EXECUTIVE COMMITTEE
Meeting Summary
Cincinnati, OH
September 12-13, 2005

Monday, September 12, 2005

Welcome and Introductions

Dr. James H. Johnson, Jr. (Howard University), Chair of the Board of Scientific Counselors (BOSC), called the meeting to order at 8:30 a.m. and welcomed the attendees to the 30th meeting of the Board. Dr. Johnson asked the BOSC members and others in attendance to introduce themselves. A list of the participants is attached to this summary.

Dr. Johnson mentioned several items that were not included on the agenda but would be addressed at this meeting, one of which was a discussion of the various designs for the BOSC logo and the model format for the summary section of the program review reports.

Review and Approval of June 2005 BOSC Meeting Minutes

Dr. Johnson asked if there were any comments on the draft minutes for the June 2-3, 2005 BOSC Executive Committee meeting. The following changes were requested:

- ✧ Move the last two sentences at the bottom of page 6 that begins with "Ms. Kowalski provided the members a handout containing …" to follow the fourth sentence in that same paragraph.
- ✧ In the fifth sentence in the first bullet on page 9, change "These programs" to "The program."
- ✧ In the third sentence in the last paragraph on page 11, insert ", and" after the words "Subcommittee Chair."
- ✧ In the first sentence of the second full paragraph on page 12, insert the words "stated that the" after "Dr. Henderson."
- ✧ In the last line on page 13, delete the words "in particular."
- ✧ In the third sentence in the last paragraph on page 15, insert the word "have" after "they may."
- ✧ In the second sentence in the first full paragraph on page 21, insert the word "have" after "also should"; change "recognize" to "recognized"; and change "state" to "stated."
- ✧ In the first sentence under the section entitled "Computational Toxicology Subcommittee Letter Report" on page 22, change the word "on" to "of."

With the incorporation of these changes, Dr. Johnson asked for a motion to approve the June meeting minutes, Dr. George Daston (Proctor & Gamble) moved to approve the minutes with the stated changes and Dr. Rogene Henderson (Lovelace Respiratory Research Institute) seconded the motion. The minutes were approved unanimously by the BOSC.

Update on Reports Transmitted to the Office of Research and Development (ORD)

Dr. Johnson stated that the BOSC has completed and submitted to ORD four program review reports, including the Endocrine Disruptors Research Program Review, Ecological Research Program Review, Human Health Research Program Review, and Particulate Matter/Ozone Research Program Review.

The Nominations Subcommittee submitted a list of four candidates to fill some of the vacant positions on the BOSC. At the June meeting, Dr. Bill Farland (ORD) indicated that ORD may want to add some names to that list of candidates. Dr. Johnson hoped to receive some feedback from ORD on the additional names.

The BOSC also has submitted three letter reports to ORD—one on the review of the new National Center for Computational Toxicology (NCCT), one on the Mercury Multi-Year Plan (MYP) review, and one on the National Coastal Condition Report review.

Efforts are underway to prepare a proceedings of the Risk Assessment Workshop, which will be posted on the BOSC Web Site (www.epa.gov/osp/bosc), and to publish abstracts of the presentations from the workshop in the journal *Environmental Science and Pollution Research–International.* The abstracts are expected to be published in the November issue of the journal. [A summary of the workshop has been published in *Environmental Science and Pollution Research—International* 2005;12(6):388-390. The extended abstracts of the presentations will be published in the *Journal of Human and Ecological Risk Assessment* in the fall of 2006.]

The report of the Drinking Water Research Program Review has just been completed and was submitted to the BOSC Executive Committee for review and approval. Dr. Johnson commented that this report could be reviewed during this meeting if the members so chose.

The report of the Global Change Research Program Review probably will be submitted to the Executive Committee in January 2006, as well as the Land Research Program Subcommittee Review Report. The Water Quality Research Program Review Report is expected to be submitted to the Executive Committee in March/April 2006, and the Science To Achieve Results (STAR) Fellowship Program Review Report should be available in May 2006.

The Air Toxics Program Review was postponed and has not been rescheduled. The Homeland Security Subcommittee will discuss the next steps after the site visit in conjunction with this meeting. The BOSC also is considering a review of the Management MYP, which was suggested by Tim Oppelt, Acting Assistant Administrator for ORD (AA/ORD), at a previous BOSC meeting. Other topics that the BOSC is considering are nanotechnology and biotechnology. Because these are small and focused efforts, the Board may only do MYP reviews and prepare letter reports. Dr. Johnson asked the BOSC members to give some thought to what is on the horizon for the next series of research-related activities. He suggested that the Board undertake one self-initiated study in the next year.

Dr. John Giesy (Michigan State University) asked if the Air Toxics review had been rescheduled. Ms. Lorelei Kowalski (EPA/ORD), the Designated Federal Officer (DFO) for the BOSC, replied that no date has been proposed yet. Dr. Johnson commented that the Office of Management and Budget (OMB) had postponed the Program Assessment Rating Tool (PART) review for the program; therefore, the BOSC

program review was postponed. Dr. Johnson explained that ORD works with OMB to identify the programs to review.

Overview of the Agenda

Dr. Johnson reviewed the meeting agenda (a copy of the agenda is attached to this summary). The major topics on the agenda for Monday morning were: the remarks from the AA/ORD, the presentation and discussion of the Drinking Water Research Subcommittee Program Review Report, an update on the status of the other subcommittee reports (i.e., PM/Ozone, Global Change, Land, Water Quality, and STAR/GRO Fellowships), and an update on the Risk Assessment Workshop products. Monday afternoon was dedicated to a site visit of the National Homeland Security Research Center (NHSRC) facilities. On Tuesday morning, the agenda included the ORD update from Dr. Bill Farland, Acting Deputy Assistant Administrator for Science; a discussion of the lessons learned for the program reviews from both ORD's and the BOSC's perspectives; a review of ORD's responses to the recent BOSC reports; a presentation on the Global Earth Observation System of Systems (GEOSS); a report of the Science Advisory Board (SAB) activities; and a discussion of future BOSC business. The agenda also allotted time for comments from members of the public.

Dr. George Lambert (University of Medicine and Dentistry of New Jersey), the SAB Liaison to the BOSC, said that the August SAB meeting was cancelled so there really was nothing new to report on SAB activities. Dr. Johnson thought the time would be used in discussing the new BOSC logo, the date for the next Executive Committee meeting, the proposed format for the program review report summaries to improve the consistency among the reports, the proposed quantitative rating tool for the program reviews, cross-cutting themes identified in the reviews conducted to date, and review and approval of the minutes of the July 29, 2005 Executive Committee conference call. Dr. Johnson asked the members if they would prefer to read the Drinking Water Research Program Review Report overnight so that it could be discussed and approved on Tuesday, or postpone the discussion and approval to a subsequent conference call. Most members thought it would be better to review the report overnight so Dr. Johnson agreed to include its discussion and approval in Tuesday's agenda.

Remarks from the BOSC DFO

Ms. Kowalski stated that the BOSC is chartered as a Federal Advisory Committee and subject to the rules and regulations of the Federal Advisory Committee Act (FACA). Therefore, this meeting was open to the public, and time was designated for public comment. A contractor, Beverly Campbell from SCG, was present to take notes to capture the presentations and discussions, and the meeting minutes will be available to the public on the BOSC Web Site after certification by the BOSC Chair, Dr. Johnson, and approval by the Executive Committee. Notice of this meeting was published in the *Federal Register*. Ms. Kowalski established an electronic public docket for the meeting, which can be accessed at www.epa.gov/edocket. The number to search for this docket is ORD-2005-0024. Ms. Kowalski commented that e-docket will be changed to a new system that is government-wide. She explained that e-docket allows public access to regulatory documents so that they can submit comments. Ms. Kowalski mentioned that she had not received any requests for public comment prior to the meeting. As DFO, she worked with EPA's ethics officials to ensure that all appropriate ethics requirements were satisfied for this meeting. Nevertheless, she asked the members to notify her during the meeting if they have any potential conflicts of interest.

Ms. Kowalski reported that Drs. Michael Clegg (University of California) and Clifford Duke (The Ecological Society of America) were unable to attend the meeting. In addition, Tim Oppelt will only be able to attend via telephone as he was called back to headquarters to assist with EPA's response to Hurricane Katrina. Although Dr. Farland was unable to attend the meeting on Monday, he was present on

Tuesday. She indicated that everyone would meet at a designated location to carpool to the NHSRC facilities for the afternoon site visit.

Ms. Kowalski asked the members to submit their timesheets and travel vouchers before departing the meeting, and their homework timesheets before the end of September. At the last meeting there was a question about including travel reimbursements and per diem amounts on W-2 Forms. Ms. Kowalski was told that the travel and per diem reimbursements are not included on W-2s. She asked that the affected members provide documentation to her that indicates otherwise so that she can show it to the appropriate authority. For those members who did not receive a W-2 last year, Ms. Kowalski is trying to track them down. Each BOSC member needs to provide an updated biosketch and curricula vitae for the BOSC Web Site; these need to be updated annually. Ms. Kowalski also asked the members to complete their confidential disclosure forms again. If a member also is on the SAB, they only have to complete the forms once for both boards. She recommended that the members save a copy of the form for their files. Dr. Jim Clark (Exxon Mobil Research and Engineering Co.) asked if it was time for the members to complete their ethics training again. Ms. Kowalski replied that everyone needed to complete that training before the January meeting. She agreed to send out information to each member so that everyone will be current by the January BOSC meeting.

Remarks From the AA/ORD

Mr. Oppelt joined the meeting via telephone at 9:15 a.m. He apologized for not being able to attend in person, explaining that he was called back to headquarters to help with EPA's response to Hurricane Katrina. He mentioned that hundreds of EPA employees were working very hard on the response. Mr. Oppelt thanked the BOSC for their work on the program reviews and other efforts. The reports are well done and very insightful; they will be helpful in focusing the programs on results and outcomes. ORD has been using the reports to improve its research programs and to support the PART reviews. The Agency has had a long-standing discussion with OMB about the role of independent expert advice in reviewing programs and OMB has finally agreed this is a valid approach for evaluating the relevance and significance of program results. Mr. Oppelt asked the BOSC to consider the quantitative rating instrument for those reviews that have been completed as a means of providing the numerical input sought by OMB in its PART reviews. He hoped that the reviews provided the BOSC with a better understanding of what ORD is doing to address environmental problems.

Mr. Oppelt was pleased to report that ORD had a budget prior to July 4, which made it easier for the programs to plan ahead. His best estimate is that the FY 2006 budget will be about $10 million below the enacted FY 2005 budget. He thought ORD did quite well given the financial constraints within the federal government. Congress provided fewer earmarks and Mr. Oppelt speculated that this may be attributed to the move of EPA's budget to Interior and Environmental Appropriations bill from the Veterans Administration and Housing and Urban Development (HUD) Appropriations bill. Last year's budget was $54 million and this year's budget is $33 million.

As a pilot in the budget, EPA received Title 42 authority to hire above the Senior Executive Service (SES) level to fill important positions (e.g., physicians, genomics experts, bioinformatics experts). EPA has authority to hire five experts per year for the next 5 years. Therefore, ORD is working to identify the most critical positions to fill in the first year. The initial focus will be on scientists rather than those who can fill management positions. This authority, along with fellowships and postdocs, will help strengthen the Agency's science capabilities. Mr. Oppelt commented that the National Institutes of Health (NIH) and other agencies use this authority extensively to retain a high-quality workforce. This authority will enable EPA to compete with the private sector for the best and brightest scientists.

OMB had suggested that $20 million of ORD's budget be designated as science and technology funds to the regulatory offices to be used to "buy" support from ORD. The program offices had been gearing up

to identify needs to be addressed by ORD, but Congress elected to keep the $20 million in ORD's budget. ORD has decided, however, to use these funds to support the short-term needs of the program and regional offices.

Mr. Oppelt mentioned that there is a moratorium on pesticides studies that use human subjects. EPA is proposing a rule for the protection of subjects in human research that will establish stringent enforceable ethical safeguards governing the conduct of third-party intentional dosing human studies intended for submission to EPA under the pesticide laws. EPA proposes to prohibit all new third-party intentional dosing research on pesticides with children and pregnant women intended for submission to EPA, and to prohibit EPA's conduct or support of any intentional dosing human studies involving pregnant women or children. The Agency also is proposing to establish a Human Studies Review Board to review study protocols and selected available studies.

There was a $5 million reduction in the budget for Superfund-related research and the Superfund Innovative Technology Evaluation (SITE) Program is being phased out. There is a $5 million Advanced Monitoring Initiative to use geospatial satellite technology that will be coordinated with the National Oceanic and Atmospheric Administration (NOAA) and the National Aeronautics and Space Administration (NASA). EPA also received a $6 million increase in homeland security funding, and although this was less than what the Agency requested, the safe buildings program has been reinstituted. The budget for pollution prevention/sustainability was reduced by $12 million.

Mr. Oppelt announced that Chuck Noss, the Executive Director of the Water Environment Research Foundation (WERF), will be joining EPA as the new National Program Director (NPD) for Water Quality. There are three remaining NPD positions to be filled and the announcements for these positions remain open.

Dr. George Gray, President Bush's nominee for AA/ORD, met with Mr. Oppelt last week. Dr. Gray is very enthusiastic about leading ORD and Mr. Oppelt thinks he will be good for the organization. The confirmation hearings probably will be held in early October and he will join the Agency in late October or early November. Mr. Oppelt said that he is scheduled to retire on January 3, 2006. He expects to return to Cincinnati in December and transition his NHSRC responsibilities before leaving the Agency. Dr. Daston commented that Dr. Gray is in his early to mid-40s and his main area of expertise is risk assessment and risk analysis. Dr. Harding asked if there would be any issues raised in the confirmation process, and Dr. Daston replied that he thought they would be much the same as those raised for John Graham (e.g., concerns about work done by the Harvard Center and questions about his potential bias toward industry).

Mr. Oppelt reported that EPA is heavily involved in the response to Hurricane Katrina, reviewing water and air sampling plans, and looking at ways to deal with the sediments that are contaminated with high concentrations of petroleum and grease components. Approximately 1 percent by weight of the sediments is total petroleum hydrocarbons from gasoline and motor oil leaking from submerged vehicles. Mr. Oppelt is a member of the group looking at the mid- and long-term aspects of the recovery to ensure that the right information is being collected to address the bigger problems (e.g., re-entering homes and businesses). EPA's emergency response staff is working 24/7 to generate and analyze the huge amount of data and information. Many organizations are gathering data including state and local governments, the U.S. Geological Survey (USGS), the Centers for Disease Control and Prevention (CDC), the U.S. Coast Guard, and the Department of Defense (DoD). He noted the DoD is looking at the potential for radiation leakage.

Mr. Oppelt asked if the BOSC members had any questions for him. Dr. Johnson asked about something Mr. Oppelt had mentioned at the June meeting—the possibility of Congress allowing ORD to determine how the earmark funds would be spent. Mr. Oppelt replied that the House budget had included such a

process but it was not included in the final bill because the Senate wanted to give it more thought. He mentioned that there has been talk about cutting earmarks because of the cost of the Katrina response. In reply to a question about the involvement of NHSRC in the Katrina response, Mr. Oppelt commented that the Center staff was participating in a week-long retreat when the hurricane hit, but they were in contact and one staff member already is assisting with developing sampling strategies. Mr. Oppelt mentioned that the rapid risk assessment tool developed by the NHSRC for terrorist threats also may be useful for assessing the risks associated with Katrina.

Dr. Lambert mentioned the bad press that EPA received following the World Trade Center disaster and asked if the Agency was making a concerted effort to provide information about Katrina to the press. Mr. Oppelt responded that the Agency is trying to post data on the Web as soon as they have undergone a quality assurance/quality control review. Even before the data are posted, however, EPA has been notifying state and local governments to issue health advisories on water bacteria and building re-entry. Mr. Oppelt commented that it is taking longer to get information out about the sediments because it is more difficult to sort out specific contaminants. He mentioned that maps and data are available on the Agency's Katrina site. Dr. Lambert noted that most of the people in the affected areas would be without access to the Web. What is EPA doing to get information to the public in those areas? Mr. Oppelt replied that most of the residents were evacuated but there are a few in areas that were not flooded. It is very difficult to communicate with those in the affected areas at this time.

Dr. Windom asked if there was a coordinated effort to assess the drinking water supply. Mr. Oppelt answered that staff from NHSRC and the National Risk Management Research Laboratory (NRMRL) is involved in that effort. These staff members are there as part of five EPA teams. There are 460 drinking water plants not functioning in Louisiana alone, and 260 of these plants have been assessed and recommendations have been made concerning what needs to be done to get them back online. He noted that much progress has been made and the main plant in New Orleans may soon be operational. Dr. Harding asked about the lead agency for issuing public health notices. Mr. Oppelt responded that CDC has the lead, and EPA has been working with that agency on issuing notices. The state and local governments also are involved in this effort. In addition, the Occupational Safety and Health Administration (OSHA) has been in the affected areas issuing notices to the response workers on how to protect themselves from disease.

Dr. Johnson praised EPA's efforts and asked Mr. Oppelt to let him know if the BOSC could be of use in the Katrina response. Mr. Oppelt thanked Dr. Johnson and the Board members for the offer and the excellent work they have done to date.

Subcommittee Reports

Dr. Johnson identified a number of items that appear to be common to the various program review reports, including (1) the effectiveness of communications, (2) the transparency of the intramural funding process, (3) integration of intramural and extramural research activities, (4) process for prioritization of the research, (5) process for assessing primary stakeholders' perception of and satisfaction with the research, (6) the balance between outputs versus outcomes (short-term versus long-term), and (7) effectiveness of the multi-agency planning process to institutionalize and harmonize resources and efforts across the government.

Drinking Water Research Program Review

Dr. Gary Sayler (University of Tennessee), Chair of the Drinking Water Research Subcommittee, apologized for not getting the draft report to the Executive Committee members prior to the meeting. He stated that the current draft of the report was discussed and approved by the Subcommittee on September 7, 2005. In addition to Dr. Sayler, the Subcommittee members included Drs. James Johnson (Executive

Committee Chair and Vice-Chair of the Subcommittee), Chi-Hsin Selene Chou (Agency for Toxic Substances and Disease Registry), James Raymer (RTI International), and David Sedlak (University of California–Berkeley). The Subcommittee also included a consultant, Dr. Mary H. Ward (National Cancer Institute). Edith Coates (ORD/NHEERL) served as the DFO for the Subcommittee. Both Drs. Sally Gutierrez and Greg Sayles who are present here today made presentations at the review meeting. There were two public conference calls and one administrative conference call held as part of the review process. Dr. Sayler then provided an overview of each section of the draft report to facilitate the Executive Committee's review. Dr. Johnson mentioned that the summary in this draft report follows the model that was included in the notebook for this Executive Committee meeting.

Dr. Sayler stated that the Subcommittee was divided into two work groups to address the two long-term goals (LTGs). He made sure that the two work groups prepared similar products so that they would mesh well in the Subcommittee report.

The draft report includes some basic introductory material that is reflective of the model included in the notebook for this Executive Committee meeting. It addresses why EPA is doing the research, identifies the Office of Water (OW) as the primary client, and explains that ORD is conducting both problem-driven (applied) and core (basic) research. Dr. Sayler stated that both the Government Performance and Results Act (GPRA) and PART reviews had some influence on the report. The Drinking Water Research Program mirrors the Drinking Water MYP. There is only one primary departure from the MYP and that is the consolidation of the three goals in the MYP into two goals in the program. The two LTGs of the program focus on regulated contaminants in drinking water (LTG 1) and unregulated contaminants in drinking water (LTG 2). LTG 3 in the MYP focused on distribution systems and source water. Dr. Sayler explained that the research on distribution systems was subsumed under LTG 1 and the work on source water became part of LTG 2. Although this makes sense, the rationale provided by EPA for consolidating the goals was not considered adequate by the Subcommittee.

The Subcommittee evaluated the program from the standpoint of its contribution to safe drinking water. Although the charge questions were not prescreened by the Executive Committee, they included many elements of the questions used for the other program reviews (e.g., relevance—public health benefits, progress on key scientific questions, and meeting client needs; scientific quality; scientific leadership; and coordination/communication). Dr. Sayler commented that because ORD's work gets filtered by other other programs, it is difficult for ORD to communicate outcomes. The Subcommittee tried to determine how research is being translated and used in policies.

The Subcommittee found that the research is relevant and critically important to EPA's mission (especially LTG 2, which includes protection and clean water and research on the Contaminant Candidate List [CCL]). ORD is trying to keep pace with the rapidly evolving science and is accomplishing that through the STAR Program. The STAR Program adds expertise and vigor to the program and addresses the latest technologies. ORD's leadership in drinking water research has been significant in the past but the funding reductions and the Safe Drinking Water Act (SDWA) have constrained the program so that it can no longer maintain an international presence. The SDWA prescribes the problems that EPA should address, which is causing ORD to loose its cutting edge. There are "islands" of strength within the program but the Agency can no longer maintain the breadth that it has in the past.

At the review meeting, representatives from OW, states, and industry made presentations that described how ORD's research is being used to yield positive outcomes. The program is clearly "bearing fruit," but ORD could do a better job of developing metrics to demonstrate how its outputs lead to positive outcomes.

The Subcommittee was asked to specifically comment on the change from three LTGs to two LTGs. The Subcommittee members were not sure that the program's resources are adequate to support the collapsed

goals. There was some concern that important topics may get lost by nesting them under just two goals. One specific example of such a topic was water reuse—a major growth area in which ORD currently invests little funding.

The Subcommittee reached a number of conclusions and made some recommendations that should help ORD improve the program. These included:

- ✧ Many of ORD's key administrative and science managerial posts, including that of the NPD for the Drinking Water Research Program, are filled by interim or acting directors. This leads to serious concern over the long-term issues of leadership, morale, and program direction within the Agency as well as the national science agenda. ORD is strongly encouraged to continue to press for timely appointments to these key leadership positions.

- ✧ The decision to consolidate three LTGs into two is not well justified. Although it may lead to a streamlined research plan, it also may result in an unintended de-emphasis of source water and distribution system research. Given budget constraints, this may be unavoidable under any circumstance, but it is likely that these research areas will continue to grow in importance partly as a result of homeland security issues and further drinking water threats. ORD should continue to evaluate the question as to whether or not the current two LTGs can adequately accommodate the research needs of source water and distribution systems research.

- ✧ The SDWA and rules drive the Drinking Water MYP and this, in turn, guides research efforts and investment in the research program; further constraining the scope of research and limiting the magnitude of "anticipatory" research in which the program can engage. ORD should evaluate strategies that could be implemented for more cutting-edge research to identify and circumscribe issues, problems, and solutions that impact on safe drinking water. One such strategy could be to invest greater resources in the STAR Program for an enlarged anticipatory research effort.

- ✧ EPA's role as a science leader is multifaceted and is perceived differently by differing constituents both within and outside the Agency. In a pure research context, however, ORD's historical leadership role in drinking water research is eroding. Although it is expected that "islands" of science and scientific leadership will be maintained, resource availability and federal regulatory mandates will define those areas where ORD will have recognizable international leadership. ORD is strongly encouraged to develop a "Science Leadership" mission statement and to identify those areas it believes to be capable of establishing or sustaining international leadership over the long term. This will be challenging given the dynamics of issues such as homeland security or global change as they are superimposed on more conventional topics and mandates in drinking water research. Without such a vision, however, ORD runs the risk of becoming too applications- and implementations-orientated in its research program with little direction for individuals to strive for scientific leadership.

- ✧ ORD's Drinking Water Research Program has had significant outputs that have been translated into outcomes largely in support of OW, its principal client, but also to the states and industry. Unless the client is active in attribution of ORD's research contributions to outcomes, these contributions are difficult to see and quantify. ORD needs to be proactive in developing metrics to document and support its assertions that translation of its research outputs are making significant contributions with respect to downstream outcomes as part of the overall logic model. If "outcomes" are indeed an important GPRA and PART process metric, then a focused effort needs to be made to make the process of outputs-to-outcomes transparent.

Dr. Herb Windom (Skidaway Institute of Oceanography) commented that many ORD programs are conducting important research, but ORD is not identifying how the information can be or is being used. Dr. Johnson stated that ORD must consider the ultimate impact of its research; ORD must have some idea

of what impact the research can make. Dr. Harding commented that development of the CCL required scientific leadership. Is there any reason that this has changed? Dr. Sayler responded that there are groups that are becoming competitors, such as WERF and USGS. Other organizations are taking the lead in certain areas, such as endocrine disruptors in drinking water. Another example is the perchlorate issue. EPA was not the leader; the Agency only served to bring the key players together.

Dr. Sayler commented that the program is doing a good job in partnering with other agencies. Dr. Clark commented that the fact that there were numerous acting directors in management positions in the program did not seem to effect its ability to partner. Dr. Sayler replied that the program needs to have managers in place long enough to champion the program and establish metrics. Dr. Clark asked about the long-term management of the program. Have there been as many acting managers in the past? Dr. Sayler said that although the Subcommittee was not certain about the impact of so many acting directors, it was a concern to the reviewers. Dr. Daston stated that this is just the nature of the way such organizations are managed. He noted that acting directors often have spent their careers working in the program and may know more about the program than someone who is brought in from outside the Agency. Dr. Daston said that it takes time to fill the NPD positions and he did not think this situation was unique to federal agencies. He suggested that the Board determine whether there was a real problem associated with the acting directors or whether this is just the nature of how ORD functions. Dr. Sayler replied that Dr. Farland should be consulted about this point to determine whether ORD is concerned about the number of acting directors. Dr. Johnson noted that this concern is not coupled with scientific leadership in the report.

Dr. Johnson asked the members to review the report overnight so that it could be discussed and approved on Tuesday. He asked Drs. Clark, Giesy, and Henderson to take the lead in discussing the report.

Particulate Matter/Ozone Research Program Review

Dr. Henderson stated that the program review meeting was held in spring 2005. Following the meeting, there was a conference call to review the draft report and make final changes before its submission to the BOSC Executive Committee. The Executive Committee reviewed and approved the report during a July 29, 2005, public conference call, and it was submitted to ORD on August 11, 2005. The report has been posted on the BOSC Web Site.

Land Research Program Review

Dr. Clark, Chair of the Land Research Subcommittee, stated that the Subcommittee will review ORD's Land Preservation and Restoration Research Program. The Subcommittee will consist of nine members who cover the fields of environmental chemistry, aquatic toxicology, environmental engineering, combustion engineering, and solid waste management. The Subcommittee will include representatives from states, federal government, non-profits, academia, and industry. Three conference calls will be held prior to the review meeting, which is scheduled for December 13-15, 2005, in Cincinnati. He hopes that the draft report will be ready to submit to the BOSC Executive Committee for review at its next meeting. ORD would like the report completed prior to the PART review, which is scheduled for spring 2006. Heather Drumm (ORD/OSP) is the DFO for this Subcommittee.

Water Quality Research Program Review

Dr. Windom reported that efforts are underway to identify members for the Subcommittee, which will need to cover a mix of disciplines. The Subcommittee has not received the draft charge questions from ORD, but the first conference call probably will be held in late November or early December 2005, and the review meeting in January 2006. Dr. Windom expects the Subcommittee to produce a draft report for submission to the BOSC Executive Committee by April 2006.

STAR/GRO Fellowships Program Review

Dr. Juarine Stewart (Morgan State University), Chair of the STAR/Greater Research Opportunities (GRO) Fellowship Subcommittee, discussed the types of expertise needed on the Subcommittee, including: life science, environmental science, physical science, economics, social science, fellowship administration (government), and fellowship administration (non-government). Dr. Stewart expected to have a list of candidates by early October. Two conference calls will be scheduled in December or January, and the review meeting probably will be held in February 2006. Dr. Johnson suggested that this Subcommittee examine the National Science Foundation's (NSF) fellowship program because OMB considers it a model program. Dr. Stewart said that she served on the NSF Committee so she has a number of contacts to obtain information on NSF's program. Dr. Lambert suggested that the Subcommittee include someone with human health expertise. Dr. Stewart replied that she will ensure that it does. Dr. Harding suggested that the Subcommittee take a look at the STAR Program review that was conducted jointly by the SAB and BOSC, recognizing that this current STAR/GRO Fellowship review focuses only on the fellowship component of the STAR Program.

Risk Assessment Workshop Update

Dr. Henderson stated that the Risk Assessment Workshop was held in February 2005 at the National Academy of Sciences in Washington, DC. Two reports resulted from the workshop. One is the proceedings of the workshop that will be posted on the BOSC Web Site and the other is a group of extended abstracts to be published in the journal *Environmental Science and Pollution Research—International*. Working with Ms. Kowalski, Dr. Henderson put together an introduction to the abstracts. She also submitted several ideas for the journal cover. Dr. Johnson pointed out that by posting the proceedings on the Web and publishing the extended abstracts in a professional journal, the BOSC is practicing what it has recommended to EPA about open access to information. [A summary of the workshop has been published in *Environmental Science and Pollution Research—International* 2005;12(6):388-390. The extended abstracts of the presentations will be published in the *Journal of Human and Ecological Risk Assessment* in the fall of 2006.]

Global Change Research Program Review

Because Dr. Duke, Vice-Chair of the Global Change Research Subcommittee, was unable to attend the meeting, Dr. Johnson provided an update of the status of this review. The Subcommittee held a conference call on August 4, 2005. The DFO distributed materials to the Subcommittee last week and there is a conference call scheduled for September 13, 2005. The review meeting will be held September 26-28, 2005, in Alexandria, Virginia. The draft report is expected to be ready for the Executive Committee to review at its January meeting.

Discussion

Dr. Stewart mentioned that the charge questions for the STAR/GRO Fellowships Program review will be somewhat different from those for the other program reviews. She asked if the Executive Committee should review the charge questions, and Dr. Johnson replied that the Chair and Vice-Chair should review them to ensure that they are inclusive of the key elements (i.e., allocation of budget/resources, communication and coordination, resource prioritization process, intramural/extramural balance, relevance, examples of metrics for outcomes, design, quality, and leadership). Dr. Henderson suggested that the Subcommittee Chair inform the DFO that this information will be needed to respond to the charge questions. Other elements that should be addressed in reviews include leveraging of resources with other agencies, national and international coordination, and the impact of research on outcomes. Dr. Windom thought the Subcommittee could request examples of outcomes from ORD, and project or forecast outcomes or use examples from the past that have led to positive outcomes.

Dr. Lambert thought it was reasonable for the programs to provide outcome measures. Dr. Johnson commented that it would be good for ORD to provide retrospective examples, but prospective examples also are needed (how ORD's current efforts will impact future outcomes even if the research results are implemented by the program offices). Dr. Sayler thought the Subcommittees would need more than examples; they also will need the metrics that are being measured to determine outcomes. Dr. Henderson stated that the ORD scientists will have to work with the program offices to provide that information. Dr. Windom agreed, adding that ORD should follow through to ascertain whether the expected outcome occurs. If the expect outcome did not occur, ORD needs to know why. Dr. Johnson concurred, stating that the program reviews are not just about the PART reviews; the BOSC reviews are much bigger and should have an impact beyond PART. He stated that a bench scientist who does not know the worth of his/her research is not operating at the Ph.D. level. Dr. Daston cautioned that it is not a problem with knowing the worth of the research, but rather whether the research is so long-term that the program offices do not appreciate the value of the research. He noted that 6 months is long-term to the program offices and ORD's core research focus usually is 5-10 years out. Dr. Johnson stated that ORD will need to predict the value of its long-term research. Dr. Windom commented that this will be very difficult to grasp without examples.

Dr. Johnson thought it might be helpful to develop a standard operating procedure (SOP) for the Subcommittees conducting program reviews. This would help the Subcommittee members prepare for the reviews.

Shortly after 12:00 noon the meeting participants recessed for lunch and reassembled in the hotel lobby to carpool to the NHSRC facilities for the afternoon site visit.

NHSRC Facility Site Visit

The first stop in the facilities tour was the Test and Evaluation (T&E) Facility located at 1600 Gest Street. The T&E facility is located on the grounds of Cincinnati's Mill Creek wastewater treatment plant. The facility is comprised of a 24,000 square foot high bay area for both bench-scale and pilot-scale research, and is supported by 14,000 square feet of recently renovated laboratories, office space, and chemical storage.

Some of the research efforts described during the T&E site visit included:

- *Water Awareness Technology Evaluation Research and Security (WATERS) Center*—The WATERS Center conducts research and development, in collaboration with academia, vendors, consultants, and other agencies, of technologies and strategies for proactive and rapid response to threats associated with drinking water supplies.

- *Pilot-Scale Tests and Systems Evaluation for the Containment, Treatment, and Decontamination of Selected Materials From Pipe Loop Equipment*—ORD is conducting experimental studies under controlled conditions to develop the necessary data to evaluate equipment, systems, materials, and procedures for the containment, treatment, and decontamination of drinking water distribution systems. This research is designed to identify the potential for various contaminants to adhere to different pipe materials at different flow regimes, and evaluate the relative performance of various decontamination techniques for different contaminants.

- *Source Water Early Warning Monitoring and Detection – Technology Evaluation and Demonstration*—This research evaluates the ability to reliably monitor source water quality using biological organisms as sensors. ORD is evaluating the use of multiple species for biosensing to

obtain a wider range of bioanalysis of the water and provide a more complete understanding of quality and safety of the water supply.

- ✧ *Small Package Plant Systems Research*—Current small drinking water systems treatment technology is not always adequate to meet current regulations. Therefore, EPA initiated research studies to evaluate the cost, performance data, reliability for the small system package plants, and amenability to remote monitoring and control for various technologies.

- ✧ *Simulated Water Distribution System – Demonstration*—ORD designed and fabricated the distribution system simulator (DSS) to evaluate and understand the dynamics that influence water quality within water distribution infrastructure systems in the United States and worldwide. The DSS unit is designed to simulate continuous flow conditions observed in a typical distribution system. There are six individual 75 feet lengths of 6-inch ductile iron pipe arranged in "pipeloop" configurations to simulate a distribution system.

- ✧ *Membrane Technologies for Recovery of Volatile Organic Compounds*—The purpose and goals of this research are to: (1) investigate and verify a specific application of pervaporation pertaining to aquifer/soil remediation; (2) generate reusable, non-contaminated isopropyl alcohol and surfactant "carriers"; and (3) reclaim and reuse solvent.

- ✧ *Product Recovery From Biomass Fermentation Processes by Perva*poration—The largest effort on this project has been targeted at improving pervaporation process efficiency through design modifications. EPA is working with a developer to demonstrate a new method for recovering and concentrating ethanol and other organic chemicals from water. This approach combines pervaporation with a vapor condensation technology called dephlegmation.

The second stop on the tour of the NHSRC facilities was the Andrew W. Briedenbach Environmental Research Center located at 26 W. Martin Luther King Drive, where the NHSRC is headquartered. The BOSC members were provided an overview of the Center and its five major research areas, followed by a tour of EPA's Biological Safety Level (BSL) 3 Laboratory and demonstration of the predictive capability model.

The NHSRC develops its research plan by envisioning various circumstances, or threat scenarios, under which attacks may occur and by seeking the advice of experts to prioritize the research. The Center is dedicated to solving real-world problems and putting technology in the hands of those who need it before they need it. Each of the NHSRC's five major research areas are described below.

Threat and Consequence Assessment

This research area addresses human exposure to chemical, biological, and radiological contaminants to define dangerous levels of these contaminants and help establish protective cleanup goals. It includes the development and enhancement of tools to improve the ability to make risk-based decisions in the field or in an emergency operations center. It also includes the development or modification of methods to enable rapid evaluation and estimation of risks during a terrorist incident involving biological, chemical, or radiological agents. In addition, this research area includes development of a methodology for microbial risk assessment, and development of risk-based guidance level goals for biological and chemical agents.

Decontamination and Consequence Management

This research area provides support for the decontamination and restoration of indoor and outdoor areas purposefully contaminated with biological, chemical, or radiological hazards. Safe disposal of contaminated food and agricultural products also are addressed. The detection research ensures that

sampling and analysis methods, both for detecting contamination and for verifying successful decontamination, will be available when needed. The containment research focuses on developing and testing methods to prevent the spread of contaminants; to protect people by providing tools, techniques, technologies, and guidance to minimize the impact of a chemical or biological attack on building occupants; and to evaluate the effectiveness and economics of chemical/biological protection measures for new and existing buildings. The goal of the decontamination research is to facilitate the selection of effective, safe, rapid, and cost-effective technologies and methods for decontaminating indoor or outdoor areas. The purpose of the disposal research is to provide guidance for disposing of contaminated materials and wastes generated during decontamination.

Water Infrastructure Protection

This research is designed to protect the nation's drinking water supplies and infrastructure, as well as wastewater collection, treatment, and disposal systems. It addresses seven areas of research needs: (1) protecting physical and cyber infrastructure; (2) identifying drinking water contaminants; (3) improving analytical methodologies and monitoring systems for drinking water; (4) containing, treating, decontaminating, and disposing of contaminated water and materials; (5) planning for contingencies and addressing infrastructure interdependencies; (6) targeting impacts on human health and informing the public about risks; and (7) protecting wastewater treatment and collection systems. More than 100 projects have been initiated to address these needs.

Response Capability Enhancement (RCE)

The Center works directly with emergency responders and local governments to provide tools and information needed to make informed decisions in the event of an attack. The program focuses on laboratory capabilities and emergency response support. Laboratory capabilities support involves ensuring the availability of adequate laboratory capacity for analyzing biological, chemical, and radiologically contaminated samples during an emergency. The program also is working to provide field analytical methods for characterizing samples sufficiently to ensure the protection of laboratory workers. Emergency response support includes the establishment of the Red Team (i.e., a team of experts from various disciplines throughout EPA), who are equipped with emergency communication devices (cellular telephones and portable computers). If activated by a homeland security emergency, this team moves to designated locations to provide scientific guidance to senior EPA officials and on-scene coordinators. The program also is developing a chemical and biological agent database that will become the foundation for a helpline, ensuring that Red Team members receive training in emergency response and are equipped and prepared to respond if activated, and generating contingency playbooks that address consequence management issues for major biological, chemical, and radiological threats.

Technology Testing and Evaluation

This program evaluates technologies that show potential for use in homeland security applications. These evaluations are used by water utilities, building owners, emergency responders, and others to make informed decisions when purchasing security technology. The program's testing process includes the use of live contaminants and takes place at federal facilities and field locations. The program is an outgrowth of EPA's successful Environmental Technology Verification (ETV) Program and often uses ETV test plans, modifying them to meeting homeland security needs. The technologies being tested include: cyanide detection technologies, rapid toxicity monitoring technologies, immunoassay test kits, rapid polymerase chain reaction (PCR) technologies, drinking water and wastewater treatment methods, and software for distribution system modeling and design. The program provides decision makers and potential users with unbiased, third-party reports that can supplement vendor-provided information. Summaries have been produced for the WaterSentinel Initiative, portable detectors, and air-cleaning technologies.

Key research products resulting from the Center include:

- ✧ A Web-based catalog of technical resources.
- ✧ A compendiuim of sampling and analysis methods.
- ✧ Design and operational guidance for building and water system protection.
- ✧ Decontamination and disposal technical guidance.
- ✧ An interactive database and expert system for rapid risk assessment.
- ✧ Technology testing and evaluation reports for commercially available detection, containment, and decontamination technology.

Tuesday, September 13, 2005

The meeting reconvened at 8:35 a.m. on Tuesday morning. Dr. Johnson reminded that BOSC members that there were a number of additional items for the day's agenda, including discussion of the quantitative rating tool, review and approval of the July 29 Conference Call minutes, discussion of the new BOSC logo, review and approval of the Drinking Water Research Program Review Report, and discussion of new projects.

ORD Update

Dr. Bill Farland presented the ORD update. He thanked the BOSC members for the tremendous number of projects that the Board has undertaken. Everyone at ORD is amazed at the amount of work the BOSC has been able to accomplish and thankful for the effort the Board has made. ORD has prepared responses to the Endocrine Disruptors Research Program Review and the Human Health Research Program Review reports, as well as the Computational Toxicology Program Review Letter Report. Dr. Farland asked the BOSC members if they had any questions about Mr. Oppelt's remarks presented yesterday. Dr. Daston commented that he thought five positions per year under the Title 42 hiring pilot seemed like a small number. He asked if there was a process for prioritizing those positions. Dr. Farland responded that the pilot includes 30 positions (5/year for 6 years), and the Laboratory and Center Directors have been discussing the priorities. They met with staff from the NIH to discuss how that agency goes about determining which positions to fill under the authority. Currently, EPA plans to use the pilot positions for hiring expert scientists.

Dr. Farland reported that ORD has been involved in two conference calls per day with the Regional Administrators and staff from Regions 4 and 6 to discuss the response to Hurricane Katrina. He stated that the reports coming in from EPA workers in the field indicate that the destruction is far worse than imagined—thousands of homes flooded or destroyed, and hundreds of thousands of cars and 50,000 boats requiring disposal. The EPA Web Site lists the monitoring that is ongoing for air, water, and wastewater.

The agenda for the January 2006 BOSC meeting may include a discussion of the budget and the balance of funds among programs and projects. A discussion of lessons learned also may be included. Dr. Johnson said that the BOSC would like the allocation of resources discussed at each program review. Dr. Farland responded that allocation is more important than amount—the BOSC should determine whether ORD is spending its money on the right research. Dr. Johnson asked if the Laboratory/Center Directors and NPDs should be invited to the January 2006 meeting to discuss the budget. Dr. Farland replied that the Laboratory/Center Directors and NPDs may be available for the January meeting if the Executive Council meeting is scheduled either just before or just after the BOSC meeting. Dr. Farland said that the Council meets monthly; he agreed to find out if the January 2006 meeting has been scheduled.

Dr. Farland commented that the program reviews are an evolving process for ORD. It is important that EPA ask the right questions of the BOSC; questions whose answers will help ORD improve its programs

and produce information that is useful for the OMB PART reviews. It is important to note, however, that the BOSC program reviews have a broader focus than the PART reviews. Dr. Johnson said that this was discussed yesterday and the Board developed a list of items that should be addressed in a program review beyond the focus of the PART reviews.

Dr. Farland asked if the BOSC members enjoyed the tour of the NHSRC facilities yesterday. He mentioned that the Center is doing a lot of good work. Would the BOSC like to take any further action with respect to the Center? Dr. Johnson commented that the tour was excellent and the Board learned a great deal about the activities of the NHSRC. He mentioned that the demonstration of the predictive capabilities model did not work, which was a little embarrassing for the staff. Dr. Johnson stated that the Board may want to undertake a review of the Center at some point in the future.

Dr. Sayler said that some of the material presented to the BOSC was dry; he speculated that the more interesting activities could not be discussed with the BOSC because of security reasons. Dr. Farland noted that there are numerous scientists with security clearances, so it would be possible to assemble a panel that could review the Center's activities and provide guidance. Dr. Clark said that he saw a clear connection between the work of the NHSRC and the oil spill response group. Dr. Farland agreed that EPA has been doing this type of research long before the NHSRC was created. Because funding is available for homeland security, the research now serves both purposes.

Dr. Windom mentioned the technology testing and evaluation spin-off from the ETV Program. He did not get the impression that the Center is making a big effort to work with the research community to develop sensors. Is there any intramural or extramural emphasis on sensor development? Dr. Farland replied that some of the Center's research programs touch on new sensor development, especially in the area of water security. There is not a large emphasis, however, on development of sensors. The Departments of Energy and Homeland Security have responsibility for sensor development, but there also is a lot occurring in the private sector.

Dr. Farland asked for the assistance of the BOSC members in identifying potential candidates for three remaining NPD positions—health, ecology, and drinking water. The positions will be advertised until November 18, 2005. A three-member panel (two from EPA and one from outside the Agency) will screen the candidates. Those who are selected in the screening process will be interviewed by ORD managers. Dr. Farland thought the BOSC might be able to help identify or provide outside individuals to reside on the three panels (one for each panel). Dr. Johnson said that the Board would discuss this issue before the meeting was adjourned.

Dr. Farland reported that Chuck Noss was selected to fill the Water Quality NPD position and he already has begun working at EPA.

The Human Studies Rule was released last week. It will protect subjects in human research by establishing stringent enforceable ethical safeguards governing the conduct of third-party intentional dosing human studies intended for submission to EPA under the pesticide laws. EPA proposes to prohibit all new third-party intentional dosing research on pesticides with children and pregnant women intended for submission to EPA, and to prohibit the Agency's conduct or support of any intentional dosing human studies involving pregnant women or children. Ms. Kowalski will provide the URL for the rule to the BOSC members. Dr. Farland noted that this proposed rule will put EPA in line with other federal agencies, particularly with regard to studies on pregnant women and children. All third-party pesticides studies must submit their protocols to the Agency for approval. EPA has 6 months to finalize the rule. Dr. Farland noted that the Human Studies Research Review Official will reside in the Office of the Science Advisor, which is in the Office of the Administrator. He noted that Dr. Peter Preuss (ORD/NCEA) has been serving in this role for years, but the Agency plans to hire an individual with ethics and clinical study expertise, and the ability to review study protocols to fill this position. The

Agency also is proposing to establish a Human Studies Review Board, which will be a FACA board, to review study protocols and selected available studies. Dr. Harding asked about the process that has been used in the past for reviewing study protocols. Dr. Farland replied that EPA relied on Institutional Review Boards (IRBs) to review study protocols. The results of the IRB reviews were submitted to the EPA senior review official, who has been Dr. Preuss, for final approval. A report by the National Academy of Sciences (NAS) suggested that EPA use a FACA board to backstop the EPA review official. All third-party dosing studies for pesticides would be required to be reviewed by the FACA board, after reviews by the IRB and EPA official.

Dr. Henderson commented that she thoroughly enjoyed the NHSRC tour but expressed some concern about the Agency allowing the Board members to tour the BSL 3 laboratory. She stated that Lovelace restricts access to its BSL 3 laboratory and would not have allowed such a tour. Dr. Farland explained that there were a number of concerns in the community when EPA wanted to develop the facility. The Agency wanted to make it clear to the public that the laboratory could contain any threat should there be some problem at the facility. He emphasized that the Agency was trying to avoid the secrecy associated with such laboratories to reassure the public that it posed no threat to the community. Dr. Henderson mentioned that there was some public concern about the Lovelace BSL 3 laboratory as well, so public tours were allowed of the laboratory prior to it becoming operational. Now it is closed and access is strictly controlled. Dr. Farland appreciated Dr. Henderson's concern, but added that there were no experiments underway in the laboratory at the present time.

Dr. Giesy said that he travels all over the world and visits facilities in many countries. He expected EPA's facilities to be better than those of other countries, but was disappointed that they were not as good. He noted that the Czech Republic has facilities that are much better than those of EPA. Dr. Giesy explained that he is not trying to criticize EPA, but was expressing his concern that the United States is falling behind. The BOSC needs to do whatever it can to help close this gap. Dr. Farland responded that EPA has substantial homeland security responsibility and is in no worse position than other agencies supporting homeland security needs. He noted that EPA was able to do a lot in response to Hurricane Katrina. The United States is no longer the benchmark of excellence in many areas. Everyone needs to think in global terms.

Dr. Johnson asked Dr. Farland for an update on the nomination status. Dr. Farland indicated that the nomination package forwarded to EPA by the BOSC included some good candidates. Mr. Oppelt thought it was important to give the NPDs and the Laboratory/Center Directors an opportunity to identify potential candidates for the vacant BOSC positions. That process has begun and Dr. Farland hopes to report the results to the BOSC very soon. One of the areas of expertise needed on the BOSC is air modeling, and ORD would like to recruit a top-notch expert in that area.

With respect to the open access issue that was discussed at the June BOSC meeting, Dr. Farland discussed it with Jack Puzak (ORD/ORMA), but there is no clear answer to the problem. The Agency will continue to follow the debate among the publishing community and do its best to publicize the results of its research.

Lessons Learned on Program Reviews—BOSC and ORD Perspectives

Dr. Johnson asked each of the Subcommittee Chairs/Vice Chairs (i.e., Drs. Harding, Henderson, Johnson, and Clegg) to describe the lessons learned in conducting the four program reviews that have been completed. Dr. Johnson said that he will present Dr. Clegg's comments because he was unable to attend the meeting.

PART Review and Subcommittee Expertise

Dr. Henderson led the discussion of two aspects of the reviews—the role of the PART reviews and the expertise of the Subcommittee members. She stated that the PART review was very important for the PM/Ozone Research Program Review. That Subcommittee was driven by the PART review and was pressured to move quickly because of the timing of that review. The Subcommittee members needed to be educated about the difference between outputs and outcomes. The ORD staff clearly explained the problems experienced in meeting the expectations of the PART reviews. One of the metrics of program success was how ORD research addressed the gaps between basic research conducted by academia and the applied research that addresses the needs of the regulatory programs. ORD needs to quantitatively measure the impact of its research on the outcomes achieved by the program offices and states. Dr. Windom mentioned that the PART review was not important in the Mercury MYP Review but it will be more important for the Water Quality Research Program Review. How was the Subcommittee educated about the PART review? Dr. Henderson replied that it was discussed during one of the early conference calls. Dr. Sayler said that the Drinking Water Subcommittee received a briefing on the PART process by EPA during one of the premeeting conference calls. Dr. Clark confirmed that it was the same for the Human Health Research Subcommittee, adding that Dr. Dale Pahl (ORD/ORMA) provided an excellent presentation on PART. Ms. Kowalski commented that ORD intends to develop a number of standard materials, such as the presentation on PART, which can be used for future program reviews to educate the Subcommittee members. This will help the Subcommittee members and improve ORD's efficiency in preparing for the program reviews. Dr. Farland noted that, unlike the Executive Committee members who have a good perspective of EPA's research programs, many of the other Subcommittee members have little knowledge about ORD and its programs. Therefore, EPA wants to provide an ORD 101 presentation to new Subcommittees that will give the members an overview of ORD and how it works. Dr. Henderson agreed that this presentation would be essential to a good review.

With respect to identifying the expertise required by the Subcommittee, Dr. Henderson stated that the DFO was instrumental in identifying the appropriate expertise needed on the PM/Ozone Subcommittee. She noted that the Subcommittee included a few individuals who had been contractors to EPA and they had very difference perspectives from the other members. They thought that contractors were not receiving credit for their work and wanted this stated in the report. Dr. Henderson did not think such a comment was appropriate and made sure that it was not included in the draft that was submitted to the Executive Committee for approval.

Charge Questions and Review Materials

Dr. Clark led the discussion on the charge questions and the review materials. He noted that some of the charge questions were lengthy and had multiple subparts (leadership, quality, productivity) that were common to numerous questions. This resulted in some repetition in the reports. There are key items that need to be included in the charge questions and these were discussed during yesterday's session. The charge questions should be focused and concise. The final report may not directly answer each part of a charge question, but it should address the key elements and combine certain responses to eliminate redundancies.

The materials prepared by ORD and distributed to the Human Health Research Subcommittee were not organized in a manner that enabled the members to quickly address the charge questions. The charge questions should be completed early in the review process and provided to the NPD (through the DFO). Early in the process, the Subcommittee should discuss with the DFO and NPD what materials are needed to answer the charge questions. The Subcommittee members also should begin writing the responses before the meeting so that they can determine if additional information is needed to answer the questions. The Human Health Research Program Review meeting was 2 ½ days, but more time was needed to cover

such a broad program. Dr. Johnson agreed that the Chairs and Vice-Chairs should ensure that the detail of the materials provided is sufficient to answer the charge questions.

Dr. Harding commented that the materials provided for the Endocrine Disruptor Research Program Review were well organized, but Dr. Clegg indicated that the materials for the Ecological Research Subcommittee were not well organized, making it more difficult to answer the charge questions. Dr. Harding mentioned that the volume of materials was large, but everything provided was useful for the review. Dr. Windom commented that the charge questions and the materials provided by ORD are critically important to these reviews. He asked about the process for addressing the charge questions. Dr. Henderson responded that one approach was to assign two Subcommittee members to ask them to prepare a draft response to each charge question before the meeting. Dr. Sayler stated that the charge questions are critical to the quality of the report. He mentioned that the charge questions for the SAB Drinking Water Report were poor and the resulting report was equally poor. He added that the charge questions for the Drinking Water Research Program Review were appropriate and well structured. Dr. Windom reported that the Mercury MYP Subcommittee modified their charge questions. Dr. Farland indicated that he was puzzled by the discussion on charge questions. The program reviews started with a common set of charge questions that were modified by each Subcommittee. There seemed to be little departure from the original set of questions. He was under the impression that the common list of questions had been working well; if that is not the case, then perhaps ORD and the Board should address this issue again. Dr. Johnson responded that the BOSC is learning as it moves forward with each review. The Board has developed a list of items to be added to each review. He thought it might be beneficial to review the original list of questions again with these additions in mind. Dr. Clark pointed out that the information needs for the PART review was a driver for the charge questions. Additional items beyond the PART review have been identified by the BOSC. He thinks that the two together give the right balance to the charge questions for the program reviews.

EPA Staff, Timelines, and FACA Process

Dr. Harding addressed the topics of EPA staff, review timelines, and the FACA process. She stated that EPA staff support for the Subcommittees had been great and was critical to the success of the reviews. The staff has been very knowledgeable about the programs. Dr. Harding also was very complimentary of the logistical support that has been provided for the Subcommittee conference calls and site visits.

The timelines have been very tight, and although the reports have been generated in the time allotted, there are varying degrees of comfort with the schedule among the different Subcommittee members. They all agreed that it takes longer to produce the final product than was estimated initially. It takes about 1 year for the entire process, from the time the BOSC agrees to do the review to the delivery of a final report. She encouraged EPA to schedule the reviews to allow time for the process.

Most Subcommittee members thought the FACA process inhibited frank discussion at the face-to-face meeting. They would have preferred an opportunity to meet privately with EPA staff to present the preliminary findings of the review. In at least one review, EPA staff offered comments that rebutted the Subcommittee's findings. Dr. Giesy added that some EPA staff were very defensive about the Ecological Research Subcommittee's comments and were even arguing among themselves about certain items. The Subcommittee members found it to be very disconcerting. Dr. Harding said that she found it awkward to present the preliminary results in a public forum. Dr. Henderson commented that her Subcommittee had some minor problems with the FACA process, but she thought it was helpful to have EPA staff present so that the members could seek clarification on certain issues. Dr. Clark agreed that the presence of EPA staff was helpful.

Dr. Johnson asked for suggestions on improving the process for future reviews. He thought that basic presentations on PART, ORD 101, the FACA process and rules, and the roles of the participants (i.e.,

Subcommittee, DFO, NPD, and EPA staff) would be useful for each new Subcommittee. Dr. Johnson mentioned the guidelines for preparing BOSC report summaries that were included in the meeting notebook. These guidelines also should be helpful to future Subcommittees.

EPA Perspective on Lessons Learned

Dr. Farland stated that ORD held a Lessons Learned on BOSC Program Reviews Meeting on July 14, 2005, at EPA headquarters. He described the lessons learned identified during the meeting. ORD should prepare for the review well in advance of the face-to-face meeting and assemble a good team that will commit the time required to prepare for the review. The charge questions for the review should be related to the R&D criteria. ORD staff found that the use of a Lotus Notes team room to develop and review materials improved efficiency. The binder materials should be optimized in terms of relevance to the charge questions and should be organized to facilitate responding to the questions. Based on comments from the Subcommittee members conducting the reviews, ORD was informed that a bibliometric analysis of the program's publications is essential. The optimal number of posters per session is between 20 to 25. A template and a common theme should be used for the posters and the NPD should review all of the posters—those from ORD staff and ORD clients (e.g., states, program offices) before they are finalized to ensure they are on target. It is important to adopt an "ORD face," particularly with the posters, erasing the distinctions between the various laboratories and centers. The presentations should be short, succinct, and focused, and they should not rehash the written materials. ORD staff found that dry runs were helpful in refining and polishing the presentations.

ORD needs to clearly explain to the Subcommittee how program-level priorities are determined, how the research program is coordinated with other programs, and how projects are selected (both intramural and extramural). The materials distributed to the Subcommittees should include information on performance measurement and describe indicators of program integration. Also, they should better describe the program's research partnerships and collaborations (including international). Some NPDs thought it was best to organize the materials by LTG, addressing each R&D criteria within each LTG. ORD needs to explain to the Subcommittee the importance of the R&D criteria and how these criteria are the basis for the program and PART reviews. More synthesis of material relative to these criteria is needed for the reviews. The NPD should prepare and guide the clients (e.g., states, program offices) on their role in the review meeting so that they understand the importance and purpose of their contribution. Most NPDs agreed that the client testimonies provided at the review meetings were invaluable. It also was suggested that the NPD think ahead to the PART review when preparing for the BOSC program review to reduce the preparation time required for the PART process.

One key to a successful review is the selection of a DFO who can commit the time when it is needed. The DFO and scientific lead need to communicate early and often during the process; the DFO is most effective when he or she is integrated into planning for the reviews. It is important to educate both the Subcommittee members and the technical team about the FACA process in advance of the review meeting. Standard presentations on FACA, ORD, PART, planning/budgeting, and the R&D investment criteria would be helpful. ORD should help identify the expertise needed on the Subcommittee to conduct the review. Three conference calls prior to the review meeting could help prepare the Subcommittee members for the review.

The materials for the review should be sent to the Subcommittee members at least 30 days in advance of the review meeting. Because of the volume of materials and the time it takes to prepare them, they probably should be sent to the Subcommittee in stages. The materials should be received by the Subcommittee at least 2 weeks before the conference call during which they will be discussed. The charge to the Subcommittee also should be discussed during a premeeting conference call. One premeeting conference call could be dedicated to the standard presentations described above.

At least 2 ½ days are needed for the review meeting, to allow time for the Subcommittee members to interact with the ORD staff, ask questions, and prepare a preliminary report. For larger programs, 3 ½ days may be more appropriate. All materials produced for the program reviews should be archived by ORD for subsequent use by EPA staff. ORD staff thought the social dinners prior to the meeting were helpful in "breaking the ice" and giving the Subcommittee members some time to get to know each other. The NPDs also recommended that the BOSC program review be completed before the PART review/budget season begins.

Dr. Farland mentioned a number of outstanding issues that were identified by ORD during its Lessons Learned Meeting. Should a press package be developed for the review? What is the clearance process for presentations, posters, and other materials developed by multiple laboratories and centers? How much of the material provided to the Subcommittees should be developed specifically for the review and how much can come from existing materials? Will there be continued support for graphics (posters, bound booklets, miniatures of the posters for handouts), bibliographic analyses, and DFOs? Should a standard format be developed for ORD responses to the BOSC program review reports? How will the program review results be used by ORD? Dr. Farland commented that he would like to highlight the fact that there is an outstanding group of experts reviewing and advising ORD on its programs. The program review reports will be used for more than the PART reviews. For example, they will be used to guide the updates of the MYPs.

Dr. Johnson questioned the importance of the client testimonies and Drs. Sayler and Henderson responded that they both thought the client testimonies were essential to determine how ORD research was affecting outcomes. This type of information is critical for the PART review. Dr. Sayler emphasized that the program review reports are written for two audiences—OMB and ORD. Dr. Farland responded that the program reviews should address more than the items associated with the PART review and the charge questions should reflect the broader focus. Dr. Windom asked if it would be appropriate to discuss client testimonies during one of the premeeting conference calls so that the Subcommittee could have input on which clients should make presentations at the face-to-face meeting. Dr. Johnson agreed that these testimonies are important when the clients are responsible for the outcomes. In response to Dr. Windom's question, Dr. Farland stated that ORD would welcome feedback from the subcommittees on which clients should present at the meeting.

Dr. Clark commented that the Human Health Research Subcommittee members talked about core research versus problem-driven research. It is more difficult for ORD to show that core research contributes to outcomes. Dr. Farland responded that it is important for ORD to relate its research to short-term needs, but unless ORD proves the importance of looking toward the future, only problem-driven research will be funded. Dr. Henderson commented that core research is essential, but acknowledged that it is difficult to convince OMB of the value of long-term research. Dr. Farland replied that EPA is making some progress with OMB, but it has been a challenge.

Ms. Kowalski stated that the Subcommittee Chairs and Vice-Chairs are critical to the reviews; they keep the group focused on the review and production of the report. She mentioned that those Subcommittees that were better informed about the FACA process seemed to function more smoothly than those that were less informed. In response to Dr. Giesy's earlier comment regarding the Ecological Research Subcommittee review meeting, she noted that it is inappropriate for EPA staff to do anything other than provide clarification in response to a question during the review meeting discussions. They should not rebut Subcommittee findings or statements. This is critical because EPA cannot be seen as trying to influence the review process. The DFO or Chair should interrupt the staff member and inform him or her that such comments are not appropriate. Ms. Kowalski asked the BOSC members to inform her if this happens at any future meetings. Although ORD is developing materials to inform all involved about the FACA process, she asked the BOSC Executive Committee members to help educate the other members of the Subcommittees on which they serve. She acknowledged that although the Subcommittees may find it

difficult to criticize the Agency in the presence of EPA staff, the Agency needs to hear both the positive and negative comments. ORD needs this honest, constructive criticism so that we can improve our programs. Dr. Johnson said that he will work with Ms. Kowalski to develop standard operating procedures (SOP) for the program reviews. This document will include a definition of the roles of the various participants; standard presentations on ORD, PART, FACA, and R&D criteria; the lessons learned by the BOSC and ORD in conducting the first five reviews; and guidelines for the format of the report. The SOP will be a living document and will be updated as needed to facilitate future reviews.

Dr. Johnson thought it might be beneficial to revisit the original charge questions to determine if the lists developed by the Subcommittees deviated significantly from that original list. He wants to ensure that the basic list of charge questions includes all of the cross-cutting themes identified in yesterday's discussion. Dr. Johnson said that he would work with Dr. Farland to review the questions. The basic list of questions (inclusive of the cross-cutting themes) will be included in the SOP. Dr. Sayler suggested adding a list of abbreviations and acronyms to the SOP.

Review and Approval of July 2005 Conference Call Minutes

Dr. Johnson asked if there were any comments on the minutes of the July 29, 2005 Executive Committee conference call. He noted that in the first sentence of the second paragraph on page 1, Dr. Henderson should be identified as the Chair of the Subcommittee and Dr. Stewart as the Vice-Chair. Dr. Daston's affiliation should be changed to Proctor & Gamble in the third paragraph on page 4. Dr. Stewart indicated that she is now the Dean and not the Interim Dean, so this should be changed on the list of Executive Committee members.

Dr. Johnson asked for a motion to approve the minutes with the requested changes. Dr. Daston moved that the minutes be approved with the changes, and Dr. Henderson seconded the motion. The July conference call minutes were approved unanimously by the BOSC Executive Committee.

ORD Responses to Recent BOSC Reports

Dr. Farland stated that Drs. Hugh Tilson (ORD/NHEERL), Acting NPD for Human Health Research, Bob Kavlock (ORD/NHEERL), Director of the National Center for Computational Toxicology, and Elaine Francis (ORD/NCER), NPD for Endocrine Disruptors Research, had joined the meeting by telephone to participate in this session.

ORD Response to the Human Health Research Program Review Report

Dr. Tilson thanked the BOSC and the Human Health Research Subcommittee for the constructive review of the program. The comments were very useful for the PART review and are being used to update the MYP to address new research for the next 3 to 5 years.

The BOSC Human Health Research Subcommittee met with program managers and staff February 28–March 2, 2005 to review the program. The final report, dated July 27, 2005, was transmitted to ORD on August 5, 2005. ORD submitted a response to the BOSC's program review to the Executive Committee on September 13, 2005.

The ORD response included a transmittal memorandum to the BOSC from the Deputy Assistant Administrator. The narrative responded to each of 27 issues identified in the report. The responses were presented in the same order as the issues appeared in the BOSC report. For each issue, ORD's response included a comment from ORD, the action item(s) identified, and the timeline determined for each issue. There were three types of comments/recommendations in the BOSC report—conceptual issues, planning and coordination issues, and implementation issues.

The conceptual issues and the ORD comments are listed below:

- ***Issue:*** The program needed to conduct a bibliometric analysis.
  ORD Comment: The bibliometric analysis was completed on April 18, 2005, and provided to the BOSC Subcommittee.

- ***Issue:*** The public health benefits of the program needed to be articulated.
  ORD Comment: The revised Human Health Research Program MYP will provide a better rationale for public health benefits.

- ***Issue:*** The conceptual framework needed to be better articulated.
  ORD Comment: The revised MYP will provide a more coherent organizing theme for the research.

- ***Issue:*** The direction of the research is too strongly influenced by external advisory bodies.
  ORD Comment: The revised MYP will be based on extensive scientist-to-scientist meetings to provide bottom-up direction of research to address strategic goals.

- ***Issue:*** The Human Health Research Program MYP needed to be revised.
  ORD Comment: The revised MYP will be ready for external review by April 2006.

- ***Issue:*** Peer review will be enhanced by providing critiques from previous reviews.
  ORD Comment: The BOSC review was the first review of ORD's Human Health Research Program. For the next program review, ORD will provide the Subcommittee the response to specific issues raised in the 2005 review.

- ***Issue:*** The program needs better documentation of collaboration of EPA scientists with those of other governmental laboratories.
  ORD Comment: Some information was included in the materials provided to the Subcommittee, but more complete documentation will be provided at the mid-cycle review.

The planning and coordination issues and the ORD comments are listed below:

- ***Issue:*** Improve interactions with international groups.
  ORD Comment: ORD staff attended the European Union meeting in June 2005, and ORD has significant involvement with the International Programme on Chemical Safety, World Health Organization (WHO).

- ***Issue:*** Coordination with NCCT.
  ORD Comment: The program has regularly scheduled meetings with NCCT and the Center will provide input into the next revision of the Human Health Research Program MYP.

- ***Issue:*** Better coordination is needed between the intramural and extramural components of the program.
  ORD Comment: The program held a workshop of intramural and extramural scientists in June 2005 to enhance coordination and collaboration. Also, the input provided by NCER on the extramural research will be incorporated into the revised MYP.

- ***Issue:*** ORD should ensure the involvement of stakeholders other than the Office of Prevention, Pesticides, and Toxic Substances (OPPTS).

ORD Comment: Significant involvement of other stakeholders already exists, but was not evident at the review. The program already has held briefings with the regional and program offices to identify research needs for revision of the MYP.

- ***Issue:*** Need to broaden stakeholder involvement in planning and prioritization of research.
  ORD Comment: Recommendations from the BOSC and PART reviews will be used in revising the MYP.

- ***Issue:*** The process should be established to leverage expertise and efforts across agencies.
  ORD Comment: This issue also was noted in the OMB PART review. ORD is developing a strategy to formalize interactions with other agencies to coordinate human health research efforts.

- ***Issue:*** The extramural grants program needs to be better advertised.
  ORD Comment: ORD is developing a strategy to expand communication of the application process and increase the applicant pool.

- ***Issue:*** The program needs to plan for leadership succession.
  ORD Comment: ORD will prepare a workplace planning document in 2006. Implementation of the plan will depend on the availability of resources.

- ***Issue:*** Broad strategies need to be developed to manage risks from thousands of new chemicals.
  ORD Comment: This falls under the purview of other research programs (Computational Toxicology, Safe Pesticides/Safe Products). The linkage of the program's research under LTG 1 to other MYPs will be emphasized.

The implementation issues and the ORD comments are listed below:

- ***Issue:*** There is a need to promote better integration of Susceptible Populations with other LTGs.
  ORD Comment: The Susceptible Population LTG will focus on life-stage issues. This focus will provide greater opportunities to integrate the research.

- ***Issue:*** There needs to be better integration between exposure and effects research.
  ORD Comment: The BOSC report noted that there is good interaction among the laboratories and centers. The next revision of the MYP will focus on identifying additional multidisciplinary research areas.

- ***Issue:*** Exposure research should include a wider range of chemicals.
  ORD Comment: ORD is working to include additional classes of chemicals in exposure research in the next revision of the MYP.

- ***Issue:*** The asthma research program should have regular group meetings.
  ORD Comment: The existing ORD asthma research coordinating committee already meets on a regular basis.

- ***Issue:*** Researchers working on aging should meet with those working on children's issues.
  ORD Comment: There is a workshop planned for April 2006, which will bring together these two groups of researchers.

- ***Issue:*** Source-to-effect research should progress to include pharmacodynamic issues.
  ORD Comment: A workshop is planned to develop strategies to include pharmacodynamic issues in source-to-effect research.

- ***Issue:*** Need to expand program expertise to include community-based participatory research.
  ORD Comment: Current research already includes community-based participatory approaches. The addition of expertise will be linked to the availability of resources over the next 2 to 4 years.

- ***Issue:*** LTG 4 needs to be better focused.
  ORD Comment: A steering group already is in place, and the Research Coordination Team (RCT) is working on developing a research plan for the future.

- ***Issue:*** Goals and a process for decision-making need to be established for LTG 4.
  ORD Comment: A steering group already is in place, and the RCT will provide internal oversight of the ongoing research.

- ***Issue:*** The criteria for demonstration projects for LTG 4 need to be explicit.
  ORD Comment: The criteria were developed and used to evaluate proposals, two of which will be funded in 2006.

- ***Issue:*** LTG 4 should be reviewed externally on a periodic basis.
  ORD Comment: ORD plans to ask the BOSC to facilitate review of the program's progress; however, progress on LTG 4 will depend on available resources.

Dr. Tilson reported that the PART review of the Human Health Research Program occurred from May to August 2005. The BOSC report was crucial in addressing issues related to the R&D investment criteria (relevance, quality, performance). The BOSC review also was essential in responding to section 4 concerning program evaluation by an independent peer review panel.

Dr. Tilson proposed that the BOSC conduct a mid-cycle review of the program in 2007, approximately 2 years after the original review. This mid-cycle review will determine the progress of the program in responding to the action items and it will provide ORD the opportunity to discuss issues that may have emerged during the interim (e.g., changes in resources). A full review of the program should be conducted in 2009, approximately 4 years after the original BOSC program review.

Dr. Farland mentioned that others will refer to mid-cycle reviews and asked that the BOSC consider conducting mid-cycle reviews on ORD programs.

ORD Response to the Computational Toxicology Research Program Letter Report

Dr. Kavlock presented the ORD response to the BOSC's letter report on the Computational Toxicology Research Program. The program involves a technology-based, hypothesis driven effort to increase the soundness of risk assessment decisions within EPA. It is designed to build the capacity to prioritize, screen, and evaluate chemicals by enhancing the predictive understanding of toxicity pathways. Program success will be measured by the ability to produce faster and more accurate risk assessments for less cost relative to traditional means and to classify chemicals by their potential to influence molecular and biochemical pathways of concern.

The BOSC advised the program to pursue collaborations. The program is shifting to a center of excellence in applying broad tools. An implementation plan is being developed and two communities of practice are being established—chemoinformatics and biological modeling. There also is a commitment to holding workshops that will enhance collaboration. Efforts are being made to extend the program's networks, including establishing communities of practice, offering rotational assignments, expanding the Computational Toxicology Implementation and Steering Committee (CTISC), reserving funding for interactions outside NCCT, scheduling monthly management level meetings with the National Exposure Research Laboratory (NERL) and National Health and Environmental Effects Research Laboratory

(NHEERL) and quarterly meetings with the NPD for Endocrine Disruptors Research, coordinating closely with the National Toxicology Program/National Institute of Environmental Health Sciences (NIEHS), and beginning work on a communications plan to distribute the program's outputs.

With respect to the BOSC's suggestion that the program add bioinformatic expertise, STAR Centers are being launched, and two bioinformatics positions have been advertised and offers are imminent. The Title 42 authority hiring pilot may allow ORD to hire a renowned bioinformatics expert. A high-throughput screening position also was advertised and an offer is imminent. The program is committing postdoc support to visual analytics and is discussing strategic staffing with ORD, which includes social science applications (economic modeling).

To keep pace with the science, the program is implementing a number of activities to forge partnerships with other organizations, including: (1) reserving resources for training; (2) participating in cross-ORD postdoctoral recruitment; (3) engaging with the International Life Sciences Institute (ILSI), WHO, and Organisation for Economic Co-Operation and Development (OECD); (4) participating in national and international forums; and (5) supporting workshops.

In response to the BOSC's recommendation that ORD develop a rationale for the Computational Toxicology Research Program and milestones for the projects, the Center is developing an implementation plan that will include annual milestones for the next 3 years.

To develop fruitful partnerships, the Center is cultivating ties to academic centers and other organizations through the STAR Environmental Bioinformatics Centers, weekly work-in-progress sessions with the NTP/NIEHS, and a workshop was held with scientists from the Pacific Northwest National Laboratory (PNNL). The Center is reserving resources for travel and for supporting conferences and workshops (both internal and external). In addition, the Center is interacting with international organizations, including ILSI, WHO, and OECD, and working with the International Science and Technology Center in Moscow to interact with former Soviet Union weapons scientists under a U.S. State Department funded program.

Collaboration with the other ORD laboratories and centers is important to expand the depth and breadth of NCCT. For example, the Center also is discussing its role in the ecological area with the other laboratories and centers. The CTISC has been broadened and the program is being extended beyond endocrine disruptors. For example, NCCT will be briefing OW at the end of September on ToxCast, which is a new way to categorize and prioritize chemicals.

ORD Response to the Endocrine Disrupting Chemicals (EDC) Research Program Review Report

Dr. Francis noted that this was the first program review conducted by the BOSC. The Subcommittee review meeting was held December 13-15, 2004, in Research Triangle Park, North Carolina. Dr. Anna Harding chaired the Subcommittee and Dr. George Daston served as the Vice-Chair. The other Subcommittee members were Drs. Glen Boyd, George Lucier, Stephen Safe, Juarine Stewart, Donn Tillitt, and Glen Van Der Kraak. The program was reviewed in terms of design, relevance, progress, contributions to scientific leadership, and resource allocation. Each of the program's three LTGs (i.e., improving the underlying science, determining the impact of EDCs, and supporting EPA's screening and testing program) was assessed for design, relevance, and progress.

The review report format was based on reports prepared for NHEERL Division-level reviews. The Executive Summary of the report identified the overall goals and charge, provided background for the research program, listed the overarching conclusions and recommendations, identified strengths and challenges of each LTG, addressed program leadership and resources, and provided an overview of the report. There was a chapter on each of the LTGs that addressed the design, relevance, progress, and strengths and challenges. The final chapter of the report focused on program leadership and resources.

With regard to program design, the Subcommittee found that the goals and scientific questions of the program were appropriate and the program included a multidisciplinary set of research areas for both human health and wildlife that cuts across the risk assessment/risk management paradigm. The program research is of direct relevance to legislation that EPA administers and it serves the program offices well. The research has been productive and of high scientific quality; of particular note is the excellent progress under LTG 3. The program leadership is recognized both nationally and internationally. The research results are disseminated in top-tier scientific journals, and the scientists are at the forefront of EDC research in screening and testing methodologies. The program's resources have been used efficiently and there has been astute leveraging with other federal agencies. The BOSC noted that continuation of the extramural grants component of the program is vital.

There were 13 unique recommendations in the BOSC report, some of which were repeated in different sections. Two were included in the Overarching Conclusions and Recommendations section, four in the LTG 1 section, five in the LTG 2 section, four in the LTG 3 section, and one in the Leadership and Program Resources section. The recommendations and ORD's response are listed below:

The recommendations and ORD responses pertaining to LTG 1 are listed below:

- ***Recommendation:*** EPA should clarify what is and is not covered by the EDC program whenever the program is reviewed.
  Action: The guiding definition and scope of the research program will be further clarified in the updated MYP and in future program reviews.
  Timeline: A draft of the updated MYP will be available in early 2006 and a mid-cycle review of the research program will take place in late 2006.

- ***Recommendation:*** ORD should strengthen the NPD's ability to oversee the program: (1) hire additional personnel; (2) elevate the position of the EDC NPD to the level of the Laboratory/Center Directors; and (3) provide budget authority to the EDC NPD.
  Action: There are federal limits on the number of personnel so the program will supplement EPA scientists by using postdocs and other fellows, and by exploring "recent graduates contracts." The NPD position has been created and details regarding the relationship to the Laboratory/Center Directors, Executive Council, Science Council, etc., are being delineated in a document that is under development. Budget authority resides with the Senior Budget Officer (SBO) in ORD; budget advice and recommendations are sought from the NPDs.
  Timeline: Finding innovative ways to supplement the EDC workforce is an ongoing effort; as NPDs begin to work together, they may be in a better position to characterize leveraging of personnel across the research programs. Details of the relationship of the NPDs within the ORD management structure are being worked out in the document that will be available in January 2006.

- ***Recommendation:*** The EDC program should dedicate full-time EPA personnel to work in wildlife toxicity.
  Action: The program will continue to engage academic wildlife toxicologists through the STAR Program and will increase efforts to collaborate across federal agencies to leverage the talent of their wildlife toxicologists. The program is developing a synthesis document that integrates published results from ORD's STAR and intramural programs on the impacts of EDCs on wildlife.
  Timeline: The program will work through the Interagency Working Group (IWG) on EDCs to increase sharing of information and leveraging research activities, such as the joint workshop on the impact of wastewater treatment plants and concentrated animal feeding operations (CAFOs) on ecosystems to be held in 2006. The synthesis document will be completed in late 2005.

- ***Recommendation:*** ORD should continue to collaborate with other federal, academic, non-governmental, and industry partners to characterize better the range of variability among species.
  Action: The program will continue to evaluate potential interspecies differences and similarities among cellular modes of action (MOAs) in-house and with partners in academia, industry, and other agencies.
  Timeline: Research on species extrapolation is scheduled to continue through FY 2007; at the fall meeting of the IWG, ORD will determine if there is any interest in having a future workshop on this topic.

- ***Recommendation:*** ORD should integrate predictive tools for prioritization into EPA's EDC program.
  Action: This recommendation is being addressed through the Computational Toxicology Research Program. The EDC NPD, planning team, and NCCT Director will ensure greater linkages among the EDCs, Computational Toxicology, and Sustainability and Pollution Prevention (SP2) Research Programs.
  Timeline: The Computational Toxicology Research Program underwent a BOSC review in April 2005, and a STAR grantees and EPA scientists workshop was held in July 2005. The EDCs MYP will be updated in early 2006, and that updated plan will include clearer linkages among the EDCs, Computational Toxicology, and SP2 Programs.

- ***Recommendation:*** Efforts should focus on the development of risk assessment paradigms for EDCs and application of the research findings.
  Action: EPA's position is that current approaches for risk assessment under specific endpoints are appropriate for use in evaluating EDCs. ORD will continue to monitor research results that may affect current risk assessment practices. If and when the Agency determines that risk assessment approaches need modification, EPA will use a guideline development process.
  Timeline: Research that may affect current risk assessment practices will be monitored on an ongoing basis.

The recommendations and ORD responses relating to LTG 2 are provided below:

- ***Recommendation:*** EPA should continue to improve its interactions with other agencies that have a strong interest in EDCs to identify new sources of environmental and human exposures, including investigating the role of pharmaceuticals as sources of EDCs; EPA should mine data made available from the High-Production Volume (HPV) Program.
  Action: ORD will use the IWG to strengthen relationships with other agencies. Efforts are underway to organize a multi-agency sponsored workshop related to sources of exposure. The program will continue to work closely with the Co-Chairs of the interagency Pharmaceuticals and Personal Care Products (PPCP) task group and look for opportunities for joint efforts. The program will work with the NPD for Water Quality Research to explore leveraging and linking with PPCP activities. The program also will work with OPPTS to make the data from the HPV and the Voluntary Children's Chemical Evaluation Program (VCCEP) available to ORD for mining.
  Timeline: An interagency workshop on wastewater treatment plants and CAFOs will be held in 2006. The STAR grantee and EPA scientists meeting on pharmaceuticals in the environment was held August 23-25, 2005, and the interagency Task Force held a workshop on July 25-26, 2005. The products of these workshops will contribute to development of a framework document that is anticipated to be completed in December 2005. The EDC NPD will be meeting with the OPPTS Office Directors in September about ways in which to improve communications of research results and will use that opportunity to request access to HPV and other data for the EDC scientists.

- ***Recommendation:*** Subsequent reviews should include poster presentations by each of the epidemiologists funded by this interagency program.

Action: Grantees will be brought together next summer for another progress review and it will be scheduled so that it does not coincide with the Program Review. Epidemiology grantees will be invited to the next EDC program review.
Timeline: The NPD and IWG will continue to monitor epidemiology research. Another progress review is planned for summer 2006, and grantees will be invited to the 2008 EDC program review.

- ***Recommendation:*** ORD should continue to investigate the common ground between ecological and human health because the Agency is in a unique position to do so.
  Action: ORD will take on the challenge to develop approaches that integrate human health and ecological assessments. ORD will consider improving the integration of projects that will contribute to evaluating human and ecological health (e.g., using the MOA approach); a pilot may be centered around CAFOs.
  Timeline: Future research directions are under discussion with the updating of the MYP by early 2006. Within the next year, several postdocs will be hired to expand efforts on CAFOs and a Request for Applications (RFA) on CAFOs will be issued in fall 2005. The MOA case study was finalized in June 2005.

- ***Recommendation:*** EPA should take the leadership role in the application of the "omics" technologies for evaluating environmental and human health effects of EDCs.
  Action: EPA is positioning itself as a leader in the "omics" field through research and policy developments. EDC scientists will continue to play a critical role in both of these areas. The NCCT Director and the EDC NPD will continue to hold frequent meetings to coordinate activities and will work with the planning team to ensure that the linkages among the Computational Toxicology, EDCs, and SP2 Programs are captured in the updated MYPs.
  Timeline: The updated MYP should be available in early 2006. Interaction with the Office of the Science Advisor's Genomic Workgroups will continue, as confirmed at the Genomics Training and Tools collaboration meeting with the Food and Drug Administration (FDA)/NIEHS/CCVAM held August 4, 2005. A draft case study on the use of toxicogenomics data in risk assessment on an endocrine active agent will be ready for for internal review by June 2006, and a workshop to review it will be held in September 2007.

The recommendations and ORD responses pertaining to LTG 3 are presented below:

- ***Recommendation:*** It will be important for ORD to train or hire experts in bioinformatics to work with the life sciences experts already on staff.
  Action: Two bioinformatics experts have been hired and a job announcement has been issued for two more. A STAR grant solicitation for Environmental Bioinformatics Research Centers (EBRCs) was announced. It will be awarded in the form of cooperative agreements so that there will be strong interactions between extramural scientists and those of ORD.
  Timeline: Two positions have been advertised for bioinformatics experts. Applications have been received, selections will be made by October 15, and the new hires should join NCCT soon thereafter. Awards for the EBRCs will be made by September 30.

- ***Recommendation:*** There should be a mechanism in place to ensure the timely transfer of protocols to OPPTS.
  Action: OPPTS senior management and the NPD will be meeting with NHEERL senior management to emphasize OPPTS' priorities and timelines, and to reach agreement on how to meet OPPTS' expectations.
  Timeline: Meetings are being scheduled in RTP and Duluth for September/October 2005.

- ***Recommendation:*** Provide a summary of the research and its relevance to EDC identification in subsequent reports and revisions of the MYP.

Action: The updated EDC MYP will include a more coherent way to summarize accomplishments, characterize their impact, and cite linkages to other relevant documents (e.g., laboratory-specific EDCs implementation plans, research frameworks, other MYPs). Research also is being summarized in three topical synthesis documents (Effects in Wildlife, Effects on Development, and Screening and Testing) that will compile and integrate the intramural and STAR extramural research accomplishments.
Timeline: The NHEERL Implementation Plan that summarizes the research was developed in October 2004. The synthesis documents will be available in late 2005, and a draft of the updated EDCs MYP will be available in early 2006.

Dr. Francis closed her presentation by thanking the BOSC Subcommittee for its thoughtful recommendations. The recommendations are being incorporated into the MYP update, and implemented in interactions with the program's clients. In addition, the recommendations are being implemented in collaborations with partners, and considered in workforce planning. EPA hopes that the BOSC will undertake a mid-cycle review of the program approximately 2 years after this initial program review and a final review approximately every 4 years.

Dr. Farland commented that ORD already is implementing the advice provided by the BOSC in the program reviews. He mentioned that ORD is trying to standardize its approach to responding to the reports; he hoped that these presentations gave the BOSC an understanding of what ORD is doing and plans to do in response to the reviews. Dr. Farland then thanked the three presenters. Dr. Johnson thanked ORD for the responses and said that he is looking forward to hearing about future changes in the programs. Dr. Clark asked if the ORD responses could be sent to the members of the respective Subcommittees. Dr. Johnson replied that all of the Subcommittee members will receive ORD's response to their report. Dr. Harding mentioned that she has worked the EDC report into a manuscript that will be submitted to *Environmental Health Perspectives*. The manuscript currently is being reviewed by the other members of the EDC Subcommittee. She hopes to submit it to the journal by the end of September.

ORD's Perspective on the Global Earth Observation System of Systems (GEOSS)

Ed Washburn (ORD/OSP) explained that GEOSS is comprehensive, coordinated, and sustained observations of the Earth system. It is designed to improve monitoring of the state of the Earth, increase understanding of Earth processes, and enhance prediction of the behavior of the Earth system. GEOSS will provide timely, quality, long-term global information as a basis for sound decision making, and the enhanced delivery of benefits to society.

GEOSS is a step toward addressing the challenges articulated by United Nations (UN) Millennium Declaration and the 2002 World Summit on Sustainable Development, including the achievement of the Millenium Development Goals.

The Earth Observation Summit- III was held in Brussels, Belgium, on February 16, 2005. At the summit, 56 countries and 33 organizations approved the GEOSS 10-year implementation plan, containing 2-year, 6-year, and 10-year outcomes, and a permanent secretariat hosted by the UN's World Meteorological Organization in Geneva.

GEOSS links data from satellite sensors, aerial sources, and ground-based monitors on land, ocean, and air to help us think globally and act locally to protect human health and the environment. The more we understand the Earth, the better stewards we become.

An ad hoc group of senior political officials from all participating countries and organizations, named the Group on Earth Observations (GEO), was formed to undertake this global effort. GEO was charged to develop a "Framework Document" plus a more comprehensive report to describe how the collective effort

could be organized to continuously monitor the state of our environment, increase understanding of dynamic Earth processes, and enhance forecasts on our environmental conditions. Furthermore, it was to address potential societal benefits if timely, high-quality, and long-term data and models were available to aid decision-makers at every level, from intergovernmental organizations to local government to individuals. Through four meetings of GEO, from late 2003 through April 2004, the required documents were prepared for ministerial review and adoption.

An interagency working group made up of 15 federal agencies and 3 White House offices developed the Strategic Plan for the U.S. Integrated Earth Observation System under the auspices of the National Science and Technology Council (NSTC) Committee on Environment and Natural Resources (CENR). The interagency working group was recently replaced by a standing subcommittee under CENR called the United States Group on Earth Observation (U.S. GEO), which will continue to develop implementation and integration plans for the United States system, and to provide input into the implementation of the global system of systems. EPA, working with other federal agencies, will provide leadership and contribute knowledge in support of GEOSS to ensure that it becomes a valuable collection of data, information, and models that can be used to better understand environmental and related problems and to support environmental decision making.

The vision of the Strategic Plan for the U.S. Integrated Earth Observation System is to enable a healthy public, economy, and planet through an integrated, comprehensive, and sustained Earth observation system. Mr. Washburn explained how Earth observations would be linked to societal benefits as better policy, management, and personal decisions are made as a result of the data. He presented a chart that identified the agencies that generate, use, or provide and use data that will lead to specific societal benefits (e.g., weather, disasters, oceans, climate, agriculture).

EPA's Report on the Environment reports on the condition of human health and the environment through an "EPA lens." It describes what EPA knows and does not know. It identifies measures/indicators to report on the status and trends, and where possible, their impacts on human health and the environment. It also identifies gaps and limitations in indicators data and research. The information from GEOSS could fill some of the gaps highlighted in the report.

Mr. Washburn provided two visualization slides combining ground-based data, aerosol data, data from airplanes, and satellite data to demonstrate the role that EPA would play in GEOSS. The first was an integrated picture of aerosols in the Southeast United States on July 20, 2004. There was a large band of forest fires in Alaska the last week of June 2004, and the figure in the slide shows that the fires impacted the air quality in the entire Southeast. Combining these data is important for states in ozone nonattainment to determine if it is a local problem or the impact of a distant problem.

Since 2003, ORD has demonstrated leadership in GEOSS through the intergovernmental ad hoc GEO, as Co-Chair of the User Requirements and Outreach Group, and key roles in the first two Earth Observation Summits, especially the second summit held on Earth Day in Japan (April 2004). ORD continues its international GEOSS leadership role in the GEO Committee on User Interface established after the third summit (February 2005), and ORD chairs the EPA GEOSS Coordinating Committee (EPA GEO), which was established in May 2005. The 2-page charter of EPA GEO has been approved. EPA GEOSS is planning ORD's FY 2006 Advanced Monitoring Initiative and serves as EPA's internal coordination mechanism and linkage with U.S. GEO.

Dr. Windom mentioned that there was a meeting sponsored by NAS about 10 years ago to discuss the Global Ocean Observation System. Many of the agencies involved in that effort were just repackaging what they were already doing. Once private sector groups starting working in this area, the federal agencies reluctantly have begun working together to create an integrated system. Is EPA actually doing anything new for GEOSS? Dr. Farland responded that EPA recognizes the need to do a better job of

collecting data and communicating with other federal agencies. Funding should be targeted at filling data gaps. He mentioned that NOAA requested funding for a large initiative in 2006 to collect information for the GEOSS strategy. EPA proposed AMI, which is broader than GEOSS. ORD will direct several million dollars in 2006 and 2007 to do work that will feed directly into GEOSS. EPA is taking advantage of certain opportunities that will improve environmental decisions.

Dr. Daston asked if there was potential for collaboration between GEOSS and NCCT on ecotoxicology modeling. Mr. Washburn replied that there was a workshop May 9-10, 2005, at which the idea of pulling together ecosystems data from different sources was discussed. They started by looking at what data are available and then at what data are needed. As the budget allows, efforts will focus on filling the gaps between these two. Dr. Windom mentioned that NSF has been trying to implement the National Ecosystem Observation Network (NEON) for a number of years. Mr. Washburn responded that EPA is watching that effort. NSF has not gotten enough funding to launch the program in a big way, but the program is alive and is being followed closely by the White House. Dr. Farland commented that NEON would feed data into GEOSS. ORD currently is thinking about how AMI and nanotechnology will be integrated into the structure; these efforts are not large enough to be programs, but there are a number of ongoing activities in each of these areas.

Dr. Johnson indicated that the next step may be to determine if there are extensions from the Computational Toxicology Research Program. The BOSC also may want to look at this along with other cross-cutting topics.

Public Comment

At 11:30 a.m., Dr. Johnson asked if anyone present would like to make a comment. No comments were presented.

SAB Activities Report

Dr. Lambert reported that the SAB has been reviewing sampling plans (water quality, sediment, air quality) for the Gulf area as part of the response to Hurricane Katrina. The August SAB meeting was cancelled so Dr. Lambert did not have any more information to report to the BOSC.

Draft Performance Measurement Tool

Dr. Farland explained that the draft performance measurement tool presented to the BOSC for consideration describes an approach for collecting quantitative data from an independent expert review, such as the BOSC program reviews. This proposed tool would be a major element in ORD's suite of critical measures developed for use in both formative (improvement) and summative (accountability) evaluation processes. ORD believes that it is important for program reviews to develop both qualitative and quantitative data using top experts from the scientific, management, and evaluation communities. The draft rating tool was designed to solicit quantitative data during an independent expert review.

Dr. Farland commented that although the program reviews conducted by the BOSC have been useful for the PART reviews, OMB would prefer that the independent reviews be as quantitative as possible. Therefore, ORD prepared this draft proposal, which outlines metrics and targets for the review, a tool for measuring the metrics, and data collection methods. The proposed performance rating tool could be used to measure success and applied to both retrospective and prospective reviews. The proposal was prepared by a staff member with extensive experience developing these types of tools, and the tool was designed to allow for the collection and analysis of a range of opinions and to generate quantitative results.

Dr. Johnson commented that the BOSC program review reports are consensus reports; the proposed tool solicits opinions of the individual Subcommittee members. It requires a different approach than was used for the reports. Should the BOSC Subcommittee complete only one survey form that represents the consensus opinion of the Subcommittee? Dr. Daston stated that the responses from ORD today indicate that the current process is working to improve the programs. Do we need to add this level of complexity to the review process? Dr. Henderson asked if this tool is to help with the PART reviews. Dr. Sayler commented that the proposed tool looks more like a project rating tool than one used to rate a program. He pointed out that the resulting score would be meaningless. Dr. Windom was concerned that the tool did not address the creativity of the program or its impact.

Dr. Farland said that the proposed tool would not replace the reports prepared by the Subcommittees. It would be an adjunct to the reports and the survey would be implemented after the review was completed. He thought the rating might help to put the consensus report in perspective. The report blends many ideas and comments and it is written as a consensus document so that all Subcommittee members can approve it. The quantitative tool would be applied at the LTG level. It would show that there was a range of opinions among the reviewers. It would be a means to quantitatively measure progress. Dr. Harding did not think the tool would show a range of opinions because the individual votes would be summarized. Dr. Farland explained that the Chair would ask each Subcommittee member to complete the tool for each LTG. The tool would be used to develop a mean score and range, but the underlying data would be available. Dr. Sayler thought a range would be more appropriate; the deviation in the range would provide some useful information. Dr. Lambert expressed concern about the reliability of the tool and did not think it would be useful. Dr. Windom thought the tool could be used to rate the LTGs, but suggested using excellent, good, fair, or poor rather than a numerical score. Dr. Henderson did not think it could be used to measure progress because it only indicates how good the program is doing at the time of the review. Dr. Windom pointed out that future ratings must increase to show progress. What if there is progress but the ratings do not increase?

Dr. Johnson said that the BOSC has two options: (1) improve the proposed tool so that it is acceptable to the Board, or (2) continue doing the program reviews without the addition of a quantitative rating component. He mentioned that when the Subcommittee conducts a review, it divides the responsibility for the different sections of the report among the members. Therefore, each member is more knowledgeable about his/her assigned areas compared to others.

Dr. Lambert commented that it would be difficult to use the tool to determine if a program has made progress since its last review. Dr. Giesy stated that something similar to this tool was instituted for publication review at Michigan State University and it was a disaster. He understands that ORD wants and needs a metric. A third option for the BOSC is to test the tool on a review and see if it is helpful. Dr. Farland said that if the tool was going to be tested using one of the reviews that was recently completed, ORD would need the data by mid-November so that it could be submitted for the PART review. Dr. Daston said that there appears to be little enthusiasm for the idea so he recommended that use of the tool be rejected by the Board. Dr. Henderson agreed, adding that she did not want to go back to her Subcommittee members and ask them to complete the survey. Dr. Johnson asked for a motion concerning the use of the tool. Dr. Daston moved that the tool be rejected by the BOSC for use in past or future program reviews. Dr. Henderson seconded the motion and the Board unanimously approved the rejection of the tool. Dr. Giesy said that he understands why ORD desires the BOSC to use such a tool. He suggested that the BOSC prepare an explanation for ORD as to why the Board members do not want to use the tool. Dr. Johnson agreed and said that he would develop a response to ORD's proposal.

Dr. Sayler said that if other agencies have used a similar tool, he would like evidence that the tool was used to produce data that are reliable and valid. Dr. Henderson suggested forming a work group to identify a better way to provide quantitative data to EPA in conjunction with the program reviews. It was

agreed that the Board would investigate alternative ways to provide more quantitative information to ORD as part of the program reviews.

Review of the Drinking Water Research Program Review Report

Dr. Clark explained that Drs. Giesy and Henderson will address comments on LTGs 1 and 2, respectively, and he would provide overarching comments on the report.

Dr. Giesy read the entire report and then went back through the section on LTG 1. He had some editorial comments that he agreed to provide to Dr. Sayler. Dr. Giesy recommended including specifics to support the statement in the report that it is clear that the ORD outputs are leading to important outcomes (page 3, line 13). This issue also is mentioned in Recommendation 5 on page 4. Dr. Sayler responded that OW, states, and utility groups made compelling presentations demonstrating that ORD outputs were leading to important outcomes. Although the outcomes are there, ORD needs to do a better job of defining them. Dr. Giesy suggested using boxes to highlight some examples of outputs leading to outcomes so that the reader can make that connection. He indicated that he did not have any other substantive comments on LTG 1.

Dr. Henderson had some editorial comments on the LTG 2 section that she agreed to provide to Dr. Sayler. On page 4, Recommendation 5, Dr. Henderson proposed that the wording be changed. Insert the words "by its clients" after the word "translated" in the first sentence of Recommendation 5. Dr. Sayler agreed to modify the wording. She also suggested inserting a period after DWRP in the first sentence on page 4 under Recommendation 3, and delete the words "which further" and insert "This" before "constrains." Dr. Henderson said that it was not clear if the Subcommittee thought the mention of omics technology was positive. If the members had an opinion about this, it should be stated clearly in the report. Dr. Sayler responded that there was a difference of opinion among the Subcommittee members on this issue. Not everyone on the Subcommittee thought that omics would be positive for the program. Alternatively, Dr. Henderson proposed that the Subcommittee offer some guidance to ORD on the issue. Dr. Johnson suggested adding that there was a range of opinions on the subject to give the statement some context.

Dr. Henderson noted that source water protection was listed as a strength on page 18, but there was no mention of whether QSAR models were considered a positive. Dr. Daston said he thought there was a comment on it; Dr. Sayler confirmed that it was mentioned on page 16. Under source water protection, several small recommendations were made but they were not included in the list of recommendations in the summary (page 18, lines 25-27 and 42-44; page 19, lines 11-12 and 22-24). Dr. Sayler replied that the recommendations for source water protection were nested under Recommendation 2. Dr. Johnson said that there is not a one-to-one correspondence between the recommendations in the text and the list in the summary. Only the major recommendations were included in that list. Dr. Sayler noted that some of the smaller recommendations are included in the list—one is in Recommendation 7. Dr. Henderson said that she had no additional comments.

Dr. Clark looked over the section on leadership. On page 3, line 31, the words "appearance of" leads the reader to think the Subcommittee disagreed about this or was unsure about it. Dr. Sayler explained that in some areas of the program collaboration was clear but it was less clear in other areas. There are differences among the different areas of the program. Dr. Clark suggested that the report elaborate on this issue so that the Subcommittee's position is clear to the reader. The report did a good job of laying out the issues on page 20. At the top of page 20, the report mentions that in areas where statutory mandates focus Agency resources, EPA can maintain scientific leadership. This statement seems to contradict the earlier comment about the number of management positions filled by individuals who are acting rather than permanent being a weakness of the program. Dr. Sayler suggested that Dr. Farland respond to the concern about the lack of permanent managers. Dr. Farland said that it is important not to equate the

number of acting managers with lack of leadership. Although ORD would prefer to have more management positions filled permanently, the Subcommittee should look for evidence of leadership or lack thereof, rather than base the statement on the number of acting managers. Dr. Johnson proposed that the recommendation be moved further back in the list of recommendations so that it carries less importance. Dr. Sayler agreed to temper the wording, stating that there is some risk of inconsistency because a permanent NPD may shift the program's priorities. Dr. Farland pointed out that the Acting NPD is functioning in the same manner as the other NPDs. Dr. Daston said that he is not comfortable with the report stating that the high number of acting managers is a weakness of the program. He commented that many of the individuals acting in the management positions have held various leadership positions in the Agency and have extensive knowledge of the program. The priorities are established by the strategy and these individuals are fully capable of understanding and implementing the strategy. Dr. Daston stated that unless there is evidence that there is a weakness resulting from the number of acting managers, he did not think the comment should be included in the report. If it is included in the report, more text should be added in the leadership section explaining that just because an individual is acting in a position does not mean that he or she lacks the ability to lead. Dr. Johnson suggested including such a statement in the text on page 21 of the report. He also proposed that the statement be removed from the conclusions and recommendations, remaining only in the body of the text.

Dr. Clark suggested that the names on page 20, lines 18-19 be removed, noting that none of the other review reports identified specific individuals by name. Dr. Johnson did not object to deleting the names. Dr. Harding proposed rewording it to state that several of the groups include internationally recognized experts. Dr. Sayler noted that on page 20, line 28 the numbers of publications were calculated to provide for quantitative comparisons. He mentioned that Dr. Sayles has indicated to the Subcommittee that the numbers are inaccurate because the calculations included administrative staff. Dr. Sayles agreed to provide more accurate numbers to the Subcommittee. Ms. Kowalski stated that if the numbers are inaccurate, they should be changed. Dr. Sayler responded that the Subcommittee members agree that they are inaccurate and everyone is more comfortable with the suggestion Dr. Sayles made on how to recalculate the numbers.

Dr. Harding suggested that the LTGs be explicitly stated in the report. Referring to the mention of non-governmental organizations (NGOs) on page 5, she thought the report should be more specific. On page 9, line 15, Dr. Harding proposed adding a little more text to explain the statement. The words "or partner" should replace "and partner" on page 10, line 17, to allow EPA more latitude in achieving progress in the area of epidemiology.

Dr. Stewart noted that the format of the section on scientific leadership differs from the rest of the report. She also stated that the title for Section V should be "Communication and Coordination" (page 21, line 6). Dr. Johnson replied that the formatting difference was intentional. He suggested adding a sentence to explain why the formatting is different from the other sections. Dr. Johnson commented that he wanted it clear that the external review mentioned on page 8, line 40 refers to both internal and external projects. Dr. Farland responded that there is a competitive process for cooperative agreements and there is a review; however, it is not necessarily an external review. Dr. Sayler agreed to reword that section.

Drs. Sayler and Johnson will revise the report based on the comments from the BOSC Executive Committee. Drs. Giesy and Clark will vet the report, and Dr. Henderson will be responsible for doing a final review of the report to ensure that all of the Board's comments have been addressed. Dr. Johnson asked for a motion to approve the Drinking Water Research Program Review Report. Dr. Giesy made a motion to approve the report with the suggested revisions and Dr. Harding seconded the motion. By show of hands, the report was unanimously approved by the BOSC.

Ms. Kowalski asked if ORD should respond only to the recommendations included in the list in the summary. Dr. Sayler replied that he thought ORD should respond to all of the recommendations in the

report, even those not listed in the summary. Ms. Kowalski needs an accurate count of the recommendations so she asked Dr. Sayler to highlight them in the report. Dr. Johnson said that the report will make it clear that those listed up front are the most important, but additional recommendations are highlighted in the text.

Next BOSC Executive Committee Meeting

The next Executive Committee meeting will be held in January or February 2006. Dr. Johnson asked the members to determine if they would be available to meet February 13-14, 2006. He asked that they send an e-mail to him and Ms. Kowalski so that the date for the next meeting can be selected.

New BOSC Logo

The majority of the Executive Committee members preferred the design with the rectangular bar across the top of the page. It was suggested that the left column of the letterhead include a list of the BOSC members. Dr. Giesy proposed removing the background color outside the two lines. Dr. Johnson thanked the members for their comments, stating that EPA will make revisions and prepare sample letterhead, report cover, and report layout. It was agreed that each page will have a draft watermark until it is final. Also, the version date should be included in a header or footer. Several format options will be distributed to the Board members for their selection. Ms. Kowalski commented that the vote could be accomplished by e-mail because this is an administrative issue and does not require a public forum.

Guidelines for BOSC Report Summaries

Referring to the draft guidelines in the meeting notebook, Dr. Johnson stated that the Executive Summaries should more correctly be titled Summaries. The Summary should capture the reader's attention and clearly and concisely communicate the main message of the report to the target audiences (e.g., sponsors, Congress, high-level policy makers), and in some cases, the general public. The Summary should include one to three paragraphs to introduce the study topic and one to two paragraphs to describe the study charge. The Subcommittee's overall message should be presented in one to two paragraphs. The key conclusions and recommendations should be identified and make up the bulk of the Summary (several pages). A recommendation should be included for each conclusion reached by the Subcommittee. The Summary should close with a paragraph that re-states the main message of the report, looking to the future to indicate how the report can be used by the sponsors and others affected by the issue or problem being addressed.

Future BOSC Activities

Dr. Johnson asked for suggestions on future activities. Dr. Farland noted a number of items that have been discussed in the past, including a program review of the Sustainability Research Program. The research strategy and the MYP were reviewed earlier this year. A review of this program could begin in January. There probably will be requests for two additional program reviews in 2006. Ms. Kowalski stated that there is more time to plan for these program reviews so it may be helpful to form the Subcommittees early and provide them more time to conduct the reviews. Dr. Johnson said that the reviews really cannot get underway until the charge questions have been developed. Ms. Kowalski responded that the Subcommittees could be established even before the charge questions are developed. Dr. Johnson asked Dr. Giesy if he would be interested in chairing a Subcommittee to review the Sustainability Technology Research Program. Dr. Giesy agreed to serve as the Chair of the Subcommittee, and Dr. Henderson said that she would serve as the Vice-Chair of the Subcommittee.

Dr. Johnson asked the BOSC members if they were interested in reviewing the Management MYP, noting that the review would result in a letter report. He agreed to Chair a work group of Executive Committee members to review the Management MYP. Dr. Daston agreed to participate on the work group.

Dr. Farland said that ORD hopes to schedule the ORD Executive Council meeting in conjunction with the February BOSC meeting so that the Laboratory/Center Directors and NPDs can spend some time with the BOSC to discuss the budget. Dr. Farland will gather some information about the validity and reliability of rating tools used by other agencies for dissemination to the BOSC. He also will inform ORD about the BOSC's decision to review the Management MYP.

Dr. Johnson agreed to acknowledge the receipt of ORD's responses to the completed program reviews. Ms. Kowalski reported that additional responses from ORD are in preparation and she will be distributing them to the BOSC members before the next meeting.

Dr. Johnson thanked the BOSC members for their enthusiastic efforts on behalf of ORD and adjourned the meeting at 1:34 p.m.

Action Items

- ✧ Ms. Kowalski will send information to the BOSC members so that each member can complete his/her required ethics training before the January 2006 meeting.

- ✧ Dr. Farland agreed to work with the ORD Executive Council to schedule its February meeting in conjuction with the BOSC meeting, which is tentatively scheduled for February 13-14, 2006.

- ✧ Ms. Kowalski will provide the URL for the Human Studies Rule to the BOSC members.

- ✧ Dr. Stewart will ensure that the STAR/GRO Fellowships Subcommittee examines the NSF's fellowship program as part of the review because OMB considers it a model program. She also will ensure that the Subcommittee includes someone with human health expertise. In addition, Dr. Stewart will suggest that the Subcommittee look at the STAR Program review that was conducted jointly by the SAB and BOSC, recognizing that this review focuses only on the fellowship component of the STAR Program.

- ✧ The Subcommittee Chairs and Vice-Chairs will review the charge questions for their respective Subcommittees to ensure that they are inclusive of the key elements (i.e., allocation of budget/resources, communication and coordination, resource prioritization process, intramural/extramural balance, relevance, design, quality, and leadership).

- ✧ Dr. Johnson will work with Ms. Kowalski to develop standard operating procedures (SOP) for the Subcommittees conducting future program reviews. This document will include a definition of the roles of the various participants; standard presentations on ORD, PART, FACA, and R&D criteria; the lessons learned by the BOSC and ORD in conducting the first five reviews; and guidelines for the format of the report. The SOP will be a living document and will be updated as needed to facilitate future reviews. It also will contain a list of abbreviations and acronyms to the SOP.

- ✧ Dr. Johnson and Dr. Farland will review the original list of charge questions again to ensure that the additional items and cross-cutting themes beyond the PART review that have been identified by the BOSC are included.

- ✧ Dr. Johnson will prepare a memorandum to ORD explaining why the BOSC unanimously rejected the use of the proposed performance rating tool for program reviews.

- ✧ The BOSC will investigate alternative ways to provide more quantitative information to ORD as part of the program reviews.

- ✧ Dr. Giesy will provide his editorial comments on the Drinking Water Research Program Review Report to Dr. Sayler for incorporation into the next draft of the report.

- ✧ Dr. Henderson will provide her editorial comments on the Drinking Water Research Program Review Report to Dr. Sayler for incorporation into the next draft of the report.

- ✧ Drs. Sayler and Johnson will revise the Drinking Water Research Program Review Report based on the comments from the BOSC Executive Committee.

- ✧ Drs. Giesy and Clark will vet the Drinking Water Research Program Review Report, and Dr. Henderson will be responsible for doing a final review of the report to ensure that all of the Board's comments have been addressed.

- ✧ Dr. Giesy agreed to serve as the Chair of the Sustainability Technology Research Program and Dr. Henderson said that she would serve as the Vice-Chair of the Subcommittee.

- ✧ Dr. Johnson agreed to chair a work group of Executive Committee members to review the Management MYP, noting that the review would result in a letter report.

- ✧ Dr. Daston agreed to participate on the work group to review the Management MYP.

- ✧ Dr. Farland will gather some information about the validity and reliability of rating tools used by other agencies for dissemination to the BOSC. He also will inform ORD about the BOSC's decision to review the Management MYP.

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B·O·S·C
BOARD OF SCIENTIFIC COUNSELORS

EXECUTIVE COMMITTEE MEETING

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Agenda

Monday, September 12, 2005

8:00 a.m. – 8:30 a.m.	Registration	
8:30 a.m. – 9:00 a.m.	Welcome and Introductions - Review of June Meeting Minutes - Reports transmitted to ORD - Overview of Agenda	Dr. James H. Johnson, Jr. Chair, Executive Committee
9:00 a.m. – 9:15 a.m.	BOSC DFO Remarks - Administrative Issues	Ms. Lori Kowalski, ORD
9:15 a.m. – 9:30 a.m.	AA/ORD Remarks	Mr. Timothy Oppelt, Acting Assistant Administrator for Office of Research and Development
9:30 a.m. – 11:00 a.m.	Subcommittee Reports Drinking Water Program Review - Chair Presentation - Discussion	Dr. Gary Sayler, Subcommittee Chair
11:00 a.m. – 11:15 a.m.	Break	
11:15 a.m. – 12:00 noon	Subcommittee Reports (Continued) - PM/Ozone Program Review - Global Change Program Review - Land Program Review - Water Quality Program Review - STAR Fellowships - Risk Assessment Workshop Update	 Dr. Rogene Henderson (Chair) Dr. Cliff Duke (Vice-Chair) Dr. Jim Clark (Chair) Dr. Herb Windom (Chair) Dr. Juarine Stewart (Chair) Dr. Rogene Henderson (Chair)
12:00 noon – 1:00 p.m.	Lunch	

1:00 p.m. – 5:15 p.m.	Site Visit to National Homeland Security Research Center (NHSRC) Facilities	NHSRC and Executive Committee
5:15 pm	Return to Hotel	
5:30 p.m.	Adjourn	

TUESDAY, SEPTEMBER 13, 2005

8:30 a.m. – 9:00 a.m.	BOSC Issues - ORD Update	Dr. William Farland, Acting Deputy for Science for Research and Development
9:00 a.m. – 10:15 a.m.	Lessons Learned on Program Reviews - BOSC and ORD Perspectives	Dr. James H. Johnson, Jr. Chair, Executive Committee/ Dr. William Farland Acting Deputy for Science for Research and Development
10:15 a.m. – 10:30 a.m.	Break	
10:30 a.m. – 11:00 a.m.	ORD Responses to Recent BOSC Reports	ORD Technical Leads
11:00 a.m. – 11:30 a.m.	Global Earth Observation System of Systems (GEOSS)	Mr. Ed Washburn, Office of Research and Development
11:30 a.m. – 11:45 a.m.	Public Comment	
11:45 a.m. – 12:15 p.m.	SAB Activities	Dr. George Lambert, SAB Liaison to the BOSC
12:15 p.m. – 1:15 p.m.	Lunch	
1:15 p.m. – 1:45p.m.	Future Discussion/Future Business - Meetings in 2006 - Nomination Subcommittee Update - Ad Hoc Communication Subcommittee	Dr. James H. Johnson, Jr. Chair, Executive Committee
1:45 p.m	Adjourn	