Board of Scientific Counselors

Management Review of the Particulate Matter Research Program

Prepared for the Assistant Administrator
Office of Research and Development
U.S. Environmental Protection Agency

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List of Acronyms

ACD	Assistant Center Director
AD	Associate Director
ALD	Assistant Laboratory Director
APG	Annual Performance Goal
APM	Annual Performance Measure
AQC	Air Quality Criteria
AQCD	Air Quality Criteria Document
AQRS	Air Quality Research Subcommittee
ARIES	Aerosol Research Inhalation Epidemiology Study
ATSDR	Agency for Toxic Substances and Disease Registry
AWMA	Air and Waste Management Association
BOSC	Board of Scientific Counselors
CAP	Concentrated Ambient Particulate
CASAC	Clean Air Scientific Advisory Committee
CD	Center Director
CDC	Centers for Disease Control and Prevention
CENR	Committee on Environment and Natural Resources
COPD	Chronic obstructive pulmonary disease
EBB	Epidemiology and Biomarker Branch
EPA	Environmental Protection Agency
EPRI	Electric Power Research Institute
FY	Fiscal Year
GPRA	Government Performance and Results Act
HEI	Health Effects Institute
HSD	Humans Studies Division
IAG	Interagency Agreement
LD	Laboratory Director
NAAQS	National Ambient Air Quality Standards
NAC	National Academy of Sciences
NARSTO	North American Research Strategy for Tropospheric Ozone
NCEA	National Center for Environmental Assessment
NCER	National Center for Environmental Research
NCERQA	National Center for Environmental Research and Quality Assurance
NERL	National Exposure Research Laboratory
NHEERL	National Health and Environmental Effects Research Laboratory
NIAID	National Institute of Allergy and Infectious Disease
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NPM	National Program Manager
NRMRL	National Risk Management Research Laboratory
NRC	National Research Council
OAQPS	Office of Air Quality Planning and Standards
ORD	Office of Research and Development
OAR	Office of Air and Radiation
OMS	Office of Mobile Sources
ORIA	Office of Radiation and Indoor Air

List of Acronyms (Continued)

ORMA	Office of Resource Management and Administration
OSP	Office of Science Policy
PI	Principal Investigator
PM	Airborne Particulate Matter
RCT	Research Coordination Team
RFA	Request for Applications
RIVM	National Institute of Public Health (The Netherlands)
RTP	Research Triangle Park
SAB	Science Advisory Board
SBIR	Small Business Innovation Research
STAR	Science to Achieve Results

Executive Summary

The Board of Scientific Counselors (BOSC) met on October 28-29, 1999, in Durham, North Carolina, to review the management of the Environmental Protection Agency's (EPA) Office of Research and Development (ORD) Particulate Matter Research Program. The review was based on a charge from the ORD, a self-study document developed by EPA-ORD in response to the BOSC's questions, and interviews conducted by BOSC Ad Hoc Subcommittees in Durham during the meeting. Ad Hoc Subcommittees on Integration, Exposure, Atmospheric Sciences, Epidemiology, Toxicology, Assessment, and Risk Management consisted of three to four members, including members of the BOSC and its consultants. In this review, the BOSC focused on the management, communication, and integration of ORD's Particulate Matter (PM) Research Program. Specific questions included:

1. Is ORD sufficiently coordinating research across categories of the risk assessment paradigm (source, exposure, dose-response, assessment, and management)?

2. Is the structure in place for the Program to address the highest priority research needs?

3. Are research activities and results being well communicated, both internally and externally.

4. Is EPA-ORD providing sufficient scientific leadership within and outside the Agency on particulate matter research?

The final charge to the BOSC was to assess whether any changes are needed in the management structure of the Program.

The BOSC found that the ORD Particulate Matter Research Program is well organized and efficient. It should be considered a model for other research programs in the Agency. The recommendations in this report are largely "fine-tuning," aimed to improve the program even further.

ORD coordinates PM research in a matrix structure that cuts across its Laboratories/Centers as well as components of the risk paradigm. There is a National Research Program Manager (NPM) and an Executive Lead. The management structure is working well; however, the BOSC recommends that ORD bolster the position of the National Program Manager so that he/she can act efficiently and decisively when changes are needed in the Program. A dedicated budget for the Program Manager should be available to provide resource sufficiency and flexibility for contingencies. For example, if there is a particulate matter air pollution event that provides a rare opportunity for data gathering, the NPM should have a budget to immediately respond to that opportunity. If it becomes apparent that a key study or person is missing in the PM program, the NPM should be able to respond directly in consultation with the Laboratory/Center Directors.

Coordination between ORD and the EPA Program Offices on particulate matter research is good. The BOSC encourages continued efforts by EPA, especially the ORD working together with the Office of Air and Radiation (OAR), to implement the Presidential directive to expand the science of particulate matter health effects and to improve air monitoring methods and cost-effective mitigation strategies.

ORD PM research priorities and, to some extent, the portfolio of projects are guided by the National Research Council (NRC) in an arrangement between EPA and the NRC. Two reports have been published including one on research progress and the portfolio (NRC, 1998), and one on priorities and long-range research (NRC, 1999). The arrangement works well and benefits the Agency.

The BOSC recommends that ORD continually update its research priorities. Some assessment tools that could aid in this endeavor are a gap analysis or sensitivity analysis to determine the efficacy of proposed risk management efforts and public health benefits of the PM Program. The BOSC is aware that a revised draft Air Quality Criteria Document (AQCD) is to be published in early November, and that a revised national risk assessment will follow. The BOSC believes that such a preliminary national risk analysis is important, and encourages its speedy completion. Such an analysis can engage the public, give a clear indication of the status of the PM Program, and identify target research areas to reduce uncertainties. Finally, the BOSC recommends that more long-range planning be performed to assess and compare the public health benefits of the PM Program relative to other pollutants, mixtures of pollutants, or other major public health priorities.

The BOSC concludes that ORD is doing a good job of coordinating its research activities and communicating its findings both within ORD and to the broader community. However, greater use of the World Wide Web might allow other scientists and the public-at-large to track the progress of its research. ORD has contracted with the Health Effects Institute (HEI) to initiate this effort, and it should be linked to the main EPA and ORD Web sites. Close communication with Congress, the public, and industry will ensure continued success and support for the PM Research Program. Therefore, this remains a very high priority for both ORD and the Agency.

The scientific leadership that EPA-ORD has shown on PM research is exemplary. Real strength is apparent in its exposure modeling, atmospheric sciences, and toxicology research. The BOSC found that expertise in epidemiology is less well developed, although it has improved with recent new hires. Continued collaboration, contracting, and leveraging with other agencies on epidemiology will be necessary for the near future.

The BOSC recommends that ORD strive to continuously examine and improve its research productivity. Better metrics are needed to determine if EPA-ORD is making an impact on the research community. Government Performance and Results Act (GPRA) indices should be examined as well. Accountability of the overall program, sub-programs, and personnel is required.

The BOSC does not recommend any major changes in management structure. However, the success of the PM Research Program depends on continued funding to complete program goals and objectives over the next several years. Congress and the Executive Branch must be continuously updated on research results as they are obtained and provided estimates of public health benefits and control costs for implementing proposed PM ambient air quality standards. Hiring freezes and cyclical budgets are an anathema to a quality research program. The BOSC recommends that EPA do everything in its power to ensure the funding that has been planned and requested for the PM research program, so that ORD can continue to perform quality research that meets the national need in this high priority area.

Chapter 1
Report of the Integration Subcommittee and Response to the Charge

Subcommittee Members: **Costel Denson, Ph.D. (Chair)**
Raymond Loehr, Ph.D. (Vice-Chair)
Carol Henry, Ph.D. (Member)
Jerald Schnoor, Ph.D. (Member)

INTRODUCTION

The U.S. Environmental Protection Agency (EPA) has been directed to develop and implement a greatly expanded, interagency research program on airborne particulate matter (PM). Program expansion benefited from inclusion by Congress of additional funds for PM research above those requested by the President for FY 1998 and FY 1999. The funding by Congress has been contingent upon, and provided at levels consistent with, recommendations prepared by the National Research Council (NRC) Committee on Research Priorities for Airborne Particulate Matter. The scope and magnitude of the research program activities reflect the importance of PM as a public health threat and the need to reduce uncertainties through research. The priority uncertainties identified by NRC include those associated with estimating actual human exposures to PM, identifying components of PM presenting hazard, elucidating mechanisms of PM toxicity alone and in combination with other air pollutants, and characterizing susceptibility, among others. The scope and magnitude of the PM Research Program also present challenges to the EPA to develop and manage a large, complex and effective multi-laboratory/center and multi-disciplinary research program. An Agency team, including Office of Research and Development (ORD) and Office of Air and Radiation (OAR) staff, has managed the intramural program and coordinated extensively with external research organizations. There is a need, given the importance of this Program to the EPA, for the BOSC to provide review and advise the Agency on the management of the PM Research Program.

This report is a response to charges from EPA's ORD to conduct a review of the current management of the PM Research Program. The general charges include:

> Conduct an evaluation of the ORD's management approach to PM research including management structure, vertical and horizontal communication and coordination, emphasizing how the ORD Laboratories and Centers work together to plan and integrate their work; and
>
> Prepare recommendations for improving PM Research Program management.

The specific charges to the BOSC were:

1. Risk Paradigm. Are the ORD Laboratories (i.e., NHEERL, NERL, NRMRL) and Centers (i.e., NCEA, NCER) sufficiently coordinating research across the risk paradigm (e.g., source-exposure-dose-response and management)?

2. Research Priorities. Are the Laboratory/Center research programs integrated to address the highest priority research needs?

3. Communication of Activities. Are the research activities and results sufficiently communicated among the Laboratories and Centers, ensuring maximum leveraging and coordination of research efforts?

4. Communication to the Broader Community. Is there sufficient communication of results to the broader scientific and regulatory communities?

5. Scientific Leadership. Is EPA-ORD providing sufficient scientific leadership within and outside the Agency?

6. Management. Are changes to the management structure and/or processes needed?

Two previous reports by the National Research Council (NRC 1998, NRC 1999) have evaluated EPA research priorities, progress, and portfolio of projects. Tracking EPA's implementation of its multi-year research portfolio developed by the NRC and its PM monitoring programs resides with the NRC and/or with the Clean Air Scientific Advisory Committee (CASAC) of the Agency's Science Advisory Board (SAB). The BOSC effort focuses on internal ORD management of the PM Program and is complementary to these NRC and CASAC efforts. The BOSC examined management and integration of the Program as structured by the risk paradigm, which cuts across Laboratory/Center cooperation, prioritization, and implementation.

Charges were conveyed from Dr. Norine Noonan, Assistant Administrator for ORD, to the BOSC in January 1999. In preparation for the BOSC review of the management of the PM Research Program, the BOSC provided a series of self-study questions to the PM National Research Program Manager (NPM) and to the Directors of the National Risk Management Research Laboratory (NRMRL), National Exposure Research Laboratory (NERL), National Health and Environmental Effects Research Laboratory (NHEERL), and the National Center for Environmental Assessment (NCEA). The BOSC requested development of a self-study document addressing overall programmatic questions posed to Drs. John Vandenberg, National Program Manager, and William Farland, ORD Executive Lead; and specific questions to the various Laboratory/Center Directors, organized into categories of the risk assessment paradigm. EPA-ORD compiled the responses to those questions in a unified self-study document, as provided in the Appendix to this report. Following receipt of the self-study report, the BOSC conducted an onsite Programmatic Review of the ORD Particulate Matter Research Program in Durham, North Carolina, on October 28-29, 1999. This report is the summary of those findings and discussions of the results at BOSC meetings on February 28-29 and May 30-31, 2000, in Washington, DC.

The report is organized into chapters that reflect the BOSC Ad Hoc Subcommittee assignments for the management review of EPA-ORD's Particulate Matter Research Program:

Chapter 1: Report of the Integration Subcommittee and Response to the Charge
Chapter 2: Report of the Exposure Subcommittee
Chapter 3: Report of the Atmospheric Sciences Subcommittee
Chapter 4: Report of the Epidemiology Subcommittee
Chapter 5: Report of the Toxicology Subcommittee
Chapter 6: Report of the Assessment Subcommittee
Chapter 7: Report of the Risk Management Subcommittee.

Major conclusions and recommendations are printed in bold-face type throughout the report and are summarized in the Executive Summary and in the Conclusions and Recommendations at the end of each chapter.

OVERALL INTEGRATION

The findings of the Integration Subcommittee that cut across the six specific charges to the BOSC are in this review are presented below. These are important to the successful integration of the overall PM Research Program.

Management

Based on its programmatic review, the BOSC concludes that the EPA-ORD PM Research Program is well organized and running efficiently. It is truly a model that EPA-ORD may wish to follow for other programs. Examples of a good management structure include the appointment of a National Program Manager and the matrix management of teams that cut across Laboratory/Center boundaries. Research funds flow to elements of the matrix with high priority, and the structure is well understood by managers in ORD. Furthermore, the distribution of "program-driven research" versus "core research" is appropriate to meet the goals of the Agency.

Still, the BOSC recognizes that matrix management has its virtues and its challenges. The PM Program Manager has no lines of authority and has limited staff. The Program depends on strong working groups and continuous coordination among managers. Contingencies and unexpected developments sometimes require immediate action by the National Program Manager to meet urgent needs. **The BOSC recommends that ORD consider approving increased budget authority to its Particulate Matter National Program Manager to ensure that he/she has the flexibility and authority to meet the goals and deliverables of the PM Program.**

Integrated Agency Leadership

In a memorandum to EPA Administrator Carol Browner on July 16, 1997, President Clinton said, *"The EPA, in partnership with other federal agencies, will develop a greatly expanded coordinated interagency PM Research Program. The Program will contribute to expanding the science associated with particulate matter health effects, as well as developing improved monitoring methods and cost-effective mitigation strategies."* To meet this directive, the Board of Scientific Counselors encourages the entire Agency to take responsibility for implementing the Presidential directive.

Coordination across programs requires integrating structures outside of the matrix. For example, integration of results from the global change program and other multimedia programs is necessary to leverage resources and optimize results for co-pollutants. Looking outside ORD to Agency regulatory staff with expertise in PM issues also is critical for the matrix management formulation to be successful. For example, OAR has considerable expertise and controls the air monitoring performed by states. **The BOSC commends the cooperation between OAR and ORD on the PM issue as a model for other programs, and encourages the continuation and fostering of such cooperation in the PM Research Program.**

Considerable effort has been placed on developing the Air Quality Criteria Document (AQCD). Now that it is nearly completed, it is important to look beyond the AQCD and to ensure the long-term success of the PM Program. For overall risk reduction to occur in the United States, EPA needs greater emphasis on mixtures of pollutants and other components of air quality, such as air toxics and ozone. **In terms of management, the BOSC recommends more long-range planning and research investments to ensure the integration of PM with other research needs.** For example, ozone remains a major public health priority; interactions between particulate matter and hazardous air pollutants (HAPs) also may prove to be important.

Metrics and Accountability

The National Research Council has played an important role in shaping the PM Research Program, but EPA is responsible for assuring that the research is useful. Having a multi-year plan that was generated from outside the Agency (NRC, 1999) by an organization with great stature, the National Academy of Sciences, is useful and may serve as a model for other programs with major public health significance. The BOSC questioned whether the Government Performance and Results Act (GPRA) should have been discussed to a greater extent in the self-study document (see Appendix) and whether GPRA can provide useful metrics or indices for managing the PM Program in the future. **The BOSC recommends that the GPRA format continue to be used in multiyear planning and other planning efforts, allowing gap analyses to be performed, and for purposes of monitoring and tracking progress**. Accountability measures need to be developed for the performance of sub-programs and personnel (Program Manager, Principal Investigators, Branch Chiefs, teams) involved in the PM Program. GPRA measures should continually be integrated into the management plan for the PM Program where possible.

Other measures of performance should be tracked to determine if EPA-ORD PM research is making an impact. Do other countries use ORD study results? Are EPA-ORD models, monitoring data, and results considered state-of-the-art by the scientific community? Are EPA-ORD and cooperator publications being cited in *Science Citations Index*? What is the impact rating of the journals in which publications are submitted? **Metrics are needed to determine if EPA research is making an impact; EPA-ORD is in the best position to develop these metrics in consultation with other stakeholders.** Productivity indices used in academia such as publications per full-time equivalent (FTE) and impact factors may help to determine progress as the Agency develops research expertise in new areas; the trend line as well as the absolute magnitude are important. We realize that many measures are already being tracked by EPA including major external awards and prestigious journal publications (*Science, Nature, Cell, Atmospheric Environment*, *Journal of Geophysical Research*, *Environmental Science and Technology*, *Environmental Health Perspectives*, and others). It would be good to make the results available to Principle Investigators, so that they fully understand that good science is greatly appreciated and paramount to the Agency.

Now that ORD has its PM Research Program in place, **the BOSC recommends that a "Gap Analysis" or similar effort at assessing the value of information be performed. This would represent a structured assessment of priorities based on a sensitivity analysis of how information gaps would affect the efficacy of risk management and public health benefits.** The analysis should be updated over time to refine and modify research priorities. Progress by an Agency can be charted as to how problems are solved (risk and uncertainties reduced), and how new priorities emerge. A continuous critical analysis of current hypotheses should incorporate the broadest possible feedback to ensure adequate exploration of alternative and competing hypotheses. In this regard, the BOSC recognizes that Air Quality Criteria Documents are developed and national risk assessments are performed at regular intervals. Such analyses are critical to possible programmatic changes in the direction of the PM Program. Assessment efforts can engage the public, give a clear indication of the status of the PM Program, and identify target research areas to reduce uncertainties.

Communications and Congressional Funding

ORD should make information dissemination a high priority, and Congress should be made fully aware at frequent intervals of the progress of its PM Program.

We recognize that, in lieu of a Congressional reallocation of Science and Technology (ST) monies, it is difficult for EPA-ORD to alter components of its research funding. Improved flexibility in funding allocations is needed. The end of the hiring freeze in 2000 was a welcome development, so that post-

doctoral positions could be allocated within ORD to fill knowledge gaps. However, the BOSC encourages EPA to continue to pursue development of a long-range research plan and assist the Agency in maintaining support for the PM Program. Increasing Congressional line items represent a threat to the long-term stability of the Program and its integration. **The BOSC recommends that EPA and ORD do everything possible to ensure flexibility of funding allocations, so that the Agency can be most responsive to national needs.**

If the Congress, the public, and leaders of industry are to make informed decisions, **EPA needs to transmit good scientific and technical information routinely, and in a manner that is easily understandable**. This is not just an ORD responsibility, but a responsibility of the entire Agency. Innovative ways to disseminate information need to be considered. World Wide Web sites, such as the PM Research Inventory that is being developed by the Health Effects Institute (HEI) for ORD, is a good method for tracking of information and dissemination to the public. It would make sense to have this site hyperlinked with EPA's Web Site.

Following are responses to the six specific charge questions on the Risk Paradigm, Research Priorities, Communication of Activities, Communication to the Broader Community, Scientific Leadership, and Management.

RISK PARADIGM

A brief description of the coordination along the risk paradigm follows. ORD develops information across the entire risk paradigm. In turn, NCEA uses extramural research developed largely through the STAR program in the National Center for Environmental Research (NCER), and research information developed through EPA intramural activities, primarily from NRMRL (for source characterization data), NERL (for exposure and atmospheric sciences data), and NHEERL (for health effects information) to produce the AQCD. The document then is turned over to its client, the Office of Air Quality Planning and Standards (OAQPS) in OAR. NCEA evaluates the world's literature in a particular subject area, such as PM, in the AQCD and prepares a research needs report. In the preparation of these documents, NCEA plays an integrative role in drawing together research findings from NRMRL, NERL, and NHEERL, as well as results from the STAR program and other extramural research (e.g., research conducted by Dutch scientists), and in the future, the five STAR PM research centers. Subsequent to the development of the AQCD, NCEA also plays a pivotal role in supporting OAR in the development the OAR staff paper, and in executive level and external briefings on risk in support of regulatory decision making. Given the key position of NCEA in the risk assessment process, coordination and integration across EPA Laboratories and Offices is critical to success. NCEA's coordination activities and mechanisms appear to be strong.

We are very positive about the overall effort, in particular the long-term planning process for research and research integration. This has resulted in funding the key areas, both (1) fundamental new science (heavily weighted to the extramural program), and (2) integrating, synthesizing, and building consensus on existing science and state-of-the-art science (primarily intramural).

Risk management alternatives currently are receiving too little focus. Although costs need not become part of the risk management process, risk-risk tradeoffs are very relevant and should be given a larger role in both setting research priorities and in thinking about risk management decisions to attain the PM National Ambient Air Quality Standards (NAAQS).

The PM research effort is well coordinated across the risk paradigm. From an organizational perspective, it is clear that a strong effort has been made to ensure the Laboratories are communicating. Over dependence upon the paradigm in shaping the research should be avoided, because the information needs of the public health and regulatory communities are extensive. The broad public health importance

of air pollution should not be obscured by division of the science into the compartments of the risk paradigm.

Within the individual realms of hazard identification and exposure assessment, the programs are well integrated. In the future, cross-integration between these two realms should be given a higher priority (e.g., does-response assessment in both animals and humans).

Animal toxicology and human exposure projects are well coordinated, and clearly are facilitated by the geographical proximity of the animal and human testing Laboratories; both whole animal and *in vitro* studies are being used effectively to guide design and interpretation of *in vivo* animal and human studies. The toxicology program is using relevant PM materials, obtained directly from demonstrated sources, and the PM materials are being used to explore and define relevant hypotheses that relate to possible human health effects. ORD needs to further integrate its epidemiology and toxicology staff as intended. ORD could proceed in a small way down this path now with exploratory studies (e.g., trying to develop exposure models for hypothesized toxic constituents). Such joint exploratory studies would foster communication and integration in the future. Current planning has exposure modeling efforts lagging data collection by a few years. Could they be more synchronous, and could the modeling efforts and documentation be published and made available earlier? **We encourage ORD to explore the use of pilot data for model development and testing.**

It is very important that ORD is starting to work with OAQPS on the Supersites program. There is good coordination with regard to health effects; however, with regard to atmospheric characterization, modeling, and monitoring, this coordination has not been very successful in the past. It is encouraging to see this improving for PM.

There is very good integration along the risk paradigm, especially at the management level and somewhat at the grassroots level, but primarily at the nearest neighbor level. Geographic proximity of the Laboratories in Research Triangle Park (RTP), NC, helps ORD integrate across the risk paradigm, which is very helpful. For those ORD PM researchers who are not proximate (e.g., those located in Reston, VA), this may be a problem. It is unclear if integration along the risk paradigm happens at the investigator level. Postdoctoral rotations might help with this. **ORD should initiate an introductory program for postdoctoral scientists to gain exposure at other key locations within ORD.** Through visits, seminars, or short rotations, they could gain an appreciation and understanding of all parts of the risk paradigm. This would be in addition to the current good practice of having postdoctoral scientists spend time in cooperative agreement laboratories that correspond to their own specializations. This would give postdoctoral scientists both personal and professional links and increase integration across ORD.

RESEARCH PRIORITIES

The Laboratories have heeded the direction of the NRC Reports and research directions are consistent with the guidance of the Academy. Research priorities have not been generated by any formal integrative process that directly identifies value of information. The priorities currently under way in risk management are intuitive. Although they appear sound, adjustments to priorities as initial research results emerge will be more difficult to justify without a more formal value-of-information assessment.

In the past, major data collection efforts have not been followed with appropriate level efforts to use and analyze the data. The example given of setting aside $1.6 million to analyze the $15-20 million effort from the Supersites program shows a continuing problem (a 1:10 ratio is too small). **More emphasis is needed on compilation and analysis of Supersites and monitoring data.**

Incentives for PIs to engage in valuable research are needed, as well as formal metrics to determine when a particular line of research has produced information that indicates "more research is not necessary" to improve Agency and state risk management decisions. In addition, the BOSC notes that there is a potential tension between promotion based primarily on peer-reviewed publications and having a research program that is flexible and responsive to changes in research priorities.

COMMUNICATION OF ACTIVITIES AND RESULTS

Coordination at high levels of the management hierarchy appears to be strong and well structured. Excellent communication networks exist among the Laboratories and Centers for keeping abreast of research results; however, optimum leverage is compromised by fiscal constraints. There is good coordination with OAR/OAQPS to address regulatory needs. This appears to be a lesson learned from the ozone experience.

Communication within ORD among the Laboratories and Centers occurs through an overall matrix structure and team building. The matrix organization and teams represent an impressive attempt to ensure communication.

There should be more interaction with the other programs; for example, the Global Change program will have similar issues (e.g., measurement techniques, impacts, trends, etc.), and more interaction is needed with the Risk Assessment Forum on methods for risk and uncertainty analysis.

The extent of staff level coordination is unclear. We cannot determine if bench-level scientists are knowledgeable of the coordination and integration that are occurring at higher levels. Concerns about this were validated in the previous NERL management review by the BOSC in 1998. In an organization the size of ORD, it must be recognized that investigator communication will be a continual challenge, particularly given the large amount of extramural work.

COMMUNICATION TO THE BROADER COMMUNITY

Impressive efforts are under way to communicate with the scientific community. Through workshop development and sponsorship, the broader scientific community is regularly engaged in sharing results and building consensus for future research directions and hypothesis generation. Communication in workshops and research meetings is an important component of coordinating with the outside community, and ORD is to be commended for the workshops it has organized and for encouraging its scientists to participate in these meetings. These workshops have been successful in reaching the research community. Peer review in these forums is an important component. Coordination (e.g., cosponsoring) of conferences with professional societies might increase the visibility, effectiveness, and regularity of this form of communication, while decreasing costs. **Emphasis should be placed on sharing basic science work, rather than program overviews.**

ORD believes that it maintains a good balance of interest across numerous stakeholders involved with its work. The energy industry and the automotive sectors are representative of the industrial sectors with which ORD interacts. ORD notes that it also interacts with the American Lung Association, public health groups, the National Governors Association, and individual states. **The extent of the interaction is unclear, in particular, with the public health research community.** The importance of ensuring that input is balanced across the various stakeholder groups cannot be overstated.

Web Sites. With regard to Web sites, the key will be their maintenance—keeping them updated and ever green. There should be some ongoing evaluation of the usefulness of the Web site, in addition to the statistics that are collected on an ongoing basis.

Communication of Science to the Regulatory Community. EPA should consider emulating NIH's practice of regularly communicating scientific progress. Other federal agencies, such as NIH, actively communicate their scientific progress in addressing regulatory issues to the general public, to the broader regulatory community, and to Congress. ORD also should consider increasing its efforts in this regard vis-a-vis EPA Headquarters. Little has been said to demonstrate the inclusion of the regulated community and state and local agencies in the research planning process. This is where the translation of research results is most critical.

ORD needs external feedback on the quality of its endeavors, in general and on specific programs such as the PM Program. One form of external feedback is the receptiveness of peer-reviewed journals and researchers to ORD research as shown by the form of publication of that research and citation of it.

LEADERSHIP

EPA clearly has played a leadership role in the area of particle research, particularly through capacity building throughout the academic community. ORD has done a good job integrating with and serving in a leadership role for other research organizations. **ORD leadership on the CENR, especially the Air Quality Research Subcommittee (AQRS), is laudable, and should be continued.** ORD toxicology investigators are well recognized in the scientific community for their leadership on PM toxicology issues. **In toxicology, ORD appears to be providing scientific leadership both nationally and internationally.**

The fact that NCEA is helping to expedite peer reviewed publications in leading scientific journals and that it is holding a major PM conference in conjunction with the Air and Waste Management Association (AWMA)—one of the largest professional societies in the air quality field—attests to ORD's leadership role in the professional community.

There is a concern that ORD is not able to recruit sufficient numbers of young scientists, thereby threatening its ability to sustain scientific leadership. ORD should explore ways of acquiring the resources and means of attracting young, talented staff to augment ORD's current staff. Insufficient information was provided to the BOSC regarding the scientific leadership provided by the professional staff of the Laboratories and Centers to fully assess this issue. However, it is clear that many of them are active and hold leadership roles in the professional communities. In the exposure area, ORD has made some excellent recent hires, though it is short senior staff in some critical areas, such as exposure modeling. To ensure that ORD's productivity in leading the science in this area, and given the recent infusion of postdoctoral scientists, it is important that ORD scientists have appropriate staff support. The NCEA authors of chapters in the AQCD appear to be leading authorities with good publication records. **In other areas, such as epidemiology, ORD is not leading.** For this area in particular, it is unclear whether ORD should develop its own expertise or cooperate with and rely more on other federal agencies that have this expertise, such as the Centers for Disease Control and Prevention (CDC). Some basic level of expertise in epidemiology is needed within EPA ORD, so that scientists in toxicology, exposure characterization, and risk assessment have close collaborators with whom to interact across the risk paradigm.

MANAGEMENT

The PM management structure is exemplary. ORD should stay the course and continually evaluate its results. The overall framework for management that is emerging includes a National Program Manager, matrix management, team approach, committee coordination horizontally, and extensive use of peer review (NRC, CASAC PM Subcommittee, extensive peer reviewed extramural program, and encouragement of peer-reviewed publications), but it is unclear how it is working at the lower levels.

Matrix management does facilitate adaptation to changing needs. For instance, the PM Program management recognized the need to link the ambient air quality monitoring programs with the research needs.

Continuity in the current highly competent and supportive program management should be a high priority planning and development activity. FTE limitations and hiring freezes have impeded the development of capacity in key areas. This is most apparent in epidemiology, although there appear to be staff limitations in other areas as well. **There clearly is a critical need for additional resources to meet the scope of ORD's activities.** Mechanisms to fill these resource gaps are needed.

ORD management should be encouraged to request ST monies to enable effective and timely responses to desirable alterations in components of the ongoing research period, i.e., improved flexibility in funding allocations. Encourage establishment of a contingency resource to rapidly respond to events that have direct and immediate implications for the impact of particle pollution on human health (e.g., forest fires and concerns of relationships of wood smoke to asthma).

There is a need for better public outreach. For example, the advocacy community, local officials, and the general public need to be creatively engaged in shaping priorities and enhancing the translation of results.

Chapter 2
Report of the Exposure Subcommittee

Subcommittee Members: **Jerald L. Schnoor, Ph.D. (Chair)**
Ann Bostrom, Ph.D. (Vice-Chair)
Jana Beth Milford, Ph.D. (Member)
Nancy K. Kim, Ph.D. (Member)

INTRODUCTION

The goal of the BOSC PM Research Program review was to evaluate the management of the PM Program rather than the scientific directions of the program. The following four questions were presented to Dr. Gary Foley, the Director of the NERL, by the BOSC, with the request that he address them with regard to exposure activities across ORD:

Describe how indoor exposures are addressed by the PM exposure research.

Discuss how the exposure efforts relate to (are integrated with) toxicological and epidemiological efforts.

Discuss how ORD is developing the fundamental tools, and staff expertise, needed to assess exposure.

Discuss, with examples, how ORD is addressing the exposure questions included in the NRC reports.

The self-study report addressed these four questions. The BOSC Subcommittee met with members of the EPA-ORD team in Durham, NC, on October 29, 1999. The Subcommittee was briefed by Dr. John Vandenberg, National Research Program Manager for Particulate Matter. The BOSC Subcommittee also met with members of the Exposure team including: Dr. Gary Foley, NERL Director; Dr. Judith Graham, NERL Associate Director for Health; Dr. Ross Highsmith, NERL Branch Chief; Dr. Roy Zweidinger, NERL Branch Chief; Dr. Haluk Ozkaynak, NERL Science Team Leader for Exposure Modeling; and Dr. Linda Sheldon, NERL Science Team Leader for Exposure Measurements.

The ORD human exposure program (conducted predominantly within NERL and the National Center for Environmental Research [NCER], but with ties and inputs from the National Health and Environmental Effects Research Laboratory [NHEERL], National Risk Management Research Laboratory [NRMRL], and National Center for Environmental Assessment [NCEA]) has two major goals: addressing the exposure questions of the NRC as described in Research Topics 1 and 2, and providing exposure-related expertise to NHEERL in its conduct of health studies, especially as related to NRC Research Topics 5 and 8. The goal of Research Topics 1 and 2 collectively is to understand the exposure of susceptible subpopulations to particulate matter (PM) and co-occurring gases of ambient origin that are likely to cause adverse health effects. The primary distinction between the two topics is that Topic 2 focuses on toxic PM species. Achieving this thus requires iterative research within "exposure" and between "exposure" and "health." Methods, measurements, and models are needed, as are inputs from health scientists to identify those PM components that may be most toxic. The goals of Research Topics 5 and 8 are to characterize hazardous PM components and to characterize susceptible subpopulations, respectively. NERL exposure analysis scientists collaborate in these health studies by providing the exposure portion of NHEERL epidemiology studies, characterization of PM before and after the concentration used in NHEERL human clinical and animal toxicological studies, characterization of

particles used in NHEERL mechanism studies, etc. The STAR program also forges such interrelationships, especially through the PM Center grants.

Integration of ORD's PM exposure research across the risk paradigm is essential for ORD to be able to provide national leadership on particulate matter research. Coordination among other offices within EPA, extramural researchers, and other government research agencies is crucial for obtaining the best science in the most cost-effective manner. Integration across the risk paradigm is illustrated by the match between projects in NERL (e.g., as specified in sections 2, 4, 5, and 7 of the NERL research plan—see self-study page 37) and the components specified by NRC in its 1998 and 1999 reports.

ORD's human exposure sciences research is fully coordinated with like research being conducted by outside public and private organizations, both national and international. Formally, this coordination occurs through organizations such as the North American Research Strategy for Tropospheric Ozone (NARSTO) and the Air Quality Subcommittee (AQSC) of the Committee on Environment and Natural Resources (CENR); ORD scientists and managers play lead roles in both of these organizations. A new standing work group of AQSC on PM Research Coordination is being formed with ORD managers as Executive Co-Chair and lead Executive Staff. Informally, exposure research is coordinated through the Coordinating Committee for PM Human Exposure Research and through the NERL PM Research Coordination Team. The Coordinating Committee for PM Research has members from NERL, NHEERL, and academic institutions performing panel studies funded by NERL, ORD's STAR program, the Health Effects Institute (HEI), the Electric Power Research Institute (EPRI), the American Petroleum Institute, and the Mickey Leland National Urban Air Toxics Research Center. The ORD PM Research Coordinating Committee has formal connections to NRMRL, NHEERL, and NCEA.

ORD leadership on the CENR, especially AQRS, is laudable, and should be continued. ORD development of the Federal Reference Method for ambient air quality monitoring of $PM_{2.5}$ also is important. Additionally, we encourage ORD to continue its efforts to bring together the atmospheric science and health effects community for particulate matter exposure research.

It has been suggested that NARSTO be expanded to provide a public/private partnership that integrates the science on the exposure side. This appears to be in the works, but coordinated by HEI, not NARSTO. **ORD should evaluate the choice of coordinating body carefully, with attention to whether HEI has the proper institutional links to make this happen effectively.**

This review focused on the written and verbal responses to the self-study questions submitted by the BOSC to EPA; the Subcommittee's review of the responses is described below. Specific Subcommittee **recommendations are identified by bold type** in the text of the review.

EVALUATION OF RESPONSE TO SELF-STUDY QUESTIONS

1. Describe how indoor exposures are addressed by the PM exposure research.

In terms of managing its research portfolio and answering regulatory questions associated with the proposed $PM_{2.5}$ rule, ORD's current focus on ambient air quality is good. However, the Subcommittee is left with some concerns regarding several aspects of indoor exposure research, including: (a) the lack of emphasis on indoor air source characterization, which will be necessary to support research on statistical and mass balance mixing models to understand the contribution of ambient air versus indoor air; (b) stronger focus on chronic obstructive pulmonary disease (COPD) than other participants in the panel studies, which could lead to critical missed opportunities on other sensitive populations (these studies do include participants with COPD, chronic heart disease, and asthma as well as healthy elderly people and minorities with low incomes); and (c) the lack of expertise in assessing human activities. This is

especially true considering the deletion of a budget for indoor air quality last year. The BOSC understands the need to move towards more exposure-related questions on indoor air, and we appreciate that there has been an expansion of activity in this regard, but we are concerned that previous areas of indoor air research may be forgotten or under appreciated.

There appears to be minimal social science expertise in ORD. Activity studies of susceptible subpopulations such as children and elderly people require such expertise; the survey and research instruments being used have been borrowed from previous studies, and it is not clear to what extent they are receiving adequate peer review. ORD should consider strengthening its social science expertise.

In the three Coop studies described in the response to the self-study questions, the majority of unhealthy participants selected are specified as COPD. **There is a need to link with researchers and projects that cover non-COPD endpoints, to avoid missing opportunities. There is a link to asthma in the Inner-City Asthma study, and there are signs that ORD is moving in this direction, but a more concerted effort is needed.**

2. Discuss how the exposure efforts relate to (are integrated with) toxicological and epidemiological efforts.

The Atlanta pilot study shows the promise of linking monitoring programs with exposure studies. The Aerosol Research Inhalation Epidemiology Study (ARIES) in Atlanta, which involved Harvard, Emory University, and others, received funding from multiple sources (including the U.S. Department of Energy, Electric Power Research Institute, American Automobile Manufacturers Association, American Petroleum Institute, and various utility companies) and is credited with contributing to Atlanta being designated one of the first EPA Supersites. The objective of ARIES was to investigate the relationship between air quality and human health with epidemiological and exposure studies, and to produce results in 2000, in time for the revisions to the National Ambient Air Quality Standards (NAAQS) for PM. **ORD should continue and expand linkages of exposure studies with existing monitoring programs (Supersites, chemical speciation, and the Science to Achieve Results [STAR] programs).** Co-location of various kinds of research at large site studies is a cost-effective strategy to get the best results for the dollars invested.

ORD is trying to integrate its epidemiological and toxicological research, but most of the deliverables are slated for completion and publication 3-5 years in the future. **Perhaps ORD could proceed in a small way down this path now with exploratory studies (e.g., trying to develop exposure models for hypothesized toxic constituents).** These studies would foster communication and speed integration in the future.

ORD coordination with the Office of Air Quality Planning and Standards (OAQPS) already has proved successful in health effects studies. It is essential that the Supersites program be similarly coordinated. On atmospheric pollutant characterization, modeling, and monitoring for other issues such coordination has not been very successful in the past. It is encouraging to see this improving in the case of particulate matter.

3. Discuss how ORD is developing the fundamental tools and staff expertise, needed to assess exposure.

The BOSC senses that there is greater staff satisfaction as a result of being able to follow projects through from conception to completion, and recommend that this continue.

It is unclear if integration across the risk paradigm happens at the level of the bench scientist. We cannot say much about staffing at the principal investigator (PI) level because, although we requested it, we were not able to meet any scientists at this level. We cannot discern if PIs are aware of the coordination and integration that is occuring at higher levels. Concerns about this were raised in the previous NERL management review by BOSC in 1998. **Post-doctorate rotations to key ORD locations might help them to see how their research fits into the "big picture."** This would be in addition to the current good practice of having post-docs spend time in laboratories of cooperators (cooperative agreements with EPA's ORD) that correspond to their own areas of specialization. This would give the post-docs both personal and professional experience and contacts, and it would increase integration across ORD. **ORD urgently needs to fill their existing post-doctorate positions.** Hiring freezes are anathema to staffing. Such freezes could give the EPA post-doctorate program a poor reputation if they result in broken promises.

Geographic proximity of the several PM laboratories at RTP, NC, helps ORD integrate across the risk paradigm. For those ORD PM researchers who are not proximate (e.g., Reston, VA), this may pose a problem.

Regarding staffing expertise, there was concern by the BOSC regarding whether the PM Program has adequate social science expertise (as noted earlier).

Workshops and Research Meetings

Communication in workshops and research meetings is an important component of coordinating with the outside community. ORD is to be commended for encouraging its scientists to participate in these events. Peer review in these forums is critical to a scientifically credible program. **Coordination (e.g., cosponsoring) of conferences with professional societies might increase the visibility, effectiveness, and regularity of this form of communication, while decreasing costs. Emphasis should be placed on sharing basic science milestones, rather than program overviews.**

While the Coordinating Committee for PM Human Exposure Research creates an excellent forum for said coordination, it was unclear to the Subcommittee if recent findings are communicated regularly in that forum. Although we did not have any formal discussions with EPA grantees, it appears that ORD may be missing an opportunity to learn from its grantees and increase communication among them. **ORD should consider making an extra effort to see that STAR grantees present their results to EPA and to one another regularly, given that STAR workshops do not appear to be held annually for all grantees. Those not directly supported by ORD, such as ATSDR grantees, may be unaware of recent progress in extramural ORD research on PM. The HEI Web Site could help with this, and might be expanded to increase cross-Laboratory and cross-Agency communication.**

In the exposure area, ORD has made some excellent recent hires such as the science leads whom we met. **It would appear that ORD is short some senior staff in critical areas, such as exposure modeling. To ensure the productivity of senior staff in leading the science, and given the recent infusion of post-docs who rely on senior scientists for mentoring, it is important that senior scientists have appropriate staff support. ORD needs more staff and administrative support to free-up science leads and Branch Chiefs. If there is an overload of administrators relative to scientists, perhaps new hires should provide clerical and other staff support.**

A good overall framework is emerging for ORD's PM Program, including:

National Program Manager
Matrix management, team approach, committee coordination horizontally

Extensive use of peer review
NRC, CASAC PM Subcommittee, BOSC
Extensive peer reviewed extramural program
Encouragement of peer-reviewed publication

This BOSC Subcommittee was impressed with the overall management framework. The only weakness may be at the first-level scientific positions—the question of whether post-doctorates and bench scientists understand the role that they play in the overall PM Research Program.

4. Discuss, with examples, how ORD is addressing the exposure questions included in the NRC reports.

NRC Recommendations

ORD is following through on the first recommendation concerning exposure, but ORD needs to begin now on the second recommendation as well. Is ORD putting the mechanisms in place now, so that when it does get data, it will be able to use them and truly integrate across the risk paradigm? ORD is conducting studies on hypothesized toxic constituents and exposure panel studies include metals, ultrafine particles, co-occurring gases, etc. NERL and NRMRL are collecting samples to study in some biological test systems. Thus, while a small element of the second NRC recommendation is underway, most of this NRC recommendation is a followup to studies in progress.

Timelines

Current planning has exposure modeling efforts lagging data collection by a few years. Could they be more synchronous, and could the modeling efforts and documentation be published and made available earlier? **We encourage ORD to explore the use of pilot data for model development and testing.**

CONCLUSIONS AND RECOMMENDATIONS

Overall, the Subcommittee was impressed with ORD's success in developing, coordinating, and integrating exposure research on PM. Notable are ORD's leadership in national and international coordination of PM exposure research, and the success of staffing changes, especially the post-doctoral program. Many of the recommendations that follow are simply to continue or strengthen current good practices.

Continue the laudable ORD leadership on the CENR. Continue efforts to bring together the atmospheric science and health effects community for particulate matter exposure research.

Evaluate carefully who should be the coordinating body for integrating exposure science, with attention to whether HEI has the proper institutional links to make this happen effectively.

Evaluate the impact of the lack of emphasis on indoor air source characterization.

Make more concerted efforts to link with researchers and projects that cover non-COPD endpoints, to avoid missing opportunities.

Continue and expand linkages of exposure studies with existing monitoring programs.

Continue efforts to bring together the atmospheric science and health effects community for particulate matter exposure research.

Explore the use of pilot data for exposure model development and testing.

Continue the good practice of allowing staff to follow projects through from conception to completion.

Strengthen social science expertise in ORD.

Provide more staff support for senior scientists, to ensure the productivity of senior staff in leading the science, recognizing that mentoring post-docs is time-consuming and necessary.

Start an introductory program for the post-docs involving rotations through other key locations within ORD so that the post-docs gain an appreciation and understanding of all parts of the risk paradigm (in addition to current rotations).

Consider making an extra effort to see that STAR grantees present their results to EPA and to one another regularly, given that STAR workshops do not appear to be held annually for all grantees. Consider expanding the HEI Web Site to increase cross-Laboratory and cross-Agency communication.

More frequent coordination (e.g., cosponsoring) of conferences with professional societies might increase the visibility, effectiveness, and regularity of this form of communication, while decreasing costs. Emphasis should be placed on sharing basic science milestones, rather than program overviews.

Chapter 3
Report of the Atmospheric Sciences Subcommittee

Subcommittee Members: **Mitchell J. Small, Ph.D. (Chair)**
Murray V. Johnston, III, Ph.D. (Member)
Armistead G. Russell, Ph.D. (Member)

INTRODUCTION

The goal of the BOSC PM Research Program review was to evaluate the management of the Program rather than its scientific directions. The following three questions were presented to Dr. Gary Foley, Director of EPA's NERL, by the BOSC:

1. Describe, with examples, how research in this area is coordinated with other efforts such as NARSTO.

2. Discuss the linkage between research on PM sampling and characterization, and research on modeling the formation, fate, and transport of PM in the atmosphere.

3. Discuss the link between the ORD research program on particle formation and characterization and exposure and health effects research.

The self-study report addressed these three questions. In addition to the meeting with the full BOSC PM review committee and the overall briefing by Dr. John Vandenberg on October 29, 1999, the Atmospheric Sciences Subcommittee met with EPA scientists and managers working in the area of atmospheric sciences, including: Dr. Gary Foley, NERL Director; Dr. Judith Graham, NERL Associate Director for Health; Dr. Jason Ching; Dr. Larry Cupitt; Dr. Kenneth Schere, Chief, Atmospheric Model Development Branch; Dr. Frank Schiermeier, Director, Atmospheric Sciences Modeling Division; Dr. James Vickery; and Dr. Russell Wiener.

PM atmospheric sciences research at EPA ORD addresses topics and disciplines affecting the formation and measurement of ambient PM, including: atmospheric chemistry, air quality modeling, ambient measurement methods development and evaluation, and source apportionment and receptor modeling. This research is necessary to support EPA's efforts to implement NAAQS for PM, including the development and application of models to show the relationship between emissions of primary PM and secondary PM precursors, and ambient PM concentrations, and monitoring methods to both support model development and ensure regulatory compliance. Modeling research includes the study of fundamental processes affecting atmospheric transport and chemistry, the efficient implementation of models in verifiable codes and computing systems, and the testing of models against observed field data. Monitoring methods research addresses both Federal Reference Methods for use in federal and state monitoring networks and new research-oriented methods for better characterization the composition and spatial and temporal distribution of ambient PM.

The ORD atmospheric sciences research program specifically addresses issues raised under NRC Topics 3 and 4[1]

[1] Both of these topics were revised and updated in the second (1999) report of the National Research Council Committee on Research Priorities for Airborne Particulate Matter. *II: Evaluating Research Progress and Updating the Portfolio*.

3. Characterization of Emissions Sources: What are the size-distribution, chemical composition, and mass-emission rates of particulate matter emitted from the collection of primary-particle sources in the United States, and what are the emissions of reactive gases that lead to secondary particle formation through atmospheric chemical reactions?

4. Air Quality-Model Development and Testing: What are the linkages between emission sources and ambient concentrations of the biologically important components of particulate matter?

In addition, the research addresses the area referred to by the NRC as "Technical Assistance," for standard development and implementation.

Although NERL maintains the principal responsibility for atmospheric sciences research within ORD, important contributions also are made by NCER, through the STAR program and the Supersites Research Centers, and NRMRL, through its emissions characterization and source profile research for input to atmospheric models. Interactions with NHEERL and NCEA also are important to ensure that the ambient modeling and monitoring research efforts are focused on the "biologically important" components of PM (see NRC Topic 4 above).

This review focused on the written and verbal responses to the self-study questions submitted by the BOSC to EPA; the Subcommittee's review of the responses is described below. Specific Subcommittee **recommendations are identified by bold type** in the text of the review.

EVALUATION OF RESPONSE TO SELF-STUDY QUESTIONS

1. Describe, with examples, how research in this (atmospheric sciences) area is coordinated with other efforts such as NARSTO.

ORD has provided effective scientific leadership in the area of atmospheric sciences, both in the development of fundamental new science and scientific methods (weighted toward the extramural program) and by integrating, synthesizing, and building consensus on the existing science and defining the state-of-the-art for regulatory assessment (primarily through the intramural program). One mechanism for ensuring leadership for, and coordination with, the broader scientific and regulatory community is through direct research collaboration. ORD has been effective in encouraging collaboration among its scientists and those in academia and other research organizations. These collaborations have, in the past, often been primarily with universities located near the particular EPA research Laboratory or Center. The STAR program provides opportunities for EPA scientists to interact with a broader, more geographically dispersed set of collaborators. **In addition to the productive collaborations with local universities, EPA scientists should be encouraged to expand their interactions to include a broader set of outside scientists, through collaboration with STAR grant recipients and other venues.**

EPA's scientific leadership on the PM issue is evident in its role in a number of outside activities and forums, including NARSTO, which is "a public/private partnership," whose membership spans government, the utilities industry, and academia throughout Mexico, the United States, and Canada. Its primary mission is to coordinate and enhance policy-relevant scientific research and assessment of tropospheric pollution behavior." (For a further description of NARSTO, see http://www.cgenv.com/Narsto/whatisnarsto.html.) While originally formed to address issues of ozone in North America, the organization has since expanded its research coordination agenda to include PM and other regional air pollutants.

EPA plays a major and leading role in NARSTO at both the scientific and managerial levels, and this appears to be having a very positive impact on how the Agency is managing the PM Program. For example, Ken Schere is a major contributor to the NARSTO assessment, and has been allowed to spend considerable time in that role. This has provided increased interaction to better understand the directions in which the community outside of EPA is moving. ORD also is playing a major role in the CENR, coordinating at the upper level management of the research. EPA coordination at the international level (beyond North America) is hampered somewhat by limitations on foreign travel—it is much easier for ORD to bring scientists from Europe and Asia to the United States for meetings than it is for EPA scientists to attend meetings overseas (e.g., in the Federal Republic of Germany, FRG). **Given the growing need for international collaboration in efforts to understand and manage atmospheric PM and related air pollution issues, EPA's leadership role in science planning would be strengthened via greater participation of EPA scientists in international meetings. In particular, the U.S.-FRG meetings are a bit sporadic and have not been directed at PM as much as ozone, and further focus on PM issues should be explored in this forum.**

2. Discuss the linkage between research on PM sampling and characterization, and research on modeling the formation, fate, and transport of PM in the atmosphere.

Sampling and measurement methods development and evaluation research is conducted in three ways: by NERL scientists, by STAR grant recipients, and by manufacturers. At the current time, NERL primarily evaluates methods for regulatory purposes, while external groups develop and evaluate research methods, as well as potential methods for future regulatory use. This arrangement of the research portfolio is appropriate because it builds upon the strengths of each sector. In the past, there has appeared to be relatively little interaction at the scientific level; this should change, and appears to be doing so, with the advent and expansion of the Supersites program. **It is important for EPA scientists to continue to take a key participatory role in the Supersites Centers, with the objective of having continued, detailed, in-house knowledge and access to expertise on the state-of-the-science in sampling and measurement methods research and how those techniques can be used to support EPA's mission.**

The issue of good interaction among EPA scientists and STAR grant recipients in the area of atmospheric sciences is of general importance. Although research activities and results are currently well coordinated across ORD Laboratories and Centers, some gaps appear in the level of interaction between STAR grant recipients and intramural researchers. These interactions appear to have occurred on more of an ad hoc basis, due to previous knowledge or experiences between the researchers, rather than as a result of consistent and well-coordinated efforts to ensure interaction. **More concerted effort is needed to ensure interaction between the full set of STAR grant recipients involved in PM research and EPA intramural researchers.**

Similarly, there appear to be opportunities for greater interaction between the ORD PM Program and other research programs, including the global change program (where PM measurement, trends, and impacts also play an important role) and broader research programs on chemical risks and risk assessment, where again ambient monitoring programs and air pollution modeling are a key component of assessment. **Additional effort is needed to ensure synergy and exchange of information between the ORD PM Research Program and related programs on global change and chemical risk assessment.**

At present, it is a bit early to fully assess the overall linkage between the sampling/characterization research and the modeling research in EPA's atmospheric sciences research program because both are in their early stages of implementation. EPA has shown that it is laying the foundation for that linkage and there are activities that show that the two communities at EPA are interacting. (Examples include emissions groups and receptor modelers discussing how to take measurements, participation on the Supersites steering committees, and urging the STAR grantees to cooperate directly with Supersites

researchers to target their research for modeling needs.) Because most of this represents what will be future efforts, it is important to assess at regular intervals how well these linkages are working. EPA is putting a lot of stock into the PM Supersites and Centers to provide an integrated effort between the PM characterization and the exposure/health effects research. Because most of this research will be conducted in the future, EPA must monitor and assess the effectiveness of the planned linkages.

One area where further improvement may be needed involves the relative allocation of funds for data collection and analysis. The example of setting aside $1.6 million to analyze about $15-20 million of data collection effort in the Supersites program (a 1:10 ratio, which is too small) suggests a continuing problem. Experience by members of the Subcommittee with data collection programs for particles and other air pollutants suggest that as much time and effort is needed to provide for effective compilation and interpretation of data as is required to collect the data in the first place. Although most data collection programs do involve a significant amount of interpretation by the investigators involved, and the Supersites program should be no exception in this regard, the potential for broader and more extensive use of the data is often unrealized. To provide the opportunity for such use, ratios (of subsequent application and interpretation budget to collection budget) closer to 1:4, or even 1:3, are considered to be preferred. Failure to provide adequate resources for data application and interpretation could specifically inhibit the ability of EPA to attribute observed PM concentrations (and suspected associated health effects) to specific sources of PM, and limit the ability to provide the tools needed by the states and the regulated community to best manage PM air quality. **More effort is needed to ensure that adequate resources are available for, and allocated to, the application and interpretation of data collected in major field studies such as Supersites. A higher proportion of resources should be allocated to the data analysis efforts that follow data collection.**

The ability to link research on ambient monitoring methods and atmospheric modeling is especially important for the practical planning and implementation of NAAQS compliance strategies. Much of the contribution of the EPA will come about through integration, consensus building, and application of existing science in these areas, and not necessarily through new science development. The efforts of EPA in this regard have been very good, with especially effective interactions indicated with the air office—OAR/OAQPS. In this regard, the research and program arms of EPA appear to have learned lessons from some of the previous, less-than-optimal experience at integrating their efforts in addressing the ozone issue.

3. Discuss the link between the ORD research program on particle monitoring and characterization and exposure and health effects research.

ORD has, through its Supersites program, encouraged particle characterization and monitoring researchers to interact with health effects researchers, e.g., to sample key constituents in the atmosphere of interest to health endpoints, has sponsored/cosponsored meetings to bring the two communities together, and has organized its internal resources to help integrate its research. In general, the Subcommittee is pleased with the degree of interaction and linkage that is evident. Although there is already significant grass-roots interaction at the "nearest neighbor" level (and this is apparent throughout ORD's program, e.g., between source and ambient concentration research, between ambient concentration and exposure, between exposure and dose and dose-response groups), greater communication among groups and laboratories at the scientist level across the *entire* risk paradigm could be further encouraged and facilitated. One example would be for the atmospheric modelers and emissions researchers to interact with those involved in dose studies. Efforts to initiate and encourage inter-laboratory projects also would help in this regard. For example selected scientists could be appointed with joint affiliation with two Laboratories, so that they can facilitate scientific communication between them. To a degree, individuals changing Laboratories can accomplish this, though this appears to be limited at this time. Another approach would be to more fully utilize integrated assessments, from emissions through atmospheric

sciences, exposure, and health effects, as a basis for organizing selected PM meetings and colloquia, explicitly identifying how the outputs from particular research efforts serve as inputs to others, as well as their specific input and importance to the overall assessment exercise. **More should be done to encourage interaction of EPA scientists at the grass- roots level across the full risk paradigm, using mechanisms such as joint appointments in EPA Laboratories or Centers, and more explicit emphasis on integrated assessment as an organizing framework for research input and coordination.**

The lack of awareness and appreciation for the broader opportunities for interaction across the full risk paradigm appears to be most serious among STAR grant recipients. These grantees have not always been aware of the opportunity for participation in major PM colloquium meetings. **A more explicit effort should be made by STAR Project Officers to encourage grant recipients working on PM issues to participate in the major PM colloquia.**

CONCLUSIONS AND RECOMMENDATIONS

The following major findings and recommendations are drawn from this evaluation of the ORD atmospheric sciences research program. These findings and recommendations are organized around the five questions posed by ORD to the BOSC for consideration in our evaluation of this program:

1. Are the ORD Laboratories (i.e., NHEERL, NERL, NRMRL) and Centers (i.e., NCEA, NCER) sufficiently coordinating research across the risk paradigm (e.g., source-exposure-dose-response and management)?

ORD's PM Research Program is very well coordinated along the risk paradigm, especially at the management level. Reasonable coordination also is apparent at the grass-roots level among EPA scientists and grant recipients; however, this appears to be limited mostly to nearest neighbor interactions (e.g., between source and ambient concentration research, between ambient concentration and exposure, between exposure and dose and dose-response), with less awareness, appreciation, and broader opportunities for interaction across the full risk paradigm. This is particularly true among STAR grant recipients, who have not always been aware of the opportunity for participation in major PM colloquium meetings.

More should be done to encourage interaction of EPA scientists at the grass-roots level across the full risk paradigm, using mechanisms such as joint appointments in EPA Laboratories or Centers, and more explicit emphasis on integrated assessment as an organizing framework for research input and coordination.

A more explicit effort should be made by STAR Project Officers to encourage grant recipients working on PM issues to participate in the major PM colloquia.

2. Are the Laboratory/Center research programs integrated to address the highest priority research needs?

The ORD research programs are very well integrated to address the highest priority research needs. Coordination with regulatory needs is especially good as a result of effective interactions with OAR/OAQPS. One area where further improvement may be needed involves the relative allocation of funds for data collection and analysis.

It is important for EPA scientists to continue to take a key participatory role in the Supersites Centers, with the objective of having continued, detailed, in-house knowledge and access to expertise on the state-of-the-science in sampling and measurement methods research and how those techniques can be used to support EPA's mission.

More effort is needed to ensure that adequate resources are available for, and allocated to, the application and interpretation of data collected in major field studies such as Supersites. A higher proportion of resources should be allocated to the data analysis efforts that follow data collection.

3. Are research activities and results sufficiently communicated among the Laboratories and Centers, ensuring maximum leveraging and coordination of research efforts?

Although research activities and results currently are well coordinated, some gaps are apparent in the level of interaction between STAR grant recipients and intramural researchers. These interactions appear to have occurred on more of an ad hoc basis, due to previous knowledge or experiences between the researchers, rather than consistent and well-coordinated efforts to ensure interaction. Similarly, there appear to be opportunities for greater interaction between the ORD PM program and other research programs, including the global change program (where PM measurement, trends, and impacts play an important role) and broader research programs on chemical risks and risk assessment.

More concerted effort is needed to ensure interaction between the full set of STAR grant recipients involved in PM research and EPA intramural researchers.

Additional effort is needed to ensure synergy and exchange of information between the ORD PM Research Program and related programs on global change and chemical risk assessment.

4. Is there sufficient communication of results to the broader scientific and regulatory community?

EPA has established and maintained very good interactions with the broader scientific and regulatory community involved with the PM issue. This is especially true *vis-a-vis* scientists at universities local to the ORD research laboratories.

In addition to the productive collaborations with local universities, EPA scientists should be encouraged to expand their interactions to include a broader set of outside scientists, through collaboration with STAR grant recipients and other venues.

5. Is EPA-ORD providing sufficient scientific leadership within and outside the Agency?

ORD has provided effective scientific leadership, both in the development of fundamental new science (weighted toward the extramural program) and integrating, synthesizing, and building consensus on existing science and defining the state-of-the-art for regulatory assessment (primarily through the intramural program). This leadership is evident in their role in outside organizations such as NARSTO. EPA leadership and coordination at the international level could be strengthened through greater participation of EPA scientists in international meetings.

Given the growing need for international collaboration in efforts to understand and manage atmospheric PM and related air pollution issues, EPA's leadership role in science planning would be strengthened via greater participation of EPA scientists in international meetings. In

particular, the U.S.-FRG meetings are a bit sporadic and have not been directed at PM as much as ozone, and further focus on PM issues should be explored in this forum.

Chapter 4
Report of the Epidemiology Subcommittee

Subcommittee Members: **Thomas A. Burke, Ph.D. (Chair)**
William E. Cooper, Ph.D. (Vice-Chair)
Jerald A. Fagliano, M.P.H., Ph.D. (Member)
Richard W. Clapp, Ph.D. (Member)

INTRODUCTION

The goal of the BOSC PM Research Program review was to evaluate the management of the PM Program rather than its scientific directions. Epidemiologic studies of air quality and human health have provided the public health basis for the Clean Air Act and the regulation of PM. Strong scientific capacity in epidemiology is essential to the success of the ORD PM Research Program. The Epidemiology Subcommittee for the BOSC review was Chaired by Dr. Thomas A. Burke, Vice Chaired by Dr. William Cooper, and included Dr. Richard Clapp of Boston University and Dr. Jerald Fagliano of the New Jersey Department of Health and Senior Services. The review focused on the three questions presented below. Written responses to these questions were submitted to the BOSC by ORD prior to the review. The findings also are based upon overview presentations from the PM management leaders, as well as detailed discussions with researchers from the Epidemiology and Biomarkers Branch and the Clinical Research Branch within the Human Studies Division, and the Pulmonary Toxicology Branch and the Immunotoxicology Branch within the Experimental Toxicology Division.

EVALUATION OF RESPONSE TO SELF-STUDY QUESTIONS

1. Describe how the EPA's epidemiology efforts are integrated with those of NIH, NIEHS, and CDC.

The epidemiologists of the Human Studies Branch have made a concerted effort to integrate their efforts with other involved agencies. However, it is important to keep in mind that the Environmental Protection Agency (EPA), the National Institutes of Health (NIH), the National Institute of Environmental Health Science (NIEHS), and the Centers for Disease Control and Prevention (CDC) have different priorities, mandates, and research agendas. These divergent missions inevitably limit integration of epidemiology research efforts on any particular topic, including PM research. Furthermore, the Committee on Environment and Natural Resources (CENR) is just now formalizing its interagency Standing Work Group on PM Research Coordination. More effective integration of epidemiology efforts are now being planned and executed with CENR oversight, however, it is too soon to evaluate the success of those efforts at this time.

There currently are interagency agreements with NIH, specifically the National Institute of Allergy and Infectious Diseases (NIAID), on the Inner City Asthma Study, where EPA has successfully integrated an environmental monitoring component onto an on-going project. In addition, there is an interagency agreement with CDC on a U.S.-Mexico border air pollution epidemiology study. There also are some informal individual collaborations between EPA epidemiologists and NIEHS or CDC researchers which seem to be well-integrated on specific clinical epidemiology issues. However, EPA has limited epidemiologic capacity to be involved in more extensive collaboration and integration with the other federal agencies at this time. It is recognized that most of ORD's research in epidemiology is of necessity extramural, but increased intramural expertise should be developed to ensure proper communication and understanding among PM toxicologists, epidemiologists, and other researchers on the problem.

Some attempts at collaboration between EPA and CDC have begun but have not progressed because programmatic priorities at CDC precluded further work. Similarly, a potential collaboration between EPA and NIEHS on gene-environment interactions has not progressed because of limited capacity at EPA in the genetic epidemiology area. For similar reasons of limited capacity, EPA has not been able to integrate with PM epidemiology research efforts by other stakeholders, such as State agencies, or to take advantage of surveillance data that might inform or enrich EPA research.

In spite of limited staffing and in-house epidemiologic capacity, EPA ORD has made impressive gains over the past year to integrate its PM epidemiology research efforts with those of other federal agencies. With the development of the CENR Work Group, these gains can be expected to continue over the next several years.

2. Describe ORD's capacity to address epidemiological issues.

The ORD capacity for epidemiological research resides primarily in the National Health and Environmental Effects Research Laboratory's (NHEERL) Epidemiology and Biomarkers Branch (EBB) in the Human Studies Division (HSD). There is a growing appreciation of epidemiology in the PM Research Program. Within the HSD, there is a small cadre of epidemiologists with diverse and complementary backgrounds. The group was described by the Laboratory Director as "lean and mean," and it is apparent that they have made excellent progress in establishing an excellent foundation for PM activities.

The greatest need in the area of epidemiological research is for additional personnel. Enhancing expertise and credibility will be difficult in the face of the growing demands for PM research. At the present time, there are only four full-time equivalents (FTEs) devoted to the PM work, and eight total investigators including those with other research responsibilities. Adequate administrative and technical support staff also are essential to assure the timeliness and quality of the work. Given the importance of epidemiology to evaluating human health risks of PM, and evaluating the efficacy of risk management efforts, the current number of FTEs is not adequate.

According to the NHEERL Laboratory Director, given the realities of fiscal and personnel constraints, it is not likely that the ORD epidemiology capacity will grow in size to rival similar groups at the CDC or the National Cancer Institute (NCI). However, it must be recognized that the ultimate credibility of science at EPA requires that the Agency achieve a level of excellence and leadership in environmental epidemiology equal to those programs. Increasing EPA responsibilities to address noncancer health effects, evaluate cumulative population risks, and develop human health indicators, will only increase the demands upon the HSD.

Formal cooperative efforts with Public Health Service agencies and university-based epidemiologists provide a mechanism to enhance the ORD capacity. The HSD has established some strong working relationships with the PM Centers, and is reaching out to establish others. Outreach to the State Epidemiologists has been initiated, and represents a potentially important step forward not only for ORD, but also for states, where there also is a critical need for developing capacity. To assure active collaboration, cooperative agreements should be considered. A number of ORD researchers have stated that cooperative agreements provide greater encouragement for collaboration than grants.

At the present time, there is a dearth of well-trained environmental epidemiologists. This is a major impediment to the Agency's efforts build capacity in epidemiology. Improved support for environmental epidemiological training is essential to the long term success and credibility of epidemiology at ORD.

3. Describe the extramural epidemiological research that EPA is funding.

Extramural epidemiological research is funded through interagency agreements, cooperative agreements, and grants. Agreements are generally developed and implemented through NHEERL and other EPA Laboratories, while grants are administered through the National Center for Environmental Research (NCER).

At present, there is a limited amount of extramural epidemiological research funded through interagency or cooperative agreements. Through an interagency agreement with NIAID, ORD (NHEERL) is providing supplemental funds and actively collaborating in a PM component to the Inner City Asthma Study sponsored by NIAID and NIEHS. ORD also has an interagency agreement with the CDC to support epidemiological studies of air pollution, including PM and other copollutants, along the U.S.-Mexico border. With the National Exposure Research Laboratory (NERL), NHEERL is contributing funds to support a health effects component to a study of PM exposure in patients with cardiovascular and pulmonary disease.

ORD also sponsors extramural research through the STAR program coordinated by NCER. The role of NHEERL in this granting process is to assist in the preparation of Requests for Applications (RFAs) and to provide "relevancy review" of proposals that have passed scientific merit review by ad hoc peer review panels. Grant awards under STAR have been made to establish five academic Airborne Particulate Matter Research Centers, each of which have capacity and plans for conducting epidemiological research. In addition, ORD has made grants to other institutions for epidemiological research on PM.

The overall scope of the extramural research program appears to be largely determined through the grant process. While this process encourages creative approaches to study, it also limits the ability of ORD to ensure the development and implementation of a tightly integrated PM Research Program. It also limits the ability of ORD/NHEERL scientist to actively collaborate, monitor, and affect the direction of research conducted by grantees.

Extramural epidemiological research activity is likely to increase as funds expand in coming years. This will increase demands on the limited number of NHEERL scientists. Additional intramural resources are needed to ensure that the overall research agenda for epidemiology remains focused and adaptable to changing priorities.

CONCLUSIONS AND RECOMMENDATIONS

Building leadership, excellence, and capacity in epidemiology is essential to the success of the PM Research Program.

ORD has succeeded in building an outstanding core staff for PM epidemiology.

Although the expertise of current researchers and managers in epidemiology is excellent, the current staffing levels for epidemiology within the Human Studies Branch are not adequate to meet the increasing intramural and extramural research needs of the PM program.

Specific management goals for the appropriate balance between intramural capacity and extramural research need to be developed.

The small size of the current epidemiology staff impedes ORD's capacity to integrate throughout the agency, oversee and participate in extramural research, and actively pursue opportunities for collaborative efforts with other agencies.

Chapter 5
Report of the Toxicology Subcommittee

Subcommittee Members: **Dr. James S. Bus, Ph.D. (Chair)**
Frederick J. Miller, Ph.D. (Member)
Hanspeter Witschi, Ph.D. (Member)

INTRODUCTION

Toxicology is an integral research component in the overall evaluation of the potential public health effects associated with PM exposure. The strength of toxicology studies is the ability to explore and test hypotheses establishing the plausibility of suspected human effects induced by PM. This review focused on the written and verbal responses to three self-study questions submitted by the BOSC to EPA; the Subcommittee's review of the response is described below. Specific Subcommittee **recommendations are identified by bold type** within the text of the review.

EVALUATION OF RESPONSE TO SELF-STUDY QUESTIONS

1. How, using examples, is the National Health and Environmental Effects Research Laboratory (NHEERL) research program addressing the toxicology questions included in the NRC report?

The NHEERL research program is effectively coordinated and integrated at a management level within the NRC health-related Research Topics 5-9. In particular, the toxicology program is effectively using relevant PM materials obtained from realistic field situations.

Animal toxicology and human exposure projects are well coordinated, and are clearly facilitated by the geographical proximity of the animal and human testing laboratories. Both whole animal and *in vitro* studies are being used effectively to guide design and interpretation of *in vivo* animal and human studies. **Attention needs to be directed to ensuring that dose-response information is available for the inhalation toxicology studies (both humans and animals).** The coordination and integration within the Utah Valley Study and Baltimore and Fresno Field studies are excellent examples of intra- and inter-Laboratory/Center activities. In the future, **management integration of exposure studies on susceptible subpopulations (NRC research topic 2) to effects (NRC research topic 8) is desirable.**

2. How is NHEERL research addressing both the strengths and weaknesses of *in vitro* and *in vivo* experimental models (or proposed to be used) in supporting assessments of potential human health effects of PM?

Efforts to integrate *in vitro* and *in vivo* studies in animals and humans have been successful. The above-mentioned Utah Valley Study could well serve as a model for similar endeavors in the future. **Management needs to ensure that investigators use *in vitro* systems in a way that capitalizes on the strengths of such systems and minimizes their weaknesses.** The primary strengths of such systems are the ability to explore and refine understanding of mechanism(s) of action of chemical and particulate toxicity at the cellular level. The value of information from such *in vitro* studies for use in risk evaluations, however, must always be considered within the context that organism-level toxicity responses are significantly impacted by the added complexity of cell-cell and cell-organ-physiological-toxicokinetic influences.

Development of long-range research management plans that deliver appropriate research results in needed timeframes should be continued, and will be essential for maintaining continued Congressional support for the technically complex PM program.

Communication of the strengths and implications of the research to the scientific community-at-large has been excellent, and has contributed to the recognition of NHEERL toxicologists as leaders in the PM research efforts. These external outreach efforts need to be continued to assure that current hypotheses are constantly scrutinized and challenged. The conduct of biomedical research is increasingly complex, requiring investigator interactions and exploitation of research information across multi-disciplinary research teams to fully understand the human health implications identified from animal and cellular toxicity studies. The data and information being generated by ORD's STAR program offers an opportunity to potentially improve the ability of NHEERL toxicology investigators to rapidly and effectively incorporate relevant toxicity information into the design and interpretation of NHEERL-based research studies. **Management should develop effective mechanisms to enable appropriate collaborations with investigators funded through the STAR program.** For example, such mechanisms might include creation of opportunities for regular face-to-face meetings of EPA and STAR investigators addressing related research hypotheses, ultimately leading to improved study designs and mutual sharing of research study materials and information.

3. How is the toxicology research program being coordinated with human exposure characterization efforts?

The animal toxicology research is well coordinated with the Agency's human clinical studies. Comparable endpoints are being addressed in many of the projects. A strength of animal toxicology studies is the ability to explore and test hypotheses establishing the plausibility of suspected human health effects induced by PM. Highly invasive methods can be used in animal toxicology studies. PM materials are being used to explore and define relevant hypotheses that relate to possible human health effects. Both *in vitro* and *in vivo* animal models are being used and developed to investigate postulated mechanisms of PM-induced tissue damage and disease. Characterization dose-response assessments in both animals and humans will be essential for defining plausible causation of potential PM-induced human health effects. Thus, **management needs to continue to support the assessment of a broader array of endpoints in the animal studies so that an assessment of the full range of potential PM effects can be elucidated.** Such efforts also will lead to mechanistic understandings of PM effects.

Extensive characterization of particles in CAPS studies is important for gaining insights on potentially putative constituents. Although access to well-characterized community PM sources is being effectively coordinated, **management needs to foster effective cross-laboratory analytical efforts to support the timely integration of particulate analytical data into toxicology studies.** Access to analytical data is critical for selection of appropriate dose and test material.

Excellent communication networks exist between the Laboratories and Centers for keeping abreast of research results. **Optimum leverage is compromised, however, by fiscal constraints, including adequate funding for assuring regular face-to-face investigator interactions.** These include not only interactions within the EPA research laboratories but also interactions with external investigators engaged in related research activities.

The toxicology program is using relevant PM materials, as is seen from the Utah Valley Studies. This PM material was obtained by creatively exploiting an historical exposure episode. **Adequate laboratory and fiscal resources should be available to rapidly respond to unanticipated events that have potential value in assessing the impact of particle pollution on human health (e.g., forest fires and concerns of relationship of wood smoke to asthma)**.

Management should be supportive of flexible allocation EPA S&T monies (e.g., re-allocations between R&D and Supply and Equipment budgets) to address not only general research needs but also unanticipated research or external environmental events.

CONCLUSIONS AND RECOMMENDATIONS

The following conclusions and recommendations were extracted from the text in this chapter:

The NHEERL research program is effectively coordinated and integrated at a management level within the NRC health-related Research Topics 5-9.

Attention needs to be directed to ensuring that dose-response information is available for the inhalation toxicology studies (both humans and animals).

Management integration of exposure studies on susceptible subpopulations (NRC research topic 2) to effects (NRC research topic 8) is desirable.

Management needs to ensure that investigators use *in vitro* systems in a way that capitalizes on the strengths of such systems and minimizes their weaknesses.

Development of long-range research management plans that deliver appropriate research results in needed timeframes should be continued.

Management should develop effective mechanisms to enable appropriate collaborations with investigators funded through the STAR program.

The animal toxicology research is well coordinated with the Agency's human clinical studies.

Management needs to continue to support the assessment of a broader array of endpoints in the animal studies so that an assessment of the full range of potential PM effects can be elucidated.

Management needs to foster effective cross-laboratory analytical efforts to support the timely integration of particulate analytical data into toxicology studies.

Optimum intra- and inter-laboratory leverage of researcher communications is compromised by fiscal constraints, including adequate funding for assuring regular face-to-face investigator interactions.

Adequate laboratory and fiscal resources should be available to rapidly respond to unanticipated events that have potential value in assessing the impact of particle pollution on human health (e.g., forest fires and concerns of relationship of wood smoke to asthma).

Management should be supportive of flexible allocation EPA S&T monies (e.g., re-allocations between R&D and Supply and Equipment budgets) to address not only general research needs but also unanticipated research or external environmental events.

Chapter 6
Report of the Assessment Subcommittee

Subcommittee Members: **Rae Zimmerman, Ph.D. (Chair)**
Marilyn Brown, Ph.D. (Vice-Chair)
Lauren Zeise, Ph.D. (Member)

INTRODUCTION

The goal of the BOSC PM research review was to evaluate the management of the PM Research Program rather than the scientific directions of the program. NCEA is one of the two centers located within ORD. NCEA's headquarters is in Washington, DC, and it has offices in RTP, NC, and Cincinnati, OH. The main mission of NCEA with respect to PM is to prepare the AQCD mandated under the Clean Air Act. NCEA conducts research as well as research needs assessments for PM that emerge during the development of the AQCD. Research emanating from this needs assessment is used as a basis for subsequent AQCDs. NCEA also has a close connection with the development and review of the *Staff Paper* on related regulatory issues produced by OAR.

This is a review of EPA's management of the PM risk assessments. Specifically, the Subcommittee addressed the following issues:

1. The methodological approach being used in the risk assessment for PM.

2. The integration of results from the intramural and extramural research programs into the assessment.

3. The incorporation of advice/recommendations contained in the BOSC Program Management Review of NCEA into the PM program.

The Assessment Subcommittee met on October 28-29, 1999, and continued the discourse thereafter via e-mail and telephone. This review is based on:

Presentations by Dr. John Vandenberg, National Research Program Manager for Particulate Matter (NPM).

A Subcommittee meeting with NCEA Director, Dr. William Farland, and NCEA RTP Division Director, Dr. Lester Grant.

A subsequent meeting with selected members of the NCEA staff, RTP Director Grant (in charge of the overall preparation of the AQCD), Chon Shoaf (responsible for NCEA planning), NCEA criteria development staff, Allan Marcus, David Mage, Larry Folinsbee, and William Wilson.

Documents provided by NCEA or prepared previously by the BOSC listed in the reference section of this chapter.

The Subcommittee's review of the self-study response is described below and the specific BOSC **recommendations are identified by bold type** in the text of the review.

EVALUATION OF RESPONSE TO SELF-STUDY QUESTIONS

1. What is the methodological approach being used in the risk assessment for PM?

The PM standard reflects an important public health concern and is a high priority for the Agency. Multiple major risk assessment documents are related to the revision of the PM standard: (1) the PM AQCD (e.g., U.S. EPA, 1996a), which provides the health effects assessment including exposure-effect relationships; (2) the PM *Staff Paper* (e.g., U.S. EPA, 1996b), which summarizes PM sources, atmospheric fate and transport, exposure, health effects, and dosimetry information and provides determinations regarding the adequacy of the current PM standard; and (3) the *Research Needs* document (e.g., U.S. EPA, 1998) delineating data and knowledge gaps identified during the development of the AQCD and research strategies to fill them. The PM AQCD and *Research Needs* documents are developed by NCEA, while the *Staff Paper* is developed by OAQPS, which is within OAR. Standard-setting and some aspects of the AQCD development process, such as the formal Clean Air Scientific Advisory Committee (CASAC) peer review of the AQCD, are Congressionally mandated. Due to its public health importance and the economic impact of regulatory action, the processes and products of the AQCD development are heavily scrutinized by the regulated and public health communities, states, Congressional staff, and others. Overall, NCEA appears to be doing a very good job managing the development of the PM AQCD and the *Research Needs* document, and the process for developing the *Staff Paper* appears sound.

Planning the Content of the PM AQCD

As explained by the Agency, the process begins with internal discussion and identification of critical issues to be addressed in the AQCD, including those identified by the NRC (NRC, 1998). This is followed by scientific workshops targeted at exploring critical issues. Research needs also are considered and intramural and extramural research may be initiated to develop critical missing data. A plan to develop the criteria document then is drafted and circulated to the CASAC for review and comment; it also is made available to the public for comment. The plan is revised as needed with the planned approach widely disseminated within EPA. This approach to planning the AQCD appears to be a good one. The apparent close working relationship with CASAC and the input from the NRC appear to be quite beneficial. One improvement to the planning process identified by the Subcommittee entails the active participation of OAR during the problem formulation phase of the risk assessment process. In particular, **the BOSC encourages in depth discussions between NCEA and OAR staff at the early stages of the assessment process, regarding the possible structures for the PM standard and the type of research and risk characterizations required to support the rulemaking for the different structures**. This now occurs at the end of the AQCD cycle, during the development of the *Research Needs* document (e.g., U.S. EPA, 1998). Thus, should an improved structure be identified that is not sufficiently supported by research and the AQCD, it will not be implemented until the subsequent AQCD cycle. **NCEA also should review its approach to consider other related issues during the problem formulation phase of the risk assessment process**. In this regard, the Subcommittee refers the Agency to a recent NRC publication on this topic (Stern and Fineberg, 1996).

A second area where improvement is needed involves consideration of health effects from PM exposures in the context of other co-occurring pollutants such as ozone. **To the extent feasible, the BOSC recommends establishment of a process whereby the PM reviews are conducted with reviews of other pollutants.** This process will ensure that analysts consider exposures to PM in the presence of other important hazardous and criteria air pollutants. The research and data analysis plans reflect this broader focus.

AQCD Development

Currently, the Agency is taking special care to coordinate the timelines for release of results from its extramural and intramural research programs and AQCD revisions. The timeline for development of the AQCD, along with the large number of entities involved, impose limitations on efficient use of grant, contract, and EPA research resources. **The BOSC recommends further strengthening of the connection between NCEA, other parts of the ORD research program, and other research resources to further improve the AQCD development program.**

Each chapter of the current PM AQCD is authored by senior scientists from NCEA, academia, and EPA Laboratories, many of whom have specialized and extensive expertise in the chapter topic. **The BOSC strongly endorses the use of such talented and experienced scientists in the drafting of the AQCD. As detailed below, the BOSC believes the maintenance of critical scientific expertise within the Agency is essential and that steps are needed to ensure continuing scientific excellence in AQCD development.** EPA noted that rather than providing the encyclopedic literature reviews of some past AQCDs, it develops an analytic review focused on critical scientific issues for the health and dosimetry characterizations. The BOSC agrees with this approach and notes that this underscores the need to maintain a highly talented and experienced staff.

The analysis and distillation of data that must occur in characterizing PM dose-effect relationships and hazards involves considerable scientific expertise and judgment. To make this process more transparent, NCEA should clearly articulate and communicate the process used in conducting such analyses.

Peer Review

Peer review of Agency work products and plans occurs at many levels and points in the AQCD development cycle. EPA engages both formal and informal peer review, depending on the nature of the document or issue. As is Congressionally mandated, the AQCD undergoes formal peer review through the CASAC, a standing committee of the EPA Science Advisory Board. Depending on the topic, the committee is augmented by consultants, with some of the same consultants across reviews to achieve continuity. In addition to the AQCD, at the Agency's discretion, other documents relevant to the establishment of air quality criteria are reviewed by CASAC, including the AQCD development plan, *Research Needs*, and the *Staff Paper*. The public also has the opportunity to comment on these documents; scientist peers in the regulated and public interest communities frequently exercise this opportunity. In addition to formal CASAC reviews, the Agency conducts workshops on the individual AQCD chapters and provides further opportunity for public comment. Finally, the Agency actively sponsors other forms of scientific peer review—it convenes scientific workshops and symposia, supports staff scientists to attend and present their PM work at other scientific meetings, informally requests review of work in progress by peers, and conducts intramural lecture series.

The BOSC commends EPA for its approach to peer review of PM research and risk assessment products. It also notes the importance of ensuring high-quality reviews. **The BOSC encourages the Agency to remain vigilant in its selection of venues and reviewers to ensure that fair, objective, and in-depth reviews occur both in fact and appearance.**

Record of AQCD

Impressively, NCEA maintains an extensive, readily accessible record of AQCD development and proceedings. This includes indexed copies of all publications relied upon in the AQCD, all comments and letters submitted to the Agency on PM AQCDs, and responses to these comments and letters. The

synthesis of findings and the references (not the publications) relied upon in AQCD development are made available on CD ROM.

Resources

The Agency has considerable experience in assessing PM exposures and health effects. Staff members are quite capable, some with extensive expertise in PM assessment and with excellent publication histories and standing in the scientific community. It is essential to maintain and build upon this scientific capability to maintain the quality of the AQCD.

More effective use of post-doctorate appointments is desirable. With 3-year appointments and the possibility of subsequent hiring, they provide an excellent mechanism for bringing in younger capable and highly trained staff to provide the scientific leadership in the AQCD program of the future.

The BOSC recommends that the Agency continue to support scientific work and professional development of staff. Cooperative research and development agreements are a good mechanism to enhance expertise of existing staff. Currently, staff appears to be functioning under tight time constraints and a large workload, and additional staff is clearly desirable. Administrative and management support are needed to recruit able young investigators into the group. EPA also should attempt other remedies. Greater rotation of Laboratory staff into the criteria development group is needed, but may require inducements to convince Laboratory staff to join in the effort. Another suggestion to increase the criteria group's scientist capabilities is through joint appointments between the Agency and universities.

2. How are the results from the intramural and extramural research programs integrated into the assessment?

Like ORD in general, NCEA depends upon workshops, organizational meetings, conferences (a lot of discussion occurs at poster sessions, which have a laboratory-level focus), reports (briefings and pre-meeting notes report), e-media, and other means of exchange for generating or obtaining research information. ORD is depending heavily upon the Web-based inventory of research that HEI has developed in collaboration with EPA. This inventory is now available online at http://www.pmra.org.

ORD also depends on many of these same methods to integrate research into the assessment. For example, the process of developing the AQCD heavily involves outside expertise through professional societies. Papers from the PM 2000 conference held by the Air and Waste Management Association (AWMA) with sponsorship by EPA and others, will undergo expedited peer review by several journals, because EPA primarily relies on peer-reviewed articles in the development of the AQCD. The journals include, for example, the *Journal of Air and Waste Management* (JAWMA), *Inhalation Toxicology*, and the *Journal of Exposure Analysis and Environmental Epidemiology*.

When the staff members were asked how they actually distill all of this information into the AQCD, they responded that expert judgment is used in part, and sometimes, for epidemiological studies, meta-analysis is used. NCEA underscored the fact that they are acquiring new statistical methods to evaluate studies better.

To ensure that secondary data incorporated into the AQCD is of highest quality, NCEA consults with individual authors and tries to acquire the underlying data to verify the published findings. Getting access to the data, however, often has proved difficult. They cited the example of the attempt to obtain data from the Harvard six cities study. Ultimately, the data had to be given to an independent third party, HEI, which then evaluated the data independently for EPA. Engaging a third party for independent review is

clearly preferable to having no review, but in general, **the BOSC recommends the establishment of a clearer data exchange protocol to enable NCEA to verify the results of outside studies as needed.**

A major NCEA product is the *Research Needs* for risk assessment that takes into account intramural and extramural research and external inputs from meetings, workshops, and conferences. The latest NCEA report is entitled, "Particulate Matter Research Needs for Human Health Risk Assessment to Support Future Reviews of the National Ambient Air Quality Standards for Particulate Matter" (U.S. EPA, 1998). The report serves as an intermediary between the research to be conducted and its integration into the criteria document and assessment. The NCEA Director indicated that they plan the *Research Needs* report 2 years prior to the preparation of the AQCD so that it can explicitly provide inputs to the document. In the case of PM, the 1998 *Research Needs* document will be an input into the Year 2000 PM AQCD. The Director indicated that the research needs assessment is vetted by the CASAC. He noted that the research needs identified affect funding decisions of other groups, such as HEI and NARSTO.

EPA's intramural and extramural PM research seems to work hand in hand. That is, much of the intramural research appears to link to an extramural research project. Intramural and extramural research are guided by the priorities outlined by the NRC (1998, 1999). The NPM, Dr. Vandenberg, pointed out that after the PM standards were established, Congress doubled, at the expense of other EPA programs, the PM budget in 1998 and 1999, but required EPA to contract with NRC to identify priorities for near- and long-term research. The 1998 and 1999 reports are two of what will be five NRC publications. So there is an expectation that EPA's work on PM will be aligned with what the NRC recommends and discussions with EPA staff suggest this will be the case. It is within this overall context that intramural and extramural research is conducted, and as such, is the context within which NCEA synthesizes this research in the AQCD.

That the NRC reports shape ORD research in general and the research upon which NCEA relies in particular, was illustrated by an example provided by Dr. Vandenberg. The first NRC report, he pointed out, was very critical of the fact that particulate monitoring was not supporting the research community. As a result of this observation, the OAR and ORD became more formally integrated. They adopted an adaptive management style—a team matrix approach that already existed within ORD. This group was able to make monitoring design recommendations for the Supersites Program (characterization of ambient environment in five to seven locations throughout the country).

Intramural Research

ORD's internal grants program is the major vehicle for generating research by staff within NCEA. The NCEA Director, Dr. Farland, indicated that overall 40 percent of NCEA's time is spent upon internal grants. The Director indicated he reserves 10 percent of his research funds to the internal grants program. This is his discretionary decision. Of the $15 million for grants, $1.5 million is reserved for internal grants (for all program areas). Of the $1.5 million, $500,000 is for PM research. The Director believes that internal grants keep the staff sharp, and develop their resources. Discussions with a recent recipient of one of these grants indicate that this is a worthwhile practice.

Extramural Research

NCEA has a variety of different sources for generating extramural research. The STAR program and the Laboratory-based research center grants are two examples. Interagency agreements are another means of generating extramural research. The ORD staff indicated that EPA worked with the National Institute of Allergy and Infectious Diseases (NIAID), for example, on the inner city asthma study. ORD also can use cooperative agreements with universities.

These programs can provide the basis for integrating research into the assessments, because they potentially can enable a large amount of interaction between internal research staff and researchers external to the agency. Whether this interaction is actually occurring was difficult to ascertain explicitly for NCEA.

NCEA incorporates extramural research in general into the AQCD in a series of stages involving a public airing of the Center's work. First, workshops are held at which researchers have the opportunity to provide inputs. Second, the criteria document development plan is produced, which identifies what NCEA will include in the AQCD. This is provided to the public and the CASAC for comment. In addition, NCEA takes draft chapters through peer-review workshops and public comment. No problems with this process were identified.

The STAR Program

The STAR program is the largest resource commitment to EPA's PM program other than the ORD staff, and it is targeted to complement ORD's capabilities. For the PM Program, the Requests for Applications (RFAs) also are designed to address key hypotheses. In addition to contributing to the specification of the RFAs, NCEA also is involved in the relevancy review of STAR grant proposals. These interactions should be helpful in promoting STAR research that adds value to NCEA's work. Whether or not they are sufficient is still an open question.

The STAR research supports many aspects of the PM program. While it was stated that the STAR grants generally do not appear to provide a great deal of support to meeting risk assessment research needs, two examples of valuable STAR grants were described. One STAR grant produced instruments to measure the semi-volatile and non-volatile components of particulate matter. These instruments were used in a follow-on critical study of heart-rate variability in dogs. A second STAR grant was awarded to Harvard University to continue development of a particle concentrator.

Five research centers have just received funding from ORD STAR grants: Harvard, New York University, the University of Rochester, University of Washington, and a consortium led by the University of Southern California. It is too early to tell the value of the Centers' contributions to the ORD PM assessment. However, the EPA Laboratories and Centers, including NCEA, have had considerable input into the preparation of the RFAs. For this reason NCEA believes there is a high probability that the grant research will be useful for the PM AQCD. **As the STAR funded research proceeds at the five university centers, ORD should develop a process to actively interact with them and to ensure that the research produced is useful to the assessment process.**

Staff Input

In discussions with the staff, some areas of ongoing research that could not be fully integrated into the current assessments were evident: (1) the role of co-pollutants and their modulation of PM levels and health effects, (2) the role of co-pollutants in model selection (NCEA currently has a cooperative agreement with the University of Washington National Research Center for Statistics and the Environment on this problem), (3) exposure measurement errors, and (4) methods to relate pollutant concentrations with sources and health effects. Some of these were valuable examples of how research needs from the 1997 AQCD were identified and carried forward for the Year 2000 AQCD. However, due to the time between the initiation of research and the publication of results, the research may not impact this cycle of criteria document development, but would be available for a future AQCD.

3. Have the advice/recommendations contained in the BOSC Program Management Review of NCEA been incorporated into the PM Program?

The NCEA self-study report identified and addressed five recommendations in the BOSC Program Management Review of NCEA. The Subcommittee compared these to the list in the Management Review and found that they matched the general areas covered in the recommendations with the exception of benchmarking, which was not addressed. How each of these five recommendations have been incorporated is described below.

Improved integration and alignment of NCEA's strategic plan and activities with the direction and priorities for the ORD Plan and the better communication of priorities to NCEA staff.

A draft NCEA Strategic Plan was prepared in early October 1999. It is now being reviewed internally and will be revised. NCEA staff indicated that NCEA strategic directions in the plan are linked closely to the ORD Strategic Plan 2000 and to program-specific strategic plans (e.g., exposure). It identifies future human resource needs.

NCEA has clearly made PM research one of its highest, if not its highest priority. This is reflected in its allocation of human resources. A dozen full-time staff primarily devote their time to the PM AQCD. It also is reflected in the numerous activities it has underway as part of the PM process.

An NCEA Web Site also has been developed. This will facilitate communication of strategic priorities to NCEA staff and externally.

Increased understanding of client needs.

NCEA appears to maintain a close relationship to what it regards as its key client, the OAR. See recommendations under Question 1 for enhanced interactions.

Improved project planning and tracking of progress toward accomplishing goals meeting client needs.

NCEA has developed a three-tiered system for tracking the progress of individual documents, where the tiers reflect the level of importance of the document.

The system of the Government Performance and Results Act (GPRA) goals and objectives also is adding rigor to the NCEA system of tracking progress. According to the PM Program Manager, monitoring of progress is expanding rapidly. A process is being developed by which EPA commits to an annual list of performance goals and performance measures. EPA is going beyond the 2-year GPRA period to 8 years—the period needed to achieve both standards setting and standards implementation. **The BOSC supports the attempt to expand the GPRA planning period to a much longer period, because it encourages a more effective use of resources.**

GPRA's major goal is clean air (GPRA goals are outcome oriented). GPRA annual reports for the Agency are required. The first one is due in March 2000.

The timeline for the PM AQCD is well specified. At least two of the following PM milestones are GPRA subgoals; therefore, these milestones are likely to be closely monitored:

External Review Draft of AQCD: October 1999
CASAC Review Public Meeting: December 1999

Second External Review Draft: June 2000
CASAC Review: September 2000
Revised PM AQCD: December 2000

The timeline for the PM regulatory activity also is clear:

2000: Revised PM AQCD
2002: NAAQS decision
2005: Revised PM AQCD
2007: NAAQS Decision
2010: $PM_{2.5}$ Standards Implemented

Given the relatively frequent cycle for criteria development and the multiple criteria, the current staff resources and the depth of the criteria document, the extent of deliberation on scientific issues may become increasingly jeopardized.

Integration and communication within and across NCEA, ORD, the Agency, federal agencies, and the broader general scientific community.

Within NCEA Units

NCEA has three divisions, each at different geographic locations: Washington, DC, RTP, and Cincinnati. Each location has a director. Resource needs are generally shared among the locations, however, resources that augment staff are concentrated in Washington, DC. For example, all of the American Association for the Advancement of Science (AAAS) Fellows are located in DC. The Subcommittee did not uncover any particular problems associated with communication among the various divisions. The Subcommittee was unable to fully explore the issue of the allocation of scarce resources among the different locations.

Across ORD Units

The PM Program Manager emphasized that ORD works through teams, and illustrated the large number of teams within the Office. NCEA, however, was not listed as a participant on any of the teams mentioned. **The BOSC recommends that the PM Program Manager reconsider the team composition to determine if greater NCEA involvement would be valuable.** However, the PM Program Manager convenes weekly telephone communications, and several NCEA staff members are present at those meetings.

An important example of interaction and communication among the EPA Laboratories occurs with respect to the temporary transfer of personnel among the Laboratories as needs arise.

Within the Agency

NCEA incorporates generic exposure information into the AQCD. OAQPS, which is officially responsible for the PM *Staff Paper*, develops a separate exposure assessment document. NCEA and that regulatory office appear to work closely. Indeed, given the close working relationship between NCEA and OAQPS in the preparation of the *Staff Paper*, opportunities for staff exchanges between these offices should be explored. Early consideration of emerging regulatory issues in the development of the *Research Needs* papers and the AQCD could be advantageous and would be facilitated by such exchanges.

Across Federal Agencies

NCEA is a major participant, through its Director, in CENR, which consists of representatives from numerous federal organizations, many of whom apparently have no history of interacting. The U.S. Department of Energy (DOE), National Oceanic and Atmospheric Administration (NOAA), and EPA representatives report to the ORD Assistant Administrator (AA) through the Air Quality Research Subcommittee, and the NCEA Director is the Executive Co-Chair of the PM Research Coordination Working Group of the Subcommittee along with a representative from the National Institute of Environmental Health Sciences (NIEHS).

The Scientific Community

NCEA interacts with the broader scientific community through many of the mechanisms identified earlier under Question 2 above for identifying and integrating research into assessment.

Acquiring appropriate human resources and expertise to ensure appropriate high quality scientific inputs to NCEA assessments.

NCEA obtains human resources and expertise for its work from a number of different sources.

The Director indicated that NCEA has a total staff of 180—100 are located in Washington, DC (of which 25 are within the Director's office); 35 are in the RTP office under the RTP Division Director's direction, roughly split between assignments to the Criteria Document program and Air Toxics; and about 30 are located in Cincinnati.

A team of approximately a dozen full-time staff members works on the AQCD along with others on detail from other EPA Laboratories and under Interagency Personnel Agreements (IPA). However, this group is not working entirely on the PM AQCD. They also are devoting some time to working on the carbon monoxide AQCD. When the list of authors and contributors to the AQCD are counted, the number more than doubles. The production of the AQCD is concentrated in RTP under the RTP Division Director. He can draw upon staff in NCEA's Washington, DC, and Cincinnati offices if necessary. **More incentives are needed to ensure that staff members from the different NCEA divisions are drawn upon by individual divisions when needed.**

During interviews with staff in the Environmental Criteria and Assessment Office and NCEA Director Farland, a shortage in human resources became evident. Staff work on multiple assessments. In some key areas, there is insufficient in-house expertise, so the expertise must be obtained externally. Although in general staff typically is working on a number of different things at one time, the PM effort involves staff predominantly dedicated to the PM AQCD at this time. However, given the timeline and the extent of work required, the effort appeared to be understaffed.

In addition to deficiencies in the numbers, particular expertise deficiencies are apparent, requiring the use of external experts as main authors. For example, there are only a few epidemiologists within NCEA, and there is very limited expertise in immunological effects. Extramurally, ORD tries to target the STAR investigators to complement intramural capabilities. As mentioned previously, the STAR program is the largest research commitment above and beyond the resources supporting NCEA's staff.

When asked about what areas of expertise require reliance on external resources, the Director responded that it varies for different documents. For PM, much of the epidemiology is conducted externally. The internal expertise in epidemiology is insufficient to cover key areas and important pollutants. As a general management issue, the Director believes that the main disciplines are covered, such as toxicology,

exposure assessment, and epidemiology, but the coverage is not deep enough. The scientific staff, therefore, is in part doing the work and in part managing professional services agreements for the outside contractors to supplement NCEA expertise. In certain key areas, such as epidemiology, greater in-house expertise would be beneficial. However, it must be acknowledged that epidemiologists need to, in general, conduct epidemiological investigations to retain their expertise. Thus, if they are only relegated to working on criteria documents, over time their expertise will diminish. Analogous situations will apply to some of the other scientific disciplines. **The Agency is encouraged to explore solutions to this dilemma, such as joint appointments between academic institutions and the EPA criteria development group or between this group and EPA research programs.**

Contracting

For the preparation of AQCDs in general, 40 percent of the staff are from outside NCEA; for the PM AQCD, 30 percent are outside NCEA. Clearly, there is a greater emphasis on in-house expertise for the PM AQCD. The Director stated that critical issues are better defined by in-house staff, and the Subcommittee agrees, especially given the short time period for this cycle of the PM AQCD development. Most of the budget, however, is understandably directed toward PM research—the dollars primarily go outside of NCEA's Environmental Criteria and Assessment Office (ECAO). A relatively small augmentation of the criteria development budget to increase staff size by 5-10 individuals could potentially render significant improvements to the criteria program in general, and the PM program in particular. A relatively small redirection of external monies to the criteria program would redress this need.

The staff clearly indicated a need for direct, external contracting of well-defined and circumscribed tasks. They believe that contracting is the only way to get a specific answer on a specific date. Over the past 10 years, a dramatic shift has occurred to move away from contracting and toward grants and cooperative agreements. Thus, the Agency has apparently less control for particular defined tasks. Although the Subcommittee was unable to fully explore this issue, it notes the value of having in place an easily applied contracting mechanism.

Obstacles to contracting were noted. Because scientists' expertise is not fully utilized when they must primarily oversee contract work, contract specialists are needed to serve as Contracting Officers, with senior scientists serving as advisors and providing general oversight for technical content.

Staff Transfers Between the Laboratories and NCEA (Temporary Assignments)

It would be helpful to rotate, on specialized assignments, more people in from the EPA research Laboratories to the NCEA AQCD development effort to take advantage of the specialized, scientific expertise within the Laboratories.

Post-Doctorates

NCEA does not have many post-doctorates. In general, NCEA and the ECAO at RTP have difficulty attracting qualified post-doctoral candidates with the necessary expertise. In a recent attempt to recruit post-doctorates, NCEA received 40 applications of which only 2 were legally qualified, that is, they had finished their Ph.D. and were an American citizen or legal immigrant. It is difficult to bring in foreign applicants because it must be established that the candidate is uniquely qualified to fill the specific area of expertise needed.

The staff indicated that NCEA has a total of only four to five post-docs. Three are in the DC office, one is in Cincinnati, and one is in RTP, primarily involved in the PM issue. Post-doctorates are attracted to the

research Laboratories more than NCEA where they can continue their academic research. This again is an area to consider creative partnerships with laboratories and universities and working with the administrative staff to overcome institutional barriers to implement promising solutions. **The Subcommittee recommends the effort and use of creative mechanisms to obtain more post-doctorates be continued and expanded.**

CONCLUSIONS AND RECOMMENDATIONS

Strengths

The Subcommittee was impressed by the magnitude and diversity of NCEA's work and the importance and very central position of its function given its limited resources. The BOSC also was impressed by NCEA's track record in producing high-quality criteria documents. The overall planning process for the PM AQCD, including the mechanisms for incorporating research in the document, were considered good approaches.

The Subcommittee regarded as a strength the fact that the Director plays such a central role in Agency-wide and inter-Agency work in the PM area through the CENR. Within ORD, the NPM and the NCEA Director seem to have a close working relationship on several committees and with respect to other aspects of the matrix management system.
The Subcommittee found that NCEA has made considerable progress in incorporating the advice and recommendations contained in the BOSC Program Management Review of NCEA into the PM program. NCEA has developed a strategic plan, made PM research a very high priority, and developed communication mechanisms in the form of the Web site. It maintains a close relationship to its key client, OAR, and has developed a mechanism to track its progress on criteria documents.

Recommendations

AQCD Development and Review Mechanisms

In depth discussions between NCEA and OAR staff at the early stages of the assessment process are encouraged, regarding the possible structures for the PM standard and the type of research and risk characterizations required to support the rulemaking for the different structures.

NCEA should review its approach to consider other related issues during the problem formulation phase of the risk assessment process.

To the extent feasible, the BOSC recommends establishment of a process whereby the PM reviews are conducted with reviews of other pollutants.

The BOSC recommends further strengthening of the connection between NCEA, other parts of the ORD research program, and other research resources to further improve the AQCD development program.

The BOSC strongly endorses the use of talented and experienced scientists in the drafting of the AQCD. The BOSC believes the maintenance of critical scientific expertise within the Agency is essential and that steps are needed to ensure continuing scientific excellence in AQCD development.

The BOSC encourages the Agency to remain vigilant in its selection of venues and reviewers to ensure that high-quality reviews occur both in fact and appearance.

The BOSC recommends the establishment of a clearer data exchange protocol to enable NCEA to verify the results of outside studies as needed.

The techniques that are being developed to expedite the synthesis of scientific information, such as the advanced statistical techniques that NCEA described, should be watched carefully and implemented as a means to expedite reviews where information is scarce.

Resources

The Subcommittee recommends the effort and use of creative mechanisms to obtain more post-doctorates be continued and expanded.

The BOSC recommends that the Agency continue to support scientific work and professional development of staff through cooperative research and development agreements and greater rotation of Laboratory staff.

The BOSC supports the attempt to expand the GPRA planning period to a much longer period, because it encourages a more effective use of resources.

As the STAR funded research proceeds at the five university centers, NCEA should develop a process to actively interact with them and to ensure that the research produced is useful to the assessment process.

More incentives are needed to ensure that staff from the different NCEA divisions are drawn upon by individual divisions when needed.

The BOSC emphasizes that proactive means be explored to expand the resources targeted to PM within NCEA. This is critical given the scope and centrality of its responsibilities for producing the AQCD and related materials. NCEA synthesizes an enormous amount of technical information from the other EPA Centers and Laboratories in the process of producing the AQCD and inputs to the *Staff Paper*. It plays a unique role in seeing that the risk assessment paradigm that links the various stages of environmental fate and transport, exposure, and health effects, is carried forward into the process of establishing PM standards. This can occur through a closer relationship with the newly established PM Centers, inter-Laboratory/Center transfers, greater access to post-doctorates, and through contract work. This can be accomplished better via improved communication between NCEA and the rest of ORD and the Agency. The channels that already have been established within the matrix management system could be used to enhance such communication. The Subcommittee recommends that such improved communications be undertaken.

The AQCDs are regarded within the scientific community as high-quality scientific documents. To some extent this status is threatened by the increasing workload, short timeframe, and limited ability to recruit and retain new scientific talent. Some augmentation of budget for modest increase in staffing as well as creative administrative solutions to bring academic and research scientists to the criteria group on a temporary, periodic, or shared basis should be given careful consideration.

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Chapter 7
Report of the Risk Management Subcommittee

Subcommittee Members: **Michael C. Kavanaugh, Ph.D., P.E. (Chair)**
Bonnie McCay, Ph.D. (Vice-Chair)
Anne Smith, Ph.D. (Member)
Cliff Davidson, Ph.D. (Member)

INTRODUCTION

The Risk Management Subcommittee was charged with conducting a management review of the National Risk Management Research Laboratory's (NRMRL) participation in the $PM_{2.5}$ research program. The following report summarizes the findings and recommendations of this Subcommittee.

NRMRL is one of three EPA Laboratories charged with conducting the $PM_{2.5}$ research program. The PM researchers, found in all branches of the Air Pollution Prevention and Control Division, are guided by a PM team headed by Gene Tucker (represented during the management review by Doug McKinney). It is our understanding that the ultimate goal of the $PM_{2.5}$ research program is not to generate data or fill gaps but to advance the understanding of what is necessary to reduce risks to human health and the environment.

NRMRL's PM research activities are focused primarily on two research areas: (1) emissions characterization, and (2) emissions control technology. These two areas provide, in part, information essential for risk management analyses of regulatory options for control of $PM_{2.5}$. Our Subcommittee found it difficult to understand the role of risk management in the $PM_{2.5}$ research program, and in particular, the precise role of NRMRL, whose primary mission is conducting risk management related research programs. The organizational role of NRMRL within the $PM_{2.5}$ program was well defined in a management diagram provided to the BOSC, at least in terms of the line structure and the position of PM researchers within it. However, risk management has not been identified as one of the 10 priority research areas by the NRC, which would suggest a modest role for NRMRL in the overall $PM_{2.5}$ research effort. Furthermore, previous NRC recommendations on the use of risk assessment in the federal government, (NRC, 1983) are very explicit on the need to maintain clear distinctions between risk assessment and risk management activities of federal agencies. Thus, our Subcommittee recognized the inherent limitations on inserting risk management concerns into a research program whose mission is driven by the risk assessment paradigm. Nonetheless, as we elaborate in the following discussion, it is our opinion that risk management issues can play a larger role in the $PM_{2.5}$ Research Program than the role described to us during this management review.

FINDINGS AND RECOMMENDATIONS

1. Breadth of Coverage. Our Subcommittee sees the need for a more global consideration of long-term research strategies for NRMRL. For example, the research should go beyond the immediate expertise of NRMRL personnel if such work is needed to advance our understanding of risk reduction.

   Current risk management research generates information on emission characterization and control technology, which can be used by OAQPS and the states. **We recommend that NRMRL focus on increasing the scope of information provided in this area, in particular how different PM constituents may increase or decrease with different control measures**.

In response to a question about the incorporation of human behavior into the "holistic" framework of EPA, we heard various accounts, including that EPA always has been reluctant to venture into an area that might suggest regulation of private property and behavior (such as with respect to indoor air pollution) and that EPA's incorporation of human dimensions is limited to studying human activity patterns (with respect to exposure questions). **We recommend that the PM program leaders enlist team and PI members in rethinking the boundaries of holistic frameworks, with a view toward recognizing the human element, even for areas traditionally focused on engineering.** To our minds, risk management also requires improved scientific knowledge of human behavior and social and economic institutions because of their strong effects on sources, prevention, and compliance.

2. Basis for Setting Research Priorities. The priority-setting process occurs at two levels: "Agency" and "Laboratory." Neither has a formal risk-based approach to priority setting. The NRC has provided guidance on priorities, but the NRC cannot be expected to refine these priorities given the scope of the NRC review. The staff pointed to the Agency's "needs document" that is produced when the criteria document is finalized as a source of information on overall Agency research priorities. However, this document apparently does not formally use risk analysis to set priorities. The staff reasoned that at the "Laboratory" level, they have good intuition about important research needs that they then communicate to the Agency planning process.

   We recommend that "what if" scenarios or sensitivity analyses would be helpful in identifying benefits and tradeoffs from risk control/management programs. Sensitivity analysis and value-of-information analysis using a pro forma risk assessment, for example, could create a clearer linkage between risk management and research needs. This cannot be expected of NRC, but EPA and its Laboratories/Centers can engage in more formal analysis of value of information.

3. Stopping Points. The stopping points for individual research projects need to be better defined. A danger is that projects, once decided upon, will continue indefinitely. Criteria for evaluating research success in producing new knowledge for better managing risks, and whether and when to shift resources to other areas of research are not evident. **We recommend that the Agency take concrete steps to continually evaluate the value of continuing individual areas of research once they have been initiated. A formal value-of-information process will help determine when research has been sufficient.**

4. Interaction with External Research Groups. Although NRMRL personnel appear to be acquainted with relevant PM research groups outside of EPA, new opportunities are developing that may enhance the value of NRMRL research. These include the Research Centers funded by EPA, especially the Supersites. A key goal of the Supersites Program is to establish research monitoring sites to characterize chemical composition and sizes of PM, to develop improved PM instrumentation, and to link PM information with source emissions and health effects data. The new instrumentation proposed for use at the Supersites will provide chemical composition and size information at high resolution, greatly enhancing the ability to conduct source-receptor modeling. As suggested by NRMRL personnel, teaming with the Supersites may provide information on whether the improved resolution permits significantly better control decisions.

5. Accountability. Accountability and authority are unclear. One apparent example that we noted is that the PM team leaders are said to be held accountable but lack either line or budget authority. This seems to be an awkward management arrangement, although we were told that it works. The team approach appears to be working despite ambiguous and awkward management structures; numerous examples of effective integration were offered.

6. Communication. Reorganization of ORD in 1995 has made a significant difference to communication among the various branches, but there is still room for improvement. Staff report that cooperation is at a historic peak; the slope is in the right direction. The general impression is that staff seems to be interacting positively.

   Research coordination with other groups occurs mainly between the "source" and "exposure" components of the paradigm, such as in a new collaboration between NRMRL and NERL on source apportionment; and between NRMRL and NHEERL on PM producing toxicity (where NRMRL does sample extraction, NHEERL does toxicity testing). Although this particular connection came about in a serendipitous way, rather than as a result of planning and needs assessment, it is apparent that renewed efforts have been under way to identify areas of collaboration between the Laboratories in this research area. These efforts should at a minimum be maintained.

7. Incentives. We were informed that promotion decisions generally follow the academic model, relying heavily on publication in peer-reviewed journals and individual development of national and international scientific reputations. Willingness to collaborate and to modify programs to address changing priorities may be hampered by narrow application of the academic model for promotion and advancement. A researcher gains more material for publication through long-term commitment to a single line of research. If one is rewarded for one's publication record, one will naturally be averse to shifting to new lines of research that may have heightened priority for the broader policy process. Similarly, researchers may naturally gravitate towards research areas that appear to be fertile ground for new and publishable findings, and these areas will not necessarily coincide with priorities for better risk management decisions. **We recommend that the Agency carefully consider how to align incentives created by promotional criteria explicitly with good programmatic priorities, even if this may mean lesser adherence to an academic view of excellence.**

8. Integration and Relevance of NRMRL. More focused involvement of NRMRL in risk management may be on the horizon, via the planned development of Risk Management Evaluation (RME) frameworks. PM is one of four pilot RME subjects. RMEs can be thought of as hypothetical scenarios for different control strategies, generating estimates of risks. RMEs might be supposed to help clarify the tradeoffs and consequences of choices of control technology and techniques. Insufficient information was provided to evaluate exactly what NRMRL intends RMEs to be and how they will function. However, RMEs could be implemented in a way that serves as the beginning of a concept to identify the decision value of research results. We recognize that the RME concept is still undergoing development and that applications of this methodology to $PM_{2.5}$ research will be exploring uncertain terrain. However, the potential benefits of this approach support aggressive development. **Therefore, we recommend that the RME concept be developed as soon as possible even in a pro-forma or preliminary manner, to show how the individual NRMRL projects would provide input for an evaluation of the efficacy of this concept. It is important to do this even before it is possible to know what actual research results will be and just how results would be used.**

EVALUATION OF RESPONSE TO SELF-STUDY QUESTIONS

1. Describe the role of risk management [research] in directing the priorities of the $PM_{2.5}$ research program.

At the time the BOSC posed this question, the BOSC was using the term "risk management" in the broadest sense of decisions that manage risks, rather than in the sense in which ORD has used this term. ORD is using the term to describe activities aimed at identifying and improving the options available as tools for managing risks. This semantic distinction has created some confusion. The NRMRL has done

its best to respond to the question in terms of how its particular capabilities and research results help direct priorities of the $PM_{2.5}$ research program.

As defined by ORD, research on risk management is quite specific, focused on improving emissions estimates and the effectiveness of control technology. Most of this is conducted by NRMRL; according to the ORD response, some is accomplished via extramural research. This extramural research was not emphasized in our meetings, although it appears that there are Small Business Innovation Research (SBIR) projects in these areas. We were left with the impression that extramural research was a minor component, possibly because there is little hypothesis-testing or "what-if" analysis going on to identify research gaps that they have not filled sufficiently using in-house research capabilities.

NRMRL's written self-study response provides a clear statement of how NRMRL fits into the overall Agency program and good examples illustrating ways its research products have helped modify the elements of the overall program. Our conversations with NRMRL leadership and staff corroborated this statement in their response to Question B.1, making it apparent that the group shares a common vision of the its roles, responsibilities, and contributions as described in Response B.1. This is a positive indication that organizational issues have been well managed and that the group can focus on meeting its goals effectively.

The self-study document and people who participated in our meetings emphasized the PM planning process as a medium for influencing priorities. A team led by Gene Tucker, a senior scientist in the Air Pollution Prevention and Control Division of NRMRL has responsibility for interfacing with line management to implement resource allocations decided by the team; the team also "serves as the focal point for interactions with other researchers and policymakers," during ORD coordination meetings, scientific and technical meetings, meetings with other federal agencies, and so on. According to the self-study document, these interactions are the major way that the risk management research group influences priorities of the PM Research Program.

Coordination of risk management research depends on the planning and priority-setting that takes place through the work of the Air Research Coordination Team (RCT). The PM research strategy of May 19, 1999, is under revision in response to review by CASAC. Therefore, we cannot determine to what extent priorities are actually reflected in risk management research.

Although there appears to be a clear organizational vision, the Risk Management Subcommittee detects that the role NRMRL currently is playing in the overall $PM_{2.5}$ research program is more reactive than proactive. Evidence of this is the fact that NRMRL's activities were not addressed in the first list of NRC priorities and were only partially accommodated in the second iteration, under "Source Characterization." Even there, NRMRL had to extend its range of capabilities to effectively serve this priority need. The fact that NRMRL adapted to be able to serve this priority need is to be commended. Another major component of its research strategies, RME (discussed in item 8 in the previous section), is on an apparent side-line that is not addressed by NRC and not core to the PM Research Plan (see p. 5, February 1999 Progress Report on Fine Particulate Matter, NRMRL). The reason for this lies in the NAAQS-setting regulatory paradigm, which does not formally consider cost or cost-effectiveness in establishing standards.

The Subcommittee believes that NRMRL should strive to build for itself a more central role in its contributions to PM risk research, despite the apparent constraints of the NAAQS decision process. For example, NRMRL has the data and core competencies to become a stronger advocate for consideration of the risk-risk tradeoffs associated with PM mass control actions. As long as there remain multiple hypotheses about which constituents of PM are potent, and whether co-pollutants may have an important role in potency, control actions that reduce PM mass in equal amounts may have very different

implications for management of health risks. They may alter the mix of PM constituents and co-pollutants in very different ways and also may alter exposure patterns. NRMRL is in a unique position to develop the data necessary to understand these tradeoffs, and to use knowledge about these tradeoffs to substantively inform priority setting for research on hazardous components, mechanisms of injury, and risk assessment for setting the NAAQS themselves. In addition to targeting its RME activities towards this more central role, NRMRL also should focus on developing innovative efforts to communicate this information effectively so that it can leverage its "risk management research" into an actual role in PM decision-making, and thus improve the quality of the risk management implicit in those decisions.

The challenge will be to communicate risk management research results in terms that highlight the relative potential that alternative control actions may actually increase risks even while they reduce total fine PM mass emitted. This will require emphasizing how PM control measures affect exposures to multiple individual constituents within the spectrum of particles, and exposures to co-pollutants that also are potential culprits. At a minimum, this will demand developing a wider range of metrics than the typical uni-dimensional estimate of cost-effectiveness at reducing total PM mass, without regard to how the composition and size distribution of that mass is affected. To be truly effective, however, NRMRL should perform integrated assessments of the likelihood that health risks would be reduced by various control methods. Such integrated assessments would combine information about how control measures alter the composition as well as mass of particles emitted with information on alternative hypotheses about what is (are) the culprit constituent(s) driving health risks. The emerging concept of an RME represents an opportunity to move in this direction.

2. Describe how the results of ORD's $PM_{2.5}$ research will be used to determine potential risk management strategies.

A key objective of NRMRL is to provide the information necessary to develop the range of potential risk reduction strategies that can be implemented by the states to meet the requirements of the Clean Air Act. The BOSC asked NRMRL to provide a summary of how research results from the ORD research portfolio on $PM_{2.5}$ will be used to guide risk management/risk reduction decisions.

The major link of NRMRL's work to risk management lies in efforts to improve data and tools used in decision-making about altemative risk management strategies. The emphasis of NRMRL is more on providing improved information for modeling and decision-making than on hypothesis-driven research. NRMRL has two functions within the current $PM_{2.5}$ management structure. The first is to lead efforts on source characterization. The second is to inform implementation agencies about the technical feasibility, potential cost, and secondary consequences of alternative control strategies.

Currently, the primary form of $PM_{2.5}$ research activities in NRMRL is source characterization. We see positive signs that this work is proceeding satisfactorily and that PIs are working in an integrated fashion, across Laboratory, Branch, and Division boundaries. The reasons for this integration appear to be partly the new ORD organizational structure, partly the leadership of the $PM_{2.5}$ program and the Branch Chiefs, and partly the inherent integration bias of the engineering branch of ORD. Whatever the causes, these signs are promising.

Examples of these projects explained to us or identified in documents reviewed by the Subcommittee include:

- Emissions characterization (wood stoves, heavy oil combustion, on-the-highway emissions, animal feeding operations, extramural and intramural projects to fingerprint $PM_{2.5}$ sources by size and composition).

Source control (capabilities of various technologies to reduce fine particulate emissions from stationary and mobile sources).

Projects in support of the second key NRMRL function, providing data for assessment of alternative control strategies, are less well advanced. The PM team for NRMRL proposes to do several things as noted in the self-study document and as presented during the breakout sessions; for example:

Sponsor workshops summarizing research results.

Publish reports and papers.

Produce a series of "integrated outputs."

Develop and implement an RME framework to integrate research results.

Although we applaud these efforts, the status of these projects is still rather vague, and lack of specific details make assessment of the effectiveness and utility of this approach difficult. **However, we strongly encourage NRMRL, and the $PM_{2.5}$ senior management to invest the resources necessary to make this effort a success.** NRMRL is ideally qualified to develop the necessary sub-models in an RME. We see this tool as an essential component in making decisions on future research priorities within the NRC framework of 10 priority research areas. RMEs can be used for hypothesis testing to determine which sources must be addressed for maximum risk reduction per dollar invested. Identifying these sources will then determine which control technologies need to be improved, or which new technologies should be developed to meet presumed emission standards. The RME approach also allows feasibility and cost effectiveness analyses of alternative state implementation plans for non-attainment areas.

Although we see many benefits to this approach, we are concerned that insufficient resources are being directed to the RME initiative. For example, there are no STAR grants addressing the topic. Extramural funding for NRMRL projects appears limited to control technology development.

In the Recommendations and Findings Section of our chapter, we have described a very broad role that we believe the RME concept should take (see item 8). **In particular, we would like to see RMEs focused on informing others about the risk trade-off associated with alternative $PM_{2.5}$ reduction techniques.** By actively informing EPA and states about the many dimensions of risk reduction, NRMRL can become an advocate for more effective risk management and serve a more effective role in the $PM_{2.5}$ research program.

Finally, **NRMRL should provide leadership within the $PM_{2.5}$ research program regarding the importance of hypothesis testing of alternative compliance and control strategies to ensure the most efficient use of research funds.** The recent letter from EPA's SAB to Carol Browner (July 1999) clearly captures this theme, and we fully support this approach.

CONCLUSIONS AND RECOMMENDATIONS

We recommend that the PM program leaders enlist team and PI members in rethinking the boundaries of holistic frameworks, with a view toward recognizing the human element, even for areas traditionally focused on engineering.

We recommend that "what if" scenarios or sensitivity analyses would be helpful in identifying benefits and tradeoffs from risk control/management programs. Sensitivity analysis and value-

of-information analysis using a pro-forma risk assessment, for example, could create a clearer linkage between risk management and research needs.

We recommend that the Agency take concrete steps to continually evaluate the value of continuing individual areas of research once they have been initiated. A formal value-of-information process will help determine when research has been sufficient.

We recommend that the Agency carefully consider how to align incentives created by promotional criteria explicitly with good programmatic priorities, even if this may mean lesser adherence to an academic view of excellence.

We recommend that the RME concept be developed as soon as possible even in a pro-forma or preliminary manner, to show how the individual NRMRL projects would provide input to it and help fill it out. It is important to do this even before it is possible to know what actual research results will be and just how results would be used.

Appendix:

Responses to Self-Study Questions