UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

January 3, 2008

EPA-CASAC-08-004

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel's Consultation on EPA's Draft *Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter*

Dear Administrator Johnson:

EPA's Clean Air Scientific Advisory Committee (CASAC), supplemented by subject-matter-expert Panelists — collectively referred to as the CASAC Particulate Matter Review Panel ("PM Panel") — held a public advisory teleconference meeting on November 30, 2007, to conduct a consultation with staff from the Agency's National Center for Environmental Assessment in Research Triangle Park, NC (NCEA-RTP), within the Office of Research and Development , and EPA's Office of Air Quality Planning and Standards (OAQPS), within the Office of Air and Radiation, on the Agency's *Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter* (Draft, October 16, 2007).

The SAB Staff Office has developed the consultation as a mechanism to advise EPA on technical issues that should be considered in the development of regulations, guidelines, or technical guidance before the Agency has taken a position. A consultation is conducted under the normal requirements of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C., App.), which include advance notice of the public meeting in the *Federal Register*.

As is our customary practice, there will be no consensus report from the CASAC as a result of this consultation, nor does the Committee expect any formal response from the Agency. The current CASAC roster is attached as Appendix A of this letter, and the CASAC PM Review

Panel roster is found in Appendix B. Finally, PM Panel members' individual written comments are provided in Appendix C.

Sincerely,

/Signed/

Dr. Rogene Henderson, Chair
Clean Air Scientific Advisory Committee

Appendices (A–C)

Appendix A – Roster of the Clean Air Scientific Advisory Committee

U.S. Environmental Protection Agency
Science Advisory Board (SAB) Staff Office
Clean Air Scientific Advisory Committee (CASAC)

CHAIR

Dr. Rogene Henderson, Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

MEMBERS

Dr. Ellis Cowling, University Distinguished Professor At-Large, Emeritus, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

Dr. James D. Crapo [M.D.], Professor, Department of Medicine, National Jewish Medical and Research Center, Denver, CO

Dr. Douglas Crawford-Brown, Director, Carolina Environmental Program; Professor, Environmental Sciences and Engineering; and Professor, Public Policy, Department of Environmental Sciences and Engineering, University of North Carolina at Chapel Hill, Chapel Hill, NC

Dr. Donna Kenski, Director of Data Analysis, Lake Michigan Air Directors Consortium (LADCO), Rosemont, IL

Dr. Armistead (Ted) Russell, Georgia Power Distinguished Professor of Environmental Engineering, Environmental Engineering Group, School of Civil and Environmental Engineering, Georgia Institute of Technology, Atlanta, GA

Dr. Jonathan Samet [M.D.], Professor and Chairman, Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

SCIENCE ADVISORY BOARD STAFF

Mr. Fred Butterfield, CASAC Designated Federal Officer, 1200 Pennsylvania Avenue, N.W., Washington, DC, 20460, Phone: 202-343-9994, Fax: 202-233-0643 (butterfield.fred@epa.gov) (Physical/Courier/FedEx Address: Fred A. Butterfield, III, EPA Science Advisory Board Staff Office (Mail Code 1400F), Woodies Building, 1025 F Street, N.W., Room 3604, Washington, DC 20004, Telephone: 202-343-9994)

Appendix B – Roster of the CASAC Particulate Matter Review Panel

U.S. Environmental Protection Agency
Science Advisory Board (SAB) Staff Office
Clean Air Scientific Advisory Committee (CASAC)
CASAC Particulate Matter Review Panel

CASAC MEMBERS

Dr. Rogene Henderson, **Chair**, Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. Ellis Cowling, University Distinguished Professor At-Large, Emeritus, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

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Dr. Jonathan Samet [M.D.], Professor and Chairman, Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

PANEL MEMBERS

Dr. Lowell Ashbaugh, Associate Research Ecologist, Crocker Nuclear Lab, University of California, Davis, Davis, CA

Mr. Ed Avol, Professor, Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, CA

Dr. Wayne Cascio [M.D.], Professor, Medicine, Cardiology, Brody School of Medicine, East Carolina University, Greenville, NC

Dr. H. Christopher Frey, Professor, Civil, Construction and Environmental Engineering, College of Engineering, North Carolina State University, Raleigh, NC

Dr. David Grantz, Director, Botany and Plant Sciences and Air Pollution Research Center, Riverside Campus and Kearney Agricultural Center, University of California, Parlier, CA

Dr. Joseph Helble, Dean and Professor, Thayer School of Engineering, Dartmouth College, Hanover, NH

Dr. Philip Hopke, Bayard D. Clarkson Distinguished Professor, Department of Chemical Engineering, Clarkson University, Potsdam, NY

Dr. Morton Lippmann, Professor, Nelson Institute of Environmental Medicine, New York University School of Medicine, Tuxedo, NY

Dr. William Malm, Research Physicist, National Park Service Air Resources Division, Cooperative Institute for Research in the Atmosphere, Colorado State University, Fort Collins, CO

Mr. Charles T. (Tom) Moore, Jr., Air Quality Program Manager, Western Governors' Association, Cooperative Institute for Research in the Atmosphere, Colorado State University, Fort Collins, CO

Dr. Robert F. Phalen, Professor, Department of Community & Environmental Medicine; Director, Air Pollution Health Effects Laboratory; Professor of Occupational & Environmental Health, Center for Occupation & Environment Health, College of Medicine, University of California, Irvine, Irvine, CA

Dr. Kent Pinkerton, Professor, Regents of the University of California, Center for Health and the Environment, University of California, Davis, CA

Mr. Richard L. Poirot, Environmental Analyst, Air Pollution Control Division, Department of Environmental Conservation, Vermont Agency of Natural Resources, Waterbury, VT

Dr. Frank Speizer [M.D.], Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

Dr. Helen Suh, Associate Professor, Environmental Health, School of Public Health, Harvard University, Boston, MA

Dr. Sverre Vedal [M.D.], Professor, Department of Environmental and Occupational Health Sciences, School of Public Health and Community Medicine, University of Washington, Seattle, WA

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Appendix C – Comments from Individual CASAC Particulate Matter Review Panel Members

This appendix contains the preliminary and/or final written comments of the individual members of the Clean Air Scientific Advisory Committee Particulate Matter Review Panel. The comments are included here to provide both a full perspective and a range of individual views expressed by Panel members during the consultation process. These comments do not represent the views of the CASAC PM Review Panel, the CASAC, the EPA Science Advisory Board, or the EPA itself. Panelists providing written comments are listed on the next page, and their individual comments follow.

Dr. Lowell Ashbaugh

Final Comments on Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter

Lowell Ashbaugh (12-09-07)

The Draft IRP is generally well written and comprehensive. I particularly appreciate the history that has brought us to this point and the path it lays out to follow for this review of the NAAQS. I commend the staff for providing a plan that is, for the most part, very well written. I have some general comments on the draft and a few specific ones.

Although the comment on pp. 8-9 regarding the exclusion of agricultural dust from the PM NAAQS is made in the context of historical action, I would raise a cautionary flag against such an exclusion (for agricultural or any other dust sources) without clear scientific evidence that it is justified. Lacking evidence, the EPA should conduct the studies necessary to investigate the health effects of these particles.

The literature search described on page 21 focuses on health effects. This is appropriate for the primary NAAQS, but should be expanded to visibility, ecosystem and climate effects for the secondary NAAQS. I don't agree that only studies of the health and welfare effects of particles from the U.S. should be considered in this review. If relevant information is available from a well-conducted and informed study outside the U.S. it should be considered. If there are caveats associated with these studies, just make them clear.

The causes of visibility reduction discussed on page 32 are not accurate. In the eastern U.S. sulfate dominates the poorest visibility days. Nitrates are important in the Midwest and in parts of the west (primarily southern California), and mostly in the winter. Organics and soil dust dominate throughout most of the west, with nitrate being important in some locations. Wildfires are an important source of organic and elemental carbon, and influence visibility episodically. These species all show seasonal dependence, as well.

Much of the IRP contains fairly specific details about how the NAAQS review will be carried out, but Section 6 on visibility and other welfare-related issues is rather general overall. Perhaps this is because the Scope and Methods Plan is being developed now.

The most significant shortcoming of the draft IRP is that it gives little consideration to ecosystem or climate effects. Climate effects, in particular, should be given much more emphasis as the latest IPCC assessment indicates the sign of the radiative forcing for particles is negative. It's extremely important to know the implications on climate effects of reducing airborne particles, and how it would affect control efforts on greenhouse gases.

On page 39, line 29, what is meant by "potential source concentrations"?

I'm concerned about the use of "expert elicitation," described on pp. 46-47, in particular that the process appears to be conducted out of public scrutiny. Will the PM Review Panel have full

review of the "expert" comments? Will it know who the experts are? What (presumably) public process is used to solicit experts for the elicitation? This entire process seems to be a bit "soft" and appears to allow bypassing the process of public review. I'd like to see some assurances that this is not the case and that the elicitation, if used, will be conducted openly with full public and panel review. If expert elicitation is a public process the plan should describe it in better detail. If not, the plan should describe how it will be conducted to allow for public scrutiny and comment.

On page 49, visibility is better defined the ability to see a target at long distances clearly. Light can be scattered out of the sight path or absorbed on its way to the viewer to remove the visual information from the target, or light can be scattered into the path of the viewer to obscure the visual information from the target with extraneous light. The definition and discussion here do not consider this important characteristic of visibility reduction.

On page 52, lines 1-3 are just a restatement that the temperature is higher during the day. Relative humidity is a function of the amount of water vapor in the air and the air temperature. As the temperature increases, the relative humidity decreases even if the specific humidity is constant. This highlights, though, a mismatch between the measurement of PM mass and visibility. The gravimetric measurement of PM mass attempts to reduce the influence of RH by equilibrating filters prior to weighing them. On the other hand, RH varies considerably during a 24-hour period and affects visibility as it does so. Comparing PM mass and visibility for shorter time periods controls the variation in RH to some degree, so the correlations improve. I don't believe this discussion belongs in the plan, though. I recommend retaining the points that will inform the plan removing the rest.

The survey recommended in the last review and discussed on pp. 53-54 was not performed – does the EPA plan to perform this work? Even if it is not completed in time for this review it could inform future reviews. Will this be addressed in the current review? Please include another sentence or two to describe EPA's intention on this point.

The section on Network Design (pp 59-61) should include a discussion of the potential need for monitors in rural areas. This is especially important for the assessment of $PM_{10-2.5}$ effects on health for rural residents in agricultural areas. Although the population density in these areas is not as high as in urban areas, the overall population is high – environmental justice demands their health needs are considered. This may be the intention of the issue on page 60, lines 12-15, but it's not clear from the wording used.

The section on Sampling Methods (pp 61-62) includes a number of important issues. It should also include a discussion of sampling artifacts. This is especially important in considering analysis of the components of PM. There should also be discussion of the method for determining OC/EC. The current IMPROVE and CSN programs are wrestling with both these issues now – it's important to address them early.

Other reviewers have found most of the minor technical editing errors. I'll include a few more editorial comments here:

Page	Line	Comment
4	20	Delete "for these purposes"
39	28	Change "which" to "that"
49	10	What "benefits" are there of materials damage from soiling?
50	7	Change "wavelength" to "wavelengths"
50	8	Remove "can"
57	10	Remove the comma after "in part"

Mr. Ed Avol

Comments on Draft Integrated Review Plan for NAAQS for Particulate Matter
Submitted by Ed Avol (Due 28Nov07)

Section 1:
Pg 10, line 23 "…EPA plans to continue to review the scientific evidence available based on particle size, considering fine and coarse-fraction particles separately." – What about emerging information on ultra-fine or nanoparticles, and on using particle number as a metric for smaller particles?

Pg 11, lines 14 to 16 "In this review, EPA will integrate the previous understanding of sensitive subpopulations with new evidence on these and possibly additional sensitive subpopulations (e.g., fetuses, neonates)." What about genetic susceptibility?

Section 2: (no comments)

Section 3:
Pg 15, line10 – consider adding the following to the end of this sentence: "…and/or whether sufficient evidence exists to warrant consideration of other indicators of PM to protect public health (e.g., ultra-fine particles or nanoparticles)."

(The paragraph that follows in the text (Pg 15, lines 11 to 18) seems to imply and allow for this consideration, but it is not explicitly stated.)

Pg 16, lines 1 to 3 – Presumably this discussion will include a review of ultra-fines and nanoparticles?

Pg 16, lines 10 and 11 – Hopefully, number concentration, and not just particle mass, will be considered?

Pg16, line 12 – "At what levels of PM exposure…" presumably defined by particle mass, or will number concentration (for ultra-fines) be considered?

Pg 16, line23 – Will genetic susceptibility be objectively considered here?

Pg 16, lines 22 to 26 – Will this discussion include consideration of susceptibility (as defined by cardiovascular, respiratory, genetic, etc) vs. vulnerability (as defined by geographical, spatial, SES, and environmental justice considerations)?

Pg 17, lines 8 to 11 – In my mind, this is a (if not THE) critical issue in this review!

Section 4:
Pg 20, lines 19 to 22 – This directive should be remembered as the effort proceeds, because the NOx and SOx ISAs have not taken this to heart.

Pg 22, lines 16 to 19 – This statement is of questionable validity and the implications of it should be carefully weighed before proceeding along this course. Quality research is informative on its own merit, regardless of its nationality. Many insightful and technically enviable studies are performed and reported on other continents, and poorly performed studies are reported in the US and Canada, too!

Pg27, lines 1 to 13 – These questions are certainly important ones, but most all of them are framed in a manner to consider primarily the current form of the standard (mass of PM2.5 or PM10). This ISA should strive to assemble and review the available data with "an open mind" to the possibility that PM mass, PM2.5, and PM10 may not be the only or best PM indicators to understand, characterize, or protect public health.

Pg 27, line 17 "Other health effects that may be evaluated…" - How is this even a question? Surely emerging published information on reproductive, neurological, and developmental outcomes will be evaluated as part of the available data resources?

Pg 28, lines 1 to 6 – The wording and concepts here are awkward and confusing: "lower than previously observed" ambient effects is an awkward way to describe this; what are "exposure time windows" – is this duration? Time of day? Season? Age of the exposed population?

Pg 29, lines 14 to 16 – There are two very different questions in this bullet: one addressing cancer and mutagenicity, and one addressing birth defects.

Pg 32, line 6 (no question mark needed)

Section 5: (no comments)

Section 6:
Pg 52, lines 1 to 15 – Why is data being presented here? Isn't this supposed to be "the plan" for what is to be done, not the doing?

Section 7:
Pg 59/60 – A network design issue to be considered is the utility of monitoring operations and reporting of data from stations in compliance. The loss of these reporting areas data is a loss to epidemiological supporting databases and damages the ability to address current and future assessments at or near current or revised standards.

Pg 62, lines 4 to 5 – Finally, on Page 62 of a 64-page report, the word "ultra-fine" appears! Hopefully, it will be considered more prominently in the ISA.

Section 8: (no comments)

Section 9: (no comments)

Dr. Wayne Cascio

Comments on Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter

Wayne Cascio – 11/23/2007

Section 4 Science Assessment

4.2 ASSESSMENT APPROACH

1. On Pg. 23, L. 8-11. The statement, "Additionally, animal researchers must limit the number of animals used in experimental protocols, and thus must use higher concentrations to observe effects." is somewhat misleading. Investigators who utilize animals in their research are not obligated to use a limited number of animals, but instead they are constrained by cost and resource issues that limit the testing of hypotheses that require large number of animals exposed to ambient levels of particulate pollution over a prolonged time. Consequently, animal studies are typically used to acquire data related to mechanisms and the exposures are purposely high to assure a response. This statement might be written as, "Additionally, animal researchers typically utilize higher concentrations to assure biological effects for the purpose of addressing mechanisms, while forgoing the possibility of assessing the long-term effects of ambient levels of particle pollution because of the associated high cost of animal and technical resources needed for such studies." There are notable and important exceptions to this generalization, but in overall the statement is true.

2. On Pg. 23, L. 21-25. The statement, "For research evaluating controlled human exposures to PM, emphasis will be placed on studies that: (1) investigate effects both on healthy populations and on potentially susceptible populations such as asthmatics or diabetics, particularly studies where subjects serve as their own control to compare responses following PM exposure and sham exposure and where responses in susceptible individuals are compared with those in age-matched healthy controls;…" refers only to asthmatics and diabetics as potentially representing susceptible populations. It is assumed that these groups are only being used as examples of possible susceptible populations; as such the statement is appropriate. If the intension is to be more inclusive, then there is significant data to support other possible susceptible groups that could be listed, e.g. those with ischemic heart disease, an ICD, or heart failure.

3. On Pg. 28, L. 18. The paragraph starts with the question, "What new evidence is available on PM-related effects on the cardiovascular system?....", and lists a number of important questions related to the short-term effects of particle pollution. Particle pollution is associated with acute coronary syndrome, myocardial infarction and stroke. All of these conditions are typically associated with a vulnerable plaque with subsequent rupture and thrombosis. Consequently, the key questions remain: 1) what is the effect of particle pollution on homeostasis and thrombosis, and what effect does particulate pollution have on rupture-prone plaques? Does oxidant stress and/or acute inflammation or autonomic effects caused by

particle pollution contribute to these adverse events?

4. On Pg. 29, L. 4. Long-term effects. Other important questions specifically related to the cardiovascular system include: What have we learned about the effect of particle pollution on blood pressure since the last review? What is the effect on particle pollution on serum lipids, and what is the mechanism explaining these changes? What is known about the effect of particle pollution of insulin-sensitivity? What is the effect of particle pollution on vascular oxidant stress?

Dr. Ellis Cowling

Dr. Ellis Cowling
North Carolina State University
November 27, 2007

Individual Comments on the October 16, 2007 Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter

Very General Comments on these NAAQS Review Processes

Before dealing with the details of my specific assignment during the November 30, 2007 CASAC Consultation on the **Draft Integrated Review Plan for Particulate Matter**, I would like to offer a few general comments about these periodic NAQQS Review processes and the changes that are being made in both the organization and focus of these reviews.

As described on page 3 of the "Draft Integrated Review Plan," the Clean Air Act of 1970 (CAA) established two general goals for management of air quality in the United States -- protection of human health and protection of public welfare. Section 108 of the CAA directs the Administrator of EPA to identify and list "air pollutants" that "in his judgment may reasonably be anticipated to endanger public health and welfare" and to issue air quality criteria for those that are listed – hence the term "Criteria Pollutants."

Section 109 of the CAA further directs the Administrator of EPA to propose and promulgate "Primary" National Ambient Air Quality Standards to protect public health and "Secondary" National Ambient Air Quality Standards to protect public welfare.

A secondary standard, as defined in Section 109, must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is required to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air …" The welfare effects of concern include, but are not limited to "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

So far, the several Administrators of EPA since 1970 have:
1) Identified six specific "Criteria Pollutants" – carbon monoxide, ozone and other photochemical oxidants, sulfur dioxide, nitrogen dioxide, particulate matter, and lead – which have thus been designated officially as requiring development and implementation of National Ambient Air Quality Standards;
2) Emphasized protection of public health as the principal (and overwhelmingly important) *de facto* focus of concern within the Agency, and public welfare as a (rarely openly acknowledged) but distinctly less important *de facto* focus of concern;
3) Established Secondary (public-welfare-based) NAAQS standards for all six criteria pollutants that almost always were identical in form (including level, indicator, statistical form,

and averaging time) to the Primary (public- health based) NAAQS standards for each of these six criteria pollutants;
4) Developed a long-standing tradition of dealing with these six specific air pollutants mainly on a "one-at-a-time" basis rather than collectively – i.e., without strong attention to the frequent interactions and simultaneous occurrence of some of these pollutants as mixtures within the air in various parts of our country;
5) Maintained a reluctant attitude about the concepts of ecologically based "Critical Loads and Critical Levels" developed in Europe as possible alternative or additional approaches to air-quality management in the US; and
6) Maintained a long-standing general focus on the related concepts of:
a) "attainment counties and non-attainment counties,"
b) "attainment demonstrations" based on mathematical modeling of a limited number of exceedance events under extreme weather conditions, and
c) "local anthropogenic sources" as opposed to "both local and regional biogenic and anthropogenic sources of emissions."

In recent years, in contrast to several of the six ideas listed above, EPA has shown increased willingness to think more holistically – and in more fully integrated ways – about both the policy-relevant science and the practical arts of air quality management aimed at protection of both public welfare and public health. These shifts in both emphasis and approach have included:
1) Participation with other federal agencies and international bodies in discussions about the "One Atmosphere," "Critical Loads–Critical Levels," and "Multiple-Pollutant–Multiple Effects" concepts;
2) Adoption of the "NOx SIP Call" in 1999 and both the "Clean Air Interstate Rule" (CAIR) and the "Clean Air Mercury Rule" (CAMR) in 2005 with their more balanced perspectives about both regional (interstate) and local sources of emissions and interactions among NOx, SOx, VOCs, "air toxics," and mercury in the formation, accumulation, and biological effects of "ozone and other photochemical oxidants," and fine, coarse, thoracic, and secondary aerosol particles;
3) Recognition of both fine and coarse PM as complex and geographically variable mixtures of sulfate-dominated, nitrate-dominated, and ammonium ion-dominated aerosols; natural biogenic and anthropogenic organic substances; heavy metals including cadmium, copper, zinc, lead, and mercury; and some other miscellaneous substances;
4) More frequent discussion about of the occurrence and both ecologically-important and public-health impacts of mixtures of air pollutants; and, most recently
5) The unprecedented decisions to:
A) Prepare and publish in September 2007 a "*Draft Plan for* [simultaneous] *Review of the Secondary National Ambient Air Quality Standards for Nitrogen Dioxide and Sulfur Dioxide;"* and
B) Separate the preparation and review of documentation, the required CASAC and public reviews, and (possibly also) the final decision-making processes for a Secondary (public-welfare-based) NAAQS from the (previously always dominating) Primary (public-health-based) NAAQS review processes.

Need for Policy Relevancy as the Dominant Concern in NAAQS Review Processes

In a May 12, 2006 summary letter to Administrator Johnson, CASAC Chair, Dr. Rogene Henderson, provided the following statement of purpose for these periodic NAAQS review processes.

"CASAC understands the goal of the NAAQS review process is to answer a critical scientific question: *"What evidence has been developed since the last review to indicate if the current primary and/or secondary NAAQS need to be revised or if an alternative level or form of these standards is needed to protect public health and/or public welfare?"*

During the past 18 months, CASAC has participated in reviews of three of the existing six criteria pollutants – particulate matter, ozone, and lead. CASAC has also joined with senior EPA administrators in a "top-to-bottom review" and the resulting recently-completed revision of the four-step NAAQS review processes that are neatly summarized on pages 2 and 3 of the present "Draft Integrated Review Plan" for PM. These two experiences have led to a seemingly slight but important need for rephrasing and refocusing of this very important "critical scientific question:"

"What scientific evidence and/or scientific insights have been developed since the last review to indicate if the current public-health based and/or the current public-welfare based NAAQS need to be revised or if alternative levels, indicators, statistical forms, or averaging times of these standards are needed to protect public health with an adequate margin of safety and to protect public welfare?"

With regard to the important distinction in purpose of the primary (public health) and secondary (public welfare) NAAQS standards, it is noteworthy that in all five cases in which a secondary NAAQS standard has been established, the secondary standard has been set "Same as Primary."

Thus, a second very critical scientific question that needs to be answered -- especially with regard to the present "Draft Integrated Review Plan" for PM as well as the other four criteria air pollutants is:

"What scientific evidence and/or scientific insights have been developed since the last review to indicate whether, and if so, what particular ecosystem components or other air-quality-related public welfare values, are more or less sensitive than the populations of humans for which primary standards are established and for this reason may require a different level, indicator, statistical form, or averaging time of a secondary standard in order to protect public welfare."

I hope these two "critical scientific questions" will be borne in mind carefully as CASAC joins with the various relevant parts of the Environmental Protection Agency in completing the upcoming reviews of the primary and secondary National Ambient Air Quality Standards for Particulate Matter.

We now have the considerable advantage that a much more complete focus can be achieved in the Integrated Science Assessment than has historically been achieved in the encyclopedic Criteria Documents that have been prepared during the years since 1970.

Thus, I recommend that every chapter of the soon to be completed PM Integrated Science Assessment, the Risk/Exposure Assessment, and the Policy Assessment/Rule Making documents contain a summary section composed almost entirely of a series of very carefully crafted statements of Conclusions and Scientific Findings that:

1) Contain the distilled essence of the most important topics covered in each chapter, and

2) Are as directly relevant as possible to the two Critically Important Scientific Questions written in bold italic type above.

In this connection, I call attention once again to the attached *"Guideline for Formulation of Statements of Scientific Findings to be Used for Policy Purposes."* These guidelines were developed and published in 1991 by the Oversight Review Board for the National Acid Precipitation Assessment Program. These Guidelines were written in the form of checklist questions by members of the Oversight Review Board (ORB) for the National Acid Precipitation Assessment Program. The members of the ORB who prepared these guidelines included: Drs. Milton Russell, former Assistant Administrator for EPA, Chauncey Starr, former Director of Research for the Electric Power Research Institute (EPRI), Tom Malone, former Foreign Secretary for the National Academy of Sciences, John Tukey, Distinguished Professor of Statistics at Princeton University, and Kenneth Starr, Nobel Prize Winner in Economics.

The intent of these distinguished authors was to assist scientists, engineers, and policy analysts dealing with other environmental research and assessment programs in formulating statements of scientific findings to be used in policy-decision processes. These guidelines are the best guides I know of for formulation of statements of scientific findings to be used for policy purposes.

GUIDELINES FOR FORMULATION OF SCIENTIFIC FINDINGS

TO BE USED FOR POLICY PURPOSES

The following guidelines in the form of checklist questions were developed by the NAPAP Oversight Review Board to assist scientists in formulating presentations of research results to be used in policy decision processes.

1) **IS THE STATEMENT SOUND?** Have the central issues been clearly identified? Does each statement contain the distilled essence of present scientific and technical understanding of the phenomenon or process to which it applies? Is the statement consistent with all relevant evidence – evidence developed either through NAPAP research or through analysis of research conducted outside of NAPAP? Is the statement contradicted by any important evidence developed through research inside or outside of NAPAP? Have apparent contradictions or interpretations of available evidence been considered in formulating the statement of principal findings?

2) **IS THE STATEMENT DIRECTIONAL AND, WHERE APPROPRIATE, QUANTITATIVE?** Does the statement correctly quantify both the direction and magnitude of trends and relationships in the phenomenon or process to which the statement is relevant? When possible, is a range of uncertainty given for each quantitative result? Have various sources of uncertainty been identified and quantified, for example, does the statement include or acknowledge errors in actual measurements, standard errors of estimate, possible biases in the availability of data, extrapolation of results beyond the mathematical,

geographical, or temporal relevancy of available information, etc. In short, are there numbers in the statement? Are the numbers correct? Are the numbers relevant to the general meaning of the statement?

3) **IS THE DEGREE OF CERTAINTY OR UNCERTAINTY OF THE STATEMENT INDICATED CLEARLY?** Have appropriate statistical tests been applied to the data used in drawing the conclusion set forth in the statement? If the statement is based on a mathematical or novel conceptual model, has the model or concept been validated? Does the statement describe the model or concept on which it is based and the degree of validity of that model or concept?

4) **IS THE STATEMENT CORRECT WITHOUT QUALIFICATION?** Are there limitations of time, space, or other special circumstances in which the statement is true? If the statement is true only in some circumstances, are these limitations described adequately and briefly?

5) **IS THE STATEMENT CLEAR AND UNAMBIGUOUS?** Are the words and phrases used in the statement understandable by the decision makers of our society? Is the statement free of specialized jargon? Will too many people misunderstand its meaning?

6) **IS THE STATEMENT AS CONCISE AS IT CAN BE MADE WITHOUT RISK OF MISUNDERSTANDING?** Are there any excess words, phrases, or ideas in the statement which are not necessary to communicate the meaning of the statement? Are there so many caveats in the statement that the statement itself is trivial, confusing, or ambiguous?

7) **IS THE STATEMENT FREE OF SCIENTIFIC OR OTHER BIASES OR IMPLICATIONS OF SOCIETAL VALUE JUDGMENTS?** Is the statement free of influence by specific schools of scientific thought? Is the statement also free of words, phrases, or concepts that have political, economic, ideological, religious, moral, or other personal-, agency-, or organization-specific values, overtones, or implications? Does the choice of how the statement is expressed rather than its specific words suggest underlying biases or value judgments? Is the tone impartial and free of special pleading? If societal value judgments have been discussed, have these judgments been identified as such and described both clearly and objectively?

8) **HAVE SOCIETAL IMPLICATIONS BEEN DESCRIBED OBJECTIVELY?** Consideration of alternative courses of action and their consequences inherently involves judgments of their feasibility and the importance of effects. For this reason, it is important to ask if a reasonable range of alternative policies or courses of action have been evaluated? Have societal implications of alternative courses of action been stated in the following general form?:

"If this [particular option] were adopted then that [particular outcome] would be expected."

9) **HAVE THE PROFESSIONAL BIASES OF AUTHORS AND REVIEWERS BEEN DESCRIBED OPENLY?** Acknowledgment of potential sources of bias is important so that readers can judge for themselves the credibility of reports and assessments.

General Comments on the Organization of the Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter

1) Key Policy-Relevant Issues. In the context of the comments on pages 1-3 (above), it was a great delight to read **Chapter 3 – Key Policy-Relevant Issues** and to find there:
A) The explicit listing of 9 well-defined policy-relevant "Issues to be Considered in the Current Review of the Primary [public-health-based] PM NAAQS" on pages 15-16; and
B) The similarly well-defined and explicit listing of 5 policy-relevant "Issues to be Considered in the Current Review of the Secondary [public-welfare-based] PM NAAQS" on page 18!

It was even more delightful to find:
C) On page 17, the separate listing of 4 additional policy-relevant questions dealing separately with each of the four requisite parts of the current public health based NAAQS Primary Standards for PM – level, indicator, statistical form, and averaging time; and
D) On pages 18 and 19, the separate listing of 3 additional policy-relevant questions dealing with each of these same four requisite parts of the current public-welfare based NAAQS Secondary Standards for PM – level, indicator, statistical form, and averaging time.

2) History of Past Reviews. It was very helpful to find a discrete section (Section 1.3 on pages 5-10) of "**Chapter 1 – Introduction**" dealing with the "History of Reviews of the NAAQS for PM." This history is very complicated – especially in recent years -- and needs to be presented much more clearly. The present prose-only description of the events leading up to the final promulgation of Primary and Secondary Standards for PM in 1971, 1987, 1997, and 2006 is very inadequate. Even more inadequate is the description of the rational behind the proposals EPA made in each successive review cycle.

My best suggestion for improvement of this very important section (Section 1.3) is to use a combination of prose description of events and rational together with a tabular presentation of the actual primary and secondary standards promulgated in each review cycle. The information presented in footnote 5 on page 9 for the current NAAQS standards for PM provides a valuable template, which could be used to construct a similarly clear presentation for each of the NAAQS Primary Standards and each of the Secondary Standards established in 1971, 1987, 1997, and 2006.

3) Mass and Size-Distribution vs Composition of Particles. EPA's decisions to start with the mass of particles (TSP) and later to differentiate between larger particles (PM_{10}) and finer particles ($PM_{2.5}$), and still later to differentiate between thoracic coarse ($PM_{10-2.5}$) and fine particulate matter ($PM_{2.5}$), and, finally, to give at least some thought to ultrafine particles ($PM_{1.0}$) is understandable because the scientific evidence about how deep into human lungs different sizes of particles can penetrate makes both mechanistic and epidemiological sense..

In Section 1.4 **"Scope of the Current Review"** in the present Draft Integrated Review Plan indicates that only limited attention will be given to the chemical composition of either fine particles ($PM_{2.5}$) or thoracic coarse particles ($PM_{10-2.5}$) from the standpoint of public health effects, or to the composition of fine particles ($PM_{2.5}$) that are assumed to be the principal cause of visibility impairment in wilderness, rural, and urban areas of the US.

- It appears from Section 1.4, that EPA intends to draw very careful distinctions between the attention that will be given to the role of nitrogen and sulfur compounds in the now-ongoing (concurrent) reviews of the:
- "Integrated Science Assessment for Sulfur Dioxide" with its major focus on the effects of various oxides of sulfur on human health,
- "Integrated Science Assessment for Nitrogen Dioxide" with its major focus on the effects of various oxides of nitrogen on human health,
- "Integrated Science Assessment for Secondary NAAQS for Nitrogen Dioxide and Sulfur Dioxide" with its major focus on the effects of various oxides of both sulfur and nitrogen on human welfare including "soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being," and the soon to be developed
- "Integrated Science Assessment for Particulate Matter" with its major focus on effects of $PM_{2.5}$ particles on both visibility and human health and the effects of thoracic coarse particles ($PM_{10-2.5}$) on human health.

As presently planned, all four of these different Integrated Science Assessment documents will be based on an unstated (and I believe unproven) assumption that it is the chemically oxidized forms of nitrogen and sulfur (NOx and SOx) that are dominant in importance in each of these four distinct NAAQS reviews, and that the similarly abundant but chemically reduced forms of these same elements (NHx and SHx) are not very important (or worthy of planned discussion) in the context of these four distinct NAAQS reviews.

As an ecologist, who is aware of the many different and important sometime beneficial and sometimes also very adverse public-welfare effects of both chemically oxidized and chemically reduced forms of reactive nitrogen, I was pleased to find that section 1.4.3 of the "Draft Plan for Review of the Secondary National Ambient Air Quality Standards for Nitrogen dioxide and Sulfur Dioxide" is titled "Ammonia." This Section also went on to say:

"The atmospheric lifetime of gas-phase NH_3 is on the order of a day; however, in the presence of sulfuric or nitric acids [or gaseous SO_2, NO, or NO_2] ammonia can form aerosols, predominantly ammonium sulfate and ammonium nitrate, with lifetimes on the order of 7-10 days. This longer lifetime gives the potential for long-range transport of nitrogen and sulfur, and contributes to fine particulate matter and regional haze. Ammonium sulfates can also participate in climate modification effects, directly through radiative cooling by light scattering, and indirectly through modification of precipitation by acting as cloud condensation nuclei. A detailed discussion of these processes is included in the PM review."

At first, I thought this special section on "ammonia" in the "Joint NOx and SOx Secondary Standards" document and all but the last sentence among the further statements quoted above would mean that EPA might be willing and interested to broaden the agency's perspectives about the many, diverse, and very significant adverse welfare effects of reactive nitrogen pollution by adding ammonia, ammonium ion, and other reduced forms of reactive nitrogen to the "Indicators of Concern" in the nitrogen and sulfur NOx and SOx joint NAAQS review -- or at least in the PM review. But my hopes were quickly dashed by EPA's apparent continuing preference to consider chemically reduced forms of nitrogen only in the context of the PM review.

Ever hopeful, I did a word "search" for the words "ammonia" and "ammonium aerosol" in the present "Draft Integrated Review Plan for Particulate Matter" and found only one "hit" – "ammonia is mentioned only on line 2 on page 62, and "ammonium aerosol" was not found anywhere within this "Draft Integrated Review Plan for PM!"

My Specific Assignment in this CASAC Consultation on the Draft Integrated Review Plan for Particulate Matter

My specific assignment in preparation for the November 30 , 2007 CASAC Consultation on the "Draft Integrated Review Plan for Particulate Matter" as outlined in Chairman Rogene Henderson's memo of October 19, 2007 is – **Section 6 (Visibility and Other Welfare-Related Assessments)**.

Chairman Henderson also gave this same assignment to two other CASAC panel colleagues – Lowell Asbaugh and David Grantz. Thus, I am very much looking forward to comparing notes with both Lowell and David during our CASAC Consultation on November 30 -- and to learning more from Bill Malm who knows more about visibility effects of PM than any person I know!

I see from Bill Malm's comments that the definitions of visibility and transparency of the atmosphere on pages 49 lines 27 and 28 are incorrect and that he raises some of the same questions I have raised earlier in these Preliminary Comments about the importance of understanding the chemical composition of fine particles in relation to their impact on visibility impairment in various parts of our country (see pages 32 line 25 through page 33 line 4.) I agree wholeheartedly with Bill Malm's question:
"Can a secondary standard be express in terms of something like an integrated variable such as total reactive nitrogen (all forms) or extinction, which includes other characteristics of PM than just mass?"

On page 52 lines 24 and 25, what is meant by the expression: "and/or preservation of the resource for its own sake?" I don't understanding what "resource" is to be preserved.

It was a pleasure to read the discussion about "public perceptions" and "public judgments" about visibility degradation in scenic vistas – very well thought out!

Dr. James Crapo

Review of Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter

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November 30, 2007

The Draft Plan for NAAQS on Particulates appropriately considers the key policy-relevant issues for both primary and secondary standards. The review should focus on new information that addresses issues relevant to the magnitude of adverse health effects occurring at exposure levels that are at or near the current NAAQS. Issues addressing cardiovascular and respiratory endpoints, as well as possibly new endpoints, will be addressed, and sensitive subpopulations at risk will be considered. In each case, correlations need to be made to particle size/mass, composition and sources/environments.

A primary challenge that should begin to be more formally considered in this review cycle is the complex interactions between particulates (both coarse and fine) with other oxidant air pollutants such as ozone, NOx and SOx. Similar adverse health effects are being identified with low levels of each of these air pollutants, and it is highly likely that these health effects are interdependent. The optimum control strategy is also likely to be interdependent. Instead of considering these interactions as confounding factors in interpreting the possible adverse health effects attributable to each pollutant independently, models involving simultaneous evaluation of the key regulated air pollutants need to be developed. I would recommend that these complex interactions be strongly recognized in the current review of the particulate NAAQS and that in the future the review of these regulated pollutants be combined into a single review that could focus on the interactions of pollutant composition in determining the activity of the pollutant mix. This could have a profound impact on determining how future regulatory policy could best protect human health.

The review of issues involved in evaluating the secondary NAAQS standard for particulates should focus on answering the question of whether or not there are adverse environmental and welfare effects of particulates at levels below the primary standard. A clear answer is needed to the question of whether or not a lower air quality standard is needed to appropriately protect environmental and welfare effects. The proposed plan to address these issues is appropriate.

Dr. Douglas Crawford-Brown

Comments on Draft Integrated Review Plan for the national Ambient Air Quality Standards for Particulate Matter

Doug Crawford-Brown (11-20-07)

As with the other Draft Plans, the key comment here is that the devil will be in the details; i.e. in the way these rather abstract notions in the Plan are executed. Still, the overall plan laid out in the document is sound and in keeping with other NAAQS analyses, and represents an expansion of the methodology and considerations in the previous NAAQS review of PM risks. My comments below relate to some specific issues within the Plan, with my attention focused mostly on the human health risk assessment components of the plan.

1. On Page 10, the authors make clear that past PM reviews focused on size-fractionated particle mass rather than particle composition. They then state that this same approach will used in the new assessment. In later sections of the document (e.g. on Page 26), there are at least hints that composition will be examined. This was confusing and should be clarified.

2. At no point in the document do the authors mention the issue of negative radiative forcing by particles in the atmosphere. This negative forcing would tend to decrease, not increase, climate change. Of course, there will be both positive and negative forcing (positive due to absorptive particles and negative due to reflective particles). This issue of climate change impacts should at least be mentioned, and I would even push for considering it in the setting of NAAQS.

3. The criteria for study selection on Page 22 are generally good. An issue that continues to worry me is the potential for double counting of effects when epidemiological studies contain mixtures of PM, ozone, NOx, etc, and these same studies are used for all of these NAAQS calculations. So, a good criterion to add would be the ability of a study to somewhat clearly separate out the individual effects of these pollutants (if there even is such a thing as the "individual" effect). I just want to be sure the SUM of the predicted effects from the various pollutants doesn't come out larger than the overall measured effect in the studies.

4. I fully support the idea of using representative geographic regions in the analysis. This will of course raise the question as to what it to be meant by "representative" for purposes of scenario analysis. There will need to be consideration of both the exposure levels and routes, and the demographic mix of a population. I would urge consideration of variability analyses that directly address equity issues in different socioeconomic and ethnic groups.

5. There is a large issue that wends its way throughout the issues raised in the document, but which is not addressed directly anywhere. It concerns the relationship between the detailed exposure assessment being proposed, which will be based essentially on constructing exposures for individuals as they move through the temporal-spatial field of concentration, and the match to the epidemiological studies. The epidemiological studies, which produce slope factors, in a sense "integrate" the movement of each individual in a study location. So the variation in these movement patterns is hidden within the slope factors. It isn't strictly legitimate mathematically to

use a slope factor developed from such a complex mixture of exposure patterns in a population and then apply a "correction factor" for inter-subject variability of exposure to these slope factors (which is what the proposed study will do). The one case where it IS at least a good approximation is when the exposure-response is a linear function. I am not pushing for any specific way of addressing this issue, but it needs to be at least recognized as a potential source of double counting exposure variability.

6. I don't fully understand why the toxicologic and human clinical studies (on Page 27) are to be used only for biological plausibility and mechanistic evidence. There at least needs to be reflection on whether the dose-response relationships seen in these studies and in the epidemiological studies are coherent. I agree that the epidemiological studies include interactive effects that might not be present in the other two kinds of studies, but the epidemiological studies also contain much more noise.

7. On Page 28, the authors use the phrase "evidence for uncertainties". I have no idea what this means.

8. On Page 30, the authors ask: What are the shapes of the concentration-response models…and how do they "influence public health impacts"? I have no idea what the part I have placed in quotation marks means.

9. On Page 31, in the bullets, I believe the second bullet needs to also ask: What are the implications of these inter-species differences for extrapolation of results to humans?

10. On Page 31, the authors ask about reaction products that can be used as biomarkers. I agree this is a good area of research, but I don't think it will help in setting the current NAAQS.

11. On Page 32, the authors are raising the issue of sensitive subpopulations. At some point in the study, they will need to determine the implications of sensitive subpopulations for interpretation of the epidemiological results. Especially at low concentrations, the exposure-response characteristics of a population would be expected to be driven more by the sensitive subpopulation (which is why the slope factor can be higher at lower concentrations).

12. On Page 34, the authors mention examining effects of PM on climate and effects of climate on PM. This is a contentious and highly uncertain area of climate change modeling, and I would not want to set up too high of an expectation about producing usable results.

13. I fully support the idea of at least examining the results of the Expert Elicitation performed by the EPA on PM concentration-response. But it is not clear how this will be integrated with the results of the epidemiological studies if they are treated as two separate ways to get at a slope factor and threshold. In fact, the Expert Elicitation was based on these epidemiological studies, and so they are not independent ways of producing an estimate. The authors also appear to suggest that the Expert Elicitation contributes primarily information on the uncertainty in concentration-response functions, in contrast to (I can only assume) information on a central tendency estimate. I believe the Expert Elicitation provides both kinds of information.

14. On Page 39, the authors state that the “EPA will consider factors which may influence the concentration distributions such as potential source concentrations, as well as the influence of local and regional pollution”. I have no idea what this sentence means, or how they intend to do this. I also don’t know what a “source concentration” is. Is it a source-specific contribution to concentration?

15. On Page 40, the authors confront the classic problem in these kinds of assessments: how well the estimates of exposure can be made in the face of complex spatio-temporal fields of concentration and the movement of individuals through those fields. I think the best approach here is to use available data on the measured ratios of ambient exposures over exposures integrated through personal samplers as a way to characterize variability, rather than relying too heavily on highly speculative calculations of exposure from first principle.

16. On Page 41, the authors mention taking into account “frequency of repeated peak exposures”, but don’t explain how this will be done or what it evens means to take these into account.

17. I am generally supportive of the use of the APEX modeling approach, subject to the caveats I noted previously. An even better approximation to exposure could be obtained by linking APEX to GIS-based transit routes, since on-or-near-road exposures probably are significant.

18. On Page 43, the issue of variability and uncertainty is raised. I don’t think it will be feasible to place the entire analysis inside a nested variability-uncertainty analysis framework, but it should be possible to do this for a few representative scenarios, and to use these results in post-processing fashion for the other scenarios simulated in the overall study.

19. On Page 46, the authors confront the issue of uncertainty in concentration-response functions. Much of the uncertainty here comes from uncertainty in the exposure estimates for the epidemiological studies. It will be important not to double count uncertainty here (once in the uncertainty of exposures for the simulations and again for uncertainty in the concentration-response functions that are based on epidemiological studies).

20. On Page 46, expert elicitation is raised as a way of getting at some of the uncertainties. I support this idea, but the elicitation must be structured properly so respondents properly fold in all of the sources of uncertainty. They then comment on page 47 that whether to use such results will depend on a decision from the Administrator as to whether the approach has value. It is not clear what will be the criterion for making such a judgment. I presume it must be based to some extent on a judgment of the degree to which such elicitations can be defended.

Dr. Christopher Frey

Comments on "Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter"

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December 26, 2007

I have grouped my comments by major topic area. Since others have made detailed comments on specific pages and so on, I have chosen here to focus on more general types of comments.

Exposure Assessment

The scope of the current review should be more clear and more clearly carried through the entire document. For example, in some places there seems to be at least an implication if not an outright statement that the question of whether the standard should be based on total mass or composition is up for consideration, but in other places the document seems to presume only a mass-based standard. As other commenters have noted, the question of whether there needs to be standards related to ultrafines and nanoparticles should be considered. Furthermore, such standards might be mass-based or based on particle counts. Whether there is enough data and evidence to develop such standards in this revision ought to be considered. If not, then identifying some priorities for data collection and research to inform the next revision could be part of the scientific agenda.

More clarity is needed regarding the overall framework for conducting risk assessments based on the source-to-outcome continuum. There seem to be two or three possible approaches mentioned or implied in this document. They are compared in Figure 1.

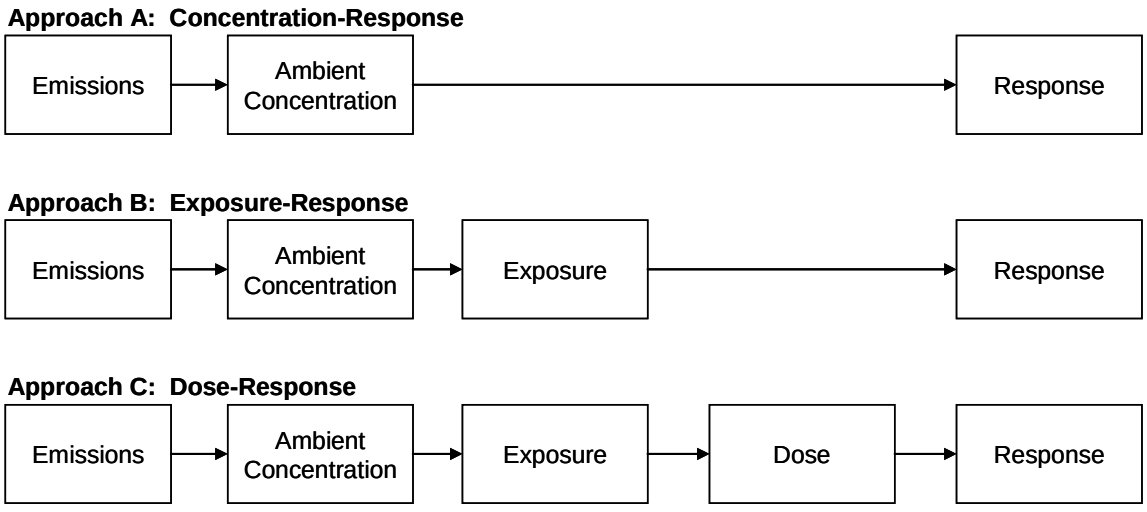

Figure 1. Alternative Conceptual Approaches to Estimating Health Impacts of Exposures to Particulate Matter

The key arguments for each approach should be laid out systematically. For example, Approach A is useful to the extent that concentration-response data are available from epidemiological studies. A disadvantage of concentration response is that it does not account for additional inter-individual variability in human exposures that result from time spent in a variety of microenvironments. For example, an indoor microenvironment can include particulate matter that has penetrated from outdoors. The exposure/concentration ratio can vary by an order of magnitude. Thus, the use of concentration alone as a surrogate for exposure may have limited explanatory capability.

Approach B involves quantification of inter-individual variability in human exposures. This approach will lead to more realism and more accuracy regarding the variability of exposures as a result of activity patterns, such as time spent at home, work, commuting in a vehicle, etc., for which exposure to PM varies but for which there is a contribution from outdoor PM. Furthermore, the ultimate method for managing adverse effects is to reduce exposures. Thus, an understanding of the relationship between emissions, ambient concentration, and exposure will inform formulation and choices among regulatory alternatives. A possible disadvantage is that there is less exposure-response information compared to C-R information. This situation could change over time. As properly pointed out in the IP, quantification of exposures will be important to interpreting differences in C-R relationships observed in multi-city studies. Furthermore, exposure assessment will require developing data, measurements, and models to set the stage for a more complete application of the risk paradigm in future reviews.

Approach C should be considered to be the goal for an assessment of adverse effects, in which there is explicit information regarding how exposure (potential dose) translates into a biologically effective dose, and regarding the response for a particular biologically effective dose. To the extent that the state of knowledge is increasing to support this type of assessment, it should be considered as a possible approach. If the state of knowledge is not adequate to support such an assessment, then guidance should be given as to what additional data and research are needed to prepare for this in a future revision of the standard, or to extend to other forms of PM not yet assessable at this time.

Furthermore, the interactions associated with multi-pollutant exposures and health effects should be identified and, where possible, quantified.

Hazard Identification

The report should be more clearly organized along the lines of a hazard identification step prior to proceeding with other aspects of the risk assessment. The hazard identification should include all of the various forms of PM mentioned in various places in the report. Having a comprehensive list up front of all of these forms of PM will lend clarity to the document. For example, the comprehensive categorization of forms of PM and their identified hazards, including nanoparticles, ultrafines, $PM_{2.5}$, PM_{10}, course PM ($PM_{10-2.5}$), etc. should be given, as well as other aspects of form such as particle mass, particle number, composition (and which species would be evaluated), and so on, that will be evaluated.

Agricultural PM
At one point in the report here is mention that agriculture PM might be considered for exclusion. A scientifically-based rationale will be critical if this is further considered.

Ambient Monitoring
There are various needs and priorities for ambient monitoring, including hotspots, spatially-representative areas, and population representative areas. The monitoring needs should be considered not only with respect to decisions on attainment of a particular NAAQS, but relative to the needs to better quantify source apportionment and population exposures to whatever form(s) of PM are regulated as well as of future regulatory interest.

Monitoring data are also needed to support assessments of multi-pollutant exposures and health effects, as well as to support accountability assessments. For purposes of accountability, in addition to considering population-representative areas, consideration should be given to emission-representative areas. To support source-apportionment studies, there needs to be adequate collection of composition data for various forms of PM.

Consideration should be given to area-wide characterizations of source apportionment versus near-source characterizations, or characterization of spatial gradients in proximity to sources (e.g., location of multiple monitors at various locations in the predominant downwind direction of a highway or other source).

The role of monitoring in accountability should be discussed, as well as its implications for strategies for siting monitors that may differ from the current regulatory focus.

There seems to be an indication from air quality modeling results that plumes of $PM_{2.5}$ tend to be area wide. Information regarding the spatial variability in $PM_{2.5}$ concentrations should be used to inform the choice of new monitoring sites. The spatial properties of other types of PM should likewise be explored (e.g., coarse, ultrafines) to determine whether there may be different needs for location of monitors. For example, as particle size increases (e.g., comparing PM_{10} to $PM_{2.5}$), the characteristic transport time tends to decrease because of gravitational settling and deposition of particles. Thus, the spatial extent of the PM plume is a function of PM size.

Wherever possible, there should be simultaneous sampling of PM precursors as well as PM at these monitoring stations. Furthermore, there should be simultaneous sampling of all criteria pollutants to provide data to support future multipollutant approaches to the NAAQS. To the extent that multipollutant interactions with PM would include other key pollutants not otherwise sampled, priorities should be identified for adding monitoring capability for such pollutants.

A methodology for identifying possible monitoring sites should include the use of portable or inexpensive monitoring methods to screen whether a location would be a good candidate for a monitoring site.

A hybrid approach of federal reference methods, federal equivalent methods, and new methods should be considered, taking into account that some data are for regulatory purposes and other data are for research or assessment/accountability purposes. For example, the use of real-time

methods for measuring or inferring highly resolved temporal variability in PM mass for a given size range should be considered as a supplement to FRMs for purposes of supporting exposure studies.

Accountability
The notion of accountability is not adequately mentioned in the document but will be critical to understanding whether changes made in the PM standards are achieving real-world benefits. Thus, there needs to consideration of data collection efforts regarding emissions, concentrations, exposures, health effects, ecological effects, and so on that enables evaluation of the effectiveness of the current PM standard and how changes in the standard lead to changes in the environment and key receptors (humans, ecosystems, etc.). The National Research Council, in a 2004 report, recommended application of an accountability approach to evaluating air quality regulations. NARSTO is in the process of evaluating how to implement accountability as part of a multi-pollutant framework.

Accountability has implications for what metrics should be used for emissions, air quality, exposure, dose, health effects, and ecosystem effects. The metrics need to be ones that should be possible to measure and monitor over time. For example, measurements of ambient PM levels should be conducted in a manner so that they can be linked to measurements of emissions and measurements of exposure.

Multi-pollutant Air Quality Management
Some mention is given of coordinated review of NAAQS for some pollutants. Even if a truly multipollutant approach is not the focus of the current PM review, EPA should be developing plans and recommendation for how the review of the PM NAAQS will be coordinated with that of other NAAQS in future reviews, and keeping this issue in mind during the course of the current review. For example, since secondary PM includes NO_x, SO_2, and some VOCs as precursors, some coordination of the NO_2, SO_2, and PM NAAQS will be beneficial. Furthermore, because the O_3 NAAQS has implications for control of precursor VOC emissions, coordination between the PM and O_3 standard also should be considered.

International Studies
There does not seem to be adequate justification given for ignoring or putting less emphasis on studies conducted outside of the U.S. Studies should be evaluated on their merits regardless of country of origin, including U.S. or Canadian based studies as well as those from other countries.

Exposure Assessment Modeling
The IP mentions that APEX might be used for modeling of human exposures. APEX has been used for assessing human exposure to criteria pollutants such as CO and O3. However, it does not appear to be the case that APEX has been used or is configured for application to PM, in the various forms that would be of relevance here. On the other hand, EPA already has a probabilistic exposure model, SHEDS-PM, that is configured for application to evaluate human exposure to PM.

EPA should introduce and compare APEX (CO, O3) and SHEDS-PM and explain/justify the choice to modify or adapt APEX for PM rather than use the existing SHEDS-PM model. It

would seem that the main focus here should be application of exposure models, rather than development of exposure models if one already exists. If EPA can justify as to why APEX should be adapted for application to PM exposures, there there needs to be more detail on how APEX will be adapted or modified for application to PM. This is not a trivial task. The development of input data for PM involves different data sources than those for CO and O_3, particularly for factors such as microenvironmental concentrations, penetration of ambient PM to indoor and in-vehicle environments, and transport characteristics of PM. Furthermore, the development of a new model will require appropriate model evaluation and validation activities. This will require significant time and effort and will need to be a clear part of the scientific agenda.

The IP mentions the Stochastic Human Exposure and Dose Simulation (SHEDS) model but does not state that SHEDS is an EPA model. It is not clear from the document that SHEDS is a product of work at EPA over approximately a 10 year period. In addition to the cited application of SHEDS to assessment of PM exposures in Philadelphia, SHEDS has also been used in recent years for assessment of PM exposures in the state of North Carolina, for all 100 counties and for each of approximately 1,500 census tracts. SHEDS has the capabilities that are stated as desirable for APEX, such as a probabilistic simulation capability for inter-individual variability. SHEDS has been evaluated using panel studies.

As I understand, APEX is coded in FORTRAN. FORTRAN is not a programming language that is the first choice for development of models that are intended for long-term use.

There should be some discussion as to the comparison between SHEDS and APEX with respect to estimation of PM exposures. SHEDS-PM is coded in SAS and in MATLAB. Recoding of a model can be an effective way to review and improve algorithms and to increase computational efficiency. The use of an object oriented language such as C+ should be considered. Another version of SHEDS (for pesticides) was recoded from SAS into C++ with improvement in computational speed. Thus, recoding of SHEDS-PM for use in assessment of human exposures to PM is one option for a modeling tool.

If APEX is to be adapted or modified for application to PM exposure estimation, then it should be benchmarked versus SHEDS-PM as part of model evaluation.

Exposure assessment is important to the assessment of health effects from ambient PM because PM penetrates into indoor and vehicle microenvironments. Thus, the exposure models must be updated to include new data and algorithms for improved characterization of such exposures. For example, in-vehicle exposure to PM is likely to be an ongoing research topic during the course of preparation of the ISA, and it is likely that the algorithms for quantifying such exposures will need to be updated as new information becomes available.

Variability, Uncertainty, and Sensitivity

Regarding the general topic of variability and uncertainty, this is mentioned in a few places in the document but it should be treated more systematically throughout all stages of the scientific assessment. EPA should posit an overall framework for dealing with variability and uncertainty, and then explain how the framework will be applied for specific components of the assessments,

such as modeling of concentrations using air quality models, interpretation of monitoring data, estimation of spatial and temporal ambient concentration fields, quantification of exposure, quantification of concentration-response, quantification of exposure-response, quantification of exposure-dose and dose-response, etc. The specific methods used for dealing with uncertainty may differ in each of these areas, but need to be consistent to enable linkages from one part of an assessment to another.

There are some related activities at EPA that will be useful resources for the PM risk assessments. For example, the Risk Assessment Forum has a Probabilistic Risk Assessment (PRA) working group and technical panel, that is pulling together information regarding methodology (in the form of a white paper, currently in draft form) and case studies on PRA, with plans to disseminate such information via seminars and an intra-agency web-based tool. There is work within the National Exposure Research Laboratory to look at the issue of how to couple air quality, exposure, and dose models, particularly with regard to propagation of variability and uncertainty from one model to another. There is an Institute of Medicine (IOM) expert panel that will be studying issues of uncertainty related to public health decision making. There are several draft reports to EPA/OAQPS on the general topic of a "Hierarchy of Methods" for dealing with uncertainty. And so on (these are just examples). Thus, there are many resources within EPA for developing a coherent framework for uncertainty analysis that can serve as a model not only for this PM review but for other NAAQS reviews in the future. In addition, there are external documents, such as the recent World Health Organization (WHO) guidance on uncertainty in exposure assessment, that can inform the development of an integrated methodology for dealing with issues of variability and uncertainty, ranging from qualitative to quantitative methods.

The conceptualization of uncertainty should take into account uncertainty in scenarios, model structure, and inputs to models. There should be a characterization (qualitative, quantitative) of each of these categories of uncertainty. If scenarios are mis-specified are models are improperly formulated, this can lead to larger errors in an estimate than uncertainty in model inputs. Uncertainties in scenarios and models typically lead to bias, which may be difficult to quantify.

Expert elicitation is part of the toolkit for quantifying uncertainty (or variability, depending on the assessment question) in situations for which representative data may not be available but for which there is an information or theoretical foundation upon which to make estimates that could correct for possible biases in the limited data set. EPA did a good job in conducting the expert elicitation for the PM C-R ratio as cited in the IP. This type of rigorous approach to expert elicitation is a good model for the elicitation method that should be used in the current PM review, if expert elicitation is needed. To help prioritize situations for which expert elicitation is needed, it may be useful to conduct sensitivity analysis with models used in the risk framework to identify those inputs for which information is lacking and that significantly influence estimates of endpoints critical to the evaluation of regulatory alternatives. Thus, sensitivity analysis methods should also be part of the toolkit. Sensitivity analysis can be used in combination with PRA to identify which uncertain or variability inputs most influence the endpoints of interest, which can be useful to informing the development of risk management strategies and/or identification of priorities for collecting additional data.

While there are some critics of expert elicitation, it is important to recognize and clearly state that ANY assessment involved HUMAN JUDGMENT. For example, in purely frequentist statistical analysis based on empirical data, judgments are made regarding which data to use for an analysis, that the data are a random and representative sample, regarding what statistical criteria to use to reject hypotheses, regarding what statistics and statistical methods to apply to the data, and so on. On the other hand, quantification and acknowledgment of uncertainty is good scientific practice.

Human Health and Ecosystems
I agree with other commenters that there needs to be more focus on ecosystems than is currently evident in the draft IP

Climate Change
The effect of climate change on ambient PM and on PM exposures and effects needs to be considered, but to what extent it needs to be considered is not clear in the document. Conceptually, it seems appropriate to consider the effect of changes in ambient PM levels on climate change, either in terms of a secondary (welfare) effect or perhaps even in terms of a primary (human health) effect. While it may be possible to approach the effect of climate change on ambient PM quantitatively (with uncertainty), the effect of PM on climate change might end up being more qualitative. If so, then it will be useful to identify data and research needs that could improve the degree of confidence of an assessment in the future (i.e. for the next review of the PM standard). From a technical perspective, there would be substantial challenges to quantifying the health and welfare effects of changes in climate with respect to changes in ambient PM form and levels. The draft IP is not clear on the scope of this issue or how it will be approached.

Dr. David Grantz

Amended Comments on the Integrated Review Plan—NAAQS PM
David A. Grantz
University of California
11/30/2007

First, let me say that the Review Plan is pretty good and very well written. Whoever produced this out of the ferment of the July meetings deserves a meritorious service award. However, there are a few issues. As usual, I guess, I will focus on the negative. I have five overall areas of concern with the plan.

1. First is the method of dealing with older information. I recognize that the new process of the science assessment is designed in part to be streamlined relative to the earlier Criteria Document-based process. Nevertheless, I have concerns that there may be unintended consequences for preservation of information that was obtained prior to the last review. This will become more serious as further iterations of the new process occur.

   On page 2, line 16-17 it is stated that the focus will be on new information (since the last CD). That is fine, but the second half of the sentence states that the ISA will reflect the most current state of knowledge. These statements may be contradictory. I believe that it is critical in the body of the report (rather than in a preliminary section of the entire ISA as suggested on page 20, line 20-22, or in an annex) to refer to older studies that remain definitive. Some of these may even be the most recent work on a subject, as scientific fashions change and work on some subjects stops. I think the IRP should be revised throughout to state that the only criterion for inclusion of studies is that the information be the most recent and relevant, not its publication date (page 20, line 19) and not that is has been subjected to reinterpretation since the last review (page 20, line 27-29). This will be particularly important for welfare effects, since many topics (effects of road dust or limestone quarry dust on vegetation comes to mind) have not been studied much in recent years but remain important.

2. Second, the concept of welfare effects has been unduly narrowed. On page 20, line 11, it is stated that deposition of particulate metals will be considered. Again on page 33, line 25-26, metals, and specifically mercury and copper, are singled out. And again on page 55, line 26. This raises the question--why include metals at all? Why exclude semi-volatile organics or base cations, to think ecologically, or organic and elemental carbon or oily particles if we think of surface soiling? These other aspects of PM are mentioned briefly (page 33, line 21-27) but discussion immediately reverts to metals (line 25). It appears that this style is used as an example, but the effect on the reader is to single out metals to the exclusion of other important components of PM. Welfare effects are complex and should be considered in their complexity in the IRP, or they will not be in the ISA.

   It is stated on page 10, line 21 and again on page 15, line 11-18, that the previous Criteria Document concluded that “size matters” and that PM should be evaluated according to

size class. This may be true for primary standard consideration, but in Chapter 4 of the preceding CD size was specifically excluded as relevant to plants. It was stated there that chemical composition of PM is far more important to vegetation and ecosystems. On page 10 and 15 this statement should be removed or moved down in the text so that it lies clearly within discussion of the primary standard. In discussion of the secondary welfare standard, more attention should be paid to chemical speciation as a major determinant of effects.

It seems to me that these decisions as to what classification is most appropriate and which compounds are of most interest should be decided after reviewing the literature, rather than before, as is done here.

Similarly, I am concerned that fate and effects of PM that happens to contain N or S will be dealt with separately (page 33-34). For example, the important subject of trends in base cation deposition will seem out of place without discussion of the acidifying effects of these excluded N and S compounds. How will this be handled? It is unclear from the text, or the discussion on 11/30/07, whether the interactions of (e.g.) base cations with acidifying species should be considered in the PM document, in the combined NOx-SOx secondary document, or in both. Much discussion on 11/30/07 centered on the need for an integrated (multi-pollutant) assessment. This decision regarding NOx and SOx secondary effects seems to work against that trend. This issue needs to be thought through carefully and explained more coherently in the IRP.

It is striking how very little attention effects on vegetation received in the IRP. Indeed, welfare effects are summarized as "Visibility and Other Welfare-Related Assessments" (both in the Chapter title, page 49; and in the text page 56, line 20). While visibility is important, has readily available data, and has political impact, it has little effect outside of itself. In contrast, potential long-term impacts on ecosystem function and resulting services have the potential to impact human welfare in many profound ways. Ecosystem effects, even though definitive data may still be lacking, should receive much greater attention to fulfill the CAA mandate to protect against uncertain effects.

3. Third, there can be no scientific reason to exclude studies performed outside of the US and Canada (page 22, line 16-17; page 23, line 29-30). There may be a political reason, and if so, the IRP should state it. Otherwise, in many areas of recent literature on PM, studies from Europe and Asia represent the most recent information. This may even be more important for the secondary standard than for the primary, as the differences in health care systems do not apply (page 22, line 18-19). Some flexibility is suggested in the current draft IRP (page 24, line 1-2) but it seems an afterthought and is broadly contradicted throughout the document.

4. Fourth (a positive view!), effects of/on climate seem both absolutely appropriate in this PM ISA and remarkably convenient to incorporate at this time (page 34, line 1-9). The IPCC has just released summary documents. There will be little need for independent modeling or other research to incorporate this absolutely current information.

5. Fifth, I am concerned that material in the annexes will be considered less important than that in the main body of the text. Yet on page 34, line 15-16, it is stated that the goal of the annexes is to identify scientific literature that is relevant. I had thought that was the objective of the ISA itself. This troubles me because of the potential prejudging of the scientific literature mentioned above, and because the CASAC and the PM panel will not be invited to review the annexes (page 35, line 4-5). In addition, the Scope and Methods Plan (page 49, line 15-16) which will be developed in parallel with the ISA, will be influential in this regard, but will be considered by CASAC and the PM panel later in the process than the ISA itself (page 56, line 9-10; schedule page 13). It became clear during the discussion of 11/30/07 that the Scope and Methods Plan will inform the Exposure and Risk Assessment, rather than the ISA. This should be made more explicit in the IRP.

Thank you for the opportunity to review this important document.

Dr. Joseph Helble

Comments on Draft Integrated Review Plan for NAAQS for PM
J. Helble, Dartmouth College 11/27/07

1. Clarification needed with regard to the extent to which the review will consider the PM-climate relationship as a secondary effect – Sections 4 and 6 of the draft IRP differ. The approach described in Section 4 seems more appropriate.

   Section 4
   p. 11 lines 25-27 "EPA will again consider…. climate-related effects…."

   p. 18 lines 1-3 "What new evidence is available on the relationship between PM… and climate-related and other welfare effects?"

   p. 34 lines 1-9 discuss in some detail climate effects to be considered in the ISA

   Section 6
   p. 49 lines 13-14 "…we do not anticipate there will be sufficient information to support quantitative analyses related to this public welfare effect in this review."

   There is no further mention of potential climate effects in Section 6.

2. p. 20 line 29 – meaning of "Generally" needs to be clarified. If non peer-reviewed sources are to be considered, the parameters guiding acceptability of such sources need to be clearly defined. Same statement applies to "usually" in line 13, page 24. Do books and reports need to be peer-reviewed to be considered?

3. p. 21 lines 17-19 add "fly ash," aerosols, smoke

4. p. 23 lines 29-30: the argument in favor of placing emphasis on U.S. studies when considering secondary effects – visibility, climate, deposition of metals - seems tenuous and should be deleted.

5. The term "characteristics" (of PM) means different things in different sections. There is overlap and the IRP should be clarified for consistent usage.

   p. 15 line 17: characteristics = size, composition, source, environment
   p. 26 lines 19 and 22: characteristics = size, composition, surface area, source
   p. 27 line 26: characteristics defined separately from size and composition
   p. 28 line 17: characteristics defined separately from size
   p. 29 line 27: characteristics defined separately from size and composition
   p. 31 line 2: physico-chemical characteristics?
   p. 33 line 3: aerosol/optical characteristics – what are "aerosol characteristics"?

6. p. 37 lines 18-19: what is an “air quality distribution?” Similar comment applies to “distribution of air quality” on p. 39, line 16. Does this mean a geographic distribution of PM concentrations in a particular region? Clarification needed.

7. p. 46, line 5 – it is likely the author meant principal, not principle

Dr. Rogene Henderson

Comments on EPA's Draft Integrated Review Plan for the NAAQS for Particulate Matter
Rogene F. Henderson
November 30, 2007

The document was generally clear and well organized. I compliment the Agency on a good job. I have a few questions covered below.

Page 10, lines 22-25: Reading this, one would think the Agency was not going to consider composition in reviewing the toxicity of PM. The rest of the document indicates this is not so. The language here should be clarified.

Page 16, Issues to be considered: The last bullet covers in a generic fashion all the important uncertainties from the last review. However, a more specific listing of those uncertainties would be helpful. Mr. Poirot has listed some of those in his comments. The toxicity of coarse particles in urban versus rural areas is an issue I would like to see noted.

Page 20, ISA: I have a concern that some time be given to how to develop an adequate ISA (generic). This is not an easy task that can readily be done "on the fly" as we push forward to meet the goal of 5-year reviews. It is such an important document, not only for PM but for all criteria pollutants, that I think a standard protocol for how one goes about developing an ISA should be developed.

Page 29, line 1: This sentence brings up an important problem on the health effects of multiple pollutants, which we all breathe. The sentence does not, however, suggest how we might get the data to support this approach. The EPA is considering a multiple pollutant approach for air quality management, but this consideration is embryonic in concept. I think we need to move toward a multiple pollutant air management policy, but perhaps that is not possible for this document.

Page 37, lines 11-26: I found this paragraph to lack clarity.

Page 41, lines 22-24: I hope that the risk assessment will include the PM 10-2.5 particles. We did not have the data to do this in the last review and it is an area where we need information.

Page 46, Expert Elicitation
The use of expert elicitation, if done properly to address well-defined questions can be helpful. But there are many ways in which expert elicitation can be misused. The experts must be carefully selected, and the use of their opinions must be justified. Any plan to use expert elicitation should be first reviewed by CASAC.

Dr. Philip Hopke

Comments from Philip K. Hopke on
Draft Integrated Review Plan

This is a generally very good document that has focused attention on most of the high value issues that need to be assessed to inform any possible policy changes with respect to the PM NAAQS. There are a few issues that need to be considered in the final plan.

Science Issues
In addition to composition (constituents) in PM, size may matter. There is a mention of fine and coarse, but there should be an assessment of where we are with respect to ultrafine (<100 nm) particles and the potential need for a particle number standard. EPA has expended considerable resources on studying the role of ultrafine particles in inducing health effects. There has been limited numbers of epidemiological studies so at this point, it is appropriate to assess where we are and the need for (or lack thereof) a standard that would be particle number concentration based.

Particle Monitoring
I continue to have considerable concerns with respect to using the difference method to obtain estimates of $PM_{10-2.5}$. It is particularly problematic to provide compositional data. Thus, there needs to be care taken to assess all of the coarse particle monitoring techniques without making any one of them into a "gold" standard. Similarly, the $PM_{2.5}$ FRM is a precise method of unknown accuracy, but known bias toward low measurements. Thus, we need to look more carefully at what we define particle mass and what is it that we want to measure. Is it not time to measure the amount of material that people actually inhale? Should it not be our goal to make accurate measurements of mass concentrations rather than mimic the inaccurate measurements of the past on which the epidemiology is based? There are ways to make appropriate adjustments in the standard values to account for the higher values that will be measured if all of the airborne particle mass is actually included. This issue is one that is central to setting of the level and the monitoring method that goes with it and requires some attention.

With respect to composition, we have been looking under limited numbers of lampposts given the nature of sample collection and laboratory analyses. We need to look at better time resolved measurements and measurements of reactive species that may be more relevant for health effects. Thus, there needs to be a discussion of whether the right composition metrics are being measured given what we have learned from other studies such as tox or epi studies and improved understanding of the mechanisms of action.

Expert Elicitation
I do not like this process whatsoever. They can chose the people they want to ensure they get the responses they want. There are fads in views that may cause bias in the outcomes. If they have critical information, it should be published in appropriate journals with appropriate reviews. I think they should not do these or use these in the process.

Dr. Donna Kenski

Comments on the Draft Integrated Review Plan for the NAAQS for Particulate Matter
Donna Kenski
Lake Michigan Air Directors Consortium
November 27, 2007

The draft plan presents a logical and consistent roadmap for reviewing the PM NAAQS. I found no major shortcomings. Specific minor issues are addressed below.

p. 16, line 1 (1st bullet): What evidence is available from recent studies focused on specific components, *size fractions,* or sources of PM…

p. 18, line 9 (bullet 3): This document should at least acknowledge the potential for positive effects with respect to climate change.

p. 19: Another policy issue that should be addressed here is how we assign value to the welfare effects—what new evidence or techniques are available for quantifying the value we place on visibility in wilderness areas as well as the urban areas we spend so much time in. This is discussed in Sections 6.2 and 6.3 but it has important policy implications and deserves a bullet in this section.

p. 20, line 11: Deposition of metals is mentioned but not organic or elemental carbon. Is this because OC and EC have no welfare effects? Do we know?

p. 26, lines 9-11: A discussion of source apportionment models and their utility for determining exposure surrogates is an excellent idea.

P. 30, bullets 1 and 2: Good – a comprehensive discussion of confounding is critical.

p. 34, lines 1-9: Climate change effects seem to be downplayed in this document. I hesitate to make that statement because the climate change discussion could easily overshadow all the other welfare effects. Still, this description leaves me wondering how far the ISA will take this climate change discussion – will PM effects on climate be compared to those from other greenhouse gases? How do we assess or evaluate changes in precipitation and temperature—what does it mean for agriculture, recreation, ecosystem health, etc.? The plan should be more explicit in how far-ranging the ISA intends to be.

p. 36, line 24: population *or* variable…

p. 49, line 10: benefits of materials damage??

p. 49, lines 10-14: I agree that a comprehensive and quantitative assessment of multiple climate change scenarios is an unrealistic goal for the ISA, but there should be plenty of information available for at least a qualitative discussion of the general direction of impacts from changing PM concentrations.

p. 52, lines 1-6: The last sentence is a little confusing. The more important point is to note that regional differences in humidity will cause different visibility impacts for the same PM concentrations.

p. 57-60: It is appropriate that Sec. 7 starts out by stating the purposes of the ambient monitoring network. Not all of these purposes are equally well served by the existing PM network. The current focus on more populated areas and the elimination of monitors in areas where no violations have occurred hinders our ability to determine spatial patterns and variability of PM. Consequently the monitoring network's ability to support exposure assessments, track trends, look at transport patterns, etc., are hindered as well. So, bravo to the authors of the plan for recognizing this problem and addressing it specifically with the bullets on p. 60.

p. 62-63: EPA may need to go to the gray literature to answer some of the questions posed in the bullets on p. 63, or perform their own analyses, since some of this work is unlikely to be published yet. I hope that's considered acceptable for the ISA.

Dr. Morton Lippmann

Comments by: **Morton Lippmann, Member, CASAC PM Panel**
Re: **Draft Integrated Review Plan [IP] for PM NAAQS**

Background:

The IP provides a comprehensive outline of EPA's plan for the CASAC's participation in reviews of key documents to be used, over the next several years, to determine whether existing PM NAAQS should be retained or revised. These include:

1) The Integrated Review Plan (IP);
2) The Science Assessment;
3) The Exposure/Risk Assessment;
4) Advance Notice of Proposed Rulemaking;
5) Proposed Rule

General Comments on the IP:

The IP, itself, is a concise, comprehensive, and well-written document that outlines a carefully considered array of tasks to be accomplished over the next few years. It gives reasonably full consideration to what was accomplished in the previous review cycle of the PM NAAQS, and what was, to CASAC's frustration, not accomplished. The preparers of the document deserve commendation for a job well done. However, it can be improved in some specific ways, as outlined below.

Specific Suggestions for Improvements:

p. 5, line 2: CASAC is a Committee mandated by the CAA, and is thereby independent, in terms of its judgments and conclusions, of SAB.

p. 11, line 2: It should be noted here that efforts are underway (and if not, are needed) for other PM components, i.e., EC, OC and specific transition metals.

p. 15, line 10: add: "and, as needed, to establish new NAAQS based on other PM components".

p. 16, line 6: replace "daily" with "short-term (daily or multi-day)".

p. 23, line 16: replace "instillation" with "lung instillation and other forms of dose administration".

p. 25, line 17: Add: "How can sources such as resuspended road dust be characterized?"

p. 27, line 17: Change: "may" to "will".

p. 29, line 22: Insert: "or exacerbating" after "initiating".

p. 30, line 5: Add: ", or benefits accruing from such interventions" after "relationships".

p. 30, line 9: Add: “VOCs” after “CO”.

pp. 30, 31: The section on “Biological Mechanisms of Action” is too limited in scope. It should be broadened, or followed, by including a section “Biological Plausibility”. It has become increasingly clear in recent years is that the literature on exposures to PM at relatively high concentrations and statistically significant associations with human health effects has been supplemented to now include many more showing statistically significant, if often subclinical, effects in normal and vulnerable human populations at PM concentrations at and below current PM NAAQS. These, and the recent CAPs studies in animal models of human disease that show comparable effects in responses and biomarkers, are particularly important in our capacity to convince the Administrator and the public that ambient PM pollution continues to be an important public health challenge.

p. 38, line 5 and beyond: The issue of assuming a “threshold model” at an arbitrary level for estimating an exposure-response relationship for PM needs to be reconsidered. While the issue remains unresolved at this time, the scientific literature on this issue has grown considerably in recent years, and the justification that it is reasonable to assume that they exist for population-based time-series and cohort studies has diminished. Thus, any plan to do analyses of exposure and/or risk based on a threshold assumption will need a much stronger rationale than it had in the last PM CD.

p. 41, lines 22-25: EPA needs to more than consider “exposures associated with ambient PM10-2.5 as well”. Unless it does, the cop-out of a lack of sufficient ambient air quality data described on p. 39, lines 5 – 10, will inevitably be available for use again.

p.44, lines 4 & 5: Will EPA really be able to “consider …… risks associated with PM10-2.5 in the ambient air, as well as risks associated with specific PM components”, or will the lack of such data be an excuse to once more not address these critical issues.

p.44, line 18: The treatment of Policy Relevant Background (PRB) in the last PM CD left many in the Past CASAC PM Panel unhappy. The need for, and treatment of PRB in this ISA will need a much better justification than it had in the last round.

p. 46, lines 11 -13: While EPA has had a long interest in harnessing the emerging field of “expert elicitation” into its arsenal for risk assessment, it remains a controversial technique among air pollution scientists, as evidenced by the CASAC PM Panel’s discussion during the Nov. 30, 2007 Public Teleconference. Staff needs to prepare a package of briefing materials for the CASAC PM Panel at an early stage if expert elicitation is to be relied on in the preparation of the PM ISA.

pp. 59 – 63: What is the purpose of Section 7.3 on Monitoring Issues to be Considered in the Current NAAQS Review? Is it to alert the CASAC Panel on the legal requirements for this NAAQS pollutant? If so, it is adequate. On the other hand, if it is to ask the CASAC Panel to discuss its adequacy as a plan to collect sufficient data to understand exposures to PM10-2.5

and/or the components of PM2,5 and PM10-2.5 on the population means and distributions of exposure for either this, or the next round of NAAQS review, then it is clearly inadequate.

Dr. William Malm

Review of "Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter"

In general the document is well written and easily understandable.

Some specific comments:

Page 5, line 7: "Particles may be emitted directly or formed in the…"—should include the reduced forms of nitrogen as well. Things like ammonia, amines, etc., have to be present to form ammonium nitrate, sulfate, or some carbonaceous particles.

Page 18, line4: How will ecosystem response be addressed in that it is deposition of particles (both coarse and fine), rain, snow, and gases that contribute? Can a secondary standard be expressed in terms of something like an integrated variable such as total reactive nitrogen (all forms) or extinction, which includes other characteristics of PM than just mass?

Page 21, line 16: Do you mean publications data base? And do these searches include visibility-related topics?

Page 32, line 25: The statement that nitrates and organics are the largest contributors to visibility reduction in the West is not true. Nitrates play a significant role primarily in parts of California and during the winter at some sites. Soil in the spring is the largest contributor to extinction at some sites, and on the average sulfates play a bigger role in visibility reduction than nitrates. In general, one could say that sulfates, nitrates, organics, and soils all contribute at times to significant visibility reduction and on the average are about the same.

Page 33, line 19: Shouldn't night sky issues be addressed? Light pollution is directly related to haze levels and the ability to see celestial landscapes.

Page 34: May want to have a section explicitly discussing the role of smoke on visibility, climate, etc., highlighting the need for understanding the emissions from fire that are currently not very well addressed, such as VOCs that contribute to SOA in a very significant way, ammonia, NOx and others.

Page 49 line 27: The statement that visibility is the degree to which the atmosphere is transparent to visibility light is very inaccurate/wrong. Depending on sun angle, the transparency of the atmosphere may be a small contributor to visibility impairment. It is the combination of transparency (or more accurately, transmittance—transparency is usually used by psychophysicists to describe human response to atmospheric haze) and scattered light added to the sight path that causes visibility impairment. It is this airlight that in many cases dominates the ability to see color, textural detail, etc., of a landscape or urban feature.

Page 50, line 8: Remove "can." It is the reduction of clarity, etc., that is the primary indicator of visibility impairment. How far one can see is just a convenient and easily understandable way to

express “visibility impairment”. One will see visibility impairment (the degradation of clarity, etc., of a landscape or urban feature) long before it is so hazy that the feature is at the limit of just being able to see it at all.

Page 52, line 13: The correlations would be best for any time period where RH was relatively constant, say, during selected night- or daytime hours. If RH was low, then PM and visibility would always correlate well.

Page 59: Under network design, should some consideration be given to species specific effects, such as PH (acidity)?

Page 60: If one is considering both fine and coarse mode ($PM_{2.5}$ and PM_{10}) standards, should the sampling cutpoint be readdressed? The fine/coarse mode cutpoint for most species is between 0.8 and 1.0 um. 2.5 um tends to be about in the middle of the coarse mode. Any error in the sampling cutpoint (due to flow rate change, etc.) can dramatically affect the relative mass collected in the fine and coarse modes and thus compliance with the standard.

Page 61: Under sampling methods, I believe it is essential to discuss sampling artifacts. They can and usually are very significant. Significant loss of both ammonium and nitrate species occurs over sampling periods that include a diurnal cycle (large temperature changes). In the Midwest and parts of California where nitrates tend to be the largest fraction of mass, these artifacts could cause error of factors of two or more in gravimetric fine mass estimates.

Could an explicit measure of number-size distribution be used as a FEM? Europeans are considering this option.

Page 63: The equivalence of thermal OC/EC measurements (and associated artifacts) should be addressed.

Mr. Tom Moore

EPA Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter, 10/16/07 draft

CASAC PM Panel Review Comments, Tom Moore, WGA/WRAP 11/30/07

The draft IRP is well-written and provides a good summary of EPA thinking for this review process. Other members of this CASAC and the PM Review Panel with previous experience on EPA committees and panels have provided useful and thoughtful comments that reduce the number that I need to make at this time. I have 3 general comments that would help me see better where EPA's process is going, and follow/advise on the process and results over the next few years.

1. ISAs for PM vs. other CAA Criteria Pollutants

With PM the broadest indicator of ambient air quality of the CAA criteria pollutants, it would be useful to have EPA specify in a summary fashion what ambient measurements and emissions sources are included in the analysis work behind each of the ISAs, carrying that organization into the review effort(s). Examples include oxidant chemistry affecting ozone/NOx/SOx and PM, ammonia a key player in multiple criteria pollutant indicators, chemical composition varying across PM size distributions, among others. This effort to define what EPA is including in one or more ISAs will be helpful in the air quality management outcomes that will ultimately result from this NAAQS review. Dr. Samet commented that "cross-referencing and 'harmonization' is needed across the ISAs", which I support – maybe this summary would be a start at that. It appears that EPA is thinking in this direction already.

2. Implementation of PM NAAQS

The effort to implement the 1997 PM NAAQS revisions provided a good example of how complicated the more sophisticated PM indicators adopted by EPA are for regulators to monitor/track, analyze impacts, and determine controls. Funding and technical resources provided by EPA and implemented by state, tribal, and local air agencies were both quite substantial, and have added to scientific understanding of the nature and causes of PM. Sources and impacts of large magnitude within the U.S., as well as natural and international out of the control of EPA and state regulators have been identified and apportioned in the regional haze analysis work of the past several years. These regulatory data and analyses form part of the basis of this review of the PM NAAQS. I think it is necessary for CASAC and the PM Panel to not only review the work products leading up to EPA decisions on the next PM NAAQS, but also to be able to clearly understand sufficient detail about the technical and scientific implementation plans of EPA that would assist in informing recommendations about the form, level, and averaging times of the next PM NAAQS.

3. Summary of CASAC and PM Panel comments on the Draft IRP

It would be helpful to have an itemized summary of the comments prepared for the 11/30 conference call, and where/how/when EPA will address those comments in their review work, given the number of comments and reviewers. This summary would likely be something EPA would already be preparing for their use.

Dr. Robert Phalen

Comments on Draft Integrated Review Plan for Particulate Matter
Robert Phalen (12/05/2007)

The Draft Plan demonstrates a clear advance in the sophistication of thinking related to the NAAQS for Particulate Matter. The Plan is clearly described and it discloses some of the many problems associated with identifying key issues that require in-depth analysis. That said, I will focus on problematic topics, some of which may mainly be useful for the EPA Administrator who must take more into account for protecting public health than what can be detailed by scientific experts. It is clear to me that continued tightening of our current air standards will produce unwanted health-related tradeoffs. The situation has changed from that faced years ago, when air pollution was a serious threat to public health. In addition, the climate change issue is too complex and unsettled for EPA to consider it in setting NAAQS for PM.

p. 4, line 20: Although "costs of implementing the standards" may not be considered, health-related tradeoffs should be. Such tradeoffs include the broad availability of affordable electrical power, food, shelter, transportation, goods, and services that are essential to a healthy population. Air quality standards have public health tradeoffs that must eventually be carefully considered.

p. 10, lines 24-25, and p.15 lines 15-18: Although it is a brave move, evaluating "specific PM components and sources" is necessary. It is generally known that metrics other than fine and coarse mass are relevant to human health effects.

p. 16, lines 12-15: "Levels of PM exposure" are identified as the primary concern. Yet, in epidemiology studies of acute health effects, small daily changes in levels (i.e. increments) are consistently providing associations with adverse health effects. Because "levels" and "changes in levels" are not the same thing, EPA must be careful in trying to set a NAAQS-PM "level" that is based on studies of "changes in levels".

p. 16, line 28, and p.24, lines 24-26: Regarding the question of "have new uncertainties emerged?," have non-PM-exposure factors that might influence the associations between PM levels and health effects been adequately considered? In addition to meteorology-related confounders, PM episodes are presumably associated with behavioral changes in use of heating/air conditioning, driving patterns, and time-activity patterns. If the scientific database permits, such additional confounders should be reviewed.

p. 29, lines 1-2; p.30, lines 8-10: Biological aerosols probably require inclusion in the list of co-pollutants.

p. 32, lines 19-22: Although hard data might not be available, there is the possibility that public exposure to ever cleaner air might lead to a diminishing of respiratory tract defenses. Microbiologists are concerned over the effects (on resistance to infection) of reduced exposure to potential pathogens. Might the public be becoming more susceptible to air pollutants as a consequence of improvements in indoor and outdoor PM levels?

p. 37, lines 22: In addition to “reductions in risk”, might local strategies to reduce PM levels also increase some forms of risk? The availability of affordable electrical power, food, goods etc. also affect public health. It is understood that this might be an issue for the Administrator, instead of EPA staff.

pp. 41-42: The APEX model is an interesting, but ambitious approach. EPA staff should weigh the effort involved against the usefulness of the data acquired.

p. 46, lines 12-13: It seems that “conducting an expert elicitation” is a good idea, given the importance of establishing appropriate NAAQS. A diverse group of experts could provide important helpful advice and new ideas to consider.

p. 47, lines 23-30: EPA is to be congratulated for considering the “broader context” of “risk/exposure” assessments. Although it is difficult to do, all of the significant consequences (for public health) of air standards (and meeting them) must be considered to the extent possible.

Dr. Kent Pinkerton

Comments on Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter

Kent E. Pinkerton (11-30-07)

The Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter is a well organized and clearly written document. Congratulations to those involved in the preparation of the document. My comments for the document are given numerically below.

1) The introduction with an overview of the NAAQS review process, legislative requirements and especially the history of reviews of the NAAQS for PM is helpful to have summarized in this document to provide the basis for the current review.

2) Pages 15-16: As stated, it will be important to insure the review of the literature is complete to address the questions posed. Key evidence to understand subpopulations and their sensitivity to PM exposure will be essential to carefully consider. I would add we need to also understand the specific responses observed in these sensitive populations that make them different from the rest of the population.

3) Pages 17-18: It is not clear to me the meaning of the terms "indicator" and "form" in the context they are used in the following phrase: …the basic elements of the NAAQS: indicator, averaging time, level and form.

4) Page 18: For this next NAAQS review, I would emphasize it is extremely important to emphasize new evidence on the relationship between PM mass/size and specific PM components.

5) Page 18: For visibility impairment and ecosystem impacts of PM, it is anticipated that these will occur at a level lower than those concentrations for which health effects have been observed or will be of concern?

6) Page 18: When the term "form" is used in this document (line 24), does this refer to chemical composition of the PM or to primary or secondary PM?

7) Pages 20-21: The scope and organization of the science assessment for the integrated review plan are well laid out in this section of the document. My concern is in the extent of how toxicological studies will be handled. Will considerations for the significance of species sensitivity, dosimetry (concentration and duration of exposure), particle size and particle composition be taken into account when considering the published literature? A number of these parameters will be essential for addressing biologic plausibility which needs to be a critical part of the next review document.

8) Pages 22-24: The criteria used for study selection is highly reasonable. I like the definition for "susceptibility" and "vulnerability". It will be critical to carefully consider those animal studies which use inhalation vs. instillation exposure to PM. It is also important to consider site-specific effects of particle exposure within the respiratory tract to determine micro-domains of response and effect that may be able to better explain non-pulmonary sequelae of particle exposure. Again, this brings to light the importance of addressing biologic plausibility for PM-related health effects that need to be a highlighted component of the next review document.

9) Page 24: The approach for new evidence evaluation and whether uncertainties of the past have been addressed or if new uncertainties have emerged is important to acknowledge and is clearly stated here in the document.

10) Page 27: Health effects – For short-term exposure to PM, for this next review process, it will be critical to ask whether there is any new evidence to more strongly implicate a specific chemical composition and/or source to better explain health effects.

11) Pages 30-31: Biological mechanisms of action – the authors of this document have created an excellent list of questions to address. I would simply add to this list a) the importance of dosimetry and b) a better understanding of specific-specific responses within the respiratory tract for PM-induced effects to better understand local and systemic impacts of particle exposure.

12) The chapter on human health assessment is well organized and extremely logical. Thank you for making this easy to follow.

13) Page 38: It will be important for the risk assessment of PM10-2.5 to be given serious and complete consideration along with PM2.5. As one reads further into this document, I am more reassured that this will be done.

14) Page 40: I would argue that rural area assessment should also be considered. Agricultural practices, especially in the state of California are often in close proximity to urban areas as well.

15) Page 42: The APEX model sounds very logical in creating the population exposure model.

16) Page 47: To conduct an expert elicitation sounds like a novel idea, but will this process allow for any cost-saving approaches to be implemented in the preparation of the literature review for this document? This program of expert elicitation should be more fully explained.

17) Page 48: To explore regional differences in PM risks is an excellent idea. This review might also emphasize the need to better understand what these differences (in PM composition, population makeup, etc) between regions of the country represent.

18) Page 49: line 10 – the term “soiling” as used in the context of this sentence is unclear. Please clarify to the reader.

19) Page 51: line 15 – Visibility in urban areas is clearly important, but what about visibility in national parks such as Yosemite and the Grand Canyon?

20) Surveys of public perception could be extremely beneficial in this current review. Since resource constraints prevented this work form being done in the last review, renewed efforts should be strongly encouraged to have this survey included in this review.

Mr. Rich Poirot

EPA Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter, 10/16/07 CASAC Review Comments, R. Poirot, VT DEC

General comments:

2. Science Policy Issues Raised in the Last PM Review

In a few - but not all – sections, the plan efficiently reflects back to specific decisions made or issues raised in the last PM review. More emphasis in these areas might be a good way to identify some key science-policy issues – and might become more useful in the future as the review cycle is shortened – and as CASAC science review comments will come after the internal EPA Policy assessment and ANPR. Some specific contentious issues raised (and not really closed) from the last review might include:

- Is there new evidence that suggests an annual $PM_{2.5}$ standard of 15 ug/m3 (rather than 12-14), provides a margin of safety for long-term exposures?
- Is there new evidence that coarse (or fine) particles in urban areas are more injurious than those in rural areas?
- Is there new evidence that indicates coarse PM emissions from all mining and agricultural activities are uniquely benign?
- Is there new evidence that there are no soiling, irritant or nuisance welfare effects from coarse particles in non-urban areas?
- Does the current 24-hour secondary $PM_{2.5}$, 24 hr. average, 98^{th} percentile, 3 year average protect against adverse visibility effects?

2. Planned Visibility Effects Review

The section summarizing planned presentation of visibility effects in the ISA (on bottom of page 32 & top of page 33) will be a useful update to information provided in the last PM CD. However, much of the proposed analysis appears to be specifically focused on regional results from the rural IMPROVE speciated aerosol network – with sites in remote Class 1 federal areas (for which a regional haze rule and "reconstructed extinction" equations which are species-specific, RH-dependent and not based on fine mass) already exist.

I think there also needs to be a separate emphasis on urban/suburban visibility and its relationship to a $PM_{2.5}$ mass indicator, perhaps limited, as was done in the last review cycle, to a 4 to 8-hour daylight-only time period (or perhaps otherwise screened for lower RH conditions). This might include analyses of the urban speciated CSN data, as well as comparisons of continuous $PM_{2.5}$ and B_{ext} data (adjusted or screened for RH effects) from airport ASOS sensors (hopefully the raw ASOS data before its been truncated and aggregated). Some focused discussion would be useful on the differences between urban & rural aerosol composition & visibility, the pros and cons of using fine mass vs. detailed PM species indicators, etc. Since the species-specific effects of sulfate and nitrate aerosols are being intentionally disregarded in the current SO2 and NO2 secondary standards review (to be addressed in this PM review), it might be appropriate to include a separate section here on visibility effects of sulfates & nitrates. An interesting science/policy discussion might consider pros and cons of addressing urban visibility

via S & N species & precursors of by fine mass indicators. How will the situation change with implementation of CAIR and other "on the books / on the way" control programs?

The plan also indicates inclusion of results of valuation studies that provide information on levels of pollution-related visibility impairment considered to be "adverse". This is very important, since the causal relationships between PM and visibility are so clear and extend to such low PM levels – with a very low perceptibility threshold. This is also an area where EPA could provide some valuable near-term research and analysis support, since good photographic survey methods are available but there hasn't been a lot of recent work in this area. Possibly there could also be some specific focus on the kinds and frequencies of (short-term, daytime) visibility impairment levels which are possible under the current shortest-term PM2.5 standard (35 ug/m3, 24-hour average, 98^{th} percentile, 3-year average) which was considered sufficient to protect against adverse visibility effects in the last review. See also specific comments on P. 55.

3. Additional Analysis of the Effects of the NAAQS Form(s)

Typically most attention in any NAAQS review gets focused on the level(s) of existing and proposed standards, while the statistical form of the standard receives relatively little attention – and this typically occurs toward the end of the process. Perhaps it will now be relegated to the policy assessment – and not subject to advance CASAC review? I think it would be useful to see some additional focus and discussion of the form and effects of using various percentiles and multi-year averaging times early on in the ISI process – both from a health or welfare effects perspective, and from an analysis of the existing measurement data. We are also generally getting much better at identifying "exceptional events" than has been the case in the past, and such events are typically removed from consideration. So that the 98^{th} percentile (7^{th} worst day in a year) or annual average is could be calculated with a number of much higher concentration days removed from consideration. Are there ways to account for this in conducting risk/exposure assessments and how should the details of the form relate to or modify the level of a standard?

Specific Comments

P. 10, lines 3, 4: Here might be a good place to add some specificity on the details of the CASAC comments, which provided a number of specific objections to the final (& draft) EPA decision(s). What better definition of "science-policy issues" can there be than those places where the scientific advice was clearly at odds with the EPA policy decision?

P. 10, lines 22-24: Is the intent in "considering fine and coarse-fraction particles separately" to focus again on specific $PM_{2.5}$ and $PM_{10-2.5}$ indicators, or might other size fractions or compositional indicators be considered?

P. 11, lines 17-28: Here (as was the case for the last PM review) there appears to be little or no intent to consider the welfare effects – soiling, irritant, nuisance, materials damage, (& to a lesser extent, visibility) of coarse particles.

P. 12, lines 3, 4: "in the gas phase" isn't quite right here and could be deleted for clarity.

P. 15, lines 30, 31: I suggest ending this bullet with more specificity: "…health effects associated with exposures to $PM_{2.5}$, PM_{10} or $PM_{10-2.5}$ or other PM indicators?"

P. 16, line 1: I suggest changing to "…specific size fractions, chemical components, or sources…"

P. 16, lines 22-26: In considering "sensitive populations" (or in considering "sources" or "exposures" or as a separate consideration), it might be informative to consider populations living near urban roadways, steel mills, smelters, mining activities, agricultural workers, etc.

P. 17, line 11 (or elsewhere): In considering PM components, sources or other indicators, it might be useful to include a question or two focused on the kinds of locations where more injurious (or more benign) kinds of coarse or fine particles tend to be found.

P. 18, lines 9-12 (or elsewhere in this section): It might be useful to include separate bullets that focus on (a) What are the most appropriate averaging times (including times of day) over which visibility effects are experienced?; and (b) What are appropriate frequencies at which adverse visibility effects should be tolerated?

P 19, line 7 (or elsewhere): It might be useful to include some bullets that specifically focus on secondary effects (soiling, irritant, nuisance, materials damage, visibility) of coarse particles and/or PM_{10}, and to consider any "urban/rural" or "mining/agricultural" differences.

P. 20, line 19: could add before "literature": "… on key science/policy issues raised during the last review and on…"

P. 25, lines 6-11: This might be re-worded or broken into 2 bullets, as most of the paragraph is not specifically related to the size-selection performance standards emphasized in the first sentence. Line 9 seems to consider only positive sampling artifacts and does not consider how sampling biases might effect the apparent mass composition or temporal pattern. It might be changed to something like "To what extent are these methods subject to positive or negative sampling artifacts? Do these sampling biases affect the magnitude or the seasonal or diurnal patterns of specific aerosol species or apparent source contributions?"

P. 25, line 14: You could add after "PM": ", and how do these relate to patterns of human exposures?"

P. 25, lines 21-27: This is an excellent suggestion for considering use of satellite data! It might be worth (another bullet) also considering if there could be enhancements to existing PM monitoring networks that would make the satellite data more useful. Perhaps satellite data could be especially useful for evaluating larger-scale radiative forcing effects of North American aerosols (over water, etc.). Also, possibly other sources of routine data – such as airport ASOS visibility - that could (as is or with modification) provide useful supplemental information on PM exposures or effects.

P. 26, line 20: Could add "number" after "area," and before "and source".

P. 26, line 28: Could add after "subpopulations": ", and how do these uncertainties vary for particles of different size or composition?"

P. 28, lines 8-28: Could add a bullet something like "What new evidence is available on effects occurring from exposures at sub-daily averaging times?"

P. 33, line 7: You could add "and from unspeciated fine mass measurements." to the end of this sentence.

P. 36, line 5: Putting location-specific risk/exposure assessments results "in a broader public health perspective" is especially important with the new NAAQS review process. Since CASAC still has a statutory duty to recommend ranges of primary and secondary standards to the Administrator – presumably before the Administrator proposes ranges in an ANPR – the risk / exposure assessment should provide detailed information (maps, graphs, tables, etc.) clearly showing areas and populations which would be protected by various combinations of short and long-term primary and secondary standards. I assume this is what's intended in the section 5.3 "current air quality characterization".

P. 46, line 13 and elsewhere: Its not really clear to me what would be the use – to the Administrator – of the proposed expert elicitation to characterize and quantify the most important sources of uncertainty. Some added detail might be helpful here. I'm not sure how much this would really illuminate the NAAQS review process, but it would certainly seem like a useful guide to future research needs. This might also be timely given the new, shorter review cycle in which current standards might be thought of somewhat more as "interim" and somewhat less as "final", and goals might be approached in iterative steps as key uncertainties are reduced. I'm not sure this is a good idea…

P. 48, lines 1&2: One kind of location might be a small city/town in mountain/valley terrain with a high incidence of woodstoves and inversions.

P. 49, line 10: I would change "benefits" to "effects".

P. 50, line 7: Add "s" to "wavelength".

P. 52, line 5: You could add "and aerosol composition" after "humidity".

P. 52, lines 11-15: Consideration of sub-daily averaging times helps minimize RH and species composition differences in different regions – i.e. strengthens the case for a single, national $PM_{2.5}$ indicator. However, there is also justification from an effects viewpoint. Urban/suburban visibility is more important during the daytime when most people are awake, scenes are illuminated, and urban light pollution is minimal.

P. 54, lines 25-27: …and considering that hygroscopic species concentrations and east/west differences will diminish under future CAIR SOx & NOx reductions.

P. 55, lines 1-22: This expanded pilot study is an excellent idea and should be given a high priority. Hopefully, a failure to conduct it in a timely manner will not become the excuse for postponing consideration of secondary standards in the current review cycle (the line 6 statement that this could help "inform this or future reviews" is cause for worry). Conversely, we would not like to see this study postponed with the excuse that it might not be completed in time to illuminate the current review. I think this raises an interesting general dilemma associated with the new, faster review cycle – its not hard to envision things that might get done in the next cycle, and how to develop the technical support in the current cycle. It seems like it would be timely to consider a more formal linkage between the NNAAQS review and EPA's research agenda than has been the case in the past, and maybe future NAAQS Integrated Review Plans could/should include a "current research needs" section.

P. 56, line 12: I assume you mean "and" rather than "or".

P. 60, lines 12-15: Other important reasons for non-urban monitoring include model development/evaluation, characterization of regional background, etc.

P. 61, lines 17-22: This is a good point, and light scattering - or RH-controlled $PM_{2.5}$ light scattering - might be an excellent choice to support a secondary visibility standard (and provide $PM_{2.5}$ mass-related info). However, there are also important issues with the use of (many different) continuous PM sampler data to support short-term health effects studies, as the different samplers may have seasonal, diurnal, species-specific and source-related biases. Understanding and quantifying or reducing these biases is important for many reasons besides visibility effects (and substantial progress would have been likely by now if EPA had not discarded staff & CASAC recommendations in the last review cycle).

P. 62, lines 1-3: Another need for "true NO2" measurements would be to support improved calibration of satellite NO2 observations, which could in turn provide invaluable information on spatial patterns and temporal trends. Possibly it would also be useful to add measurements of ultrafine particles or size distributions at some sites.

P. 63, lines 15-19: This sounds like a good idea. You could add "or primary" after "secondary" in line 16.

Dr. Armistead (Ted) Russell

Review of EPA PM Integrated Review (Amended)

I am generally pleased with the integrated review plan for the PM NAAQS. I think the plan still should push for focusing on factors most relevant to reconsideration/revision of the standard, and identifying and quantifying the key uncertainties. One of those that will likely take more effort than appears to be indicated by the Draft Plan is on the impact of PM on climate, and the resulting health impacts from there. The importance of PM on climate deserves more explicit consideration in the Key Policy Relevant Issues section, both in issues regarding the primary and secondary NAAQS. It is important to identify early on how this issue will be addressed. Further, I was hoping to see more emphasis on how individual components will be treated throughout the process, including exposure assessment and risk assessment. One could see that given the very different impacts sulfate has on visibility and climate versus other components, there is an added impetus to consider the different impacts of individual species, with consideration for species-specific standards for both the primary and secondary NAAQS. My concerns go to the outline for the ISA as well: there should be a sections in Chapters 2, 3 (potential mechanisms and mortality/morbidity associated with climate change impacts from PM: the literature in this domain is thin, but growing), 4, 6 and 7 dealing with climate.

The document might discuss more how they might use source apportioned PM impacts.

Given that I was asked to comment particularly on the Policy Assessment/Rulemaking section, the first comment to be made is… my, how short! More seriously, key to the policy assessment is quantitative information as to the number and type of affected individuals at each level/form of a possible standard, and quantitative uncertainties in those estimates. Further, quantitative assessment of the affected environments is needed (what level of visibility reduction in what areas). This should be the focus of the ANPR. The current description of the ANPR suggests that it may not be as quantitative as needed for the task at hand. Further, the role of PM on climate will likely be a tremendous issue with which the policy makers will have to deal. The climate issue will likely have to be a significant consideration in the Policy Assessment aspects of the proposed rule making. The ANPR will also need to address how different sources will impact different components of PM and hence have different health and welfare impacts.

Some specifics:

Page 32: Remove the "?" on the first bullet.

Page 34: The discussion on the impact of PM on climate is awkward and rather short. There is much going on here that will need to be accounted for.

Page 41, line 1: If the most recent 3-year period is viewed as being uncharacteristically high or low in PM, this may have to be changed.

Page 44, line 18 (and prior references to PRB): Given what happened with the PRB discussion in the ozone review, how PRB is used needs to be well laid out. As noted in the ozone review by

CASAC, the importance of PRB was questioned in that the level where an adverse effect is seen was not viewed as being dependent on a background, and the PRB concept was viewed as a distraction. The PM ISA should take on how the PRB will be used much more clearly than is done here or in the ozone review.

Page 52, line 20: The two Chestnut papers are not in the reference list.

Page 64, line 3: Add $PM_{10-2.5}$

Dr. Jonathan M. Samet

Comments on the Draft Integrated Review Plan for PM

Jonathan M. Samet MD, MS

This note provides my final comments concerning the Draft Integrated Review Plan for PM (dated October 16, 2007). In addition to the Specific Comments provided below, I have the following general concerns:

- In previous comments concerning the NO_x and SO_x ISAs, I have expressed concern with regard to the process used to carry out the reviews. In particular, I have been concerned by an inadequately developed and documented protocol for the final synthesis and evaluation of the evidence. Criteria for doing so have not been well specified and discussions of overall findings have been limited as a result. Looking to implementation of the PM ISA, I call for the development of a more formal review protocol, drawing on lessons learned to date. In particular, the protocol should set out criteria for study selection, both for epidemiological and toxicological studies, for evaluation of individual studies, and for overall summary and synthesis of evidence. There needs to be specific discussion of the criteria used for causal inference.

- As I commented on the NO_x ISA, a framework for causation of adverse effects by PM that highlights the roles of other pollutants needs to be developed. Greater specificity needs to be brought to the concepts of confounding and effect modification, particularly given the complicated interrelationships among the criteria pollutants, including particularly the contributions of SO_x and NO_x to secondary particle formation.

- In general, policy relevant scientific topics have been selected for review and in Chapter 4, the list of items to be considered is appropriate.

Specific Comments:

Page #	Line #	Comment
11	2	There needs to be a cross-referencing and "harmonization" across the ISAs.
15	27	"altered the (level of) scientific support…"
16	12	What is the nature of the dose-response relationships of PM with the risk for the various adverse effects?
20	29	"Generally" Universally? This needs to be spelled out.
22	12	"effect modification" Synergism is a form of effect modification.
27	21-22	The material from lines 21 on is too superficial
29	25	"against a causal" Not really appropriate to anticipate evidence "against". What does this mean?
30	15	How does effect modification lead to uncertainty? Explain.
30	19	Shape?
21	9	What is a PM reaction product? A biomarker of injury?

Page #	Line #	Comment
21	17	“Susceptible and vulnerable” Remember that this is an issue of effect modification.
32	19	“The ISA will present concepts…” Not clear as to what this means: “defining adverse health effects?

Dr. Frank Speizer

Pre Conference Call Comments on EPA Draft Integrated Review Plan for NAAQS for Particulate Matter-Draft dated October, 16, 2007

Submitted by Frank E. Speizer, MD

Date November 20, 2007

General Comments;

The draft is generally well written and reasonably outlines the process proposed to be followed. There is a bit formality in how the information is presented that is redundant but seems to contain the necessary components. There is a tendency for the general statements to be lacking important components but these components are then usually contained in the detailed text that follows each section. What is not clear is that if one was to rely only on the general statements important components would be left out. For example in the discussion of Health Effects on page 27-28, the general approach suggests that the effects to be discussed would relate to respiratory and cardiovascular end points and public health impacts of such. It is only later the text describes the potential for assessing lung inflammation, host defense, potential oxidative stress, biomarkers of effects, etc. The concern is how the emphasis will be placed. I simply would have thought it would have useful to indicate the full range of issues to be considered in the initial paragraphs.

Specific Comments:

Page 10, top of page. In the discussion of the legislative history and what has come before, there is a bit of rewriting of history that may or may not be accurate or may be open to different interpretation. The implication is that CASAC by suggestion of a Henderson 2006b letter signed off and was in agreement with the Administrator on the final PM promulgated standard. That was certainly not the case and if the Henderson letter is to be mentioned its position should be more accurately stated.

Page 11-12. In listing that this review will consider the impacts on visibility impairment related to mixtures of aerosol compounds… including nitrates and sulfates. (and) In addition …climate-related effects…the specter of other combustion related products must also be considered and this raises the issue of global warming from energy production. At least lip service needs to be offered as to where the issue will be handled if not here.

Chapter 3, page 15, lines 7-10. This statement say the policy relevant issues related to annual primary and secondary standards for PM2.5 and PM10. Although discussed in subsequent sections below, but as indicated above, is this presuming too much as to what the policy relevant issues are? What about course fraction? What about speciation? Who is deciding that PM10 is or is not on the table as such? This seems to be stating the policy relevant cart before the scientific basis horse.

Page 16, bullet beginning line 22. Discussed later in text there are two components to understanding subpopulations. Mentioned here are potentially “sensitive” groups but discussed

later is potentially "vulnerable" groups and each are defined differently. Shouldn't this be considered here? It is also not clear that fetuses and neonates are the best examples for additional groups. What about asthmatics, children, diabetics, etc?

Chapter 4. Section on Literature Search and criteria for Study Selection. Although one could argue that focusing on US and Canada would give us more "relevant" literature it may not be the case. Certainly the western European experience is relevant. Beyond that it is worth considering other summarized data bases. For example, PAPA-SAN that has been put together by HEI is an extremely well documented assessment of the Asian literature and may provide some additional insights that would not be available for the US literature. It would be extremely important to scan the world literature for additional information that can give insight into the potential for health disparity role as another potential susceptible group.

Page 24. under Welfare; An avenue of data that is seemingly not considered is satellite imagery which may provide insight into loss of forestation associated with pollution.

Page 25, Source of Dose. Besides worrying about the commercial samplers, additional consideration needs to be given where samples are located, frequency of sampling and chemistry that is being performed on the samples (comes up later on page 26).

Page 27, line 18. There may be more important systems to look at than neurological. If we are likely to "run out of time" in this assessment I suggest that other systems be considered at a higher priority. One might organized the thinking (beyond cardiovascular, respiratory, and reproductive) to include inflammatory, autonomic, physiologic, and cellular responses.

Page 28, bullet beginning on line 18. Suggest consider separating the several concepts in this bullet. There is a big difference between counting ER visits and evaluating reversibility of HRV changes. Similarly vascular and endothelial function are very different from hospitalizations and how they interplay in providing evidence for "coherence or plausibility for effects of different PM sizes…." Again would downplay efforts directed toward "…renal, hepatic, nervous, or other systems?" What other systems?

Page 29, bullet beginning on line 14. Suggest separate …cancer, …mutagenic .. genotoxic effects from PM effect on fetus or infant. These two categories really are very different.

Page 32, line 21. Start now and make sure the estimates of people in specific at risk populations WILL BE AVAILABLE rather than the sentence that implies staff might be able to find the data!

Page 34, lines 25-28. Suggest these mentioned tables be separated into those with speciation data being provided separately so that staff can assess what questions about speciated particles have been asked and which will be needed to be asked in the next round.
Chapter 5

Discussion beginning bottom o page 38, line 23 on the PM10-2.5 and continuing on top of page 39 describes well the problem. What is not here is a strategy going forward. What is staff going to do to improve specifically on this question of additional data for a proper quantitative risk

assessment for course fraction? I assume they will look for more data but there may only be a limited amount and at what point is there enough for a quantitative assessment?

Page 40 line 13 and footnote 14. There are a fair amount of data derived from satellite and GIS data that might provide sufficient information for exposure assessment. It may not be in the open peer literature but probably does exist in Government Publications. The following pages clearly indicate that the staff are serious about attempting to do this assessment right. They hopefully will have sufficient time and resources to do it right.

Section 5.5, beginning on page 43: This reads rather well and is encouraging that a reasonable health risk assessment will be performed for PM 2.5 and PM 10-2.5 at alternative levels. But staff needs to keep an open mind to the possibility that there may be sufficient data to consider some alternative indicators in terms of potential speciation of particles for which similar calculations may be necessary. These might include specific metal components, or specific mixtures, and even consideration of smaller size fractions (doubtful that enough data will be available but this should at least be identified as a problem). Alternatively, consideration might be given to a "source identifier (e.g. Stationary vs. Traffic for specific particle components).

Page 46-47. The document raises the issue of using a formal expert elicitation as part of this review. It would be good to see the peer reviewed (and accepted) previous effort in this direction. Quite frankly I am not sure it should be the Administrator's "position" of whether such a project would inform him or her (after all by the time this occurs there is likely to be a new Administrator). More important would be how the science of conducting such an effort would stand up to peer review and if it did how the data were used and seen by CASAC and others in the ISA.

Chapter 6
Page 52, Surveys of Public Perception. Not on this list is "soiling index", which had significant economic impact in the past. This is an old measure, that may have gone away but it at least should be mentioned and if there are data available that are relatively new should be reported.

Page 54, line 9 A survey not done. We are now going on seven years later, and in spite of having been reviewed and agreed to in concept the work apparently has not been done. Is EPA going to include a public perception survey or not? It certainly would inform the Administrator of how relevant these issues are. Perhaps the Administrator already knows what the public perceives, and therefore cannot justify spending the trivial amount necessary to document or refute his prejudices. But once again it is worth pointing out that the final decision in 2011 is likely to be made by a different Administrator.

Chapter 7
Page 60, 3 questions on criteria for defining population-oriented sampling. There is a resource limitation issue embedded in these questions. If one wants to have a better estimate of population exposure than the first issue must be dealt with. If there are hot spots this may require a totally different resource allocation and may not relate to population exposure. (E.g. the hot spot may be on the side of a mountain up wind from a source with no people around!). Can EPA and state government afford both? It would be of interest for EPA to provide data on

what is being done. What percent is adequately covered by existing monitoring? Do we have a handle on what proportion of known hot spots are being monitored? Is there a plan or are there data that get us at least part way there? Will this review lead to some recommendations on future monitoring schemes?

Dr. Helen Suh

Pre Conference Call Comments on EPA Draft Integrated Review Plan for NAAQS for Particulate Matter-Draft (October 16, 2007)

Prepared by Helen H. Suh
November 20, 2007

General Comments

The draft clearly and concisely presents a plan to assess scientific evidence for PM. The organization of the ISA is somewhat confusing, however, as subsections overlap in terms of relevant topics and questions. For example, the subsection on susceptibility and vulnerability was placed near the end of Section 4.0 (Science Assessment), even though it was relevant to many earlier subsections. As a result, questions would arise in earlier sections that were subsequently addressed in later parts. While this confusion is difficult to avoid entirely, an initial listing of topics to be covered in each section or some initial discussion in the earlier section with cross-referencing may help. In terms of subject matter, it may not be possible to separate the discussion of scientific evidence by particle size (e.g., fine and coarse particles) (as stated in Section 1.4), since many PM components and sources are relevant to both PM size categories, creating possible redundancies, and since it is unclear how ultra-fine particles and PM10 will be considered in this framework.

Specific Comments

Page 11, Line 11: The word "peak" should be removed, as hourly non-peak exposures are also of concern.

Page 16, Line 9: The relationship between various health endpoints and different lag periods should also consider lag periods shorter than one day.

Page 21,22: Literature search is appropriate and makes a lot of sense. However, epidemiologic literature searches should specifically consider panel studies that examine PM-mediated intermediate health outcomes, since these studies can complement findings from toxicological studies and can help elucidate important PM-relevant biological pathways. Similarly, cellular toxicological studies should be included in the toxicological literature search, although with less emphasis, as they may help to elucidate important biological pathways.

Page 22, Lines 9-13: Item 5 is not clearly stated, as "synergistic effects of PM with other pollutants" is a type of "effect modification (e.g., is the effect of PM on health endpoints modified by the presence of copollutants)"

Page 22, Line 15: Will emphasis be given to all studies (e.g., not just epidemiologic studies) conducted in the US?

Page 24: It would be helpful to remind readers in the opening paragraph of the "Content and Organization of the ISA" that as possible, the ISA will address questions about PM by size, composition, other characteristic, averaging period, etc., since answers to questions will vary by these factors.

Page 27, Line 15-16: The sentence "Short-term exposure studies (e.g., population-level studies using time-series analyses, field/panel studies) rely on temporal variation in exposure while long-term exposure studies (e.g., longitudinal cohort studies) rely on spatial variability of exposure." is not completely accurate, as an increasing number of exposure studies consider spatio-temporal variation. Perhaps the sentence should be revised by adding the word "primarily" or "historically".

Page 27, Line 18-20: Although ultra-fine particles are captured in the phrase "particle characteristics such as chemical composition, size, surface area, and source", the ISA should consider ultra-fine particles explicitly.

Page 27, Line 24-25: The question regarding relationships between PM exposure and exposure to gaseous co-pollutants should be restated to also ask about the relation between exposures to specific PM size fractions and components and corresponding exposures to gaseous co-pollutants.

Page 26-27: A question regarding identification of "vulnerable" individuals should be included.

Page 31, Health Effects Section: The health effect section should also consider questions regarding relevant short-term exposure time periods, specifically examining hourly and daily exposure windows.

Page 30, Uncertainties Subsection: Uncertainty section should discuss consistency of findings among and between epidemiological and toxicological studies regarding observed effects and biological pathways.

Appendix B: The proposed outline should include a separate discussion of biological plausibility, independent of the susceptibility discussion in section 4.

Dr. Sverre Vedal

Comments on EPA draft Integrated Review Plan for the PM NAAQS
November 30, 2007
Sverre Vedal

Chapter 3.
1. My only suggestion for this chapter is to include among the policy relevant questions (pp.15-16) the issue of PM exposure of the susceptible subpopulations, especially the ill elderly. This point is included later in chapters 4 and 5.

Chapter 5.
1. There were no surprises in this draft plan, indicating to me that an incremental approach is proposed that builds on previous efforts. This is reasonable. Additions include: (1) the proposal to use the APEX model in the exposure assessment, as was done for the ozone review; and, (2) the possible use of expert elicitation with a view to being able to carry out a more formal quantitative risk assessment.

2. Regarding APEX, I unfortunately don't remember well how much of an impact that use of the APEX model had on the deliberations in the case of ozone. It's possible that it was central to the various scenarios that made up the risk assessment. Although there have undoubtedly been advances made in modeling personal PM exposures, I suspect the challenges in applying an exposure model like APEX to PM are going to be even greater than they were in the case of ozone. Nevertheless, I think it's worth pursuing here. It would be valuable to compare estimated risks when exposure is based on a personal exposure model vs. the city-wide exposure approach used for the last PM review. An attempt at validating the model estimates would also be valuable, but that may already be a given.

3. Regarding the possible use of expert elicitation, I applaud the attempt to move toward a more formal quantitative risk assessment. It is clear that the parameters for several of the uncertainty inputs to a formal quantitative risk assessment will be difficult to estimate. The expert elicitation, to my mind, is a way of integrating all of this otherwise unquantifiable uncertainty in order to allow it to be better incorporated into the risk assessment. Having said that, I have reservations about expert elicitation, more relating to the actual implementation than the concept. Most obvious is that results are critically dependent on the makeup of the expert panel, but there are others as well. If the expert elicitation is badly done, it could be more harmful than beneficial, and so will obviously need to be done with great care.

4. An issue that has interested me for some time is the translation of effect estimates (i.e., coefficients) from time series (short-term exposure) studies into impacts in specific cities, as is planned here, and as has been done many times before. My point may be trivial, or not. It is often stated, as it is in this draft (p.45, 1st para), that effect estimates relate a change in PM concentration to a change in the endpoint. In fact, they estimate the effect of a difference in PM concentration relative to another concentration. Coefficients from time series models are generated by assessing the relationship of a concentration at one point in time (averaged in various ways) to a corresponding count of events at a point in time. It is not relevant when the

pairings of PM and endpoint occur relative to other pairings, i.e., the pairs are "exchangeable," in statistical parlance. The concept of change does not rear its head. One could instead model changes in both the concentrations and endpoint, but this is not done; this might be considered a future research need. At issue here is whether cities that exhibit more day to day change in concentrations would be expected to experience more PM-related effects than cities with very little change. To put a finer point on it, the approach used by EPA (and everyone else) assumes that a city with very high concentrations that change little from day to day will experience a much larger health impact from short-term PM exposures than a city with substantially lower concentrations, but that change markedly from day to day. Now, it may be that it doesn't matter, because if change is important, adverse effects of increases from day to day might be offset by beneficial effects of decreases. It is possible that data from multi-city studies such as NMMAPS, or others that have more complete daily data, could be used to shed light on the matter. Regardless, because of its implications for estimating impacts, which is central to the planned risk assessment, it would be nice if we could put this issue to rest. Specifically, is it a non-issue because time-series studies don't in fact estimate effects of change, and it's therefore just a matter of being more precise in our terminology, or is it an issue?

5. Small point: I was unclear about the statement, "...if evidence indicates that such an analysis would prove to be useful" in reference to performing exposure assessments in locations where epidemiological studies have been performed (p.40). What evidence would be used to determine this? Related to this is whether it is intended to use effect estimates (concentration-response functions) from individual studies in the specific cities, or whether effect estimates from multi-city studies will be used instead? Sensitivity analyses that allow both approaches to be compared would be the most informative.

NOTICE

This letter has been written as part of the activities of the U.S. Environmental Protection Agency's (EPA) Clean Air Scientific Advisory Committee (CASAC), a Federal advisory committee administratively located under the EPA Science Advisory Board (SAB) Staff Office that is chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. The CASAC is structured to provide balanced, expert assessment of scientific matters related to issue and problems facing the Agency. This letter has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. CASAC letter and reports are posted on the SAB Web site at: http://www.epa.gov/sab.