

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR SCIENCE ADVISORY BOARD

January 12, 2009

EPA-SAB-09-010

The Honorable Stephen L. Johnson Administrator U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460

Subject: Particulate Matter Research Centers Program Advisory Report: An SAB Advisory Report

Dear Administrator Johnson:

The EPA Science Advisory Board (SAB) Particulate Matter (PM) Research Centers Advisory Panel met on October 1-2, 2008 to consider questions posed by EPA on the future directions of its PM Research Centers program. The Panel concluded that this program has been very successful and that its continuation, especially in a form that would begin to move this area of research into assessments of mixtures of air pollutants, would be of great value. This report provides the SAB's advice in response to EPA's three charge questions, which addressed the contributions of the existing program, multiple pollutant strategies and Center structure.

The SAB concluded that the existing PM Centers continue to advance research on key issues relevant to EPA's mission. The Centers have made critical advances in improving the scientific understanding of and reducing and characterizing scientific uncertainty in atmospheric particle composition, transformation, exposure, and health impacts. The advances have been extensively cited in EPA documents supporting policy decisions and have been influential in the scientific community. The SAB recommends that the EPA continue to use a variety of performance indicators to assess Center performance and recommends additional measures be added to those already used in the Center evaluations. Additional measures should broaden the range of indicators of Center impacts on the scientific community and the range of indicators that document the extent to which Center work is used in support of Agency decisions. Additional measures should also characterize the extent to which Center resources are supplemented by research support from other EPA programs and from other governmental and non-governmental research programs.

The SAB also concluded that the Centers Program, a component of EPA's Science to Achieve Results (STAR) program, has produced benefits over those that would be expected in traditional extramural grant mechanisms involving individual investigators or small teams of investigators focusing on relatively narrow topical areas. These benefits included flexibility and adaptability in research programs, the creation of large inter-disciplinary teams, the development of unique research infrastructures, and the ability to support high risk pilot research. The SAB recommends that a substantial fraction of the EPA's extramural research efforts continue to be funded through Centers that are regularly evaluated and re-competed, but also noted that both Centers and individual or small team research initiatives are essential.

The SAB concluded that the Centers have already begun to address broad sets of air pollutants that contribute to exposure and health effects and agreed with the agency that more could be done to enhance multi-pollutant approaches in the future Center activities. Specifically, the SAB recommends that multi-pollutant approaches should be strongly encouraged by EPA in applications for PM Research Centers, with clear encouragement of efforts to develop innovative methods that address multi-pollutant atmospheric transformation, exposure, toxicology, and epidemiology. Although the SAB generally agreed with the Agency's suggestion that organizing its multi-pollutant efforts around sources could be useful, it cautioned that an over-emphasis on near-roadway exposures in such efforts could under-represent the importance of other sources and the atmospheric transformation of their emissions that are significant contributors to exposure. The Panel also concluded that the future Center activities could usefully address another important and broad direction; the regional differences in pollutant mixtures, and potential differences in health effects.

Finally, regarding recommendations for advice on changes to the structure of the PM Centers, the SAB recognized the successes of the PM Centers program over its history. Because of the Program's success, some panel members questioned the need to make major changes in the structure of the program. The SAB offers some comments in this report on the strengths and weaknesses of several structural changes that were proposed by the EPA, as well as additional comments on important issues identified by the review Panel. Among these are that: a) the notion that all Centers should study identical research topics was not supported; b) requiring all Centers to have a Regional focus was not supported, though the need to consider regional differences in pollutant mixtures by some Centers was considered to be useful; c) requiring both large and small Centers within the total program was not supported by the majority of the panel; and d) there is a need to have Center structures that support and encourage research partnerships. In addition, the SAB endorsed other activities that will enhance whatever structure that the EPA decides upon for the continued Centers program. Among these are that: a) Centers must continue their use of outside, independent expert reviews of their programs to evaluate their progress, and b) Centers should be given the flexibility to change their program content to reflect advice obtained from these groups without jeopardizing their continued funding either as a result of changing research foci or from completion of specific components of the research. Additionally, Centers should continue to coordinate research both among the Centers and with the relevant research programs within EPA.

The SAB appreciates the opportunity to review and comment on EPA's plans to continue its Particulate Matter Centers program. We look forward to your response to our comments and we would be pleased to continue to work with EPA as it further develops and implements this important research program.

### Sincerely,

/Signed/

Dr. Deborah L. Swackhamer Chair Science Advisory Board /Signed/

Dr. David T. Allen Chair SAB Particulate Matter Research Centers Program Advisory Panel

#### **NOTICE**

This report has been written as part of the activities of the EPA Science Advisory Board (SAB), a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names of commercial products constitute a recommendation for use. Reports of the SAB are posted on the EPA website at http://www.epa.gov/sab.

#### U.S. Environmental Protection Agency Science Advisory Board (SAB)

#### SAB Particulate Matter (PM) Research Centers Program Advisory Panel

#### **CHAIR**

**Dr. David T. Allen**, Gertz Regents Professor of Chemical Engineering, Department of Chemical Engineering, and Director, Center for Energy and Environmental Resources, University of Texas, Austin

#### PANEL MEMBERS

Mr. Bart Croes, Chief, Research Division, California Air Resources Board, Sacramento, CA

**Dr. Bruce Fowler**, Assistant Director for Science, Division of Toxicology and Environmental Medicine, Office of the Director, Agency for Toxic Substances and Disease Registry, U.S. Centers for Disease Control and Prevention (ATSDR/CDC), Chamblee, GA

Dr. Terry Gordon, Professor, Environmental Medicine, NYU School of Medicine, Tuxedo, NY

**Mr. Daniel Greenbaum**, President, Health Effects Institute, Charlestown Navy Yard, Boston, MA

**Dr. Steven Kleeberger**, Professor and Lab Chief, Laboratory of Respiratory Biology, National Institute of Environmental Health Sciences, National Institutes of Health (NIH/NIEHS), Research Triangle Park, NC

**Dr. George Lambert [M.D.]**, Associate Professor of Pediatrics, Director, Center for Childhood Neurotoxicology, Robert Wood Johnson Medical School-UMDNJ, New Brunswick/Piscataway, NJ

Dr. Frederick J. Miller, Independent consultant, Cary, NC

**Dr. Peter Scheff**, Professor, Environmental and Occupational Health Sciences, School of Public Health, University of Illinois at Chicago, Chicago, IL

Dr. Bryan Shaw, Commissioner, Texas Commission on Environmental Quality, Austin, TX

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

#### **SCIENCE ADVISORY BOARD STAFF**

**Mr. Thomas Miller**, Designated Federal Officer, US EPA Science Advisory Board, 1200 Pennsylvania Ave., (Mail Code 1400F), Washington, DC 20460

### U.S. Environmental Protection Agency Science Advisory Board BOARD

#### **CHAIR**

Dr. Deborah L. Swackhamer, University of Minnesota, St. Paul, MN

#### **SAB MEMBERS**

- Dr. David T. Allen, University of Texas, Austin, TX
- Dr. John Balbus, Environmental Defense Fund, Washington, DC
- **Dr. Gregory Biddinger**, ExxonMobil Biomedical Sciences, Inc., Houston, TX
- **Dr. Timothy Buckley**, The Ohio State University, Columbus, OH
- **Dr. Thomas Burke**, Johns Hopkins University, Baltimore, MD
- Dr. James Bus, The Dow Chemical Company, Midland, MI
- Dr. Deborah Cory-Slechta, University of Rochester, NY
- **Dr. Terry Daniel**, University of Arizona, Tucson, AZ
- Dr. Otto C. Doering III, Purdue University, W. Lafayette, IN
- Dr. David A. Dzombak, Carnegie Mellon University, Pittsburgh, PA
- Dr. T. Taylor Eighmy, University of New Hampshire, Durham, NH
- **Dr. Baruch Fischhoff**, Carnegie Mellon University, Pittsburgh, PA
- Dr. James Galloway, University of Virginia, Charlottesville, VA
- Dr. John P. Giesy, University of Saskatchewan, Saskatoon, Saskatchewan
- **Dr. James K. Hammitt**, Harvard University, Boston, MA Also Member: COUNCIL
- Dr. Rogene Henderson, Lovelace Respiratory Research Institute, Albuquerque, NM
- Dr. James H. Johnson, Howard University, Washington, DC
- **Dr. Bernd Kahn**, Georgia Institute of Technology, Atlanta, GA

- **Dr. Agnes Kane**, Brown University, Providence, RI
- Dr. Meryl Karol, University of Pittsburgh, Pittsburgh, PA
- Dr. Catherine Kling, Iowa State University, Ames, IA
- Dr. George Lambert, Robert Wood Johnson Medical School-UMDNJ, Belle Mead, NJ
- Dr. Jill Lipoti, New Jersey Department of Environmental Protection, Trenton, NJ
- Dr. Lee D. McMullen, Snyder & Associates, Inc., Ankeny, IA
- Dr. Judith L. Meyer, University of Georgia, Lopez Island, WA
- **Dr. Jana Milford**, University of Colorado, Boulder, CO
- Dr. Christine Moe, Emory University, Atlanta, GA
- Dr. M. Granger Morgan, Carnegie Mellon University, Pittsburgh, PA
- Dr. Duncan Patten, Montana State University, Bozeman, MT
- Mr. David Rejeski, Woodrow Wilson International Center for Scholars, Washington, DC
- Dr. Stephen M. Roberts, University of Florida, Gainesville, FL
- **Dr. Joan B. Rose**, Michigan State University, East Lansing, MI
- **Dr. Jonathan M. Samet**, University of Southern California, Los Angeles, CA Also Member: CASAC
- **Dr. James Sanders**, Skidaway Institute of Oceanography, Savannah, GA
- **Dr. Jerald Schnoor**, University of Iowa, Iowa City, IA
- **Dr. Kathleen Segerson**, University of Connecticut, Storrs, CT
- Dr. Kristin Shrader-Frechette, University of Notre Dame, Notre Dame, IN
- Dr. V. Kerry Smith, Arizona State University, Tempe, AZ
- Dr. Thomas L. Theis, University of Illinois at Chicago, Chicago, IL
- Dr. Valerie Thomas, Georgia Institute of Technology, Atlanta, GA
- Dr. Barton H. (Buzz) Thompson, Jr., Stanford University, Stanford, CA

Dr. Robert Twiss, University of California-Berkeley, Ross, CA

Dr. Thomas S. Wallsten, University of Maryland, College Park, MD

Dr. Lauren Zeise, California Environmental Protection Agency, Oakland, CA

### SCIENCE ADVISORY BOARD STAFF

Mr. Thomas Miller, Washington, DC

### **Table of Contents**

1. INTRODUCTION
1.1 BACKGROUND INFORMATION:
1.2 EPA CHARGE TO THE SAB PM RESEARCH CENTERS PROGRAM ADVISORY PANEL2
2. RESPONSE TO CHARGE QUESTIONS
2.1 CHARGE QUESTION 1. HOW WELL HAVE THE PM CENTERS CONTINUED TO CONTRIBUTE TO ADVANCING
RESEARCH ON KEY PM ISSUES MOST RELEVANT TO EPA'S MISSION?
2.2 CHARGE QUESTION 2. WHAT ADVICE DOES THE PANEL HAVE ON HOW TO MOVE TO A MULTI-POLLUTANT APPROACH IN THE PM CENTERS PROGRAM?4
2.3 CHARGE QUESTION 3. WHAT STRENGTHS AND WEAKNESSES DOES THE PANEL SEE IN DIFFERENT OPTIONS FOR A FUTURE CENTERS RESEARCH PROGRAM?
REFERENCES9
LIST OF ACRONYMS
APPENDIX: EPA CHARGE TO THE SAB – MEMORANDUM FROM W.H. SANDERS11

#### 1. INTRODUCTION

The EPA Science Advisory Board (SAB) was asked by the U. S. Environmental Protection Agency to conduct a review of its Particulate Matter Research Centers Program (US EPA, 2008). EPA was interested in the SAB's advice on: a) the worth of the PM Research Centers past contributions to advancing key particulate matter research in support of EPA's mission; b) the potential for broadening the Centers' programs to have more of a multi-pollutant focus; and c) the strengths and weaknesses of various alternative Center structures that might be used in the future. This advisory provides the SAB's advice to the Administrator as a result of an advisory meeting held on October 1 and 2, 2008 in Washington, DC.

#### 1.1 Background Information:

In 1998, the Congress directed the Environmental Protection Agency to establish as many as five university-based PM research centers as part of the expanded Office of Research and Development (ORD) PM research program. The first PM research centers were funded from 1999 to 2005 with a total program budget of \$8 million annually (see the following URL: <a href="http://es.epa.gov/ncer/science/pm/centers.html">http://es.epa.gov/ncer/science/pm/centers.html</a>). In the original Request for Applications (RFA), prospective centers were asked to propose an integrated research program on the health effects of PM, including exposure, dosimetry, toxicology and epidemiology. ORD's PM Research Centers program was initially shaped by recommendations from the National Research Council.

In 2002, ORD requested that the Science Advisory Board conduct an interim review of EPA's PM research centers program, the report from which is found at the following URL: <a href="http://yosemite.epa.gov/sab/sabproduct.nsf/6374FD2B32EFE730852570CA007415FE/\$File/ec02008.pdf">http://yosemite.epa.gov/sab/sabproduct.nsf/6374FD2B32EFE730852570CA007415FE/\$File/ec02008.pdf</a>. This review was instrumental in providing additional guidance to ORD for the second phase of the program (2005–2010).

In 2004, ORD held a second competition for the PM Research Centers program. This RFA asked respondents to address the central theme of "linking health effects to PM sources and components," and to focus on the research priorities of susceptibility, biological mechanisms, exposure-response relationships, and source linkages. From this RFA, five current centers are funded for 2005–2010 with the overall 5-year total program budget at \$40 million (see: http://cfpub.epa.gov/ncer\_abstracts/index.cfm/fuseaction/outlinks.centers/centerGroup/19).

At the request of EPA ORD's National Center for Environmental Research (NCER) the SAB Staff Office formed an expert panel to comment on the Agency's current PM research centers program and to advise EPA concerning the possible structures and strategic direction for the program as ORD contemplates funding a third round of air pollution research centers into the future, *i.e.*, from 2010 to 2015 (see *Federal Register*, 73 FR 5838, of January 31, 2008 which announced the formation of an SAB *ad hoc* panel for this advisory activity and requested public nominations of qualified experts to serve on this panel and the SAB Panel Formation record, US EPA SAB, 2008).

#### 1.2 EPA Charge to the SAB PM Research Centers Program Advisory Panel

The Agency asked the SAB for advice on the effectiveness of the current Particulate Matter Research Centers Program and for suggestions for improved program structures and strategic directions for the 2010-2015 program. EPA provided a number of documents to the SAB to consider as it responded to the Agency Charge. These included a lengthy memorandum from the Director of the National Center for Environmental Research that described the program's history, structure, and a detailed explanation of the EPA charge questions as well as background information on each (see Sanders, W.H., 2008 attached).

EPA asked that the Panel focus on several charge questions during its review. EPA's asked, "...within the context of the current state-of-the-science and the priorities for the EPA Air research program:"

- a) How well have the PM Centers continued to contribute to advancing research on key PM issues most relevant to EPA's mission?
- b) What advice does the panel have on how to move to a multi-pollutant approach in the PM Centers program?

One prominent theme of EPA's multi-year research plan for Air is the need to better understand air pollution effects within the context of the entire ambient mixture. What advice does the panel have regarding the appropriate balance between single-pollutant and multipollutant research? What additional broad strategic directions should EPA consider for a future Centers Research Program?

# c) What strengths and weaknesses does the panel see in different structural options for a future Centers Research Program?

Given the strategic directions discussed above, please comment on various approaches EPA could consider for the *structure* of a future air pollution Centers program. For example, a future Centers program might continue with a common theme for all Centers, or might seek Centers that specialize in different research areas. In addition, some Centers might address a broad research portfolio while others have a more targeted focus. EPA may consider funding fewer Centers in order to maintain appropriate program balance with the individual STAR grants and intramural research programs. EPA is seeking the panel's views on the strengths and weaknesses of different approaches for the structure of the program.

#### 2. RESPONSE TO CHARGE QUESTIONS

# 2.1 Charge Question 1. <u>How well have the PM Centers continued to contribute to advancing research on key PM issues most relevant to EPA's mission?</u>

The PM Centers continue to advance research on key issues relevant to EPA's mission. The Centers have made critical advances in improving the scientific understanding of and reducing and characterizing scientific uncertainty in atmospheric particle composition, transformation, exposure, and health impacts. The documentation reviewed by the panel demonstrated that PM Center investigators:

- a) are recognized as world leaders in PM health effects research,
- b) have improved understanding of the epidemiology and toxicology of particulate matter,
- c) have identified mechanisms for PM health effects,
- d) have improved our understanding of the populations most susceptible to PM health risks,
- e) have identified new micro-environments (e.g., roadways) that lead to air pollutant exposures,
- f) have developed new technologies and instruments for PM research,
- g) have advanced the understanding of source specific health impacts, and
- h) have enhanced the range of expertise available to the EPA in assessing PM health impacts.

The first set of Centers, funded from 1999-2005, produced more than 500 publications, a rate of publications per dollar of funding that is 20% higher than the publication rate per dollar of funding for comparable STAR grants. These publications have been influential, as evidenced by citation rates that are higher than average citation rates in the fields covered by the publications. For example, a 2007 analysis of ORD Air Program publications indicated that about 37% of PM Center papers are in the top 10% in overall citation rate, 6% of PM Center papers are in the top 1%, and 3% are in the top 0.1%.

The assessments of a variety of expert panels have provided additional endorsements of the scientific impact and the relevance of the work of the PM Centers. These have included assessments by BOSC (BOSC, 2005) an SAB panel (US EPA SAB, 2002); the National Research Council of the National Academies (NAS/NRC, 2004) and professional organizations such as the American Heart Association (Brook, 2004), and the American Academy of Pediatrics (AAP, 2004).

The work of the Centers has also been extensively cited in EPA documents supporting policy decisions. The Centers' work contributed to the 2007 PM NAAQS review and the Integrated Science Assessment (ISA) for PM. PM Center work has also influenced policy decisions in regulatory organizations beyond EPA, such as the California law requiring that schools must be at least 500 feet from freeways.

The panel recommends that the EPA continue to use a variety of performance indicators to assess Center performance, and that additional measures be added to those already used in the Center evaluations.

One set of additional measures should characterize the extent to which Center resources are supplemented by other research support. Such supplemental funding from outside of the EPA should not become a requirement of the Centers program, but the extent of supplementation can serve as an indicator of the interest by organizations outside of EPA in the work of the Centers.

A second set of additional measures should broaden the range of indicators that assess Center impacts on the scientific community. Current measures are focused on numbers of journal publications, citations, and students trained. The Centers could also begin to track the impact that program graduates are having on the field after they leave the Centers.

A third set of additional measures should broaden the range of indicators that document the extent to which Center work is used in support of Agency decisions. Current measures focus on documents developed in support of setting National Ambient Air Quality Standards. The Center's work has also been used in Regulatory Impact Assessments, in assessing the costs and benefits of the Clean Air Act (Section 812 analysis), and in other documents developed by EPA in support of its regulatory mission. These uses of the Centers' work should be tracked.

Finally, the panel concluded that the Centers Program produced benefits over those that would be expected in traditional STAR grant mechanisms, which typically involve individual investigators or small teams of investigators focusing on relatively narrow topical areas. These benefits include flexibility and adaptability in research programs, the creation of large inter-disciplinary teams, the development of unique research infrastructures, and the ability to support high risk pilot research. The advantages of Center programs, as compared to traditional STAR grant funding mechanisms, will be expanded on in response to charge question 3. The panel recommends that a substantial fraction of the EPA's extramural research efforts continue to be funded through Centers that are regularly evaluated and re-competed, but also notes that both Centers and individual or small team research initiatives are essential.

# 2.2 Charge Question 2. What advice does the panel have on how to move to a multi-pollutant approach in the PM Centers program?

EPA noted that, "One prominent theme of EPA's multi-year research plan for Air is the need to better understand air pollution effects within the context of the entire ambient mixture." The Agency asked the SAB, "What advice does the panel have regarding the appropriate balance between single-pollutant and multipollutant research? What additional broad strategic directions should EPA consider for a future Centers Research Program?"

In reviewing the contributions of the PM Centers program to date, and its potential for the future, the Panel found that the Centers have already begun to make contributions to efforts to address the broader set of pollutants that contribute to exposure and health effects and agreed with the agency that more could be done to enhance multipollutant approaches in the next round of Centers. The Panel also found that the next round of Centers could usefully address another

important and broad direction: the regional differences in pollutant mixtures, and potential regional differences in health effects.

Enhancing Multipollutant Approaches in the Centers Program: In 2004, the NRC's Committees on *Research Priorities for Airborne Particulate Matter* and *Air Quality Management in the United States* (NAS/NRC, 2004) recommended that the nation's efforts to improve air quality should move from its historical single-pollutant-at-a-time regulatory approach to a multipollutant approach that provides both the science and the regulatory programs to allow for the most cost-effective interventions to reduce exposure and improve public health. Although the setting of multipollutant ambient air quality standards is likely well in the future, the agency is working with states to develop multipollutant air quality management plans, and seeking to move its air quality research program to a multi-pollutant perspective that can increasingly identify the effects of the simultaneous co-exposure to many different pollutants that humans and the ecosystem face.

There are hundreds of compounds in the ambient mix of pollutants; the agency has focused on a subset of these which have been the main targets of the Clean Air Act: the so-called criteria pollutants (especially PM and ozone) as well as some air toxics. As the Centers begin to examine mixtures of air pollutants, the Panel agreed that a focus on mixtures of criteria pollutants and air toxics is useful (e.g., considering the impacts of exposure to mixtures of PM and air toxics). The Panel also noted that there are significant "multipollutant" challenges within some pollutant classes, especially PM. For example PM can be viewed as a mixture of ultrafine particles and larger particles; PM can also be viewed as a mixture of inorganic acids and salts, organic compounds and soot-like material. Current research on differential impacts of PM components may also inform questions of effects of multipollutant mixtures.

The Panel agrees that the Agency should find ways to re-direct the PM Centers program so that it is better able to address the broader multi-pollutant context. The development of a more robust set of atmospheric chemistry, exposure, dosimetry, toxicology and epidemiology research methods will be essential to building the evidence necessary to support both nearer term decisions by states and localities about the best integrated intervention strategies, and to laying the foundation for the development of multipollutant ambient standards in the future.

#### Specifically, the Panel found:

- a) Multi-pollutant approaches should be strongly encouraged by EPA in applications for PM Research Centers, with clear encouragement of efforts to develop innovative methods that address multi-pollutant atmospheric transformation, exposure, dosimetry, toxicology, and epidemiology. These new methods could include a range of approaches, from computational toxicology and genomics to enhanced statistical methods for identifying principal components or factors, to novel analytic chemistry.
- b) The Panel felt that while the Agency should provide a strong incentive for multipollutant approaches, it should not mandate specific approaches, but rely on the skills and innovation of the research community to propose new approaches.

- c) The Panel generally agreed with the Agency's suggestion that organizing its multipollutant efforts around sources could be useful, but cautioned that an overemphasis only on near-roadway exposures in such efforts could substantially underrepresent the importance of other sources and the atmospheric transformation of their emissions that are also significant contributors to exposure.
- d) Finally, it will be important to balance the interest in a multipollutant approach with the need to continue answering single pollutant questions that can inform nearer term decisions critical to the Agency's mission to improve public health. This should include science to inform standard setting (e.g., better understanding PM exposure-response and the relative toxicity of PM components). It also should inform regulatory strategy (e.g. better tools for source apportionment). But even in these instances, the Centers program should emphasize the need to generate such pollutant-specific data as much as possible in a multi-pollutant context to enhance its interpretation.

**Addressing Regional Differences:** The panel noted the well-known differences in pollutant sources and mixtures in different regions, and emerging evidence of differences in health effects, and found that exploring, characterizing, and understanding these regional differences in exposure and effect should also be a broader direction to be encouraged in a new round of Center awards.

- a) As with multi-pollutant approaches the Panel felt that systematic approaches to addressing regional differences should be strongly encouraged by EPA, with a clear indication that such efforts will enhance the applicant's chances of being selected. Here too, the Panel felt that while the Agency should provide a strong incentive for addressing regional differences, it should not mandate specific approaches, but rely on the skills and innovation of the research community to propose new approaches.
- b) The Panel further found that addressing these regional differences could take two forms:
  - i First, individual centers that could demonstrate a systematic approach to exploring and understanding differences in exposure and health in two or more regions should be encouraged; and
  - ii Second, once centers are selected, and to the extent that they represent geographical differences in their location and focus, EPA should foster enhanced collaboration and coordination among the relevant centers on regional differences.

# 2.3 Charge Question 3. What strengths and weaknesses does the panel see in different options for a future Centers Research Program?

The PM Centers panel recognizes the successes of the PM Centers program over the last 8 years as discussed in Charge question 1. In addition, the Panel noted that the program has been

adaptive, adding and deleting elements in response to reviews and changing scientific understanding of key issues. Since the Program is successful, some members questioned the need to make major changes, suggesting "if it's not broken, do not fix it." However, as the Agency redirects the Centers toward more multi-pollutant approaches and examination of regional differences, some structural and operational changes should be considered. The panel considered both specific structural changes for the Centers program under consideration by the Agency, and broader structural and operational features of the Centers. These are described, by topic, in paragraphs a) through g).

a) The agency asked the panel to consider whether all Center applicants should address the same research topics.

The panel agreed that the PM Centers should be asked to choose from among a described set of priority research topics, as has been the case in the past, however, the notion that all Centers should study identical research topics was not supported. The RFA should describe the range of desired research and let the applicants decide on the exact research topics and approaches. It is then up to the Agency to select an appropriate research portfolio, based on quality, relevancy, and the extent to which the applicants propose research topics which complement other Intramural and Extramural research programs.

b) The agency asked the panel to consider whether all Center applicants should have a regional focus.

The consensus of the Panel was that the requirement of funding Centers based on their regional locations would not be a structurally beneficial alteration to the Program, despite some benefits in supporting regulatory decisions, such as providing closer links to regional, state, and local officials and facilitating identification of regional issues.

There are important regional differences in atmospheric contaminants and health outcomes that need to be studied and understood. The development of regional centers may help delineate these differences; however, other scientific approaches may be scientifically better and more cost effective. For example, as noted above in response to Question 2, individual centers could explore and understand differences in exposure and health in two or more regions and EPA could foster enhanced collaboration and coordination among the centers on regional differences.

c) The agency asked the panel to consider whether individual Centers should continue to be funded at their current level or whether a larger number of Centers, funded at a smaller level would be more effective.

There are advantages and disadvantages to having only Centers funded at or near the current level (large Centers) or a mixture of large and small Centers. The funding of both large and small Centers was favored by a minority of the panel. The main concern of most of the panel was that funding limited or small Centers would diminish the impact of

the program and would diminish some of the advantages of large Centers cited in response to Charge question 1.

The funding of small Centers would allow Research Centers that are not as comprehensive or developed as the large Centers to be funded and develop their research program. The funding of small Centers also provides the agency the opportunity to select research programs that may fill a very specific research need. While the funding of small centers has advantages the loss of the large Center effect and the transfer of funding from large to small Centers were not supported by the majority of the Panel members.

d) The panel encourages the Centers to develop core laboratories that can be shared and to pursue supplementary funding

Other potential structural elements that the Agency is encouraged to entertain is the potential use of Core laboratories shared among the Centers; and encouraging the Centers to identify complementary research programs that can supplement Center activities. The Panel also recommends that the EPA search to find research partners that may help fund this Program. NIEHS, NIGMS, ALA, AHA, ATS would be just some of the federal and non federal programs that may help fund this research. Other Centers programs of the EPA have been successful in developing outside EPA funding to share costs of the program. The focus of funding from other agencies should be to augment Center research, rather than as a replacement for EPA funding.

e) The panel encourages the Centers to continue their tradition of ongoing evaluation and scientific flexibility

The Centers must continue to have a process for periodic evaluation of research programs. The Centers should have the flexibility to end projects that have come to a reasonable endpoint and begin new projects. This should be done in consultation with the Center oversight committees and the Agency.

f) The panel encourages the Centers to continue their tradition of internal integration and integration with the agency.

The Centers have a strong tradition of integration of science, data, and methodology, allowing rapid progress of the state of the art in science and methods within individual Centers and within the PM Centers program. Integration with internal agency programs should be encouraged to the extent practicable.

g) The panel encourages the Centers to continue their tradition of strong External Advisory Panels

The Centers should continue their use of external advisory Panels. Some panel members felt that it may be helpful if the Centers consider community involvement in the Panels, particularly if the Center has a regional focus, however there was not a panel consensus on this recommendation.

#### REFERENCES

AAP. 2004. "Ambient air pollution: Health hazards to children." American Academy of Pediatrics; Committee on Environmental Health. *Pediatrics*: 114:1699-1707.

BOSC. 2005. "Report of the Board of Scientific Counselors (BOSC) review of EPA's PM and Ozone Research Program. US EPA Board of Scientific Counselors, August 11, 2005. http://www.epa.gov/OSP/bosc/pdf/pm0508rpt.pdf.

Brook, R.D. 2004. "Air pollution and cardiovascular disease. A statement for healthcare professionals from the expert panel on population and prevention science of the American Heart Association. *Circulation*: 109:2655-2671.

NAS/NRC. 2004. "Research Priorities for airborne Particulate Matter-IV-Continuing research Progress." Committee on Research Priorities for airborne Particulate Matter, Board on Environmental Studies and Toxicology, Divison of Earth and Life Studies, National Research Council of the National Academies. The National Academies Press., Washington, DC.

Sanders, W.H. 2008. "Particulate Matter Research Centers Program SAB Advisory Panel Meeting." Memorandum from Dr. William H. Sanders to Mr. Fred Butterfield. September 10, 2008.

<u>US EPA SAB. 2002. "Interim Review of the Particulate Matter (PM) Research Centers: An SAB Report," EPA-SAB-EC-02-008, May 24, 2002.</u>

US EPA SAB. 2008. "Formation of Science Advisory Board (SAB) Particulate Matter (PM) Research Centers Program Advisory Panel." Memorandum from Mr. Fred Butterfield to Dr. Vanessa Vu, June 19, 2008.

#### LIST OF ACRONYMS

AAP American Academy of Pediatrics
AHA American Heart Association
ALA American Lung Association
ATS American Thoracic Society

BOSC Board of Scientific Counselors to the US EPA ORD Assistant Administrator

EPA U.S. Environmental Protection Agency

FR Federal Register

ISA Integrated Science Assessment of the NAAQS review process

NAAQS National Ambient Air Quality Standards

NCER National Center for Environmental Research of the US EPA ORD

NIEHS National Institute of Environmental Health Sciences NIGMS National Institute of General Medical Sciences

NRC National Research Council of the National Academies

ORD US EPA Office of Research and Development

PANEL The EPA SAB Particulate Matter Research Centers Program Advisory Panel

PM Particulate Matter

RFA Request for Applications (for Grant Proposals)

SAB Science Advisory Board

STAR Science To Achieve Results Program

### Appendix



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20004

#### **September 10, 2008**

#### **MEMORANDUM**

**SUBJECT:** Particulate Matter Research Centers Program SAB Advisory Panel

Meeting

**FROM:** William H. Sanders III, Dr. P.H.

Director

National Center for Environmental Research, Washington, DC

Office of Research and Development

**TO:** Fred Butterfield

Designated Federal Officer

SAB Advisory Panel

EPA Science Advisory Board Staff Office (1400F)

This memorandum provides background information and transmits charge questions for the upcoming meeting of the EPA Science Advisory Board (SAB) Particulate Matter Research Centers Program Advisory Panel. The Panel is scheduled to meet on October 1-2, 2008 in Washington, DC, to advise the Office of Research and Development (ORD) on the Particulate Matter (PM) Research Centers Program and, subsequently, to provide the EPA Administrator with its advice and recommendations on the future directions of this program. Please forward this memorandum to the members of the SAB Advisory Panel in preparation for this review.

Attached to this memorandum is a twelve-page "Explanation of the Charge and Supporting Materials." This document explains the rationale behind ORD's request for this advisory panel and information to assist the panelists in addressing the charge questions. In addition to this memorandum, all members of the SAB Advisory Panel will receive a CD-ROM containing supporting documents referenced in the following pages. Hard-copies of these documents can be provided upon request. These supporting materials are also posted on the EPA-NCER Web site at the following URL: <a href="http://es.epa.gov/ncer/science/pm/2008sab/index.html">http://es.epa.gov/ncer/science/pm/2008sab/index.html</a>.

We appreciate the efforts of the SAB Advisory Panel in preparing for this upcoming meeting, and we look forward to discussing the PM Research Centers Program with the Panel in detail on October 1-2. Should you have any questions regarding the attached explanatory document or the CD-ROM of supporting documents, please contact Stacey Katz, NCER, at phone: 202-343-9855, or email: <a href="mailto:katz.stacey@epa.gov">katz.stacey@epa.gov</a>, or Gail Robarge, NCER, at phone 202-343-9857, or email: <a href="mailto:Robarge.gail@epa.gov">Robarge.gail@epa.gov</a>.

Attachment

### Science Advisory Board Advisory Panel Meeting Particulate Matter Research Centers Program

#### **Explanation of the Charge and Supporting Materials**

#### **Overall Charge Question**

In the context of the current state-of-the-science and the priorities for the EPA Air research program, the Office of Research and Development (ORD) seeks advice on the possible structures and strategic direction of an Air Research Centers program for 2010 – 2015.

#### **Background**

#### Particulate Matter Research Centers

EPA established new air quality standards for particulate matter (PM) smaller than 2.5µm in 1997 based on findings relating exposure to these fine particles with adverse health effects, including increased hospitalizations and premature deaths. In the 1998 EPA Appropriations bill. Congress augmented the President's recommended EPA budget by over \$22 million to address uncertainties in the evidence on PM health effects. A part of the expanded ORD research program was a directive to EPA to establish as many as five university-based particulate matter research centers (Tab 4-K). In addition, EPA was directed to provide support to the National Academy of Sciences National Research Council to develop priorities for a comprehensive PM research program and review of research progress over the next five years. The recommendations in the NRC Committee's first report, Research Priorities for Airborne Particulate Matter<sup>1</sup>, were used as a major source of guidance for the PM Centers Request for Applications (RFA). Prospective Centers were asked to propose an integrated research program on the health effects of PM, addressing a set of research needs in the areas of exposure, dosimetry, toxicology and epidemiology (Tab 4-L). The first research Centers were funded from 1999 – 2005, with a total program budget of \$8 million annually (Tab 4-M). Although the initial funding was awarded for five years, the Centers were funded for a sixth year, so that the final NAS report could be considered in the next solicitation.

In 2002, with the first PM Centers grants at a midway point, the EPA Science Advisory Board (SAB) conducted an interim review that recommended continuing the Centers program, while maintaining a balance of Centers and individual grants (Tab 4-N). Subsequent to the positive SAB review and the issuance of the 2004 NRC report<sup>1</sup>, a second PM Centers competition was held. The recommendations and conclusions in the interim SAB review and the final NRC report were highly influential in the development

<sup>&</sup>lt;sup>1</sup> http://search.nap.edu/nap-cgi/de2007.cgi?term=Research+Priorities+for+Airborne

of the second PM Centers solicitation. The 2004 RFA focused on understanding which sources and components in the particle mixture, as well as which size fractions or other physical attributes are most responsible for observed adverse effects (Tab 4-O). The RFA asked respondents to address the central theme of "linking health effects to PM sources and components," and to focus on the research priorities of susceptibility, biological mechanisms, exposure-response relationships, and source linkages (although applicants were not required to address all four topics). While the 2004 RFA did not require specific scientific disciplines to be included in the proposal, the RFA emphasized the need for integration, focusing on research strengths, partnering with others who have complementary strengths, and showing how integration would occur. From the second competition, five current Centers are funded for 2005-2010 (program budget of \$8 million annually).

#### **Original and Current PM Research Centers**

**Harvard University PM Research Center** (Director: Petros Koutrakis), 1999-2005 and 2005-2010

Johns Hopkins PM Research Center (Director: Jonathan Samet), 2005-2010

Northwest Research Center for Particulate Air Pollution and Health (Director: Jane Koenig) 1999-2005

New York University PM Center (Director: Morton Lippmann) 1999-2005

San Joaquin Valley Aerosol Health Effects Center at UC Davis (Director: Anthony Wexler) 2005-2010

Southern California Particle Center (Director: John Froines) 1999-2005 and 2005-2010

University of Rochester PM Research Center (Director: Gunter Oberdorster) 1999-2005 and 2005-2010

EPA is now seeking the advice of the SAB before announcing a third competition. Current plans are for an RFA to be issued in 2009, in anticipation of funding Centers for 2010 - 2015.

#### ORD Multi-Year Plan for Clean Air Research

ORD's National Program Director for Clean Air Research led the recent revision of the plan that explains goals and priorities in air research. The program is now guided by the Clean Air Research Multi-Year Plan² (MYP), 2008-2012 (see inside pocket of notebook). It addresses research in the areas of PM, ozone, and air toxics, combined into a single, comprehensive plan, and emphasizes the need to move from a single-pollutant focus to a multi-pollutant approach. The plan was reviewed by a panel of external scientists through ORD's Board of Scientific Counselors. The two long-term goals (LTGs) of this plan are:

4

<sup>&</sup>lt;sup>2</sup> http://www.epa.gov/ord/npd/pdfs/Air-MYP-narrative-final.pdf

LTG 1: Reduce uncertainties in standard setting and air quality management decisions due to advances in air pollution science

LTG 2: Reduce uncertainties in linking health and environmental effects to air pollution sources.

The MYP envisions a coordinated program of air research, describing goals and objectives to be addressed jointly by the EPA intramural research laboratories and the extramural research grants program. The current PM Centers are conducting work that will contribute to many of the annual performance goals and measures in the plan.

The intramural and extramural air research programs are highly integrated and complement each other throughout the MYP. In certain areas, such as epidemiology, the extramural program provides the bulk of research, whereas other areas, such as combustion engineering, are primarily the focus of the intramural program. Significant research efforts in areas such as toxicology, exposure, controlled human exposure and atmospheric science are actively supported in both the intra- and extramural programs and carefully coordinated to achieve the long-term and annual performance goals specified in the MYP.

#### Coordination with Other Air Research Programs

As ORD considers future strategic directions, ORD is cognizant that other agencies also fund highly relevant research. For ORD, critical considerations are EPA's unique research niche and its mission as a regulatory agency. In research areas where other large funders, such as the National Institutes of Health or the National Science Foundation, have major initiatives, EPA involvement makes sense if the focus is more related to the Agency's mission. For example, the NIEHS strategic plan (2006-2011)<sup>3</sup> emphasizes gene-environment interactions; cross cutting problems in human biology and human disease; improved community-linked research; and sensitive markers of environmental exposure. In this context, EPA is only likely to fund research on gene-environment interactions that is very targeted to specific research questions of interest to EPA. EPA also coordinates with other sponsors of air pollution research, including the California Air Resources Board<sup>4</sup> and the Health Effects Institute (HEI)<sup>5</sup> – interaction takes various forms, such as providing input to strategic plans and research solicitations, participating in review of applications, and collaborating on workshops.

#### EPA's Extramural Air Research Grants Program

EPA's National Center for Environmental Research (NCER)'s extramural research is conducted principally through the Science to Achieve Results (STAR) program. STAR is a competitive, rigorously peer-reviewed program of research grants that solicits proposals

<sup>&</sup>lt;sup>3</sup> NIEHS strategic plan: <a href="http://www.niehs.nih.gov/about/od/strategicplan/index.cfm">http://www.niehs.nih.gov/about/od/strategicplan/index.cfm</a>

<sup>&</sup>lt;sup>4</sup> California Air Resources Board strategic plan: <a href="http://www.arb.ca.gov/research/apr/apr.htm">http://www.arb.ca.gov/research/apr/apr.htm</a>

<sup>&</sup>lt;sup>5</sup> HEI strategic plan: http://www.healtheffects.org/Pubs/StrategicPlan2005-2010.pdf

from scientists at universities and nonprofit institutions in response to targeted Requests for Applications (RFAs) issued by NCER. The RFAs address research priorities in ORD's multi-year research plan. They are developed in conjunction with the National Program Director and scientific staff from ORD laboratories, regions, and the EPA Office of Air and Radiation, considering input from external scientific advisory panels and workshops. In recent years, the NCER Air Research program has funded \$15-18 million in air grants annually, out of the total STAR budget of approximately \$55-65 million (Tab 4-P). Each year, \$8 million of the NCER Air budget funds the inter-disciplinary PM Research Centers.

#### STAR Individual Research Grants

Each year, \$6-8 million from NCER Air budget is awarded through RFAs for individual grants. In contrast to Centers, these RFAs can be targeted to very specific research topics that require a particular focus. Given the complexity of air research Centers, funding for a five year period is needed to accomplish all of the Centers objectives, many of which are cross-discipline. Individual grants tend to be three years in duration and allow EPA to solicit proposals in response to quickly emerging issues and targeted needs for research methods development. In addition, individual grants provide ORD with the ability to address a single topic, such as effects of long-term exposures to PM or assessing the potential toxicity of coarse PM, with single, dedicated grants. Recent RFAs for individual STAR grants have addressed high priority, focused research needs, for example:

- A prospective epidemiological study to examine the health effects of long-term exposure to PM. The investigators are studying the effects of exposure to air pollution on 8700 people aged 50-89 prospectively for ten years. This is the largest research grant ever funded by EPA, and it is a joint effort with the National Institutes of Health's National Heart, Lung, and Blood Institute (NHLBI). The majority of the study population recruitment and medical examinations are conducted through the NHLBI Multi-Ethnic Study of Atherosclerosis. The air pollution study, known as MESA-Air<sup>6</sup>, will provide new and critically important information on the role of PM and other air pollutants in cardiovascular disease and mortality.
- Atmospheric science studies focused on measurement and modeling methods, with a special emphasis on understanding the sources of carbonaceous particulate matter.
- Research to understand the sources, composition and effects of **coarse** particulate matter, including research by both atmospheric and health scientists.
- **Innovative approaches** to using advanced measurement and modeling techniques that can strengthen the air quality and exposure aspects of

<sup>&</sup>lt;sup>6</sup> MESA-Air fact sheet <a href="http://es.epa.gov/ncer/publications/factsheets/mesa">http://es.epa.gov/ncer/publications/factsheets/mesa</a> air.pdf

epidemiologic studies.

A complete list of STAR RFAs in the Air Program and a description of the process through which RFAs are developed and grants awarded can be found in Section 4-Q.

#### **Specific Charge Questions**

# Charge Question 1. How well have the PM Centers continued to contribute to advancing research on key PM issues most relevant to EPA's mission?

#### Advancing Research Most Relevant to EPA's mission

EPA believes the PM Centers have contributed significantly to the scientific literature on exposure to and effects of airborne PM. To support this conclusion, a range of evidence is provided in section 2 of the SAB panel notebook and described briefly here.

From a scientific perspective, the Centers have made major contributions in many areas of PM research. At the SAB panel meeting, Dr. Dan Costa, EPA's National Program Director for Clean Air Research, will present some key examples of how the PM Centers have played a role in advancing air pollution research, selected from the Centers' integrated summaries of accomplishments and progress reports. Additionally, Dr. Costa will provide an EPA scientific perspective on the benefits that have resulted from the Centers program, for example:

- Recognized as world leaders in investigating the health effects associated with exposure to ultrafine particles and in characterizing the chemical composition, sources, and atmospheric processing of ultrafine particles;
- Advanced the theory of oxidative stress as a key mechanism by which PM causes adverse health effects, including elucidating the role of reactive oxygen species;
- Developed cutting edge technologies for PM research, e.g., size-specific particle concentrators, personal exposure monitors, single particle analyzers;
- Produced unique contributions in epidemiology and biostatistics, areas which complement the EPA intramural program;
- Played a key role in research to link health effects of PM to sources, e.g., demonstrating that emissions near roadways are of special concern;
- Participated in cooperative efforts among Centers and with EPA, including advances in controlled human exposure studies.

A discussion of these and other outcomes is provided in a brief report by senior EPA scientist Dr. Robert Devlin (Tab 1-A).

#### **Summary Report from Original Centers**

The major scientific findings of the original PM Centers (1999-2005) are summarized in a final report to EPA (Tab 1-B)<sup>7</sup>. This summary report was drawn from three technical reports which were prepared by working groups from across the five PM Centers and

<sup>&</sup>lt;sup>7</sup> A manuscript integrating and summarizing the Centers findings is under review for publication in Environmental Health Perspectives.

address the following topics: PM health effects including epidemiology and toxicology, mechanisms of PM toxicity, and PM characterization and exposure; all contain extensive references to previously published findings (Tab 4-R, and <a href="http://es.epa.gov/ncer/science/pm/centers.html">http://es.epa.gov/ncer/science/pm/centers.html</a>).

### **Current Center Progress Reports**

The productivity of the current Centers is presented in progress reports prepared by each Center. Rather than provide only the annual update for this past year, the Centers summarized their progress over the last three years, highlighting preliminary findings and their significance (Tab 1-C). These reports illustrate the extent to which the PM Centers conduct multi-disciplinary research. In addition, the multiple authors of many PM Center publications illustrate the multi-disciplinary cooperation within the Centers.

#### Research Impacts

At the SAB panel meeting, the Office of Air Quality, Planning and Standards' (OAQPS) Director of the Health and Environmental Impacts Division, Lydia Wegman, will discuss the National Ambient Air Quality Standards (NAAAQS) setting process, and how the PM Center science supports air quality regulation and decision-making (Tab 4-S). Of note, PM Center publications play prominently in the review of the PM NAAQS and in the development of state, local, and public health and air quality policies (Tab 1-D). The Centers' work contributed to the 2007 PM NAAQS review and will certainly impact the upcoming EPA Integrated Science Assessment (ISA) for PM. As part of the 2007 review, ORD prepared a "provisional assessment" of research studies published between 2002 and 2006 that were of potentially greatest relevance to assessing the health effects of PM. Of the 215 national and international citations in this PM provisional assessment, 71 (or 33%) were PM Center papers.

Also, the Centers' work has been cited in policy statements from the American Heart Association and the American Academy of Pediatrics. For example, the American Heart Association issued a scientific statement on air pollution and cardiovascular disease, reviewing the literature and addressing the public health indications for clinicians and policy implications for regulators. Of the statement's 108 recent citations (since 2000), which include international sources, 18 (or 17%) were PM Center papers. PM Center work also influences state and local policy decisions – for example, the California state law specifying that schools must be sited at least 500 feet away from freeways.

Beyond air pollution, the Centers' work is significantly influencing new directions in science. For example, toxicological work by the Southern California Particle Center has been cited in a recent NAS report on "Toxicology in the 21st Century" as contributing to "a revolution taking place in biology." Also, studies of ultrafine particles by the University of Rochester and Southern California PM Centers are providing a foundation for studying the health effects of nanoparticles (Tab 1-D).

#### Bibliographic Analyses

As one aspect of assessing productivity of research programs, ORD has begun analyzing publications data. The original PM Centers collectively authored over 500 publications. An analysis of these papers with respect to citation rates, publication in high impact journals, and other features demonstrates that this program is highly productive and far exceeds expectations. For example, when the frequency of citation of PM Center publications was compared to that of all publications in their field, 37% of PM Center publications ranked in the top 10% (3.7 times as many as expected), and 5.5% of PM Center publications ranked in the top 1% (5.5 times as many as expected). As explained in the brief report (Tab 1-E), this analysis primarily focuses on publications from the original Centers, since the current Centers have not yet reached a critical mass of publications. Although the publications analyses show that publication counts do not peak until the last year of a Center, the current Centers have published over 100 papers to date.

#### External Review of PM Research Program

The PM Centers program is an integral part of the EPA Air Research Program and as such has been included in the reviews of the Air Research Program by ORD's external Board of Scientific Counselors (BOSC). Conclusions from the 2005 review relating to the high quality of the air research program and integration between the intramural and extramural programs (Tab 1-F) include:

"The ORD PM & O<sub>3</sub> Research Program has resulted in significant reductions in scientific uncertainty in critical areas."

"The Subcommittee finds a high degree of integration in the conduct of intramural and extramural research across the various laboratories, centers, and scientific disciplines."

"The Subcommittee finds the overall science being conducted by the ORD PM & O<sub>3</sub> Research Program in both intramural and extramural research laboratories to be of high quality as indicated by: (a) scholarship and scientific publications; (b) credentials of participating investigators; (c) integrative and outcome-oriented program design; and (d) building of a knowledge and information database."

In September 2007, the Clean Air program underwent a "mid-cycle review" by the BOSC and was rated as "exceeds expectations" in the context of performance categories established by the Office of Management and Budget. The quality and impact of the Air program publications, weighted heavily by Center publications, were specifically cited by the BOSC in its report.

#### Interactions, Scientific Training, and External Advice

In assessing the success of the PM Centers, several other factors are relevant including evidence such as: 1) examples of interaction among the Centers, with EPA scientists and the broader scientific community and the subsequent benefits of those activities; 2) scientific training provided by the five Centers to almost 90 post-doctoral students and over 50 graduate students in an interdisciplinary environment, inspiring the next generation of air pollution researchers; and 3) guidance and oversight by external scientific advisory committees, comprised of highly-respected scientists, including senior scientists from other PM Centers and EPA (Tab 1-G).

# Charge Question 2. What advice does the panel have on how to move to a multi-pollutant approach in the PM Centers program?

# ORD's Multi-year Plan for Clean Air Research: Moving Towards Multi-Pollutant Research

EPA's Multi-year Plan (MYP) for Air research recognizes the importance of providing research to support the single-pollutant regulatory program at EPA, while moving the program toward a multi-pollutant focus that better reflects the complexity of real-world air pollution exposures (excerpts, Tab 2-H).<sup>8</sup> As noted above, the plan includes two major long-term goals (LTGs):

LTG 1: Reduce uncertainties in standard setting and air quality management decisions due to advances in air pollution science

LTG 2: Reduce uncertainties in linking health and environmental effects to air pollution sources.

The first LTG (LTG 1) supports the following priorities/themes:

- 1) Developing the NAAQS and other air quality regulations includes research on health effects of PM size fractions, PM components, effects of long-term exposure, biological mechanisms, and susceptibility
- 2) Implementing air quality regulations includes measurement methods, emissions factors, modeling, source apportionment, and air quality forecasting

The second LTG (LTG 2) is more multi-pollutant in nature and is oriented toward three research themes

1) Launching a multi-pollutant research program

-

<sup>&</sup>lt;sup>8</sup> EPA is cognizant that air pollution conditions in the future will need to be understood in the context of changing global conditions. ORD's Clean Air MYP does not focus on how climate change will affect air quality, as that is currently one of the main focus areas for EPA's Global Change research program (<a href="http://www.epa.gov/ord/npd/globalresearch-intro.htm">http://www.epa.gov/ord/npd/globalresearch-intro.htm</a>).

- 2) Identifying specific source-to-health linkages, with initial emphasis on "near roadway" impacts
- 3) Assessing the health and environmental improvements due to past regulatory actions

#### External Advice on Moving Toward a Multi-Pollutant Focus

Multiple external advisory committees have encouraged EPA to move to a multi-pollutant approach to researching, assessing and managing air pollution risks

- "There is an opportunity and a critical need to shift the focus of the EPA program from a single pollutant, PM, to a multipollutant orientation. Because of the momentum that the PM research program has generated over the past 6 years, now is an opportune time to begin orienting EPA's air quality research program toward a broader scope that specifically considers all components of the atmosphere PM and the other criteria pollutants, hazardous pollutants, and the other nonclassified components of the atmosphere. The committee envisions a transformation from a PM-focused research program to a multiple air pollutant program (MAPP)." (NRC. Research Priorities for Airborne Particulate Matter, IV: Continuing Research Progress. 2004, <a href="http://www.nap.edu/catalog.php?record\_id=10957">http://www.nap.edu/catalog.php?record\_id=10957</a>; See Executive Summary in Tab 2-J)
- "Air quality management should...strive to take an integrated multipollutant approach to controlling emissions of pollutants posing the most significant risks." (National Research Council. Air Quality Management in the United States. 2004, <a href="http://www.nap.edu/catalog.php?record\_id=10728">http://www.nap.edu/catalog.php?record\_id=10728</a>)
- "For the SIPs States are required to submit over the next several years, EPA and S/L/T should promote the consideration of multipollutant impacts, including the impacts of air toxics, and where there is discretion, select regulatory approaches that maximize benefits from controlling key air toxics, as well as ozone, PM<sub>2.5</sub>, and regional haze. The SIP process provides an opportunity for many urban areas to include key toxic air pollutants in a comprehensive, multipollutant air quality plan." (Air Quality Management Work Group. Recommendations to the Clean Air Act Advisory Committee. January 2005, <a href="http://www.epa.gov/air/caaac/aqm/report1-17-05.pdf">http://www.epa.gov/air/caaac/aqm/report1-17-05.pdf</a>)

EPA's own regulatory Office of Air Quality Planning and Standards (OAQPS) has reorganized to encourage a multi-pollutant focus, rather than its former "stove-piped" split between criteria pollutants and air toxics (Tab 2-I). It also is designed to develop expertise and leadership in multi-pollutant, sector-based approaches.

#### Current PM Center Research Focus

Currently, the PM Research Centers' primary goal is to link PM sources and components to health effects, emphasizing the following general research areas:

- susceptibility to the adverse effects of exposure to PM of different composition or from different sources
- biological mechanisms by which PM and/or PM components cause adverse effects

- exposure-response relationships for biologically important constituents/sizes of PM and PM from different sources
- relationships between emissions sources and ambient concentrations of PM, its components and size fractions.

#### The Challenge

As ORD contemplates the next round of research centers, the challenge is moving from PM-focused Centers to broader "air pollution" Centers that will address source-to-health effects questions from a multi-pollutant perspective. Yet understanding about PM sources and components is just beginning. For example, monitoring data have only recently become available to begin assessing the effects of exposure to PM components. ORD has just begun to support research specifically on coarse particles, and studies on ultrafine particles are still relatively new. Thus, ORD expects to continue PM research for the next several years. However, considering the next competition for research centers, ORD would like to emphasize moving toward a multi-pollutant program that reflects a more realistic view of air pollution science.

#### Request for SAB Panel Advice

Recognizing the importance of anticipating future research priorities, while continuing to address the research needs of EPA's current regulatory program, ORD asks the panel for advice on how to address these competing priorities in the future by providing insights on strategic directions for the Centers. ORD asks the panel for advice on how to move the Centers toward a multi-pollutant program.

The emphasis on linking health effects to PM sources and components is relatively recent. Does it make sense to continue on this path in some capacity? Similarly, as research on effects from exposure to specific components and size fractions of PM gets underway, do questions of biological mechanisms and susceptibility continue to be top priorities?

If ORD continues some Center work on single pollutant themes, how should the program address the growing scientific and technical challenges of complying with new national ambient air quality standards?

Given a multi-pollutant strategic direction, how can Air Research Centers best contribute to moving the air pollution science forward using this approach? Are the primary questions health-related, compliance-related or both? How should ORD approach multi-pollutant research? Is it a combination of a few air pollutants that often track together, or must it be a large, complex mixture consisting of multiple criteria and hazardous air pollutants? What is the appropriate balance of health, exposure and atmospheric science research in multi-pollutant Centers?

ORD believes that the panel's insights on the questions above will be invaluable in charting future directions for the PM Centers program as it evolves into an Air Research Centers program.

# Charge Question 3: What strengths and weaknesses does the panel see in different structural options for a future Centers Research Program?

EPA would like to think broadly about how the structure of Research Centers would affect the research program. As ORD contemplates changes in strategic direction for the program, and in light of declining resources, ORD would also like to consider whether the Centers program structure used for the past 10 years should be continued or could be improved. In the context of the strategic directions discussed in the second charge question, we request the SAB panel discuss and articulate strengths and weaknesses of each option below – and as needed, strengths and weaknesses of any additional scenarios the Panel suggests.

Given the different perspectives of panel members, this charge question intentionally asks the panel to illuminate the strengths and weaknesses of **each** option below. ORD is **not** requesting that one preferred structural option be recommended. The panel brings a breadth of perspectives that could shed light on implications of each option that ORD may not anticipate when moving forward with developing the next Research Centers RFA. ORD plans to incorporate the feedback received from the panel regarding structural options into the RFA writing team's discussions. All of these perspectives will be considered collectively to determine which structure will best meet the objectives of the RFA.

In the current budget climate, ORD is expecting to reduce the size of the Centers program. Current Centers are funded at approximately \$1.6 million each, or \$8 million total annually. Given resource projections, a balanced program between the Centers and other extramural research would be in the \$6-7 million dollar range which would fund four Centers of the current size. This would allow ORD to maintain the STAR individual grants program in the range of \$6-7 million, as well as continuing to provide funding for the intramural air research program. ORD will consider whether to continue to fund five Centers at a reduced funding level (e.g. \$1-1.2 million per year per Center) or whether to reduce to four Centers in order to maintain approximately the current funding level. ORD welcomes the SAB panel's views on this issue.

Research topics mentioned in the options below refer to a general research area, e.g., in the last RFA – susceptibility, biological mechanisms, source linkages. Within each topic in the RFA, specific science questions are given for the applicant to address.

#### Structural Options For Research Centers Program (Tab 3)

#### 1. Same research topics for all applicants – large Centers

This RFA would continue with the structure that EPA has used to date. It would include several research topics, listing specific science questions within each. All applicants would propose interdisciplinary research in response. Usually, each applicant addresses most of the questions listed in the RFA.

#### Strengths

- When multiple Centers address the same questions using different approaches, they produce a rich set of results that can be analyzed and compared at multiple levels. Examples include: statistical methods, technological innovations, and biological and atmospheric insights.
- Easier to foster collaboration among the Centers as they all would be addressing similar issues with different approaches.

#### Weaknesses

- With limited resources it may not be most efficient to have all Centers addressing the same set of questions.
- Most Centers will not have strong efforts in all areas.

#### 2. Regional Centers

This type of RFA would require Centers to have a regional focus, reflecting the understanding that air pollution exposures and effects may vary by region of the country depending on predominant sources, land use, and atmospheric conditions. The RFA would also require specific ties to state and local air quality decision makers and public health officials in that region. The topic areas could be loosely defined, in order to allow freedom for Centers to choose the air pollution research questions of most importance to their regions. The intent would be to develop strong links between health and atmospheric science researchers. The assumption with this option is that there could be more than one Center in any given region. There would be no pre-determined regions for the RFA. Selection of Centers would be based on a combination of scientific excellence and regional representation.

#### Strengths

- Would promote research on effective implementation strategies to achieve air quality goals.
- Ties to state and local air quality decision makers and public health officials in the regions will enhance the relevance and outcomes of the research.

#### Weaknesses

 Studies addressing national problems or impacts would be less likely to be proposed under this option. • More difficult to promote collaborations across Centers.

#### 3. Big and small Centers

This RFA would solicit a certain number of large and small Centers. One example could be 2 large, multi-disciplinary Centers at current size and 3 or 4 smaller Centers at half size. The smaller Centers have the option of being multi-disciplinary, but smaller in scope. The topics for each size would be defined in the RFA.

#### Strengths

- Would make possible both large Centers modeled after the current ones that can address broad multi-disciplinary questions, as well as smaller Centers that could be targeted to specific areas.
- Would expand the range of applicants to include groups that are excellent in limited areas but not large enough to compete for a large Center.

#### Weaknesses

Cross-Center efforts would be more challenging.

#### 4. <u>Choice of one topic – large Centers</u>

This RFA would fund large, multi-disciplinary Centers. The RFA would include two research topics and applicants would be required to respond to only one. The RFA would describe the scientific uncertainties of interest within each topic and present scientific questions under each. As an example, EPA might fund one Center studying the first topic and three Centers studying another topic (or 2 and 2).

#### Strengths

- Would allow applicants to focus the application on areas of strength and expertise instead of trying to cover multiple or too broad topics.
- Promotes more focus within a given Center and advances the science in two distinct areas.

#### Weaknesses

- May not receive strong scientific applications in both areas, resulting in a limited scope of the program.
- Cross-Center efforts would be less likely across Centers addressing different topics.

#### 5. Other – Such as a hybrid of any options above