UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

September 15, 2005

EPA-SAB-CASAC-05-012

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) Review of the EPA Staff Recommendations Concerning a Potential Thoracic Coarse PM Standard in the *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information* (Final PM OAQPS Staff Paper, EPA-452/R-05-005, June 2005)

Dear Administrator Johnson:

EPA's Clean Air Scientific Advisory Committee (CASAC or "Committee"), supplemented by subject-matter-expert Panelists — collectively referred to as the CASAC Particulate Matter (PM) Review Panel ("Panel") — held a public teleconference on August 11, 2005 to review the EPA staff recommendations concerning a potential thoracic coarse PM standard in the *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information* (Final PM OAQPS Staff Paper, EPA-452/R-05-005, June 2005).

The CASAC PM Review Panel agrees that this report adequately represents their views. The chartered CASAC — whose seven members are also members of the Panel — fully endorses the Panel's report and hereby forwards it to you as the Committee's consensus report on this subject. The current Clean Air Scientific Advisory Committee roster is found in Appendix A of this report, and the CASAC PM Review Panel roster is attached as Appendix B. Discussion questions for the Panel provided by the CASAC are contained in Appendix C to this report, and Panelists' individual review comments are provided in Appendix D.

This meeting was a continuation of the CASAC PM Review Panel's peer review of the Agency's *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information* (Second Draft PM Staff Paper, January 2005) and a related draft technical report, *Particulate Matter Health Risk Assessment for Selected Urban Areas: Second Draft Report* (Second Draft PM Risk Assessment, January 2005).

The Panel met in a public meeting held on April 6-7, 2005 in Durham, NC to conduct a peer review of these documents. This was followed by a public teleconference held on May 18, 2005 to review and approve the Panel's report from its April meeting. The Panel's letter/report to you from this April 2005 meeting, dated June 6, 2005, is found at the following URL: http://www.epa.gov/sab/pdf/casac-05-007.pdf.

In its review of the EPA staff recommendations concerning a potential thoracic coarse PM national ambient air quality standard (NAAQS), there was general concurrence among Panel members that there was a need for a specific primary standard to address particles in the size range of 2.5 to 10 microns, as EPA staff recommended in the Final PM Staff Paper. The Committee agrees with the summary of the scientific data regarding the potential adverse health effects from exposures to thoracic coarse particles in Section 5.4 of the Staff Paper. The Committee is also in general agreement with EPA staff observations that coarse particles in urban or industrial areas are likely to be enriched by anthropogenic pollutants that tend to be inherently more toxic than the windblown crustal material which typically dominates coarse particle mass in arid rural areas. Most but not all Panel members were supportive of the EPA staff recommendation to specify an urban coarse particle indicator of $UPM_{10-2.5}$. Some members recommended specifying a national $PM_{10-2.5}$ standard accompanied by monitoring and exceptional-events guidance that emphasized urban influences.

The CASAC notes that it is important to recognize that the urban coarse particle indicator for the standard represents a surrogate for the components of the urban coarse PM that differ in composition from coarse-mode particles of natural origin. Sufficient data are lacking at the present time to set standards based specifically on composition. Therefore, there is a need for substantial future research on the health effects of coarse-mode particles, and CASAC recommends that monitoring of both rural areas as well as urban areas be done for total $PM_{10-2.5}$ levels, distribution and composition. Moreover, the collection of coarse PM data in selected locations for compliance-monitoring purposes should be coordinated with epidemiological and toxicological research efforts as soon as this monitoring capability is in place. It is recognized that, as more information on the toxicity of rural dusts is acquired, the name and/or geographical focus of a coarse-particle indicator may need to be reconsidered.

The Committee also supports the use of a 24-hour averaging time and agrees that an annual averaging time for $PM_{10-2.5}$ is not currently warranted. Furthermore, the CASAC strongly recommends use of the 98th percentile, which is more statistically-robust than the 99^{th} percentile, together with the use of a three-year average of this statistic. In addition, there was general agreement among Panel members that Agency staff had presented a reasonable justification for the ranges proposed, with most members favoring levels at the upper end of the range for the 98^{th} percentile form. Overall, therefore, the Committee finds that the Agency has been responsive to the previous advice and recommendations of the CASAC. By use of the indicator $UPM_{10-2.5}$, the Agency is taking a next step toward including composition as well as size in its regulations of ambient air PM. The Committee sees this process as a progressive one and reiterates that, as our knowledge of the potential toxicity of rural $PM_{10-2.5}$ increases, the potential need for regulation of rural $PM_{10-2.5}$ particles may need to be reevaluated.

1. Background

The CASAC, comprised of seven members appointed by the EPA Administrator, was established under section 109(d)(2) of the Clean Air Act (CAA or "Act") (42 U.S.C. § 7409) as an independent scientific advisory committee, in part to provide advice, information and recommendations on the scientific and technical aspects of issues related to air quality criteria and NAAQS under sections 108 and 109 of the Act. Section 109(d)(1) of the CAA requires that EPA carry out a periodic review and revision, where appropriate, of the air quality criteria and the NAAQS for "criteria" air pollutants such as PM. The CASAC, which is administratively located under EPA's Science Advisory Board (SAB) Staff Office, is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. The CASAC PM Review Panel is comprised of the seven members of the chartered (statutory) Clean Air Scientific Advisory Committee, supplemented by fifteen technical experts.

Under section 108 of the CAA, the Agency is required to establish NAAQS for each pollutant for which EPA has issued criteria, including PM. Section 109(d) of the Act subsequently requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health and welfare. EPA is also to revise the NAAQS, if appropriate, based on the revised criteria. The purpose of the PM Staff Paper is to evaluate the policy implications of the key scientific and technical information contained in a related document, EPA's revised Air Quality Criteria [Document] (AQCD) for Particulate Matter (EPA/600/P-99/002aF & -bF, October 2004) and to identify critical elements that EPA believes should be considered in the review of the PM NAAQS. The Staff Paper for PM is intended to "bridge the gap" between the scientific review contained in the PM AQCD and the public health and welfare policy judgments required of the Administrator in reviewing the PM NAAQS.

In the letter/report to the EPA Administrator from its April 6-7 meeting, the Panel informed you that:

> "… after the Panel has reviewed the Final Staff Paper and Risk Assessment for Particulate Matter following its issuance on June 30, 2005, the Panel will meet again this summer via a public teleconference to consider the final Staff Paper's recommendations concerning the setting of a coarse PM standard. Subsequent to the Panel's teleconference meeting, we will send you a separate letter providing the Panel's recommendations concerning $PM_{10-2.5}$ as an indicator together with our views on the averaging time, statistical form, and level of any potential daily $PM_{10-2.5}$ standard."

Section 5.4 of the Final PM staff Paper, which discusses the Thoracic Coarse Particle Standard, is found on pages 5-47 through 5-71 of the document. This section was the focal point of the Panel's teleconference meeting.

2. CASAC Review of the EPA Staff Recommendations Concerning a Potential Thoracic Coarse PM Standard in the Final PM OAQPS Staff Paper

a. Indicator for a Thoracic Coarse Particle Standard

There was general concurrence among the members of the Panel that there was a need for a specific primary standard to address particles in the size range of 2.5 to 10 microns, as the Agency staff recommended in the Final PM Staff Paper. The Committee agrees with the summary of the scientific data regarding the potential adverse health effects from exposures to thoracic coarse particles in Section 5.4 of the Staff Paper. The body of evidence on health effects associated with exposure to thoracic coarse particles that is relevant to $PM_{10-2.5}$ is limited. However, several U.S. and Canadian studies do provide convincing data that there is an association between short-term exposure to $PM_{10-2.5}$ and various morbidity endpoints. Associations with mortality endpoints were suggestive but not as convincing as were the morbidity endpoints. These data showing adverse health effects associated with exposure to $PM_{10-2.5}$ primarily come from studies of urban environments. Little is known about the potential toxicity of rural dusts, although the 2000 and 2003 Coachella Valley, CA studies from Ostro *et al.* showed significant adverse health effects, primarily involving exposures to coarse-mode particles arising from crustal sources. $PM_{10-2.5}$ concentrations in urban and industrial areas may be commonly enriched by a number of contaminants not commonly found in crustal material.

CASAC generally agrees with EPA staff conclusions that thoracic coarse particles in urban areas can be expected to differ in composition from those in rural areas and that evidence of associations with health effects related to urban coarse-mode particles would not necessarily apply to non-urban or rural coarse particles (although it is likely that there will be some overlap of the same contaminants in both areas.) Most Panel members concurred that the current scarcity of information on the toxicity of rural dusts makes it necessary for the Agency to base its regulations on the known toxicity of urban-derived coarse particles, and that an urban coarse particle indicator should be specified as $UPM_{10-2.5}$. Other Panel members recommended specifying a national $PM_{10-2.5}$ standard accompanied by monitoring and exceptional-events guidance that emphasized urban influences. Some members also expressed concerns whether EPA would be able to specify a clear definition of "urban" to effectively determine in advance the specific conditions in which the standard would (and would not) apply. It is recognized that, as more information on the toxicity of rural dusts is acquired, the name and/or geographical focus of a coarse-particle indicator may need to be reconsidered.

In establishing the parameters for the thoracic coarse particle monitoring network, the Agency should consider the estimated risk reduction in health outcomes (or, alternately stated, the potential national benefits of reducing the public health risks) associated with a reduction in thoracic coarse particles in areas with smaller populations as well as those with large populations. There is a paucity of data currently available on health outcomes related to thoracic coarse particles in rural areas and limited information on the composition and toxicity of rural area coarse particles. This underscores the need for monitoring thoracic coarse particle levels and for population-based health-effects studies in those rural areas where it is feasible to conduct such studies.

It is important to recognize that the use of an urban coarse particle standard with $UPM_{10-2.5}$ mass as an indicator is intended to provide protection against those components of $PM_{10-2.5}$ that arise from anthropogenic activities occurring in or near urban and industrial areas. Sufficient data are lacking at the present time to set standards based specifically on composition and, thus, there is a need for substantial future research on the health effects of coarse-mode particles. Data on both urban and rural exposures to coarse-mode particles as defined by $PM_{10-2.5}$ mass are needed, and there is a need for more data that relate the composition of the particulate matter to adverse health effects. We anticipate that future coarse- and fine-mode particulate standards will give greater weight to particulate composition as a critical element in defining the risk of adverse health effects. Data are needed on ambient concentrations in each size range in terms of mass concentrations and speciation. Continuous monitors for mass, as well as for key components or source-related tracers, will provide the best and most cost-effective means of collecting such data for both epidemiologic research and compliance monitoring. Moreover, the collection of coarse PM data in selected locations for compliance-monitoring purposes should be coordinated with epidemiological and toxicological research efforts as soon as this monitoring capability is in place.

CASAC recommends that monitoring of both rural and urban areas be done for total particulate levels, size distribution and composition. It is essential to have data collected on a wide range of both urban and rural areas in order to determine whether or not the proposed $UPM_{10-2.5}$ standard should be modified at the time of future reviews. Finally, some members of the Panel recommended that a secondary $PM_{10-2.5}$ standard be set at the same level as used for the (primary) $UPM_{10-2.5}$ standard. The geographical applicability of this secondary standard should not necessarily be constrained only to urban areas, as the irritant, nuisance soiling, materials damage and ecological effects of coarse particles are not uniquely related to urban contaminants.

b. Averaging Time and Statistical Form for a Thoracic Coarse Particle Standard

The limited results available from epidemiological studies suggest short-term morbidity effects (*e.g.*, respiratory- and cardiac-related hospital admissions, respiratory symptoms in children) are associated with $PM_{10-2.5}$ and that this indicator variable may indeed be causative, at least for those urban areas in which these studies were conducted. The evidence for short-term mortality effects from exposure to coarse particles is less convincing, and the epidemiological studies do not (except in a very few studies) suggest any clear associations with long-term, chronic exposures. The bases for EPA's proposed retention of a 24-hour averaging time and high-percentile (98^{th} or 99^{th}) statistical form, and the elimination of the annual averaging time for coarse particles, are well described in Chapter 5 of the Final PM Staff Paper. The CASAC finds this discussion both to be balanced and to reflect adequately the options that are reasonable for the EPA Administrator to consider for the averaging time and statistical form of a short-term $PM_{10-2.5}$ standard. Specifically, the Committee supports the use of a 24-hour averaging time and agrees that an annual averaging time for $PM_{10-2.5}$ is not currently warranted.

The CASAC also strongly recommends use of the 98th percentile, which is more statistically-robust than the 99^{th} percentile, together with the use of a three-year average of this statistic. This use of this statistic will tend to minimize measurement error and spatial variability, which are larger for coarse-mode particles than for fine PM. It would also tend to minimize the influence in arid areas of occasional but extreme excursion contributions from rural, coarse-

mode dust sources that are thought to be inherently less toxic than coarse-mode particles heavily enriched with urban source contaminants

To a certain degree, however, the conclusions reached by EPA staff regarding the lack of a basis for an annual averaging time reflect more an absence of evidence than they do any evidence of absence of effects from long-term exposures. In a similar way, the evidence suggesting that all types of "non-urban" coarse particles are relatively benign is also quite limited. The only way that these issues will be resolved is if additional epidemiological studies are conducted in both urban and rural areas that examine whether there are morbidity and/or mortality effects from short-term and long-term exposure to coarse-mode particulate matter. For these and other PM NAAQS studies, a rich database will be needed on ambient concentrations in each size range in terms of mass concentrations and composition.

c. Level for a Thoracic Coarse Particle Standard

There was general agreement among Panel members that Agency staff had presented a reasonable justification for the ranges of levels proposed. In contrast, there was one member who thought the lower bounds as proposed would leave a substantial portion of the population (particularly in the Northeast) at continued significant risk, and several members who supported the lower ends of the proposed ranges. However, because of the significant uncertainties resulting from the limited number of studies to date, in which $PM_{10-2.5}$ has been measured, and potentially large exposure measurement errors in the available coarse-particle databases, a more stringent lower bound was not generally supported.

Overall, the Panel found that the Agency has been responsive to the previous advice and recommendations of the CASAC. By use of the indicator $UPM_{10-2.5}$, the Agency is taking a next step toward including composition as well as size in its regulations of ambient air PM. The Committee sees this process as a progressive one and reiterates that, as our knowledge of the potential toxicity of rural $PM_{10-2.5}$ particles increases, the need for primary health standards for rural $PM_{10-2.5}$ particles may need to be reevaluated.

The Clean Air Scientific Advisory Committee and the CASAC Particulate Matter Review Panel have been pleased to advise the Agency in this extremely important and difficult task of setting appropriate standards for airborne coarse particles. As always, we wish EPA well as the Agency continues this process.

Sincerely,

/Signed/

Dr. Rogene Henderson, Chair
Clean Air Scientific Advisory Committee

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, North Carolina State University, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

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

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

Dr. Frederick J. Miller, Consultant, Cary, NC

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

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

Dr. Barbara Zielinska, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

SCIENCE ADVISORY BOARD STAFF

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* Immediate past CASAC Chair

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*

CHAIR

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

MEMBERS

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

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

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

Dr. Jane Q. Koenig, Professor, Department of Environmental Health, School of Public Health and Community Medicine, University of Washington, Seattle, WA

Dr. Petros Koutrakis, Professor of Environmental Science, Environmental Health , School of Public Health, Harvard University (HSPH), Boston, MA

Dr. Allan Legge, President, Biosphere Solutions, Calgary, Alberta

Dr. Paul J. Lioy, Associate Director and Professor, Environmental and Occupational Health Sciences Institute, UMDNJ - Robert Wood Johnson Medical School, NJ

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

Dr. Joe Mauderly, Vice President, Senior Scientist, and Director, National Environmental Respiratory Center, Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. Roger O. McClellan, Consultant, Albuquerque, NM

Dr. Frederick J. Miller*, Consultant, Cary, NC

Dr. Gunter Oberdorster, Professor of Toxicology, Department of Environmental Medicine, School of Medicine and Dentistry, University of Rochester, Rochester, NY

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

Dr. Robert D. Rowe, President, Stratus Consulting, Inc., Boulder, CO

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

Dr. Frank Speizer*, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

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

Mr. Ronald White, Research Scientist, Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

Dr. Warren H. White, Visiting Professor, Crocker Nuclear Laboratory, University of California - Davis, Davis, CA

Dr. George T. Wolff, Principal Scientist, General Motors Corporation, Detroit, MI

Dr. Barbara Zielinska*, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

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* Members of the statutory Clean Air Scientific Advisory Committee (CASAC) appointed by the EPA Administrator

**Immediate past CASAC Chair

Appendix C – Discussion Questions for the CASAC PM Review Panel

With specific consideration of the aforementioned section in EPA's Final PM Staff Paper dealing with the thoracic coarse particulate matter standard, the Panel will focus its review on the following discussion questions:

Overall, has the Agency been responsive to the previous advice and recommendations of the CASAC; and, specifically, does the CASAC PM Review Panel have any additional recommendations on the conclusions of the Final PM Staff Paper with respect to:

b. Replacing the current primary PM_{10} standards with an *indicator* of urban thoracic coarse particles (*i.e.*, $UPM_{10\text{-}2.5)}$?

Lead Discussants: James Crapo, Phil Hopke

c. Retaining a *24-hour averaging time* for a $UPM_{10\text{-}2.5}$ standard to protect against health effects associated with short-term exposure periods, with consideration given to the use of either a 98th or 99th percentile *statistical form*; and, furthermore, to Staff's choosing not to retain an annual averaging time for protection against such health effects?

Lead Discussants: Fred Miller, Rich Poirot

d. Setting a 24-hour $UPM_{10\text{-}2.5}$ standard with a *level* in the range of approximately 50 to 70 $\mu g/m^3$, 98th percentile form, or approximately 60 to 85 $\mu g/m^3$, 99th percentile form?

Lead Discussants: Frank Speizer, Barb Zielinska

Appendix D – Review Comments from Individual CASAC PM Review Panelists

This appendix contains the preliminary and/or final written review comments of the individual members of the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel who submitted such comments electronically. The comments are included here to provide both a full perspective and a range of individual views expressed by Panel members during the review 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. The views of the CASAC PM Review Panel and the CASAC as a whole are contained in the text of the report to which this appendix is attached. Panelists providing review comments are listed on the next page, and their individual comments follow.

Panelist **Page #**

Dr. James D. Crapo

The revisions of Chapter 5 in the staff paper are excellent and appropriately summarize the state of current knowledge underlying the staff recommendations. I concur with the fundamental recommendations in section 5.4. The discussion of issues arising from the staff paper by CASAC members and the available public comments highlight a number of critical areas that require discussion at the teleconference on 8/11/05.

The critical issue that underlies the conflicts of opinion regarding the staff recommendations is that, while there is a growing body of evidence suggesting that there are health effects associated with coarse thoracic particles, this body of evidence is still highly limited. In addition, the composition of coarse mode particles varies dramatically among regions with most of the data suggesting adverse health effects being associated with studies of urban population centers. The composition of coarse mode particles appears to be critical to the findings of adverse health risks and there is not sufficient data to consider regulation of coarse mode particles based on composition. The recommended indicator would be based primarily on particle size and dose.

Issues that need to be resolved in the CASAC discussion include:

- The impact of the precedent being set by creating an urban standard rather than a global standard.
- How urban will be defined. The definition using a metropolitan statistical area (MSA) as described by Dr. Hopke is an appropriate starting point but leaves open appropriate questions regarding possible impacts of this standard on areas either not included or not monitored under the standard.
- The need for and the strategy for future research on adverse health effects of coarse mode particles including exposures in widely different rural areas.
- The monitoring plan — the current plan suggests monitoring focused on urban areas. If monitoring is not done in rural zones and if monitoring does not include assessment of particle composition, it will significantly hamper future research on possible adverse effects in those regions not monitored.

Dr. Philip Hopke

I think the revised section 5.4 is generally very good, but I have not seen a clear definition of "urban" in the document. Is an "urban" area any part of a metropolitan statistical area or an area with a population density greater than some specified value? The definition of an MSA from the Census Bureau web site is:

> **Metropolitan statistical area (MSA)**
> A geographic entity defined by the federal Office of Management and Budget for use by federal statistical agencies, based on the concept of a core area with a large population nucleus, plus adjacent communities having a high degree of economic and social integration with that core. Qualification of an MSA requires the presence of a city with 50,000 or more inhabitants, or the presence of an Urbanized Area (UA) and a total population of at least 100,000 (75,000 in New England). The county or counties containing the largest city and surrounding densely settled territory are central counties of the MSA. Additional outlying counties qualify to be included in the MSA by meeting certain other criteria of metropolitan character, such as a specified minimum population density or percentage of the population that is urban. MSAs in New England are defined in terms of minor civil divisions, following rules concerning commuting and population density.

This definition impresses me as a good potential starting point for defining "urban."

It can then be contrasted with "rural" as being outside an MSA. However, it is probably best to reduce or eliminate suburban as that seems to me to confuse the issue. Since we believe traffic provides significant input to the urban coarse particles that lead to adverse health effects and suburban areas typically have significant traffic, they should be included in "urban" areas when in an MSA.

There is some discussion of this issue when discussing a monitoring strategy, but I think explicit definitions of "urban" and "rural" are important to provide clarity in the development of the indicator for the standard.

Dr. Jane Q. Koenig

Staff paper and closure letter
July 2005
Koenig

I reread the section on coarse particles. Generally it is well written. It certainly could be reduced in length.

I only have a few points.

P 47. Why spend so much time describing what we didn't know in 1997?

P 58. I have a really negative reaction to the use of UPM10. Are we going to start using UPM2.5, UCO, etc, etc. Of course it is urban air pollution we are discussing. We do not monitor in rural areas so how would we know the characteristics and concentrations of rural PM.

5-67. I don't think we should emphasize the fact that studies find effects where PM is violated. We don't know that the health associations seen are only on days exceeding the std. For example, in Phoenix, although PM10 exceeded the std in 1996, and 1997 it did not in 1995. And PMcf peaks were lower than PM10. In Seattle in 1989, the range of PM10 was 6-103; however the highest quartile average was 55. I don't know what information we get from using maximum values.

5-70. Since the staff bring up the concept of "an adequate margin of safety," I would like to know where it is!!

5-72. Again the conc-response curve is listed as an uncertainty. Which CR curve. For CD and PM2.5, for asthma ED visits and PM2.5; for hospital admits for CD, or for respiratory disease. There is not one fixed CR curve. It appears that falling back on it is an excuse for not moving forward.

In response to Rogene's letter:

a. As mentioned, I think the concept of urban thoracic coarse particles just confuses the issue.

b. I assume the state of the art monitoring devices will drive the averaging time. If the monitor is gravimetric we have to use a 24 hour mean. Is a continuous 10-2.5 monitor on the horizon? If so I would be in favor of deploying it.

c. I don't see the wisdom of just keeping the PM10 std (essentially). I would like to see a standard that would be about equivalent to the PM2.5 std. If in fact PM10 is about 50 or 55% 2.5.

I am sorry I will not be able to hear the discussions. This is a crucial step in regulation of PM to protect the public health.

Dr. Allan Legge

Review Comments: August 9, 2005
"Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information" OAQPS Staff Paper June, 2005 EPA-452/R-05-005.

By: Allan H. Legge PhD.
Biosphere Solutions

Chapter 6.3 Effects on Vegetation and Ecosystems
Overall this section is an improvement over the earlier draft. The following are a few specific comments related to this section.

1. Page 6-32, bottom para, first line.
"Impacts on threatened and endangered species." should be in bold.

2. Page 6-37, top para, second line from bottom.
i) Should read "spruce (*Picea glauca*)" not " spruce (*Picea glacus*).
ii) Should read "eastern white pine (*Pinus strobus*)" not "eastern white pine (Pinus strobus)".

3. Page 6-45, second para, first sentence.
It is noted that "Data from these deposition networks demonstrate that N and S compounds are being deposited in amounts known to be sufficient to affect sensitive terrestrial and aquatic ecosystems over time." For clarity, it is suggested that the sentence be rewritten to read "Data from these deposition networks have demonstrated that N and S compounds are being deposited in sufficient amounts over time to affect sensitive terrestrial and aquatic ecosystems."

4.Pages 6-45 to 6-48, Section 6.3.9 Critical Loads
Overall this section is well done. That being said, there is confusion towards the end of this section on pages 6-47 and 6-48 regarding the very concept of a 'critical load' in the European sense. It is noted ,for example on the last two line of the top paragraph of page 6-48, that "Thus, it is not clear whether a CL could be developed just for a portion of the total N or S input that is contributed by PM." While this statement sounds reasonable, it is misleading. It is very important for Staff to keep in mind the definition of a 'critical load' (CL) as noted on page 6-45 , to understand how the 'critical load' concept has been developed and applied in Europe and to recognize that the philosophy behind 'critical loads' is very different from that behind criteria pollutants. While it may be possible to determine for some locations and receptors the amount of the total N and S load that is contributed by PM, it would be inappropriate to call that contribution a CL (critical load). An ecosystem responds to the total cumulative load and not just to parts of that load. Staff needs to make it very clear that the approach to environmental protection of vegetation and ecosystems needs to be re-evaluated because PM is only part of the issue.

5. Page 6-48 to 6-49, Section 6.3.7 Summary and Conclusions

The conclusions reached by Staff are based within the science as presented in the PMCD and the legislative requirements of the Clean Air Act regarding criteria pollutants. It is agreed "that there is insufficient information available to recommend for consideration an ecologically defined secondary standard that is specifically targeted for protection of vegetation and ecosystems against the adverse effects potentially associated with the levels of PM-related stressors of nitrate and sulfate found in the ambient air."

Dr. Paul J. Lioy

US EPA Final PM Staff Paper – June 2005: Comments on the Proposed Thoracic Particulate Matter Primary NAAQS -- July 25,2005

By: Paul J. Lioy, Ph.D.
Deputy Director of the
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Chapter 5: Staff Conclusions and Recommendations on the Primary PM NAAQS
Section 5.4 Thoracic Coarse Particle Standards

The need for a short term Thoracic Particle Standard was evaluated by CASAC over the past half year. It was clear to the members of CASAC that it would be appropriate to set such a standard; however, the initial presentations by EPA Staff on the type and form of a standard were not adequate, and confusing. The latter point was noted in my previous written comments. After reviewing section 5.4, and the recommendations in subsection 5.4.5 of the Final Staff Paper, I am pleased to see that EPA Staff understood the concerns expressed by CASAC in its June 6, 2005 letter to the Administrator about the type and form of a $PM_{10-2.5}$ NAAQS. At this time, I strongly endorse the setting of an Urban Particulate Matter Standard that is defined as **$UPM_{10-2.5}$**. It will address the health effects issues that have been presented for coarse particle exposure in urban environments. Further, areas where the coarse particles have not been seriously contaminated by urban toxicants will not be burdened with achieving compliance to a poorly characterized general coarse particle NAAQS.

More research needs to be done to improve our knowledge base on short term exposure and health effects associated with $UPM_{10-2.5}$, and I support the recommendations on Page 5-72. I will also add that we must obtain a clearer picture of intensity, frequency and duration of population exposures to $UPM_{10-2.5}$. This will help reduce uncertainties that exist about the use of a 24 hr average for the standard. At this time I do not think the data are strong enough to support a shorter duration standard. Thus, I support the use of the 24 hour averaging time. The $UPM_{10-2.5}$ is clearly an exposure based problem, as stated on page 5-65, which should encourage the US EPA to develop continuous monitors as one component of a $UPM_{10-2.5}$ monitoring network. The Agency should support and/or conduct research to establish the gradient of $UPM_{10-2.5}$ levels from the source to the human receptor (exposures), as well as the averaging times needed to examine health effects that may be caused by peak exposures. The analyses of such data will improve the development of exposure metrics for future epidemiological investigations and help define the time course of dose administration in toxicological investigations. Many of the details about these uncertainties have been stated on pages 5-72 to 5-74.

The range of levels selected for the 24 hour $UPM_{10-2.5}$, "approximately 60-70 ug/m3 with a 98^{th} %tile form" seem reasonable based upon the current level of health effects information on coarse particle exposures. I am also pleased with the agency's initial thoughts about the design of the monitoring network for the implementation of the $UPM_{10-2.5}$. These are clearly laid out on

pages 5.59-5.60: CBSA/CSA's with greater than 100,000 people, and a focus on the more highly densely populated areas in the urban area. Such an approach will eliminate small towns and vast rural areas from dealing with compliance issues. The design would be appropriate for the base monitoring network, and can be used to begin identifying situations, e.g. high density populations near a $UPM_{10-2.5}$ source area, where detailed $UPM_{10-2.5}$ chemical and morphological characterization, and continuous monitoring can be implemented to collect currently unavailable data. These results will significantly improve the scientific community's ability to address key uncertainties, and provide a basis for developing future epidemiological studies.

Dr. Morton Lippmann

Based on my earlier comments to the Panel members assigned to organize the responses to the three Section 5.4 issues, and the teleconference discussions on these and other issues, the following are my individual recommendations:

1) I endorse the Staff Paper recommendation that there should be a short-term (24 hr) NAAQS that applies to the PM10-2.5 that is found in urban U.S. settings, recognizing that UPM10-2.5 serves as a surrogate indicator for thoracic coarse particles that are contaminated by surface coatings of pollutants of anthropogenic origin.

2) It is important to recognize that UPM10-2.5 is the first PM NAAQS to be explicitly defined in terms of the role of component anthropogenic sources, and that future size-selective PM NAAQS (for fine, thoracic coarse, and possibly for ultrafine PM) will be needed for specific components and/or source categories in order to provide efficient means of public health protection.

3) A rich data resource will be needed for such future PM NAAQS. It will need to include: data on ambient concentrations in each size range in terms of mass concentrations and speciation. Continuous monitors for mass, and for key components or source-related tracers, will provide the best and most cost-effective means of collecting such data for both epidemiologic research and compliance monitoring.

4) The UPM10-2.5 short-term NAAQS should be based a 98th %ile form, and a UPM10-2.5 annual NAAQS is not needed.

5) I agree that the recommended levels for the 98th percentile form, i.e., in the range of approximately 50 to 70 ug/m3, does provide a comparable level of protection for the U.S. as a whole against the health effects associated with thoracic coarse particles that is now provided by the current 24 hour PM10 NAAQS. However, I do not believe that this concentration range provides an adequate degree of protection against the morbidity effects described in this Staff Paper. I consider these effects to be adverse in terms of public health, especially for the northeastern U.S. As noted on page 5-68, paragraph 1, lines 7 & 8, the average equivalency level to the current PM10 NAAQS in the northeastern U.S. is 40 ug/m3, and the NMMAPS study indicated that the daily mortality coefficient for the northeast was twice that for the U.S. as a whole. Also, please note that while the 98th% levels in the center of downtown Detroit were about twice as high as the 36 *u*g/m3 measured at the Windsor sites, they were not representative of those for the Detroit metropolitan population as a whole. Considering the available information, I recommend that, in order to be public health protective with a margin-of-safety, the upper bound, rather than the lower bound, for the range for the UPM10-2.5 NAAQS, be 50 ug/m3.

6) In my view, the Agency has been quite responsive to the previous advice and recommendations of the CASAC with regard to setting a 24-hour UPM10-2.5 standard. The revisions to Section 5.4 were very well developed and clearly presented.

Dr. Joe Mauderly

Comments on Section 5.4 of Chapter 5 of the OAQPS Final PM Staff Paper

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In general, these sections of the final PM Staff Paper represent a reasonable analysis of the situation regarding thoracic coarse PM, and a reasonable set of conclusions. Given current information, I agree with the establishment of a thoracic coarse standard, with $PM_{10-2.5}$ mass as the indicator, and with 24 hr as the averaging time. The ranges of proposed concentrations and statistical forms seem appropriate.

I am less enthusiastic about the proposed implementation strategy. The proposed limitation of monitoring (and thus the practical application of the standard) to population statistical areas of 100,000 or greater appears arbitrary and is not defended well. Although the rationale for focusing on "urban" PM is presented, no clear justification is given for this cut-off population size. It is stated on page 5-59 that this focus would result in a monitoring network of approximately 350 areas, but that is a fact - not a justification. From that point in the text, it appears assumed that the 100,000-person area cut-off has been selected. Without debating the meaning of the terms "urban" and "rural" (which the chapter does not attempt to define, but certainly employs heavily), it must be admitted that persons in cities and towns having populations less than 100,000 are exposed to the same types of thoracic coarse PM of concern in larger urban areas (i.e., road dusts and certain industrial-contaminated non-road dusts). The fact that the epidemiological data are derived from large population centers does not mean that people in smaller cities are not exposed to the same PM or that they do not bear the same risk.

Just as PM size is being employed in the regulatory strategy as a surrogate for composition (and thus source), population size is, in effect, being proposed as a surrogate for dividing between exposures to different classes of coarse thoracic PM (i.e., composition and source). However, the latter surrogate division almost certainly distinguishes less well than the former.

I agree that current information supports protection from paved road dust and coarse particles from non-agricultural sources much more clearly than it supports protection from less-contaminated soil and agricultural dusts. Keeping in mind that we make this judgment based on only indirect evidence (we have virtually no information on the toxicity of most "rural dusts"), such a distinction seems appropriate at this time. The problem is that limiting the application of the standard to population units of 100,000 or greater excludes protection of many people from "urban" types of PM. There may be no other practical solution at this time for distinguishing between "urban" and "rural" dusts, and protecting the majority of the population is better than protecting none. However, the Staff Paper does not make clear that any other potential solutions were considered.

The issue of monitoring strategy is critical. As the Staff Paper notes, exposures to thoracic coarse PM are more likely to vary by time and location than exposures to fine PM. This begs the question of monitor location, as Staff notes, but it also begs the question of whether monitoring (and thus regulatory) strategies should be driven more by the location of greatest population exposure rather than the location of greatest population residence. The Staff Paper touches on this issue, but perhaps more thought should be given as to how this might be extended to better address the issue of "urban" vs. "rural" PM. Perhaps monitors could be strategically located in smaller cities and towns to target the dusts of greatest concern. In that sense, monitor location, rather than population size, would become a surrogate distinction between "urban" and "rural" PM.

Overall, it seems that more energy might be directed toward conceiving and weighing alternative approaches to identifying and limiting exposures to the coarse PM of greatest concern, and to laying out a strategy to improve the information base. The current proposal is a temporary patch.

Dr. Roger O. McClellan

Review Comments

on

"Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS, June 30, 2005"

by

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August 29, 2005

A. Summary

Consistent with the agreement reached between EPA and CASAC, I have reviewed Section 5.4 of the final PM Staff Paper. In my opinion, this final section on the setting of a coarse particle standard is well written and easy to read. It provides a well-crafted argument for setting a $UPM_{10-2.5}$ National Ambient Air Quality Standard with a 24-hour averaging time. In my opinion, the evidence for $PM_{10-2.5}$ causing adverse health effects is sparse and highly uncertain. In my opinion, it is only when the evidence focuses on urban coarse particulate matter that a case can be made for coarse particle standard. I am not at all convinced by the PM_{10} equivalence argument. The limited scientific evidence available leads me to endorse the upper end of the range proposed by EPA, namely, 70 $\mu g/m^3$ with a 98^{th} percentile form.

I am disappointed that CASAC was forced to abandon the "closure letter" process. The current situation illustrates how adherence to a court-ordered deadline can result in a document being pre-maturely finalized with science taking a "back seat."

B. Background for Review

The CASAC Particulate Matter Panel previously reviewed two drafts of the Particulate Matter Staff Paper; the first was a cursory review of a very rough first draft and the second review was a more comprehensive review of EPA's penultimate draft.

As the formal CASAC PM Panel review meeting was convened, the EPA Science Advisory Board staff announced that a decision had been made that CASAC would no longer offer "closure letters" on either Criteria Documents or Staff Papers. This radical departure from the standard modus operandi for CASAC meant that the EPA Office of Air Quality Planning and Standards would take the advice offered by CASAC on the second draft Staff Paper and prepare the final Staff Paper. During the course of a teleconference meeting to finalize comments on the draft Staff Paper, substantial concern was raised about the portion of the Staff Paper dealing with recommendations for a primary (health-based) NAAQS with a $PM_{10-2.5}$ indicator. In response to this dissatisfaction, the EPA staff and CASAC agreed that CASAC would be allowed to offer comments on this section of the final Staff Paper, presumably with any advice being offered by CASAC to be considered in later steps of the rule making on the PM NAAQS. I do not recall any comments by EPA with regard to revising the final Staff Paper, the version issued on June 30, 2005. As a result, any comments offered now by CASAC are essentially a historical footnote likely to be overlooked by any except the most ardent student of the PM NAAQS setting process.

If CASAC had been operating as it had from its inception, instead of under the new rules, I strongly suspect CASAC would have not offered a "closure letter" on the second draft Staff Paper. Rather, I suspect that CASAC would have recommended another round of review, as has occurred. That would have resulted in a "closure letter" and EPA revision of the Staff Paper to reflect the advice provided by CASAC.

In developing my comments I am proceeding on the assumption that the Staff Paper has been finalized, i.e., the June 30, 2005 version. Hence, I see no value in my (or for that matter, anyone) providing detailed line by line comments on what has already been finalized. Alternatively, I will provide general comments and focus on the Staff Paper recommendations for the four elements of a NAAQS.

C. General Comments on Section 5.4. Thoracic Coarse Particle Standards

In general, this section is well written, easy to read and provides a well-crafted argument for setting a $PM_{10-2.5}$ NAAQS. The presentation is generally balanced although it leans toward that of the "one-handed scientist" Senator Edmund Muskie was seeking when the original Clean Air Act legislation was being debated. (He is reported to have said – "I wish we could hear testimony from a one-handed scientist, I am getting tired of hearing – on the one hand and then on the other hand!"). That is to say the EPA argument tends to be unidirectional on a narrow path presuming that a primary (health-based) $PM_{10-2.5}$ standard will be set.

I am pleased that the staff has appropriately elected to repeatedly use the word – "associated" in describing the relationship between increased levels of $PM_{10-2.5}$ and increases in morbidity and mortality rates above background. In my professional opinion, a causal relationship between $PM_{10-2.5}$ exposure and an increase in adverse health effects has not been demonstrated. I am also pleased that they repeatedly called attention to the paucity of the evidence and, frequently, contradictory nature of the evidence for an association between $PM_{10-2.5}$ and increased morbidity and mortality. The critical question that must be asked is whether these highly uncertain associations are sufficient evidence for adverse health effects to warrant the establishment of a coarse particle standard. As I indicated in my earlier review comments (5/20/05), on the second draft of the Staff Paper I do not feel the evidence is sufficient for setting a $PM_{10-2.5}$ NAAQS without further specification. The use of the indicator, $UPM_{10-2.5}$ or, alternatively, $PM_{U10-2.5}$, may provide a construct under which the uncertainty evidence for urban

coarse particles barely meets the requirements of the Clean Air Act for designation of a Criteria Pollutant Indicator. I suspect that ultimately the matter may be decided by the Courts.

I am disappointed that the EPA staff continues to use the argument that a $PM_{10-2.5}$ standard is needed to promote the continued monitoring of this size fraction. This "come along, go along" argument obviously appeals to all of us who are scientists and would like to see more monitoring data for use in epidemiological studies. EPA should be more forthright in acknowledging it has means other than NAAQSs to obtain monitoring data.

I was disappointed that the Staff Paper did not acknowledge, perhaps by a lengthy footnote or in a separate section, that the NAAQS were never intended to be the primary means by which the Federal Government regulated what is in the air. There are other means available such as the sections of the Clean Air Act dealing with hazardous and toxic air pollutants. Some EPA staff, some commenters and, indeed, some CASAC members seem to argue that if a chemical or agent can be described as existing in a particulate form (a solid or liquid mass suspended in air), then it is fair game to suggest that somehow the PM NAAQS should be set to protect against exposure to that kind of particulate matter. I think this is absurd. Yes, infectious agents as particles can be found in air. Yes, pesticides can be found in particles in the air. Yes, many individual elements, which in some valence states, as well as some organic chemicals, are found in the particle phase in the air and with sufficient exposure are known to cause disease. And, yes, there is even evidence of dung being resuspended in the air near high density livestock operations and most people find it repugnant to think about inhaling dung. However, none of this is evidence that the PM NAAQS should be set to protect against these materials. There are wide ranges of other means at the disposal of the EPA for dealing with these specialized cases.

D. Comments on the Proposed Coarse Fraction Standard

1. Indicator: I reluctantly concur with the Staff Paper recommendation for use of a $UPM_{10-2.5}$ indicator. It is only when the evidence focuses on high-level exposures in urban areas to $PM_{10-2.5}$ that the evidence is potentially sufficient for setting a $PM_{10-2.5}$ standard. I also understand the difficulty of conducting epidemiological studies that are not dominated by urban residents and, thus, epidemiological evidence will be dominated by urban studies.

2. Averaging Time: I concur with the Staff Paper recommendation for using a 24-hour averaging time and not setting an annual standard.

3. **Numerical Level and Statistical Form**: I only find the upper end of the range proposed by EPA acceptable based on the weak scientific evidence, i.e., 70 $\mu g/m^3$ with use of a 98^{th} percentile form. I agree that with the EPA's interpretation of the uncertainties in the database on $UPM_{10-2.5}$ and, thus, it is my opinion that a lower level cannot be scientifically justified.

E. Postlogue

As an alternative to a primary (health-based) standard for the $PM_{10-2.5}$ fraction, the EPA should explore the establishment of a welfare standard for $UPM_{10-2.5}$. Such a standard might be more readily justified and be easier to implement. It would also satisfy those individuals who feel a standard is needed to get $PM_{10-2.5}$ monitoring. I have always been convinced that EPA could find means other than setting a standard to get monitoring data. Setting a health-based NAAQS is a "heavy hammer" to use to get monitoring data. Why not set a $PM_{10-2.5}$ welfare standard and avoid the court challenge to setting a $UPM_{10-2.5}$ standard that some will argue does not protect public health in non-urban areas.

Dr. Frederick J. Miller

Comments on OAQPS Staff Paper, EPA-452/R-05-005, June 2005

As one associated with EPA's change from Total Suspended Particulate Matter to concern for inhalable particles and eventually to size-resolved Particulate Matter (PM) standards, I would rather see the Agency use the abbreviation for coarse mode particles of concern in urban environments of $PMU_{10-2.5}$ or perhaps $PM_{U10-2.5}$. This would keep the collection of particulate matter standards all with the same initial abbreviation of PM. Then the letter or number following PM would refer to the size cut or to the geographical area or whatever.

Indicator Variable

Section 5.4 covers all of the elements relevant for a Thoracic Coarse Particle Standard. OAQPS staff did a good job of revising the staff paper in a short time period while still covering the major issues. The argument for the indicator variable being based upon PM10-2.5 is strengthened compared to earlier drafts. Moreover, the reader no longer gets the feeling that staff are "begging the question" and referring to the evolution of PM standards as a basis for their selection of the indicator variable.

That being said, I still consider the shift to an urban based standard as problematic. As other PM Panel members have commented, the selection of population areas of 100,000 is an arbitrary definition of "urban". On page 5-59, I would like to know what percentage of the population is captured by the 350 areas that would be contained in the monitoring network. Given that there is little scientific health evidence for concern for the more crustal coarse mode particles present in Western areas of the United States where agricultural, ranching, and farming activities contribute significantly to PM10, I would think a better strategy for defining "urban" would be a "bottom up" analysis of population density in the west to arrive at a population density for the definition of "urban". Staff have appropriately recognized the difficulty of site selection for monitors that will be involved with any "urban coarse mode" standard. During the teleconference on August 11, 2005, Ms. Karen Martin of OAQPS provided clarification about the network and how the 100,000 population was used as an example of the approach rather than being indicative of a "fine line" for the monitoring network.

Averaging times and statistical form

The argument for a 24-hour averaging time for a $UPM_{10-2.5}$ standard is straightforward. Currently, there is a paucity of monitoring data using shorter averaging times let alone the collection of health effects data using shorter collection times for PM mass. Staff have accurately assessed that there is essentially little evidence contained in the PM Criteria Document that would currently support a concern for long-term exposures to thoracic coarse-mode particles.

Relative to the percentile of the distribution to use for the statistical form, I strongly favor the more robust 98^{th} percentile over that of the 99^{th} percentile. Given that establishing an urban coarse mode standard can be viewed as "somewhat of a stretch" given the small amount of underlying health effects data in comparison to that available for establishing a fine-mode standard, I would not like to see the more extreme values (as reflected in the 99^{th} percentile)

driving regulatory compliance. Moreover, the 99th percentile may well be capturing those events where "rural coarse mode materials" are contributing to urban measurements due to natural events.

Level of an urban coarse-mode standard

The author(s) of Section 5.4.4.1 on Evidence-based Considerations overuse the expression "closer examination of the air quality data/information" in discussing the health effect studies and associated air monitoring PM levels. One gets the impression that "those who went before' didn't do such a good job but now we have it right. Leaving such an impression was undoubtedly not the intent of the authors.

The discussion of studies in support of the range of levels that the EPA Administrator might consider for an urban coarse-mode standard is a very good one. Staff provide appropriate caveats as to how far one can use the existing studies to arrive at potential ranges depending upon the percentile of the distribution used for the statistical form of the standard. Among these caveats is that of the likely large exposure measurement error in $PM_{10-2.5}$ studies. Given all of the uncertainties surrounding establishment of a daily urban coarse-mode standard, I agree with the approach staff have taken of basically identifying a range of levels intended to afford protection generally equivalent to what has been afforded by the current PM_{10} daily standard. Significant extrapolation beyond these somewhat "equivalent ranges" is not warranted at this time.

Dr. Günter Oberdörster

G. Oberdörster
CASAC – teleconference, 8/11/05
8/5/05

Overall, the revised final PM Staff Paper reflects well the present state of knowledge and presents good discussions to arrive at recommendations of primary and secondary PM NAAQS. My comments focus on the coarse or thoracic standard:

The Staff Paper gives a reasonable justification for establishing an $UPM_{10-2.5}$ standard, stressing repeatedly the limited database, available evidence and uncertainties to support the 24 hour $UPM_{10-2.5}$ standard to be set between 50 and 85 $\mu g/m^3$ (depending on whether the 98^{th} or 99^{th} percentile is chosen). While restricting the standard to urban areas ("urban" still to be defined?) where most of the population lives makes sense, the additional rationale to exclude rural areas because of the lower toxicity of crustal dust needs to be viewed with some caution: although toxicological and epidemiological studies show acute effects of urban coarse PM to be mostly due to anthropogenic contaminants, there are no comparative studies with rural dust on which to base statements such as: "… it is not appropriate to conclude that evidence of associations with health effects related to urban coarse particles would also apply to non-urban or rural coarse particles" (p. 5-57). Yes, there are toxicity studies with Mt. St. Helens dust (and also with simulated moondust from old lava fields) that show very little toxicity. And the Spokane study evaluated acute effects (mortality in people) of exposures from dust storms at concentrations >200 $\mu g/m^3$ and found no increased mortality. But Mt. St. Helens dust is not a surrogate for rural dust, which may contain different silicates with greater toxicity and other crustal materials. For example, even if rural dust is not contaminated from mining activities or with biological (LPS, fungi, spores) materials, crystalline silica is one component that can be present, and we certainly cannot assume that all rural dust will behave like Mt. St. Helens dust. For crystalline silica the 8-hr. time weighted TLV is 50 $\mu g/m^3$, for a healthy adult worker in an occupational setting. This TLV on a 24 hour basis is much lower than the proposed $UPM_{10-2.5}$ which is supposed to protect the most sensitive part of the population. Of course, this TLV is to prevent long-term effects (fibrosis, cancer). The Spokane study with high dust storm concentration does not provide evidence of actual human exposures (indoors?); only acute effects were analyzed which should be emphasized in the Staff Paper (add the word "acute" to health effects in the concluding sentence of that study on p. 5-56), and contrasted with the potential for long-term effects of rural dust.

Again, overall the Staff's recommendation of setting a $UPM_{10-2.5}$ makes good sense. However, my point is that "ignoring" the rural dust when setting an $UPM_{10-2.5}$ should not be based on the assumed differential toxicities between the two, in the absence of comparative toxicity data and not knowing the chemical composition, *e.g.*, presence of active crystalline silica. (future research need). I see the main justification for the focus on $UPM_{10-2.5}$ in being able to cover the most densely populated areas, given the limited available resources and lack of data to cover the rest as well. Potential long-term effects of coarse PM should also be considered and mentioned as an area of further research need.

Mr. Rich Poirot

Comments on Chapter 5 of June, 2005 EPA PM Staff Paper, R. Poirot, August 4, 2005

"Issue b" from Chair Rogene Henderson's 7/21/05 memo on upcoming CASAC Particulate Matter Review Panel Teleconference was:

"Retaining a *24-hour averaging time* for a $UPM_{10-2.5}$ standard to protect against health effects associated with short-term exposure periods, with consideration given to the use of either a 98th or 99th percentile *statistical form*; and, furthermore, to Staff's choosing not to retain an annual averaging time for protection against such health effects?"

My comments on this question are included in combined comments from Fred Miller and me. Following are my individual comments on two other aspects of the proposed coarse particle standards in section 5.4 of EPA's June, 2005 PM Staff paper.

Replacing PM_{10} Standards?

Issue a: "Replacing the current primary PM_{10} standards with an *indicator* of urban thoracic coarse particles (*i.e.*, $UPM_{10-2.5}$)?"

I generally agree with the logic behind the proposed distinction between urban and rural coarse particles, and can't think of a better way than the proposed population/density approach to distinguish between coarse particles (predominantly composed of soil-derived mineral matter in most rural and urban areas, but) which tend to become "contaminated" or enriched with motor vehicle or industrial source-related pollutants in urban areas. Another argument for this distinction that might also be considered is that the coarse particle morphology is likely to be potentially more injurious for urban road dust particles, ground up & freshly fractured by urban traffic, than for the relatively rounded-edged particles of wind-blown desert sand. See for example the discussion on "old dust" vs. "new dust" in Winkenwerder (2002) at: http://www.gulflink.osd.mil/particulate_final/v and associated references.

However, it should also be recognized that the population/density approach for defining urban & rural coarse particles (and their inherent compositions & toxicities) is necessarily imprecise. There are high traffic, dusty areas and/or industrial sources in areas where populations do not exceed the "urban" definition. Nor do we really have very good indications of the compositions (including various complex biological materials) of different kinds of rural dusts - for example southwestern desert soils containing *Coccidioides sp* fungi, soils from cattle feed lots enriched with fecal matter, antibiotics, etc., soils from intensive farming areas enriched with various pesticides, herbicides & fungicides, or dust from the many various types of mining operations and associated processes (none of the which are likely to be well represented by toxicological evaluations of Mt. St. Helen's ash). It may also be noted from the Smith et al. (2000) evaluation of coarse particle mortality associations in Phoenix, that the authors identified separate crustal and metal-enriched coarse mass components using factor analysis, but noted strongest mortality

associations during the spring and summer months when the metal-enriched particle concentrations were lowest (and the crustal component was highest). I concur completely with Joe Mauderly's comments on this topic, and think that at a minimum there should be some fraction of future monitoring & research resources devoted to further characterization of coarse rural particles and their potential effects in different source regions.

Secondary $PM_{10-2.5}$?

On a related topic, its not entirely clear whether or not the proposal includes a secondary $PM_{10-2.5}$ standard set equal to the primary, and if so whether this would apply, like the primary standard, only in urban areas. I don't see a specific recommendation for a secondary coarse standard, but sections of the staff paper like the following seem suggest otherwise. For example:

7.4.4 (1) "Consideration should be given to setting secondary PM standards that at a minimum retain the level of protection afforded by the current PM standards, so as to continue control of ambient fine and coarse-fraction particles,…"

7.4.4 (2) "…for consistency with the primary standards, staff recommends that consideration be given to basing secondary standards on the same indicators that are used as the basis for the suite of primary PM standards."

7.4.4 (last paragraph) "…the available information does not provide a sufficient basis for the development of distinct national secondary standards to protect against such effects beyond the protection likely to be afforded by the suite of primary PM standards."

At least part of the justification for selecting a specific level for a short-term $UPM_{10-2.5}$ standard is the 2-part argument that: there is no indication that the current PM_{10} primary (& secondary) standard is overly stringent (or lenient), and a 98_{th} %tile $PM_{10-2.5}$ of about 65-70 ug/m3 is approximately equivalent to the current short-term PM_{10} standard. So is there now new evidence indicating the PM_{10} secondary standard was overly protective, or that the effects on ecosystems & materials occur only in large cities?

If there is no secondary standard, or if it applies only in "urban" areas, it should be clearly recognized that for non-"urban" areas, this represents a substantial relaxation (elimination) of any protection afforded by current PM_{10} (primary = secondary) standards. Many successful stack and process emissions control and/or dust suppression actions and procedures have been undertaken for coarse PM-emitting sources in non-urban areas, motivated at least in part by exceedances of national PM_{10} standards. Roughly half the states have legislation that essentially prohibits establishment of air quality standards that are more stringent than federal standards. No federal standards, no state standards, no incentive for controls of any coarse emissions in rural areas…

A possible option would be to set a primary $PM_{10-2.5}$ standard, with a secondary standard set equal to it, and have the primary standard apply only in large urban areas, while the secondary standard would apply everywhere. The "no required attainment date" for secondary standards

would provide the flexibility to exempt certain activities emitting "benign" coarse particles, but would not allow "backsliding" on coarse particle controls already in place on non-urban sources. This might also encourage, or at least allow for, some $PM_{10-2.5}$ monitoring in non-large-urban locations, without incurring the risk of recording exceedances of primary standards, and would soften the sharp but arbitrary distinction between CBSAs with populations falling just above or below the 100,000 cutoff.

Comments addressing discussion question b contained in Dr. Rogene Henderson's 7/21/05 memo on upcoming CASAC PM Panel Teleconference on 8/11/05
Rich Poirot and Fred Miller

> Retaining a *24-hour averaging time* for a UPM10-2.5 standard to protect against health effects associated with short-term exposure periods, with consideration given to the use of either a 98th or 99th percentile *statistical form*; and, furthermore, to Staff's choosing not to retain an annual averaging time for protection against such health effects?

The limited epidemiological evidence seems to suggest short-term morbidity and to a lesser extent mortality effects from coarse particles, but does not (except in a very few studies) suggest any clear associations with long-term, chronic exposures. The bases for EPA's proposed retention of a 24-hour averaging time and high percentile (98^{th} or 99^{th}), and elimination of the annual averaging time are adequately described in Chapter 5 of the latest version of the OAQPS Staff Paper and are reasonable. To a certain degree, however, the conclusions reached by staff reflect more an absence of evidence than they do any evidence of absence of effects from long-term exposures. The only way this issue will be resolved is if additional epidemiology studies are conducted that examine whether there are morbidity and/or mortality effects from long term exposure to coarse mode particulate matter.

Relative to the percentile of the distribution that the averaging time should be associated with, the more statistically robust 98^{th} percentile is recommended. This is especially important for $UPM_{10-2.5}$ since substantial measurement error is likely to be the case. In addition, since the extremes of the distribution may well reflect excursion contributions from rural coarse mode sources that are not viewed to be as toxic as urban coarse mode particles contaminated with other materials, use of the 98^{th} percentile should tend to help focus regulatory compliance of $UPM_{10-2.5}$ on truly urban coarse mode particles.

Given that the data base studying the potential long term effects of coarse mode particles is scant in comparison to that for $PM_{2.5}$, several "devil's advocate" comments are provided below suggesting reasons why an annual standard may be worth considering in a future standards review cycle.

- Coarse particles in both urban and rural areas are composed, on a mass basis, primarily of crustal minerals at most times and places. An "urban-only" focus is based on the assumed enrichment or contamination of this crustal matter with a wide range of "metals" (including As, Cd, Cr, Mn, Ni, Pb, and Zn), and organic compounds (including PAHs, other POM, etc.).

All of the above are as likely (or more so) to produce long-term effects from chronic, cumulative exposures as they are from short-term spikes. Most of the above contaminants are also routinely sampled for in urban air toxics networks (using PM_{10} samplers) and are considered either carcinogenic or likely to cause chronic systemic toxicity (rather than short-term effects) in most air toxics risk management programs.

- Individuals can and do take steps to reduce exposures to peak coarse PM events; they stay or go inside on very dusty days (see for example Gordian et al. (1996); Ostro et al. (2000)). As an aside, this kind of avoidance behavior would seem like direct evidence that coarse particles do have public welfare effects (irritant in this case). Such effects, which are not limited to urban locations or pollutants, are not discussed in the staff paper.

- In any urban area, but especially in more arid Western states (or during prolonged dry periods anywhere), the $PM_{10-2.5}$ mass will be a mixture of assumed relatively benign rural dust and potentially harmful urban dust. The Spokane "dust storm" study (Schwartz et al., 1999) cited on p. 5-56 provides a good example, as Spokane will qualify as an urban area under the proposed population/density definition. The question is how to distinguish between the urban and rural dusts in urban areas that also experience influences from rural dust sources. This is easy for big events but very difficult for small ones. Phoenix is another obvious example (as are most southwestern cities), where breaking out urban and rural or making "exceptional or natural event" allowances for rural dust impacts is likely to be very challenging – especially if there are only continuous $PM_{10-2.5}$ methods (which preclude chemical filter analysis) and/or if there is no $PM_{10-2.5}$ monitoring in dusty upwind rural areas.

- On a related topic, the emissions modulation of natural $PM_{10-2.5}$ sources is extremely episodic, whereas the emissions of urban coarse particles – especially from industrial sources and paved road dust – are relatively constant. High wind speeds are not needed to entrain contaminated paved road dust, as constant motor vehicle traffic provides sufficient wind energy, and highest urban road dust concentrations often occur on stagnation days, which have the lowest wind speeds. Thus, a short-term $PM_{10-2.5}$ standard will tend to emphasize times and places most heavily impacted by "the good dust" and de-emphasize the chronic, long-term exposures to "the bad dust". At a minimum, EPA should recognize that a short-term $UPM_{10-2.5}$ standard at a high percentile will require carefully crafted monitoring guidelines as well as new exceptional and natural events policies.

Dr. Jonathan M. Samet

COMMENTS CONCERNING

REVISED OAQPS STAFF PAPER ON PARTICULATE MATTER, JUNE 2005

Jonathan M. Samet
Johns Hopkins Bloomberg School of Public Health
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General Comments:

In this review, the Clean Air Scientific Advisory Committee (CASAC) has been asked to address portions of the revised Staff Paper related to the proposed standard for thoracic coarse urban particulate matter (UPM10-2.5), as well as to judge the extent to which the revisions are responsive to other concerns. My comments focus on the materials related to UPM10-2.5. In general, the revised Staff Paper satisfactorily responds to concerns raised on other matters.

The CASAC was asked to evaluate responsiveness around coarse particles by responding to three questions. In addition to the three questions posed to the CASAC, general consideration needs to be given to the level of certainty needed to advance a new National Ambient Air Quality Standard (NAAQS). While I am not aware of any explicit statement in this regard, the level of certainty has generally appeared to be that a causal association can be inferred for one or more adverse health effects at concentrations of the particular pollutant to which the population is exposed. As set out in the Criteria Document and Staff Paper, there are criteria for evaluating the causality of associations which have proved useful for evidence appraisal and causal inference. Additionally, descriptors for the strength of causal inferences have been developed and are widely used; for example, in reports of the Surgeon General or of the Institute of Medicine and the National Research Council. The descriptors of strength of causal inference extend from full confidence in causation to inadequate evidence.

The Staff Paper acknowledges that the evidence base in support of causality is far stronger for $PM_{2.5}$ than for the proposed new indicator, UPM10-2.5. Its language in Chapter 3 acknowledges the differing strength of evidence. For $PM_{2.5}$, the body of evidence is characterized as: "…supports an inference of causation for $PM_{2.5}$ and a broad range of health effects" (page 357) and as "likely causally associated with" other health effects (page 358). For UPM10-2.5, the evidence is noted to be less strong and is characterized as "suggestive" (page 358). In Chapter 5, when providing a rationale for implementing the new standard, the Staff Paper states: "Taken together, staff concludes that the health evidence, including dosimetric, toxicologic and epidemiologic study findings, supports retaining standards to protect against effects associated with short-term exposure to thoracic coarse particles. This conclusion is inherently based on the same evidence that led to a characterization of the association of coarse particle measures with adverse health effects as "suggestive". While a rationale is given for proposing the new

standard, I suggest that the precedent set by proposing the UPM10-2.5 standard in the face of this level of evidence receive explicit discussion.

Absent a standard for UPM10-2.5, the Agency does not have a basis for implementing a national monitoring network and obtaining data on concentrations of UPM10-2.5 that would characterize exposures of the population to this PM indicator and support the conduct of epidemiologic research. Consequently, there is a need to either move forward on a relatively weak body of evidence or to overstate the strength of the evidence available. The Staff Paper appears to do both. I found the discussion of dosimetry (page 5-48, for example) to overstate the importance of comparative doses of particles delivered to the alveolar region by the two size fractions, $PM_{2.5}$ and UPM10-2.5. The cited example of mouth breathers refers to some uncertain fraction of the population and, not surprisingly, deposition of mass could be substantial for UPM10-2.5, Toxicological data are limited, as is the body of relevant epidemiological research.

The proposed standard for UPM10-2.5 refers to a particular size fraction claimed to have some specific characteristics related to sources in urban particles and for which toxicity is inferred. Other recent reviews of the evidence on particle characteristics and sources have found the data to be inconclusive as to whether toxicity can yet be linked to specific characteristics of particles and back to the sources of these particles. The fourth report of the National Research Council's Committee on Research Priorities for Airborne Particulate Matter concluded that there had been little advance in understanding the characteristics of particles determining likelihood of injury leading to the various adverse health effects. Since that report was published, there has been little additional evidence to reduce uncertainty. Dr. Henderson's letter of June 6, 2005 appropriately characterizes the joint view of the CASAC members around the suggestive nature of the evidence for a causal association of coarse particles with adverse health effects but with acknowledgement of the high level of uncertainty in the face of limited evidence.

I recognize the need for a monitoring network to support further research and the basis for concern as to the health consequences of UPM10-2.5. However, CASAC should clearly acknowledge the state of the evidence on this new indicator and note the need for the Agency to further elaborate its criteria for evidence evaluation and decision-making. Additionally, the setting of the new standard for UPM10-2.5 and the implementation of a monitoring network inevitably focuses future research on this particular size fraction as it will be operationally defined.

Specific Questions

Question 1:

My general remarks above address, in part, the scientific basis for moving forward with the new standard. The Agency has been responsive to the comments of CASAC. I note that the letter of June 6, 2005 emphasizes the high degree of uncertainty and the need for further research. The tone of the Staff Paper conveys a degree of certainty that may not be warranted.

Question 2:

The limited evidence available supports a 24-hr averaging time for UPM10-2.5 and not considering an annual averaging time. The observational evidence for a longer term standard is extremely limited but the mechanistic considerations support a shorter averaging time.

Question 3:

Given the limited evidence available, I find it difficult to offer a strong preference for a particular range for the UPM10-2.5 standard. The Staff Paper adequately sets out the rationale for the selected range.

Dr. Frank Speizer

Individual Review Comments on Section 5.4 THORACIC COURSE PARTICLE STANDARDS—Staff Paper, June 2005.

Submitted by Frank E. Speizer

General Comment:

In general, I found the section reasonably well written and logically presented. Although the choice of UPM10-2.5 describes what we are looking for it does not define well enough when and where we find it. Up front we need to admit that it must be a relative term and set out some criteria for all of us to agree upon that make the measurement of interest first to go out and measure it and then to pay attention to the potential health related associations that might be found. I think unless we do this we will never get to agreement as to what should go forward as a potential standard. On the other hand the numbers chosen for the range of the 24 hour standard seem to take the uncertainty into account well and I have no trouble dealing with these. Thus, if we can define where we will want the measurements to be made, I think we can sign off.

Specific Comments:

Page 5-48, end of first paragraph.

…locations where PM10-2.5 is the predominant fraction. Can predominant fraction be better defined or defined more specifically? (Eg. >50, 60, 70%,XX% of total PM10?, Some other measure of source or lack of source?)

Page 5-49, second to last paragraph, last sentence beginning: "In areas with …"

Make more quantitative. "There were xx studies that showed positive associations although not significant and xx reported negative associations"

Page 5-50, paragraph 2. Consider rewriting. The first sentence seems inconsistent with the second. "…staff concludes…short term exposure… (must be epidemiology) yet in second sentence "Staff believes…substantial uncertainties…and …suggests high degree of caution in interpreting the evidence, …" I think the problem are the underlined adjectives.

Page 5-51, Table 5-2. The table is not intuitive. It says higher levels of cut points associated with lower risk. Is it a labeling problem?

Page 5-54. first full paragraph under section 5.4.2.1: Last two sentences in paragraph. I think this needs to be expanded somewhat. Although accurate as presented in tends to leave a dichotomy that doesn't really exist. Somehow the last sentence needs to be changed to reflect the fact that these difference are only a matter of degree, and the degree at which this becomes important needs to be better defined. In addition, the suggestion here, and in the next paragraph is that "road dust" is the primary source of interest. In fact, traffic related pollutants might be a better term since this would include resuspended road dust as well as the combustion products, which might be more important.

Page 5-55, first sentence on page. Is it really true that "nationwide" unpaved roads are the main source of PM10-2.5, or is it the main source of TSP, which are the "rocks" we see from unpaved roads?

Page 5-59 (bottom) to top of Page 5-60. Last sentence of this paragraph. What does this suggestion do to existing source oriented monitoring program? Is staff suggesting that this be done away with if we move to this Census oriented monitoring?

Page 5-72, last paragraph, discussion of spatial variability and uncertainty of health effects. Spatial uncertainty, due to both proximity to sources as well as the nature of sources at point of measurement, is different from uncertainty in the health effects. Not clear that the former adds to the uncertainty of latter. Eg. If see health effects does that mean the relation is uncertain? Doubtful, in fact if exposure measure was less uncertain, likely the health effect would be stronger. If do not see health effects, more likely due to misclassification of exposure, and therefore more uncertain.

Page 5-72, bottom of same paragraph. "…influence of measurement error and exposure error…" These are easy terms to use but unclear as to what they mean in this context.

Page 5-73, item 4 sentence beginning "Numerous new analyses… Not clear, thought needs to be reworded.

Dr. Sverre Vedal

September 2005
Comments on PM Staff Paper
Sverre Vedal

Chapter 5 (Staff Conclusions and Recommendations on Primary PM NAAQS – focus on Section 4 [Thoracic coarse particle standards])

General:
Although I find the approach to a coarse PM standard as outlined in the staff paper to be on the right track, I have reservations about its implementation. Since the approach is breaking new ground, it is not unexpected that it has a "work in progress" flavor.

Specifics:
1. The definition of an urban coarse standard is problematic. While I agree that we only have sufficient evidence to act on urban-type coarse PM at this point, based on the flavor of the Staff Paper, regardless of expressions to the contrary, because we do not measure composition, by default this means that "urban" will be defined by some measure of population size or density. That's where I have a problem. Somewhat simplistically, the two extreme alternatives for attempting to set a standard for coarse PM of the urban type are: 1) to restrict application of the standard to urban areas, with "urban" defined as suggested in the staff paper, i.e., using some measure of population size or density, or 2) to apply the standard uniformly across the country, with exceptions made for situations where there is a strong likelihood that elevations in coarse PM are either not of urban origin or not of urban-type composition. The first approach raises potential problems that in my opinion exceed those faced by using a national coarse standard with exceptions. That is, there seem to be any number of possible scenarios imaginable where exceeding a coarse standard with urban-type coarse PM would occur in settings that would not qualify as urban based on either population size or density.

2. The issue of equivalency with the PM_{10} standard (p. 67) is a particularly sticky one, given that the ratio of coarse to PM_{10} varies across the country. Therefore, western US cities in general, as they did for PM_{10}, could shoulder most of the burden of the standard. Also, the average of monitoring sites is heavily skewed toward eastern US cities (p. 68), so that 60/150 (a ratio of 0.40) for the 98^{th} percentile would be lower than that for many western US cities and higher than that for many eastern cities. This attempt at equivalency, then, seems to result in a discrimination against western US cities, as did the PM_{10} standards.

3. EPA staff necessarily struggled (p. 59) with the potentially competing objectives of recommending monitoring in locations of expected high coarse PM concentrations and of monitoring in locations that represent the population-orientation. The suggestion as to monitoring scales (p. 60) seems incredibly ambitious (and naïve), given the current density of PM monitoring networks in the US, although given the much more dramatic urban spatial variability of coarse PM than fine PM, such monitoring networks would seemingly be required.

4. Although I agree with (but with a fair amount of uncertainty) the range of concentrations proposed for the alternative coarse PM standard, the following points should not be forgotten. First, the suggested alternative level of the coarse standard, as noted, is at the extreme upper end (above the 99th percentile) of concentrations measured in the cities in which health studies on morbidity endpoints have been performed, reflecting, so the argument goes, the relative uncertainty in the epidemiological findings and the relative rarity of toxicological data. Interestingly, this is largely not the case for the cities in which mortality outcomes have been investigated, but these studies have been relegated to "second tier" status in the Staff Paper. Second, if the PM_{10} standard were being considered today, it is unlikely that a level of 150 $\mu g/m^3$ would be retained, calling into question the soundness of the approach based on equivalency.

5. The notion of exposure measurement error is introduced (p. 66) in shoring up the argument that the coarse PM observational findings are exceptionally uncertain. While exposure measurement error is certainly more pronounced for coarse PM than it is for fine PM, because of the greater spatial variability and a much different outdoor-indoor relationship, it should also be kept in mind that the expected effect of greater measurement error is typically to even further underestimate true effects. Because estimates of effect are based on ambient coarse PM concentrations, and because ambient levels are typically substantially greater than indoor or personal levels with exposure being greatly overestimated, the potency of coarse PM to which one is exposed would be underestimated. Also, the fact that the absolute degree of error likely increases with concentration (approximately in proportion to concentration) provides an additional mechanism by which estimates based on ambient concentrations result in underestimation of the coarse PM effect. This mechanism results in further underestimation of the size of the effects, but has little impact on precision (certainty). In short, while measurement error may make the estimates of effect more uncertain, the sizes of the effects that are estimated are very likely more substantially underestimated than are those for fine PM.

6. The attempt to dismiss the mortality studies is not entirely successful in view of the results reported for cardiovascular outcomes (Fig 3-1, p. 3-13). Parenthetically, the quality of the reproduction of this important figure is very poor when compared with the January 2005 draft version.

7. Finally, the justifiable focus on urban coarse PM should not, of course, lull us into thinking that all non-urban coarse PM is benign. I am largely in agreement with Rich Poirot's comments on this subject, and with his interesting suggestion, in order to prevent in effect a relaxation of the standard in non-urban areas, of having an equivalent secondary standard apply everywhere without distinguishing urban from non-urban.

<u>Minor points</u>:

p. 51 Table 5.2. In order to be correct, and more understandable, this should be "person-days" of cough, not "days."

p. 56 The Coachella Valley findings are conspicuously absent from this discussion mortality due to the coarse fraction. These are relevant in any attempt to argue that non-urban coarse PM is relatively benign.

Mr. Ronald H. White

US EPA Final PM Staff Paper (June 2005)
Revised Comments of Ronald White
August 15, 2005

Chapter 5: Staff Conclusions and Recommendations on the Primary PM NAAQS
Section 5.4 Thoracic Coarse Particle Standards

A. This section of Chapter 5 of the Final PM Staff Paper represents a substantial improvement over the previous discussion of this issue in the 2nd Draft PM Staff Paper. The Agency has been responsive to the advice previously provided by CASAC on this issue at the April 2005 meeting and in its June 2005 letter.

The EPA staff presentation at the August 11, 2005 CASAC conference call meeting clarified the Agency's intention to focus on utilizing the term "urban" in defining thoracic coarse particles as an indicator of particle compositional toxicity rather than a rigid limitation to a specific population-based regulatory application. However, I remain concerned with, and opposed to, the inclusion of this still undefined concept of an "urban" particle that serves as a surrogate for particle composition and toxicity into the proposed thoracic coarse particle standard indicator. As I noted at the April 2005 CASAC meeting, the thoracic coarse particle standard indicator should be defined on the basis of particle size and potential toxicity rather than the magnitude or density of the population impacted by exposure. The Committee's discussions on the regulatory implications of the available information on thoracic coarse particle toxicity focused on potential strategies for excluding from regulation those thoracic coarse particles that are primarily crustal in nature and uncontaminated by toxic components from other pollution sources are based on limited evidence to date that exposure to these particles are not likely to cause significant health concerns. However thoracic coarse particles contaminated by emissions from mobile, stationary and area sources of pollution in populated areas, irrespective of the size of the exposed population, do present a potential public health concern. Given the diverse types of sources and potentially toxic contaminants, relying on other regulatory authorities (e.g. §112 of the Clean Air Act) to address these sources of particle toxicity is not a viable national solution to this issue. EPA has sufficient discretion through various regulatory strategies to ensure that national implementation of a $PM_{10-2.5}$ NAAQS is focused on those areas with exposure to coarse particles that present the greatest public health concern.

There is a paucity of data currently available on health outcomes related to thoracic coarse particles in rural areas and limited information on the composition and toxicity of rural area coarse particles, which underscores the need for monitoring thoracic coarse particle levels and for health effects studies in rural areas for research purposes. The fact that the relatively limited epidemiologic evidence to date regarding mortality and morbidity health effects from exposure to thoracic coarse particles is provided by studies conducted primarily in larger urban areas reflects the preference for large sample sizes to address requirements for adequate study power in epidemiologic studies, as well as the availability of sufficient fine and coarse PM monitoring data to establish $PM_{10-2.5}$ exposures.

While the magnitude of the absolute risk reduction in health outcomes from reducing thoracic coarse particle exposures in areas with relatively smaller populations may be relatively small on an individual basis, the collective national risk reduction benefits resulting from implementation of a coarse PM NAAQS in populated areas impacted by mobile, stationary or areas sources should be assessed by EPA and considered in establishing the parameters for the thoracic coarse particle monitoring network. For those counties that previously monitored compliance with the PM_{10} NAAQS and would no longer be required to monitor for $PM_{10-2.5}$ under EPA's proposed monitoring implementation strategy, EPA should require that prior to excluding these counties from the $PM_{10-2.5}$ monitoring network a demonstration be made based on emissions inventories and source-receptor modeling that no air pollution sources exist which are likely to result in substantial contamination of the $PM_{10-2.5}$ fraction by toxic air pollutant components.

B. I agree with the Agency's proposal to retain a 24-hour averaging time for the thoracic coarse PM NAAQS, and the selection of a 98^{th} or 99^{th} percentile statistical form for determining compliance. Based on the health effects evidence available to date, I also concur with the decision not to set a thoracic coarse PM NAAQS based on an annual average. This decision should be revisited as part of the next review of the PM NAAQS to determine if new health effects information warrants establishing an annual average (or some other long-term exposure metric) thoracic coarse PM NAAQS.

C. I concur that the proposed ranges for the level of the thoracic coarse PM NAAQS are reasonable based on the health evidence available to date. I believe the health evidence for morbidity effects (and to a lesser degree for short-term mortality effects) is sufficient to provide a basis for selecting a level for the 24-hour standard at the bottom of the ranges proposed in the final Staff Paper. Though not available in time for inclusion in the final PM Criteria Document, the recent published evidence of health impacts associated with thoracic coarse particles discussed in the Staff Paper comments submitted by the American Lung Association, as well as the just released article by Chen et al.[1] regarding the association of thoracic coarse particles and respiratory hospital admissions in Vancouver, Canada, provide additional support for selecting a level for the 98^{th} or 99^{th} percentile form of the thoracic coarse PM NAAQS at the bottom of the ranges proposed in the final Staff Paper to provide greater public health protection.

[1] Chen Y, Yang Q, Krewski D, Burnett RT, Shi Y, McGrail KM. The Effect of Coarse Ambient Particulate Matter on First, Second, and Overall Hospital Admissions for Respiratory Disease Among the Elderly. *Inhalation Toxicology*; Volume 17, Number 12 / November 2005 (on-line) pp. 649-655.

Dr. Warren H. White

Comments on the replacement of current primary PM_{10} standards with an indicator of urban thoracic coarse particles, $UPM_{10\text{-}2.5}$. Warren H. White, 8/7/05
revised & extended 8/12/05

Most panelists agreed at the last CASAC meeting on PM that the Agency should emphasize the health risks of urban over rural $PM_{10\text{-}2.5}$. Various vehicles were suggested for establishing this focus, including the guidelines that will be needed for siting monitors and flagging events, neither of which attracts quite the intense scrutiny of the NAAQS proper. These guidelines' empirical and operational flexibility seem a real advantage, given the paucity of hard data available on $PM_{10\text{-}2.5}$. I am uncomfortable with the Agency's proposal to instead write "urban" into the very *indicator* of the NAAQS.

The most obvious problem with UPM is that of defining the "U", as other panelists have already noted. But the more troubling consequence of adding a "U" before PM is that there is then absolutely no reason to stop at the coarse fraction. Consider the arguments made for $UPM_{10\text{-}2.5}$ (my paraphrases):

1. *"There is no epi or tox evidence that rural exposures to uncontaminated natural crustal materials cause significant health effects."*

Well, where is the epi or tox evidence that rural exposures to uncontaminated sulfate and nitrate salts cause significant health effects? Did I miss a bunch of rural epi studies? Lots of chamber subjects have breathed lots of pure sulfate salts without significant effect, have they not? Isn't that why we don't have a sulfate NAAQS? Why shouldn't we think that the $PM_{2.5}$ effects seen in urban epidemiological studies actually come from the same things we worry about with $PM_{10\text{-}2.5}$: iron, nickel, cadmium, chromium, polycyclic aromatic hydrocarbons, and so on?

2. *"$PM_{2.5}$ travels long distances with little dilution, so farmers and ranchers are exposed to urban $PM_{2.5}$. $PM_{10\text{-}2.5}$ doesn't travel much, so their $PM_{10\text{-}2.5}$ exposures are only to material of local origin."*

Ranchers and farmers (and their husbands) are indeed exposed to $PM_{2.5}$ of urban origin, but it is chemically not the same $PM_{2.5}$ to which their city cousins are exposed. $PM_{2.5}$ mass concentrations may well remain high or even increase during transport over large distances, but that is because atmospheric reactions along the way produce secondary sulfates and other products to offset the dilution and loss of primary urban emissions.

Maybe the Devil's advocacy presented above is marginally more tortured than the reasoning in section 5.4, but there obviously are stakeholders with incentives to pursue it. The Agency is then going to find it awkward to maintain that all $PM_{2.5}$ is equi-toxic while at the same time arguing that $PM_{10\text{-}2.5}$ toxicity is determined by composition. And it is a fact that urban fine particles are "dirtier" in the same way urban coarse particles are. Consider "the relative amount of iron, one of the metals that has been noted as being of some interest in the studies of mechanisms of toxicity for PM" (page 5-54). Iron is well-characterized by the IMPROVE network, the best-measured of the elements the SP mentions as being of concern. The following table gives average recent concentrations in three cities and near-by rural areas. (Washington DC was until recently the sole urban site in the IMPROVE network.)

	$PM_{2.5}$ ug/m3	$PM_{2.5}$ Fe ng/m3	Fe/$PM_{2.5}$ ppm	period
Seattle	7.9	0.072	9082	8/01 - 5/04
Olympic penninsula	3.0	0.009	2962	
Washington DC	13.9	0.112	8038	1/00 - 5/04
Shenandoah NP	9.8	0.025	2524	
Phoenix	11.4	0.286	25138	4/01 - 5/04
Tonto NM	5.3	0.088	16483	

The column Fe/$PM_{2.5}$ gives the fraction of ambient $PM_{2.5}$ mass contributed by Fe. The relative abundance of iron is about three times higher in Seattle and Washington DC than at near-by rural sites. The less-pronounced urban enrichment observed in Phoenix is presumably due to much higher baseline of soil concentrations to which the industrial and vehicular Fe increment is there added.

The reference in the last bullet on 5-53 to "the more heterogeneous nature of the … chemical composition of thoracic coarse particles" seems rather off-the-wall, given the well documented differences between the regional sulfate hazes of the east and the organic and nitrate hazes of many western cities, not to mention the urban-rural differences illustrated in this table.

Finally, I want to second Rich Poirot's point that rural $PM_{10-2.5}$ is not all clean dust. Is it actually known, for example, that the aerosolized dung of cattle feedlots is completely benign? Why does California limit farm workers' exposures immediately following certain soil and crop treatments?

Additional comments following 8/11/05 teleconference:

I don't understand how my fellow panelists can blithely accept a NAAQS for UPM when no one has yet put forward a plausible account of how UPM might be defined and then monitored in ambient air. What, exactly, *is* the indicator we spent 3+ hours debating through the "your call is important to us" elevator music? In more concrete terms, how will we know if we are in compliance with a NAAQS for UPM?

An untenable answer would be that a 98^{th} percentile $PM_{10-2.5}$ concentration above a certain level is an exceedance of the UPM NAAQS if it is measured inside certain geographical boundaries, and is not an exceedance if measured outside those boundaries. First, Karen Martin made clear that this is not what EPA has in mind; second, the air quality managers of several non-urban districts in the West made clear that it would be a disaster for their populations; third, a geographically restricted standard would by definition fail to be a **N**AAQS.

The Agency rightly intends UPM to denote a category of PM defined by composition and morphology rather than by geographic location. But the FRM candidates currently in view will monitor only mass, not composition or morphology.

Consider a monitor whose location is not clearly urban, and suppose that it records $PM_{10-2.5}$ concentrations above the NAAQS level on many days of the year. (If no such site existed, there would then be no reason to introduce the UPM concept – occasional exceedances can be handled through guidance on exceptional or natural events.) To establish that this monitor is in compliance with a 98^{th} (or 99^{th}!) percentile NAAQS, it will not be sufficient to document that tillage and other approved activities account for the vast majority of dusty days. It will be necessary to show that UPM concentrations did not exceed the NAAQS on more than 1 or 2 days (1 in 3 day monitoring) or 3 or 6 days (continuous monitoring) out of the entire year. How is that to be done, when we have composition data only from occasional special studies, if at all?

If $PM_{10-2.5}$ concentrations from uncontaminated soil dust are high on 70 days a year, one might argue that it's no big deal if $UPM_{10-2.5}$ concentrations are at similar levels on 7 more days a year. But that would just bring us back to the "solution" of red-lining certain geographic areas, a solution that we already rejected as an untenable.

It just gets worse as more-realistic scenarios are considered. The above discussion imagines measured concentrations to represent either "urban" or "clean" $PM_{10-2.5}$. But UPM is itself conceived as an indefinite mixture, of largely-natural dusts with urban contaminants. If the 90 $\mu g/m^3$ of $PM_{10-2.5}$ captured by our monitor is half local crustal material and half transported UPM, then have we, or have we not, exceeded a UPM NAAQS set in the 50-85 $\mu g/m^3$ range? That is, at what level of dilution by clean dusts does UPM cease to be UPM? That is a question that will arise as soon as the receptor modelers get to work.

Several of us meet again in September to review, among other things, the Agency's "coarse particle … network data quality objectives" – I suppose the UPM DQOs will answer all my questions!

I do sympathize with Agency Staff, because they have worked very hard to be responsive to the Committee. I think the problem is that they're getting bad advice from "the vast majority" of us, to use Phil Hopke's phrase. I think "the vast majority" of my colleagues have reverted to a pre-scientific "miasma theory" of disease causation, with UPM as the replacement for "foul and foetid odors." If I raised my voice during our teleconference and am lapsing into outrage here, it is because I want clearly to dissociate myself from what I consider a mistake of historic proportions. I don't see how the indicators $PM_{2.5}$ and $UPM_{10-2.5}$ can both survive the inevitable legal challenges, particularly when the last-minute addition of the "U" clearly does not arise from any information not already available to our deliberations on $PM_{2.5}$. And I fear the consequences to air quality of a possibly major set-back in court.

Dr. George Wolff

Review Comments

on

"Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS, June 30, 2005" – Coarse Particle Recommendations

George T. Wolff
(9/05)

1. The scientific evidence to support a health-based $PM_{10-2.5}$ NAAQS is weak and inconsistent. Nevertheless, I agree there should be a 24-hour $PM_{10-2.5}$ NAAQS.

2. There is no justification for an annual $PM_{10-2.5}$ NAAQS.

3. The form of the NAAQS should be the 98^{th} percentile for all the reasons stated by myself and other CASAC members. Based on our previous discussions of extreme values, I am disappointed that the Agency would even consider a 99^{th} percentile.

4. I support setting the NAAQS to be equivalent in stringency to the former 24-hr NAAQS of 150 $\mu g/m^3$. The Agency has not made a compelling case that this is 70. I think a case can be made in some geographic areas that it should be higher. In any event, I favor setting the NAAQS no lower than 70.

5. Based on the existing data, it is inappropriate to invoke the precautionary principle to rationalize setting a NAAQS lower than 70.

6. The information cited to state that that urban $PM_{10-2.5}$ is more toxic than rural $PM_{10-2.5}$ is not convincing, and it is based largely on anecdotal information.

7. The evidence from epidemiological studies for an association between $PM_{10-2.5}$ is extremely weak and inconsistent, and should not be used as a basis for selecting the level of the NAAQS.

8. The potential toxicity of the contemporary carbon fraction of the coarse carbon PM has not been adequately explored.

9. Speciation of both rural and urban $PM_{10-2.5}$ is needed to advance the science.

10. There is no basis presented in either the Staff Paper or Criteria Document for a secondary $PM_{10-2.5}$ NAAQS.

11. I regret that CASAC's standard operating procedure of reviewing a document until the Panel reaches closure has been suspended. If it had not been suspended, I do not believe we would have come to closure on this version and the final document would have been a better product.

Dr. Barbara Zielinska

US EPA Final PM Staff Paper - Comments on Thoracic Coarse Particle Standards, Section 5.4

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In my opinion, this section of the Final Staff Paper is well-written and presents a very reasonable set of recommendations. In light of current limited information concerning the health effect and composition of the coarse thoracic particles, the proposed Urban Particulate Matter Standard ($UPM_{10-2.5}$) seems to be the optimal (although not perfect) solution. $UPM_{10-2.5}$ would serve as a surrogate for those harmful components of urban coarse particles that are presumably different from those present in coarse particles of natural origin. The setting of this standard at the level roughly equivalent to the current PM_{10} standard would insure that the level of health protection would not be lower than with the current standard, meanwhile also allowing the acquisition of additional data, ultimately expanding our understanding of this size fraction of ambient PM.

I agree that there is little basis for retaining an annual $PM_{10-2.5}$ standard; therefore I support 24-hr averaging time for an $UPM_{10-2.5.}$ Likewise, the shorter averaging time is currently not justified from the health effects point of view and due to the lack of reliable short-time monitoring methods. I support the staff's conclusion regarding the necessity for development of an FRM for an $UPM_{10-2.5}$ mass as well as FEMs for appropriate continuous measurements methods.

The proposed level for the 24-hr $UPM_{10-2.5}$ standard in the range of 50 to 70 ug/m^3, 98th percentile form or 60 to 85 ug/m^3, 99th percentile form, seems to be reasonable as well. Taking into account the limited number of health studies in which $PM_{10-2.5}$ has been measured and potentially large uncertainties related to available exposure measurements for coarse particles, I would rather favor the consideration of the upper end of these ranges (specifically, 60 -70 ug/m^3, 98th percentile form). Also, I favor the more robust 98th percentile over that of the 99th percentile.

One area of concern is the lack of a clear definition of "urban" versus "rural" terms. In this regard, the explanation offered by Dr. Karin Martin during the August 11, 2005 conference call, clarified EPA's intent to focus on urban particle toxicity rather than to limit the reach of the standard to large population centers only. The Staff Paper discussion regarding the design of $UPM_{10-2.5}$ monitoring network based on the population/density approach (page 5-59 and 5-60) seems to be appropriate. The initial idea of positioning the monitors in more densely populated areas, such as in the U.S. Census Block Groups characterized by population densities greater than 500 people per square mile, seems to be justified. Given the correlations between density of traffic and total population and population density measures, such criterion will ensure representative monitor locations in the areas of greatest population exposure to elevated concentration of traffic-contaminated coarse thoracic particles. On the other hand, since our understanding of "rural" coarse particles is very poor, it would be desirable to retain some monitoring in the selected "rural" areas for PM level, size distribution and chemical composition.

NOTICE

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