U.S. Environmental Protection Agency
Office of Research and Development

BOARD OF SCIENTIFIC COUNSELORS EXECUTIVE COMMITTEE MEETING

Arlington, Virginia
August 17 - 18, 1998

Monday, August 17, 1998

Introduction/Overview of the Meeting

Dr. Costel Denson (University of Delaware), Chair of the Board of Scientific Counselors (BOSC) Executive Committee, called the meeting to order at 9:00 a.m. He expressed his appreciation to the BOSC members in attendance and offered a special welcome to Dr. Joan Daisy (Chair, Science Advisory Board). He quickly reviewed the agenda and noted the following changes due to scheduling conflicts: Dr. Peter Preuss (EPA/NCERQA) will make his presentation at 3:00 p.m. on the STAR Program solicitations and other RFAs related to particulate matter (PM); the "State of ORD" presentation by Mr. Henry Longest II (Acting AA/ORD) was rescheduled for 3:30 p.m.

Dr. Denson asked BOSC members to review the summary of the April 30-May 1, 1998, BOSC meeting before he asks for formal approval of the minutes. He also requested members to review those sections of the minutes that discussed the PM issue, specifically pages 6-9 and 11-13, to prepare them for discussion of this issue later in the meeting. Dr. Denson also mentioned that many of the Action Items listed at the end of the summary had not been completed. He asked BOSC members to review those items and complete the tasks before the next meeting. Copies of an article on the ORD reorganization, which was published in *Nature*, were distributed to BOSC members by Dr. Denson.

Announcements From the Designated Federal Official (DFO)

Ms. Shirley Hamilton (EPA/NCERQA), the DFO for the BOSC, announced that EPA is automating its payroll system. This change, which was implemented to reduce the time required to receive reimbursements, will require that all payments to BOSC members be deposited directly into their accounts. She provided each member a Faststart Direct Deposit Form (Form 2231) and requested that members complete items 1 through 3 and return the forms to her during the meeting or mail them to her following the meeting. Dr. William Cooper (Michigan State University) expressed some concern about computer security and asked Ms. Hamilton to check into this matter. Dr. Cooper also asked how he would know when payments had been deposited. Ms. Hamilton replied that he would received an e-mail message indicating that a deposit had been made. Dr. James Bus (Dow Chemical Company) asked if this automation process was holding up past payments. Dr. Preuss responded that it was not delaying past payments, but it would hold up future payments.

Activities of the Science Advisory Board

Dr. Joan Daisy presented an overview of EPA's Science Advisory Board (SAB), which included the history and purpose of the SAB, the structure of the SAB, its operation and activities, and the SAB strategic planning retreat. She provided a handout of her presentation to the BOSC members.

History and Purpose. The SAB was established by Congress in 1978 under the Environmental Research, Development, and Demonstration Authorization Act. The purpose of the SAB is to provide independent technical advice and peer review on scientific, engineering, and economic aspects of environmental problems and issues to the EPA Administrator. Although the SAB reports to the Administrator, it also may be requested to provide advice to Congress and its Committees. The SAB, like the BOSC, must comply with the Federal Advisory Committee Act (FACA).

Structure of the SAB. The SAB has an Executive Committee and 10 Standing Committees, including:

- Executive Committee—Chair, Chairs of Standing Committees, and Members at Large (EC).
- Advisory Council on Clean Air Compliance Analysis (CCACA).
- Clean Air Scientific Advisory Committee (CASAC).
- Drinking Water Committee (DWC).
- Environmental Economics Advisory Committee (EEAC).
- Environmental Engineering Committee (EEC).
- Ecological Processes and Effects Committee (EPEC).
- Environmental Health Committee (EHC).
- Integrated Human Exposure Committee (IHEC).
- Radiation Advisory Committee (RAC).
- Research Strategies Advisory Committee (RSAC).

There are approximately 100 members, each of whom is appointed for a 2-year term, which is renewable once. In addition, approximately 300 consultants serve the SAB on an as needed basis. The SAB has a staff of 20 who serve as Designated Federal Officials as well as Dr. Donald Barnes, who serves as the Director.

Membership. Nominations for SAB membership are solicited annually from a number of sources; diversity and balance are sought. Each member who is appointed to the SAB must be qualified by education, training, and experience to evaluate scientific and technical matters of interest to EPA; the technical needs of the committees also are considered. No SAB member may be a full-time government employee and members are subject to conflict-of-interest regulations.

SAB Activities. The SAB conducts formal *technical reviews* of key Agency reports and documents that present the consensus view of the committee. The SAB also *reviews research budgets and strategic research plans*. In addition, the SAB issues *advisories* (input on technical issues during the development process), provides *consultations* (less formal input to the Agency on a technical issue before EPA has begun substantive work on the issue), and prepares *commentaries* (committee-initiated advice on a technical issue that the Board believes should be brought to the Administrator's attention).

The Research Strategies Advisory Committee provides advice to the Agency on strategic research planning and issues, reviews the proposed EPA research budget each year, and reviews major EPA research programs as needed.

Projects and Processes. The Administrator's Office and other EPA Offices request SAB reviews, advisories, and consultations annually and throughout the year. The SAB reviews the list of requests and selects projects on the basis of specific criteria. The selected projects are assigned to one of the Standing Committees or an *Ad Hoc* Committee. The Committee then carries out its assignment and sends a report to the Executive Committee for review. The Executive Committee reviews the report to ensure that:

- The charge is addressed adequately.
- The report is clear and substantive.
- Any special issues have been addressed adequately.
- Policy issues are indicated and treated appropriately.

The Executive Committee then sends the report, with a cover letter signed by the Executive Committee Chair and the Committee Chair, to the EPA Administrator.

SAB Strategic Planning Retreat. The first retreat was held in November 1997. A number of changes in EPA were identified and discussed at the retreat, including:

- New decisionmaking approaches at the Agency (e.g., Project XL, Common Sense Initiative).
- Emerging science and environmental issues call for SAB-facilitated interaction between the Agency and the scientific community.
- New crosscutting initiatives and programs at EPA call for more up-front, strategic advice (e.g., Children's Health Initiative).
- Availability of multiple avenues for peer review and science advice permits more strategic activities by the SAB.

According to a recent survey of SAB members, they believe that, to be successful, the Board must not only give sound technical advice but make a difference in the way that science is developed and used. The SAB members also believe that the new directions in EPA demand new directions for the SAB. To meet the changing needs of its customers and maintain a high level of success, the SAB needs to be significantly more strategic in its approach to providing scientific advice on environmental issues. The Board needs to provide more up-front planning and scoping advice, as opposed to the "end of pipe" peer review. At the same time, the SAB must maintain and improve the quality of advice and peer review on specific issues. The SAB's strategic plan involves:

- Improving SAB-Wide Operations
  - Improved timeliness
  - Improved project selection
    - More strategic project selection
    - Meetings of Executive Committee members with relevant EPA Assistant Administrators (AAs) and staff
  - Communications and Agency feedback
    - Executive Committee liaisons to Program Offices
    - Oral briefings after completion of a report
    - Short summaries for some reports
  - Orientation of new members and chairs
  - Interactions with other FACAs and other agencies

- ✦ Improving Specific SAB Elements
  - ✧ Redirect the RSAC
    - Adapt RSAC role to be complementary to new ORD BOSC
  - ✧ Develop approaches for scientific peer review of cost/benefit and other economic analyses and integrate economics expertise into broader SAB work
- ✦ Developing New Initiatives
  - ✧ Take on a limited number of strategic projects (e.g., Modeling Subcommittee, Secondary Use of Data Subcommittee)
  - ✧ Take on catalytic role in conducting workshops on important scientific issues
  - ✧ Other (e.g., Integrated Risk Project)

SAB Integrated Risk Project. Congress requested the SAB to update the "Reducing Risk" report. The Chair of the Committee assigned this project is Genevieve Matonoski (past SAB Chair). The Committee has been working on the project for more than 2 years and the peer review of the report is expected in Fall 1998. The peer review will be conducted by SAB members who did not serve on the Committee responsible for preparing the report. The report, titled *Integrated Environmental Decisionmaking in the 21st Century*, will probably be released by December 1998, at which time, the SAB will begin working with EPA to further develop and implement the Committee's recommendations.

Dr. Cooper asked how the SAB will remain objective in critiquing EPA reports and strategies if the Board becomes involved in the development process. Dr. Daisy responded that the members involved in developing the report/strategy would not serve on the review committee. She also mentioned that the Executive Committee members would like to meet with staff from the EPA Program Offices once each year to obtain feedback concerning the helpfulness and timeliness of SAB reviews, advisories, etc. The SAB also plans to prepare one-page descriptions of SAB reports so that the general public can understand the role of the Board and its activities.

One issue of concern to the BOSC is the integration of socioeconomic and technical issues. Dr. Cooper mentioned that EPA initiated a joint research program with the National Science Foundation (NSF) that required researchers to build in the economic component up front. To his knowledge, this is the first time that EPA has required this type of up-front integration. Dr. Rae Zimmerman (New York University) added that economics may not go far enough—socioeconomic issues should be included. Dr. Daisy responded that the SAB is aware of this need and she believes that socioeconomic issues will be eventually folded in. Dr. Denson added that it is important to recognize that EPA does not always have to take cost into consideration when developing policies. Dr. Preuss noted that consideration of cost varies from program to program—for pesticides, EPA must consider cost; for water, EPA must consider feasibility. He added that EPA has a large economics group already working on this issue. This group also is working with the SAB's EEAC to develop an economics research plan. (ORD does not currently have an intramural component for economics.) The Agency also is trying to develop a research plan for social sciences, which involves defining a program that has never existed before. Dr. Daisy pointed out that there are only a few economists that have dealt with environmental issues.

Dr. Daisy mentioned that many of the SAB's reports can be accessed through the SAB Web Page, which is under the Administrator's section of EPA's Web Site. Dr. Zimmerman asked if draft reports are available to the public during the review process. Dr. Daisy responded that they are made available on the EPA Web Site as soon as the report is submitted to the Executive Committee.

One BOSC member expressed some concern about the lack of integration among ORD, Program Offices, and Regional Offices. Another member pointed out that these relationships vary considerably depending on

the individuals who are doing the work. Dr. Daisy mentioned that the SAB's EPEC recently did a peer review for one of the Regional Offices. She indicated that the Office was very pleased with the review and the recommendations made by the EPEC to improve the product. Dr. Daisy added that, based on this experience, that particular Regional Office is likely to request future peer reviews.

Dr. Jerald Schnoor (University of Iowa) asked if the SAB has analyzed the role of the Board's reports/reviews in changing EPA policy. Dr. Daisy replied that several SAB committees conducted a self study. The SAB also has distributed a questionnaire to obtain feedback regarding what approaches taken by the Board have been most effective through the years. Dr. Barnes pointed out that the SAB's activities also are influenced by the Administrator.

Dr. Cooper asked how the BOSC could integrate the PM reviews of the SAB and the National Research Council (NRC). The NRC report indicated that EPA needs a portfolio of short-, medium-, and long-term research, and the report, which was prepared in a very short timeframe, suggests 10 research areas. The SAB CASAC report also makes some research recommendations. The question that the BOSC needs to address is: How does EPA carry out this research and ensure that it is well integrated with the extramural program? Dr. Daisy suggested that the BOSC may want to invite the CASAC Chair to attend the next meeting to discuss the science issues and the rationale behind the Committee's recommendations. A representative from NRC also could be invited to the next meeting. Dr. Daisy mentioned that the NRC report did a fairly thorough job covering the science associated with the $PM_{2.5}$ issue. She added that the CASAC has identified research gaps that must be addressed to help EPA make better decisions regarding PM. Dr. William Pierson (Desert Research Institute), who is a member of CASAC, indicated that the Committee sent a letter to Administrator Carol Browner that summarized CASAC's findings and recommendations. Dr. Pierson agreed to provide Ms. Hamilton a copy of this letter and the CASAC report for distribution to the BOSC.

BOSC Subcommittee Reports

Dr. Denson indicated that there are no specific reports from the Subcommittees. The BOSC has created only one standing committee—the Nominating Committee. This Committee recently prepared a list of candidates for BOSC membership, which the BOSC Chair submitted to the Acting AA/ORD. The Committee was successful in identifying a number of qualified women, but were unable to recommend any minorities. Mr. Longest has not yet taken any action regarding this list of nominees because he was concerned about increasing diversity among the BOSC members. Dr. Denson informed Mr. Longest that the Nominating Committee had tried to identify qualified women and under-represented minorities. Mr. Longest asked Dr. Denson what specific efforts were undertaken by the Nominating Committee to identify under-represented minorities. Dr. Cooper, who served on the Nominating Committee, responded that there are a number of qualified minorities involved in environmental issues, but they do not possess the specific scientific expertise that was sought by the Nominating Committee to fill the vacant positions.

Dr. Denson stressed the importance of membership diversity and challenged the BOSC members to develop innovative techniques to broaden the base in terms of membership diversity. He suggested that there may be some way to mentor under-represented minorities (e.g., select some qualified candidates to serve on BOSC *Ad Hoc* Subcommittees) so that they will eventually have the experience and knowledge needed to serve as a member of the BOSC.

Dr. Cooper suggested that one approach to identifying potential nominees would be to review EPA's list of peer reviewers for grant applications. Dr. Preuss suggested that a better approach may be to look through the list of EPA grantees. Dr. Zimmerman asked if the race data reported by Principal Investigators (PIs) and Co-PIs are computerized. If so, this would be a good source of information on minority scientists. She suggested that the Office of Environmental Justice may be another good source. Dr. Preuss also mentioned that EPA funds a number of programs/centers at minority institutions. Dr. Denson suggested the possibility of mentoring post doctoral fellows in an effort to "grow up" future BOSC members. The BOSC also could

contact associations of Historically Black Colleges and Hispanic Universities to identify qualified minorities for the Board. Dr. Preuss suggested that EPA could assist with these contacts. He also mentioned that he has recently subscribed to a service offered by the Community of Science. This is a non-profit organization that places CVs on a national computer system. There are currently 20,000 CVs on the system. Dr. Preuss plans to work with Historically Black Colleges and Hispanic Universities to ensure that these institutions have the opportunity to provide CVs for the system. BOSC members will be able to access this system because they are EPA employees. A number of federal agencies, such as the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) have minority investigator programs that could be used to identify potential candidates. Dr. Denson indicated that it will take these and other avenues to identify qualified minority candidates and he would like the BOSC to take a more creative approach in the future.

Dr. Pierson and Dr. Cooper asked Dr. Denson if it was necessary to redo the list of nominees put forth to Mr. Longest. Dr. Denson replied that the list did not need to be redone, but he wants the BOSC to recognize the need to work toward a different approach for the future. Dr. Denson suggested that the BOSC form an *Ad Hoc* Subcommittee to work with the Nominating Committee to develop innovative techniques that can be used to increase BOSC membership diversity. Dr. Mitchell Small (Carnegie-Mellon University) volunteered to serve on the *Ad Hoc* Subcommittee to address this issue. Dr. Denson asked Dr. Small to serve as the Chair of the Subcommittee and he agreed. Dr. Denson also asked Dr. Preuss and Dr. Pierson to serve on the Subcommittee and both agreed. He suggested that Dr. Marilyn Brown (Oak Ridge National Laboratory) serve on the Subcommittee and volunteered to contact her about this issue. He also asked Dr. Bus to provide the Subcommittee information regarding his CDC program suggestion and Dr. Zimmerman to provide information on her Environmental Justice suggestion. The charge to this *Ad Hoc* Subcommittee is to develop a plan to increase the pool of under-represented minorities and women who are qualified to serve on the BOSC. Dr. Denson indicated that the Subcommittee should broaden its focus beyond scientists. He asked the Subcommittee to prepare a preliminary report for presentation at the next BOSC meeting.

Dr. Denson wanted to clarify an issue that was reported in the minutes from the April 30-May 1 meeting. At that meeting, he indicated that Dr. Zimmerman had agreed to serve on an *Ad Hoc* Subcommittee that was charged with preparing a plan on how the BOSC will interact with the ORD Laboratories and Centers. Dr. Zimmerman has no recollection of agreeing to serve on this Subcommittee. Regardless, Dr. Denson would like this Subcommittee to move forward with the following charge: review the proposal that was presented by Dr. Preuss at the April 30-May 1 meeting regarding what the Laboratories/Centers have requested from the BOSC as well as the minutes from the past two meetings and then prepare a report for the Executive Committee about future interactions. Dr. Schnoor agreed to serve on this Subcommittee and Dr. Cooper (Chair of the Subcommittee) indicated that the two of them would prepare a report for presentation to the Executive Committee tomorrow afternoon. Dr. Zimmerman pointed out that the Laboratory/Center Directors want followup assistance with regard to implementing the suggestions from the BOSC review. An example of the type of followup assistance that could be provided by the BOSC is to review the strategic plan developed by the National Exposure Research Laboratory (NERL), which was recommended in the NERL review report. Dr. Cooper said he would like to followup with NERL and provide advice on how to implement their strategic plan.

PM Issue Discussion

Dr. Denson indicated that some portion of the afternoon and most of tomorrow's discussion would be devoted to defining the BOSC's role regarding the PM issue. Mr. Longest has charged the BOSC with looking at the $PM_{2.5}$ issue. Dr. Denson indicated that during the discussions, the BOSC needs to articulate and define what the Board plans to do and identify the BOSC's niche relative to ORD and the PM issue. Dr. Cooper asked the other BOSC members to articulate the $PM_{2.5}$ issue. Dr. Daisy responded that the available epidemiological data indicate that PM may be responsible for an estimated 60,000 deaths per year. Although this estimate has been revised to 15,000 deaths per year, the EPA Administrator believes that PM may pose

a serious health problem. However, there are not sufficient data to determine if $PM_{2.5}$ is responsible for the health problem. Dr. Daisy believes that there is a problem and that EPA must take the lead in conducting the research to better understand and address the problem. She indicated that many of the key research needs and gaps have been identified in the NRC and CASAC reports. In her opinion, these reports contain some sound recommendations for the Agency. Mr. Longest has asked the BOSC to determine if EPA is in a position, in terms of personnel and resources, to address the research needs identified in these reports and EPA's research needs document. Also, the BOSC should determine if the research supported by EPA will enable the Agency to develop the answers needed to solve/address the PM problem. Dr. Cooper replied that this is not a trivial task. Dr. Denson believes that the BOSC needs to look at horizontal integration within ORD regarding the PM issue.

Dr. Preuss indicated that EPA has worked with the CASAC to identify the areas where research is needed. NRC looked at this report and recommended that emphasis be placed on different priorities. The NRC report included a set of recommendations on which to spend EPA's funds. Mr. Longest would like the BOSC to review how this research is being implemented. He wants the BOSC to help ORD ensure that the research is phased and timed appropriately to ensure that the research results and data are available when they are needed. Mr. Longest would like the BOSC to focus on the implementation of the PM research program. The BOSC should start with the assumption that the set of priorities in the NRC report is a given. Dr. Denson added that the BOSC needs to make sure that the $100 million allocated by Congress to the PM issue is spent appropriately to obtain the needed outcome/product. He also suggested that the BOSC may want to develop a review strategy that is similar to that used for the Laboratory/Center reviews. He would like to look at horizontal integration. Which components within ORD are looking at the PM issue? Are their efforts integrated? Are they working on compatible time scales? Are there adequate interfaces? Will each group working on the issue have the information it needs from other groups when it is needed? Dr. Denson mentioned that the idea of looking at horizontal integration was fueled by the apparent lack of integration and coordination between the two PM case studies presented at the site visits conducted during the Laboratory/Center reviews. Dr. Cooper asked if EPA had made any decisions about how the $100 million will be allocated. Dr. Preuss responded that the resource allocation has been completed. He added that some of this information will be presented by Dr. John Vandenberg (EPA/NHEERL) later today.

Prior to breaking for lunch, Dr. Denson reviewed the agenda for the afternoon. Presentations will be made by Dr. Vandenberg, Dr. Preuss, and Mr. Longest, followed by discussion of the PM issue. Mr. Longest, Dr. Larry Reiter (Science Advisor/ORD), and Dr. Vandenberg met with Senate Appropriations staff this morning; Mr. Longest will provide a brief report on that meeting.

Airborne Particulate Matter: EPA's Research Program

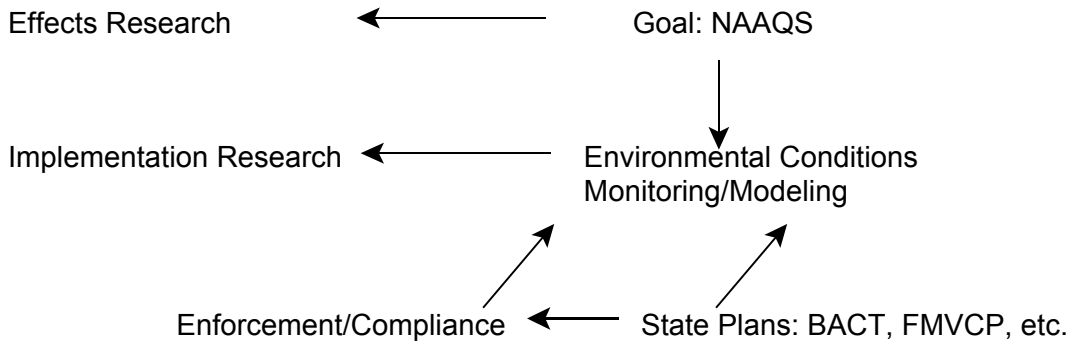
Dr. Vandenberg presented an overview of EPA's PM research program. He agreed to provide more information to the BOSC in the future as needed. The "major points" of the PM research program are:

- It is a big responsibility that the Agency has taken seriously
  - PM is ORD's largest health research program
- EPA is taking a team approach to management
  - All levels working together
  - ORD and Program staff working together
- Communication/coordination is a hallmark of the program
  - NRC
  - Other research organizations
  - Internal to EPA
- Implementation of the program is underway.

Dr. Vandenberg quoted the following charge to EPA to expand its PM research program: "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." This charge was quoted from the *Implementation Plan for Revised Air Quality Standards for Ozone and Particulate Matter*. One BOSC member asked Dr. Vandenberg to describe the role of the NRC in the PM research planning process. He replied that NRC is charged with developing a comprehensive near-term research plan and a long-term research plan as well as a plan to monitor how the research program is being carried out. Dr. Vandenberg indicated that this was one of the "strings" attached to the $100 million of funding appropriated to EPA for PM research.

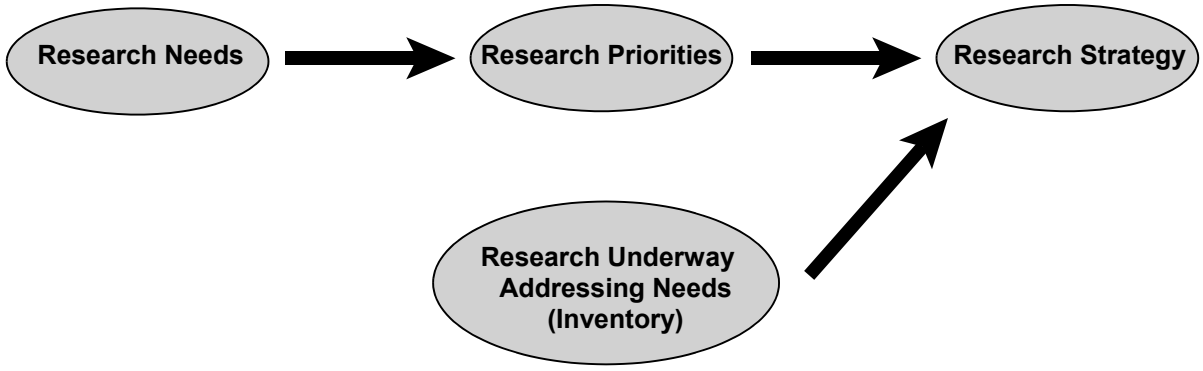
Dr. Vandenberg presented a framework for air quality management (Exhibit 1) and a diagram depicting the research planning process (Exhibit 2).

Exhibit 1. Framework for Air Quality Management



Traditionally, air research is separated into setting standards and then implementing them. This framework shows both of these components. The NRC report emphasizes effects/exposure research, but the next NRC report will take a closer look at implementation research. EPA is trying to develop a balanced portfolio between effects/exposure research and implementation research. The Agency is in the process of developing and implementing a PM research strategy.

Exhibit 2. Research Planning Process

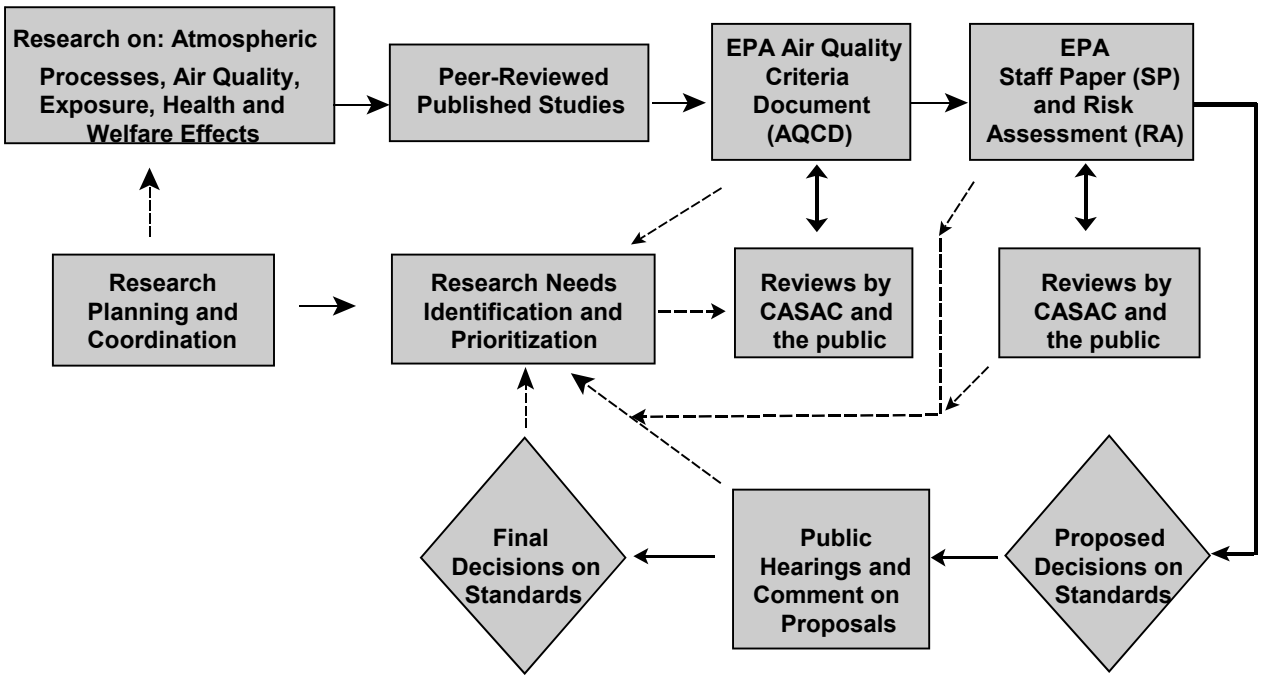


Dr. Vandenberg also provided a diagram that depicted the NAAQS review/revision process, from research on atomospheric processes, air quality, exposure, and health and welfare effects to final decisions on standards (Exhibit 3).

EPA is working to identify current efforts in PM. The Agency is identifying and evaluating the type, extent, and participants in research on PM. An inventory of public and private research programs and activities is being developed, which includes health and NARSTO-A efforts. This inventory will be useful for program coordination, communication, and priority setting. Dr. Vandenberg identified the following steps that EPA is taking to implement the expanded PM research program:

- Evaluate NRC recommendations (on page 101 of the report)
- Internal
  - Alignment of EPA program with NRC recommendations
  - Identify changes needed, where to stay the course, and where re-evaluation is needed

Exhibit 3. NAAQS Review/Revision Process



- External
  - Evaluate inventory of public/private research
  - Coordinate with other federal agencies
  - Coordinate with partners (Health Effects Institute, NARSTO-A)

Dr. Vandenberg presented a table that compared EPA's FY 1998 and FY 1999 budgets to the NRC recommended budget for each of the NRC research areas (Exhibit 4). The NRC recommended budget for FY 1998 was $39.6 million and the EPA enacted budget was $50.2 million. For FY 1999, the NRC recommended budget is $45.7 million and the President's budget request for EPA's PM research is $28.7 million. The table in Exhibit 4 shows the breakdown of these funds by research area. Approximately $8 million will go to PM research centers and $2 million will go to the NRC for the second report and monitoring research progress. A small fraction of the funding will be used to support in-house research efforts and the remainder will go into peer-reviewed grants to fund extramural research.

EPA is currently developing a research strategy that will provide a road map for the next 5+ years. The Agency has benefitted from numerous planning/review activities over the last several years, including: research needs and strategy documents (CASAC reviews), PM workshops (health and NARSTO), and NRC Committee. As part of the research strategy development, EPA identified the program's vision, goals, and guiding principles. The strategy will strengthen research collaborations and provide a basis for development of Laboratory PM plans.

The goal of EPA's PM research program is to provide scientific leadership to:

- ✦ Develop/implement a national research strategy.
- ✦ Promote integration and coordination of efforts by EPA and its partners.
- ✦ Insure national effort is focused on highest priorities to maximize use of resources and benefits of research.

Dr. Vandenberg identified the federal agencies that have and will continue to address PM research needs. For epidemiology (chronic, acute, etc.) research needs, the primary agencies are the National Institute of Environmental Health Science (NIEHS) and EPA; for mechanisms (metals, organics, etc.) research needs, the primary agencies are the Department of Health and Human Services (DHHS) and EPA; for exposure (methods, personal, etc.) research needs, the primary agencies are EPA and the CDC; for atmospheric science (formation, fate, etc.) research needs, the primary agencies are the Department of Energy and EPA. Dr. Vandenberg pointed out that EPA is the biggest player in the PM issue with a program of $50 million; NIEHS is next with a program of approximately $10-20 million.

EPA has participated in and contributed to a number of PM workshops over the past 2 years, including:

- ✦ Federal meetings (September 1997, June 1998) and CENR meeting.
- ✦ PM-NARSTO (September 1997, July 1998).
- ✦ Health priorities (November 1997).
- ✦ Atmospheric science priorities (November 1997).
- ✦ National Academy of Science meetings (January, February, June 1998).
- ✦ Co-sponsorship of professional society/other meetings (ISEA/ISEE, NRCES, etc.).

Dr. Vandenberg presented an organization chart that depicted EPA's PM research planning structure (Exhibit 5). Bill Farland is the EPA Executive Lead. John Vandenberg is responsible for development of the strategy/plan for PM effects research (NAAQS) and Les Grant is responsible for identifying research needs for PM effects research. This component of the organization focuses on epidemiology, mechanisms/ toxicology, and exposure. Jim Vickery is responsible for development of an implementation strategy/plan (NARSTO-A). This part of the organization focuses on exposure, atmospheric science, monitoring/ modeling, and risk management.

Dr. Vandenberg wrapped up his presentation with a chart (Exhibit 6) that showed how EPA was building accountability into the planning and implementation processes of the PM research program.

Exhibit 4. Comparison of EPA FY 1998 and FY 1999 Budgets to NRC Recommendations

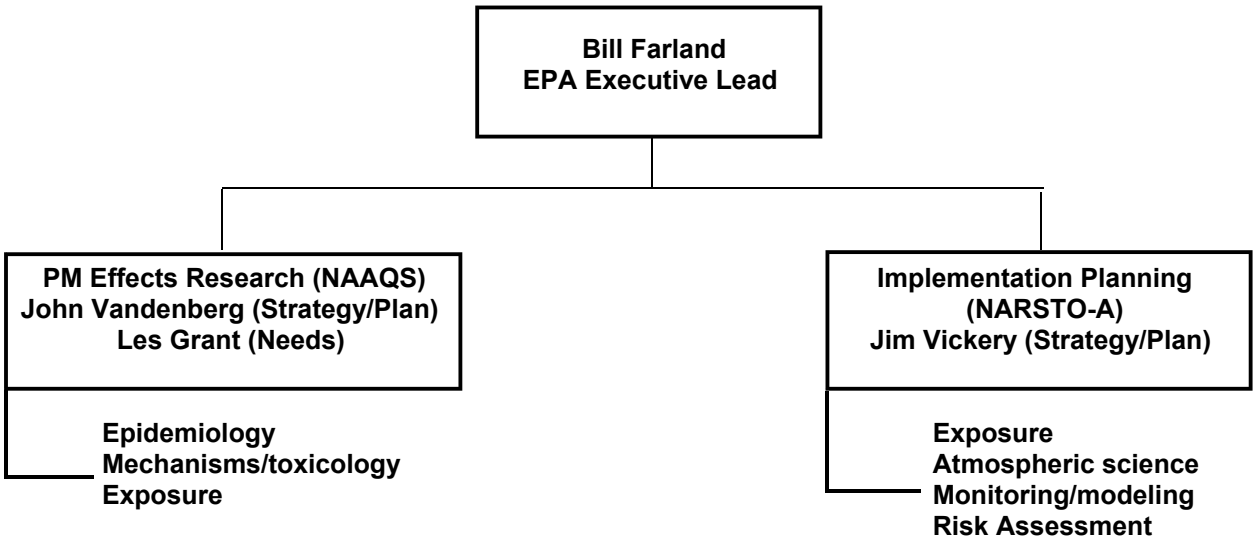
I. National Research Council highest priority research areas

NRC Research Area	NRC FY98 *$M*	EPA Enacted FY98 *$M*	NRC FY99 *$M*	EPA Pres. Bud FY 99 *$M*
1 Outdoor measures vs. actual human exposures	3	7.4	3	3.7
2 Exposure suscept. subpops. to PM components	0	0.0	0	0.0
3 Source-receptor measurement tools	4	5.1	4	4.4
4 Application of methods & models	1	0.0	1	0.0
5 Assess hazardous PM components	8	5.8	9	4.5
6 Dosimetry	3	1.0	1.5	0.5
7 Effects of PM and Copollutants	4	4.9	9	0.8
8 Susceptible subpopulations	2	7.5	2	3.2
9 Mechanisms of injury	9.5	7.5	9.5	4.3
10 Analysis and measurement	1.5	1.1	2.5	0.6
Subtotal	**36**	**40.1**	**41.5**	**21.9**
Management (NRC: flat 10% of above)	3.6	1.9	4.2	0.0
Subtotal	**39.6**	**42.0**	**45.7**	**21.9**

II. Implementation-related research

Atmospheric chemistry, modeling, source apportionment		2.9		2.5
Emissions characterization, emission factors and controls		4.0		3.0
Criteria Document development		1.3		1.3
Subtotal		**8.2**		**6.8**
Total		**50.2**		**28.7**

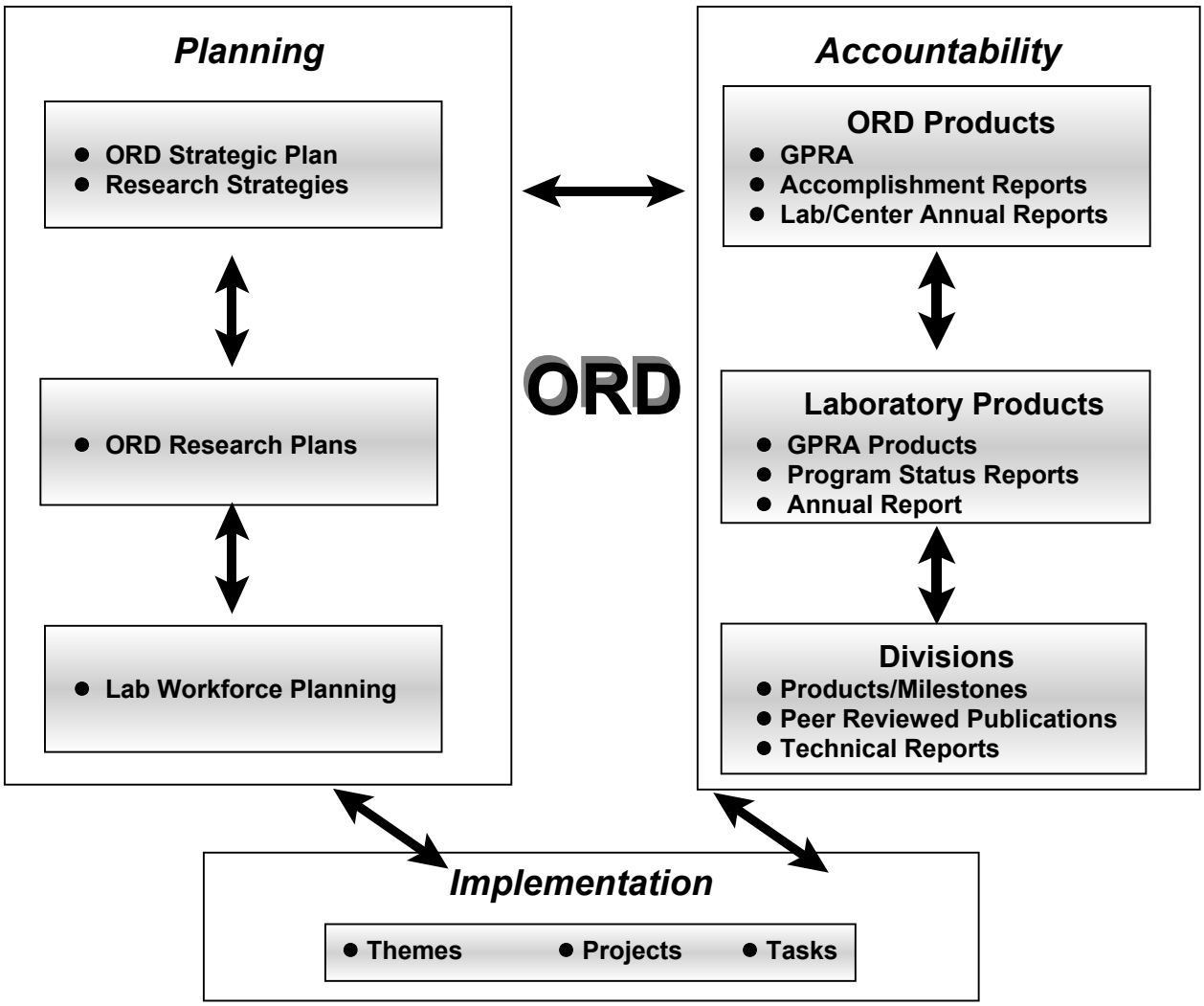
Exhibit 5. EPA PM Research Planning Structure



Dr. Cooper pointed out that NERL would be a key player in EPA's PM research program. He noted that there is a gap between what NERL is willing to do to support the PM program and what the Laboratory is capable of doing. How will the BOSC know if EPA has the appropriate staff to implement the research strategy? Dr. Vandenberg responded that several key scientists have been brought into the Agency during the past several months. Dr. Cooper asked if these individuals will be able to "come online" in the timeframe that will be required to implement such an ambitious research plan. Dr. Vandenberg indicated that NERL has recently brought on 21 post doctoral researchers (a total of 50 post docs have been brought into EPA during the past several months). Do the ORD Laboratories have the man power to do this research? This is a question that should be addressed by the BOSC.

Dr. Denson expressed some concern that the PM research program was being managed by an Assistant Laboratory Director (ALD). He asked if the ALD has sufficient "clout" within the Agency to implement such a complex, visible research program. Dr. Preuss pointed out that the ALD makes recommendations to the AA/ORD as well as the Laboratory and Center Directors who will be involved in supporting the PM research program. Dr. Denson mentioned that in matrix organizations, it is very important to appoint managers who have the appropriate level of authority to be effective. Mr. Longest responded that ORD is trying to determine whether a Program Manager should be appointed for each of the top 10 strategies. The Program Manager would have the "clout" necessary to implement and manage the program. There is a precedent for appointing Program Managers for large programs at EPA—the Environmental Monitoring and Assessment Program (EMAP), for example, is coordinated by a Program Manager. Mr. Longest pointed out that Dr. Vandenberg is essentially serving as the Program Manager for the PM research program. He is providing leadership for the program and he is getting support from the Laboratories/Centers. Dr. Reiter indicated that this Program Manager issue is one of the topics that could be considered by the BOSC. He also reiterated Mr. Longest's request that ORD would like the BOSC to help them look at implementation of the PM research program. Dr. Zimmerman asked Mr. Longest to clarify Dr. Vandenberg's function and responsibilities. Mr. Longest replied that Dr. Vandenberg has coordinated the development of a document that contains the various elements of EPA's PM research program. He also has developed a breakdown of projects, FTEs, and dollars that will be used to implement and manage the program. Dr. Vandenberg will work with the other ALDs to refine the line-by-line budget. In addition, Dr. Vandenberg keeps senior EPA managers informed about the PM research program. Dr. Preuss noted that Dr. Vandenberg's value added to the PM research program is that he understands the science and has taken the time to learn the program.

Exhibit 6. Building Accountability Into EPA's PM Research Program



He is the one individual within EPA who knows what each component of the Agency is doing in terms of the PM issue. Dr. Vandenberg's role is to work with other ALDs to help guide and fashion the strategies and plans for what will be done in the future. It will be the responsibility of the line managers to ensure that the individual research projects are implemented and managed effectively. Dr. Schnoor asked what would happen if a Laboratory or Center Director did not agree with Dr. Vandenberg's allocation of resources. Dr. Reiter suggested that in the event of such a disagreement, the issue could be presented before the Executive Council.

Dr. Small pointed out that EPA will not want to be evaluated on how well they implement the research program, but whether the new NAAQS established by EPA are effectively protecting human health from the risks associated with PM. Dr. Cooper asked Dr. Vandenberg if EPA has been challenged for failing to include ecological effects in the PM research program. Dr. Vandenberg responded that EPA probably has not looked at ecological effects because the current risk estimates are so high with respect to human health. Dr. Cooper cautioned Dr. Vandenberg to prepare an answer to this question in case it comes up in the future.

State of ORD

Mr. Longest provided a brief update on the state of ORD. He mentioned that the new AA/ORD (from the Florida Institute of Technology) will probably be confirmed in September and come to the Agency shortly thereafter. He indicated that the BOSC will have to look to her for future guidance regarding the PM issue. Bob Perciasepe has left the Office of Water to serve as the AA for the Office of Air and Radiation. Chuck Fox will be the new AA for the Office of Water (pending Senate approval).

Mr. Longest reported that ORD has already completed the budget process for FY 2000; OMB hearings for the FY 2000 budget will be held in September. He expects that ORD will get feedback regarding the FY 2000 budget in late November. Although a continuing resolution is likely on October 1, 1998, Mr. Longest indicated that there may be enough latitude to keep moving forward on the PM issue. He asked the BOSC members if there were any questions regarding their charge concerning the PM issue. Dr. Cooper responded that the BOSC members are trying to figure out how they could best help EPA with the PM issue. He asked if the BOSC could have information on ORD's personnel changes since the Laboratory/Center reviews. Mr. Longest agreed to provide workforce profiles of the Laboratories/Centers to the BOSC to allow them to assess whether ORD has the personnel required to implement the PM research program.

Mr. Longest reported that two surveys of ORD employees have been completed and a third survey will be conducted soon. Analysis of the responses to the two completed surveys has resulted in the identification of 12 themes. Mr. Longest agreed to provide the BOSC with a list of these 12 themes.

One BOSC member asked how the Laboratories and Centers are using the review reports prepared by the BOSC. Dr. Reiter responded that the Laboratories/Centers have been asked to prepare action plans in response to the reports. Dr. Cooper asked if the BOSC will review these action plans. Is there any other function for the BOSC members with regard to the Laboratory/Center reviews? Dr. Reiter and Mr. Longest agreed to keep the BOSC informed about what is occurring in the Laboratories and Centers. Dr. Denson indicated that he expected to receive a written, formal response from EPA regarding the recommendations in the reports. Mr. Longest replied that the BOSC will receive a written response.

STAR Program and RFAs Related to PM

Dr. Preuss provided an overview of the STAR Program and the process for developing PM-related RFAs. He pointed out that a large portion of EPA's PM research dollars will be used to fund extramural research grants and centers. NCERQA is taking two approaches to solicit extramural research support for the Agency's PM research program. The first approach is to develop RFAs for targeted research directed towards specific PM science needs. The second is to fund investigator-initiated exploratory research related to PM. In developing the PM-related RFAs, NCERQA tries to build on what EPA and other organizations have already learned or accomplished. The ORD Strategic Plan, EPA's Research Needs Document, the ORD Research Plan, and the CASAC and NRC reviews are taken into consideration during the RFA development process. The RFAs are developed by a team of EPA scientists from ORD and the Program and Regional Offices. All applications received in response to RFAs are subjected to independent peer review by external scientists and an internal review by EPA scientists to ensure that the research proposed is relevant to the Agency's needs. This internal review also considers whether the proposed research complements EPA's intramural research program and the research done by other organizations. NCERQA also coordinates PM research with other federal agencies as well as public and private organizations (e.g., Health Effects Institute).

Dr. Preuss identified the following major science questions that have been posed in PM-related RFAs issued from 1995 through 1998:

- How can the atmospheric formation and transport of PM from precursor emissions be accurately predicted?
- What are the ambient levels of PM by composition and size?
- What are the associations between long-term exposure to PM and adverse health effects, including time of life lost, chronic illness, and conditions that increase susceptibility to air pollutants?
- What are the causal mechanisms by which PM, alone or in combination with other pollutants, may cause health effects?
- What is the magnitude and variability of errors in assessment of exposure to PM?

NCERQA has issued a number of PM-related RFAs under the STAR Program during the last 4 years. In FY 1995, a broad solicitation was issued under the STAR Program on Ambient Air Quality (PM, tropospheric ozone, and toxics); an RFA for exploratory research also was issued by NCERQA. In FY 1996, an Ambient Air Quality RFA (a continuation of the FY 1995 RFA) was published; NCERQA also issued an RFA for exploratory research. In FY 1997, three PM-related RFAs were issued under the STAR Program, including: Tropospheric Ozone and Fine Particulates (integrates atmospheric science), Special Opportunity in Tropospheric Ozone (three regional centers to investigate interactions of ozone and PM), and Health Effects and Exposure to Particulate Matter and Associated Air Pollutants. In FY 1998, four PM-related RFAs were issued under the STAR Program, including Air Pollution Chemistry and Physics, Health Effects and Exposure to Particulate Matter and Associated Air Pollutants, Exploratory Research, and Airborne Particulate Matter (PM) Centers. Dr. Preuss provided information on the number of PM-related grants awarded from FY 1994 through FY 1998, as well as the dollars associated with those grants (Exhibit 7). He also provided a breakdown by topic of grants funded from FY 1994 through FY 1998 (Exhibit 8).

Exhibit 7. PM-Related Grants by Year

Fiscal Year	Number of Grants	Approximate Dollars ($M)
1994	5	1.8
1995	8	3
1996	18	6.8
1997	12	6.8
1998	19	13

Dr. Preuss provided BOSC members with a copy of a 1998 STAR Research Grant Announcement for Airborne Particulate Matter (PM) Centers. This announcement, which closes on October 28, 1998, invites research grant applications to establish PM Centers to address priority research needs in:

- Exposure—relationships between ambient PM and personal exposure in potentially susceptible subpopulations.

- Dosimetry/Modeling Extrapolation—pulmonary depositions and cell-specific dose of PM and PM-associated constituents.

Exhibit 8. PM-Related Grants by Topic (FY 1994 - FY 1998)

Grant Topic	Number of Grants	Approximate Dollars ($M)
NRC 1: Outdoor measures vs. actual human exposures	2	1
NRC 5: Assess hazardous PM components	4	2
NRC 7: Effects of PM and Co-Pollutants	6	2
NRC 9: Mechanisms of Injury	7	2.8
Methods/Monitoring	17	10
Chemistry/Physics/Models	13	6
PM Centers*	5	8

* The awards for the five PM Centers will be issued in early 1999 and will result in a $40 million commitment over the next 5 years. It is anticipated that the PM Centers will conduct research covering at least 8 of the 10 NRC research topic areas.

- Toxicology—identification of causative constituents of PM-related health risks.

- Epidemiology—relationship of PM and co-pollutant exposures to increased human mortality and morbidity.

The PM Centers RFA follows the guidance provided by the NRC. Specifically, it encourages multidisciplinary consortia, requires integration of research and coordinated planning among PIs, leverages existing and future PM air quality databases, develops plans for information sharing, and creates science advisory committees. Dr. Preuss indicated that ORD may want to focus on using the PM Centers to address a particular priority area. He mentioned that NCERQA hopes to get grant applications that integrate two or more of the priority research themes. Dr. Preuss also pointed out that applicants could propose virtual centers (i.e., all of the required expertise would not reside within one institution), and he expects to get applications from a variety of consortia.

Dr. Cooper asked about the protocol for the dosimetry study. Dr. Vandenberg replied that the dosimetry studies will measure how far down in the lungs the particles go and where they go in the lungs. He indicated that there is a lot of work being done to couple exposure and dosimetry. There was some discussion concerning the higher potency and toxicity of the smaller particles currently passing through the control devices. Dr. Small noted that atmospheric chemistry is not included in the PM Centers announcement. Dr. Preuss responded that this topic will be incorporated later after EPA has some information on speciation and toxicology. According to Dr. Preuss, there had been considerable discussion within ORD regarding what to include in the PM Centers RFA. It was decided that the PIs should be allowed some flexibility in their proposals. Dr. Small also mentioned that the development of risk assessment methods is not specified in the PM Centers RFA. Dr. Vandenberg replied that the RFA is broad enough to include risk assessment methods development as well as other topics.

Dr. Preuss mentioned that there are numerous activities planned or underway to facilitate science integration among PM researchers. These include:

- Planning Workshop for PM Centers
- Annual Science Workshops
  - Grantees
  - Centers
  - ORD Scientists
  - Program Offices/Regions
  - Others (HEI? ... Lovelace? ...)
  - Workshop Proceedings
- Participation in Professional Society Meetings
- Web Page (abstracts, Interim Reports)
- STAR Reports: research-in-progress

EPA participates in and sponsors workshops to allow PIs to interact with one another and talk about their research. Dr. Cooper warned that integration sounds good, but it often limits competition and independent, free thinking which can be beneficial. He thinks this is more of a concern with the PM issue because it is a relatively small community of researchers who think similarly. Dr. Preuss replied that several organizations that have not been working on the PM issue have shown interest in the PM Center announcement. Dr. Cooper suggested that some of the experts who will be reviewing the grant applications be selected from outside the PM research community. Dr. Preuss replied that the applications will undergo an external review for science and an internal review for relevance. He indicated that EPA will bring in toxicologists, geneticists, and other experts whose primary research area is not PM to participate in the external review. Dr. Zimmerman asked if EPA was concerned about timing the PM research to meet the regulatory timetable. The research must be completed by mid-2000 in order to determine the next set of NAAQS within the regulatory timeframe. Dr. Preuss responded that the ultimate goal is to implement the new standards within the next decade. He is confident that EPA can address the fundamental questions that must be answered for the new standards within that time period.

Dr. Denson asked how EPA plans to measure the impact of the Centers' research in meeting the specific PM research needs and providing the information needed by the Agency to establish new NAAQS. Dr. Preuss replied that it is much easier to measure products and outcomes than impacts. EPA plans to ensure that the Centers and other STAR Program grantees are carrying out the required research. NCERQA also will continue to search for ways to make the research more useful to the Program Offices. Dr. Cooper pointed out the importance of selecting endpoints for the PM research program that will not set the Agency up for failure.

Wrap-Up

In wrapping up the discussion for the day, Dr. Denson asked each of the BOSC members to review the charge presented by Mr. Longest at the April/May meeting and to define an action plan regarding the PM issue before the second day of the meeting convenes in the morning. He also asked the BOSC members to consider the following questions: Do we want to develop a set of questions in a manner similar to that used for the Laboratory/Center reviews? Do we want to look at the horizontal integration among the Laboratories and Centers relative to the PM research program?

Dr. Denson indicated that Dr. Cooper and Dr. Schnoor will present their report regarding future interaction between the BOSC and ORD Laboratories/Centers tomorrow.

Tuesday, August 18, 1998

Dr. Denson called the meeting to order at 8:45 a.m., and quickly reviewed the items on the agenda that remained to be covered, including: the report on future interaction between the BOSC and ORD Laboratories/Centers; identification of work areas, goals, and objectives, and development of an action plan for the PM issue; establishment of committees to work on the PM issue; determination of the next steps; and selection of a date for the next BOSC meeting.

Defining Issues on PM Research

Dr. Denson asked if anyone wanted to share their action plan for the PM issue that he/she prepared overnight. Dr. Cooper responded that he is not sure that all of the issues have been defined, even though EPA is acting as if they have been defined. He cautioned that EPA could be setting itself up for failure unless the Agency is very careful. He recommended that the BOSC help EPA develop a strategy that will prevent such failure, including the careful definition of the assessment endpoints. Dr. Zimmerman argued that EPA already knows enough about some of the uncertainties associated with PM to move forward. She pointed out that EPA is working within the framework of the risk assessment paradigm, trying to integrate exposure, dose, etc. This will require horizontal integration across the Laboratories and Centers. Dr. Pierson asked what the Agency will do if they find out that PM is not associated with the observed health effects, and pointed out that it may take a long time to find the answers. Dr. Zimmerman agreed, but added that EPA needs to put a system in place to find the "real" answers, regardless of how long it takes. Dr. Bus believes that epidemiology is a key issue because there is a distinct weakness within EPA in this area.

Dr. Denson noted that the PM issue will cut across all of the Laboratories and horizontal integration will be key to the program. Dr. Schnoor pointed out that EPA will not have a toxicological system in place in time to find the answers needed by 2002, which is a key date in the regulatory timeline. He suggested that the BOSC's review should make it very clear that EPA will not find the answers by that date. Dr. Denson expressed the need to develop a regulatory timeline as well as a science timeline to determine how they relate to each other. Dr. Cooper warned that the science timeline should be realistic. For example, he indicated that the $50 million for research should be spent over 10 years, instead of 2-5 years. Dr. Cooper volunteered to write a few paragraphs on the issues raised thus far during the discussion (i.e., horizontal integration, define endpoints, science/research timeline vs. regulatory timeline).

Another BOSC member pointed out that EPA does not have all of the human resources and intellectual capital needed to do the required PM research. EPA will have to rely on extramural researchers to support the program. Another issue identified during the discussion was communication. How will ORD ensure effective communication among the various internal and external researchers working on the PM issue? Dr. Small asked if EPA had developed a coherent strategic research plan for PM. He believes that EPA has developed pieces of a plan but not one single document that lays out the PM research strategy. Dr. Small also pointed out that this plan should be readily available (via ORD's Web Site) to researchers within the Agency as well as those outside EPA. The strategy also should be designed to allow the research to be phased in over time. Dr. Denson mentioned that the BOSC may need more information form EPA regarding where the Agency is in the strategic planning process. Does EPA have a strategic plan for PM? If so, copies of the plan should be provided to the BOSC. Dr. Denson also suggested that the BOSC may want to talk with the EPA staff members who are working on the strategy. Dr. Cooper added that the BOSC also would like to see the implementation plan for the strategy (if one exists). The implementation plan should identify what research will be done, who will do the research, the resources required for the research, etc.

Dr. Denson cautioned the BOSC members that they will have to work within the constraints of the NRC report. That report created the goals, objectives, and priorities. The NRC report is a benchmark against which EPA must measure. Dr. Schnoor asked why epidemiology, mechanisms/toxicology, and exposure were separated from exposure, atmospheric science, monitoring/modeling, and risk management on Dr. Vandenberg's PM Research Planning Structure handout (see Exhibit 5). One BOSC member cautioned that

Implementation Planning in that exhibit refers to regulatory implementation not implementation planning for the PM research program. Dr. Cooper pointed out that such a structure will require EPA to spend numerous hours trying to integrate PM research with federal agencies as well as public and private organizations. Dr. Denson and Dr. Zimmerman both expressed some concern about the amount of time that EPA has already spent talking to these various organizations when the Agency should have been focusing on developing a plan and moving forward to implement it. Dr. Zimmerman noted that Dr. Vandenberg's personal skills have been responsible for moving the PM program forward. She asked what would happen if he left EPA or was reassigned.

Dr. Cooper suggested that the BOSC request information from EPA that goes beyond what Dr. Vandenberg presented (i.e., beyond the conceptual design for the PM research program). He wants to see an implementation plan that clearly defines what PM research EPA plans to do. Dr. Small added that he would like to see the PM research strategy too. The strategy should identify the critical questions/issues to be addressed and the implementation plan should describe how the Agency will go about answering/addressing those questions/issues. The BOSC should determine if the plan clearly states the mission and goals of the program as well as the methods for achieving those goals. Is the plan contained in a single document that is readily accessible to researchers? Dr. Cooper stated that EPA conducts research to determine ways to reduce risk or to improve the science base in an effort to reduce the uncertainty associated with the risk. EPA's goal should be to develop the capability to do a risk assessment using the $PM_{2.5}$ standard within 5 years. The Agency also should be able to answer the question: How much risk is reduced by going from PM_{10} to $PM_{2.5}$ standards? Dr. Zimmerman suggested that the PM research projects should be sorted along stages of the risk assessment process to see how the research fits into the risk assessment paradigm. Such an approach would ensure that the Agency does not loose the value of the ongoing research.

Dr. Denson reiterated that the BOSC is concerned with horizontal integration and coordination. Dr. Zimmerman agreed and expressed her concern about how EPA is coordinating the groups of PM research projects. She also pointed out that almost all of the epidemiology work is being done by extramural researchers. The BOSC members agreed that EPA is strong in the areas of exposure, modeling, monitoring, and risk management. EPA is not as strong in the area of toxicology and is even weaker in the area of epidemiology. It was noted that many of the scientists that will be doing the in-house research on exposure are post-doctoral researchers, not senior scientists. Dr. Schnoor thinks that EPA can address the exposure questions over the next 5 years. He added that the BOSC will need information on the personnel changes that have taken place since the review. Dr. Denson formally requested an updated personnel profile for the ORD Laboratories and Centers relative to the PM issue. The BOSC suggested that EPA could recruit some expertise through the STAR Program or through consultants or contractors.

Dr. Denson noted that EPA is on the line with the PM issue. The EPA Administrator believes that there is enough information to move forward with more stringent regulations and she has already made EPA's position clear. One of the BOSC members suggested that the Board review a draft of each PM-related RFA before it is released. This would give the BOSC members some insight into what it is that the Agency is asking the extramural research community to do. Dr. Schnoor cautioned EPA not to promise to have identified a causative mechanism by 2002. He does not think it will be done within the next 5 years. However, he believes that EPA will be able to determine whether $PM_{2.5}$ is better correlated to mortality data than PM_{10} during the next 5 years. One BOSC member suggested that EPA needs to go back and do an epidemiological assessment on $PM_{2.5}$ data. Without an answer to this issue, Congress probably will not endorse moving to the $PM_{2.5}$ standard. The BOSC members agreed that epidemiology should be a high priority; particularly because it was the epidemiological data that prompted the Administrator to propose the new rule in the first place. Although there are 15,000 deaths per year attributed to PM, EPA has not yet determined that these deaths are directly associated with PM; however, there is some scientific evidence to support such a conclusion. Dr. Cooper warned that EPA should consider the at risk populations separately. There is a bimodal distribution (probably a peak at 10-15 years and another at 60-75 years) separated by approximately 50 years of age. The respiratory stress among these two populations is probably caused by very different mechanisms. Dr. Cooper warned that EPA would be very lucky if an effect is observed within

5 years after particle reduction. However, because many children develop asthma within their first 5 years of life, a reduction in mortality could be detected in that time period. Dr. Cooper asked if a child who had already developed asthma would recover after the exposure stopped. No one had an answer for that question. Dr. Denson suggested that Dr. Brian Leaderer (Yale University) should be involved in the epidemiology issue because that is his area of expertise. Dr. Bus warned the BOSC that they should not assume, before the research is completed, that PM is directly associated with the increase in asthma cases. He asked if the Agency was looking to see if there are other factors that could be causing the increase in asthma cases (e.g., diet, activity, physician reporting). Dr. Bus pointed out that the number of cases are rising while the levels of PM are decreasing. This might lead us to doubt that PM is responsible for the increase in asthma.

Dr. Denson mentioned that the PM Centers will be conducting some of the critical research needed to address the PM issue. He also pointed out that forward funding of the Centers will be important to ensure stability. Year-to-year funding variations could be problematic for the PM Centers. Dr. Denson indicated that funding priorities should match the Agency's research priorities. One BOSC member pointed out that NRC did not prioritize the 10 research areas; EPA has not prioritized them either. Dr. Cooper noted that EPA has, in effect, prioritized the research areas by the way that the Agency has assigned the research funds to the 10 areas.

Dr. Zimmerman asked if workshops are conducted by the STAR Program to promote science integration and communication among researchers. One member recalled that Dr. Preuss had mentioned the workshops in his presentation yesterday. Dr. Zimmerman suggested that the BOSC evaluate the workshops to determine if they are effective in promoting science integration and information exchange. Another BOSC member asked if EPA was trying to ensure adequate redundancy among PM research areas. This is important because the Agency should look for a convergence of different research communities (i.e., research convergence). If there are multiple research groups working on a particular issue and the research does not converge, this information may be very important to EPA. The BOSC agreed that, for critical areas, EPA should ensure adequate redundancy. Because there is a limit to the funding available, the areas of redundancy should be selected carefully. Dr. Pierson suggested that epidemiology is an area where redundancy would be important. Dr. Bus agreed and suggested that EPA fund groups that agree with the Agency's position and groups that do not agree. Dr. Denson believes that EPA could identify the key areas/questions and then work with the BOSC to determine which areas require redundancy.

Dr. Bus asked if there will be any international cooperation in the PM research program. Europe has higher PM levels than the United States; therefore there may be some opportunities there. Eastern Europe has observed dose-response relationships with childhood asthma and mortality, but their PM levels are higher. One BOSC member asked how EPA plans to keep all of the different stakeholders informed about the Agency's research efforts. All of the stakeholders need to be kept informed so that they can visualize what will be coming in the future. It also was suggested that EPA have a periodic review of the progress made in the PM research program so that the Agency can reallocate research funds as needed. The BOSC did not believe that EPA should do an annual evaluation, but there is a need to do an in-house reassessment within some reasonable timeframe. Dr. Bus provided the analogy of how private industry uses a gate-keeping system to make "go/no go" decisions at different phases of the project. Dr. Cooper added that it is important for EPA to identify several projects that the Agency is sure can be completed successfully and include those in the strategy.

Dr. Denson asked if the BOSC can use any of the process developed for the Laboratory/Center reviews. Dr. Schnoor asked for some clarification regarding the BOSC's charge. Dr. Denson replied that the BOSC was going to conduct a programmatic (not technical) review of the $PM_{2.5}$ issue. The BOSC will review ORD's planning processes and implementation of the PM research program. Dr. Cooper mentioned that the BOSC may want to emphasize some areas on which EPA has placed less emphasis. Dr. Denson reminded the BOSC that the NRC report is a given in terms of priorities and critical questions.

Dr. Denson asked that the BOSC members be provided copies of the CASAC report. In response to a question from a BOSC member, Dr. Pierson replied that the CASAC reviewed the criteria document developed by EPA and the NARSTO-A white paper. He thought that the CASAC might have reviewed ORD's PM research strategy. Dr. Pierson mentioned that the CASAC report was submitted to the Administrator several months ago. Dr. Denson asked Ms. Hamilton to provide copies of the CASAC report to the BOSC. Dr. Pierson provided a copy of the report to Ms. Hamilton who agreed to distribute copies to the BOSC members. Dr. Zimmerman asked if the EPA document (dated January 1998) that she received from Dr. Preuss was the PM research plan. One BOSC member replied that it is a research needs document that ORD prepared in response to the CASAC report. The letter from CASAC to the Administrator, which accompanied the CASAC report, is included in that EPA document. Because some pages were missing from the ORD document that was sent to the BOSC members, Dr. Denson asked Ms. Hamilton to send out complete copies of the report. Dr. Denson also asked Ms. Hamilton to determine if EPA has developed a research plan for $PM_{2.5}$. If so, he requested that Ms. Hamilton send copies of the plan to the BOSC members. Dr. Denson also requested copies of the NRC report, the NARSTO-A white paper and charter plan, and the Criteria Air Pollutants Progress Report. He also asked Dr. Pierson to work with Ms. Hamilton to identify and distribute copies of all the reports/documents relevant to $PM_{2.5}$ that have been prepared or reviewed by the SAB.

Dr. Denson asked the BOSC members to help him define the scope of the review that will be undertaken by the Board. Should we develop a list of questions to organize the information obtained/developed? Does EPA need integrated research plans? Will the BOSC members make any site visits to the Laboratories during this PM review? Dr. Cooper expressed some concern about integrated research plans. He did not think it would be worthwhile to over-integrate. Dr. Small added that some research areas may require integration, while others will not.

During the discussion, Dr. Denson captured a list of issues and questions identified by the BOSC members (see Attachment 1). He asked each BOSC member present at the meeting to identify those areas in which they are interested and if they are willing to take the lead for a particular area. The interest of each member present is identified in Exhibit 9. Dr. Denson will work on establishing *ad hoc* committees to address these areas. He indicated that although Dr. Leaderer and Dr. Ray Loehr (The University of Texas at Austin) are not present at this meeting, they both will be key players on the committees. Dr. Denson will contact them to determine their areas of interest. He also will put together a list of the BOSC members who agreed to work on various tasks and e-mail it to every BOSC member. Dr. Denson suggested that the BOSC may want to fine tune the list of areas/questions developed during the brainstorming session (Attachment 1) at the next meeting, when other members of the Board are present.

Dr. Zimmerman asked if anyone was interested in the ecology issue. Dr. Cooper responded that it would be too much of a road block at this stage.

BOSC Strategy for Interacting With ORD Laboratories/Centers

Dr. Cooper and Dr. Schnoor prepared a handout (see Attachment 2) entitled "BOSC Laboratory Strategy" and distributed it to the members present at the meeting. They recommended that BOSC activities that involve ORD-wide analyses continue to use the current committee structure of two co-chairs augmented with three to five outside reviewers. Following such reviews, the co-chairs should be available for Laboratory-specific consultations to advise and monitor the implementation of the BOSC recommendations. These consultations would require no written reports and the co-chairs would be representing only themselves. As each new review is initiated, a new set of co-chairs would be appointed for each Laboratory/Center. This

Exhibit 9. Areas of Interest

BOSC Member	Area(s) of Interest	Assignment/Comment
James Bus	✧ Communications process ✧ Virtual PM Center communications ✧ Effectiveness of workshops	Dr. Bus will develop a list of questions regarding the communications process for review by an *ad hoc* subcommittee
Mitchell Small	✧ Timeline ✧ Compare science/research timeline to regulatory/funding timeline ✧ Responsiveness to regulatory needs	Dr. Cooper agreed to write a paragraph on the timeline issue Dr. Small will develop a list of questions regarding the timeline issue for review by an *ad hoc* subcommittee
Rae Zimmerman	✧ How existing and proposed research programs map into risk assessment/risk management paradigm ✧ How existing organizational and management structure maps onto the communications process (inter- and intra-lab)	Dr. Zimmerman will develop a list of questions regarding these issues for review by an *ad hoc* subcommittee
Jerald Schnoor	✧ Reducing risk and/or reducing uncertainty ✧ How much risk is reduced from PM_{10} to $PM_{2.5}$?	Related to Dr. Zimmerman's first area of interest
William Cooper	✧ Dollars ✧ Centers funding (forward funding) ✧ Sustained funding ✧ Research redundancy/ convergence ✧ CDC epidemiological study	Dr. Cooper will develop a scenario analysis (i.e., Base Budget [worst case] = Scenario 1; Expanded Budget = Scenario 2, etc.)
William Pierson	✧ CDC epidemiological study ✧ Global partners (Eastern/ Western Europe, Far East)	Dr. Pierson will develop a summary of the CASAC review (what happened and when) for circulation to the BOSC
Costel Denson	✧ CDC epidemiological study ✧ International epidemiological data ✧ Management techniques EPA will use to synthesize all the information to make decisions	Independent validation of epidemiological data is needed

structure will provide a consultation service for the Laboratories/Centers without locking the BOSC into a system of standing committees.

Dr. Denson agreed that he did not want to be locked into standing committees corresponding to the Laboratories/Centers. Item I of the strategy mentioned division reviews. Several BOSC members expressed some concern about the BOSC undertaking division reviews. Another member suggested that the strategy

include consultation reports under Item I. Dr. Small expressed concern about the co-chairs providing advice to the Laboratories/Centers. He does not want to be placed into the position of becoming the "scape goat" for failures. An alternative would be for the co-chairs to prepare progress reports that document the Laboratory's/Center's progress on responding to the BOSC's recommendations. Dr. Cooper believes that the Laboratory/Center Directors would prefer informal consultations with the co-chairs. Another BOSC member suggested that the co-chairs could prepare consultation reports. However, Dr. Cooper pointed out that the co-chairs cannot speak for the entire BOSC. The co-chairs could possibly document suggestions for the Laboratories/Centers. Ms. Hamilton warned BOSC members to avoid FACA violations. No more than two BOSC members can meet with a Laboratory/Center in a closed meeting. The co-chairs could prepare a one-page communication to send to the Laboratory/Center Director. Dr. Denson liked the notion of a consultation report. These reports could be patterned after those of the SAB. The consultation reports will be prepared by the co-chairs and reviewed by the BOSC. Dr. Denson suggested that the BOSC try this approach and if it does not work then a different approach will be developed. All of the BOSC members agreed that the co-chairs should be changed periodically. This issue will be put forth for a vote at the next BOSC meeting.

Scheduling the Next BOSC Meeting

Dr. Denson would like to schedule the last BOSC meeting in 1998 as well as those for 1999. Ms. Hamilton will send each BOSC member a calendar so that the meetings can be scheduled on dates when all of the BOSC members will be available to attend. The target dates for the four annual meetings are:

- Late October/Early November
- February
- End of April/Early May
- Mid to Late August

Dr. Small suggested that the BOSC may want to schedule a meeting to overlap with an ORD workshop. This would allow members an opportunity to evaluate the effectiveness of these workshops in facilitating science integration and communication. Dr. Denson asked if it was necessary to do this in conjunction with a BOSC meeting. He was concerned about asking BOSC members to be out of their offices for such an extended period of time. Dr. Denson asked if funds could be made available to allow BOSC members to attend one of the workshops. Ms. Hamilton responded that it might be possible. She agreed to provide Dr. Denson a schedule for ORD's workshops. Dr. Denson thanked the BOSC members for their participation and made a motion to adjourn the meeting. The motion was seconded and the meeting was adjourned.

Action Items

The following action items were identified during the meeting:

- Each BOSC member must complete items 1 through 3 on the Faststart Direct Deposit Form (Form 2231) and return the form to Ms. Hamilton during the meeting or mail them to her following the meeting.

- Ms. Hamilton agreed to check into the matter of computer security regarding the direct deposit of payments to BOSC members in response to Dr. Cooper's concerns.

- Dr. Small agreed to serve as the Chair of the *Ad Hoc* Subcommittee charged with developing a plan to increase the pool of under-represented minorities and women to serve on the BOSC. Dr. Preuss and Dr. Pierson agreed to serve on this Subcommittee. Dr. Denson will contact Dr. Marilyn Brown to determine if she if willing to serve on this Subcommittee. Dr. Bus will provide information/input to the Subcommittee regarding the CDC program and Dr. Zimmerman will provide information about Environmental Justice as a source for potential candidates. Dr. Denson asked the Subcommittee to prepare a preliminary report for presentation at the next BOSC meeting.

- Mr. Longest agreed to provide current workforce profiles of the ORD Laboratories/Centers to the BOSC members to allow them to assess whether ORD has the personnel required to implement the PM research program.

- Mr. Longest agreed to provide the BOSC with a list of the12 themes that have been identified from analysis of the results of the two surveys conducted by ORD.

- Dr. Reiter and Mr. Longest agreed to keep the BOSC informed about what is occurring in the Laboratories/Centers regarding implementation of the BOSC's recommendations. Mr. Longest also agreed to provide a written, formal response from EPA regarding the recommendations in the BOSC's Laboratory/Center review reports.

- Dr. Cooper volunteered to write a few paragraphs on the issues of horizontal integration, defining endpoints, and science/research timeline versus regulatory timeline.

- Ms. Hamilton will determine if EPA has prepared a strategic plan and an implementation plan for PM research. If so, she will provide copies of these plans to the BOSC.

- Ms. Hamilton will provide copies of the CASAC report to the BOSC members. She also will send copies of the following reports to the BOSC members: the NRC report, the NARSTO-A white paper and charter plan, and the Criteria Air Pollutants Progress Report. In addition, Ms. Hamilton will work with Dr. Pierson to identify and distribute copies of all the reports/documents relevant to $PM_{2.5}$ that have been prepared or reviewed by the SAB.

- Dr. Denson will work on establishing *ad hoc* subcommittees to address the areas of interest in Exhibit 9. He also will contact Dr. Leaderer and Dr. Loehr to determine their areas of interest and develop a list of the BOSC members who agreed to work on various tasks and e-mail it to every BOSC member.

- Dr. Denson indicated that the BOSC will vote on the strategy for interacting with ORD Laboratories/ Centers proposed by the Subcommittee at the next meeting.

- Ms. Hamilton will send each BOSC member a calendar for the remainder of 1998 and 1999 so that they can indicate those dates on which they will not be available for a BOSC meeting. The calendars should be returned to Ms. Hamilton as soon as possible.

- Ms. Hamilton agreed to provide Dr. Denson a schedule for ORD's workshops.

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Attachment 1
BOSC Brainstorming Session
August 18, 1998

- Timeline
- Dollars
- Assumption: Is there really a connection between PM & health effects?
- Horizontal integration
- Define endpoints
- Compare science/research timeline vs. regulatory/funding timeline
- Human resources and intellectual capital
- Communications process
- Strategic research plan around PM
- Strategic Plan: State mission and goals as well as methods of implementation.
- Reduce risk and/or reduce uncertainty
- PM_{10} ➜ $PM_{2.5}$ How much is risk reduced?
- Coordination of research plans/programs
- Missing link is causative mechanism (what is causing the response)
- Area where EPA is weak is epi
- Implementation—Mechanism for attaining external research communities
- Causative Mechanism—May not be identified in 5 years
- epi on 2.5 not 10. Is this the problem? Bi-modal distribution by age, by mechanism
- Centers/Funding. Forward funding
- Sustained funding. Critical research should be done in centers if funding runs out.
- Virtual center communications
- Evaluate workshops
- Research: Convergence/Redundancy. Validate: hypothesis driven
  - For certain critical areas we want to see redundancy.
  - Identify key questions—funding redundant, ask EPA
- Global Partner Eastern/Western Europe, Far East. Interactions: opportunity to work with others
- Transparency. Stakeholders made aware of progress/changes. Gate-keepers.
- CDC epi study mandated

Attachment 2
BOSC Laboratory Strategy

I. BOSC activities that involve ORD-wide analyses should continue to utilize the current committee structure of two co-chairpersons augmented with three to five outside reviewers. The combinations of co-chairs of this type includes program, division, and strategic plan reviews.

   Program reviews fit the BOSC mission the best and the division reviews could be nested as case studies within the overall structure of program review.

II. Following BOSC review, like the recent Laboratory reviews, the co-chairs should be available for Laboratory-specific consultations to advise and monitor the implementation of the BOSC recommendations. There would be no written reports to the BOSC and the co-chairs would be representing only themselves.

   A new round of BOSC ORD-wide activity would reset the assignments and a new set of co-chairs would be associated with each Laboratory. Replacements on BOSC would assume the co-chair assignment of the person being rotated off. This structure will provide a consultation service for the Laboratories without locking the BOSC into a system of standing committees.