concluding chapter (9) was about welfare effects. Perhaps what is being referred to here is the next to last chapter, 8, about susceptible populations.

P. 3-7, line 24: "This and subsequent key components of the process currently followed for the development of an ISA are presented in Figure 3-1…". Figure 3-1 doesn't actually show "This", which refers to the Call for Information described earlier in this paragraph. Suggest changing the sentence to "Key components of the process…". Please see comments below on Figure 3-1.

P. 3-9, Figure 3-1:

- In the first box, "See Figure III" should be removed.
- In the 3rd box, the title "Develop Initial Sections" seems rather meaningless. This really is the "meat" of the ISA evidence review, not just the "initial" sections. Suggest finding a better title for the left side of this box.
- 6th box (left): "Draft Integrated Science Assessment"…isn't that what the whole figure is about? "Evaluation and integration of newly published studies"…does this mean studies published since the initial literature review was completed? Not clear what this box is trying to do.

P. 3-11, line 32: "…conclusions about the strength of inference from study results will be made by weighing the authors' conclusions and independently evaluating study quality…". The phrase "weighing the authors' conclusions" is unclear, and seems to contradict the previous sentence, which states "…but not by considering whether the study results are positive, negative, or null."

The evaluation of study quality is vague, and it is unclear what is done with the results. Is each study given some kind of quality rating? Are poor quality studies rejected from consideration? How does study quality impact the ISA? It is important to make clear whether or not there are objective criteria for these determinations, and how the quality ratings are used. Obviously the variety of studies and approaches limits the ability to be very quantitative about this, but at present this section touts a "uniform approach" that is not well supported in the text. Perhaps need to be clearer about the limitations here.

Section 3.4.3, Integration. This section is generally well written, and the hierarchy of causality determinations is a strength. However, perhaps more needs to be said about how the causality ratings are assigned during the development of the ISA. These are in fact judgements based on the weight of the evidence, and this should be acknowledged here. "Scientists" are referenced, but are these EPA scientists or are others included? Is consensus among the drafters required, and if not how is lack of consensus handled? Need to indicate what measures are undertaken to avoid bias on the part of the scientists making these judgements. This may well be documented elsewhere, and that could be referenced here. It may help to point out that initial determinations of causality in the draft ISA will be part of the CASAC review and available for public comment before finalizing the ISA.

Page 3-17, line 27 and elsewhere: Not clear what is meant by "new preference studies".

Dr. H. Christopher Frey

Comments on Chapter 2

To what extent does the Panel find that Chapter 2 clearly articulates the decisions made in the last review of the primary (sections 2.1.1, 2.1.2) and secondary (sections 2.2.1, 2.2.2) PM standards, and the rationales supporting those decisions?

The chapter does a good job of concisely articulating the key policy-relevant science issues and the decisions made in the last review. In particular, the chapter does a good job of highlighting the key scientific uncertainties from the last review.

To what extent does the Panel find that the policy-relevant questions presented in sections 2.1.3 (primary) and 2.2.3 (secondary) appropriately characterize the key scientific and policy issues for consideration in the current review? Are there additional issues that should be considered?

The policy-relevant questions listed are appropriate and thorough.

In particular, there should be systematic treatment of the answer to this question: *To what extent have important uncertainties in the evidence from the last review been addressed, and have new uncertainties emerged?*

In this regard, I also call EPA's attention to CASAC's identification of "Areas for Future Research" that were included in the "CASAC Review of Policy Assessment for the Review of the PM NAAQS – Second External Review Draft (June 2010)" EPA-CASAC-10-015, September 10, 2010, by CASAC Chair Jon Samet. The issues raised in this CASAC report regarding priorities for new research should be addressed in the ISA and as appropriate in the HREA and WREA, such as to what extent have new research and programs addressed these issues (chapter numbers and page numbers refer to the 2nd draft of the policy assessment from the last review) (bold is added for emphasis).

- "*The Second Draft Policy Assessment has identified scientific issues that will need to be addressed in order to improve EPA's scientific basis for promulgating PM standards in the future. As stated in our letter of May 17, 2010, CASAC urges the Agency to reinvigorate research that might lead to* ***new indicators that may be more directly linked to the health and welfare effects associated with ambient concentrations of PM****. CASAC also suggests the* ***ongoing collection of more comprehensive PM monitoring data****, including* ***expanding the range of sizes*** *to provide information in the* ***ultrafine particle range****, and* ***adding measurements of numbers, chemistry, species, and related emissions characteristics*** *of particles. CASAC strongly urges EPA to pursue research to* ***develop a Federal Reference Method for a Directly Measured PM2.5 Light Extinction Indicator*** *and to* ***develop baseline light extinction data so that it will be available for the next 5 year review cycle****. CASAC is available to provide advice on priorities for PM-related research.*"
- "The opportunities for epidemiological research to effectively address the knowledge gaps on the effects, and concentration-response relationships, of PM components and source-related mixtures cannot be achieved without **additional monitoring data to provide PM speciation and better**

temporal and spatial resolution. Only the EPA can provide the impetus and support for such an enhancement in air quality monitoring."

- "The research needs to address **uncertainties in health outcomes, exposure durations of concern, and susceptible populations** that are also very nicely outlined are well targeted [in the Policy Assessment], and can be effectively studied in human populations. Such studies, to be most productive, **will need the enhanced monitoring data**, as recognized by EPA staff."
- C-R functions should have quantitative confidence bounds.
- "Generating time-activity data to support probabilistic scenario-based exposure models, such as **additional activity diary data to incorporate into the Consolidated Human Activity Database (CHAD)**."
- "**Characterizing indoor exposures to PM of ambient origin**. For example, the penetration of ambient PM2.5 and PM10 into indoor microenvironments (home, work, school, restaurant, bar, vehicle) should be better characterized, particularly taking into account differences in penetration with respect to particle size and composition. Given the greater amount of time we spend in indoor vs. outdoor environments, the need for these data is compelling."
- "Addressing the **bidirectional linkages between climate change and concentration, size distribution and composition of PM in the PM10, PM2.5, and ultrafine particle (UFP) fractions**. This would include assessing the relative effects of climate cooling due to aerosols (e.g., sulfate) vs. climate warming due to elemental carbon. Effects of increased wildfires, windblown dust and pollen seasonality are also of interest."
- "Continuing support of **toxicological research in terms of chemical components, sources and subfractions (to include UFP).** Toxicological studies will address biological plausibility and give insights as to possible mechanisms. Although C-R relationships are a challenge to extrapolate from animal to human, animal studies do provide an effective means to conduct controlled and well-characterized exposure scenarios to examine C-R relationships."
- "CASAC looks forward to **the planned implementation of monitors that measure PM10-2.5, rather than PM10**. There is a critical need for national monitoring data on PM10-2.5 in order to provide a basis for epidemiological studies that focus on this size fraction. Furthermore, there is a need for speciated data to support health effects research. Spatial and temporal variability in coarse particle mass and composition need to be characterized. In addition, the national monitoring data will support a baseline for ambient air quality in order to compare with health effects data in order to assess whether there is a need for a more stringent standard.
- With regard to visibility: "In the first category, preference studies, the details noted by EPA all identify a **strong need for additional urban visibility preference studies** conducted using consistent methodology. The range of 50% acceptability values discussed as possible standards are based on just four studies (Figure 4-2), which, given the large spread in values, provide only limited confidence that the benchmark candidate protection levels cover the appropriate range of preference values. Studies using a range of urban scenes (including, but not limited to, iconic scenes – "valued scenic elements" such as those in the Washington DC study), should also be considered.
- "In the second category related to methods of measurement, CASAC supports the **proposal to conduct studies in several cities**, pairing direct monitoring of light extinction with enhanced monitoring of PM size and composition distributions (i.e., continuous PM speciation monitoring). **Additional work should also be conducted to understand the contribution of PM10-2.5 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). These data gaps are addressed in different ways in the discussion of future research needs elsewhere in the Second Draft Policy Assessment (Sections 2.5 and 3.5). Moreover, the development of continuous monitoring methods for specific PM components addressed in Section 2.5 is equally applicable here. **Improved understanding of size-dependent PM composition** would also help address the questions related to the role of scattering and absorbing aerosols in climate forcing that are raised in Section 5.2.4"

Other Considerations: With regard to monitoring issues, the draft text indicates that EPA may wish to request that the CASAC Ambient Air Monitoring Subcommittee be convened to provide formal scientific input. Given the various monitoring issues identified in this chapter, it seems prudent to proceed with this request. For example, the one topic along of evaluating the availability and performance of low-cost PM sensors would be sufficient to merit more attention. Furthermore, since PM measurements tend to entail an "operational definition" of particulate matter, measurements made by different instruments are not necessarily directly comparable. Evaluation and advice regarding the interpretation of PM measurements from the myriad of instruments that have been used in the regulatory monitoring networks and in research studies could be very useful. Another issue that may emerge from the comparison of PM measurements from near roadway versus community-based or area monitors is that the particle composition is likely to be different. Implications of such differences for interpretation of data merit attention.

Exposure Assessment: Section 4.3 discusses the potential role of exposure assessment. A key role that merits more attention is the use of stochastic population-based exposure modeling to help explain variability in C-R relationships among cities that might be associated with differences in population demographics or factors that would affect the overall average ratio of exposure concentration to ambient concentration in a city, such as building stock and air exchange rates. The latter are also influenced by season and climate zone.

Dr. Terry Gordon

Overall organization and clarity: To what extent does the Panel find that the draft IRP is clearly organized and that it appropriately communicates the plan for the current review of the PM NAAQS and the key scientific and policy issues that will guide the review?

The overall organization and clarity are excellent. In addition, this may be a bit radical, but given the process design for the 5 year cycles, this planning document step seems a bit unnecessary. Much of the wording is consistent from NAAQS substance to substance, and the real information for deliberation is in the ISAs. So why not use a fixed and formatted Planning Document that is the same for all substances?

Under the discussion of the History (section 1.3, page 1-8), the first paragraph stresses secondary particle formation and leaves out sources for directly emitted PM (e.g., resuspension, wind blown, stack emissions) – perhaps the section could be better balanced.

Chapter 4 (Health Risk and Exposure Assessment):

To what extent does Chapter 4 clearly and adequately describe the scope and specific issues, including the identification of the most important uncertainties, to be considered in developing the HREA Planning Document for this review?

The Chapter clearly describes the scope and issues to be considered, including the uncertainties.

Is there additional information that should be considered or are there additional issues that should be addressed in considering the potential for risk and/or exposure analyses in the current review?

This reviewer is not aware of any additional issues to be considered in regards to the risk or exposure analyses. There did seem to be a large emphasis on urban data and risk considerations to the point of the rural risks being lost or at least very low in priority.

Chapter 6 (Policy Assessment and Rule Making):

On page 6-1, it is puzzling why it says REAs, 'if available', will be used in the PA. I've always assumed that REAs are an integral if not the integral support document for the Policy Assessment.

Dr. Jack Harkema

Comments on Chapter 1, Introduction

Overall the sections on legislative requirements (1.1), overview of the NAAQS review process (1.2), history of reviews of the PM NAAQS (1.3), general scope of the current review (1.4) and anticipated schedule for the current review (1.5) are clearly and concisely articulated and provide the necessary introductory information and outline for the remainder of the document.

It would be helpful for the reader to provide definitions and examples for *sensitive group*s and *at-risk populations* early in the document and prior to their use in this chapter (i.e., p1-3 l12 and p1-13 l27) and in subsequent chapters. In this regard, how susceptibility and vulnerability relate to sensitive groups and at-risk populations could be incorporated in these definition(s) and examples and explained in more detail in later chapter(s).

Query. In 1.1 (Legislative Requirements), should more emphasis be placed on sensitive groups and at-risk populations in regards to the adequate margin of safety (e.g., 1-3, l1-14)?

Dr. Joel Kaufman

Overall I find this to be a well-organized, thorough and clear document. I congratulate the EPA program staff for clearly articulating their approach to developing the documents needed in this review. The document identifies the key questions and issues that will dominate the consideration of the PM NAAQS.

Chapter 1 is a concise regulatory history and framing of the process.

I have only minor comments, which regarding a few of the choices made by staff as they look toward developing the ISA, and find that most of these comments are well-reflected in the consensus document.

With regard to section 3.1.2 on Defining Policy-Relevant Literature, I do not fully agree with the decision that experimental studies of source-based mixtures (e.g., diesel exhaust, gasoline exhaust, wood smoke) are only relevant if they can assess the independent effect of PM in the mixture under study. Studies of source-based mixtures, especially when they can be performed in a clinical setting (i.e., in the species of interest and hence without concern about inter-species differences) have been rather informative about not only mode of action but also consistency of human health effects. Hence even studies that have not used attempts to disentangle the independent effects of PM from the mixture (as by filtration or other approaches) should be considered where relevant to the questions at hand in considering health effects of PM.

Dr. Patrick Kinney

Comments on Chapter 4

EPA staff are to be commended on the quality and comprehensiveness of this draft document. I found it technically sound, comprehensive and clearly written. My comments relate to the scope work that is planned for the next phase.

Overall comments:
EPA should give serious consideration to expanding the geographic scope of the health risk assessment to the entire continental US. The 2010 assessment focused on just 15 cities. Given the current state of the art for air pollution risk assessment, there is no obvious reason why the assessment shouldn't be nationwide. If not nationwide, then it should include a larger number of cities as well as suburban and rural areas. It would also be helpful in this draft document to explain what technical constraints led to the former decision to restrict to 15 cities. Do these constraints still exist? There have been so many nationwide PM-related risk assessments that it's hard to justify such a restricted approach given the importance of the PM NAAQS process. Also, I would question the assumption stated on page 4-16 in the "spatial scale of the analysis" paragraph that uncertainties are high when doing assessments in areas that weren't part of underlying epidemiologic studies, at least for long-term exposure effects.

Regarding at-risk life stages, consideration should be given to taking into account the long-term cardiovascular disease risks posed to children and young adults by long-term exposure to PM. Though the ACS study only included adults over age 30, there's no biological reason why PM only becomes risky at that age. We have plenty of analogies to draw on from the smoking and ETS literatures to show that early-life exposures lead to long-term risks.

Regarding the exposure assessment, I encourage EPA to consider carrying out an exposure assessment. I think it's very valuable in showing what proportion of the population gets exposed over the short and long term to unusually high levels of PM, how those people may differ in terms of demographics, and what factors lead to their higher exposures.

Page 4-3, line 17: This text is explaining the criteria used for choosing cities in the 2010 assessment. Criterion 2 – "inclusion in an epidemiologic study providing effect estimates" is overly restrictive and I advise EPA to consider dropping it for the new assessment.

Page 4-3, footnote 84, first line: change "at a given time" to "in a given time period"

Page 4-4, footnote 88: the divergent effect thresholds used for short-term and long-term exposure seem difficult to rationalize, and I suggest EPA try to come up with a single, consistent approach in the next assessment.

Page 4-5, footnote 91: the first and second sentences appear to contradict each other. Please clarify/revise.

Page 4-7, line 26: change "mortality risk" to "PM-related mortality risk"

Page 4-24, table 4-2: additional key uncertainties include possible changes over time in air exchange rates and in time-activity patterns. These data inputs were surveyed many years ago, and there may have been changes in both.

Dr. Michael Kleinman

Comments on Chapter 3

To what extent does Chapter 3 clearly and adequately describe the scope, specific issues to be considered, and organization of the ISA?

Overall the chapter clearly describes the factors listed above. The section defining "policy-relevant literature" was helpful in summarizing the complexity of the PM with respect to size and composition. Although it is assumed it might be useful to make sure that it is clearly stated that UFP are contained in nearly all ambient studies of PM2.5.

What are the panel's views on the overall scope of the ISA? Does the planned scope ensure that the EPA will capture the scientific literature most pertinent to the ISA's focus, which is answering the question, "Is there an independent effect of PM on health and welfare at relevant ambient concentrations?"

Overall the planned approach is sound. Some emphasis should be given to seasonal variations in health effects that might relate to systematic differences in particle composition/toxicity as a function high and low photochemical activity. In section 3.4.4 relating to atmospheric chemistry we could add to bullet point 5: What uncertainties exist concerning the sources and atmospheric chemistry of PM 37 components (both primary and secondary particles)? How does PM composition change over various spatial and temporal scales? Are there new information available regarding the role of seasonal variations in atmospheric chemistry and photochemistry on the toxicity of ambient PM? What new information is available regarding the composition of the PM size fractions that could not be well 1 characterized during the last review (e.g., coarse PM, ultrafine PM)?

What are the panel's views on the approaches outlined in Chapter 3 to streamline the discussion in some sections of the ISA? What are the panel's views on EPA's plans to produce an assessment that is concise and forms an adequate scientific foundation for subsequent steps of the NAAQS review process?

The approach outlined for the health and welfare effects will allow for the EPA to provide a focused assessment of the scientific evidence that can more directly inform policy-relevant considerations is quite detailed and should adequately provide the necessary foundation for the review.

Dr. Rob McConnell

To what extent does Chapter 3 clearly and adequately describe the scope, specific issues to be considered, and organization of the ISA?

The chapter clearly and adequately describes the scope, specific issues to be considered, and organization of the ISA.

What are the panel's views on the overall scope of the ISA? Does the planned scope ensure that the EPA will capture the scientific literature most pertinent to the ISA's focus, which is answering the question, "Is there an independent effect of PM on health and welfare at relevant ambient concentrations?"

In general, the strategy proposed to identify the relevant literature is appropriate. One potential reconsideration might be the automatic exclusion of all commentaries. Although these might not generally contain new primary data, some selected ones might provide novel insights into mechanisms or interpretation of the literature.

Some additional questions that merit consideration:

The impact of recent revelations of uncertainties in emission profiles, especially for diesel exhaust particulate, is not identified as a potentially relevant issue. Allegations that the emissions from some vehicles have not been appropriately reported by the manufacturers or adequately characterized in emissions assessments may be relevant to the ISA.

The scope of work does not exclude consideration of on-road (eg. commuting) exposures, which are increasingly recognized to result in health-relevant exposures, but they are not mentioned. These might appropriately be included in the review. There are other recently recognized sources of heavy PM exposure, such as ultrafine particles from large airports.

As a minor clarification, the distinction of effects of short-term exposure studies ("i.e., exposures ranging from hours to days to weeks") that primarily rely on temporal variation in exposure from effects of long-term exposure studies ("i.e., 13 exposures ranging from months to years") that rely on spatial variability of exposure is, in general, appropriate. Conceptually, however, exposures that vary seasonally over months may reflect temporal variation with high relevance for some outcomes, for example trimester-specific gestational effects of exposure. To the extent possible, harmonization of evaluation of effects across temporal windows of exposure would be helpful.

Does the restriction to studies of exposures below 2 mg/m3 preclude inclusion of studies that would help strengthen causal inference based on an evaluation of concentration-response or dose-response relationships, for example studies of effects of occupational exposures to diesel exhaust particulate components of the PM mixture? To the extent recent studies attempting to examine the integrated exposure response relationship across a range extending to secondhand or personal tobacco smoke exposure is relevant to the ISA, the 2 mg/m3 restriction should be loosened. A related issue is the apparent restriction of toxicological studies to those below 2 mg/m3 PM, if I understood correctly. This seems likely to preclude assessment of dose-response relationships and to dramatically reduce power to identify effects in animal studies.

Finally, it is not clear to me why studies evaluating risk of cancer will not include studies that use PM filter extracts ("because they may not mimic what is bioavailable in vivo"), or on studies of individual PM

components (“due to the inability to compare effects to the current mass-based PM indicator”). Does the focus on size preclude an integrated assessment of the role of some key components, for examples metals, that are found in multiple size fractions?

What are the panel’s views on the approaches outlined in Chapter 3 to streamline the discussion in some sections of the ISA? What are the panel’s views on EPA’s plans to produce an assessment that is concise and forms an adequate scientific foundation for subsequent steps of the NAAQS review process?

In general, the approach to streamlining the discussion seems reasonable, as long as there is a clear rationale for excluding literature that is not relevant to the development of a standard.

Dr. David B. Peden

Overall, the plan for the review is quite strong; these comments are fine points.

To what extent does Chapter 3 clearly an adequately describe the scope, specific issues to be considered, and organization of the ISA?

Overall, the plan outlined in Chapter 3 is well presented and straightforward. The specific issues to be reviewed are appropriate and address the scientific needs for assessment of data to review the PM NAAQS.

What are the panel's views on the overall scope of the ISA? Does the planned scope ensure that the EPA will capture the scientific literature most pertinent to the ISA's focus, which is answering the question, "Is there an independent effect of PM on health and welfare at relevant ambient concentrations?"

The approach to capture a broad body of evidence appears to this reviewer to be comprehensive and should identify appropriate literature for health effects, welfare, climate and ecologic effects of PM.

What are the panel's views on the approaches outlined in Chapter 3 to streamline the discussion in some sections of the ISA? What are the panel's views on EPA's plans to produce an assessment that is concise and forms an adequate scientific foundation for subsequent steps of the NAAQS review process?

It is laudable to begin the review by building on the previous NAAQS review and basically updating that document. However, as noted, there should be careful assessment of the areas of uncertainty present from the previous review, and comment specifically as to whether these areas have been better defined, remain uncertain, or shown to not be problematic.

While it is clear that this document is meant to address the need to review PM standards, it seems appropriate and useful to provide focus on PM exposure/health effects issues which could improve public health with specific attention to subsets of exposure. This is added for emphasis and for consideration in the overall advice to the EPA:

1. Health effects associated with PM near arterial roads. This could lead to better zoning or other regulation that local authorities might undertake. It also points out for the public pros/cons of living in these locations

2. Agree with attention to both acute effects of PM as well as chronic impacts. With regard to acute effects, understanding/identification of those groups at risk can provide insight for regulatory, systematic and personal interventions which may be suggested. With regard to chronic effects, examination of impact of regular exposure to PM on disease development, and modifications of normal physiology (e.g. changes in FVC)
3. Windows of exposure are important, especially with regard to any health effects which may persist after pre- or peri-natal exposure

4. Relationship of PM exposure to specific diseases (some obvious/others not) might be useful. For instance, determining what is known about PM impact on people with disorders/conditions which are in the top 5 leading causes of morbidity and mortality for adults and children

5. Agree with assessment of modes of action

There is also discussion of quality of study which seems somewhat borrowed from the medical approach to studies (e.g. Cochrane Reviews; metaanalyses), with an assessment of level of evidence in study. While it is appropriate that the level of rigor and confidence in results be assessed and considered, new and early observation should not be excluded from the review. It may be useful to have appropriate statistical expertise available to assess power and reliability of findings.

Mr. Richard Poirot

Overall organization and clarity

To what extent does the Panel find that the draft IRP is clearly organized and that it appropriately communicates the plan for the current review of the PM NAAQS and the key scientific and policy issues that will guide the review?

The draft IRP is clearly organized and clearly presented. It does a good job of identifying critical science questions, identifying areas of greatest uncertainties and approaches for reducing those uncertainties. In some cases, a bit more detail would have been useful. For example, a brief summary of major discussion topics or issues raised at the February 2015 kickoff workshop would have been informative.

Chapter 2

To what extent does the Panel find that Chapter 2 clearly articulates the decisions made in the last review of the primary (sections 2.1.1, 2.1.2) and secondary (sections 2.2.1, 2.2.2) PM standards, and the rationales supporting those decisions?

Chapter 2 clearly summarizes the decisions and supporting rationales presented in the final rulemaking from the last review. For the secondary visibility standards (2.2.2), this doesn't really convey the large body of work conducted by EPA staff, the deliberation process, decisions made and information developed over the full course of the review. The conclusions and associated rationales from the final rule (i.e. "why the Agency won't set a separate secondary standard this time") were minimally consistent with the final policy assessment document and associated CASAC comments. On page 2-27, the draft IRP indicates "The current review of the secondary PM2.5 and PM10 standards will build upon the conclusions from the last review…" It would be preferable if this said something like "…build upon the knowledge and experience gained from the last review".

To what extent does the Panel find that the policy-relevant questions presented in sections 2.1.3 (primary) and 2.2.3 (secondary) appropriately characterize the key scientific and policy issues for consideration in the current review? Are there additional issues that should be considered?

Excellent lists of policy-relevant questions are presented in sections 2.1.3 and 2.2.3. There's also a useful, but somewhat disconnected summarization on ambient monitoring networks in section 2.3.1. It might be informative to more directly link the monitoring network information to the NAAQS-relevant questions. For example, if a sub-daily primary $PM_{2.5}$ or PM_{10} standard is considered, is the existing continuous mass instrumentation (and network coverage) sufficient to support a 1-hour averaging time? Which PM components or other size fractions are sufficiently well characterized in current networks that they could be seriously considered as alternative indicators? For a secondary standard, direct, continuous measurements of PM light extinction were strongly advocated by the CASAC PM panel and AAMMS Committee in the last review, along with recommendations for establishment of a small pilot network to evaluate alternative methods. What progress has been made in this regard? What options are available for determining sub-daily PM light extinction data from existing network data? The advantages of the PM light extinction indicator advocated in the last review (vs. the fine mass indicator

considered in all previous reviews) are diminished if it can't be measured directly or calculated reasonably well from existing measurement data. Considering the most recent evidence of PM health and welfare effects (and generally static or shrinking monitoring budgets), what are the most important PM information needs that are not being addressed by current monitoring networks?

Chapter 3 (Science Assessment)

To what extent does Chapter 3 clearly and adequately describe the scope, specific issues to be considered, and organization of the ISA?

Chapter 3 provides a very clear picture of the planned scope, organization and issues considered in the ISA.

What are the panel's views on the overall scope of the ISA? Does the planned scope ensure that the EPA will capture the scientific literature most pertinent to the ISA's focus, which is answering the question, "Is there an independent effect of PM on health and welfare at relevant ambient concentrations?"

Yes, the overall scope looks very good.

What are the panel's views on the approaches outlined in Chapter 3 to streamline the discussion in some sections of the ISA? What are the panel's views on EPA's plans to produce an assessment that is concise and forms an adequate scientific foundation for subsequent steps of the NAAQS review process?

I'm not sure I completely understand this question. I think the "streamlined" approach generally employed when ISAs replaced criteria documents – focusing on the newest, most policy relevant information, and addressing key uncertainties identified in the previous review – is desirable. I think it is also very difficult to present a coherent story of "what's new and important" without a sound introductory summary of "what we knew before". In addition, an exclusive focus on previous uncertainties – without also emphasizing issues which are understood with highest confidence may present an unbalanced picture of the state of the knowledge.

Chapter 4 (Health Risk and Exposure Assessment)

To what extent does Chapter 4 clearly and adequately describe the scope and specific issues, including the identification of the most important uncertainties, to be considered in developing the HREA Planning Document for this review?

Chapter 4 clearly describes the scope, issues and important uncertainties to be considered in planning the HREA. I wonder if the specific approach(s) employed to roll back concentrations to simulate just meeting the current or potential alternative standards could be a source of significant uncertainty. Conceivably similar PM reductions could be achieved by a variety of different regional or local emissions reductions of various PM species. Are the HREA results sensitive to the specific rollback approaches? For example how does the rollback effect time periods or locations when concentrations are well below standards or other thresholds and what are the health implications? Have past applications of proportional rollback estimates ever been compared to actual declining PM concentrations?

Is there additional information that should be considered or are there additional issues that should be addressed in considering the potential for risk and/or exposure analyses in the current review?

The section 4.3 discussion of planned quantitative assessments (p. 4-11) indicates a logical major focus on $PM_{2.5}$ mass, but also indicates that – pending available information – alternative particle sizes or PM components could also be considered. Could alternative averaging times (seasonal or sub-daily) also be considered, if warranted?

I like the suggested consideration of a quantitative population-based microenvironmental exposure assessment discussed in section 4.3.2. If feasible, this might be an informative way to evaluate microenvironments with unique source, particle size, composition, other pollutants and or exposure time patterns – for example near-road environments or wood smoke in mountain valleys.

Chapter 5 (Welfare Risk and Exposure Assessment)

To what extent does Chapter 5 clearly and adequately describe the scope and specific issues, including the identification of the most important uncertainties, to be considered in developing the WREA Planning Document for this review?

Given that the details of the WREA, if conducted, are partly dependent on the yet-to-be-developed ISA, I think the general scope and identified issues presented here sufficiently clear and adequate. The identified list of uncertainties and limitations from the last review is reasonable. One general comment is that this list of uncertainties is specific to the proposed indicator of "PM light extinction" considered in the last review. A $PM_{2.5}$ mass indicator, considered as the basis for visibility-based secondary standards in all previous PM NAAQS reviews, also has merit and the advantage that it could be directly measured on an hourly or sub-daily basis with existing networks. The variability associated with effects of differing hygroscopic species composition and RH levels is relatively minor, and could be accommodated by a variety of approaches. It might also be logical to intentionally remove the variability in RH from the regulatory metric – as was done with the regional haze rule.

One of the major sources of uncertainty, the largest source of variation among the low and high bounds of potential secondary standards presented to the Administrator in the last two PM NAAQS review cycles (and a loophole which will always allow a "no secondary standard is needed" decision) is the form of the standard. The past review suggested a range somewhere (anywhere) between the 90^{th} and 98^{th} percentile, while the previous (2006) PM NAAQS review recommended a sub-daily $PM_{2.5}$ indicator with a level between 20 and 30 ug/m3 but a range of forms between the 92nd & 98^{th} percentile. There is poor justification to support any specific percentile, but off hand, the idea that people find a specific level of visibility unacceptable, but only after the 36^{th} day it occurs each year seems kind of a stretch. The IRP identifies "the degree of visibility impairment versus frequency and duration" as an area of major uncertainty. I agree, and think the details of the form should be more heavily emphasized throughout the review process.

Is there additional information that should be considered or additional issues that should be addressed in considering the potential for quantitative analyses for welfare effects in the current review?

One major focus area in the last Urban Focused Visibility Assessment was a review and synthesis of information from a relatively limited number of urban visibility preference studies. While I'm not aware of many new preference studies (one in Beijing, of questionable relevance), an informative re-assessment of the data and images from the existing visibility preference studies was conducted by Bill Malm (2011) who noted that the "The best predictor of acceptability level is apparent contrast of a prevalent distant, but not necessarily dominant, feature." This helps explain the most of the variability in in unacceptable visibility levels (in DV) across the different studies. An important implication is that consistently across all study areas (and specifically for the photos used in those different studies), people found the visibility unacceptable as the most distant objects begin to disappear. So for any urban area, the relative inherent distances to objects in the local "viewscape" may be an important consideration.

Along similar lines, John Molenar who developed the WinHaze model used to provide the range of photos employed in several of the available preference studies, has recently developed the ability to add clouds to the baseline and haze-modified images. Adding clouds (typically absent in the base WinHaze images) provided more realistic images but also added relatively distant objects – especially in images of cityscapes in flat areas like St. Louis and Washington DC – and tended to substantially reduce the light extinction or deciview levels people found unacceptable in those areas. The implication is that the upper end of the 20 to 30 DV of acceptable visibility may be substantially overstated.

Malm, W.C., Molenar, J.V., Pitchford, M.L., Deck, L.B. Which visibility indicators best represent a population's preference for a level of visual air quality?, Paper 2011-A-596-AWMA, Air & Waste Management Association 104th Annual Conference, Orlando, June 21-24, 2011.

Molenar, J.V and Malm, W.C (2012) Effect of Clouds on the Perception of Regional and Urban Haze, Presentation at Colorado State University, 9/27/2012.

Chapter 6 (Policy Assessment and Rulemaking)

To what extent does Chapter 6 clearly summarize the general process for the policy assessment and rulemaking phases of this review?
Chapter 6 clearly and briefly summarizes a planned general process for the policy assessment (PA) and rule making phases of the NAAQS review. The excellent list of policy-relevant questions posed in chapter 2 provides a clear picture of the major issues to be addressed in the PA. The absence of additional detail is appropriate here since the content of the PA is dependent on results of the yet-to-be-developed Science Assessment and Risk Assessments. Additional policy-relevant questions are likely to emerge during the course of the NAAQS review.

The proposed schedule for the NAAQS review presented in chapter 1 (p. 1-19) looks reasonable and identifies planned releases for a first and second review draft PA documents in Fall 2018 and Fall 2019. However, chapter 6 seems to back off on this plan, indicating "staff will prepare at least one draft PA". Advance planning for several review drafts is preferable since past PA documents often contain complex new or newly synthesized information that might benefit from careful review and feedback, and experience from other NAAQS reviews suggests that review schedules tend to get compressed toward the end, leaving less time for thorough PA review(s).

Dr. Jeremy Sarnat

Comments on Chapter 4

To what extent does Chapter 4 clearly and adequately describe the scope and specific issues, including the identification of the most important uncertainties, to be considered in developing the HREA Planning Document for this review?

Overall, this is a clear and reasonable approach for the development of the PM HREA. Specifically, EPA staff should be commended on the scope and consideration of potential sources of uncertainty and variability, inherent in this process. I believe the focus on characterizing the shape of C-R functions, especially at low PM concentrations, to be a particularly critical factor. I also note the attention paid to ensuring transparency throughout the process and accessibility for various stakeholders (e.g., the possibility of using both quantitative and qualitative sensitivity analyses, as well as various approaches for describing uncertainty). The overarching plan to replicate the the planning process taken during the 2009 HREA for PM, also seems reasonable.

My relatively minor comments relate mainly to elements that may be important to consider during a formal planning stage for a HREA.

- While thorough, many of the sources of variability, cited in the draft IRP, seem to be presented as static 'snapshots' of factors that may explain between-city heterogeneity in risk. Is there a process for including changing patterns? Is it possible, for example, to consider ongoing and predicted demographic trends related to baseline comorbidities in the selected? Information about accelerated aging patterns and socio-economic changes, may be better able to capture true population risk now and during a complete NAAQS cycle. Future trends in PM concentrations, for example, are routinely considered as part of health impact assessments.

Is there additional information that should be considered or are there additional issues that should be addressed in considering the potential for risk and/or exposure analyses in the current review?

- The decision not to conduct an Exposure Assessment during the 2009 HREA was based, in part, on '*uncertainties surrounding the purpose of such an assessment* (p 4-20).' Given this acknowledgment, my recommendation for the IRP would be to more clearly define its purpose at this stage in the process. As currently written, I see several potential purposes or potential contributions of an Exposure Assessment; none stated explicitly in the current IRP draft.
- Related to comment above: Although I appreciate the theoretical distinction between an epidemiologic analysis and an exposure assessment; as presented, the difference between the Epidemiology-Based Risk Assessment and Exposure Assessment in the draft IRP is unclear. The question of whether exposure modeling (i.e., using APEX) constitutes a more sensitive indicator of PM-mediated population risks than stationary ambient sites is still unresolved. I think it's plausible to view the exposure models serving as potential alternative exposure metrics, similar to composite or single-site ambient monitoring.

- The document mentions that '*characterizing health risks for the current review of the primary PM NAAQS could include conducting air quality analyses to support quantitative assessments of risk and exposure in specific urban areas* (p 4-10).' Does this include exposure model validation? How extensive will these analyses be? This is a small point, but this statement caught my attention and more insight into the nature and scope of these analyses could be helpful.

Dr. James J. Schauer

Comments on Chapter 4 (Health Risk and Exposure Assessment):

To what extent does Chapter 4 clearly and adequately describe the scope and specific issues, including the identification of the most important uncertainties, to be considered in developing the HREA Planning Document for this review?

Chapter 4 provides a clear and well-articulated approach to defining the scope and the issues that should be considered in developing the HREA Planning Document. As outline in the chapter, there are potentially a large number of new assessments that could be included in the HREA, but the criteria for determining which new assessments will be deemed "appropriate:" or "adequate" are not defined. I am not sure that these criteria can be established as this time but this may need to be explicitly addressed in the HREA Planning Document.

Is there additional information that should be considered or are there additional issues that should be addressed?

As stated above, the framework for determining what new assessments are "appropriate" and "adequate" should be discussed.

Dr. Elizabeth (Lianne) A. Sheppard

Comments on Chapter 4:

To what extent does Chapter 4 clearly and adequately describe the scope and specific issues, including the identification of the most important uncertainties, to be considered in developing the HREA Planning Document for this review?

I believe Chapter 4 does a good job clearly describing the scope and specific issues relevant to a HREA. One important point was not addressed: What are the criteria the HREA Planning Document will use to determine whether or not a HREA is justified? Resource considerations are important and should be weighed against the anticipated benefit from any potential risk and exposure assessments.

With respect to considerations of potential quantitative assessments in the HREA, I suggest that the framing of the questions and approach should be updated to reflect the more sophisticated exposure assessment approaches that are now commonplace in cohort studies. Characterization of risk on a national scale (l 25-6) is very appropriate for annual average exposures given the availability of national ambient PM prediction models. Predicted exposure (at e.g., subjects' residences) is now preferred over metrics such as nearest monitor where a single measurement represents exposure for a large population. Thus "putting results into a national public health perspective" (p 4-11 l 1-2) should be the target of any HREA analyses for long-term exposures. I don't think planning for these should be viewed following a previous approach that focused on selected urban areas. If the HREA will continue to focus on selected urban areas for the annual standard, then it should also explicitly address EPA's rationale for not focusing on characterizing risk on a national scale.

Is there additional information that should be considered or are there additional issues that should be addressed in considering the potential for risk and/or exposure analyses in the current review?

Since the last review there has been considerable advancement in PM exposure modeling, meaning that we have good modeled estimates of PM2.5 at all census tract centroids. The HREA should consider using modeled PM rather than relying only on monitored PM. National exposure modeling papers to consider include Kim et al, EHP 2016 (http://ehp.niehs.nih.gov/EHP131/) and Di et al, ES&T 2016 (http://pubs.acs.org/doi/abs/10.1021/acs.est.5b06121); full citations below.

Monitor siting is a new and potentially important issue for consideration. If a set of monitors doesn't fully represent the population being considered, then recent theoretical research into exposure measurement error has shown this lack of *spatial compatibility* can affect inference in epidemiologic studies (see e.g. Szpiro & Paciorek 2013). This may affect the set of estimates and their uncertainties reported in the literature. I believe it is less likely to affect risk assessment since (in currently unpublished research) we found that predictions of pollutants from spatially compatible and incompatible networks were highly correlated.

P 4-15 l 34: The discussion of exposure metrics should be expanded to address considerations of whether to use individual monitors or modeled surfaces for long-term exposure.

Comments on Table 4-1: Areas of Uncertainty…: Broadening the assessment to the entire nation changes the transferability considerations. In addition to using composite monitors, there should be a discussion about uncertainty due to exposure modeling (as well as to which monitors are included in an exposure model). For long-term studies, multi-city studies are presumably going to be used. Potential measurement error is not only due to population mobility.

Other comments on Chapter 4

1. The document is clearly written and organized. It makes good use of explanatory footnotes.
2. As part of the HREA Planning Document and eventual HREA (if any), EPA should consider making its computer code available to the public.
3. P 4-17 l 12: Reword "cascade the impact" to improve clarity.
4. Table 4-2 comments. If APEX is to be used, consider:
    a. MESA Air can provide predictions of PM2.5 for census tracts; thus tract-to-tract spatial variation of annual average PM2.5 is available for use in APEX.
    b. Near roadside and in-vehicle exposures are important sources so they should be considered even if they are very uncertain.
    c. It makes sense to prioritize geographic areas well represented in CHAD and for which AER distributions have been developed.
    d. It would be useful to better account for habitual repeated behaviors of individuals in the application of CHAD, thus overcoming an important limitation of this database. Consider whether some small studies should be conducted to directly address this issue so that appropriate use of the 2-day activity data can be made to better address habitual activity patterns of individuals. This is clearly important for application to long-term exposures.

Comments on other chapters

1. Figure 2-1: The consideration of indicators should also reflect that indicators that aren't focused on size may be entertained.
2. P 2-34 l 9: Clarify wording.
3. P 3-6 organization of the PM ISA: Consider adding a high-level outline of the ISA to this section.

References cited above:

Kim SY, Olives C, Sheppard L, Sampson PD, Larson TV, Keller JP, Kaufman JD. Historical Prediction Modeling Approach for Estimating Long-Term Concentrations of PM2.5 in Cohort Studies before the 1999 Implementation of Widespread Monitoring. Environ Health Perspect; http://dx.doi.org/10.1289/EHP131

Qian Di, Itai Kloog, Petros Koutrakis, Alexei Lyapustin, Yujie Wang, and Joel Schwartz. Assessing PM2.5 Exposures with High Spatiotemporal Resolution across the Continental United States. Environmental Science & Technology 2016 50 (9), 4712-4721
DOI: 10.1021/acs.est.5b06121

Szpiro, AA, Paciorek, CJ. Measurement error in two-stage analyses, with application to air pollution epidemiology. Environmetrics 2013, 24 (8), 501-517. DOI: 10.1002/env.2233

Dr. Barbara Turpin

I was asked to focus my attention on Chapter 3. Briefly, I will say that the entire document is very clearly written. Regarding the policy-relevant questions presented in Chapter 2 (Section 2.2.3), the scope of the climate-related analysis to be included and excluded could be more clearly articulated. There are likely to be new insights in the current literature regarding light absorption by organic PM and the sources/formation of light absorbing organic PM. There are also likely new insights about the effects of coatings on the optical properties of black (elemental) carbon. These insights may need to be considered in the visibility section and in climate section (depending on the scope). Additionally, averaging times require different consideration for climate.

Generally speaking, Chapter 3 does clearly and adequately describe the scope and issues to be considered and the organization is clear, with a few minor exceptions. Areas of clarification and areas that should be defined more narrowly to accomplish a concise and streamlined ISA are documented below:

Section 3-2: The evaluation of epidemiologic studies. The text mentions an examination of evidence on the impact of PM sources on associations. This text should be clarified to explicitly include atmospheric (secondary) PM formation as well. This dominant PM "source" may be overlooked as written.

Toxicological studies: Another important question is: Do new studies provide new insights regarding affects of PM components? This assessment needs to be provided somewhere. It is not communicated in this section.

Page 3-3 line 26 "(2) the fate, transport and transformation of PM in the environment"

Page 3-5 line 25 "semi-volatile organics" should also include low volatility organics" or just say "particle-phase organics"

Section 3.2 – where will information related to affects associated with "components" and "sources" be presented?

Page 3-10 line 12 - Search terms should also include "aerosol" or perhaps "ambient aerosol"

Page 3-15 line 32 - Uncertainties in aerosol affects on climate include optical affects of multicomponent aerosols, for example changes in optical properties when primary combustion aerosol (containing black and brown carbon) is coated with scattering components like sulfate. Additionally, substantial uncertainties exist concerning the sources and atmospheric burden of light absorbing (brown) organic carbon. Progress has been made in both areas recently.

Page 3-18 line 7 -- ISA text regarding measurements should be more narrowly defined. "Measurements that advance the science" is overly broad.
Page 3-18 line 17 - "and strategies for accounting for semi-volatile organic emissions" this is important, but does not belong in this sentence.

Page 3-18 line 22 - this bullet should also include particulate organonitrate. A great deal of progress has been made understanding its sources and formation. This is an area of anthropogenic – biogenic interaction.

Page 3-18 line 26 - not just the role of semi-volatile organic gases, but also the role of volatile, water-soluble organic gases.

Page 3-19 line 33 - What about uncertainties in time-activity patterns for populations of increased risk?

Page 3-20 line 23 - "what are the uncertainties in data from chemical transport models, satellites and fused products at the extremes of the concentration distribution" This question should be about both high/low concentration times and locations, e.g. near roadway).

Exposure section - I do not see any mention of sensitive populations in the exposure questions.

Page 3-24 line 32; Page 4-15 line 20 – When I read "sources" here, I read "sources/formation" but others will not understand that a large fraction of fine and ultrafine PM is formed in the atmosphere and that PM composition, properties and behavior is dramatically changed between emission and inhalation. Thus, it would be helpful to explicitly write "sources/formation" or sources (including atmospheric formation).

Section 3.4.9 – Lifestages: I expect that this topic will be one of those were there will remain important uncertainties that should be articulated for further (future) work.

Page 3-26 – Ecosystem effects: Contributions of organic gases and organic PM to deposition are not easily isolated. What advances have been made in separating the effects of gaseous and particulate organics, and improving linkages specifically between particulate organic matter, deposition and ecological affects? (This question belongs somewhere in Chapter 3)

Page 3-27 - Note that substantial progress has been made understanding light absorption by primary and secondary organic PM, which may contribute to improved linkages between PM and visibility. (This information belongs somewhere in Chapter 3 and pertains to both visibility and climate)

Page 3-28 line 7 - and brown carbon (light absorbing organic carbon) and effects of mixtures on optical properties. Both are topics of active research. There probably should be a question in this section on predictive tools.

Chapter 5 – this material is very clearly articulated, especially the uncertainties.
Page 5-14 – Climate: The reasoning here makes a lot of sense to me. **Extreme care** must be taken to not underestimate uncertainties, if a quantitative assessment of the effects of NAAQS on climate were to be conducted.

Dr. Sverre Vedal

Comments on Chapter 2

To what extent does the Panel find that Chapter 2 clearly articulates the decisions made in the last review of the primary (sections 2.1.1, 2.1.2) and secondary (sections 2.2.1, 2.2.2) PM standards, and the rationales supporting those decisions?

The review of the decisions and their rationale is generally well done and is faithful to their content and spirit, as I remember them.

Minor points:

p.2-8, line 20. I understand the context of this, but don't believe that part of the motivation for the 24-hr standard was that it also provided protection against PM effects "of shorter-than-daily exposure periods." However, there may be reference to that somewhere in the Federal Register.

p.2-8, line 5 & 2-9, line 6. I believe there was also discussion of neurological outcomes even at that time, in addition to reproductive and developmental outcomes, although this also had little impact on recommendations regarding the level of the standard.

To what extent does the Panel find that the policy-relevant questions presented in sections 2.1.3 (primary) and 2.2.3 (secondary) appropriately characterize the key scientific and policy issues for consideration in the current review? Are there additional issues that should be considered?

Primary $PM_{2.5}$ standard.

With respect to the primary standard (section 2.1.3), there are clearly several issues that will be central to this round of deliberations on the annual and 24-hour $PM_{2.5}$ standards:

1. Most notably, is there scientific justification for an even lower level of the annual standard?
2. Is there now sufficient evidence to propose either annual or 24-hour $PM_{2.5}$ standards based on chemical composition or on source? The primary issue will likely be whether PM from coal combustion (and/or an indicator of coal combustion) should receive special attention in the annual standard.
3. Is there justification for an additional, or an alternative, indicator, specifically $PM_{0.1}$?
4. In light of findings from several human clinical studies involving experimental chamber studies with exposure periods on the order of only a few hours, is there justification for adding an alternative shorter averaging period?
5. While acknowledging that such an approach is not allowable at this time, is there justification for considering regional standards based on, for example, either: i) PM composition or source; ii) degree of short-term variability in PM concentrations; or iii) regional heterogeneity of reported health effect findings? These are interrelated, of course, to some extent at least.

These and other issues relating to the primary $PM_{2.5}$ standard were, apart from #5 above, covered by the policy-relevant questions posed in the Draft PM Integrated Review Plan. I have no additional questions to add. My #5, above, may be a non-starter and so may not rise to a level to be included in the list of questions.

Primary PM_{10} standard.

Regarding the primary PM_{10} standard, the principal issue will be whether to retain the standard or replace it with a $PM_{10-2.5}$ standard, and if not, whether the current level of the PM_{10} standard should be retained. There have been a number of $PM_{10-2.5}$ findings reported since the last round, including human clinical findings from experimental studies, so clearly these will need to be integrated into these deliberations.

The policy-relevant questions relating to the PM_{10} standard are thorough and clear.

PM monitoring.

Regarding monitoring, I initially thought it a bit odd to include this discussion here, but considering that there are clear policy-relevant issues to be addressed relative to monitoring, I believe it's appropriately included here. To integrate better with the rest of this chapter, staff might consider adding policy-relevant questions relating to monitoring.

Dr. Ronald E. Wyzga

p. 2-16, ll. 36: I'm surprised that there is no bullet here to talk about the roles of different PM components and characteristics, as well as sources. I add the category of characteristics because some recent papers have suggested the importance of ROS or reactive oxygenate species; although it is unlikely that such a characteristic would be used to define a NAAQS, significant results for such a characteristic could be informative.

p. 3-4, ll. 1-2: I would add "the role of PM components, characteristics, and sources in assessing PM effects"

ll. 3-4: Is 2 mg/m^3 relevant? Should the upper limit be lowered?

p. 3-5: ll. 5-8: If a study found a significant response to a component or group of components, it should not be discounted. It can be nevertheless informative; for example, it could provide valuable information about mechanism, and if a component were shown to be particularly toxic, it would be important to ensure that any proposed NAAQS is protective for that component. Results for specific components could be compared to studies that consider "composite measures". I would add that for PM, "composite measures" are not uniform and are likely to vary over time and space. There is precedent for considering components in NAAQS discussions; for example, although the NAAQS is for oxides of nitrogen, focus is directed at one component of that composite measure, NO_2.

p. 3-10, l. 24: what is the anticipated cut-off date? Table 1-3 is vague.

p. 3-22, l 30: See my comments for p. 3-5. Studies with "composite measures" clearly need to be considered; however, studies of specific components and characteristics can also be informative. I would therefore broaden the focus.

p. 3-23: should also add: what new evidence is available for the effects of PM components, characteristics and sources?

p. 3-24: l 24: Another possible bullet; To what extent do historical exposures influence associations between current levels of PM and health responses? This particularly important for chronic diseases, such as cancer, where historical and/or cumulative exposures are likely important.

l. 33: I would add "characteristics" to components and sources.

p. 4-9, ll. 15: lags couid also be of concern with respect to long-term studies. See ll. 28-31.

p. 4-15, l. 12: is this premature without reference to the ISA?

l. 20: I would add "characteristics" as well. See my comment for p. 2-16.

p. 4-14, Table 4-1: The choice of a dose-response function can also lead to significant uncertainty and should be added to the table. .

p. 4-17, Section 4.3.1.3: To the extent possible I would like to see uncertainty embedded into the analyses rather than considered in a series of disjoint sensitivity analyses. Although the current approach to uncertainty can be informative, there would be advantages to the Agency following the advice of the National Academy in a report prepared for the EPA. (NRC. 2002. Estimating the Public Health Benefits

of Proposed Air Pollution Regulations. http://www.nap.edu/openbook.php?record_id=10511.) That report concludes that a revised process "will use probability distributions to replace model components that are treated as known fixed values. Of necessity, the probability distributions for the uncertain model components will have to reflect a combination of empirical observations and expert judgment. This will result in a more realistic picture of the overall uncertainty in the analyses." (p. 143).

p. 4-23, l. 8: CHAD may be the best dataset currently available, but it is based on old data (pre-2000) that may not accurately portray current activity patterns.

p. 4-24, Table 4.2: The relevance of the CHAD dataset for current activity patterns also adds uncertainty.

Charge Question for Chapter 6: *To what extent does Chapter 6 clearly summarize the general process for the policy assessment and rule-making phases of this review?*

This is a very short chapter, barely 3 pages long. It is, however, reasonable in the context of the draft IRP.

Specific comments

p. 6-1, l. 8: Why wouldn't the REA be available? The Agency should take steps to ensure that any REA is used to inform the Policy Assessment.