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

BOARD OF SCIENTIFIC COUNSELORS EXECUTIVE COMMITTEE MEETING

Washington, DC
February 28-29, 2000

Monday—February 28, 2000

Introduction and Overview of the Meeting

Dr. Costel Denson (University of Delaware), Chair of the Board of Scientific Counselors, called the meeting to order at 9:10 a.m. He noted that there was a full agenda for the 1½-day meeting. He indicated that his goal for the meeting was to develop a plan to finalize the particulate matter ($PM_{2.5}$) research program review following the presentations by the subcommittee Chairs/Vice Chairs. Dr. Denson mentioned that much of the second day will be devoted to the Science Advisory Board (SAB)/BOSC joint review of the Science to Achieve Results (STAR) Program. He noted that a vote to approve the draft report will be taken following the presentation on the draft report. Another item on the agenda for tomorrow is the renewal of the BOSC charter.

Dr. Denson briefly described the approach used by the BOSC to review the $PM_{2.5}$ research program. He reminded the BOSC members that the report will have to address the six charge questions (expanded to seven questions by the BOSC) submitted to the BOSC by the Assistant Administrator for the Office of Research and Development (AA/ORD). Dr. Denson explained that the BOSC developed a list of additional questions that were based on Dr. John Vandenberg's (EPA/ORD) presentation to the Board approximately 1 year ago. The BOSC formed seven *ad hoc* subcommittees—the Exposure, Atmospheric Sciences, Epidemiology, Toxicology, Assessment, Risk Management, and Integration Subcommittees. The first six of these subcommittees developed draft reports based on ORD's responses to the questions as well as interviews conducted during the October 1999 meeting in Durham, NC. These subcommittees also prepared a list of bullets for inclusion in the integration report to be prepared by the Integration Subcommittee. Dr. Denson pointed out that each of these draft reports will be chapters in the final report submitted to EPA.

Approval of October Minutes

Dr. Denson reported that both he and Ms. Shirley Hamilton (EPA/ORD) had reviewed and approved the minutes from the October meeting. He asked for a motion to approve the minutes and Dr. Ann Bostrom (Georgia Institute of Technology) moved to approve the minutes. Dr. Mitchell Small (Carnegie-Mellon University) seconded the motion and the minutes were approved unanimously.

State of ORD

Dr. Harold Zenick (EPA/ORD), Acting Deputy Assistant Administrator for Science, described the state of ORD. He noted that EPA continues to support a strong research and development (R&D) program that promotes science within EPA, including:

- ✧ Four new "senior scientist" positions.
- ✧ Multi-year planning pilots (5 to 6 pilots are now underway including one on PM).
- ✧ National Program Managers for key programs including PM, drinking water, global, endocrine disruptors, and EMAP.
- ✧ EPA-wide Science Inventory and Science Plan.
- ✧ ORD's Strategic Plan 2000.

The Agency also is promoting science with the university research community through the STAR Program. This $107.3 million program includes research grants ($86.9 million), STAR graduate fellowships ($10 million), and exploratory grants ($10.4 million).

Dr. Zenick mentioned that ORD is not the only entity within EPA that conducts research. He noted that a number of advisory boards have suggested that EPA integrate its research efforts. Dr. Dorothy Patton (EPA/ORD) is leading an effort to develop principles for research. These principles will be designed to ensure that the Agency is doing the right science and that EPA is doing the science right. An Agency-wide inventory of research also is being assembled to provide an overview of the depth and breadth of the research being conducted throughout EPA. This inventory also will help determine how the research is integrated. Dr. Zenick indicated that the inventory will be maintained and made available to the public.

ORD's Strategic Plan 2000 will explain how ORD plans to operationalize the research agenda over the next several years. Dr. Zenick reminded the BOSC members that ORD developed a strategic plan to guide its research in 1996; that plan has been updated and it continues to guide ORD's research efforts. The vision statement in ORD's Strategic Plan 2000 is that ORD's discovery and innovation revolutionalize environmental decision-making. It builds on ORD's 1997 Strategic Plan and it will achieve this vision by:

- ✧ Setting long-term goals.
- ✧ Describing what is needed to accomplish these goals.
- ✧ Establishing performance measures to track progress.

The goals in the Strategic Plan 2000 are to: (1) support the Agency's mission, (2) be a high-performing science organization, (3) be a leader in the environmental community, (4) integrate all facets of risk-based environmental protection, and (5) anticipate future environmental issues.

ORD's research planning process includes input from EPA's Strategic Plan and Government Performance Results Act (GPRA) goals, ORD's strategic planning (the Strategic Plan and peer-reviewed research plans), customer/user needs (EPA Program Offices and Regions as well as federal research partners), and outside peer advice (SAB, BOSC, National Research Council, National Association of Public Administration, and scientific peer reviews).

Dr. Zenick identified the changes in ORD's strategic program for FY 2001. The areas of emphasis will be:

- ✧ Particulate Matter (epidemiology)
- ✧ Drinking Water (including CCL)

- ✧ Food Quality Protection Act (Cumulative Risk/Intermittent Exposure)
- ✧ Resource Conservation and Recovery Act Corrective Action
- ✧ Global Change
- ✧ Integrated Science for Ecosystem Challenges (ISEC)
- ✧ Coastal Monitoring Initiative
- ✧ Children's Environmental Health
- ✧ Human Health Risk Assessment
- ✧ Endocrine Disruptors.

He explained that the ISEC comes out of the Committee on Environment and Natural Resources (CENR) and focuses on forecasting what ecosystems may be most vulnerable and strategies for protecting those ecosystems. The Children's Environmental Health area focuses on enhancing exposure evaluation; it is a modest but well-targeted asthma strategy. Dr. Zenick noted that there will be decreased emphasis on pollution prevention/new technologies in FY 2001. ORD is moving away from environmental engineering economics and focusing more on valuation research.

Dr. Zenick indicated that the FY 2001 Presidential budget for ORD is $530 million, which is actually a slight increase over the $536.3 million FY 2000 budget when the Congressional earmarks are taken into consideration. He pointed out that $43.6 million (8 percent) of the $536.3 million in FY 2000 were earmarked for specific programs or institutions. The percentage of ORD's budget that has been earmarked during the past 7 years has ranged between 3 and 9 percent. Dr. Zenick noted that earmarks are not carried over into the next year. One BOSC member asked why ORD's budget was decreased in 1996. Dr. Zenick replied that he thought the decrease occurred earlier than 1996, but that he did not know the exact reasons for that budget decrease.

In comparing the FY 2000 pending enacted budget to the FY 2001 President's budget for ORD, Dr. Zenick presented a bar graph that illustrated the budget increases by goal. This graph showed a $10 million increase in Clean Air, $8.4 million increase in Clean Water, $2.4 million increase in Safe Food, $1.6 million increase in Safe Communities, $3.5 million increase in Safe Waste, $2.1 million increase in Global Risks, $0.6 million increase in Empowering People, and $8.6 million increase in Sound Science. Dr. Rae Zimmerman (New York University) asked if the goal areas are equally funded. Dr. Zenick responded that the areas are not funded equally. For example, the Sound Science Goal accounts for approximately 40 percent of the budget. He noted that Clean Air and Clean Water account for the largest portion of the budget. Dr. Zimmerman asked if there are cross-cutting areas; for example, PM and children's health (asthma). Dr. Zenick replied that all areas have been asked to include a focus on children's health. He indicated that the asthma strategy will be integrated with the PM work and the efforts on children's health. He noted that ORD looks for opportunities for coordination across goals and centers.

Dr. Peter Preuss (EPA/ORD) indicated that ORD has been funding a group of children's health centers for the past 2 years. Five of these centers focus on asthma and ORD ensures that their efforts are integrated with others funded and conducted by EPA. Dr. Denson asked if there are a number of programs and disciplines within the Sound Science area. Dr. Zenick responded that the intent of the Sound Science area is to maintain the ability to conduct long-term core research that is not driven by specific problems. Dr. Bostrom asked what research is included in the area of Empowering People. Dr. Zenick replied that this area includes a number of risk assessment tools, including IRIS and an ecological database. He noted that EMPAC also was under this area until it was moved to the Office of Information. In response to a question regarding why EMPAC was moved, Dr. Preuss responded that EMPAC is more of a public information program. Dr. Denson asked Dr. Zenick to identify the STAR funding on his graph. Dr. Zenick replied that the STAR Program is integrated across all goals. Dr. Preuss added that if the budget is reduced, it would affect both the intramural efforts and the STAR Program. He noted that line items have a huge impact on both intramural and extramural efforts because they are planned together.

PM Research Review Discussion

Dr. Denson indicated that this session will involve presentations by the Chairs/Vice Chairs of the subcommittees created to review ORD's $PM_{2.5}$ research program. Each of the draft reports prepared by the subcommittees will become a chapter in the final report. Dr. Denson pointed out that the reports need more consistency in construction. He added that the Integration Subcommittee will pull the integration bullets identified by the other six subcommittees together and write the integration section. The Integration Subcommittee also will prepare the Executive Summary for the report. Dr. Denson mentioned that Dr. Joe Elder (EPA/ORD) prepared a rough draft of the bullets provided by the subcommittees that will be handed out later during the meeting. Dr. Denson noted that some subcommittees did not identify integration bullets. For those subcommittees, Dr. Elder tried to identify integration issues and included them in his draft. Dr. Denson asked that the BOSC members review that draft and provide comments to him before the conclusion of the meeting. He will work with Dr. Ray Loehr (University of Texas) and Dr. Carol Henry (Chemical Manufacturers Association) to develop the integration section, but he needs input from the BOSC members regarding what to include in that section. In response to a question concerning whether the integration bullets should be included in both the subcommittee reports and the integration section, Dr. Denson replied that they should only be included in the integration section. The Chairs/Vice Chairs of the subcommittees should determine what should be transferred from the report to the integration section.

Exposure Subcommittee Draft Report Discussion

Dr. Bostrom, Vice Chair of the Exposure Subcommittee, provided a brief overview of the exposure report. She indicated that the format of the report is not consistent with the other subcommittee reports. Dr. Denson asked BOSC members to provide input on the format for each chapter. The BOSC members agreed that each chapter should include an introduction, the questions that were asked by the subcommittee, a discussion of the self-study responses, and recommendations/conclusions drawn by the subcommittee. Dr. Denson noted that some of the reports, including exposure, did not contain a recommendations section. Dr. Bostrom responded that the recommendations were presented in the body of the report, not in a separate section. It was agreed that an executive summary for each report was not necessary. Dr. James Bus (The Dow Chemical Company) noted that the sentences in bold in the draft report could be pulled together as a recommendations section. Dr. Denson thought the conclusions and recommendations should be in bold type in the body of the report and then summarized at the end of the chapter. Dr. Bonnie McCay (Rutgers State University) pointed out that her subcommittee pulled the recommendations out of the body of the report and presented them in the last section. Should the recommendations be inserted into the text? Dr. Denson replied that they should be placed in the body of the report in bold text. Dr. Bostrom indicated that she will have to discuss the comments received from Dr. Vandenberg with the other subcommittee members before she can provide the requested clarifications. Dr. Denson asked that each report identify the members of the subcommittee and their affiliations. Another BOSC member suggested that all of the subcommittee members could be identified in an appendix to the entire report. Dr. Denson agreed with that approach.

One BOSC member pointed out that the exposure report mentions in several places that ORD lacks social science expertise; however, this point is not emphasized in the conclusions. Dr. Bostrom agreed that this point should be incorporated into the final section of the exposure report. She also suggested that the point regarding modeling efforts preceding data availability should be reworded. Dr. Zimmerman asked for a description of the Atlanta pilot study. Dr. Bostrom replied that the Electric Power Research Institute (EPRI) and the American Petroleum Institute (API) are conducting the study and EPA is collaborating with them. She mentioned that Atlanta is one of the Supersites. Dr. Zimmerman asked that a sentence describing the study be added to the report. Dr. Bostrom also agreed that the report should acknowledge that the PM research program is relatively new and therefore the lack of publications is not surprising.

Dr. Bostrom pointed out that the exposure report included a section entitled other issues, which addressed communication, Web sites, and metrics. Dr. Denson suggested that these issues with the exception of metrics be moved to the integration section. Dr. Bostrom asked if it would be appropriate to refer to the National Center for Environmental Research (NCER) communication plan even though it was not discussed during the review. Dr. Denson replied that it should not be mentioned in the report if it was not discussed. Dr. Bostrom acknowledged that there are several recommendations in the exposure report that are broad and should probably be included in the integration section (e.g., post-doc integration across laboratories/centers). She agreed to review the recommendations to determine which should remain with the exposure chapter and which should be included in the integration chapter. Dr. Vandenberg agreed to determine if EPA had any additional comments on the exposure report. If so, he will try to provide them to the BOSC before the close of the meeting. He mentioned that the use of the word guidance with regard to the Health Effects Institute (HEI) is inaccurate. He noted that the report should clarify HEI's role, which is more to broker public-private coordination, not to provide guidance. Dr. Denson agreed to verify with the Chair whether "guidance" is the word the subcommittee wishes to use. Dr. Small pointed out that EPA reacted strongly to this wording because the word "guidance" has specific meaning to EPA

Dr. Marilyn Brown (Oak Ridge National Laboratory) commented on the first paragraph on page 4 of the exposure report. Should the report suggest that ORD develop formal ways to increase communication between ORD scientists and EPA grantees. Dr. Bostrom asked if it would be appropriate to mention the STAR reviews. She noted that although these workshops are supposed to occur annually, they do not. Dr. Brown added that this comment also is relevant to the STAR Program Review Report. Dr. Bus thought that comment should be included in the integration section. Dr. Judy Graham (EPA/ORD) noted that everyone working on exposure studies meets twice each year. She added that new grantees are invited to these meetings, but they are strictly for panel studies. Dr. Bostrom agreed to clarify this issue in the report. Dr. Zimmerman noted that the last paragraph on page 2 is not clear. She asked that an explanation regarding why it is essential for ORD to work with the Office of Air Quality Planning and Standards (OAQPS) be added to the report. Dr. Zimmerman also asked Dr. Bostrom to clarify the problem indirectly referred to in the third paragraph on page 4 (beginning with "In the exposure area"). In addition, Dr. Zimmerman asked if the subcommittee had identified anything more immediate than journal publications to measure productivity. She noted that conference presentations are a faster means of obtaining feedback than journal publications. Dr. Bostrom agreed to address Dr. Zimmerman's comments.

Dr. McCay pointed out that there are a number of redundancies in the exposure report, including the lack of social science expertise and integration across the risk paradigm. Dr. Bostrom agreed to review the report and eliminate these redundancies.

Atmospheric Sciences Subcommittee Draft Report Discussion

Dr. Small, Chair of the Atmospheric Sciences Subcommittee, indicated that the atmospheric sciences report was organized around the charge questions from ORD. He noted that the questions posed by the BOSC and the responses from ORD were interspersed into the charge question framework. He acknowledged that, based on the earlier discussion regarding report format, the atmospheric sciences report will have to be reworked around the self-study questions. Dr. Bus asked if the self-study questions were included in the current draft. Dr. Small replied that the self-study questions were printed in italics and the recommendations of the subcommittee were preceded by arrows. He agreed to reformat the report and identify the recommendations using bold text. In addition, he noted that some of the text should be moved to the integration chapter. Dr. Small mentioned that the report reflects the experiences of the subcommittee members with regard to particle characterization and monitoring and health effects research.

The subcommittee members thought that the 1:10 ratio identified on page 2, Question 2 was too small. They believe that too little is spent on analysis relative to the amount spent on collection. The

subcommittee recommended that ORD increase efforts to ensure that adequate resources are available for, and allocated to, the analysis of data collected in major field studies, such as Supersites. The subcommittee also recommended that ORD clarify its role, including intramural and extramural programs, on new science development versus science integration, application, and consensus building. He mentioned that ORD needs to identify consensus tools for regulatory application.

Dr. Jim Vickery (EPA/ORD) asked if the second recommendation on page 2 is referring to the fact that there needs to be a different balance in these roles. Can the subcommittee be more clear? Dr. Small responded that integration, application, and consensus building have been sequential activities in the past, and the subcommittee members thought better interaction and integration was needed. Dr. Vickery mentioned that he did not provide any comments on the draft report because there were no technical errors.

Dr. Small recommended increasing involvement of STAR grantees and ensuring that they are involved in efforts that cut across the risk paradigm. Dr. Small commented that integration across the risk paradigm was good at the management level. Dr. Vickery responded that there is good integration in the field, but at the bench level there is little interaction across the risk paradigm. One BOSC member pointed out that the first recommendation on page 3 under Question 3 is redundant with previous recommendations. On page 3, Question 4, regarding communication of results, Dr. Small warned that ORD should expand collaboration beyond local universities. Dr. Brown commented that increasing the involvement of STAR grantees should accomplish that expansion because these grantees are located all over the country. She suggested that the comment be reworded so that local collaboration is not sacrificed for national collaboration. The sentence could be reworded as follows: "In addition to the productive collaboration with local universities, ORD should expand their vision and horizon ..." Dr. Small agreed to consider rewording this recommendation.

Dr. Vandenberg pointed out that international integration (mentioned on page 4) is complicated by the difficulties associated with obtaining approval of international travel. He indicated that ORD has paid for international experts to attend meetings in the United States. Dr. Small acknowledged the difficulties but recommended that ORD work to find more opportunities to bring international scientists and EPA scientists and grantees together as equals. Dr. Vickery asked if the subcommittee's recommendations/comments concerning STAR grantees also apply to EPA scientists. Dr. Small replied that he was not sure; the comments were focused on STAR grantees. He noted that STAR grantee participation needs to be improved, and he agreed to clarify the recommendation in the report.

Dr. Vickery asked if the subcommittee had a recommendation concerning the 1:10 ratio mentioned on page 2, Question 2. What ratio would be better? Dr. Small replied that it might be helpful to determine the ratios for other programs. He indicated that the subcommittee members had strong feelings about this point and he agreed to consult them concerning a better ratio. Dr. Brown cautioned against suggesting a specific ratio because the ratio probably varies for different scientific studies.

Dr. Small agreed to consider all of the comments and suggestions, and to work with the other subcommittee members to revise the atmospheric sciences report. He also will prepare an introduction for the report and reformat it according to the guidelines established earlier by Dr. Denson.

Toxicology Subcommittee Draft Report Discussion

Dr. Bus, Chair of the Toxicology Subcommittee, indicated that the toxicology report addressed both the self-study and the charge questions. Dr. Denson pointed out that the charge questions will be addressed in the integration report. Dr. Bus mentioned that the subcommittee included a number of conclusions under the charge questions, but they could be reworked into the self-study questions. He noted that there is some redundancy between those recommendations under the charge questions and the ones associated with the self-study questions.

With regard to the first charge question, Dr. Bus indicated that there is good correlation between the National Research Council (NRC) topic areas and ORD's PM research program. The subcommittee members were satisfied that relevant PM materials were being used for toxicology studies. The subcommittee recommended that ORD needs to ensure that dose-response information is available for the inhalation toxicology studies. The subcommittee also recommended increased emphasis on management integration of exposure studies on susceptible subpopulations. Both *in vitro* and *in vivo* models are being used and developed to investigate postulated mechanisms of PM-induced tissue damage and disease. Dr. Bus noted that the subcommittee members were quite impressed with the Utah Valley Studies. They were an excellent model of integration. The subcommittee recommended that ORD continue to develop long-range research management plans that deliver appropriate research results in needed timeframes. He added that ORD should continue to identify milestones and that they should not all be long term. The subcommittee found that communication and collaboration are areas that need attention. The extramural and intramural efforts need to be aligned but not redundant.

The Toxicology Subcommittee recommended that ORD management needs to foster effective cross-laboratory analytical efforts to support the timely integration of particulate analytical data into toxicology studies. The analytical efforts are lagging behind and ORD needs to ensure that the momentum is maintained. The subcommittee also suggested that ORD ensure that adequate contingency laboratory and fiscal resources should be developed to rapidly respond to events that have potential implications for assessing the impact of particle pollution on human health. The current funding does not allow flexibility to adapt to those types of events. Once budgets are determined and funding is allocated, it is difficult to adapt to changing circumstances or changing hypotheses. Dr. Bus indicated that the toxicology group was doing an effective job of making their research visible to the outside scientific community. Dr. Brown asked if it would be possible to refine the conclusions and recommendations to give greater specificity to EPA Can we give them some ideas about how to, for example, set aside contingency funds or integrate with the STAR Program? Dr. Bus replied that the subcommittee did not have any suggestions on how to ensure that contingency funds are available. Dr. Vandenberg noted that it is not easy to move funds after the budgets have been approved. Dr. Bus replied that the subcommittee members found that lack of flexibility frustrating because ORD could not position itself to take advantage of unexpected opportunities. Dr. Vandenberg indicated that ORD has some flexibility in that the annual budget can be spent over 2 years instead of 1 year—this avoids panic spending at the end of the fiscal year.

Dr. Zimmerman pointed out that there is little mention of regulatory communities under charge Question 4. Dr. Bus responded that the subcommittee viewed the question in context of how science helps EPA make better regulatory decisions. Dr. Bostrom asked to what extent ORD is following the communication plan. Dr. Vandenberg replied that ORD uses a variety of ways to communicate. Following the PM 2000 meeting in Charleston, SC, ORD staff met to discuss the presentations. Dr. Bostrom asked if that was typical. Dr. Vandenberg replied that it was not typical and occurred primarily because there was a large number of ORD and Office of Air and Radiation (OAR) staff at that meeting who will be involved in developing the criteria document. Dr. Bostrom asked about communication with Congress. Dr. Vandenberg replied that communication with Congress is accomplished through formal briefings and responses to inquiries. He mentioned that Dr. Zenick recently briefed Congress using the same presentation he used earlier today. Also, Dr. Vandenberg is drafting comments for the AA/ORD's presentation to Congress. This presentation will relate ORD's accomplishments and their importance to regulatory development, including some illustrative examples. In response to Dr. Bostrom's question concerning NCER's communication plan, Dr. Vandenberg indicated that the plan was not discussed during the PM review.

Mr. Jack Puzak (EPA/ORD) indicated that the NCER communication plan was prepared about 3-4 years ago to improve communication of information from the STAR Program within EPA and to Agency constituents. He also mentioned that NCER is piloting state-of-science documents to determine if that method is appropriate for getting information out to researchers and EPA staff. Mr. Puzak pointed out

that NCER has implemented a variety of methods to distribute STAR research results to the Program Offices. NCER has found that unless the information is presented in a manner that indicates how the research affects them, the Program Offices do not use it. He mentioned that NCER has not updated the communication plan, but indicated that it will be readdressed in the Strategic Plan 2000 process. He noted that NCER's goal is to get scientific results to the right people in the most effective manner possible.

To conclude the discussion of the toxicology report, Dr. Bus indicated that he will revise the format of the report and address the various comments of the BOSC members.

Assessment Subcommittee Draft Report Discussion

Dr. Zimmerman pointed out that the format of the assessment report differs from the other reports. For example, the assessment report includes a list of the documents that the subcommittee reviewed (in the references section). The introduction of the report describes the overall purpose of the National Center for Environmental Assessment (NCEA) and the scope of the subcommittee's review, which addressed:

- ✧ The methodological approach being used in risk assessment for PM.
- ✧ The integration of results from the intramural and extramural research programs into the assessment.
- ✧ The incorporation of advice/recommendations contained in the BOSC Program Management Review of NCEA into the PM program.

The introduction also includes a list of the presentations that were made to the subcommittee during the review. Dr. Zimmerman explained that multiple major risk assessment documents are related to the revision of the PM standard. These include the PM Air Quality Criteria Document (AQCD), the PM Staff Paper, and the Research Needs document. On page 2 of the report, the process for planning and preparing the AQCD is described. She noted that the subcommittee encouraged in depth discussions between NCEA and OAR staff at the early stages of the assessment process. Dr. Zimmerman indicated that this involvement needs to take place before the problem formulation stage rather than the end of the AQCD development cycle. The subcommittee also recommended that NCEA consider other related issues during the problem formulation stage—possibly establishing a process whereby PM reviews could be conducted with reviews of other pollutants (e.g., ozone). Another recommendation is to strengthen the connection between NCEA, other parts of the ORD research program, and other research resources to further improve the AQCD development program. Dr. Zimmerman noted that the talent and experience of the scientists involved in drafting the AQCD is extensive and the subcommittee recommended that the Agency take the steps necessary to ensure continued scientific excellence in AQCD development.

Dr. Zimmerman noted that the Agency relies on the Clean Air Scientific Advisory Committee (CASAC) and workshops for peer review of Agency work products and plans. The subcommittee encouraged EPA to remain vigilant in its selection of venues and reviewers to ensure that fair, objective, and in depth reviews occur. Dr. Zimmerman indicated that Question 2, regarding the integration of results from the intramural and extramural research programs into the assessment, was the most difficult to address. One problem noted during the review was the difficulty of obtaining original data for analyses. The BOSC subcommittee recommended that EPA establish a clearer data exchange protocol to enable NCEA to verify the results of outside studies as needed.

In terms of intramural research, about 40 percent of NCEA's staff time is spent on internal grants. The NCEA Director reserves 10 percent of NCEA's funding for the internal grants program. Dr. Zimmerman mentioned that the STAR Program, the laboratory-based research center grants, and interagency agreements are some examples of NCEA's sources for generating extramural research. The

subcommittee recommended that NCEA develop a process to formally interact with these extramural research sources.

A description of the input provided during discussions with staff is provided on page 7 of the report. With regard to incorporation of advice/recommendations contained in the BOSC Program Management Review of NCEA into the PM program, Dr. Zimmerman indicated that the BOSC's recommendations have been addressed, with the exception of benchmarking. The subcommittee found that NCEA had taken efforts to improve integration and alignment of its strategic plan and activities with the direction and priorities of the ORD plan. In addition, NCEA is maintaining close relationships with OAR, its key client. NCEA also has improved its process for project planning and tracking of progress. The BOSC supports the attempt to expand the GPRA planning period because it encourages more effective use of resources.

In regard to integration and communication with NCEA's units, Dr. Zimmerman pointed out that NCEA's divisions are geographically separated. Although resources are shared among the locations, the resources that augment staff are concentrated in Washington, DC. The subcommittee recommended that ORD develop more incentives to ensure that staff members from the different NCEA divisions are drawn upon by individual divisions when needed. The subcommittee suggested that temporary transfers of staff between the Laboratories and NCEA might be used to enhance integration of scientific expertise. The subcommittee also recommended that NCEA continue and expand its efforts to use creative mechanisms to obtain more post-doctorates. During the interviews, staff identified a need for direct, external contracting of well-defined and circumscribed tasks. They indicated that contracting was the only way to get a specific answer on a particular date. An extensive list of the subcommittee's conclusions and recommendations was provided on pages 11-13 of the report. Dr. Zimmerman then briefly described the recommendations as well as NCEA's strengths.

Dr. Brown indicated that ORD's comments and corrections on the draft assessment report are helpful. She agreed to work with Dr. Zimmerman to revise the report. She thanked Dr. Vandenberg for correcting the statement about ORD originally developing the particle concentrator (page 6). Dr. Brown also noted ORD's clarification concerning its collaboration with HEI in developing the Web-based inventory of research. Dr. Vandenberg pointed out that the role of HEI in the Harvard six cities study was actually to broker the agreement so that the health records could be audited by an independent fourth party (i.e., University of Ottawa). He clarified that neither EPA nor HEI had access to the original data, but HEI provided resources for the University of Ottawa to audit and reanalyze the data. Dr. Brown mentioned that data ownership and privacy protection of individuals are significant concerns. Dr. Bus noted that these concerns also apply to toxicological data generated under the STAR Program, because all federally funded information must be made available under the Freedom of Information Act. He pointed out that OMB Circular 110 states that EPA owns the data generated under cooperative agreements and grants. If data are used for regulation, they must be made available to the public. This circular applies to all awards after October 1, 1999. Dr. Bus noted, however, that although EPA does not own the data it has the right to use the data without any fees. Dr. Zimmerman asked if ORD had experienced any other problems in obtaining access to data. Dr. Vandenberg replied that there also was a situation similar to the Harvard six-cities study with the American Cancer Society study.

Dr. Zimmerman pointed out that there is a list of three journals at the top of page 5 of the report. A fourth journal was mentioned during the review and she asked if ORD could provide the title of that fourth journal. Dr. Les Grant agreed to provide that information as soon as possible.

Dr. Vandenberg expressed some concern about the phrasing of the first bullet under Recommendation 1 on page 11. He suggested that the subcommittee consider changing the wording from "support the rulemaking for the different structures" to "increase the scientific foundations of ..." He pointed out that research is not directed by policy and it is not conducted simply to support rulemaking. The science should not be conducted to support the policy. Dr. Jim Vickery (EPA/ORD) asked about the

recommendation on establishing a process whereby PM reviews could be conducted with reviews of other pollutants. He noted that Les Grant would be concerned about this recommendation. How involved should this be? Dr. Vandenberg added that staff limitations would make such reviews very difficult. Dr. Vickery pointed out that this would be a fundamental shift from current practice, which is to move from one criteria document to another. Dr. Small replied that it should be implemented even though it would involve significant change. There is so much synergy and overlap. He believes that the BOSC should push ORD in that direction.

Risk Management Subcommittee Draft Report Discussion

Dr. McCay, Vice Chair of the Risk Management Subcommittee, provided an overview of the draft risk management report. She pointed out that there were only two self-study questions. The responses to those questions are presented on pages 4-7 of the report. Dr. McCay acknowledged that the report would have to be reorganized to conform to the format specified by Dr. Denson. She began her presentation by describing the response to the second self-study question, which asked how the results of ORD's PM research will be used to determine potential risk management strategies. Dr. McCay noted that the National Risk Management Research Laboratory (NRMRL) serves the following two functions within the current PM management structure: (1) to lead efforts on source characterization, and (2) to inform implementation agencies about the technical feasibility, potential cost, and secondary consequences of alternative control strategies.

Dr. McCay pointed out that the draft report includes a list of eight findings and recommendations. She noted the third recommendation regarding ending points. The subcommittee recommended that the Agency take concrete steps to periodically assess the value of continuing individual areas of research once they have been initiated. She suggested that perhaps ORD should move forward with a pilot for assessing alternative strategies. Dr. McCay also pointed out that there are no STAR grants related to this topic and there is very limited funding in alternative control strategies. The Risk Management Evaluation (RME) concept is one method for NRMRL to broaden its efforts. She noted that the subcommittee had a different perception of risk management than NRMRL. The subcommittee viewed risk management as informed decisions to manage risks.

Dr. McCay mentioned that accountability and authority are unclear. One apparent example that the subcommittee noted was that the PM team leaders are supposed to be held accountable, but they lack line and budget authority. Despite this lack of clarity, the team approach appears to be working despite ambiguous and awkward management structures. The subcommittee noted that although communication appears to be at a historic peak, there is still room for improvement. In addition, much of the coordination to date has resulted from personal connections and chance encounters rather than as a result of planning and needs assessment. The subcommittee also recommended that the Agency carefully consider how to align incentives created by promotional criteria explicitly with good programmatic priorities, even if this may mean less adherence to an academic view of excellence. Dr. Bostrom pointed out that EPA is concerned about the reputation of its scientists; therefore, the Agency is adhering to the academic model. She noted that the report does not acknowledge the historical problem experienced by EPA. Dr. Bus added that companies that do science must develop different incentive programs than those used for academia. He indicated that company scientists as well as those at EPA, must develop expertise centers. This differs from the academic scientist who is conducting research and publishing the results. Dr. Bostrom asked about some incentives used by such companies. Dr. Bus indicated that these scientists have a different client base whose needs they must serve. It is essential to obtain feedback from those clients to determine if the needs are being met. For example, if the National Health and Environmental Effects Research Laboratory (NHEERL) is not providing NCEA the right technical advice, then it should be reflected in performance evaluations. Dr. Bus added that promotion criteria is not just a function of counting papers, they also include involvement in the scientific community, invitations to speak at conferences, and original thinking. Dr. McCay mentioned that it is supposed to be the same in academia,

but everyone is convinced that it is really the number of publications. She agreed to modify the wording regarding incentives.

Dr. Brown asked about the breadth of coverage recommendation on page 1 of the report. She noted that this recommendation to focus on increasing the scope of information provided in this area, in particular how different PM constituents may increase or decrease with different control measures, may be technical and not management. She suggested that the recommendation be changed to read that NRMRL needs a system to allow it to respond to the needs such as the one cited. Dr. McCay asked if this issue should be moved to the integration section. She noted that NRMRL is not equipped to examine human behavior. Dr. Small indicated that this issue also was mentioned in the exposure report. He added that human behavior has an impact on exposure and the generation of pollutants in indoor environments.

Dr. McCay suggested that the issue be included in the integration section in more general terms. She also mentioned that the first self-study question on page 4 was not a very good question to ask the Laboratory. However, the response to the question helped the subcommittee learn how PM fits into the overall program and the PM planning process and how priorities are established. It is a very incremental process and many participate in it. The subcommittee members thought that the process was not adequate; NRMRL needs to do a better job of weighing priorities. The subcommittee suggested the use of "what if" scenarios or sensitivity analyses in identifying benefits and tradeoffs from risk control/management programs. Dr. McCay also pointed out that NRMRL's role appears to be quite marginal to the NRC priorities. She noted that the Laboratory is struggling to adapt and make its efforts more important to those priorities. The subcommittee report offers some suggestions on who NRMRL could accomplish this; for example, conduct more risk tradeoff analyses.

Dr. Denson indicated that NRMRL's marginal role could result from NRMRL's lack of forcefulness or failure of the National Program Manager to invite the laboratory to fully participate. Dr. Small asked if it could result from the fact that the majority of NRMRL staff is not located in Research Triangle Park, NC. Mr. Puzak pointed out that NRMRL's traditional focus has been engineering, which could account for their marginal involvement. Dr. Denson suggested that the subcommittee revisit the NRMRL management review report. He asked the subcommittee members to consider the impact of the statement that NRMRL's role has been marginalized. Dr. Small mentioned that such wording implies purposeful intent. Dr. McCay stated that there was no reason to believe it was purposeful. Dr. Vandenberg noted that NRMRL's role (evaluating risk management activities) was not included in the NRC priority list. He explained that the National Academy of Sciences (NAS) removed that role because it considered such evaluation outside the purview of the program. Dr. Vandenberg acknowledged that this was one of the pieces missing from the NRC PM priorities; another is monitoring methods. Dr. McCay agreed that marginalized may be too strong. Dr. Vandenberg added that the commentary is useful and could perhaps be included in the integration report. He also noted that ORD misunderstood the first self-study question from the subcommittee.

Dr. McCay agreed to address EPA's comments as well as those of the BOSC members. She also noted that the discussion of the charge questions will be moved to the integration report. Dr. Vandenberg agreed to provide any additional comments from ORD's risk management staff as soon as possible (see page 16; comments were provided on February 28).

Integration Report Discussion

In response to a member's question, Dr. Denson indicated that the outline provided in the handout prepared by Dr. Elder was for the entire report, not just the integration section. He asked the BOSC members to identify any themes that should be included in the integration report. Dr. McCay noted that one theme is that because the risk paradigm is very broad, it is difficult for any unit or program to cover it entirely. Therefore, integration is critical and it is a major challenge. Dr. Bostrom mentioned that the framework for managing the PM program is an excellent model for integrating across disciplines. The

structure helps with intra/inter coordination, communication, prioritization, and scientific leadership. Dr. Brown noted that there were a number of cross-cutting issues associated with staff resources. She pointed out that the Agency's current experts are stretched thin and there are areas in which EPA does not have adequate expertise. Dr. Bus suggested that the Agency could use the STAR program to fill those expertise gaps. Dr. Brown also encouraged more integration with STAR grantees. Members agreed that a more systematic approach to integration between intramural and extramural research is needed. ORD should leverage whatever is available to cover its human resource limitations. The BOSC members identified the following items for inclusion in the integration section:

- ✧ Are there management arrangements to integrate PM research with research on other co-pollutants (i.e., those pollutants related to the PM issue)?

- ✧ Note the expressed need for contracts and the fact that this need is not unique to the PM issue but results, in part, from ORD's reorganization.

- ✧ The need for budgetary flexibility to take advantage of opportunities. It has been improved, but is it truly flexible enough?

- ✧ Has the narrow focus of the PM program led to the exclusion of alternative hypotheses for health effects? Very little of the PM work is hypothesis driven.

- ✧ Is the PM program absorbing resources at the expense of other programs?

- ✧ What is the breadth of concern, sensitivity?

- ✧ Are the ORD Laboratories efficiently coordinating research across the risk paradigm?

Dr. Bus expressed some concern about removing the charge questions from the chapters. Will the bullets make sense if they are taken out of context and placed in the integration chapter? Dr. Bostrom pointed out that if they are left in the chapters there will be considerable redundancy. Dr. Bus suggested that only the redundant issues be removed and placed in the integration section. Dr. Bostrom asked if one individual should be assigned to each charge question and tasked with preparing a response. Dr. Brown mentioned that specifics are not that useful; the integration section should identify generalities. She agreed that only those points found in several chapters should be included in the integration section. Dr. Denson noted that there are redundancies among the responses to the charge questions. He also commented that there are idiosyncratic findings that do not merit inclusion in the integration chapter.

Dr. Denson led a discussion of the bullets on the handout prepared by Dr. Elder (see Attachment 1). Please refer to Attachment 1 for the text of the referenced statements in the following discussion.

Risk Paradigm (RP)

- ✧ "Risk management alternatives are currently receiving too little focus. Although costs need not become part of the risk management process, risk-risk tradeoffs are very relevant and should be given a larger role in both setting research priorities and in thinking about risk management decisions to attain the PM NAAQS." This statement, referred to as RP 1 in Dr. Elder's handout, should be kept in the Risk Paradigm section of the integration chapter.

- ✧ "The PM research effort is well coordinated across the risk paradigm. From an organizational perspective, it is clear that a strong effort has been made to make sure the Labs are communicating. Overdependence upon the paradigm in shaping the research should be avoided, because the information needs of the public health and regulatory communities are extensive." This statement, referred to as RP 2 seems to contradict the findings of the other subcommittees. It should be

combined with the following statement "The broad public health importance of air pollution should not be obscured by division of the science into the compartments of the risk paradigm," which is referred to as RP 3 in Dr. Elder's handout.

- ✧ The following statement "We are very positive about the overall effort, in particular the long-term planning process for research and research integration and that this has resulted in funding the key areas, both (a) fundamental new science (heavily weighted to the extramural program, and (b) integrating, synthesizing, and building concensus on existing science and state of the art science (primarily intramural)," referred to as RP 4 in Dr. Elder's handout, should be moved to the introduction of the Risk Paradigm section.

- ✧ The BOSC members agreed that the next three statements in Dr. Elder's handout (referred to as RP 5, RP 6, and RP 7) are appropriate for the integration section.

- ✧ Statements RP 8, RP 9, and RP 10 should be combined.

- ✧ The statement referred to as RP 11 should be moved to the introduction of the Risk Paradigm section.

Priorities (P)

- ✧ The following statement, referred to as P 1 in Dr. Elder's handout, is a good introduction to the priorities section: "The Laboratories have heeded the direction of the NAS Report and research directions are consistent with the guidance of the Academy."

- ✧ The next statement, referred to as P 2, should be deleted.

- ✧ Statement P 3 is appropriate.
- ✧ Statement P 4 should be deleted.

- ✧ Statements P 5, P 6, and P 7 should be moved into the introduction for the integration section.

- ✧ Statement P 8 is appropriate.

- ✧ Statement P 9 should be moved into the introduction for the integration section.

- ✧ Statement P 10 should be combined with statement RP 6. Dr. Bostrom agreed to rewrite the combined bullet.

- ✧ Statement P 11 should be combined with RP 6.

- ✧ Statements P 12, P 13, P 14, and P 15 should be deleted.

Communication (CAR)

- ✧ Statement CAR 1 is appropriate.

- ✧ Statement CAR 2 should be combined with statement CAR 4. The question regarding meetings in CAR 4 should be deleted.

- ✧ Statement CAR 3 is appropriate.

- ✧ The first phrase in statement CAR 5 should be combined with statement CAR 1. The remainder of the phrase should be reworded. (Note: Some words may have been deleted when this bullet was copied from the report.)

- ✧ Statement CAR 6 should be combined with statement CAR 7.

- ✧ Statement CAR 8 should be deleted.

- ✧ Statement CAR 9 should be reworded and combined with statement CAR 10.

- ✧ Statement CAR 11 is appropriate.

- ✧ Statements CAR 12, CAR 13, and CAR 14 should be deleted.

Communication to the Broader Community (CBC)

- ✧ Statement CBC 1 should be moved to the end of the Communication to the Broader Community section.

- ✧ Statement CBC 2 should be deleted.

- ✧ Statement CBC 3 should be combined with statement CBC 1. Dr. Tom Burke (Johns Hopkins University) should clarify this statement.

- ✧ Statement CBC 4 should be moved to the front of this section. One member commented that workshops could be used for consensus building/prioritization.

- ✧ Statement CBC 5 should be deleted.

- ✧ Statement CBC 6 should be reworded, changing NCEA to ORD.

- ✧ Statement CBC 7 should be combined with statement CBC 4.

- ✧ Statement CBC 8 is already covered in statement CBC 4.

- ✧ Statement CBC 9 should be merged with Integration 5 on the flip chart (see Attachment 2 for flip chart notes).

- ✧ Statement CBC 10 should be rewritten and combined with Integration 5 on the flip chart.

- ✧ Statement CBC 11 needs to be rewritten to be more general. This is an important point because the Web site should be evaluated as a communication tool.

- ✧ Statement CBC 12 should be rewritten; it is unclear without specifics.

Leadership (L)

- ✧ Statements L 1, L 2, L 3, L 4, and L 5 should be combined.

- ✧ Statement L 6 is appropriate. American Waste Management Association should be Air and Waste Management Association.

- ✧ Statements L 7, L 8, L 9, and L 10 should be combined because they all relate to recruitment, development, and retention.

- ✧ Delete statements L 11, L 12, L 13, and L 14.

- ✧ Statement L 15 should be retained in the integration section, but the exact location within that section has not been determined.

- ✧ Delete statements L 16, L 17, and L 18.

Management Changes Needed (MAN)

- ✧ In statement MAN 1, "appropriate" should be replaced by "exemplary." The second sentence should be deleted because there are always suggestions for improvement. Are changes to management structure and/or processes needed to ensure success?

- ✧ Statement MAN 2 should be combined with statement MAN 4. This idea is captured in Integration 2 on the flip chart (see Attachment 2).

- ✧ Statement MAN 3 is appropriate. Is there enough depth in the program so that when personnel changes occur the program will continue?

- ✧ Statements MAN 4 and MAN 5 are appropriate.

- ✧ Statement MAN 6 should be moved to the priorities section.

- ✧ Delete statement MAN 7.

- ✧ Statement MAN 8 should be moved to the communications section.

- ✧ The last two sentences in statement MAN 9 should be deleted. Can appropriate metrics be established?

- ✧ Statement MAN 10 should be combined with statements L 7, L 8, L 9, and L 10.

- ✧ Statement MAN 11 should be moved to the priorities section.

- ✧ Statements MAN 12 and MAN 13 are already captured in the management section.

- ✧ Statement MAN 14 is appropriate. Across different areas there are different degrees of emphasis. Can the epidemiology expertise be accessed through the extramural program?

- ✧ Statement MAN 15 is the same as item 5 on the flip chart (see Attachment 2).

- ✧ Statement MAN 16 is the same as item 8 on the flip chart (see Attachment 1).

- ✧ Statement MAN 17 is appropriate. This item is related to sustainability.

- ✧ Statement MAN 18 is appropriate.

- ✧ Statement MAN 19 is appropriate. This also should be referenced in the communication section.

- ✧ Delete statements MAN 20 and MAN 21.

Dr. Denson concluded this discussion by agreeing to work with the other members of the Integration Subcommittee to develop the integration chapter based on this input.

Before adjourning the meeting for the day, Dr. Denson mentioned that the charter for the BOSC must be renewed. This will be a topic of discussion during tomorrow's session. Dr. Preuss pointed out that most members of the BOSC have been on the Board since its inception. He asked the members to give some thought to the term length, Chair rotation, whether there should be a Vice Chair, and the process for nominating new members. Dr. Vandenberg provided several comments on the draft risk management report that he had received from Research Triangle Park. These comments included concern over the use of the word marginalized. They also pointed out that the risk management evaluation system was in response to the BOSC management review of the Laboratory. Another comment was that a hiring freeze had made it difficult to hire staff. Dr. Denson then adjourned the meeting for the day.

Tuesday—February 29, 2000

Overview and Review Process and Summary of BOSC/RSAC Subcommittee Findings

Dr. Denson convened the meeting at 8:38 a.m., and quickly reviewed several changes in the day's agenda. He reminded the BOSC members that the AA/ORD had requested that the BOSC and the SAB conduct a joint review of the STAR program. Dr. Brown served as Co-Chair of the STAR Program Review Subcommittee, which was a joint subcommittee of the SAB (Research Strategies Advisory Committee [RSAC]) and the BOSC. Dr. William Cooper (Michigan State University) and Dr. Ann Bostrom (Georgia Institute of Technology) also served on this subcommittee. Dr. Denson participated in all of the meetings and conference calls associated with the STAR program review. He commented that the subcommittee did an outstanding job with the review and indicated that the BOSC needed to vote on the acceptance or rejection of the report. Dr. Denson also pointed out that the results of this discussion will be presented at the SAB meeting next week. He will attend that meeting and Dr. Brown will be available by telephone to answer any questions that may arise.

Dr. Brown briefly described the review process and summarized the subcommittee's findings. She noted that the review focused on the management and structure of the STAR Program rather than an assessment of the progress to date because the program has only been in existence since 1995. She indicated that the goal of the STAR Program is to "include this country's universities and nonprofit centers in EPA's research program and to ensure the best possible quality of science in areas of highest risk and greatest importance to the Agency." The STAR Program, which is administered by NCER, consists of four components:

- ✧ Focused Requests for Applications (RFAs) targeted to national environmental science needs as related to the mission of the Agency;
- ✧ The Exploratory Research Grants Program, which provides support for investigator-initiated grants in broad areas of environmental science;
- ✧ The Graduate Fellowship Program, which provides support for master's and doctoral students in environmental science, engineering, and policy; and
- ✧ The Environmental Research Centers Program, which focuses on long-term, multidisciplinary research issues.

Dr. Brown indicated that the charge to the STAR Review Subcommittee was to assess the following:

- ✧ Is the STAR Program structured to support outstanding scientists and technically meritorious research? Is the outreach to potential applicants, the review of proposals, and the management of awards structured to foster high-quality science?

- ✧ Is the STAR Program effectively integrated with ORD's in-house programs and with other EPA programs? Are the topics selected for STAR solicitations consistent with the priorities identified in the Agency's Strategic Plan? Are there other opportunities where the STAR Program could significantly contribute to the Agency's strategic goals?

- ✧ Is the STAR Program communicating well within the Agency, with the external scientific and regulatory communities, and with other stakeholders? Is there sufficient leveraging and coordination of research efforts?

- ✧ What systems should be in place to monitor the Program's impacts, costs, credibility, and effectiveness, and to what extent are these in place already? What metrics of success in determining the effectiveness of grants to have impacts on Agency decisions should be developed? What information should be collected today on metrics of success for the STAR grants? How should Program Offices and other agency customers for the grant products be involved in the establishment of criteria for measuring the impacts of the program?

The findings of the subcommittee are described on pages 8, 9, and 10 of the draft report. Dr. Brown noted that the most important findings include the following: (1) the STAR Program appears to be structured and managed so as to play a key role in generating high quality science, (2) it is conducted by highly qualified scientists, and (3) the program addresses topics that are relevant to the environmental problems identified in EPA's Strategic Plan. Dr. Brown pointed out that EPA has implemented this extensive extramural program without appreciable increases in internal staffing. Pages 8 and 9 of the report describe some constructive suggestions for mid-course improvements in the program relative to the charge questions. The subcommittee noted that staff resources and technology/information transfer were worthy of more significant consideration.

Staff Resources. Three NCER divisions administer the STAR Program—the Environmental Science Research Division, the Environmental Engineering Research Division, and the Peer Review Division. The approximately 36 staff in these three divisions, including 18 Project Officers, manage the STAR Program as well as EPA's Small Business Innovation Research (SBIR) Program and several university-based research centers that are not part of the STAR Program. Dr. Brown noted that although the ratio of STAR Program applicants per Project Officer and the ratio of active grants per Project Officer are comparable to ratios associated with the National Science Foundation (NSF) grants program, the NCER Project Officers have the additional responsibility of transferring the information to maximize the value of the STAR grants to the Agency. Dr. Brown indicated that the NCER Project Officers are responsible for:

- ✧ Planning, through participation on Research Coordination Teams (RCTs) and interagency committees;

- ✧ Preparation of solicitations, outreach to potential applicants, and proposal review;

- ✧ Monitoring and quality assurance during the life cycle of the projects; and

- ✧ Summarizing, communicating, and marketing project results to promote their use by the Agency (i.e., technology transfer).

Dr. Brown indicated that the subcommittee did not identify any means to significantly increase management efficiencies among NCER staff. The subcommittee suggested that the Project Officers might benefit by scaling back the number of visits to STAR grantees. Perhaps a sorting process could be

developed to identify and eliminate site visits that would offer the lowest return on investment. The subcommittee concluded that greater EPA staff resources are required to maximize the public's return on investment in the STAR Program.

Technology Transfer/Information Transfer. The subcommittee recommended that NCER place greater emphasis and attention on developing and implementing the tools, management processes, and procedures for ensuring that the information and results of the STAR Program are being rapidly and effectively transferred to the Agency and other potential users. NCER should look for ways to shorten the time frames for getting peer-reviewed information to users and making the information easily accessible by potential users. In addition to the mechanisms currently being explored by NCER (e.g., program goal roadmaps, Web site keyword searches, and State-of-the-Science Reports), the subcommittee suggested that NCER develop peer-reviewed workshop proceedings.

Dr. Brown pointed out that Section 4 of the report is organized around the charge questions. She summarized the findings contained in each section.

Supporting High Quality Science. The first section focuses on supporting high-quality science and addresses outreach to potential applicants, review of proposals, and management of awards. She noted that NCER's Web Site is working very well and it is easy to track the number of hits to the overall site as well as the individual pages. These hits also can be broken down by country. Dr. Brown indicated that the site had 130,000 hits in December 1999. One BOSC member asked if NCER tracks the number of hits focused on RFAs versus the number of hits from visitors searching for research results. Dr. Brown responded that additional information on the Web Site was provided in the Appendix A of the report.

The structure of the STAR proposal review process is similar to those used by the high-quality programs at the NSF and the National Institutes of Health (NIH), and the criteria used in the grant review process seem both appropriate and clearly stated. Dr. Brown noted that the subcommittee did not assess if the review process has resulted in the selection of the best scientific proposals. The responses to topical RFAs are evaluated using a two-tiered approach. First, proposals are reviewed by independent panels to determine their scientific and technical merit. Panels assign ratings of excellent, very good, good, fair, or poor to each proposal. Following the technical review, those proposals rated excellent and very good undergo a relevancy review by the Agency before final funding decisions are made.

The subcommittee analyzed the success rates of STAR Program grant proposals for solicitations closing in FY1998. The subcommittee found that the success rate for the STAR Program (10.5%) is lower than that experienced by NSF (approximately 30%). Dr. Brown indicated that the subcommittee attributed this lower success rate to the relevancy review—following the relevancy review of the FY1998 proposals only 45 percent of the proposals rated excellent or very good were funded. Dr. Peter Preuss, Director of NCER, pointed out that it is the available funding and not the relevancy review that is responsible for the low success rate. He noted that in only one case (i.e., Indicators of Global Climate Change) has the relevancy review been responsible for preventing a proposal from being funded. He added that the relevancy reviewers are not asked to determine whether a project should be funded; instead, they are asked to rank the proposals in order of relevance to the Agency's mission. NCER then uses this ranking to determine how many proposals can be funded with the resources available. Dr. Preuss noted that he personally scrutinizes those proposals that receive an excellent rating during the technical review and a lower ranking in the relevancy review, which places them below the funding cutoff. If warranted by the quality of the proposal, it may be funded despite the lower relevancy ranking. Dr. Brown mentioned that the Exploratory Research Grants had lower success rates than the targeted RFA grants.

The subcommittee suggested that NCER write more targeted RFAs and tighten up the scope statements so that the success rate of the best quality applications increases while ensuring the relevance of the research to the Agency. The subcommittee also encouraged the Agency to prepare more detailed documentation of the relevancy review so that the applicants will be better informed about what is being sought.

Applicants who are rejected based on lower scores from the relevancy review should receive specific information about the reasons (including budgetary reasons) for their rejection. The subcommittee also suggested that the Agency provide individual reviewer comments (anonymously) to the applicants who are declined. Another subcommittee suggestion was to distribute abstracts of the proposals to reviewers prior to the review meeting and ask them to designate which proposals they feel most comfortable reviewing. This process would facilitate a better matching of proposals to reviewers' capabilities. The subcommittee also recommended that reviewer scoring biases be normalized before panel decisions are made. In addition, the subcommittee suggested that NCER include more international experts on the independent panels and consider the use of *ad hoc* reviewers (i.e., reviewers who receive only one proposal to review and do not attend panel meetings) when proposals are highly diverse or involve fields for which recruitment of panelists is difficult.

With regard to managing awards, the subcommittee encouraged the Agency to adopt computerized management systems to the maximum extent possible. Electronic filing of grant applications and electronic distribution of proposals to reviewers (when possible) would be helpful.

Supporting the Agency's Strategic Goals. This section of the report addressed integration with ORD's inhouse and other EPA programs, planning, relevancy review, interactions during the course of the STAR grant, program review workshops, balancing the research portfolio, and transfer of STAR results. Involvement of ORD, Program Offices, and Regional Offices in the STAR Program occurs primarily during the planning process through the RCTs. The RCTs, which are organized largely along media lines, include representatives from ORD and Program and Regional Offices. These teams conduct the final relevancy review of STAR applications that have received excellent and very good ratings by independent peer reviewers. The subcommittee applauded NCER's innovative efforts to improve integration of STAR Program grants and communication of results to target audiences. The subcommittee recommended that NCER expand cooperation and partnerships with other parts of ORD, with EPA Program and Regional Offices, and with other federal, private, and international research organizations.

The process used to select RFA topics appears to be robust, appropriate, and well-integrated with Program Office needs and ORD and Agency-wide strategic plans. Use of the RCTs appears to be a good, direct approach for involving the key players and stakeholders. The subcommittee noted that further consideration of the extent to which regional office needs and issues are factored into the planning process is warranted. There is only limited Regional Office representation on the RCTs; therefore, Regional Offices have limited input into RFA definition and relevancy reviews. The subcommittee noted that NCER's new multi-year planning initiative, designed to demonstrate how the outputs of the STAR Program and other ORD efforts support the strategic plan, should be an effective mechanism for identifying potential future RFA topics for STAR. The subcommittee suggested that the Agency select several STAR research grants as case examples and evaluate the effectiveness of the coordination with the relevant client offices and the degree to which the awards are supporting the Agency's strategic goals. This self assessment could lead to ideas for further improvements in integration.

To strengthen the relevancy review and foster integration within ORD and across the Agency, EPA might consider strengthening the involvement of ORD staff in the relevancy review. This could be accomplished by having EPA staff review the full proposals and peer reviews for all scientifically meritorious STAR applications, instead of simply having the relevancy review conducted on the basis of abstracts and the peer review panel's summary comments.

The subcommittee noted that there are no specific mechanisms to ensure closer working relationships between EPA scientists and STAR grantees and an ongoing awareness of EPA's evolving needs. The subcommittee suggested two possible activities for strengthening communication between Agency personnel and STAR grantees: (1) meetings between STAR Program principal investigators and Agency

staff to discuss integration opportunities, and (2) establishment of STAR points of contact at ORD's Laboratories and Centers as well as in Program Offices.

The subcommittee suggested that feedback on the success of the annual program review workshops relative to increasing interactions between STAR researchers and relevant EPA personnel would be useful. The subcommittee also suggested that the workshop proceedings be expanded to include a record of discussions, exchange of ideas, integration across research projects, and their relevancy for environmental decision making.

Dr. Brown noted that the growth of the STAR Program has resulted in a significant shift in the nature of the Agency's extramural R&D performers (toward university and nonprofit centers and away from for-profit contractors and interagency agreements), and in the financial mechanisms used to secure these resources. Although the STAR Review Subcommittee did not assess whether the current balance among intramural research, contract activities, and STAR grants is appropriate, it did suggest that EPA should develop an ongoing process for assessing and directing the allocation of resources across types of research organizations and funding mechanisms. The subcommittee noted that NCER's new multi-year planning efforts will provide a framework for the Agency to consider, and to explain, the balance of R&D performers in individual research areas.

Dr. Brown pointed out that NCER has a number of initiatives to enhance the transfer of STAR results. For example, NCER's Web Site contains annual reports and summaries, NCER invites program office staff to participate in annual workshops, and NCER conducts targeted Web searches for EPA personnel to identify relevant STAR grants. The subcommittee noted that more needs to be done to effectively integrate results. One suggestion was to expedite the peer review process for STAR results. NCER is exploring the use of "State of the Science" reports, which independently gather and integrate the research findings from several grants on related topics. These synthesis reports could be peer reviewed prior to release. Other techniques suggested by the subcommittee include: sponsoring workshops with peer-reviewed proceedings, arranging for special issues of journals to accelerate review and publication of results, and conducting peer review panels of STAR research results in the same manner as the initial review of the STAR applications.

Communication and Coordination. The subcommittee noted that ORD fosters communication about the STAR Program through the Internet, publications, and workshops as well as site visits, informal communications, and other means. The subcommittee pointed out that, although these mechanisms appear to be appropriate, most are relatively passive and rely on an interested audience that will actively search for new information. The subcommittee suggested that NCER identify and test more proactive mechanisms to further enhance this critical component of the STAR Program. The NCER Web Site could benefit from updating and possibly further promotion. The subcommittee suggested surveying a representative group of potential users of STAR results to measure awareness of the program and evaluate the effectiveness of its communication strategies. The subcommittee indicated that formal investigations of the effectiveness of STAR communication efforts are warranted. For example, the evaluation of program workshops might be done using a simple questionnaire of the sort used at many conferences. Internal evaluation of the program's outreach effectiveness could provide insight into how to improve current efforts, raise awareness within the Program Offices of the STAR Program's potential usefulness to them, and even suggest new ways of ensuring that STAR results reach the appropriate EPA users.

The subcommittee recommended that the partnerships established with other federal agencies for joint research solicitations be continued. The subcommittee also suggested that, as the STAR Program becomes more amenable to quantitative assessments, the costs, benefits, and relative paybacks of these partnerships should be appraised. Dr. Brown noted that the Decision Making and Valuation for Environmental Policy program, which is conducted in collaboration with the NSF, is currently being evaluated by the NSF. Lessons learned from the evaluation may help EPA improve this and future joint efforts. The

subcommittee encouraged ORD to expand its joint endeavors, including possible joint funding of STAR research with private foundations and international agencies and research organizations.

Metrics of Success. The subcommittee suggested that ORD consider multiple approaches to evaluate the STAR Program's impacts, costs, credibility, and effectiveness. NAS has identified four important ways that the Nation benefits from its investment in federal research: knowledge advancement, knowledge application, human capital development, and mission advancement. The subcommittee identified several potential metrics of success as they relate to the following groupings in the NAS report:

- ✧ The STAR Program's contribution to EPA's Sound Science goal, which includes knowledge advancement, knowledge application, and human capital development; and

- ✧ The STAR Program's role in supporting EPA's environmental risk assessment and risk management goals, which is the mission advancement benefit noted by NAS and the impacts of decision making in the EPA Strategic Plan.

A good measure of scientific excellence is the rate of citations of peer-reviewed publications by other scientists. Various citation indices are available that could be used as a good measure of the frequency with which STAR grant studies are referenced by others. Another measure of scientific excellence is the frequency of national awards given out by professional research organizations for research conducted by STAR Program grantees.

Possible measures of "influence diffusion" from the STAR Program might include the extent of followup funding by other agencies and the movement of STAR-funded researchers (e.g., doctoral students and post-doctoral fellows) to other research institutions. ORD could ask grantees and fellows to keep EPA apprised of the employment whereabouts of such researchers, at least through the first post-university job. The evaluation of the program's success could then include the fraction of the STAR beneficiaries who move on to environment-relevant jobs in academia, government, and the private sector.

The measures of success of the STAR Program relative to mission advancement should address the timeliness and dissemination of the information to the users, including the Program and Regional Offices as well as EPA researchers. In addition, it is critical that Program Offices and other Agency customers for the grant products be involved in the establishment of criteria for measuring the impacts of the program. The subcommittee recommended that NCER directly engage these customers, perhaps through a newly constituted RCT, in defining the criteria for evaluating the STAR Program's contribution to advancing the Agency's mission. The subcommittee also suggested that ORD consider the following types of metrics and data collection activities:

- ✧ Conduct a peer review of the results and reports of a sample of STAR grantees in a manner similar to that for the proposals, to see how the research actually rates with respect to scientific quality (poor to excellent). Consider the NAS study as well as the EPA Strategic Plan criteria of relevance, quality, and leadership to evaluate each product.

- ✧ Evaluate the use of information generated by selected individual grants relative to the EPA and ORD goals. Request that grantees include in their summary reports a self assessment of how data should or could be used to address strategic goals. This information would allow ORD to quickly assess the relevance of the research product and would force researchers to think about possible applications of their results.

- ✧ Conduct a relevancy evaluation (perhaps by the RCT) of selected individual grants after review of the products to determine if they remain relevant and why or why not.

- ✧ Evaluate citations to STAR project publications in EPA regulatory documents as another measure of STAR's success with respect to the Agency's mission.

- ✧ Define lessons learned from these assessments to suggest different proposal review methods, RFA specifications, or interaction mechanisms that can improve the quality and relevance of future efforts.

- ✧ Determine the time frame required for information from the grant program to reach the Program Office, Regional Office, or researcher.

- ✧ Poll customers within and outside the Agency regarding the value of STAR products. Suggested questions to include in such a questionnaire were presented in the report. When a sufficient database of questionnaire responses have been accumulated, it should be analyzed to see how many STAR products have had a discernible impact on EPA or other programs and how these impacts are distributed with respect to degree of impact and size of program impacted.

Implementation Issues. The STAR Review Subcommittee suggested that NCER seek assistance from decision-analysis experts to help ORD develop a monitoring and evaluation system for the STAR Program. EPA also should plan on securing the services of a qualified, highly respected, independent organization to conduct and publish the evaluation of the STAR Program. Sufficient funds should be budgeted to compile and analyze program data, prepare well-documented case studies and a final report, and define continuous improvement techniques. Dr. Brown noted that the subcommittee did not identify a specific budgetary amount for the evaluation, but she suggested that approximately 2-3 percent of the STAR Program's annual budget should be set aside for the evaluation.

Presentation by Discussants

Drs. Zimmerman and Small agreed to review the draft report prepared by the STAR Review Subcommittee. Dr. Zimmerman indicated that the report was quite thorough and she found it very interesting. She suggested that the report could be improved by:

- ✧ Inserting a purpose statement at the beginning of the report (she noted that the purpose statement in the second paragraph on page 1 of the Executive Summary could be used). This statement should indicate that one of the main purposes of the review is to provide a framework for future reviews of the STAR Program.

- ✧ Including a graphic alignment between the STAR research areas and the categories in the Agency's strategic plan. (Dr. Preuss indicated that NCER has developed such a graphic and could provide it to the STAR Review Subcommittee.) Are the grant awards distributed appropriately across the STAR topics?

- ✧ Indicating that the section entitled Staff Resources (Section 3a, page 8) refers to more than staff. There are a number of other resources such as panel reviewers. Also in that section, the subcommittee could compute the ratios in terms of application review time per Project Officer and post-award monitoring time per Project Officer instead of applicants per Project Officer and active grants per Project Officer. She suggested adding a few sentences on Project Officer turnover and the skills match between the Project Officers and the grants. This will help in evaluating NCER's resource needs.

- ✧ In Section 3b (page 9) on Technology/Information Transfer, Dr. Zimmerman suggested that the subcommittee consider an additional strategy where stakeholders help design the project. She noted that some RFAs emphasize inclusion of stakeholders because it may enhance use of results in the end.

Dr. Small noted that he had a negative response to the wording of the first recommendation listed on page 3 in the Executive Summary. He cautioned against the wording "more targeted" because it could be misconstrued as "narrowly focused RFAs" that would lead to less applicants or to limiting the creativity of applicants. He suggested that ORD provide more guidance to potential applicants about relevancy and why certain proposals are not funded.

Dr. Small indicated that one method of reducing the low success rate could be to request preproposals. This process would limit the number of unacceptable proposals as well as the number of full proposals prepared by the scientific community. He noted, however, that this approach may be more appropriate for a private funding organization. Dr. McCay agreed that this approach could be useful for providing proposers feedback on how they could reshape their proposals to make them more relevant to the Agency's mission. Dr. Preuss asked about how the preproposals should be reviewed. Would NCER have to convene twice as many panels? Dr. McCay indicated that the preproposals could be evaluated by the same panel convened later for review of the full proposals, or the preproposals could be reviewed by an internal panel.

Dr. Brown noted that the subcommittee members thought a low success rate (i.e., an excessive amount of resources are being wasted on unsuccessful proposals) might be discouraging to proposers; however, she pointed out that the Agency continues to receive a large number of proposals. Dr. Preuss suggested that the first recommendation in the list in the Executive Summary could be reworded to focus on the goal of what NCER is trying to achieve. For example, "the Agency should identify and implement ways to raise the low proposal acceptance rate, increase the success rate of the best quality applications, and enhance the relevance of the research." Dr. Small agreed that the recommendation should be reworded. Eliminate the words "more targeted" and indicate that the Agency should provide more information in RFAs to enable proposers to better determine relevancy.

Dr. Brown pointed out that Dr. Randy Seeker, Chair of the STAR Review Subcommittee had a strong opinion about that recommendation. Dr. Preuss clarified that ORD does not want to limit academic creativity, but the research has to be relevant to the Agency's mission. He also noted that there is a limit to how specific EPA can be in an RFA.

Dr. Small indicated that the report should include some criteria for selection of the case examples referred to in Section 4.2 under Planning (page 16). Should the cases be selected randomly? Should exemplary cases be selected to demonstrate the effectiveness of the program? Should some randomly selected cases be evaluated along with some exemplary cases? Dr. Small also noted that the suggestion regarding formal investigations of the effectiveness of the STAR Program communication efforts (on page 19) should be emphasized. In addition, more explanation is needed in the Implementation Issues section on page 23. The report should indicate that the study referred to in that section is a future study to quantify the impacts of the STAR Program. Dr. Zimmerman suggested that there should be an ongoing evaluation process, not just a one-time or periodic evaluation. Dr. Brown indicated that the subcommittee focused the report on steps that could be taken between now and that future quantitative evaluation (e.g., formal communications assessment, implementation of data collection mechanisms). She agreed that the subcommittee should expand the paragraph on Implementation Issues.

With regard to the subcommittee's suggestion that NCER include more international experts on the review panels, Dr. Small asked that the report include more information about what these scientists can and cannot do. Are they precluded from submitting a proposal? He also suggested that there is considerable redundancy in the letter, the Executive Summary, the body of the report, and the section on conclusions and recommendations. Should the letter be shortened to eliminate some of this redundancy? If the subcommittee elects not to shorten the letter, he suggested that the letter be consistent with the Executive Summary and the remainder of the report. For example, the letter includes only some of the recommendations that are in the Executive Summary and Conclusions and Recommendations. Dr. Small recommended that the subcommittee consistently carry its ideas throughout the entire report—from the

letter to the Executive Summary to the Conclusions and Recommendations section. Dr. Denson agreed that these components should be consistent.

Dr. Small asked if ORD could review descriptions of summer projects (such as those in NEMS) to identify ideas for new RFAs. Dr. Preuss responded that he did not think NEMS was still published; however, ORD could review fellowship applications and reports to generate new ideas for RFAs. Dr. Small also noted that papers often are published 3-5 years after a grant is completed. ORD should consider awarding small publication grants (about $1,000) to STAR grantees to assist with the publication costs. STAR grantees would be eligible for these mini-grants up to 5 years after completion of their grant; one of the requirements for award would be that the principal investigator provides EPA a list of the publications associated with the grant. Dr. Bostrom pointed out that the administrative costs for managing the mini grants may make such a suggestion unreasonable.

Dr. Bus asked if there are any legal restrictions that prohibit for-profit organizations from receiving a STAR grant. Mr. Puzak replied that assistance agreements are only awarded to nonprofit organizations. Dr. Preuss pointed out that the funding for the STAR Program comes under a number of different authorizations, some of which are restricted to nonprofit and some of which are not. Although the general policy is that grants are awarded only to nonprofit organizations, there have been some exceptions, particularly to allow participation of federal laboratories when the research is conducted in conjunction with another agency. Dr. Bus asked if the language in the report regarding the exclusion of for-profit organizations from the STAR Program could be softened (e.g., the STAR Program mission mentions only non-profit organizations). Dr. Bostrom pointed out that the report includes a suggestion to conduct joint research with foundations. Dr. Bus added that some of the best proposals that he has reviewed have come from for-profit centers.

Dr. Denson expressed some concern about the use of passive verbs in the report. For example, the first sentence in Section 3 (page 8) states: "The Subcommittee's review of the STAR Program **suggests** a program ..." The second sentence states: "the program **appears** to be structure and managed ..." He asked Dr. Brown to convey his concern to the subcommittee and ask the members to reconsider the wording when reviewing the report. He asked that the STAR Review Subcommittee consider strengthening these verbs whenever possible. Dr. Small indicated that he had not been concerned about the wording and the use of passive verbs. He noted that the report could include a sentence in the beginning explaining that the subcommittee did not conduct an indepth study. Dr. Brown agreed to convey these suggestions to the subcommittee; she noted that the subcommittee may prefer passive verbs in some cases. Dr. Bus suggested that the wording "the subcommittee believes" could be used in lieu of "appears." Dr. Preuss pointed out that the wording in the letter is stronger than the wording in the report. For example, the letter states: "the STAR Program is structured and managed so as to generate high-quality science, conducted by well-qualified scientists, on topics that are relevant ..."

Dr. Bostrom requested that the report include references to the BOSC review of NCER and the NCER communication plan. She indicated that the subcommittee refused to include statements regarding these two items in the report. Ms. Stephanie Sanzone (EPA/SAB) pointed out that Dr. Seeker did not want to specifically discuss the communication plan in the report because the subcommittee had not received copies or reviewed the plan. Dr. Bostrom asked that the STAR Review Subcommittee members be provided copies of the NCER communication plan. Dr. Denson asked Ms. Hamilton to provide copies of the communication plan to the STAR Review Subcommittee. Dr. Denson called for a vote regarding the BOSC's acceptance of the STAR review report. Dr. Bus made a motion to accept the report and Dr. McCay seconded the motion. The report was approved unanimously.

Next Steps—STAR Draft Report

Dr. Brown indicated that the SAB will review the STAR report at the meeting on March 7. She will be available via teleconference to convey the BOSC's comments and to answer any questions the SAB members might have regarding the report. Dr. Denson will be present at that meeting as well. Following the meeting, the report will be revised based on the comments received from the BOSC and the SAB. Dr. Bostrom requested that she be allowed to review the revised report before it is finalized and published. Dr. Brown agreed that each STAR Review Subcommittee member should have an opportunity to review the revised draft before it is finalized. She noted that the subcommittee plans to finalize the report before Dr. Norine Noonan (AA/ORD) testifies before Congress on March 29.

Epidemiology Subcommittee Draft Report

Because Dr. Burke, who was scheduled to arrive at 10:00 a.m. today, was unable to attend the meeting, Dr. Denson decided to postpone discussion of the epidemiology report until the next meeting. Dr. Denson agreed to provide Dr. Burke information regarding how the report should be formatted as soon as possible.

BOSC Charter Renewal and Membership Process Discussion

Dr. Preuss identified the following four issues regarding the BOSC charter renewal and the membership process:

- ✧ Renewal of the BOSC charter. A copy of the existing charter was circulated to members during yesterday's meeting. Ms. Hamilton indicated that there will be some changes in the 2000 charter; for example, item 3d will be changed from "ORD laboratories" to "ORD national laboratories and centers."

- ✧ Terms and term limits for BOSC members. What is an appropriate term? Should there be term limits? Should a Vice Chair be designated?

- ✧ Rotation of members and how it should be accomplished. There currently are 12 BOSC members. Should 5 members be rotated off the Board and 8 new members added for a total of 15 members?

- ✧ Process for nominating new members. Previously, a Nomination Subcommittee was created to identify potential candidates for the BOSC. Should another subcommittee be formed?

Dr. Preuss noted that the terms of all BOSC members end in August 2000. The terms will be renewed for those members who will remain on the Board. Dr. Preuss indicated that EPA would like to broadly advertise the Board positions in the Federal Register, through letters to professional societies and minority organizations, notices on Web sites, and other means. The next stage will be to develop a full list of names to present to the BOSC for review. The Board members could narrow that list down to a list of potential candidates to present to the AA/ORD. Dr. Preuss indicated that he will be contacting each BOSC member to ascertain whether he/she would like to serve another term. He will report the results of those telephone contacts at the next BOSC meeting in May and hopes to have the new members appointed by August. Dr. Preuss has discussed these plans with the AA/ORD and she agrees with this approach.

Dr. Denson thought it might be helpful to look at the history of the appointments. Different members had different terms. What about subcommittees and consultants? Could these individuals provide a source of potential members when someone leaves the Board? Dr. Denson pointed out that he personally contacted candidates to invite them to become a BOSC member. He believes that personal contact may be

necessary to secure new members. In response to the comment about subcommittee members as possible candidates, Ms. Hamilton pointed out that many of these subcommittee members are on the SAB or were too specialized to serve on the BOSC. However, she thought that the list should be reviewed for possible candidates. Dr. Denson thought that it was important to sustain the momentum that the BOSC has worked hard to gain over the past 2 years.

Dr. Preuss asked if the Standard Operating Procedures for the BOSC should state that a member who does not come to three sequential meetings will be removed from the Board. Exceptions could be made for extenuating circumstances. Ms. Hamilton indicated that she will be working to complete the charter and asked the BOSC members to provide comments to her as soon as possible.

Dr. Brown agreed with the approach of broadly advertising the Board vacancies. She also thought that designation of a Vice Chair could be very helpful, particularly when the Chair is unable to attend in the event of an emergency. Dr. Brown noted that eight new members may be too many. She indicated that it took her almost 12 months to understand the process and begin to contribute. Six new members and nine incumbent members may be more effective. She thought 4 years would be an appropriate term. Those existing members whose terms are renewed would stay for another 2-3 years. Three current members could be rotated off the Board and replaced by three new members as well as three additional members to fill out the BOSC membership (for a total of six new members). She emphasized the importance of maintaining an appropriate mix of disciplines.

Dr. Preuss asked that members send letters or e-mail messages to him or Ms. Hamilton regarding these issues. Dr. Denson stressed the importance of cultural diversity—more women and minorities are needed on the Board. Dr. Bostrom thought the Board may be too small to warrant a Vice Chair. Dr. Preuss pointed out that the Vice Chair is not needed because of the BOSC's size, but to serve in the Chair's stead in the event of an emergency.

Ms. Hamilton asked the BOSC members to send her any comments on the charter or Standard Operating Procedures. She also asked members to send her calendars of their availability for the month of May so that a date for the next meeting could be determined. Dr. Preuss indicated that the agenda for the next meeting will include a discussion of nominees, the next issues to be undertaken by the BOSC, and the new charter. He reminded members of the list of issues prepared by the Laboratory and Center Directors, identifying areas for which BOSC input would be helpful.

Dr. Denson indicated that all of the items on the agenda had been addressed and he thanked the BOSC members for their participation. Dr. Bostrom moved that the meeting be adjourned and Dr. Small seconded the motion. Dr. Denson adjourned the meeting at 11:09 a.m.

Action Items

The following action items were identified during the meeting discussions:

- ✧ The Integration Subcommittee will pull together the bullets and integration themes identified by the other subcommittees and prepare the integration section.

- ✧ The Integration Subcommittee will draft the Executive Summary for the report.

- ✧ The Chairs/Vice Chairs of the subcommittees should determine which items should be transferred from their subcommittee reports to the integration chapter. This information should be provided to Dr. Denson.

- ✧ Dr. Bostrom agreed to address the BOSC's comments and work with the other members of the Exposure Subcommittee to revise the report.

- ✧ Dr. Small agreed to reformat the report and identify the recommendations in bold text. He also agreed to address the BOSC's comments as well as those from EPA in the revised report prepared by the Atmospheric Sciences Subcommittee.

- ✧ Dr. Bus agreed to work with the other Toxicology Subcommittee members to address the BOSC's and EPA's comments in the revised the toxicology report.

- ✧ Dr. Brown agreed to work with the other members of the Assessment Subcommittee to address the comments of the BOSC and EPA when revising the report.

- ✧ Dr. Les Grant agreed to provide Dr. Zimmerman the title of the fourth journal mentioned during the review in Durham, NC.

- ✧ Dr. McCay agreed to work with the other members of the Risk Management Subcommittee to revise the report based on the comments from the BOSC and EPA.

- ✧ Dr. Brown agreed to convey the BOSC's suggestions/comments regarding the STAR Review Report to the STAR Review Subcommittee.

- ✧ Dr. Denson asked Ms. Hamilton to provide copies of NCER's communication plan to the STAR Review Subcommittee members.

- ✧ Dr. Bostrom requested that each STAR Review Subcommittee member be given an opportunity to review the revised STAR Review Report before it is finalized and published.

- ✧ Dr. Denson will notify Dr. Burke that the discussion of the epidemiology report had been postponed until the next meeting. Dr. Denson also will inform Dr. Burke about how the report should be formatted.

- ✧ Dr. Preuss asked BOSC members to send letters or e-mail message to him or Ms. Hamilton regarding issues associated with charter renewal, terms and term limits, rotation of members, appointment of a Vice Chair, and nominating new members.

- ✧ Ms. Hamilton asked the BOSC members to send her any comments on the charter or Standard Operating Procedures. She also asked members to send her calendars of their availability for the month of May so that the date for the next meeting can be determined.

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ATTACHMENT 1:
Dr. Joe Elder's Handout on the Integration Section

ATTACHMENT 2:
Integration Themes
From the Flip Chart

Integration Themes

1. Integration is a major challenge because risk paradigm is broad.

2. Organizational structure that was put in place for PM2.5 is exemplary and extended (NPM, matrix, peer review, team).

3. Organizational/management structure facilitates intra/inter coordination, communication, prioritization, science leadership.

4. Human resources.

5. More integration of intramural and extramural (e.g., STAR) to address resource limitations.

6. Are there management arrangement to integrate PM research with other co-pollutants?

7. Note expressed need for contracts, which is not unique to PM issue (combine with intramural and extramural).

8. Budget flexibility: is it enough?

9. Alternative hypothesis for health effects other than PM.

10. INTRO 12.