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

Received as of 05-18-16

Mr. George 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. 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".

<u>Additional Comments</u>

- 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 welfare effects (Page 3-5, Lines 16-26), this reviewer disagrees with removing N and S from the PM consideration and does not agree with the argument 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.

References

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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)

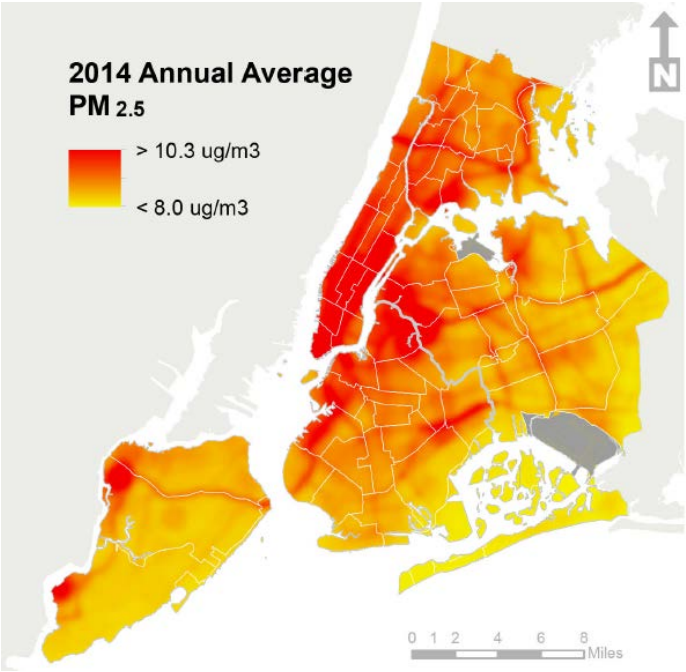
While the Clean Air Act separates primary (health) and secondary (welfare) effects of air pollution, there is increasing evidence of links between traditional welfare indicators such as visibility and health. A growing number of papers are showing that living in "green" communities is associated with 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

IRP 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.



[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

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?

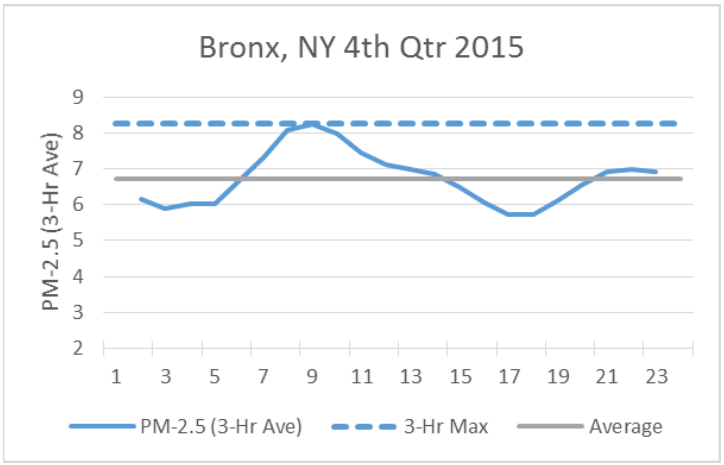
This comment could fit into several sections in the IRP. I propose a new averaging time for the PM NAAQS that accounts for regularly occurring elevated sub-daily PM exposure. Urban areas typically have sources such as traffic, industry or biomass related space heating that cause elevated PM-2.5 for several 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.

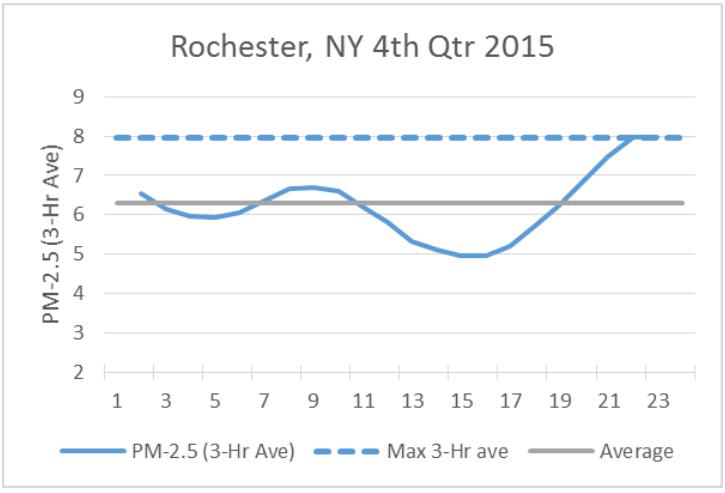
I propose to use a quarterly diurnal average of PM-2.5 values that are then smoothed by a center 3-Hr rolling average. The NAAQS could then be set at the maximum 3-hr diurnal average for the quarter. PM-2.5 FEMs at urban NCore sites can provide the 1-hr data used to calculate the quarterly diurnal rolling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

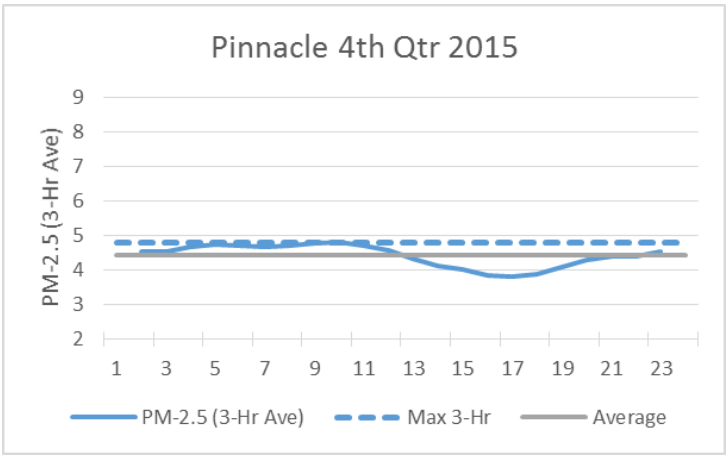
This averaging time provides for regulation of sub-daily PM exposures but it has the stability of a longer term average. Non-repetitive PM sources and noisy 1-hr FEM data will not materially affect the quarterly diurnal average. The plots below provide a 4th Quarter 2015 example for a traffic impacted 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.

IRP 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

[2] Camnet:www.hazecam.net

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.

IRP 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

IRP 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. 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.

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

***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. 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 <u>transformation</u> 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. 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.

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, and it could be compared to studies that consider "composite measures".

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

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

p. 4-9, ll. 15: lags could 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.

p. 4-14, Table 4-1: The choice of a dose-response function can also lead to uncertainty.

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.

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.

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 IRB.

Specific comments

p. 6-1, l. 8: Why wouldn't the REA be available?

p. 6-1 , l. 19: Is there a need to define what is meant by an "evidence-based " approach as opposed to "an exposure-/risk-based" approach? I would also ask whether it is appropriate to consider these risks in the presence of other planned regulations (e.g., Regional Haze rule, other NAAQS, Cross-State Air Transport Rules, and MATS?)