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

BOARD OF SCIENTIFIC COUNSELORS EXECUTIVE COMMITTEE MEETING

Durham, NC
October 28 - 29, 1999

Thursday, October 28, 1999

Introduction and Purpose 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 indicated that the purpose of this meeting was to conduct a program review of the Office of Research and Development's (ORD) particulate matter (PM) research program. He explained that the BOSC provides independent advice and counsel to the Assistant Administrator of ORD (AA/ORD), including evaluation of research procedures, policies, administration, and other program management issues. Dr. Denson indicated that the subject of this review is the self-study questions that were submitted to ORD. He thanked the ORD staff for submitting timely responses to those questions and he acknowledged Dr. Peter Preuss' (EPA/ORD/NCERQA) efforts in distributing the questions and organizing the responses. Ms. Shirley Hamilton (EPA/ORD/NCERQA), the Designated Federal Official (DFO) for the BOSC, asked participants to complete and sign the travel forms included in the meeting notebook.

Dr. Denson introduced Dr. Hal Zenick (EPA/ORD) who was representing Dr. Norine Noonan (AA/ORD) at the meeting. Dr. Zenick thanked the BOSC members for providing input regarding the coordination, collaboration, and communication associated with the PM program. He asked the BOSC to provide feedback on how well ORD is coordinating this program across federal agencies and stakeholders, and suggested that this review could serve as a model for reviewing other programs.

Dr. Preuss welcomed participants and introduced the Laboratory/Center Directors present at the meeting, including himself, Dr. Larry Reiter (EPA/ORD/NHEERL), Dr. Gary Foley (EPA/ORD/NERL), Dr. William Farland (EPA/ORD/NCEA), and Dr. Hugh McKinnon (EPA/ORD/NRMRL) who was representing Dr. Timothy Oppelt. Dr. Preuss asked the BOSC Subcommittee members to focus on the management of the program because other groups (e.g., National Research Council/National Academy of Sciences [NRC/NAS], Science Advisory Board [SAB]) were reviewing the scientific issues. He reminded the participants that Mr. Henry Longest (EPA/ORD) had asked the BOSC to undertake this review to ensure that ORD is doing everything possible to enhance coordination, collaboration, and communication. Dr. Preuss pointed out that the BOSC report on the PM research program review will be widely distributed. He asked that reviewers identify both strengths and weaknesses in the program management (i.e., what is going well and what needs to be improved). Dr. Preuss acknowledged the tremendous efforts of the ORD staff who helped prepare the responses to the self-study questions.

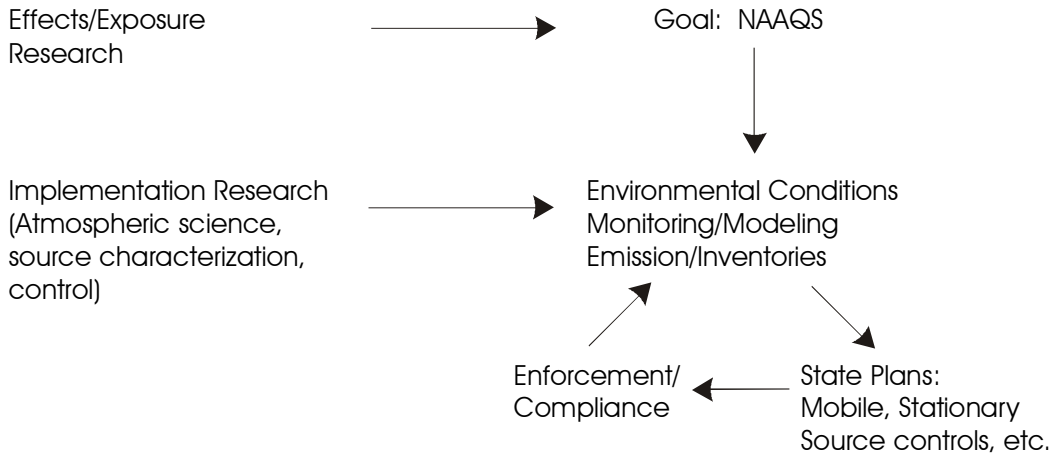
Dr. Denson introduced Dr. Joe Elder (EPA/ORD/NHEERL) who will work with the Subcommittees to develop the BOSC review report. Dr. Denson asked that the Subcommittees prepare and submit bullets for inclusion in the report of the Integration Subcommittee by 3:00 p.m. on Friday. He indicated that the

Integration Subcommittee will be responsible for pulling the entire report together with the help of Dr. Elder. Each Subcommittee will prepare a report that addresses ORD's responses to the self-study questions and the issues discussed during the interviews. He reminded participants to address the six questions in the charge from ORD when preparing the Subcommittee reports.

ORD's PM Research Program

Dr. John Vandenberg (EPA/ORD/NHEERL) outlined his presentation on the management overview of ORD's PM research program, which included the context, drivers, management structures and approach, and response to self-study questions. The context for the PM research program is depicted in Figure 1.

Figure 1. Science for a Purpose: Research Linkage to Framework for Air Quality Management



Dr. Vandenberg identified the following three drivers behind the PM research program:

- Driver 1: Presidential—Federal Particulate Matter Research Coordination. "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."

- Driver 2: Congressional—Research Budget Expansion. Congress nearly doubled the budget for EPA's PM research program for fiscal years 1998 and 1999, with the requirement that EPA contract with the National Research Council to identify priorities for near- and long-term research.

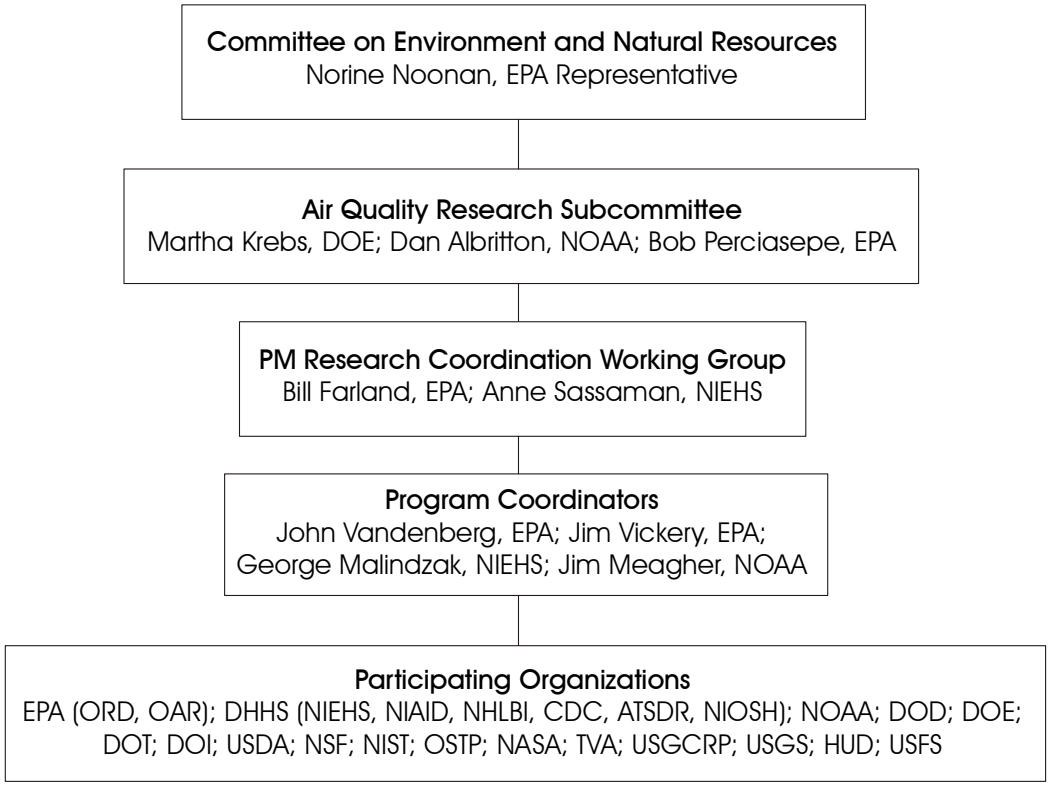
- Driver 3: Scientific—National Research Council (NRC) Recommendations (1999). These recommendations include:

    1. Outdoor measures versus actual human exposures.
    2. Exposure of susceptible subpopulations to toxic PM components.
    3. Characterization of emissions sources.
    4. Air quality model development and testing.
    5. Assessment of hazardous PM components.
    6. Dosimetry: deposition and fate of particles in the respiratory tract.
    7. Combined effects of PM and gaseous pollutants.
    8. Susceptible subpopulations.
    9. Mechanisms of injury.

10. Analysis and measurement.

Dr. Vandenberg noted that the NRC revised recommendations 3 and 4 above from the list published in 1998. He pointed out that EPA's PM research program is consistent with the 1999 NRC recommendations. He also mentioned that the Committee on Environment and Natural Resources (CENR) is expanding the charter of its Air Quality Subcommittee to more actively encompass all federally sponsored PM research, including health research. The NRC believes that this expansion should be encouraged to promote greater coordination of federal resources on PM research. Dr. Vandenberg indicated that the Air Quality Subcommittee would serve as the focal point for cross-agency coordination at the federal level. Dr. Vandenberg presented the CENR organization (see Figure 2) and how EPA's PM Program Coordinators relate to that structure.

Figure 2. CENR Organization



Dr. Vandenberg commented that there has never been a federal program that involved this level of interaction among so many federal agencies. He noted that ORD coordinates the PM research program using a matrix management system. This system is depicted in Figure 3.

Dr. Vandenberg explained that the research is conducted using a team approach, and input always is obtained from line management. He noted that the Assistant Laboratory Directors (ALDs) and Assistant Center Directors (ACDs) have little role in implementation; their primary focus is management and integration. Dr. Vandenberg stressed the importance of the feedback loop between integration and planning, which enables the research findings to be integrated across the ORD matrix.

The ORD PM research planning structure is presented in Figure 4. Dr. Vandenberg serves as the National Research Program Director. He pointed out that there are only four programs within EPA that have been assigned a National Program Director. All four of these programs are very large, highly visible, and integrated across multiple Laboratories/Centers.

Figure 3. ORD Matrix Management

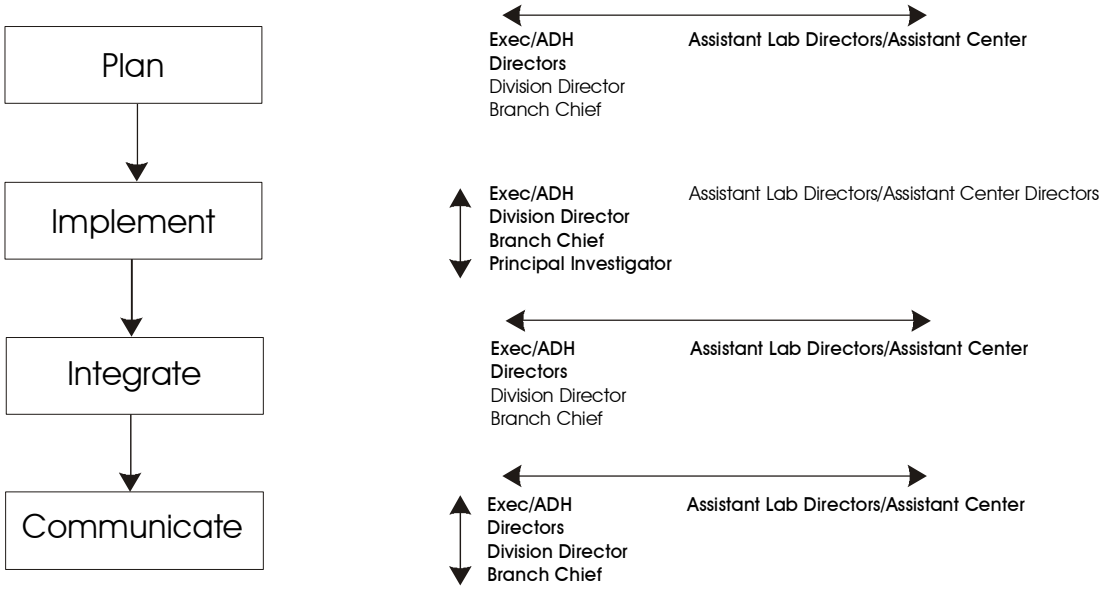
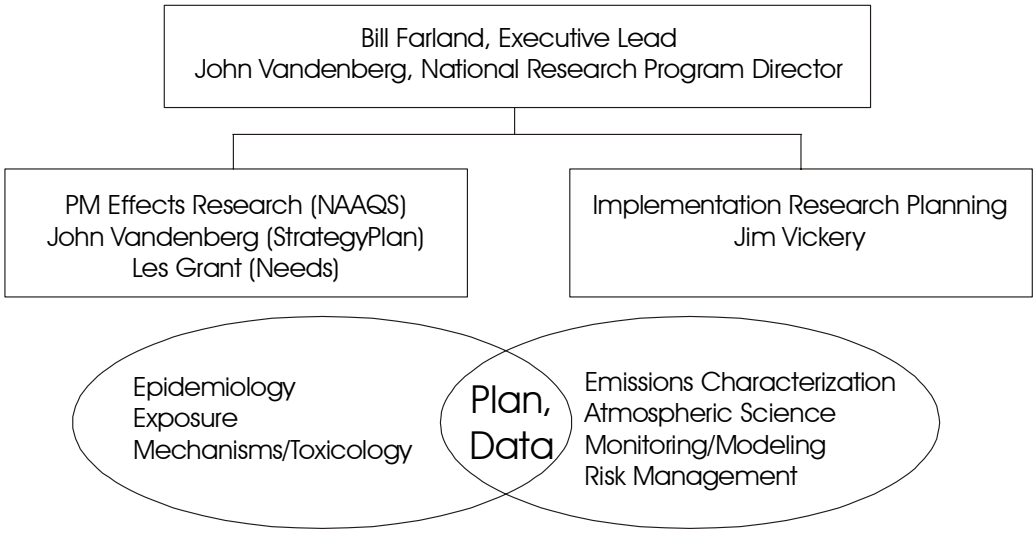


Figure 4. ORD PM Research Planning Structure



Dr. Vandenberg indicated that the PM planning team participants include team management, core team leads, and key staff. He noted that the participation of these individuals is important for planning, coordination, and integration. Dr. Vandenberg presented the research matrix depicted in Figure 5. He explained that three asterisks indicate more involvement and one asterisk refers to less involvement (but some involvement is required).

Figure 5. Research Matrix

	Source	Exposure	Effects	Assessment	Management
1. Outdoor vs. Actual Exposure	✤	✤✤✤	✤	✤	
2. Exposure to Toxic PM		✤✤✤	✤	✤	
3. Source Characterization	✤✤✤	✤✤		✤	✤✤✤
4. Models	✤	✤✤✤		✤	
5. PM Characterization	✤	✤✤	✤✤✤	✤	✤✤
6. Dosimetry		✤	✤✤✤	✤✤	
7. PM/Co-pollutants	✤	✤	✤✤✤	✤	✤
8. Susceptibility			✤✤✤	✤	
9. Mechanisms			✤✤✤	✤	
10. Analysis		✤		✤✤✤	
Criteria Document		✤	✤	✤✤✤	

Dr. Vandenberg provided several team examples to illustrate how the research efforts were integrated across ORD Laboratories/Centers. These examples are depicted in Figure 6.

Figure 6. Team Examples

Cross-Division		
Mechanisms of toxicity	HSD	ETD
Measurements/Models	AMD	HEASD
Cross-ORD		
Epi-exposure	NHEERL	NERL
Source-effects	NRMRL	NHEERL
OAR-ORD		
Supersites	OAQPS	ORD
Chemical speciation	OAQPS	ORD
Cross-Feds/Private		
Atmospheric Sciences	EPA-NOAA-DOE-industry	
Inventory	EPA-HEI-NARSTO	

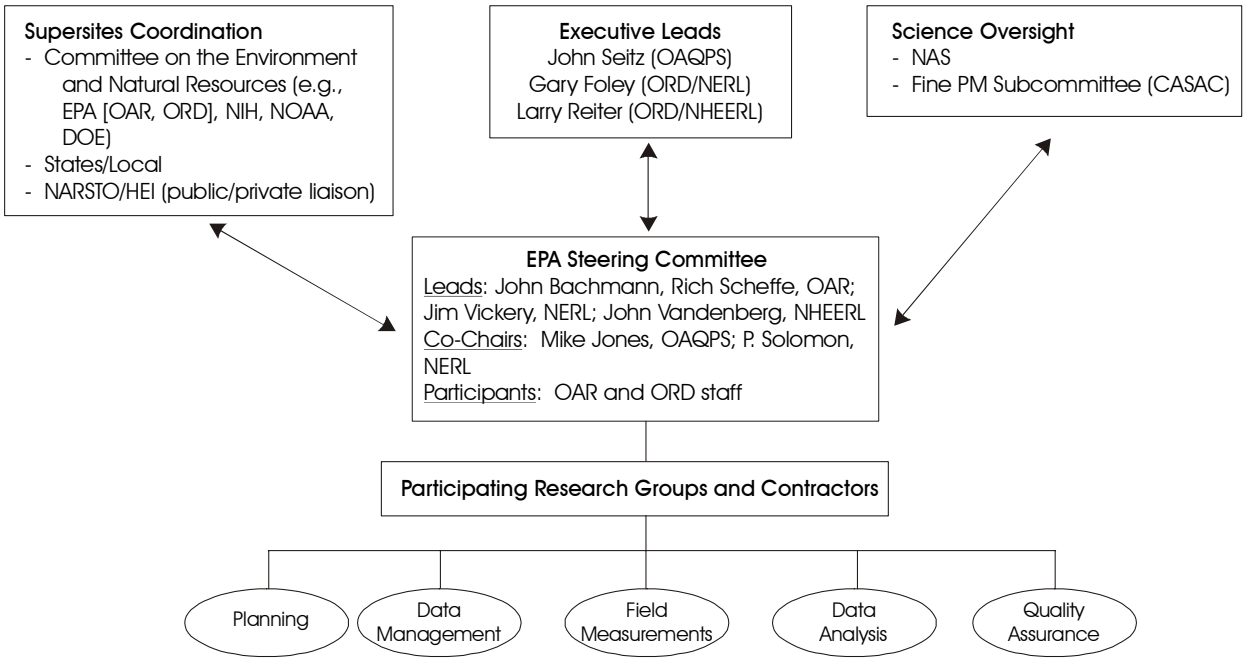
HSD = Human Studies Division, ETD = Experimental Toxicology Division, ATM = Atmospheric Modeling Division, HEASD = Human Exposure and Atmospheric Science Division, and NARSTO = North American Research Strategy for Tropospheric Ozone.

Dr. Vandenberg explained that, at different levels within ORD, there are teams to foster interaction among different Laboratories and Centers, and with the Program Office and other stakeholders. Team-based research planning and implementation that cut across institutional and disciplinary barriers was of high priority and a strength of the PM program. An example of an effective team has developed between the ORD and OAR regarding ambient monitoring systems.

The relationship between monitoring and research is illustrated in Figure 7. Dr. Vandenberg pointed out that EPA was criticized for not integrating monitoring with research. EPA addressed this criticism by formalizing a structure to create a bridge between the Office of Air and Radiation (OAR) and ORD. This

adaptive management approach responded to the criticisms and fulfilled the need for integration. Dr. Vandenberg mentioned that this framework was applied in recommending sites for EPA's Supersites Program. This is an effort to characterize the ambient air in different locations throughout the United States.

Figure 7. Research/Monitoring Organizational Chart



Dr. Vandenberg described the communications activities undertaken by ORD to inform the public and private sectors about the research being conducted and the results obtained. These communications activities include: workshops (e.g., Atmospheric Science/Exposure/Health), organizational meetings (e.g., CENR PM Working Group), conferences (e.g., 3rd Colloquium on PM Health), reports (e.g., NRC materials, publications), and e-media (e.g., Web site construction). He mentioned that ORD is working with the Health Effects Institute (HEI) to develop an inventory that will identify the research being conducted and the organization that is doing the research. EPA is taking the lead on developing this inventory in an effort to identify gaps.

Dr. Vandenberg presented the following responses to the self-study questions prepared by the BOSC:

Question 1: Research coordination of PM research vis-a-vis the risk paradigm
Answer: Teams: cross-federal, cross-Laboratory/Center, and cross-Division.

Question 2: Integration with others
Answer: Through planning, inventory development, peer reviews, and science workshops.

Question 3: Integration to address highest priority needs
Answer: Functional, horizontal, research/monitoring, and intramural/extramural integration.

Question 4: Leadership and results communication
Answer: International ORD scientific leadership; lead others via sponsorship and strong contributions to domestic and international planning and research activities. Communications varied and numerous.

Question 5: Risks, problems, and vulnerabilities; monitoring progress

Answer: Monitoring expanding rapidly; GPRA requires formal commitments to products and goals on an annual basis (GPRA is a good progress tracking tool). Science unknowns and resources are always an issue.

Question 6: Adaptive management and response to change

Answer: Matrix management approach is flexible, strong core team (with fall-back staff if an individual leaves EPA) and clear research directions yield responsive program.

Question 7: Human resource management

Answer: Line versus ALD roles are clear vis-a-vis hiring and management oversight. Recognition including promotions, awards, and job satisfaction are important incentives to staff development. Most staff working on this program have high job satisfaction.

Dr. Denson thanked Dr. Vandenberg for his excellent presentation and opened the floor for questions. Dr. Vandenberg indicated that if he could not answer a specific question today, he would provide an answer as soon as possible. Dr. Frederick Miller (Chemical Industry Institute of Toxicology) asked how many of the 200 FTEs are conducting research and how many are responsible for oversight/management. Dr. Vandenberg responded that of the 60 people in NHEERL, there are 14 responsible for planning and management (approximately 20 percent). Dr. Reiter indicated that about 15-20 percent of the staff in NHEERL are responsible for planning and management. Dr. Preuss added that there are a number of others working on the PM issue through grants and the centers. In addition, some of the Principal Investigators (PI) at EPA generate knowledge as well as manage research. Dr. Thomas Burke (Johns Hopkins University) pointed out that the authority is at the executive level. Dr. Farland responded that the Executive Council, which includes Norine Noonan, Hal Zenick, Gary Foley, Larry Reiter, Peter Preuss, William Farland, and Tim Oppelt, makes the final decisions based on guidance from the research planning teams. One participant asked how ORD coordinates the PM program with the National Park Service and other countries. Dr. Vandenberg responded that the National Park Service is involved and has been very active in the Subcommittee on Air Quality. With regard to coordination across international organizations, Dr. Vandenberg indicated that the World Health Organization (WHO) and similar organizations have been involved in the planning process. Dr. Jim Vickery (EPA/ORD/NERL) pointed out that NARSTO includes Canada and Mexico. He noted that European countries, South America, and southeast Asia also have been involved in planning activities.

Dr. Michael Kavanaugh (Malcolm Pirnie) asked about the right metrics for evaluating a program from a management perspective. What are some specifics regarding the metrics that EPA would like the BOSC to use in evaluating the program? How are the resources divided between management and research? Dr. Vandenberg replied that the same type of metrics that would be appropriate for monitoring progress would be appropriate for the PM research program. Some are broad; for example: How do you sustain a budget? How does EPA communicate with Congressional staff? Other metrics are narrow; for example, science accomplishments. He indicated that the narrower measures are more difficult to identify. One means could be to look at the impacts. Examine the air quality criteria document to determine how science is improving decision making and standard setting processes. This is difficult, but not impossible, to do. Dr. Preuss mentioned another metric: To what degree has EPA currently identified gaps and worked with others to ensure that the PM program is filling those gaps? This will be critical if EPA is to have any answers to include in the criteria document.

Dr. Vandenberg pointed out that GPRA ties together the tracking of performance and accomplishments with the actual impact. He noted that to attain the standard in 2010, there are a number of earlier goals that must be met. The GPRA performance measures tend to be outcome oriented and ORD has developed a multi-year research plan to help identify the products and outcomes that need to be achieved by 2004. Dr. Farland added that GPRA is designed to deal with outcomes rather than outputs. If the major goal is clean air, then all of the annual goals and measures are tied to that outcome goal. He noted that this is not

an easy task for science agencies. Dr. Denson asked if ORD has prepared a "mock" GPRA report as others have done. Dr. Farland responded that such an exercise is underway. He added that EPA is required to prepare a GPRA report annually; the report is due in March 2000. He noted that it is very difficult to justify the PM research program on an outcomes basis rather than an outputs basis. Dr. Denson pointed out that this is a vulnerability. ORD must be ready. He asked ORD to provide a GPRA chart that indicates when certain goals/outcomes can be achieved. Dr. Preuss indicated that ORD has been working on a multi-year plan that identifies annual goals. He noted that EPA's strategic plan was formed around GPRA. Each Office has developed a series of goals and measures for each year. There also are a number of pilots underway for which there are 100+ measures over the next 6-7 years; these will be used to measure future programs. He believes that EPA is far ahead of any other science organization in dealing with GPRA. Dr. Mitchell Small (Carnegie-Mellon University) asked if Dr. Preuss could provide the BOSC copies of the multi-year plan. Dr. Preuss responded that he will provide the BOSC copies, but he is not sure when the plan will be completed. Dr. Rae Zimmerman (New York University) asked how ORD determines if a study is good. Dr. Vandenberg replied that a formal criteria document will be prepared. This document is developed with significant input and undergoes extensive public and internal review. Subsequently, a staff paper is developed that explains what the science means to decision makers. ORD plays an important role in staff paper development to ensure that the science is being used appropriately. Dr. Farland indicated that preparation of the staff paper requires extensive analysis and more integration and evaluation of the research results to ensure that the information is valuable to decision makers. Dr. Vandenberg indicated that a winnowing process is used to identify research gaps and needs for inclusion in the staff paper. He noted that the feedback loop is important.

Dr. Lauren Zeise (Office of Environmental Health Hazard Assessment) asked how EPA determines what issues and aspects to include in the criteria document. Dr. Les Grant (EPA/ORD/NCEA) responded that OAR and ORD Laboratories/Centers identify key issues; they also conduct issue-oriented workshops to obtain additional information. The criteria document development plan is then prepared. This plan identifies key issues and what the document will contain. This is reviewed by the public and the SAB. The document is then modified based on the comments received. Draft chapters are prepared and reviewed through preliminary review workshops. The document is revised and then sent to the CASAC for review. Dr. Farland noted that the paradigm has shifted somewhat. Problem formulation is conducted much earlier in the process to ensure that the final product meets the needs of the client. Regarding EPA's draft Research Strategy for Particulate Matter, Dr. Carol Henry (Chemical Manufacturers Association) asked how Dr. Vandenberg implements the changes suggested by the CASAC. Dr. Vandenberg replied that the team reviews all responses to the questions received from the CASAC to ensure that they represent the ORD-wide view. Each change suggested by the CASAC or resulting from a CASAC question are implemented by rewriting the document. The strategy also will be revised based on CASAC comments and suggestions.

Dr. Reiter pointed out that ORD is planning in three different years at any point in time—current programs, next year's budget, and the President's budget. Because representatives from the Laboratories/Centers and OAR have a strong influence on the research that is implemented, any changes suggested by CASAC or the National Academy of Sciences (NAS) are reflected in the portfolio that is proposed for upcoming years. Dr. Miller asked if there was a formal mechanism for documenting responses to suggested changes. How is an up-to-date research inventory maintained? Dr. Vandenberg responded that one of the first tasks of the working group is to update the inventory. He also would like the research community to participate in updating the inventory. EPA will work with NARSTO to ensure that the inventory is complete. The inventory will be made available online very soon.

Dr. Marilyn Brown (Oak Ridge National Laboratory) noted that matrix management has many advantages and challenges. A significant challenge is that the milestones are contingent upon activities of others over whom Dr. Vandenberg has no authority. There are a number of parallel programs (e.g., global climate change), but many milestones could be better achieved with program integration. Dr. Vandenberg indicated that ORD's formal research planning process includes such integration. Cross-cutting meetings

are held several times each year to ensure that ORD is looking across programs and that appropriate ties are being built. Also at these meetings, the ALDs and ACDs try to identify gaps and missed opportunities. Through a team approach, consensus is reached quickly in establishing a research portfolio that addresses the scientific questions.

John Bachmann (EPA/OAQPS) commented that ORD does not control monitoring, but ORD is working closely with OAR on the monitoring program. Dr. Vandenberg pointed out that ORD worked with PM centers and the PIs of epidemiology and toxicity studies to ensure that the monitors were placed appropriately.

Dr. Armistead Russell (Georgia Institute of Technology) asked if integration is better at lower levels. What is done to integrate across laboratories? Dr. Vandenberg responded that integration must take place at the PI level. The Baltimore study is an example of such integration. The effects and exposure laboratories worked together at the PI level. He noted that there was strong upper management support for that study and stressed the importance of upper management support for integration. Dr. Russell asked how much management drove the integration. Dr. Vandenberg replied that there is a fair amount of management drive behind the integration to overcome the natural tendency for researchers to focus on their own interests. Dr. Judy Graham (EPA/ORD/NERL) added that the issue impacts whether the integration is vertical or horizontal. Some integration comes from the top down; in other cases, it is the researcher who determines who should work together. The Laboratories work together as a team to create the experimental design and how the laboratories should integrate within the program. Dr. Jana Milford (University of Colorado) asked if there are any expertise limitations that will prohibit EPA from conducting the necessary research. Dr. Vandenberg responded that ORD has a strong intramural program; in some areas they have adequate expertise, but not enough resources. Therefore, ORD focuses on targeting the extramural program on research that compliments that of the intramural researchers. The Science to Achieve Results (STAR) program is the Agency's largest commitment to extramural PM research. Dr. Reiter added that there is a Laboratory-based research program that allows ORD to pull in expertise from other federal agencies through interagency agreements and from the private sector through cooperative agreements. Therefore, ORD has three sources of research—intramural, investigator-initiated STAR and Center grants, and Laboratory-based. Dr. Vandenberg noted that ORD also has a post-doctoral program that brings more FTEs to the program and helps build capacity.

Dr. Small asked if Dr. Vandenberg could provide a demonstration of the research inventory because it was not yet available on the Web. Dr. Vandenberg indicated that he could provide some screen shots. He also pointed out that the original inventory is in the back of the National Research Council (NRC) research priorities book. This book includes the core data, but the inventory now is more structured and includes abstracts. Dr. Small indicated that it would be helpful to have a list of the leading scientists identified in the inventory. Dr. Vandenberg mentioned that there are biosketches of the scientists in the report that was sent earlier to the BOSC. Dr. Small also requested a list of the five new PM sectors. Dr. Vandenberg agreed to provide that to participants today. Dr. Burke asked how ORD avoided isolating the PIs from the decision making process. How do ORD managers insulate the scientists from the political comments so that they can continue with the research without removing them from the decision making process? Dr. Vandenberg responded that the scientists are not isolated, but there is a buffer in the form of the National Research Council Committee. This committee created the list of research issues and recommendations and there is significant Congressional support for those recommendations. Dr. Vandenberg added that there are a number of Congressional inquiries. Congress wants to know, for example, what will be included in the criteria document. They are, however, aware that the EPA is not likely to identify a "silver bullet" to solve the PM problem. Therefore, their expectations are realistic. Dr. Farland pointed out that ORD includes the EPA Program Offices in the planning process to prevent them from reassigning resources to address other questions/issues. Dr. Preuss noted that there has been little political pressure regarding the PM issue; however, Congress may loose interest in it or a change in Administration may significantly affect the program. That is when the program becomes vulnerable. How can we immunize ourselves? The NRC is a good buffer.

Dr. Jerald Schnoor (University of Iowa) indicated that ORD has organized the program around the 10 questions from the NRC report. Are there alternative hypotheses being developed? Dr. Vandenberg responded that a group of experts was brought together to develop alternative hypotheses. He noted that the exploration of these alternatives is being encouraged in the STAR program. He acknowledged that this could be a weakness of the program, in that ORD relies upon the scientific community to respond to the STAR program solicitations; however, priorities had to be established because of the myriad of alternative hypotheses. The program is hypothesis-oriented and it is consistent with the NRC report. Dr. Preuss added that STAR/Center proposals are subjected to an internal review to ensure that alternatives are being covered. Dr. Reiter pointed out that the PM program is covering all 10 of the items identified in the NRC report. Dr. Ann Bostrom (National Science Foundation) noted that peer review often promotes conservative approaches. How does ORD deal with this and how are the peer review panels selected? Dr. Vandenberg replied that the RFAs are drafted by the team and are designed to focus on the gaps. The RFAs identify what the team wants outside researchers to explore. Dr. Preuss indicated that it is difficult to prevent conservative approaches; however, if the internal review indicates that the work should be funded, EPA will fund it. The internal group explicitly discusses riskiness. With regard to panel selection, Dr. Preuss indicated that reviewers are selected using a process that is similar to other agencies. Each grant is usually assigned to three primary reviewers; Centers are assigned 10 primary reviewers because of the size and importance of these awards. He noted that it has been very difficult to identify peer reviewers within the United States who were not involved in the PM program. Therefore, ORD looked to Canada and other countries to identify the required expertise for peer review panels.

Dr. Bostrom asked if there is any way that the BOSC can assist ORD in cutting through the "red tape" often involved in expending resources. Dr. Vandenberg replied that ORD has implemented appropriate administrative controls. Dr. Foley indicated that ORD is aware of the legal and regulatory constraints and the areas where it has flexibility. He noted that ORD will find ways to streamline processes when necessary. Dr. Bostrom noted that there are a number of committees and groups that appear to involve the same people. She requested a list of the committees/groups and asked if there was a way that ORD could streamline the number of committees/groups. Dr. Vandenberg responded that the same names appear primarily because of the ALDs and ACDs who are responsible for much of the integration, planning, and coordination. He noted that there are only three major committees/groups. Dr. Bostrom also asked if ORD is coordinating workshops with other agencies/organizations. Dr. Vandenberg replied that ORD is coordinating its next large PM meeting with a number of other groups.

Dr. Henry asked if the management structure of the PM program is a good model. Is NAS oversight a good model? Dr. Vandenberg indicated that it is a good model for managing a program. He added that NAS oversight also is good as long as it does not include instruction on how the work should be done. He noted that there was too much direction on how to do the research in the second NAS report. Dr. Henry pointed out that the NAS recommended several things that appeared to be easy to implement, but EPA has not done so yet. NAS has no authority over EPA to ensure that these are implemented and to change the Agency's priorities. Dr. Zenick noted that the relationship between NAS and EPA will evolve and a proper balance will be developed. Dr. Reiter mentioned that the NAS report described a multi-year research plan for PM. There is value in that. This multi-year plan puts EPA in a much stronger position to argue for resources. In addition, because the NAS report came from outside the EPA, it had credibility. He noted that EPA's plan is very similar to the NAS plan.

Dr. Miller asked if there was an infusion of funds for the PM research program or were the funds reassigned from other programs within EPA. Dr. Preuss replied that ORD's budget has been flat for the past 4 years; therefore, it was a reassignment of funds. Dr. Miller asked if the funding was contingent upon EPA following NRC's recommendations. Dr. Vandenberg replied that Dr. Miller's wording may be too strong. EPA views NRC's 10 recommendations as a guide. He indicated that he can identify how the resources allocated to the PM program align with the NRC recommendations. Dr. Kavanaugh pointed out that the document sent earlier to the BOSC has a list of the funds and how they have been allocated. He asked about number 7 because of the large increase from $1.9 million to $7.4 million. Dr. Vandenberg

replied that the allocation reflects internal shifting as well as the STAR program funding. He noted that decisions regarding the allocation of internal funding are guided by the research plans developed by the line managers.

Dr. Ray Loehr (University of Texas) asked what approach ORD plans to take to disseminate the research results and incorporate them into the decision making framework within the Agency. Dr. Vandenberg responded that most of the results are formally reported in the criteria document. That is a well known mechanism for communicating research results. The formality of that process also lends credibility. Dr. Loehr asked to what extent does Dr. Vandenberg or others brief the Administrator and Congress on the scientific results that are important to decision making. Dr. Vandenberg replied that the OAR is responsible for much of the briefing activity. He added that ORD often supports OAR in briefing the Administrator and Congress.

Dr. Denson closed this discussion session by reiterating the charge to the Subcommittees. He reminded the participants to review the responses to the self-study questions and the responses to the ORD charge questions. He noted that the challenge is to identify areas/issues that have not been mentioned or discussed. Dr. Denson indicated that Dr. Loehr and Dr. Henry, who are members of the Integration Subcommittee, have identified a number of specific points for each Subcommittee to address. Dr. Loehr asked each Subcommittee to provide input regarding the integration functions. Identify what has worked and where more work is needed. Also identify both positive aspects and areas that need improvement. Dr. Henry asked the Subcommittees to provide input on managing accountability—team and team member performance. Also identify how ORD is managing interaction with external stakeholders. She noted that Dr. Vandenberg mentioned federal interaction, but not stakeholder (which includes the regulated community) interaction. What would stakeholders say about the PM program? Dr. Denson pointed out that this should be a positive exercise that will help ORD succeed in its mission. What can we do to help them move forward? Dr. Denson then dismissed participants to attend the four concurrent breakout sessions—Exposure/Atmospheric, Epidemiology/Toxicology, Assessment, and Risk Management. Following the breakout sessions, there were six concurrent sessions (i.e., Exposure, Atmospheric, Epidemiology, Toxicology, Assessment, and Risk Management), during which interviews were conducted with the Laboratory/Center science managers and staff scientists.

Friday, October 29, 1999

Dr. Denson opened the morning session and Ms. Hamilton reminded the BOSC Subcommittee members to submit their travel forms before leaving the meeting.

Integration Across the Risk Management Paradigm

Dr. William Farland indicated that integration is a key element of ORD's strategic goals and plans. This integration includes management integration, science integration, and how to measure success for integration. He noted the importance of integration across the PM program and the integration of planning efforts with program implementation. There has been considerable discussion about cross-disciplinary integration and how that can be accomplished across Laboratories/Centers and within Laboratories/Centers. He acknowledged that there is room for improvement, but that ORD has made a substantial effort to accomplish science integration. Another important aspect of integration involves the intramural and extramural programs—how the STAR program is integrated with intramural research efforts. Dr. Farland also mentioned the importance of measuring integration success. What is the effect of integration on risk management and how standards are set? He noted that ORD has not identified specific measures of success for integration.

Dr. Peter Preuss indicated that 1-2 years from now there should be no gap areas that are not being addressed. The research efforts should cover the entire spectrum. During yesterday's sessions, the

discussion focused on the questions that the BOSC had distributed to ORD; however, there are many other documents/materials that ORD did not provide to the BOSC. Dr. Preuss indicated that additional information would be provided if requested. He mentioned that the criteria document will identify the degree to which the science comes together. Are there other success measures?

Dr. Burke noted that ORD has expended tremendous resources and talent on this effort. Are there questions that are not being addressed? What did ORD terminate to fund the PM research program? Dr. Vandenberg responded that most of the funding was taken from the ozone program. Dr. Burke replied that ozone is important. Does ORD have enough capacity to implement the PM program and efforts to address another new issue? Dr. Preuss noted that the BOSC's questions did not go that far. Given that ORD's budget is flat, other programs must be sacrificed to fund the PM program. There are many different factors that affect these budget shifts. Dr. Preuss did not think the BOSC should focus on this issue.

Dr. Small indicated that it is important to have good interaction between the PM and other programs. He noted that EPA has considerable talent in the area of uncertainty analysis. Is the PM program integrated with those experts? Links need to be built between the PM program and other programs to facilitate a smooth transition when the PM program winds down and the PM issue is solved. Dr. Reiter indicated that ORD has tried to deal with this issue by structuring the research program along Agency goals. Goal 8 of the EPA strategic plan is sound science. Much of the work in support of Goal 8 focuses on conducting research to improve the scientific basis for conducting risk assessment. Many links have been made under this goal. Dr. Farland agreed that the focus is how to integrate ORD's efforts under sound science. For example, one objective is to develop strategic methods and risk assessment models that will be useful for PM and other programs. He noted that there is considerable integration in the air program, but he acknowledged that it could be planned more effectively.

Dr. Miller indicated that the interaction between ozone and particles is seasonal. The ozone problem has not been solved and EPA has a legislational requirement for generating new knowledge about the ozone issue. Dr. Vandenberg replied that ORD recognizes that need, but the overall budget is flat. He noted that the indoor air program was eliminated as a separate program; some of the research has been incorporated into the PM program. Dr. Miller suggested that one of the BOSC's recommendations could be that EPA needs to take a more global orientation to air issues. Dr. Zenick noted that Drs. Noonan and Perciasepe (AA/OAR) met with the Chair of the CASAC to discuss this issue. They agreed to form a small group to scope out what should be done to address the outdoor/indoor air issues.

Dr. Henry pointed out that there are some fundamental technical questions that underlie ORD's efforts. She suggested looking across programs to identify opportunities where the PM program could fund research that might be helpful in addressing other issues of concern to ORD. Common, generic issues should be identified. Dr. Preuss agreed that such an approach is important. He noted that ORD has tried to develop a risk-based program and criteria have been identified to winnow out those issues that have little impact on risk. The PM program stands out because of the magnitude of the risk assessment that has been done in that program compared to other areas. Dr. Preuss mentioned that approximately half of ORD's research program focuses on scientific questions that underlie all problem areas. ORD needs to help outsiders understand how that research relates to other programs.

Dr. Zenick commented that integration is a key issue. As the Administration changes, there will be management changes within federal agencies, and it may be more difficult to keep the federal partners involved. What can ORD do to keep these federal partners working together for the next 5-10 years? Dr. Reiter pointed out that this is not just an external problem. How do we keep EPA involved for the next 5-10 years? Dr. Henry stressed the importance of continuing to work with the National Institutes of Health.

Dr. Denson wrapped up the morning discussion by describing the content of the report on the PM research program that will be prepared by the BOSC. The report will contain: (1) an executive summary; (2) an introduction that describes the process and recommendations; (3) a chapter on the self-study questions; (4) chapters for each of the Subcommittees that will include a list of the self-study questions, commentary on ORD's responses to the questions, and recommendations from the BOSC; and (5) bullets on the six questions in the charge letter from the AA/ORD. Dr. Denson suggested that the next BOSC meeting be held in Washington, DC, in January; possibly January 27-28. He asked members to notify Ms. Hamilton regarding their availability. Ms. Hamilton mentioned that a report to Congress is due. Dr. Denson agreed to provide Ms. Hamilton with a list of accomplishments for the report as soon as possible. Dr. Denson then adjourned the meeting so that Subcommittee members could meet to begin preparing their respective chapters of the report on the PM research program.

Action Items

- ✧ Dr. Small asked Dr. Preuss to provide the BOSC copies of ORD's multi-year plan. Dr. Preuss agreed to provide copies of the plan as soon as it is available.

- ✧ Dr. Denson agreed to provide to Ms. Hamilton a list of accomplishments for inclusion in the report to Congress.

- ✧ Subcommittee members will prepare draft chapters and bullets on the six charge questions for inclusion in the review report.

- ✧ The Integration Subcommittee will prepare the final report, which will include: (1) an executive summary; (2) an introduction that describes the process and recommendations; (3) a chapter on the self-study questions; (4) chapters for each of the Subcommittees that will include a list of the self-study questions, commentary on ORD's responses to the questions, and recommendations from the BOSC; and (5) bullets on the six questions in the charge letter from the AA/ORD.

- ✧ BOSC members will notify Ms. Hamilton regarding their availability for the next BOSC meeting, tentatively scheduled for January 2000.

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