B·O·S·C
BOARD OF SCIENTIFIC COUNSELORS

37th EXECUTIVE COMMITTEE FACE-TO-FACE MEETING SUMMARY

Renaissance M Street Hotel
Washington, DC

January 24-25, 2008

THURSDAY, JANUARY 24, 2008

Welcome and Introductions

Dr. Gary Sayler, University of Tennessee, Chair of the BOSC Executive Committee

Dr. Gary Sayler, Chair of the Executive Committee of the Board of Scientific Counselors (BOSC) called the meeting to order at 8:34 a.m. He welcomed everyone to the 37th meeting of the BOSC Executive Committee. He noted that all of the members were present with the exception of Dr. John Giesy who was in China. The agenda for the meeting is quite full. Because there will be participants by telephone during the meeting, Dr. Sayler asked the members to be sure to use their microphones when speaking. He mentioned that there has been a change in the agenda. Dr. Kevin Teichman's presentation on BOSC Performance Material Requests that was scheduled for 4:45 p.m. today has been moved to 10:45 a.m. tomorrow, and Dr. George Lambert will provide his update of Science Advisory Board (SAB) activities at 4:45 p.m. today.

Review of September Meeting Minutes

Dr. Sayler stated that the draft summary for the September 17, 2007 meeting was in the notebook. He asked if there were any comments on the minutes. Dr. Carol Weiss asked for a revision to the wording in the second paragraph on page 13. The second sentence reads: "Although the Executive Committee developed a four point rating tool, no review has included more than two of the four ratings." Although this statement is correct, the point Dr. Weiss was trying to make is that no review has used the highest or the lowest ratings, only the middle two ratings. She asked that the sentence be changed to reflect this point.

Dr. Lambert asked that the word "larger" be replaced with the word "smaller" in line 35 on page 20. The National Advisory Council for Environmental Policy and Technology (NACEPT) is reviewing the smaller document, which is a summary of the larger Report on the Environment (ROE). He also noted that "Dr. Morgan Granger" on page 21, line 5 should be changed to Dr. Granger Morgan. Dr. Deborah Swackhamer pointed out the same correction needed for Dr. Morgan's name on page 27, line 25.

When no additional comments were offered, Dr. Sayler called for a motion to approve the September meeting minutes. Dr. Rogene Henderson moved to approve the minutes and Dr. Charles Haas seconded the motion. The minutes were approved unanimously by vote of the BOSC Executive Committee.

Overview of the Agenda

Dr. Sayler stated that the next item on the agenda is the remarks of the Designated Federal Officer (DFO) for the BOSC, followed by the remarks of the Assistant Administrator for the U.S. Environmental Protection Agency's (EPA) Office of Research and Development (ORD). The ORD responses to four of the BOSC reports then will be presented. Following the lunch break, there will be presentations on three draft reports—the Endocrine Disrupting Chemicals (EDCs) Mid-Cycle Review Draft Report, the Air Toxics Mid-Cycle Review Draft Report, and the National Center for Environmental Research (NCER) Standing Subcommittee Draft Letter Report. These reports are being presented to the Executive Committee for approval. These presentations will be followed by the public comment period. The Sustainability Research Program Review Draft Report will be presented following the break. Updates on the mid-cycle review, program review, and standing subcommittees will be presented, and the day's meeting will close with the update on SAB activities. Friday's agenda includes a discussion of the rating tool guidance, an update on BOSC workgroups, the ORD update, a presentation on the National Children's Study, and a presentation on BOSC Performance Material Requests. The meeting concludes with a discussion of future business. Dr. Sayler asked if there were any comments on the agenda. No comments were offered.

BOSC Designated Federal Officer Remarks

Ms. Lorelei Kowalski, DFO, EPA/ORD

Ms. Lorelei Kowalski, DFO for the BOSC Executive Committee, thanked Dr. Sayler for agreeing to serve as the new Executive Committee Chair and she welcomed the members to the meeting. She 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). As the DFO for the BOSC Executive Committee, she is responsible for ensuring that BOSC activities comply with FACA. Therefore, this meeting was open to the public, and time was designated for public comment. A contractor, Beverly Campbell from SCG, is present to take notes that capture the presentations and discussions. She will prepare the meeting minutes, which will be made available to the public on the BOSC Web Site after approval by the Executive Committee and certification by the BOSC Chair. The Chair must certify the minutes within 90 days following the meeting. Notice of this meeting was published in the *Federal Register*. Ms. Kowalski established an electronic public docket for the meeting on the Federal Docket Management System (FDMS), which can be accessed at http://www.regulations.gov. The number to search for this docket is EPA-HQ-ORD-2007-1200. The *Federal Register* notice and the agenda were available to the public on the docket. Ms. Kowalski mentioned that she received requests for public comment prior to the meeting, and there is time set aside on the agenda at 2:30 p.m. for those comments as well as any others. She asked that public comments be limited to 3 minutes.

As DFO, Ms. Kowalski has worked with EPA's ethics officials to ensure that all appropriate ethics requirements were satisfied for the Executive Committee members. The members have completed the required ethics training and updated their confidential disclosure forms, which must be done annually. It is her responsibility to ensure that there are no conflicts of interest. She asked the Executive Committee members to keep this in mind during the meeting and to notify her of any potential conflicts. Because some members have grants or cooperative agreements with EPA, potential conflicts of interest could arise.

Each BOSC member should have received a notebook of materials by mail as well as additional materials by e-mail prior to the meeting. Three of the ORD responses to BOSC reports were in the notebook and a fourth was sent by e-mail. For those members who did not receive that e-mail, copies of the response are available at the registration table. Ms. Kowalski mentioned that, in the past, she was asked to provide copies of the original BOSC reports to accompany the ORD responses. To avoid increasing the size of the notebook, the BOSC reports were included on a CD-ROM in the front of the notebook. She confirmed

that all members present had received their notebooks. Ms. Kowalski pointed out that the notebook also included worksheets and travel vouchers, which were to be completed and submitted to her, along with members' hotel bills, prior to leaving the meeting. She reminded the members that they must submit receipts for all expenses in excess of $75. Receipts for rental cars are required regardless of the cost.

Ms. Kowalski distributed three handouts that listed the activities of the BOSC and its subcommittees. The first described the Fiscal Year (FY) 2008-2009 projects of the BOSC and their status. The second identified the subcommittee, workgroup, and vettor activities for each Executive Committee member. The third handout was a timeline depicting the BOSC workload from April 2007 to May 2009. This timeline identified program review, mid-cycle review, and standing subcommittee meetings, and the months in which Executive Committee meetings were or would be held were highlighted in blue. Ms. Kowalski reminded the members and other attendees to sign in at the registration desk if they had not done so already. She noted that the telephone line to allow individuals to call in to hear the discussions would be open during both days of the meeting.

Because there has been some confusion about subcommittee working time versus subcommittee work group time, Ms. Kowalski explained that subcommittee working time on a meeting agenda is covered by FACA, which means that the session must remain open to the public and the discussions should be captured in the meeting notes. Conversely, subcommittee work group time would not appear on the meeting agenda and would be scheduled by the subcommittee chair to take place either before or after the meeting for the day. Subcommittee work group time is not be subject to FACA requirements since work groups are, by definition, comprised of less than one-half of the subcommittee members. She emphasized that all topics listed on a meeting agenda are subject to FACA and open to the public.

Ms. Kowalski commented that EPA implemented a new travel system in January 2008. She tried to get all of the travel arrangements for this meeting completed in December before this change occurred, but there were a couple of members who had to use the new system. Unlike the old system where the ORD contacted a travel agency to book travel, the new system is automated. When booking travel, the government contract carriers show up first, because government employees (including Special Government Employees) are required to use these carriers unless there is a compelling reason to do otherwise. Although Ms. Kowalski will try to accommodate the members as much as possible, with specific travel requests, there may be limited flexibility with the new system. She stated that the Agency will attempt to ensure that the travel arrangements match the departure and return times as closely as possible. She noted that Drs. Ryan and Henderson, who used the new system, received automatically generated e-mails from the system that did not include their travel information, and is not sure if they can be turned off. She is hoping that vouchers can be signed electronically, which should ultimately make travel arrangements more efficient. Ms. Kowalski added that the travel function has been centralized and the contact for BOSC travel is now Troy Rutkofske. Members will likely receive a call from Mr. Rutkofske if there is a problem with travel arrangements. Dr. Henderson mentioned that the new system did not have her frequent flyer information and Dr. Ryan said the name on his ticket was incorrect because it did not include his first initial. In addition to the new travel system, the Agency now requires that all hotels used for EPA meetings be on an approved list.

Ms. Kowalski asked members to access the My Pay system if they had not done so for some time because it takes about 2 weeks to get a new password if your password has expired. Members will need to access the system to download their W-2 forms. Dr. Weiss asked for the URL for the My Pay system and Ms. Kowalski replied that it is http://www.mypay.gov. Ms. Kowalski noted that there have been payment issues for the NCER Standing Subcommittee members and she is working to resolve the problem. She usually e-mails members notifying them to expect payment. She asked that members contact her if they do not receive payment after this notification.

At the conclusion of the DFO's remarks, Dr. Sayler welcomed Dr. George Gray, the Assistant Administrator for ORD.

Assistant Administrator for Research and Development Remarks

Dr. George Gray, Assistant Administrator for Research and Development, EPA/ORD

Dr. George Gray welcomed Dr. Sayler as the new Chair and thanked the BOSC members for their efforts to help ORD improve its programs. He apologized for the travel glitches and assured the members that Ms. Kowalski works diligently to prevent such problems. He commended her for the excellent job she has done supporting the BOSC.

Dr. Gray noted that a number of reports are being discussed and approved at this meeting. At the September Executive Committee meeting, he highlighted some of the ideas and recommendations from the reports that were being approved at that time. He did not want to take the time to do that at this meeting, but he did focus on a few items in the ORD responses. The Safe Pesticides/Safe Products (SP2) report recommended that ORD focus more on exposure and exposure assessment. The report also recommended that EPA validate the models and use modern techniques. Dr. Gray said that the entire Agency is thinking about this topic. Two years ago, EPA asked the National Academy of Sciences (NAS) to examine the way that the Agency is using models in decision-making. The NAS report was received about 4 months ago. He noted that the BOSC's comments reflect many of the ides in the NAS report. EPA is giving considerable thought to validating and applying models as well as the life cycle of models (they need to be updated periodically). Within EPA's Office of the Science Advisor (OSA) is a group called the Council for Regulatory Environmental Modeling (CREM). This council of senior managers from across the Agency was created to promote consistency and consensus among environmental model developers and users. Dr. Gray commented that most of the modeling in the Agency is done by ORD and the Office of Air and Radiation (OAR). EPA is working to create the structure to support models and the people who use them. ORD is acting on the BOSC's advice.

Dr. Gray said he had read the reports that the BOSC will be discussing at this meeting. One item that resonated with him was the value of information techniques mentioned in the NCER Standing Subcommittee report. EPA often processes data in models that make predictions on which the Agency bases decisions. There is uncertainty in that. If the Agency can quantitatively characterize the uncertainty, then EPA can make better decisions to protect public health and the environment. The NCER Standing Subcommittee is advising ORD to think about applying value of information techniques to extramural research to help the Agency fund those grants that will have the greatest impact on improving the Agency's future decisions.

Dr. Gray indicated that he would not be able to stay at the meeting longer because the ORD Executive Council was meeting today as well. That meeting is focused on strategic planning for 2010; the NPDs and other mangers are thinking about where ORD will go in the next few years. Dr. Gray closed his comments by stating that the BOSC's reports are very important to ORD and many of the recommendations already are being implemented. He asked if there were any comments or questions.

Dr. Henderson asked how the Supreme Court ruling that CO_2 should be regulated as a pollutant affected ORD. Dr. Gray replied that CO_2 is a criteria air pollutant but does not require a National Ambient Air Quality Standard (NAAQS). He mentioned an executive order that requires EPA to work with the Department of Transportation (DOT) on fuel economy standards. EPA was working on that when Congress passed the Energy Independence and Security Act, which preempted EPA's and DOT's efforts by setting standards. Dr. Gray noted that the Supreme Court ruling was focused on mobile sources (vehicle emissions). Most of the regulations associated with CO_2 will be handled by OAR; however, ORD will have to deal with a variety of CO_2 and climate change issues. ORD is investing effort into geological sequestration of CO_2 to determine if it will affect groundwater when it is injected in the

ground. ORD also is the EPA lead for the U.S. Climate Change Science Program (CCSP). ORD is researching the impacts of climate change on air quality; ORD is trying to help the program offices anticipate and be ready to deal with the problems that may arise from climate change. EPA also helped model the intensity and frequency of rainfalls to help the Agency and others understand what changes will need to be made when making decisions. In addition, ORD brought four global circulation models down to regional levels to predict changes that will occur in ozone levels as the climate changes. Dr. Gray reported that the models gave very different predictions—one would predict that ozone would increase and another that it would decrease. He stressed that the greatest uncertainty is in the models.

Another area of responsibility assigned to EPA by executive order is to examine the environmental and public health effects during the life cycle of the use of biofuels. Dr. Gray mentioned that no additional resources have been given the Agency to address these new responsibilities.

Dr. Demerjian commented that the significant increase in production of biofuels will have numerous environmental impacts on air, water, and land. He sees this as a more immediate problem than the implications of climate change. Dr. Gray responded that biofuels currently is not in any of ORD's Multi-Year Plans (MYPs). ORD understands that this is a significant area and is developing a biofuels research strategy, which should be completed this spring. Sixty-two people within EPA are working on that strategy, identifying issues (e.g., permitting) and possible effects that require research. Dr. Gray said he serves on the Biomass R&D Board chaired by the U.S. Department of Agriculture (USDA) and the Department of Energy (DOE). EPA has had to fight to keep environmental and sustainability issues on the table, but now the board members recognize that the shift from fossil to biofuels must be done in a way that prevents environmental problems and is sustainable. Biofuels will become a major focus of the sustainability research program. EPA is looking at crops and crop practices and is responsible for testing and certifying new fuels. Cars using these fuels are driven 100,000 miles to determine durability and tail pipe emissions. EPA is modeling those emissions to determine what happens to atmospheric chemistry. ORD is working with Regions 7 and 5 to take the lead on those efforts. Dr. Demerjian asked if there were regulations in place for biodiesel. Dr. Gray answered that he did not know. For new fuels, the Agency has to certify them as the same or not worse than existing alternatives.

Dr. Daston endorsed the value of information approach. He asked Dr. Gray to expand on his earlier comment about ORD's interest in value of information techniques. Dr. Daston also asked about the BOSC's role in strategic planning. He noted that the BOSC has been functioning more as a peer review group and less as an advisor to help ORD strategize about its research. The BOSC program reviews include the research strategies but it is from a "down in the weeds" perspective rather than a higher level strategy perspective. Will ORD consider using the BOSC to help with strategic planning? Dr. Gray replied that the NPDs currently are thinking through their MYPs and where they want to go for the next 5 years. ORD involves the BOSC in its plans during the mid-cycle reviews, but not at the level where all the programs come together and ORD makes choices of increasing or decreasing a program based on budget. The BOSC certainly has influenced ORD's strategies and impacted what is emphasized and de-emphasized. For example, the BOSC suggested that the Drinking Water program de-emphasize research on disinfection byproducts (DBPs) and the program has implemented that recommendation. The BOSC does have an impact on ORD's strategies, but he agreed that the Board could assist ORD in thinking about the best way to balance its portfolio.

With regard to Dr. Daston's first question, Dr. Gray stated that he did not have much to add on value of information except that ORD is working to quantitatively assess uncertainty. Dr. Duke suggested that there be a presentation on the value of information at a future BOSC meeting. Dr. Gray said he would like to see the BOSC take up this issue and provide ORD advice on applying these tools. Dr. Philbert indicated that Drs. Seth Tuler and Adam Finkel were the NCER Standing Subcommittee members who proposed the value of information recommendation.

Dr. Lambert mentioned the National Institutes of Health (NIH)'s Rapid Access to Intervention Development (RAID) program. He suggested that this might be a great program for ORD to examine as a model for accelerating the application of research. Dr. Gray commented that ORD also can learn a great deal from the pharmaceutical industry. He thanked the BOSC for its advice and assured the Board members that ORD takes it very seriously.

ORD Response to BOSC Safe Pesticides/Safe Products (SP2) Report

Dr. Elaine Francis, NPD for the SP2 Program, EPA/ORD

Dr. Elaine Francis, the NPD for the SP2 Research Program, stated that the face-to-face meeting review meeting was held February 7-9, 2007 in Research Triangle Park (RTP), North Carolina. Drs. Anna Harding and Barry Ryan served as the Subcommittee Chair and Vice-Chair, respectively. The other Subcommittee members were Craig Adams, Jerald Ault, Elly Best, Carlos Blanco, Joel Coates, Richard Di Giulio, and Judy Graham. The review assessed the program in terms of relevance, structure, performance, quality, scientific leadership, and coordination and communication. The Subcommittee used the rating tool to provide a summary assessment by long-term goal (LTG). This assessment was based on the appropriateness, quality, and use of ORD science. This was the first time the rating tool was implemented for a program review. The Subcommittee's report was transmitted to ORD on July 23, 2007.

Overall, the Subcommittee thought the SP2 Research Program was very successful. The quality of the research is high and this finding was supported by strong evidence of relatively high publication and citation rates in high-visibility journals of significant scientific reputation and by how quickly the papers are cited, recognized, and ultimately used by the Agency. The program's goals are well articulated and the framework is well thought out, logical, and laid out in a reasonable and integrated manner. The program is relevant to the Agency's mission and it fills a unique niche. For all three LTGs, the program appears to be making solid progress on achievement of long-term program goals and on meeting intermediate range milestones. The scientific leadership of the program is strong. The researchers are highly trained and energized and many are leaders in their fields. The program's coordination and communication are very good; they occur vertically and horizontally within and outside EPA. The program has extensive interaction with EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS), organizes meetings with the Science To Achieve Results (STAR) grantees, and communicates at professional meetings.

For the summary assessment, the BOSC Subcommittee rated LTG 1 as exceeds expectations, LTG 2 as meets expectations, and LTG 3 as meets expectations. The report included 22 comments/recommendations which were broken down as follows: relevance—1, structure—16, performance—0, quality—2, scientific leadership—1, coordination and communication—2, and outcomes—0.

ORD's response to the report was transmitted to the BOSC on January 12, 2008. The narrative summarizes the specific comments and recommendations followed by ORD's responses. Also included is the action and timeline for each response. In addition, the ORD response includes a table containing the specific recommendations and associated action items and timeline for response.

Dr. Francis then presented the ORD responses to the recommendations, which had been grouped into nine categories.

Clarification of Annual Performance Goals (APGs) and Annual Performance Measures (APMs)

BOSC Recommendation 2: Retain flexibility of the research structure to emerging science: APGs/APMs need to be clear.

BOSC Recommendation 3: Clarify the relationship between APGs and APMs; ensure consistency between text and research.

BOSC Recommendation 7: Emphasize the need for transparent validation/verification of research products.

BOSC Recommendation 14: Revise APGs to ensure there are sufficient resources to reach goals.

ORD Response: Improving APGs and APMs is an ongoing process. The next update of the MYP will: (1) clarify the generic relationship between APGs and APMs, (2) reflect new metrics for APGs/APMs agreed upon with the Office of Management and Budget (OMB), (3) reflect improvements in clarity and consistency in APGs/APMs, (4) reword the specifically identified APG to clarify the distinction that ORD develops methods/models while the validation is conducted by an independent group of experts, and (5) continue to have APGs/APMs that are achievable given the available resources in mind.

Exposure Research

BOSC Recommendation 4: Greater emphasis is needed on exposure-related research.

BOSC Recommendation 6: Perform an integrated evaluation of human health to provide advice on program balance, especially with respect to exposure.

ORD Response: ORD is shifting full-time equivalents (FTEs) for exposure research to the SP2 Program. Dr. Francis commented that about 90 percent of the program's research currently is effects research, but this is consistent with OPPTS' indication that it needed ORD to conduct effects research. With the additional FTEs, the program will be about 85 percent effects research and 15 percent exposure research (both ecological and health). An Implementation Plan for exposure research that is integrated with the effects research is under development and will be completed in 2008. The next update of the MYP will incorporate the strengthened exposure research and include an approach that provides stronger evidence of linkages to exposure research (that is relevant to OPPTS' needs) conducted through other ORD programs.

Dr. Demerjian asked if there was a relationship between this exposure research and the National Exposure Research Laboratory (NERL). Dr. Francis responded that the additional FTEs are from NERL. She clarified that these FTEs are not additional; they are just being reassigned to this program.

Clarification of Criteria

BOSC Recommendation 8: Clarify criteria used to select new compounds for study and expand the current list.

BOSC Recommendation 16: Describe criteria for prioritization of future work should additional resources become available.

ORD Response: The next update of the MYP will: (1) clarify how OPPTS identifies and prioritizes those research elements needed in the shorter term, based on impending regulatory decisions or data gaps; (2) provide greater detail on the prioritization process used to accelerate research previously identified as

high priority, should resources become available; and (3) provide stronger descriptions of potential new research directions based on discussions with OPPTS senior managers.

Dr. Francis commented that the appendix of the MYP described the research that would be conducted if the program's budget was increased. In 2006, this actually happened and the program used the funding to jump start a few projects earlier than planned and to expand some other efforts.

Improvements to LTG 2—Ecological Risk Assessment Approaches

BOSC Recommendation 9: Begin movement towards an ecosystems approach that fully assesses population and community risks.

BOSC Recommendation 10: Further develop mathematical foundations that underpin current efforts.

BOSC Recommendation 11: Pursue collaborations and extend development to advance high performance computing methods for probabilistic risk assessment.

ORD Response: The shift of exposure FTEs into the program will result in moving toward an integrated (exposure-effects), spatially explicit risk assessment program for targeted populations and communities that will expand their utility. These recommendations will be addressed through the development of the exposure Implementation Plan and will be incorporated into the next iteration of the MYP. Efforts are ongoing to develop Web-based applications of ORD products and to seek research partners to help provide tools that the program's clients can access readily.

Improvements to LTG 3—Biotechnology

BOSC Recommendation 1: Include an approach to address issues of mitigation potential on gene transfer, effects on non-target organisms, and targeted species resistance.

BOSC Recommendation 12: Broaden the scope of the program to include additional topics identified by the reviewers.

ORD Response: Field-scale protocols for non-target species effects are being developed and applied. A workshop on Pollen-Mediated Gene Flow was held in 2007. A report on testing and evaluation of resistance management models that track development of resistance in genetically modified crops will be released in 2009. Limitations in resources prevent the program from expanding into the additional areas identified by the BOSC reviewers; however, the program is continually seeking partners to broaden the scope of the program. For example, in 2007, a joint Request for Applications (RFA) on food allergenicity was issued with the National Institute of Allergy and Infectious Diseases (NIAID).

Cross-Disciplinary Approaches, Collaborations, and Communications

BOSC Recommendation 13: Maintain and build upon existing cross-disciplinary and cross-organizational collaborations.

BOSC Recommendation 17: Grow and collaborate in the areas of statistical analyses, bioinformatics, theoretical mathematical model building, and probabilistic risk assessments.

BOSC Recommendation 21: Emphasize communication with other federal laboratories.

BOSC Recommendations 22: Develop a more focused communications program to regions and other program offices.

ORD Response: The update of the MYP will provide greater detail on the extensive ongoing collaborations with scientists in other federal agencies and research organizations. Significant collaborations are occurring in the area of bioinformatics with the STAR-funded Environmental Bioinformatics Research Centers. Four senior bioinformaticians and systems biologists have been hired recently by ORD. The program will continue to seek new collaborations and expand efforts to improve coordination and communications. An ORD-OPPTS (and other program/regional offices) senior managers' meeting will be held in 2008.

Continue Current Practices

BOSC Recommendation 19: The peer review process should be continued.

BOSC Recommendation 20: Continue to reward scientific excellence and minimize administrative burdens.

ORD Response: Existing guidance and policies are continually followed to ensure programs and products are appropriately peer reviewed. All available mechanisms are used to reward and retain our scientists and to recruit new ones.

Nanotechnology

BOSC Recommendation 15: More rapidly develop a research program in nanotechnology and collaborate with other international organizations.

ORD Response: A Nanomaterials Research Strategy has been developed. EPA is collaborating with other federal agencies to develop complementary research portfolios and with academic institutions to fill knowledge gaps. The program is collaborating internationally as part of the Organisation for Economic Co-Operation and Development's (OECD) efforts.

Additional Information for Reviews

BOSC Recommendation 18: Map service awards (as well as peer reviewed papers) to individual program elements to better designate high quality products.

ORD Response: The program will continue to include service awards in biosketches for all BOSC reviews and in integrated tabular format, where possible. Guidance regarding the value-added of collection and presentation of more detailed information for BOSC reviews is a topic of discussion at this meeting. ORD will continue to provide the BOSC the information that it needs to conduct the reviews.

In closing, Dr. Francis stated that EPA is grateful to the BOSC Subcommittee for the program review and the thoughtful comments and recommendations in the report. The comments and recommendations will be addressed through updating of the MYP, interactions with the program's clients, collaborations with partners, and the way the program conducts routine business. The SP2 Research Program had a Program Assessment Rating Tool (PART) review in March-August 2007 and will undergo a BOSC mid-cycle review in 2009 and a full BOSC program review in 2011. ORD looks forward to continued interactions with the BOSC.

Dr. Sayler thanked Dr. Francis for her presentation and asked if Dr. Ryan, who served on this Subcommittee, had any comments. Dr. Ryan stated that the Subcommittee was quite diverse with a variety of disciplines represented. He added that ORD has done a good job of addressing the Subcommittee's comments and recommendations.

Dr. Falk asked if the PART reviews cover similar issues as the BOSC reviews. Dr. Francis responded that PART is largely performance based. The PART review has four sections and focuses on relevance, efficiency, collaboration, and outcomes. The program prepares information to answer the questions and one of the items provided is the BOSC review report. Dr. Sayler mentioned that the BOSC has had several presentations on PART and the connection between the two reviews.

Dr. Lambert commented that it appears to be a great program that has little funding. Is there any interaction with the National Children's Study, which has considerable funding? Dr. Francis responded that program staff has been involved in the committees associated with the National Children's Study and is aware of its progress, but most of EPA's child health research is conducted under the Human Health Research Program. She added that the SP2 program is aware that pesticides are part of the study.

ORD Responses to BOSC Mid-Cycle Reports

ORD National Program Directors

Ecological Research Program Mid-Cycle Review Report

Dr. Iris Goodman, EPA/ORD

On behalf of Dr. Rick Linthurst, NPD for Ecological Research, Dr. Iris Goodman presented ORD's response to the mid-cycle review report on the Ecological Research Program. She explained that her presentation included some background information, an overview of the response to the recommendations in the BOSC report, a brief description of the OMB PART review of the program, and the next steps.

The mid-cycle review for the Ecological Research Program was held on May 23, 2007. The final BOSC report was delivered to EPA on August 23, 2007, and the ORD response to the report was submitted to the BOSC in January 2008.

The ORD response included a transmittal memorandum to the BOSC from ORD's Deputy Assistant Administrator. The narrative of the response identified the specific comments and recommendations in the BOSC report. It identified each of the 16 recommendations in the order as they appeared in the BOSC report and included a response, action items, and timeline for each recommendation. The ORD response also included a summary table that identified the action items and timeline for each recommendation.

The BOSC comments and recommendations were grouped into four major categories: general follow-up to the 2005 and 2007 BOSC reviews of the program (3 recommendations), follow-up to related performance measures (3 recommendations), outreach and education (4 recommendations), and enhancing collaborations and leadership (6 recommendations).

Dr. Goodman then presented the responses to the recommendations by category.

General Follow-up to 2005 and 2007 BOSC Reviews

BOSC Recommendation 1: ORD is encouraged to sustain its commitment to action items and follow-ups…

BOSC Recommendation 2: Developing a revised MYP with specific approaches … to incorporate ecosystem services as key assessment and management approaches should remain a high priority…

BOSC Recommendation 3: The Program is encouraged to continue to develop plans… for… 2005 recommendations not addressed in the mid-cycle…

ORD Response: The program appreciated the positive feedback from the BOSC and is committed to sustaining its commitments to action items to the greatest extent possible, subject to budget and staffing constraints. The cross-ORD Ecological Research Program science team met in February, August, and November 2007. Teams now are working to complete the draft MYP by February 2008 and the draft implementation plans by July 2008. The program's research plans will address specific issues recommended by the BOSC (e.g., documenting outreach to non-traditional stakeholders, quantifying how program funds and research are leveraged), and follow-through with technology transfer of program results.

Follow-up Related to Performance Measures

BOSC Recommendation 4: Additional performance metrics should be considered…

BOSC Recommendation 5: Although the (existing) metrics…are good, there is much room for improvement in application of these metrics…

BOSC Recommendation 6: The BOSC recommends…greater emphasis on tracking and documenting application of program research results by decision-makers…

ORD Response: The program agrees that additional performance metrics are needed and that a key barometer of success is to document program results leading to better decision-making and improved environmental outcomes. The Ecological Research Program has developed additional proposed metrics, which will be included in the research implementation plan. More work remains to be done in this area. The application of metrics has been a difficult issue for ORD, including the Ecological Research Program, especially with respect to actions related to changes in metrics. One caution noted by the program, is that there often is a considerable time delay between a change instituted by decision-makers and the empirical demonstration of improved environmental outcomes. Dr. Goodman stated that ORD would appreciate any specific suggestions the BOSC may have for additional metrics.

Outreach and Education

BOSC Recommendation 12: ORD is encouraged to engage stakeholders and collaborators with communication strategies…

BOSC Recommendation 13: …be prepared to listen and integrate stakeholder input into planning process…

BOSC Recommendation 14: …workshops, short courses, and field demonstrations should become core aspects of the program's communication strategy…

BOSC Recommendation 16: As possible, staff with communication and education experience should be hired…In addition, research teams should be encouraged to engage in outreach…

ORD Response: The program has created a new team devoted to outreach and education and that team currently is developing a communication strategy to engage diverse clients, stakeholders, and collaborators. The program is reaching across EPA to engage communication and education talent. Each Ecological Research Program place-based study continues to identify stakeholders within the study area. The stakeholders are invited to express their needs and interests in ecosystem services (e.g., the Future Midwestern Landscapes Study has held two such meetings in November 2007 and January 2008). For 2008, the priority for the Outreach Team is to hold workshops to identify key needs, concerns, and issues. The team also is developing educational materials to help clients understand ecosystem services, the value of incorporating services into decision-making, and the benefits of doing so. The materials also help them

become involved in program decision support tools. A cadre of outside experts is being assembled to advise the program. In addition to being highly regarded scientists, many of these experts are very experienced educators. They are drawn from many disciplines, including social scientists, economists, spatial analysts, and modelers. The program also has launched an accelerated EPA- and ORD-wide seminar series on ecosystem services. From March to December 2007, the program held 20 90-minute seminars, given by in-house as well as external experts. This seminar series is ongoing.

Enhancing Collaborations

BOSC Recommendation 10: …engage non-traditional EPA partners and stakeholders in discussions…on economic and human uses…

BOSC Recommendation 7: …recommend ORD closely assess…contributions of EPA and extramural scientists and find ways to continue to support and enhance collaborative research…

BOSC Recommendation 11: …assess skills and areas of expertise among…current staff and subsequent efforts to fill identified gaps…such as ecosystem valuation and economics.

ORD Response: The program is engaging non-traditional partners via formal collaborative agreements with a number of organizations, including:

- National Geographic—to develop a national atlas of ecosystem services.
- The Natural Capital Project—comprised of The Nature Conservancy, World Wildlife Fund, and Stanford University, involves collaborations to develop and refine methods to map and value ecosystem services. This project is starting in the Willamette River Basin.
- World Resources Institute—collaborations to mainstream ecosystem services into business decision-making.
- Gund Institute for Ecological Economics, University of Vermont—to test and refine the Multi-scale Integration of Models for Ecosystem Service (MIMES) at the program place-based study areas.
- Harvard University—collaboration with environmental law students to research (1) how existing laws address ecosystem services, and (2) how new laws could be crafted to address legal, social, geographic, and ecological issues associated with ecosystem services.

ORD agrees that extramural programs are vital, but the program still is constrained by very limited extramural funds. The program is assembling 24 outside experts and post-docs to work with in-house staff on a limited hourly basis. This will maximize return on scarce funds, especially for accessing social scientists to complement in-house research skills. The program is prepared to hear diverse views, but so far has heard many common themes and issues.

Enhancing Leadership

BOSC Recommendation 8: …continue discussions on ecological indicators among Agency researchers and decision-makers, as well as other stakeholder groups.

BOSC Recommendation 9: …commit time and resources to strategically planning research to support decision-making, including gaining input from a variety of stakeholders…that have significant history in managing lands for valued ecosystem services.

BOSC Recommendation 15: …expand program clients beyond the present core of other EPA offices…especially other natural resource agencies and organizations…that can assist in translating program research into action.

ORD Response: The program has taken a lead role in new uses for ecological indicators. In July 2007, the program sponsored the "Common Ground" meeting on spatial indicators and metrics for ecosystem services. Also in July 2007, the program had its initial meeting with National Geographic on the atlas of ecosystem services. In October 2007, the program was invited to participate in the NAS meeting on Ecosystem Services and Biofuels. There were three Ecological Research Program presentations at that meeting. Also in October 2007, the program co-sponsored the Workshop on Valuing Ecosystem Services for Decision Making with the U.S. Geological Survey (USGS) and USDA's Forest Service. There were three program presentations at that workshop. Dr. Goodman noted that spatially explicit ecological indicators and ecosystem service metrics now are a high priority for many agencies and non-governmental organizations (NGOs) and the Ecological Research Program anticipates important new uses (e.g., for periodic assessments of trends in ecosystem services).

The program is leading many areas of research in ecosystem services. A program staff member co-chairs the Ecosystem Services Workgroup, which reports to the Office of Science and Technology Policy (OSTP) via the Committee on Environment and Natural Resources (CENR) Subcommittee on Ecological Systems. The workgroup was launched in October 2007, and it meets monthly. The initial meetings explored federal needs for decision-making related to ecosystem services. The member agencies include EPA, USGS, USDA, Fish and Wildlife Service, National Oceanic and Atmospheric Administration (NOAA), Department of Defense (DOD), DOE, National Science Foundation, and the Smithsonian. The workgroup's roles are to: (1) serve as a focal point for federal agency and private-sector coordination on ecosystem services, including how to translate research into action; and (2) prepare a white paper for the incoming administration on the federal role in science and technology for ecosystem services.

Dr. Goodman provided an overview of how the program has fared in its last three PART reviews. In 2003, the program had a budget of $108 million and received a PART review rating of "Results Not Demonstrated." In 2005, the program had a budget of $87 million, and it received a PART review rating of "Ineffective." In 2007, the program's budget had dropped to $79 million, and it received a PART review rating of "Moderately Effective." The Ecological Research Program now is the second-highest rated program in EPA ORD, after the Human Health Risk Assessment Program. Dr. Goodman then provided OMB's definition of "Moderately Effective." In general, a program rated Moderately Effective has set ambitious goals and is well-managed. Moderately Effective programs likely need to improve their efficiency to address other problems in the programs' design or management in order to achieve better results.

In closing her presentation, Dr. Goodman stated that the SAB review of the proposed Ecological Research Program budget (follow-up to the SAB's review of ORD's strategic directions in October 2007) will take place February 28-29, 2008. An SAB Subcommittee will review the program's MYP April 9-11, 2008, and a full BOSC program review of the Ecological Research Program is tentatively scheduled for May 2009.

Discussion

Dr. Henderson congratulated the program on its improved PART review rating. In her role as the Chair of the Clean Air Science Advisory Committee (CASAC), Dr. Henderson has heard repeatedly that EPA uses health defaults because there is not enough information on the effects of toxins on the environment. CASAC member Ellis Cowling is always saying that EPA needs to look at the critical load approach that is used in Europe. Is this something the Ecological Research Program should do? Dr. Goodman

responded that program staff members have attended European conferences and have been invited to participate in European groups, but there are no formal collaborations as yet.

Dr. Swackhamer asked if the program has received good feedback from stakeholders regarding ecosystem services. Dr. Goodman replied that there are a variety of stakeholders. The conservation folks are extremely enthusiastic and the states/regions provide good feedback on how the tools can be used to address their issues. The regions think it is a good way to look at the environment as a whole. Because it is not immediately obvious what ecosystem services can do for many of the program's stakeholders, the program is creating visual ways of representing how restoration can change ecosystem services so clients can see the results.

Dr. Swackhamer commented that the ecosystem services focus provides a good focal point for the wonderful collaborations with National Geographic. Will this new focus allow EPA to develop better relationships with federal partners, such as the U.S. Fish and Wildlife Service and others involved in protecting endangered species? Dr. Goodman answered that there is a real hunger in other agencies; they actively participate in meetings and are interested in collaborating with EPA to help set directions.

Dr. Weiss praised the program's outreach and education efforts, particularly with local and regional groups. She thought this might be a good opportunity to find out what influences decision-making and learn more about the impacts of policy changes, which will help with the development of metrics. Dr. Goodman replied that one of the program's main areas of focus is creating metrics and maps of services. The program is building on what was learned in the Environmental Monitoring and Assessment Program (EMAP). It is looking retrospectively at the effects decisions had on the environment and developing models to predict likely consequences of future decisions. The program is working with the top people in the field of natural resource accounting.

Dr. Duke asked how the CENR workgroup is serving as a focal point for private-sector coordination on ecosystem services given that it is a federal group. Dr. Goodman responded that it is part of the charter; she thought the workgroup was examining how the federal community can best work with the private sector to collaborate and avoid duplication of effort. She added that there is another workgroup that represents the private sector. The federal work group sets the federal role so that it can be described to the private sector. Dr. Goodman could not recall the name of the private sector workgroup.

Dr. Lambert mentioned that the SAB review of the ROE was led by Dr. Swackhamer. That report made it clear that different agencies use different metrics to monitor that are not compatible. Is the program working with other agencies to coordinate metrics so that the data can be combined? Dr. Goodman answered that the program is working with other federal agencies to lay the groundwork for a common set of metrics. The program has developed a catalog of what to use to measure ecoservices.

Drinking Water Research Program Mid-Cycle Review Report

Dr. Audrey Levine, NPD for Drinking Water Research, EPA/ORD

Dr. Audrey Levine, the NPD for Drinking Water Research, stated that the Drinking Water Research Program underwent a full BOSC program review in 2005 and the mid-cycle review took place on May 23, 2007, in Newport, Rhode Island. The BOSC mid-cycle review report was submitted to ORD in August 2007 and ORD transmitted its response to the BOSC in January 2008. There were 16 recommendations in the report, which Dr. Levine grouped into five categories: strategic planning, research prioritization, resource allocation, program evaluation, and leadership. Dr. Levine then presented the ORD responses to the BOSC's recommendations.

Strategic Planning

BOSC Recommendation 3: Strategic planning should be pursued at several levels: research prioritization, resource procurement and allocation, maintaining and promoting a leadership agenda, and integration of emerging environmental concerns.

BOSC Recommendation 11: Specific strategies need to be developed to address important research areas such as climate change, nanotechnology, and water reuse.

ORD Response: Efforts are underway across ORD to develop more effective approaches for strategic planning. The NPDs have an annual opportunity to discuss strategic directions with the SAB and ORD's Executive Council, which allows ORD to evaluate research progress and reassess research needs. The restructuring of the Drinking Water MYP has enabled the development of a more integrated research program to address waterborne contaminants and fostered the inclusion of some new and emerging issues including water infrastructure, geologic sequestration of carbon, and sustainable water systems. Cross-ORD discussions also are in progress to assess the efficacy to consolidating the Drinking Water and the Water Quality MYPs into a single MYP. Other cross-program research efforts include developing a research program to address drinking water issues associated with climate change in collaboration with the Global Change Research Program and identifying water issues in conjunction with the National Biofuels Research Strategy. There also are cross-program efforts with ORD's research programs in human health, EDCs, and SP2 (chemical contaminants in drinking water).

Research Prioritization

BOSC Recommendation 1: Develop a resource analysis matrix to facilitate prioritization and funding for the thematic research agenda.

BOSC Recommendation 2: Subcommittee emphasized timely completion of the Drinking Water MYP.

BOSC Recommendation 6: Develop a conceptual model to better link LTGs, APGs, and APMs. Incorporate a well-defined strategy for allocation of resources.

ORD Response: Alternative approaches for developing strategic directions are being explored, including: setting up a drinking water research steering committee, developing a process for weighting research priorities, and exploring opportunities for leveraging resources across other ORD programs and other research efforts. The Drinking Water MYP (2008-2014) was completely revised to correspond to the new LTGs and thematic areas. The draft MYP is undergoing internal review and should be finalized by March 2008. An initial attempt was made to develop a conceptual model for integrating the program's goals, resources, and capabilities in the revised MYP. Dr. Levine hopes to refine this model during the annual planning activities. She noted that the program is reluctant to base decisions on extramural funding solely on the status of "resident" expertise within ORD. Dr. Levine mentioned the concept of research life cycle. This requires defining research needs with inputs from the program offices, regions, states, and tribes; regulatory drivers; congressional mandates; external reviews (BOSC, SAB); and the research community. It also requires annual realignment of priorities with EPA goals and strategic directions, program office priorities, BOSC and SAB feedback, and constraints (budget, laboratory capabilities/capacity). The research yields products such as methods, models, data, etc. The research outcomes must be evaluated to determine, for example, if the research needs were met and if the research products are being used to improve Agency decisions.

Resource Allocation

BOSC Recommendation 12: The Subcommittee highlighted the value of collaborating with other ORD programs, other federal agencies, and other organizations.

BOSC Recommendation 16: Leverage program resources through strategic use of cooperative agreements and collaborations, particularly to address emerging research issues.

ORD Response: The program agrees that collaborating and developing integrated research programs is important and there are ongoing efforts in place to foster collaboration both internally (with other research programs) and externally. The role of existing and potential cooperative agreements and research collaborations will be more prominently articulated in the 2009 BOSC review of the Drinking Water Research Program.

Program Evaluation

BOSC Recommendation 4: Further investigate, refine, and apply the bibliometric and partner document analysis and surveys. Consider the following: discriminating between the contributions of extramural and intramural research, determining whether indices of high publication citation rates or impact factors are equivalent among disciplines and organizations, and enhancing partner diversity beyond EPA program offices.

BOSC Recommendation 5: Provide more consistency in intra-Agency communication and evaluation procedures.

BOSC Recommendation 7: Benchmark goals and measures against the results of other organizations that do similar work.

BOSC Recommendation 10: The Subcommittee emphasized the importance of intra-Agency communication across laboratories, centers, and program offices.

BOSC Recommendation 13: Integrate performance metrics into annual performance reviews to promote alignment with the Agency's goals.

BOSC Recommendation 14: The Subcommittee cautioned against overreliance on bibliometric analyses and highlighted the need to establish reference values to facilitate accurate assessment and comparisons across disciplines and agencies. The Subcommittee also recognized the need for the investment of time and resources to advance the use of bibliometric analyses.

BOSC Recommendation 15: Develop uniform metrics to track program progress over time.

ORD Response: ORD currently is exploring the application of data mining tools to provide a more comprehensive evaluation of the degree to which ORD research products are used in achieving environmental outcomes. ORD believes that information about the productivity of the entire program (both intramural and extramural) provides greater insight regarding the impact of the program and its overall applicability and utility than could be achieved through separately evaluating research outputs (publications and citing of these publications) by source. It was unclear to ORD how determining whether indices of high publication citation rates or impact factors are equivalent among disciplines and organizations would facilitate review of the program. The program's clients include not only the program offices but also the regional offices (which provide input from states and tribes). Other program partners include the water industry (utilities, agencies, associations, and research groups). The involvement of partners/stakeholders varies from project to project. The program is exploring approaches for a more

systematic evaluation of the outcomes of the Drinking Water Research Program research products among a broader audience (beyond program offices).

The program will make efforts to provide better documentation of its communication and evaluation processes, and their impact, in future program reviews.

ORD has funded an NAS study entitled Evaluating the Efficiency of Research and Development Programs at the Environmental Protection Agency. It is anticipated that the results from this study will help to identify approaches used by other organizations that have potential applications for improving ORD's current approaches to evaluating and benchmarking its research.

ORD has several activities in place to foster intra-Agency communication, including a monthly seminar series to highlight current research projects (intramural and extramural). The program also hosted and/or participated in topical workshops to promote dialog among researchers and to strategize on research needs.

With respect to annual performance reviews of ORD scientists, laboratory and center managers are using performance metrics (e.g., contribution to an MYP APM) in performance evaluations.

ORD currently is working toward developing a comprehensive bibliographic database to facilitate analysis of research outcomes and to document research activities related to LTGs and APGs. As the report noted, some of these analyses can be resource intensive, so ORD hopes to develop a systematic process for tracking research effectiveness.

Because of the diversity of research outputs (methods, models, publications, data, guidance documents), it is unlikely that a single metric can be universally applied. The utility of developing a time-series analysis to track progress will be explored in conjunction with the 2009 BOSC and 2010 PART reviews.

Dr. Levine noted that the program's diverse research products are used by the Agency in a variety of ways: regulatory decisions, implementation guidance, adoption of methods by industry, and adoption of models by industry. Feedback from the program offices, regions, and industry provides evidence that the research products are being used.

Leadership

BOSC Recommendation 8: There is a need for consistent approaches for fostering scientific leadership.

BOSC Recommendation 9: There is a need for more interactions with other agencies.

ORD Response: ORD is exploring ways to address scientific leadership, including enhancing its mentoring programs, recruiting post-doctoral fellows, promoting visibility of research through publications in high impact journals, encouraging participation in Gordon Research conferences and similar venues, and hosting workshops to promote interactions and collaboration among STAR and ORD research teams.

The program currently collaborates with a number of federal agencies, including: USGS, USDA, the Food and Drug Administration (FDA), U.S. Army Corps of Engineers (USACE), Department of Homeland Security (DHS), and the Oak Ridge Institute for Science and Education (ORISE). Internationally, the program participates in the Global Water Research Coalition and has collaborated with groups in South Africa and China on specific research issues. The program also interacts with several research foundations, including the American Water Works Association Research Foundation (AWWARF), the Water Environment Research Foundation (WERF), and the WateReuse Foundation

(WRF). Researchers partner with numerous utilities, water agencies (Ohio River Valley Water Sanitation Commission), states, and regions to address drinking water research issues. Efforts are ongoing to foster these relationships, as time and resources permit. The program will give greater emphasis to describing interactions with other agencies in future reviews.

In closing her presentation, Dr. Levine stated that the BOSC recommendations are helpful in strengthening the program. The next BOSC program review will take place in 2009, and it will provide an opportunity to evaluate program effectiveness with the new structure and revisit performance evaluation and program metrics.

Discussion

Dr. Haas asked if USGS was involved in the program's CO_2 sequestration project. Dr. Levine responded that DOE is the major player. This research is very expensive; DOE is setting up the field sites and EPA is working with DOE on research issues related to monitoring, modeling, site characterization, evaluating the potential fate and transport of the plumes, and safeguards for protecting underground sources of drinking water and developing indicators of endangerment.

Dr. Demerjian commented that he thought the Drinking Water and Ecoservices Programs should be closely linked. Biofuels is an example of where these two programs should be linked to ensure that the modeling systems are compatible. Dr. Levine replied that the Drinking Water Research Program is not a big player in the biofuels effort, but it is important that potential impacts on drinking water quality and availability are considered in the modeling efforts. Dr. Demerjian stated that the drinking water health outcomes could be the Ecoservices Program's link to accountability. Dr. Levine said that the programs have not explored that but she thought it was a good suggestion.

Dr. Haas asked about quantifying the value of source water protection. How does EPA assess the effectiveness of source water protection? Dr. Levine responded that the program is trying to address this issue. This is a challenging question because of the time-scale needed to demonstrate results in comparison to impacts associated with changing land-use and water-use practices. The focus of the program is on developing, testing, and implementing best management practices (BMPs). There is a need, however, for metrics that can quantify the effectiveness of various approaches.

Dr. Sayler thanked Dr. Levine for her presentation and for responding to the members' questions.

Human Health Research Program Mid-Cycle Review Report
Dr. Hugh Tilson, National Institute of Environmental Health Sciences (former NPD for Human Health Research, EPA/ORD)

The Human Health Research Program underwent a full BOSC program review in January 2005. The report for that review was received by ORD in August 2005, and ORD responded in September 2005. The mid-cycle review of the program was held in January 2007. The report was submitted to ORD on July 23, 2007, and the ORD response was transmitted to the BOSC in January 2008.

The charge questions for the mid-cycle review were as follows:

- How responsive has the program been to recommendations from the 2005 review?
- How clear is the rationale for the revised MYP and are revisions consistent with the 2005 BOSC recommendations?
- How meaningful are the performance metrics as indicators of impact?

- ✍ What advice can the BOSC provide concerning the emerging area to evaluate risk management decisions?

The mid-cycle review report included 19 specific recommendations. The ORD response addressed each recommendation and provided a detailed timeline and status for each. Dr. Tilson then summarized the BOSC findings for each charge question.

BOSC Charge Question #1: How responsive has the program been to recommendations from the 2005 review?

BOSC Findings: ORD made a significant effort to respond to the recommendations. The BOSC was favorably impressed with ORD's response to the previous program review. ORD takes the BOSC reviews seriously and is open to changing approaches. ORD is able to add components to the research program to address concerns of various review committees including the BOSC.

Charge Question #2: How clear is the rationale for the revised MYP and are revisions consistent with the 2005 BOSC recommendations?

BOSC Findings: The revised MYP responded to comments made at the 2005 review. The mid-cycle review provided insights concerning ongoing changes and new directions. The report noted that LTG 4 could serve as a unifying theme and recommended that ORD broaden the main objective for LTG 4 to reflect the growing emphasis on evaluating and demonstrating the impact of its research on improving environmental health. The strategic rationale guiding the MYP is clear and the revised MYP demonstrates a commitment to transparent planning and prioritization of research. The revised MYP focuses on defining realistic and meaningful outputs and outcomes and it makes it easier to track relevance of products to customers.

BOSC Charge Question #3: How meaningful are the performance metrics as indicators of impact?

BOSC Findings: The connection between the APGs and APMs is clear and there is a timeline for meeting goals. The MYP needs a plan for evaluation of goals. The program has not been as effective in establishing performance metrics. The program was commended for conducting the bibliometric analysis as it provides a diversity of information that can be used to develop performance metrics commonly used in the research community that are based on peer-reviewed publications and their impact. Basic quantitative evaluations can be developed such as publications per research dollar invested, per FTE, and per year. Performance-based measures that link directly to publications and their impact could be developed to guide ORD in assessing the significance of its research. Further, this information should be stratified by intramural and extramural research activities and included as an integral component of performance metrics for a number of programs. The program has a good approach for documenting client use, but a survey might be added. More documentation is needed on how the program's products improve environmental health.

BOSC Charge Question #4: What advice can the BOSC provide concerning the emerging area to evaluate risk management decisions?

BOSC Findings: ORD should broaden the mission statement of the Human Health Research Program to include this element. The program's research questions and activities need to be better focused and the linkages between other LTGs and this area need to be clarified. The program should develop a plan to allow stakeholders to track how risk management decisions support risk assessment (e.g., survey).

As the framework document (which identifies research needs based on the ROE) continues to evolve, additional details would be helpful regarding the rationale that will be used to formulate the criteria for prioritizing which risk management decisions to evaluate (once they have been identified). The framework should include an assessment of resources (human and financial) that will be needed for a viable program. Benchmarks of effectiveness of the risk management decisions on improvements in environmental health should be developed.

Dr. Tilson mentioned that in fall 2007, the program held a workshop on how to interpret biomonitoring data to address some of the issues in the ROE. Because he was no longer the NPD, Dr. Tilson could not say how the program will follow-up on the BOSC's recommendations regarding the framework, but he did know that ORD was taking steps to address them.

Dr. Tilson closed his presentation by stating that there will be a full BOSC program review of the Human Health Research Program in late 2008 (approximately 4 years after the last program review). The program is expected to undergo an OMB PART review in 2009.

Dr. Tilson asked Dr. Sally Darney, the Acting NPD for Human Health Research, if she would like to address the future plans for the program. Dr. Darney said that she had worked closely with Dr. Tilson on the transition for the last few weeks and she jumped in with both feet on the workshop that Dr. Tilson mentioned. At that workshop, several case studies were presented that focused on addressing the continuum from exposure to effect and how linkages can be made. The program has started to work on this topic. Expertise and resources will continue to be a challenge for the program and modeling and exposure data will continue to be important. Dr. Darney added that epidemiological expertise is an issue and getting the epidemiologists to talk to the toxicologists continues to be a challenge.

Dr. Tilson asked if there were any questions for him or Dr. Darney.

Discussion

Dr. Daston noted that the program's strengths have been hazard assessment in the risk assessment equation and looking at animal data to see how they compare to human responses. He cautioned that biomonitoring data can lead to poor decisions if they are taken out of context. Biomonitoring data do not always provide useful information about risk; more information is needed on translating exposure to risk. The program will have a role in that. Dr. Daston liked the idea of bringing in more epidemiological expertise, but he recognized that limited resources made that difficult.

Dr. Tilson stated that the framework document was developed to frame the research to address problems identified in the ROE. The program is trying to make connections between exposure and health outcomes. Indicators to identify the connections are needed and the program is making a more concerted effort to identify indicators.

Dr. Philbert noted that epidemiologic studies are expensive, take a long time, and do not always identify the linkages. Are there opportunities to work with other agencies on epidemiologic studies? Are there specific diseases that could be used as a model and provide markers where linkages are not clear? Dr. Tilson responded that such research would have to be conducted in collaboration with other federal agencies such as the Centers for Disease Control and Prevention (CDC) and National Institute of Environmental Health Sciences (NIEHS) and organizations. With regard to Dr. Philbert's question about specific models of disease, ORD has been successful in developing animal models of asthma and has a good understanding of the susceptibility factors. The models can predict human response. Another possible model would be reproductive toxicology. The program could look back to see if there are any bioindicators that might be useful in predicting health outcomes.

Dr. Darney added that the National Children's Study offers the program opportunities for partnering. The study is looking at health outcomes throughout growth and development. EPA will have access to the data and the opportunity to model them and mine useful information from them.

Dr. Weiss asked if the workshop case studies looked at the influence of policy and regulation on the health outcomes. Dr. Darney responded that they did not. The case studies were evaluating the public health impact of decisions. Dr. Weiss suggested that the program think about ways to measure the effect of the research on those who develop guidelines and regulations. Is the research influencing what decision makers do? She cautioned against skipping that step and going straight to public health outcomes. Dr. Demerjian stated that one of the long-term goals of the National Health and Environmental Effects Research Laboratory (NHEERL) is to reduce uncertainty in linking air quality with health outcomes.

Subcommittee Draft Reports

Subcommittee Chairs

EDCs Research Mid-Cycle Review Draft Report

Dr. Deborah Swackhamer, Chair of the EDCs Research Mid-Cycle Review Subcommittee

Dr. Swackhamer commented that this was the first time she had been involved in a BOSC review. An eight-member subcommittee of the BOSC conducted a full program review of the EDCs Research Program in December 2004. A four-member Mid-Cycle Review Subcommittee was formed by the BOSC to conduct a mid-cycle review of the program in 2007. In addition to herself, the members of the EDCs Research Mid-Cycle Review Subcommittee were Drs. Glen Boyd, Stephen Safe, and Glen Van Der Kraak. An organizational teleconference was held in August 2007 and the face-to-face meeting was held in September 2007. There were follow-up conference calls in October and November 2007 to complete the Subcommittee's report.

The charge questions for the mid-cycle review were:

- How responsive has the program been to the recommendations from the 2004 BOSC program review?
- To what extent does the updated draft MYP provide a coherent framework and rationale for addressing priority research needs?
- Are there performance metrics the program should be using in addition to the current indicators for regularly assessing research progress?
- What advice can the BOSC provide regarding the planned narrower focus and directions of the program given its evolution and budget impacts?
- Please rate the progress made by the program in response to the BOSC review of 2004.

Dr. Swackhamer then summarized the Subcommittee's findings for each charge question:

Charge Question #1: How responsive has the program been to the recommendations from the 2004 BOSC program review?

Subcommittee Findings: The program has been very responsive to the recommendations from the 2004 program review. Most of the recommendations have been implemented and the program has fostered partnerships and leveraged other programs to build its workforce.

For LTG 1 (i.e., more in-depth understanding of EDC science), the program continues to provide scientific results to reduce the uncertainty regarding EDCs and facilitates science-based environmental decision-making. The program continues to be challenged by wildlife toxicology. The program is active in species extrapolation and at the forefront of using –omics, computational modeling, and whole animal endpoints to identify biomarkers of exposure. The program is addressing the appropriate scientific questions to meet LTG 1.

With regard to LTG 2 (impact of EDCs on humans, wildlife, and the environment), many of the recommendations from the program review have been addressed, including partnering with other agencies. Epidemiology research should continue to be partnered with other agencies. The program has played a lead in –omics technological advances and has made modest progress in addressing the integration of ecological and human health assessment.

For LTG 3 (screening and testing program), the program has demonstrated a speedy response and development of resources for producing high-quality science in response to the 2004 recommendations.

Charge Question #2: To what extent does the updated draft MYP provide a coherent framework and rationale for addressing priority research needs?

Subcommittee Findings: The updated draft MYP is logical and provides a coherent framework and rationale for addressing priority research needs. It provides informative background on how the program fits into the Agency's priorities.

Charge Question #3: Are there performance metrics the program should be using in addition to the current indicators for regularly assessing research progress?

Subcommittee Findings: Metrics must be considered carefully in the context of budget, FTEs, and the amount of time a particular activity has been underway. Additional performance metrics the program may want to consider include:

- Number of papers in high impact journals (as a percentage of the total).
- Distribution of papers published in journals with low to high citation indices.
- Number of invitations to present at national and international meetings (not organized or sponsored by EPA).
- Other scientific recognition (e.g., awards) to scientists participating in the program.
- Number and percentage of intra- and inter-agency and laboratory collaborative publications.
- Number of program scientists serving on journal editorial boards.
- Number of program scientists serving on scientific advisory councils or boards.

The program should develop metrics to assess: collaboration with outside agencies, universities, industry, and the international community; the use of research outcomes in decision-making; and the effectiveness of communication exchanges, workshops, etc.

Charge Question #4: What advice can the BOSC provide regarding the planned narrower focus and directions of the program given its evolution and budget impacts?

Subcommittee Findings: The ongoing evaluation and planning activities should be continued. The Subcommittee did not identify any obvious research gaps or research needs not being addressed by the program. The program should take more leadership in risk management. It should consider more harmonization regarding the results of EDC scientific studies and their applications.

Charge Question #5: Please rate the progress made by the program in response to the BOSC review of 2004.

Subcommittee Findings: The Subcommittee found that the program overall exceeds expectations. The quality of the program is exceptional, the speed with which the program has achieved its goals exceeds expectations, and the success of the program meets expectations.

Dr. Sayler stated that Dr. Daston served as the vettor for this report. He asked Dr. Daston to provide his comments.

Dr. Daston thought it was a good review of the program's progress in responding to the 2004 program review. He was concerned about the way the response to the third charge question was presented in the report. The vast majority of the measures focus on individual scholarship and although they are appropriate, they do not communicate the value of the program. He suggested that the section on program measures precede the section on individual scholarship.

With regard to the response to Charge Question #5, Dr. Daston thought additional justification for the rating may be required. He specifically pointed out the qualifying aspect with respect to the efficiency of the program—the Subcommittee thought the efficiency exceeded expectations **given budgetary constraints**. Dr. Daston asked if the budget was cut unexpectedly after the APMs and APGs were determined. If the budget did not change from that anticipated in the MYP, then the program's efficiency may only meet expectations. The report did not make it clear if the budget reduction came after the APMs and APGs were established. Dr. Swackhamer responded that the budget cuts were drastic and they occurred after the 2004 program review. She agreed to expand on this point in the report.

Dr. Sayler reminded the Executive Committee members that the mid-cycle review is not a technical evaluation of the program; it is an evaluation of the program's progress since the program review. He reviewed the two changes requested by Dr. Daston: (1) reverse the individual scholarship and program measures in the response to Charge Question #3 to emphasize program metrics, and (2) expand on the response to Charge Question #5 to qualify the exceeds expectations rating for efficiency.

Dr. Sayler asked if anyone was troubled by the fact that the recommendations were not presented in a list. Dr. Daston did not think the lack of a list of recommendations was a problem. The mid-cycle review is focused on how the program has responded to the recommendations from the program review, rather than providing the program with a new list of recommendations. He mentioned that there were a few comments in the report that could be cast as recommendations (e.g., for metrics), but he was not concerned about the lack of a list. Dr. Sayler asked if the report provided enough guidance so that ORD could respond. Dr. Daston replied that he thought it was clear where the program still needs work.

When there were no additional comments on the report, Dr. Sayler asked if the Executive Committee should vote on accepting the report with the proposed edits. Dr. Daston made a motion to accept the EDCs Mid-Cycle Review Subcommittee Report with the proposed changes. Dr. Weiss seconded the motion. The report was unanimously approved by the Executive Committee with the proposed changes.

Dr. Swackhamer will incorporate the changes and Dr. Daston will verify that they have been made as requested by the Executive Committee before the report is formally transmitted to ORD.

Air Research Mid-Cycle Review Draft Report
Dr. Rogene Henderson, Chair of the Air Mid-Cycle Review Subcommittee

Dr. Henderson stated that the mid-cycle review of the Air Research Program (formerly the PM/Ozone Research Program) was conducted by the five-member Air Mid-Cycle Review Subcommittee. Dr. Henderson served as the Subcommittee Chair and the other members were Ken Demerjian, Bart Croes, Peipei Ping, and Christian Seigneur. The program underwent a full BOSC program review in 2005. All five of the Mid-Cycle Review Subcommittee members served on the subcommittee that conducted the 2005 program review.

The mid-cycle review focused on the program's response to the 2005 program review. In 2005, the program was struggling with its PART review and Dr. Dan Costa had just been appointed the NPD. Much of the program was in flux at the time of the 2005 review. Since then, the program has been expanded to include air toxics, which is consistent with the Agency's move toward the multi-pollutant, one-atmosphere approach. Metrics was a focus of the program review and Dr. Henderson did not think the Subcommittee had been very helpful in identifying performance metrics. Since the program review, however, the program has developed some metrics and has divided source to outcome into two components: (1) air quality and exposure, and (2) exposure to health effects.

Dr. Henderson then summarized the responses to the charge questions, which begin on page 4 of the report.

Charge Question #1: Do the currently planned revisions to the Air Research Program adequately address the 2005 BOSC PM and Ozone Subcommittee's 2005 program review recommendations?

Subcommittee Findings: There were nine recommendations in the 2005 program review report. The first recommendation from the program review was to develop and maintain a formalized process for assessing its primary stakeholders' perceptions of and satisfaction with its role in the source-to-health outcome process. The program developed and distributed a survey to clients (OAR and regional offices). Survey responses were good with a few exceptions; the NPD explained that those respondents wanted the program to focus more on ecological effects but there was inadequate funding to do so.

The second recommendation was to revise the wording of the two LTGs. The LTGs were revised in accordance with the recommendation.

The third recommendation from the program review was to embrace two to three hypothesis-driven pilot studies that would demonstrate the source-to-health outcome concept to provide a reasonable metric to measure program success. ORD is using a few studies to test hypotheses according to the source-to-health outcome framework. The example presented was the set of near-roadway studies that include monitoring and modeling of air toxics, exposure assessment, and health studies in the vicinity of roadways. Other examples proposed by the program include pollutant effects of coal-fired power plant emissions and the potential health effects associated with nickel emissions from coal-fired power plants in the northeastern United States.

The fourth recommendation was to reconsider the decision to completely divest of ozone health research. The program had to divest of ozone health research because of budget cuts; however, ozone is being addressed through multi-pollutant studies related to PM.

The fifth recommendation was to solicit input from and coordinate research with other federal agencies, states, and private organizations. The program solicits input and coordinates research through the Research Coordination Team, which includes staff from the program and regional offices. The program also coordinates with NIEHS; the National Heart, Lung, and Blood Institute (NHLBI); the California Air

Resources Board (CARB); Regional Planning Organizations (RPOs); USDA; DOD; and private trade associations such as the Electric Power Research Institute (EPRI) and the Coordinating Research Council (CRC). EPA is a key member and funder of the North American Research Strategy for Tropospheric Ozone (NARSTO). EPA also is involved in reviewing CRC-funded research.

The sixth recommendation was to commit to maintain the strong balance between intramural and extramural research. The program continues to maintain strong extramural and intramural research efforts.

The seventh recommendation was to subject funding decisions for intramural projects to review by the Air Research Coordination Team (RCT). EPA has maintained the role of the RCT in the new format used within ORD to manage air research (i.e., with research coordinated by the NPDs). The Near-Roadway Research Initiative, for example, was reviewed by the RCT and the clients of this research project.

The eighth recommendation was to include a discussion in the MYP indicating how the National Research Council (NRC) goals flow into the cross-cutting research issues and how these are embodied under the two LTGs. The draft MYP is organized along these lines. The Subcommittee found the organization of the APGs in Figure 4 to be very useful for understanding how the various research issues are interrelated within the source-to-health outcome framework.

The ninth recommendation was to set aside funding for anticipatory research needs and take steps to identify and highlight key anticipatory research needs. The program staff indicated that it is not feasible to set aside special research funds that are not assigned to a specific research effort; however, each ORD principal investigator has the discretion to use 10 percent of his/her research budget on research items that are not determined *a priori*. The Subcommittee agreed that this flexibility satisfies the BOSC's recommendation.

Charge Question #2: Does the proposed structure for the revised MYP provide a coherent framework for addressing priority research needs?

Subcommittee Findings: The proposed structure for the revised MYP meets all and exceeds some of its goals with respect to providing a coherent framework for addressing priority research needs. The revised MYP clearly articulates the framework and timeline for research to address the two updated LTGs. These revised LTGs define and promote the research aims and highlight the priorities of the program with well-designed milestones. The scientific investigative activities and achievements of the program demonstrate high quality in its scientific merits, high impact in its affiliated scientific community, and exceptional value in its scholarly activities. The outstanding progress of the program is evidenced by: (1) merits in scholarship and strong productivity, (2) significant impact of the program in the scientific community as demonstrated by the strength of the scientific publications, (3) success and progress of the program as demonstrated by its key accomplishments, (4) success and progress of the program as demonstrated by its contributions to building a knowledge base and information database, and (5) success and progress of the program in its ability to better target the needs of the community with the revised LTGs.

Charge Question #3: Does the draft MYP (2007-2012) adequately address critical research to meet regulatory mandates of the Clean Air Act (CAA)?

Subcommittee Findings: The draft MYP clearly addresses important research needs identified in EPA documents and in critical assessments undertaken by external organizations (most notably the NRC Committees and the 2005 BOSC program review). It adequately addresses critical research to meet the regulatory mandates of the CAA, and in some cases, exceeds expectations. With periodic feedback from the primary research clients, the program can become even more relevant to the most important regulatory and programmatic needs of the Agency and the nation's Air Research Program.

Charge Question #4: Does the approach used to integrate PM, Ozone, and Air Toxics into one overall research program address the concerns raised by the BOSC in the 2005 program review?

Subcommittee Findings: During the 2005 program review, there was some concern that the redirection of the program, which started in the late 1990s, from an emphasis on ozone to PM health research, may have overshot a reasonable balance point and that ORD should reconsider its decision to divest of its ozone health research program. ORD expects to advance a rational approach for supporting a multi-pollutant program that would, if viable, employ a more holistic approach to health outcomes associated with NAAQS, hazardous air pollutants (HAPs), and PM. The ability to break away from the pollutant-by-pollutant NAAQS paradigm will very much depend on assessing synergisms in health outcomes resulting from multi-pollutant exposures. This is a laudable goal, but one that may be unrealistic in the near term.

ORD has responded to the concerns expressed in the program review stating that it is not fiscally feasible to continue with an independent ozone health research program and meet the needs of the Air Research Program. ORD has provided a rationale for how ozone, along with other pollutants, will be factored into a multi-pollutant health assessment approach.

Charge Question #5: Do the existing program performance measures provide appropriate quantifiable indices of progress? What improvements does the Subcommittee recommend?

Subcommittee Findings: Definite progress has been made since the 2005 program review in thinking through the appropriate performance measures for the program. The Air Research Program has used a client satisfaction survey instrument to document how well it is meeting the needs of OAR and the regional offices. Another performance measure is the use of external review bodies to evaluate program goals and progress. Table 4 in the draft MYP lists appropriate PART measures for annual and long-term outputs and outcomes, but does not specify how the measures will be quantified. The completion of the LTGs and associated APGs and measures can provide a basis for measuring progress. For LTG 1, the program plans to measure the percentage of program outputs appearing in NAAQS documents. Surveys of OAR staff members on their satisfaction with the reduction of uncertainties by the program investigations are another measurable outcome. Another measure might be the money saved from the setting of new standards, based on the cost-benefit analysis of the new standards. For LTG 2, the planned accountability studies and associated cooperative programs should offer measurable outcomes. The program has proposed the possibility of identifying 10 to 15 source categories that contribute the vast majority of air pollutant emissions and measuring progress toward understanding relationships between emissions from these sources and health by taking a two-phased approach. The first phase would be designed to reduce uncertainty in understanding relationships between sources and air quality and the second phase would be designed to reduce uncertainty in understanding relationships between air quality and public health. Although measuring progress in either phase presents significant challenges, progress in the second phase is particularly difficult to measure. For the first phase, performance measures can be quantitated by monitoring changes in emissions and modeling resultant changes in exposures following the institution of regulations or some type of intervention. Possible measures of outcome for the second phase are less apparent because they depend on available epidemiology data to quantify the expected adverse health effects of the exposures. In linking sources to outcomes, the program suggested focusing on (1) near roadways, (2) near other specific sources, and (3) specific geographical areas impacted by several sources. The Subcommittee agreed with this approach and recommended that the program continue to contribute information that is lacking on the characteristics of emissions that are associated with adverse health effects.

Charge Question #6: Please rate the progress made by the Air Research Program in moving the program forward in response to the BOSC program review of 2005.

Subcommittee Findings: The progress in response to the 2005 BOSC program review exceeds expectations. The bibliometric analysis was quite impressive and some of the members rated it as exceptional. Overall, the program is meeting its goals and conducting the appropriate high-quality science to meet those goals.

Dr. Sayler stated that Dr. Ryan was a vettor for this report. Dr. Ryan indicated that Dr. John Giesy also reviewed the report and provided his comments to Dr. Ryan. The report is concise and well written. He suggested a few changes to make it more appropriate for a diverse audience. Dr. Ryan agreed to provide his changes electronically to Dr. Henderson. He indicated that the changes were editorial in nature and quite minor.

Dr. Duke asked if it was a conscious decision not to call out recommendations in the report. There appear to be some in the report; for example, page 10, lines 5-6; page 11, lines 7-9; page 15, lines 4-7; and page 15, line 39. He asked if these should be highlighted as recommendations.

Dr. Henderson replied that the Subcommittee decided not to make a list of recommendations. Should the recommendations be highlighted in bold as was done in the EDCs report? Dr. Swackhamer commented that the EDCs Mid-Cycle Review Subcommittee decided not to create a list of recommendations, but wanted to make sure the salient points were clear so it was decided to make the text bold. Dr. Henderson said she liked that approach. Dr. Demerjian pointed out that only one of the items Dr. Duke identified used the term recommend. Another approach would be to avoid using the word recommend and highlight the points in bold text. Dr. Sayler noted that it is fine to include recommendations in a mid-cycle review report but the most important observations should be highlighted. Ms. Kowalski commented that the subcommittees are free to develop the reports as they choose. She noted, however, that ORD has to look at the reports and pull out the recommendations and they are not always obvious. Therefore, it is helpful if the subcommittee highlights the items to which ORD should respond. Dr. Sayler stated that if the subcommittee report does not emphasize what the BOSC thinks is important, the NPD may emphasize something else. Dr. Demerjian thought the mid-cycle reviews were reporting on the program's progress and should only contain recommendations if the program has gotten off course and needs to make a correction. Dr. Ryan thought the use of the word recommend in the report was fine. Dr. Duke did not disagree that the primary purpose of the mid-cycle review is to assess progress, but added that the subcommittees are being asked questions that go beyond assessing progress since the program review. For example, the subcommittees have been asked to suggest potential performance metrics. Dr. Henderson did not see the need to include a list of recommendations; however, she would like to highlight the major points to make it easier for ORD to respond. Dr. Sayler thought that would be a good approach. He asked Dr. Henderson to specifically review the items identified by Dr. Duke. Dr. Henderson will make these changes and incorporate the editorial comments from Drs. Ryan and Giesy.

Dr. Swackhamer mentioned she had chaired the SAB subcommittee that reviewed EPA's ROE. That subcommittee is strongly recommending that the Agency develop indicators to determine how well the nation is doing relative to health impact. Did the Air Mid-Cycle Review include any discussions about feeding the information from this program into the ROE? Dr. Henderson asked Dr. Dan Costa, the NPD for Air Research, if the program had any input into the ROE. Dr. Costa replied that program staff members review the ROE and interact with the individuals who work on the report. He mentioned that the program used the 2003 ROE to ensure that it was addressing some of the needs identified. Dr. Henderson asked if Dr. Swackhamer was suggesting that this be added as a recommendation. Dr. Swackhamer replied that the ROE has only two FTEs; it draws on good will from others in the Agency and the Air Research Program could make a contribution. Dr. Costa said that the program would be happy to help in any way that it can. Dr. Sayler asked if the recommendation that the program make information available for the ROE should be added to the report. Dr. Costa responded that the program is trying to make the information available through its Web site. Dr. Sayler asked if there was agreement that the report should include a statement about the program making information available for the ROE.

Dr. Weiss said she did not think it was appropriate to add such a statement to the report because it was not in the charge questions and was not discussed by the Subcommittee. Dr. Henderson indicated that she could insert it under Charge Question #1, with reference to the program review recommendation on coordinating research with other federal agencies. Dr. Sayler stated that this is a BOSC report so this is an issue that can be decided by the Executive Committee. If the Executive Committee wants to add this recommendation, it is empowered to do so. He noted that the recommendation could be included in the transmittal letter to ORD. Dr. Henderson liked that idea. Dr. Swackhamer volunteered to provide a sentence to Dr. Sayler that could be inserted in the transmittal letter. She also agreed to add a corresponding recommendation in the SAB report on the ROE review.

Dr. Demerjian thought it was a bit presumptuous to assume that the Air Research Program was not communicating with the individuals who prepare the ROE. He thought it was so obvious that he did not think it was worth making the point. Dr. Swackhamer noted that the SAB subcommittee is recommending substantial changes to the ROE. Her comment may sound superfluous to the BOSC but the SAB subcommittee is recommending that the ROE take a similar approach to that taken by the Air Research Program. In this context, the comment makes more sense. The model development of the Air Research Program could influence the ROE. Dr. Demerjian agreed and withdrew his objection.

Dr. Sayler then called for a motion to approve the report with the suggested changes. Dr. Ryan moved to accept the report with noted changes, and Dr. Weiss seconded the motion. The report was unanimously approved by the BOSC Executive Committee.

NCER Standing Subcommittee Draft Report

Dr. Martin Philbert, Chair of the NCER Standing Subcommittee

Dr. Philbert stated that the NCER Standing Subcommittee includes eight members in addition to himself as well as two consultants. The members are listed on page 14 of the draft letter report. He indicated that the review was very interesting and the Subcommittee members learned a great deal about NCER. The Subcommittee's charge was one question: What steps can NCER take to more effectively engage the external scientific community to better craft a forward-looking portfolio and meet evolving Agency needs? This question was broken down into three specific questions:

- Regarding NCER's niche in ORD and in the greater environmental federal research and development realm, what can it do to more flexibly address emerging issues and technologies and provide timely responses to rising scientific needs of the Agency?

- What advice can be offered on ways to measure and improve the effectiveness of NCER's communication so that decision makers will make greater use of the Center's products?

- What metrics are most useful for measuring the impact of NCER's work?

Dr. Philbert mentioned that the recommendations on pages 2 and 3 of the letter report are intentionally not numbered because the Subcommittee did not want to infer priority. For the review, the Subcommittee formed three workgroups and each workgroup addressed one of the three specific questions.

The response to the first question was organized around the two themes that emerged from a deconstruction of the charge question: identifying the most valuable research and identifying the most imminent research. The Subcommittee recommended that ORD generate a prioritized list of metrics that may be used to evaluate the need to address emerging issues. NCER should initiate a dialogue with EPA program offices, and with outside stakeholders, about what information is most needed for their mission. To support this effort, NCER should fund "meta-research" into value-of-information theory, software, and training. NCER should increase its efforts on cross-media, multiple-substance, and life-cycle

research. NCER should balance its extramural research portfolio by funding some social science, cognitive science, and engineering research. In addition, NCER should consider use of an unsolicited grant submission process to encourage the generation of relevant scientific questions that do not exactly match the wording of existing RFAs.

For the second charge question, the Subcommittee members reviewed many different communications products and found that NCER disseminates its communication materials effectively, that its products are of high quality, and that they appear to be aptly suited to their target audiences. There also is evidence that some of NCER's products have impacted policy, but the Subcommittee did not have enough information to judge the extent of this effectiveness. NCER also appears to understand the importance of developing relationships with key audiences to elicit feedback and improve communication efforts.

The third charge question focused on metrics. The Subcommittee found that the bibliometric analyses already undertaken by NCER are an important first step in measuring impact and will provide, over time, a good baseline point of reference. NCER should continue its efforts to expand these analyses to link NCER's research with actual rulemaking. NCER should make a broader effort to demonstrate the links between the Center's research to other approaches beyond rulemaking such as market-based incentives (e.g., emissions trading), information strategies (which are critical to addressing problems such as radon), and the work to develop better environmental technologies or to specify their use (such as Best Available Control Technologies). It would be useful to demonstrate how EPA-funded research has provided inputs to strategies and policies that have measurable impacts. The Subcommittee also recommended that NCER take a more thorough look at the impact of technologies funded through the Small Business Innovation Research (SBIR) Program. NCER should analyze its research portfolio annually to determine how much funding is actually dedicated to emerging issues. The Subcommittee was concerned that the entire allocation for emerging scientific research has been committed to nanotechnology.

Dr. Sayler interrupted Dr. Philbert's presentation at this point to call for public comments.

Public Comments

At 2:30 p.m., Dr. Sayler asked if there was anyone present who wanted to make a public comment.

Joining by telephone, Dr. S. Stanley Young from the National Institute of Statistical Sciences (NISS) stated that NISS is a non-profit institute that deals with questions of statistics. He referred to a recent paper entitled, Incorporating Historical Control Data When Comparing Tumor Incidence Rates, which was written by Shyamal Peddada, Gregg Dinse, and Grace Kissling and published in the *Journal of the American Statistical Association* in 2007. The work was requested by the National Toxicology Program (NTP) Board of Scientific Counselors. He explained that by adding more animals to the control group, the standard error is made smaller so that more things are likely to be statistically significant. Nothing in the paper mentions "multiple testing"—a very serious and well known problem for these complex studies.

Long-term rodent tests have many hundreds of statistical tests. The fact that rats and mice and males and females predict one another poorly implies that there may well be many false positive results. There is no correction for multiple testing in the analysis of these complex studies.

Dr. Young asked that the BOSC Executive Committee consider the following recommendations:

- ✍ Survey methods of multiple testing adjustment.
- ✍ Compute multiple testing adjustments for all future studies (give unadjusted and adjusted p-values).

- ✍ Compute multiple testing adjustments for all past studies (give unadjusted and adjusted p-values).

Dr. Young concluded his remarks by stating that if an analysis is done without multiple testing, it may be reporting false positives.

Dr. Sayler thanked Dr. Young for his comments and then asked Dr. Dale Dunn, who joined the meeting by telephone, for his comments. He noted that a copy of Dr. Dunn's comments had been distributed to the members.

Dr. Dunn said that in recent months he had provided materials and commentary on the integrity issues that fall with the mission of the BOSC. The submissions and commentary were for the Human Health Risk Assessment Subcommittee and the National Exposure Research Laboratory Standing Subcommittee meetings. For the Executive Committee, Dr. Dunn renewed his concerns about the following:

1. EPA-sponsored scientists have repeatedly used relative risk in the negligible range as proof of health effects causation, in spite of epidemiology rules to the contrary, as recited in the *Reference Manual on Scientific Evidence,* published by the Federal Judicial Center.

2. The same is true of EPA-sponsored science on the issue of high dose rodent toxicology combined with linear modeling with no threshold. Again, Dr. Dunn submitted the *Reference Manual* chapter on toxicology.

3. In addition to the *Reference Manual* materials, he submitted the brief filed on behalf of the American Council on Science and Health and many distinguished scientists criticizing EPA linear modeling and no threshold toxicology.

Dr. Dunn did not resubmit these materials today, because they already are available to the Executive Committee, in addition to submissions by Dr. Stan Young on multiple testing unreliability and Dr. James Enstrom's submissions on his concerns about conduct in the scientific community that stifles inquiry and penalizes legitimate scientists.

The Executive Committee is composed of members much more expert than Dr. Dunn in the problems of data dredging in small effects science. EPA also is embarked on a new series of toxicology projects that will increase the chance for problems—the genomic effects toxicology and small effects chemical toxicology research projects that increases the risk of more uncertain and unreliable research in health effects.

Dr. Dunn asked the Executive Committee to begin to make more inquiries in these areas, and to hold EPA to a higher standard of reliability. The BOSC represents the interests of the public in assuring EPA science does not just promote the interests and agendas of the EPA, but a balanced and reliable effort on behalf of the public interest and deserving of the public's trust. Dr. Dunn thanked the members for their consideration.

Dr. Sayler thanked Dr. Dunn for his comments and asked if there was anyone else present who would like to make a comment. No additional comments were offered.

NCER Standing Subcommittee Draft Report (Continued)

Dr. Martin Philbert, Chair of the NCER Standing Subcommittee

Dr. Philbert said he had concluded his remarks about the report so Dr. Sayler asked Dr. Duke, who vetted the report, to provide his comments.

Dr. Duke thought that the report was interesting and would be useful to the Center. He was very interested in the focus on value of information. He suggested that this could be the focus of a future BOSC project. Dr. Duke found that the section headers in the report did not map well with the charge questions so they were difficult to follow. He also found it difficult to identify the recommendations listed in the summary section in the text of the report. It should be easier to match the recommendations to the report text so that the reader can find more information or the explanation that led to the recommendation.

Dr. Duke thought there was overlap between the last recommendation under priority setting (page 2), which focused on unsolicited grant submissions and the last recommendation under frontiers (page 3), which concerned the Exploratory Grant mechanism. He found the recommendation on page 3, lines 21-22 and again on page 10, line 47 to be open-ended and vague. He also thought the report stopped abruptly and would benefit from a few concluding remarks. In addition, the table on page 12 should include references for the time to impact.

Dr. Sayler asked Dr. Philbert if he could address any of these comments. Dr. Philbert responded that he could address the overlap in the recommendations on pages 2 and 3. He explained that NCER has a separate pot of money for Exploratory Grants that recently has been used exclusively for nanotechnology. These grants are very different from the investigator-initiated grants described on page 2.

Dr. Demerjian viewed the Standing Subcommittee's role as providing advice and counsel to the Center rather than an evaluation. Is the evaluative tone of this report just a function of the charge questions that were addressed? He instructed the NERL Standing Subcommittee members that they were not to evaluate NERL's programs. Dr. Demerjian also asked if there was any discussion of competitive versus earmarked grants. Dr. Philbert answered that there was no discussion of competitive versus earmarked grants. With respect to the evaluative tone of the report, Dr. Philbert stated that the Subcommittee may have run afoul of the original intent for these standing subcommittees. This report was initially formatted as a program review but was subsequently reformatted to be a letter report.

Dr. Sayler commented that the standing subcommittee reports are new for the BOSC and Dr. Demerjian's concept is close to what was initially envisioned. Dr. Sayler said he was a little uncomfortable with the tone of the report because it should be written as advice rather than an evaluation.

Dr. Haas stated that value of information is an interesting tool in the toolbox to judge among competing research but he was concerned that it may become the predominant tool in the toolbox. There is value in surprise—researchers may uncover things they never expected and could be very useful. Another concern was that EPA cannot anticipate future regulations so valuing information now may lead to excluding things that could be quite valuable in the future. Dr. Daston did not see value of information as excluding the use of other approaches. Dr. Haas was concerned that the way the report was written, it could be interpreted that way. Dr. Philbert responded that the Subcommittee placed emphasis on value of information because it has not been a priority in the past. ORD should add it to the criteria it uses to compare research, but it should not be the only criterion.

Dr. Sayler asked if the three questions on page 1 were developed by the Subcommittee or NCER. Dr. Philbert replied that NCER developed the questions. Dr. Sayler asked Dr. Duke if he thought the report should be modified and re-reviewed by the Executive Committee before it is approved. Dr. Duke did not think that these changes could be considered merely editorial and he would be more comfortable if the report was revised and then re-reviewed. Dr. Philbert said he would be glad to change the tone of the report to one that would be more appropriate. Dr. Daston agreed that the standing subcommittees are to serve as a sounding board off of which the Laboratory or Center Director can bounce ideas and receive advice; however, it may be necessary in some cases to do a review. He did not see this report as inconsistent with the intent of the standing subcommittees. He noted that the Computational Toxicology Subcommittee is the first standing subcommittee, but it is different because it was formed at the same

time the Center was established to help guide its planning and implementation efforts. The first review covered the Center's overall strategy. Dr. Daston did not think the NCER report needed to be rewritten. Dr. Sayler agreed with Dr. Daston that the report did not have to be completely rewritten. Dr. Weiss pointed out that at the September meeting Dr. Haas raised the issue of how difficult it is for ORD to fund good basic extramural research that is of high relevance to EPA's mission and suggested looking at various extramural vehicles used by other agencies that could benefit EPA.

Dr. Sayler appreciated Dr. Daston's perspective but he was more closely aligned with Dr. Duke's comments. Because these recommendations go to ORD and not just NCER, he was not certain that the BOSC should weigh in this heavily at this point in time. Dr. Duke said he did not have any problem with the level of detail or the content of the report, but the tone should be changed.

Dr. Sayler thought a re-examination of the report by the Subcommittee was warranted to take a look at how the advice is presented. He did not think the report was ready for an approval vote today. He suggested that the Executive Committee review and approve the revised report on a future conference call. Dr. Philbert agreed to revise the report in response to the Executive Committee's comments. Dr. Demerjian suggested that the recommendations could be reworded as suggestions for consideration by the NCER Director. He asked if NCER had been reviewed by the BOSC. Ms. Kowalski responded that NCER's fellowship programs were reviewed a couple of years ago and the Center was reviewed twice by the BOSC. In addition, the STAR Program was reviewed jointly by the SAB and the BOSC. The reports from these reviews are available on the BOSC Web Site (http://www.epa.gov/osp/bosc).

Dr. Sayler stated that this report resembles a program review without the benefit of a full review process. Drs. Duke and Haas agreed to provide some suggestions to Dr. Philbert concerning how the report could be revised. Dr. Philbert asked if the revised report had to go back to the Subcommittee for review. Dr. Sayler responded that it did not require Subcommittee review. The revised report should be sent to Ms. Kowalski for distribution to the Executive Committee. The Executive Committee then will review and approve the report on a future conference call.

Revised Technology for Sustainability Program Review Draft Report
Dr. Wayne Landis, Vice Chair of the Technology for Sustainability Subcommittee

Because Dr. Giesy, Chair of the Technology for Sustainability Subcommittee, was unable to attend the meeting, Dr. Landis, Vice Chair of the Subcommittee, agreed to present the revised report to the Executive Committee.

Dr. Landis stated that the Subcommittee members included Dr. Giesy and himself, along with Concepción Jiménez-González, Earl Beaver, Martin Abraham, and Ted Tomasi. Peter Blaze Corcoran was a consultant to the Subcommittee and the DFO was Clois Slocum.

In reviewing the previous draft of the report, the Executive Committee asked the Subcommittee to identify specific examples in a number of rating specifications, review the final ratings and conclusions, perform final editing, and submit a revised report to the BOSC.

The LTGs for the Science and Technology for Sustainability (STS) Program are:

LTG 1: Identify and create scientifically based sustainability metrics.

LTG 2: Develop decision support tools that promote environmental stewardship and sustainable management practices.

LTG 3: Develop, apply, and demonstrate innovative technologies that solve environmental problems and provide sustainable outcomes.

The Subcommittee assigned an overall qualitative score as well as scores for two of the three LTGs. These scores reflect the quality and significance of the research as well as the extent to which the program is meeting or making measurable progress toward the stated goals.

The Subcommittee's overall impression is that it is an excellent program that has made many substantial contributions to the science of sustainability. The program's research staff is first rate, but a critical mass is lacking in some areas. Reorganization of the program provides an opportunity to refocus the program elements for maximum impact.

The Subcommittee assigned the overall program a score of meets expectations. Where the program does not exceed expectations the primary reasons are that these program elements are small and lack critical mass or they are elements in transition. The STS Program has some excellent researchers who are world leaders in their fields and the quality of the research is apparent.

Limited resources rather than the critical questions direct the types of studies that are undertaken. For this reason, the research might not be the highest priority or it may not move the science forward as rapidly as otherwise could be achieved, threatening the leadership role of the research program.

The Subcommittee suggested that the program ensure that there is integration and continuity among the elements during the plan for transition. The potential impact of the STS Program is limited by lack of a critical mass and resources. In developing the STS Program, ORD must make as much use as possible of capabilities across ORD and with an awareness of developments in programs outside of EPA. Currently, much of the work being conducted by the STS Program is eclipsed by the magnitude and pace of advancements in industrial and academic communities across the world. Thus, in developing the plan, the program must make strategic decisions on where it can make an impact on the overall field.

The Subcommittee did not assign a rating for LTG 1. The program has just begun to address this goal and there has not been enough time for the Subcommittee to make a long-term recommendation. The Subcommittee did, however, offer some suggestions for implementing the program. The development of sustainability metrics is a critical component of the overall effort, because these are the measures on which the success of all activities needs to be evaluated. It is not clear how the metrics to be developed within this element will be informed and used in other LTGs.

The Subcommittee inserted the following examples for LTG 1:

- For instance, in the Environmental Technology Verification (ETV) Program, metrics used to evaluate the performance of technologies have been successful. The ETV Program evaluates devices that measure important sustainability metrics that would not be done elsewhere.

- The Technology for Sustainable Environment (TSE) Program was a very strong program with innovation, productivity, and highly cited papers. It was a cost-effective way to enhance participation in these research questions. An extramural program could be crafted to emphasize metrics and how technologies move towards improving the measures.

The Subcommittee suggested that the evaluation of the metrics should be done systematically and quantitatively. This can be accomplished by: (1) designing critical experiments that allow testing of hypotheses within the realm of defined metrics, and (2) evaluating the predictability of models and conducting sensitivity analyses. There needs to be significant interaction between this LTG and the others, particularly LTGs 1 and 2, which are intimately tied together.

The Subcommittee assigned a rating of exceeds expectations for LTG 2. The program is relatively mature in this area and a great deal of progress has been made. The progress toward achieving this LTG has been excellent and has had a large impact on the field of sustainability.

The Subcommittee inserted the following examples for LTG 2 into the report:

- TRACI (Tool for the Reduction and Assessment of Chemical and Other Environmental Impacts) is used routinely by academic and industrial stakeholders across the globe as a way to evaluate environmental life cycle impacts. As the program morphs to a sustainability-oriented decision-making process, the life cycle assessment aspect will become critical.

- There is a project underway to better understand the environmental effects of different processes. The proposed research plan includes how to incorporate spatial and temporal relationships among these processes.

The Subcommittee suggested that LTG 2 could be improved through targeted extramural collaborations on the development of new tools or cooperation on the advancement of existing tools or tools being developed in the private sector. Efforts should be made to reach a wider set of stakeholders, such as NGOs and state agencies. The actual outputs and outcomes could be more clearly defined and communicated to targeted sectors.

The Subcommittee assigned a rating of meets expectations for LTG 3. Although the Subcommittee members found the overall performance of the program, relative to LTG 3, to be meeting expectations, a range of performances was observed.

The Subcommittee inserted in the report the following examples for LTG 3:

- The People, Prosperity, and the Planet (P3), SBIR, and ETV Programs all have been highly relevant to the mission of EPA and the elements in these programs should be preserved whenever possible.

- The relevance and impact of the Green Technology Program is less apparent and this program needs to be assessed internally to determine if it is serving a function that is not being met already by the private sector and academia.

For LTG 3, all of the program elements and the Green Technology Program in particular are in need of refinement to better address sustainability issues and to demonstrate and articulate the role that they play in contributing to sustainable outcomes. The Subcommittee suggested that following:

- P3—integrate sustainability metrics into judging criteria.

- SBIR Program—integrate potential impact on sustainability metrics into program solicitations and selections, and into program evaluation.

- ETV Program—broaden the mission to evaluate and verify additional components of the sustainability program and look for opportunities to support emerging markets in trading, offsets, and mitigation.

- Green Technology Program—examine carefully the rationale for the selection of target areas/technologies to better address market failures and tie outcome measures to sustainable measures and metrics.

Dr. Landis' concluding remarks focused on the overall assessment of the program. Historically, the Pollution Prevention and New Technology (P2NT) Program has been a leader in innovations in the science. Many of the current staff members still are considered global leaders in the field of sustainability. A lack of critical mass, however, has eroded the impact that the program currently has and will have in the future. The program has had a number of significant outcomes and has influenced the development of global science, but currently, other worldwide institutions are having a greater impact on the progress of sustainability science.

Dr. Sayler asked if there was Subcommittee consensus and Dr. Landis responded that there was a strong consensus. Dr. Sayler then asked Dr. Demerjian, who agreed to vet this report, to provide his comments.

Dr. Demerjian reminded the Executive Committee members that, at the last meeting, he asked the Subcommittee to insert a paragraph or two to describe the objectives of the program. The Subcommittee has attempted to address this comment on page 8 of the revised report. Dr. Demerjian said this addition still was not clear to him. What are the metrics in terms of sustainability? Can that be clarified? Does the program have a series of objectives that describes the meaning of sustainability? Does the program provide metrics for those objectives? Dr. Landis replied that the program did provide some metrics. He did not work on that section of the report and could not offer further explanation. He added that there currently is no consensus on the definition of sustainability. That may be one of the reasons certain areas lack metrics. Dr. Demerjian thought this might be a problem for the program given that it is required to be sustainable. Dr. Landis responded that it is a problem for the whole field and not just this program. A definition of sustainability is needed. Dr. Demerjian said he found this troublesome. He asked if someone present could identify objectives with respect to EPA's view of sustainability. Dr. Alan Hecht answered that Dr. Demerjian's question is on target but it has to be placed in context. The program as conceived has driven a tremendous amount of discussion within the Agency regarding sustainability metrics. The program offices and others within EPA have begun to wrestle with this issue. OAR has developed some metrics. One positive outcome is that the program offices are trying to figure out what they can do to measure sustainability. They are looking beyond what is in the ROE and will converge on a number of test cases that can become part of the program and strengthen the ROE. Dr. Landis asked that the Executive Committee members keep in mind that the information for this review was provided by EPA 9 months ago and much has changed since then. The Agency has moved on but this was not included in the report.

Dr. Demerjian thought it would be beneficial to include concrete examples of metrics for sustainability to give the reader a better understanding of those metrics. He referred to the bulleted items beginning on the bottom of page 8 and continuing on page 9. Could the Subcommittee provide an example for each one of these bullets? Dr. Demerjian said he was most familiar with the ETV Program, but he was not certain what was meant by incorporating "sustainability metrics in all evaluations." It sounds like jargon to him.

Dr. Sayler asked how much of this concern was attributable to the lack of a uniform consensus on the definition of sustainability. Dr. Landis replied that the report represents the consensus of the Subcommittee; to add more detail would be difficult. Dr. Sayler suggested adding a statement indicating that the Subcommittee could not define or provide examples because of the lack of consensus on a definition of sustainability and propose that the Agency move forward to work on this issue. Dr. Demerjian said that comment should be connected to LTG 1. Dr. Sayler asked Dr. Landis to include this as a recommendation and Dr. Landis thought that was a good solution. The recommendation should read something like "the Agency should continue to develop a sustainability definition and relative metrics for sustainability as part of this research program because there are too many different definitions in the field. Dr. Daston agreed with adding this recommendation, but he thought it was more than a definition. It is more like creating a framework for thinking about metrics. What is the program trying to achieve? A framework by which metrics can be consistently evaluated is needed. Dr. Landis thought that sounded reasonable to him. Such a framework would be worthwhile if the Agency can develop it. He agreed to

incorporate that into the report. Dr. Sayler suggested that it be inserted in the front of the report. Dr. Landis will make that change and send the revised report to Ms. Kowalski.

Dr. Sayler asked if that change addressed the members' concerns. Dr. Duke responded that he was fine with the addition. Dr. Swackhamer commented that she found the report very difficult to read. She has read it three times and still is having trouble understanding it. The report is not organized in a manner that makes sense to her. She did not, however, want to delay the submission of the report to ORD. Dr. Sayler then called for a motion to accept the report. Dr. Duke moved to approve the repot with the proposed change and Dr. Weiss seconded the motion. The report was approved by majority vote of the Executive Committee members with three abstentions.

Dr. Landis said he would send the revised report to Ms. Kowalski by Friday, January 25. Ms. Kowalski will send the report to the vettors who will verify that the requested change has been made. Dr. Sayler will draft the transmittal letter and the report will be submitted to ORD.

Mid-Cycle Review Subcommittees

Subcommittee Chairs

Global Change Research Mid-Cycle Review

Dr. Clifford Duke, Vice-Chair of the Global Change Research Mid-Cycle Review Subcommittee

Dr. Duke reported that the Global Change Research Mid-Cycle Review Subcommittee is chaired by Dr. Milton Russell. In addition to Drs. Russell and Duke, who serves as the Subcommittee Vice-Chair, the Subcommittee includes Rita Colwell, Patrick Mulholland, Ruth Reck, and Claudia Nierenberg. The Subcommittee had two conference calls prior to the face-to-face review meeting, which was held on January 23, 2008. Dr. Joel Scheraga, the NPD for Global Change Research, provided input during the meeting. The Subcommittee is on track to have a draft report to the Executive Committee for review at the May meeting. The members are working on their assigned sections of the report. Dr. Falk has agreed to be the vettor for this report. Dr. Duke asked if Dr. Russell will be invited to present the report at the May meeting. Ms. Kowalski replied that Dr. Russell would receive that invitation.

Land Research Mid-Cycle Review

Ms. Heather Drumm, DFO for the Land Research Mid-Cycle Review Subcommittee

Ms. Heather Drumm, the DFO for the Land Research Mid-Cycle Review Subcommittee, reported that the Subcommittee has been formed with the exception of a chair. She is waiting to hear from Charlie Menzie, who chaired the BOSC subcommittee that conducted the 2006 program review. She reported that Jim Clark, former Chair of the BOSC Executive Committee, and Dr. Haas are on the Subcommittee. The Subcommittee will have two conference calls before the face-to-face meeting in May, which will be held at a location to be determined.

Program Review Subcommittees

Subcommittee Chairs

Human Health Risk Assessment Research Program Review

Dr. George Daston, Chair of the Human Health Risk Assessment Research Subcommittee

Dr. Daston reported that the report is nearly completed. The program review was conducted at a 2 ½-day face-to-face meeting in Bethesda, Maryland, in mid-November. There were poster sessions that covered the LTGs and the Subcommittee got a good start on the report before leaving the meeting. There has been one conference call since the meeting to discuss the draft report. The report was revised following that

call but because the report did not include a summary section, an additional call to approve that section will be held in February. Overall, the Subcommittee thought it was an extremely strong program and it has received good marks from OMB. The program has clear cut, well-defined performance measures. There are annual requirements, such as 16 Integrated Risk Information System (IRIS) assessments. The program is meeting its goals and stretching its resources to do it. LTG 2 concerns updates of the Integrated Science Assessments and those are on a 5-year update/review cycle. The program and regional offices appear to be very satisfied with the program. LTG 3 involves the development of new tools and methodologies. Performance for this goal is less prescribed than for the other LTGs. The program is a leader in translating basic research to tools that can be used for risk assessment. Dr. Daston expects to submit the report to the Executive Committee for review at the May meeting.

Dr. Sayler asked who worked on IRIS and Dr. Daston responded that the work is done by an internal group.

Homeland Security Research Program Review

Dr. Gary Sayler, Chair of the Homeland Security Research Subcommittee

Dr. Sayler stated that the face-to-face review meeting for the Homeland Security Research Program will be held May 28-30, 2008 in Cincinnati, Ohio. Most of the security clearances for the members are in place but a few are still in progress. Conference calls have been scheduled for April 2, April 23, and May 7. Dr. Sayler said he expects to have the report ready for the Executive Committee to review at its September meeting.

Dr. Henderson asked how the Executive Committee members can review the report if they do not have security clearances. Ms. Kowalski replied that a small portion of the program review meeting will be closed to the public, but the materials reviewed in that session will not be included in the report. Those materials are being provided to the Subcommittee members to help them understand the program. The Subcommittee's report, which will be reviewed by the Executive Committee, will be a publically available document.

Standing Subcommittees

Subcommittee Chairs

Computational Toxicology Subcommittee

Dr. George Daston, Chair of the Computational Toxicology Subcommittee

Dr. Daston reported that the Computational Toxicology Subcommittee met December 17-18, 2007 in RTP. A letter report from that review will be completed in the near future. The Subcommittee will have a conference call in mid-February to review and approve the report. This was the third review conducted by the Subcommittee. These reviews evaluate aspects of the program, the way in which it functions, and the progress it is making. The program's strategy was to have products in the near term and long term and the program is beginning to bear fruit. One of the near term products is ToxCast, which is a way of compiling all that is known about a chemical (physical chemistry to test results) into a database that is searchable by many parameters. The program also is doing high throughput screening (HTS) on different cellular endpoints to augment what already is known. This program was alluded to in the presentations on the ORD responses to the Drinking Water and Ecological Mid-Cycle Review Reports. The Office of Pesticide Programs (OPP) and the Office of Pollution Prevention and Toxics (OPPT) are clients of the Computational Toxicology Research Program. The program is taking off in the area of informatics—developing large relational databases on toxicity studies and outcomes—to address relationships between chemicals and toxicity. The program is investigating what can be done to use computing power to ask new questions of the data available. ORD has hired some new experts who have contributed greatly to the program. One of the long-term products is the Virtual Liver. Toxic substances are metabolized by the

liver and this is a way of modeling what goes on in the liver, both pharmacokinetics and pharmacodynamics. This will be a model for other computer-based approaches in the future.

The program has strong outreach within the Agency. For example, the program created communities of practice that include members from across EPA. The program is collaborating with many others outside the Agency, including international organizations. Dr. Daston said that he has never seen a more productive group in EPA. The staff is enthusiastic and the program's work is impressive.

Dr. Daston concluded his remarks by stating that the letter report will be ready for the Executive Committee's review after mid-February.

Dr. Henderson noted that ToxCast sounds similar to CDC's toxicology profiles. Is there redundancy with those profiles? Dr. Daston agreed that there may be some redundancy, but he thinks the program's efforts take the toxicology profiles to the next level. Dr. Henderson asked if the program is working with NIEHS to take into consideration the metabolization of carcinogens. She pointed out that screening assays do not take metabolism into account. This appears to be a clear area for collaboration. Dr. Daston replied that the program is working with NIEHS and this is definitely on their radar screen. He added that the HTS data from the National Toxicology Program (NTP) are being fed into ToxCast.

Dr. Sayler asked Dr. Henderson if she would serve as a vettor for the letter report and Dr. Henderson agreed.

NCER Standing Subcommittee
Dr. Martin Philbert, Chair of the NCER Standing Subcommittee

Dr. Philbert said that the Subcommittee had addressed only one of several potential charge questions that NCER wanted the Subcommittee to address. Dr. Philbert will discuss with NCER what should be done next. Ms. Kowalski pointed out that when the Subcommittee was formed, NCER had a different Director. The new Director is working to figure out how he wants to utilize the Subcommittee.

Dr. Sayler asked if there were any questions about the standing subcommittee activities. He asked if the Laboratory/Center Directors can contact Subcommittee members directly. Ms. Kowalski replied that it is permissible under FACA for the Laboratory/Center Directors to contact the Subcommittee members as individuals but not as a member of an advisory group.

NERL Standing Subcommittee
Dr. Ken Demerjian, Chair of the NERL Standing Subcommittee

Dr. Demerjian reported that the NERL Standing Subcommittee met face-to-face December 11-12, 2007 in RTP. There was one conference call before this meeting. In addition to Dr. Demerjian who chairs the Subcommittee, the Subcommittee includes Steven Bartell, Joseph DePinto, Douglas Dockery, and Michelle Frey. Before that initial call, Dr. Demerjian and the DFO had talked with Dr. Larry Reiter, the Director of NERL, about possible charge questions. NERL then developed the draft charge for the Subcommittee.

Dr. Demerjian received comments from all of the Subcommittee members and assembled them into a draft report. The draft was discussed by the Subcommittee during a conference call that was held January 18, 2008. The comments from that call need to be incorporated into the report. The focus of the review was the exposure framework guidelines. Dr. Demerjian emphasized to the Subcommittee members that they were not charged to evaluate the laboratory but to provide advice. He mentioned that NERL has been trying to get this framework completed for quite some time. He commented that the Subcommittee

members all thought it was a worthwhile exercise for NERL because providing exposure assessments is a primary charge of that laboratory.

The report is approximately 20 pages with a 2-page summary. Dr. Demerjian expects to have a second draft of the report within 2 weeks. He mentioned that the minutes for the meeting were comprehensive and quite good and he encouraged the Executive Committee members who want to learn more to read the minutes.

Dr. Sayler said that he was supposed to vet this report, but given his new responsibilities as Chair, he has asked Dr. Falk to serve as the vettor, and Dr. Falk has agreed.

Referring to an issue that came up following Dr. Gray's remarks earlier in the day, Dr. Sayler commented that the standing subcommittees may be more involved in ORD's strategic planning efforts. Dr. Demerjian agreed, with respect to NERL, but not ORD as a whole. Dr. Daston noted that the Computational Toxicology Subcommittee definitely has been involved in the strategic planning for the National Center for Computational Toxicology (NCCT). Dr. Philbert agreed that the NCER Standing Subcommittee also was involved in strategic planning.

SAB Activities

Dr. George Lambert, SAB Liaison to the BOSC

Dr. George Lambert, SAB Liaison to the BOSC, stressed that the SAB would welcome the input of the BOSC on any of its activities. He mentioned that there is considerable cross-over—Drs. Henderson and Swackhamer are on the SAB; Drs. Jim Johnson and Jim Clark, former BOSC Chairs, also are on the SAB. Dr. Sayler serves on the SAB Drinking Water Committee.

Referring to the FY 2008 Operating Plan for the EPA SAB, which was distributed to the Executive Committee members, Dr. Lambert highlighted two activities in the final stages—the Preparedness for Manmade and Natural Disasters and the Strategic Directions of EPA's Research and Development Program. The reports for both of these activities are being finalized. For the Natural Disasters effort, the SAB met with industry representatives to learn from their experiences. For the Strategic Directions of EPA's Research and Development Program, the SAB met with ORD staff in RTP. The NPDs presented their strategic plans for the future and then they sat down with the SAB members to discuss these plans. A 5-year plan for each major program was presented and the SAB members provided feedback. This was an excellent meeting and it looks like this may become an annual event for the October meeting. Dr. Lambert noted that the meeting to review the FY 2009 budget will take place February 28-29, 2008. The FY 2009 budget went from EPA to the White House and now it is the President's budget with very little opportunity for change. He noted that to have a real impact on the budget, the SAB would have to be providing input long before the budget reaches this stage. Dr. Granger Morgan, the Chair of the SAB, testifies before Congress about the budget each year and although some believe that this does have some impact on EPA's budget, it would be better to try to impact the budget earlier in the process.

He mentioned that Dr. Swackhamer is leading the SAB review of the ROE. Dr. Lambert asked if she wanted to say a few words about that review. Dr. Swackhamer reported that the final draft of the report is in the hands of the committee and then it will be submitted to the SAB for a vote.

Dr. Lambert pointed out that the CASAC has a very busy schedule. He noted that Dr. Henderson chairs CASAC and he asked if she had any comments. Dr. Henderson said that reviewing NAAQS on a 5-year cycle is keeping the CASAC very busy. There is a new review process, some of which is working well and some of which is not.

Referring to the FY 2008 Operating Plan for the EPA Advisory Council on the Clean Air Compliance Analysis, Dr. Lambert thought that the BOSC members might be interested in the Clean Air Act Benefits and Costs (1990-2020) Study report.

Dr. Lambert commented that Dr. Granger Morgan has made a difference as the SAB Chair. There is more interaction between the SAB and the Agency and the Board is providing more input on EPA's strategic planning.

Dr. Sayler asked if the BOSC could participate in the annual strategic planning meeting in October. Dr. Lambert thought Vanessa Vu would be open to that suggestion. Dr. Swackhamer agreed that the BOSC's participation would be beneficial because her participation on the BOSC helped her contribute more to that meeting. The SAB makes sure that the emphasis matches the budget but BOSC participation would enhance the input provided to EPA. Dr. Lambert agreed that the BOSC should be included. Dr. Lambert also invited the BOSC members to attend the February budget review meeting. That meeting will focus on the ORD research programs and four cross-cutting areas—climate change, sensitive human and ecological populations, urban sprawl, and environmental disasters.

Dr. Swackhamer asked why there were only standing subcommittees for three of the ORD laboratories/centers. Ms. Kowalski explained that the Computational Toxicology Subcommittee was formed when the NCCT was established to provide advice as that Center started up. About 2 years ago, the concept of standing subcommittees for the laboratories and centers was discussed through a joint session of the BOSC and the ORD Executive Council. Both agreed it was worthwhile to do this. The BOSC agreed to implement two pilot standing subcommittees and ORD was asked to determine which laboratories/centers would be selected. ORD thought it would be useful to pilot one laboratory subcommittee and one center subcommittee. The BOSC and ORD need to determine if there is interest in continuing the current standing subcommittees or if there is any interest in expanding to other laboratories/centers. Dr. Demerjian said he would like to get feedback from NERL and NCER concerning the usefulness of these subcommittees.

Before adjourning the meeting for the day, Dr. Sayler reminded the members to read the rating tool guidance handout before tomorrow morning. The meeting was adjourned at 4:50 p.m.

FRIDAY, JANUARY 25, 2008

Dr. Sayler called the meeting to order at 8:35 a.m. He quickly reviewed what was accomplished yesterday. The Executive Committee reviewed and approved the Sustainability Research Program Review Report as well as the EDCs Research Mid-Cycle Review Report and the Air Research Mid-Cycle Review Report. The NCER Standing Subcommittee Report will be revised and reviewed and approved by the Executive Committee during a future conference call.

Rating Tool Guidance

Dr. Gary Sayler, Chair of the BOSC Executive Committee

Dr. Sayler confirmed that the members had received the two handouts on rating tool guidance. One handout focused on program reviews and the other on mid-cycle reviews. The guidance describes the scope of the reviews, how to organize the reports, and how to apply the rating tool. Both documents make it clear that the format of the report is the decision of the subcommittee chair. The guidance offers suggestions to aid the subcommittees in conducting these reviews. Dr. Sayler stressed that a mid-cycle report can include recommendations if the subcommittee wants to do so.

Dr. Swackhamer commented that a mid-cycle review is primarily a progress check. She thought the process for a mid-cycle review had gotten rather cumbersome given that it was a quick review to confirm

that the program is on track. The BOSC prepares and submits a report to which the program then has to respond, which increases the workload for both sides. For a mid-cycle review, could the subcommittee just orally report to the program managers that things are going well?

Dr. Sayler agreed that the mid-cycle reviews may be causing an unnecessary burden on the programs. If a mid-cycle review is straightforward, such a simplified approach may be warranted. In some cases, however, the program has changed substantially and recommendations may be appropriate. Dr. Swackhamer acknowledged that there are differences among the reviews, but she was still concerned about the added burden that the mid-cycle reviews place on the programs.

Dr. Henderson commented that for the mid-cycle review of the Air Research Program, the program was doing well and the subcommittee tried to minimize the work for the program as much as possible. The report was short and easy to write. She suggested adding a sentence at the end of the report to state that the program is performing well and no response from the program is necessary. She asked if there is a requirement that ORD respond to the reports. Ms. Kowalski explained that, although there is no legal requirement for ORD to respond, the Executive Committee Chair at the time she became the DFO asked ORD to provide a response to BOSC reports. It is also an EPA best practice to respond to committee recommendations. If there are no recommendations in the report, ORD would not have to respond or could provide a very brief response back to the BOSC. Ms. Kowalski commented that she finds the responses to be very helpful because she has to track and enter into a database each year how many recommendations were given by the BOSC and how many of the recommendations were responded to by ORD.

Dr. Duke pointed out that the charge questions for the mid-cycle reviews often go beyond a simple progress review. For example, some reviews have included requests for input regarding customer surveys and others for input concerning performance metrics. These are appropriate questions and ORD needs guidance on these issues, but they go beyond a simple assessment of progress since the program review. Dr. Weiss asked if the Executive Committee should work with ORD to develop a common set of charge questions. Does the rating question have to be included? Dr. Sayler responded that every mid-cycle review will include a request for an overall rating. He reminded the members that this rating is not focused on technical issues, but on progress.

Dr. Weiss supported Dr. Henderson's suggestion of adding a sentence that indicates to ORD that no response is required.

Dr. Sayler mentioned that during yesterday's discussion, it was suggested that the report could emphasize points rather than make recommendations. Is it better to specify recommendations? Ms. Kowalski responded that if there are recommendations and they are not specifically identified, it makes it more difficult for ORD to respond to the BOSC's advice.

Dr. Haas said that the Executive Committee could determine whether a response to a mid-cycle review report was warranted and could indicate that in the transmittal letter from the chair. Dr. Teichman said that ORD would respond to anything in the report that was written as a recommendation; responses to suggestions would be at the discretion of the NPD.

Dr. Swackhamer acknowledged the importance of a paper trail of response. Perhaps the BOSC could indicate the level of response required (e.g., a written response and presentation or just a written response). Dr. Teichman said that this decision is for the Executive Committee; ORD will respond as the BOSC requires. Dr. Sayler asked if the members supported the idea of adding a qualifier regarding ORD's response at the end of each report. Dr. Demerjian asked if the qualifier would come from the subcommittee or the Executive Committee and Dr. Henderson pointed out that the Executive Committee would have to approve it regardless. She thought this was a good idea for mid-cycle review reports. Dr.

Sayler noted that this does not decrease the workload of the program in preparing for the mid-cycle reviews. It will only decrease the effort at the end of the process.

Dr. Demerjian commented that the complexity of the mid-cycle review is dependent to some degree on the original program review. If the program review included 22 recommendations, then there will be more work to prepare for the mid-cycle review. He agreed with the qualifier suggestion, stating that the BOSC should not add to the program's burden. Dr. Weiss suggested lightening the workload by spacing the reviews further apart. Ms. Kowalski replied that the reviews are scheduled so that the BOSC reviews take place before the PART reviews. In the first year, the program reviews were conducted in a very tight timeframe. Now, the reviews have been spaced out so that the workload is more manageable. The PART reviews are on a 5-year cycle so the BOSC reviews are on a similar cycle.

Dr. Daston noted that, as a matter of principle, the BOSC reviews are not linked to the PART reviews. The BOSC is trying to help EPA improve its programs. The fact that the BOSC reports are useful submissions for PART reviews is good, but that is not their primary purpose. Perhaps the BOSC should think about why it conducts these reviews. What is their purpose? He was concerned about developing strict guidelines for conducting these reviews. The BOSC needs flexibility in these reviews to determine if the program is meeting its customers' needs. Dr. Daston agreed that the BOSC should not make additional work for EPA or the Executive Committee, particularly if it is not helpful to ORD. The guidance for the reviews is fine, but it should be left as suggestions to allow for flexibility.

Dr. Teichman said that his presentation later today would touch on many of these issues. He suggested that the Executive Committee may want to table this discussion until that time.

Dr. Sayler mentioned that the suggestion for adding a statement about the level of ORD response required into the reports could be added to the guidance. Dr. Duke asked if he could share the guidance with the Global Change Research Mid-Cycle Review Subcommittee. Dr. Sayler confirmed that it was okay to share it with subcommittee members. Ms. Kowalski explained that she intended to add the guidance to the Subcommittee Chair Handbook to help the chairs prepare for these reviews.

Dr. Sayler noted that there is a distinct difference between applying the rating tool for a program review and applying it for a mid-cycle review. For a program review, the rating tool is applied to each LTG and for a mid-cycle review it is applied to an overall rating of progress. He asked if the BOSC is expected to do an overall rating for a program review. Ms. Kowalski replied that the rating tool was intended to be applied only to the LTGs for program reviews. One subcommittee did include an overall rating for the program in its report, but that was not requested in the charge.

Dr. Sayler stated that the guidance does a good job of laying out the expectations for these reviews and the types of materials the subcommittee will be provided. He asked if there were any other comments on the guidance. Dr. Haas said that when he reads the reports he does not get much sense of what the program is about. He would appreciate some background information on the program and its LTGs, APMs, and APGs. This could accompany the report when it is submitted to the Executive Committee for review.

Dr. Henderson agreed that it is difficult to evaluate the report without that information, but she did not want to include more detail than necessary in these reports. Dr. Haas suggested that the subcommittee chair work with the NPD to develop a 2-3 page summary of the program to accompany the report.

Dr. Falk sympathized with Dr. Haas' comments. He often has not known enough about the programs to evaluate the reports. A summary of the program would be helpful. Ms. Kowalski mentioned that during one of the early conference calls for each subcommittee, there is a presentation on the program. ORD could provide a copy of that presentation to the Executive Committee along with the report to be

reviewed. The MYP also may be helpful. Perhaps she could work with the BOSC to develop a 2-page template. ORD then could pull the relevant material into the template. This would make the information provided to the Executive Committee consistent across the various programs. This 2-pager could accompany the draft report when it is sent to the Executive Committee for review.

Dr. Sayler commented that much of this information is available online but the Executive Committee members must take the time to review it. Dr. Haas said he found the EPA Web Site difficult to use. Dr. Sayler responded that the BOSC Web Site, however, is very easy to use.

Dr. Swackhamer thought the 2-page template was a good idea. Dr. Henderson agreed and thanked Ms. Kowalski for offering to do that. She mentioned that many of the difficulties in reviewing the Sustainability Report probably stemmed from a lack of familiarity with the program.

Dr. Swackhamer asked if the Executive Committee needed to approve the guidelines. Dr. Sayler replied that a vote was not necessary; the discussion was intended to get input from the members. Dr. Swackhamer said there was a paragraph in the guidance that puzzled her. In the second paragraph under Appling the BOSC Long-Term Goal Rating on page 2, there is the following sentence: "All really means all." This was confusing to her. Dr. Sayler explained that this comes from the definitions of the ratings. It is referring to the fact that the program must be meeting all of its goals and not most of its goals. Dr. Swackhamer asked that Dr. Sayler's explanation be added to the guidance to make this clear.

Workgroup Update

Dr. Gary Sayler, Chair of the BOSC Executive Committee

Dr. Sayler referred to the handout entitled Draft Scope of Work for BOSC Executive Committee Workgroups. Dr. Jim Clark, the former Executive Committee Chair, drafted this handout for the consideration of the members. Are there areas that the BOSC wants to examine that are not covered by the current reviews? He asked for the members' comments.

Dr. Philbert asked about the first item under Workgroup 1, which indicated that the workgroup would review ongoing nanotechnology review and assessment efforts. What is the intent of reviewing a review? Dr. Sayler replied that he was not sure of the context and could not elaborate. Perhaps Dr. Clark was referring to reviews of nanotechnology that are conducted outside of EPA. Dr. Teichman did not know Dr. Clark's intent, but thought he could be referring to the federal agency review to figure out ORD's future role. He did not think it was meant to be a review of a review; it was probably a review of a research strategy.

Dr. Sayler commented that the handout was prepared to spur discussion about workgroup activities. Dr. Daston thought nanotechnology would be a good topic for the BOSC to review to make sure ORD is supporting the Agency in the decisions that must be made. He is concerned, however, about the BOSC generating products for which there is no customer. Perhaps the BOSC could provide EPA a list of topics for which the Board could provide advice to ORD and then ask EPA to identify those topics for which they would like input. Dr. Sayler suggested forming a workgroup to think about this list and what the Board could offer ORD. It might be helpful to hold a workshop to inform the BOSC about additional issues that are of concern to ORD.

Dr. Henderson shared Dr. Daston's concerns about preparing a product for which there is no customer. She thought it would be useful to review ORD's nanotechnology program. Dr. Sayler commented that the workgroup may be able to identify a niche for EPA that will help the Agency get more of the federal funding devoted to nanotechnology. He noted, however, that ORD already may be doing this by interacting with other federal agencies. Dr. Demerjian stated that there are multiple ways that nanotechnology enters EPA's arena. The workgroup could identify the major players and look at EPA's

role in defining the impact of nanotechnology in terms of exposures. The workgroup could help ORD define the issues that the Agency needs to address. There are some papers on this topic that might be useful.

Dr. Weiss noted that these workgroup efforts would involve the BOSC in the strategic planning efforts of ORD as was mentioned earlier in the discussion following Dr. Gray's presentation. Dr. Falk commented that the Agency has developed a research strategy for nanotechnology. Perhaps the workgroup could review that strategy and inform the Executive Committee about what the BOSC could do to help ORD. Another option would be for EPA to brief the Executive Committee on the strategy and then discuss the options for a workgroup. Dr. Lambert supported that approach. He thought it would be beneficial to have EPA brief the BOSC about the Agency's nanotechnology efforts relative to those of other agencies. Dr. Demerjian suggested getting input from the program offices to find out what they see as potential problems in the future. Dr. Daston mentioned that EPA has identified an expert on regulating nanotechnology and he works in OPPTS. He is working now to figure out how EPA will regulate nanotechnology.

Dr. Sayler agreed that nanotechnology is a good topic for the BOSC; he will request a presentation on the Agency's nanotechnology efforts at an upcoming Executive Committee meeting. Following that presentation, the Executive Committee will consider the feasibility of forming a workgroup to address this topic. Dr. Teichman mentioned that Jim Willis and Jeff Morris probably would be involved in that presentation to the BOSC. These are the individuals who wrote the paper that was mentioned earlier. Dr. Philbert stated that the NRC is forming a committee to review the Federal Government's nanotechnology responsibilities. Less than 3 percent of the federal dollars allocated to nanotechnology are spent on health and environmental effects.

Dr. Sayler said he would like to develop a list of potential topics for workgroups. He asked that members send their suggestions to him and Ms. Kowalski.

Workgroup 2 on the handout was suggested by Dr. Haas. The focus of this workgroup would be to determine if there are mechanisms used by other agencies that might be used by EPA to acquire research that is relevant to the Agency's needs. Dr. Haas mentioned that the Agency relied more heavily on the use of cooperative agreements years ago.

Dr. Weiss commented that the NIH R12 grants allow the federal agency to have more say in the direction of the research. It is a grant mechanism that functions more like a contract. For example, the federal project officer can strategize with the principal investigator about the direction of the research. There are other mechanisms that EPA may want to consider. The government has tried a variety of mechanisms—some of which have failed and others of which were quite successful.

Dr. Sayler asked for suggestions on how to inform the Executive Committee about these alternative mechanisms. Dr. Haas proposed pooling the knowledge of the members and reaching out to others to acquire the needed information, which would be incorporated into a summary report. The BOSC then can work with Dr. Teichman and other ORD managers to determine if any of these mechanisms could be useful to EPA.

Dr. Sayler asked if Drs. Haas and Weiss would be interested in serving on this workgroup. Both indicated their interest. Dr. Weiss pointed out that this topic is related to the earlier discussion about NCER and the need to fund research that is responsive to the Agency's needs.

Dr. Demerjian asked if the BOSC would entertain other venues for workgroups and Dr. Sayler affirmed that it would.

Dr. Sayler proposed that the workgroup prepare a white paper on the different vehicles used by other agencies. Dr. Henderson asked for clarification of the product. Would this be an information paper? Would it include recommendations? Dr. Haas responded that the content of the paper would depend on what the workgroup found when gathering information from other agencies. Dr. Swackhamer asked if the product would be a letter report that recommended to ORD the consideration of additional mechanisms. Dr. Sayler envisioned that the workgroup would develop a paper for the BOSC Executive Committee, which would be used to determine if the topic warrants preparation of a letter report. Dr. Henderson was concerned that it might appear to be self-serving if the BOSC suggests mechanisms for EPA to fund more extramural research. Dr. Sayler thought that could be handled by acknowledging the fact that Board members receive extramural funding from federal agencies. Dr. Henderson asked if there was a major problem concerning extramural mechanisms that needs to be addressed. Dr. Lambert suggested looking at the STAR Program and EPA's future plans for that program. Dr. Sayler thought the workgroup would go beyond what EPA is doing to get a broader view of mechanisms used by the Federal Government. Dr. Philbert asked if there are specific Agency needs or gaps. Dr. Sayler noted that a number of BOSC review reports have mentioned that narrowness of EPA's RFAs and the Agency's limited ability to fund research that supports EPA's needs. Dr. Haas said that he was not comfortable critiquing what the Agency is doing now; he simply wanted to inform EPA about other possible mechanisms.

Dr. Falk asked if the first sentence under Workgroup 2 in the handout is true. The sentence reads, "BOSC program reviews have reported that existing ORD approaches to writing competitive solicitations on certain topical areas often fail to generate the quality or quantity of responses or specific focus of benefit to EPA program areas." Does EPA agree with this statement? Dr. Teichman replied that EPA makes an extraordinary effort to encourage the best scientists to apply for grants. If the Executive Committee members think differently, then he would like to hear their perceptions.

Dr. Demerjian commented that STAR RFAs are targeted for one-shot deals. They are not designed to create a foundation to support ORD by building up the required expertise. With targeted RFAs, if the grant does not yield a product in 3 years, the researcher will not get another grant. Many physical scientists completely ignore EPA's RFAs because the grants will not support their programs.

Dr. Duke suggested that before pursuing this effort, the workgroup should look at the program reviews and determine if that first sentence is true.

Dr. Sayler proposed that Drs. Haas and Weiss prepare a paper exploring funding mechanisms used by other federal agencies. They also should look at the program reviews to see if this is an issue for ORD. The paper will be submitted to the BOSC Executive Committee and it will be used to determine if this warrants more investigation or preparation of a letter report. He asked if the paper could be prepared before the September meeting.

Dr. Henderson did not like the first sentence that had been referenced by Dr. Falk. She thought the white paper should define the problem, if there is one, and then the Executive Committee should consider whether the topic is worth pursuing. Dr. Haas withdrew his name from the workgroup based on the scope described by Dr. Sayler. He did not want this to become an exercise of looking through past program reviews. Dr. Sayler replied that this issue has been noted in several reviews and then asked Dr. Weiss for her input. Dr. Weiss thought the workgroup should focus on mechanisms used by other agencies that might be helpful to EPA. This information could be beneficial to ORD. Dr. Falk commented that such an approach would avoid Dr. Henderson's concerns and might be helpful to ORD. It also moves away from assessing the truth of the sentence in the handout. Dr. Sayler postponed the remainder of this discussion to move on to the next item on the agenda.

National Children's Study

James Quackenboss, EPA/ORD/NERL

James Quackenboss provided a brief overview of the National Children's Study (NCS) and described EPA's role and involvement in the NCS and the Agency's review of the NCS Research Plan.

The NCS is the largest long-term study of children's health and development ever to be conducted in the United States. The study will include approximately 100,000 children to allow the study of important but less common outcomes. It is a longitudinal study of children, families, and their environment from before or early pregnancy to age 21. Environment is defined broadly to include chemical, physical, behavioral, social, and cultural. It provides a platform for children's environmental health research.

The aims of the NCS are to identify potential environmental effects (harmful, harmless, and helpful). For important conditions and diseases of children, it will consider potential preventable causes. The study is hypothesis driven; the hypotheses were developed by a large group from the scientific community. A key concept is that exposure begins with pregnancy. With n ~ 100,000, the NCS has the power to study high-priority conditions. Gene environment interaction will be examined and it will serve as a national resource for future studies.

Mr. Quackenboss provided some examples of the priority exposures and priority health outcomes for the NCS. The priority exposures encompass physical environment (e.g., housing quality, neighborhood), chemical exposures (e.g., pesticides, metals), biologic environment (e.g., infectious agents, endotoxins, diet), genetics (e.g., interaction between environmental factors and genes), and psychosocial milieu (e.g., families, socioeconomic status, institutions, social networks). The priority health outcomes include pregnancy outcomes (e.g., preterm, birth defects), neurodevelopment and behavior (autism, schizophrenia, learning disabilities), injury (e.g., head trauma), asthma (e.g., asthma incidence and exacerbation), and obesity and physical development (e.g., obesity, diabetes, altered puberty).

The next slide described the process for selecting the study sample. EPA helped to lead deliberation of the options for sample selection, which resulted in the decision to use a national probability sample. Mr. Quackenboss then presented a map indicating the locations of the study sites across the United States, including 2007 locations, Vanguard locations, and 2008-2010 locations.

There will be 13 face-to-face contacts over the 21-year study period. The contacts will be more frequent early in the study. Between visits, there will be ongoing data collection by phone, e-mail, etc. The 13 face-to-face contacts occur at the first trimester, second trimester (study ultrasound), third trimester, birth (place of delivery), 6 and 12 months, and 3, 5, 7, 9, 12, 16, and 20 years.

From FY 2000-2006, the NCS was funded at $50 million/year from the existing budgets of NIH, EPA, and CDC. One major focus during this period was the study design, methods development, and infrastructure—the study plan was developed and the Coordinating Center and seven Vanguard Centers were established. Also from FY 2000-2006, there were 30 workshops, 20 scientific reviews, and 19 pilot studies; hypotheses and exposure and outcome measures were developed; and protocol is in progress.

In FY 2007, the funding increased to $69 million, which allowed the NCS to prepare for recruitment and enrollment at the Vanguard Centers ("Pilot" phase), develop the Information Management System (IMS), and establish additional centers for expanded locations toward the full sample.

The funding for FY 2008 is $110.9 million. This allows the NCS to prepare the centers to begin the Main Study (Wave 1), develop the Manual of Operations for the Main Study, and fund the current and recruit additional centers (Waves 2 and 3). The President's budget for FY 2009 is due in February 2008. It is

uncertain what the NCS budget will be, but to conduct the full study, the NCS needs $3 billion/year from FY 2008-2034.

Mr. Quackenboss presented a timeline for the NCS. From 2000-present, the focus was pilot studies and methods development. In 2004, the Study Design and Study Plan were developed and Requests for Proposals (RFPs) were posted for the Coordinating and Vanguard Centers. In 2005, the initial contracts for the Coordinating and Vanguard Centers were awarded. In 2007, the first phase of the study protocol was completed and the Wave 1 Study Center contracts were awarded. In 2008, the study will be reviewed by OMB, peers, and the Institutional Review Boards. Also in 2008, there will be procurements for repository and laboratory services. In 2008-2009, contracts will be awarded for additional centers and locations (Waves 2 and 3) and, pending funding and necessary approvals, the pilot cohort at the Vanguard Centers will begin. From 2009-2014, the full study at the Vanguard Centers and additional centers will begin. The first study results will become available in 2010 (methods, pilots, preliminary findings), and in 2015, the full data set for outcomes of pregnancy will be available.

EPA has been involved from the very beginning with the NCS as a full partner with the Department of Health and Human Services (DHHS). The National Institute of Child and Human Development (NICHD) leads a consortium of federal agencies (EPA, CDC, and NIH) to plan and implement the study. Each agency has four representatives on the Interagency Coordinating Committee (ICC) and EPA currently chairs the ICC. The Executive Steering Committee includes the EPA and CDC members from the ICC.

For the NCS, EPA has provided advice and expertise on environmental exposures, measurements, methods, and quality assurance; health outcomes associated with environmental exposures; and aggregate exposures and cumulative risks (interactions). EPA scientists participated on the NCS Working Groups and conducted method development/evaluation studies that were jointly reviewed and sponsored with CDC and NIH. EPA's grant initiatives support research that is applicable to the NCS (e.g., Children's Centers, early indicators, and exposure classification models). EPA's ORD has an *ex officio* member on the NCS Federal Advisory Committee and EPA scientists have worked on detail to the NCS Program Office.

Mr. Quackenboss presented a diagram of the organizational structure of the NCS that highlighted the points of EPA involvement. He noted that EPA has contributed people who have influenced the direction and development of the study to a much greater extent than would be expected by the funding the Agency has provided.

There are a number of benefits of EPA's participation in the NCS. EPA can access the results of a study that directly links human exposure to health status, thus yielding better estimates for children. It offers the unique potential to identify long-term effects of early (fetal, neonatal) exposures. The NCS provides EPA with a rich database for risk assessment. Longitudinal exposure measures can be linked to long-term health effects of early exposures. It also provides the opportunity to assess community-level cumulative risks. The NCS provides EPA access to national data linking source-exposure-effect, which may help evaluate the consequences/effectiveness of regulatory decisions. It leverages EPA resources for children's environmental health research and it demonstrates EPA's strong commitment to ensure that children are adequately protected.

The NCS will address important issues for environmental risk assessment, such as: (1) contribution of multiple exposures to childhood disease, (2) long-term health effects from early exposures, (3) factors that alter susceptibility (e.g., specific genetic polymorphisms, immune deficiencies), (4) disparities in health outcomes (e.g., race, ethnicity, poverty, housing, income, nutrition), and (5) results to reduce reliance on uncertainty factors and defaults in risk assessments to protect children.

There was an EPA-wide review of the NCS Research Plan. High-level officials, including the EPA Administrator, were briefed in the period from April-June 2007. The Research Plan was sent to all EPA program and regional offices for review in July 2007. Conference calls to discuss the plan were held in August and September 2007, with comments due by September 30. The comments were consolidated and summarized and a teleconference was held in December to prioritize the recommendations.

The background, study design, and measures in the Research Plan describe what will be done and why. The plan will undergo peer review (NRC), agency review, and public comment. The Research Plan is approximately 600 pages and it is available on the NCS Web Site (http://www.NationalChildrensStudy.gov). Volume 1 of the plan is in three parts. Part 1 is the background, conceptual framework, hypotheses, and preliminary studies; Part 2 is the study design, outcome measures, exposure measures, analyses, and human subjects protection; and Part 3 is management and support. Volume 2 of the plan provides supporting documents.

The review of the Research Plan provided EPA the opportunity to: examine the NCS Research Plan for relevance to the Agency's mission, identify potential uses of the data and results, and identify refinements that improve the relevancy to EPA's mission. The review also allowed EPA to identify potential integration with Agency research efforts and priorities, as well as potential adjunct studies and long-term interactions. Mr. Quackenboss explained that adjunct studies are those that use the NCS data, participants, or their samples. These studies are outside of the "core" NCS protocol and are generally supported with non-NCS funding. The NCS Program Office coordinates the review and approval of adjunct studies, and the participation of NCS investigators is a requirement. The benefit of adjunct studies is that they enhance the breadth, depth, and value of the NCS, and could provide EPA an opportunity to use the NCS as a platform to address Agency-specific needs.

The prioritized list of recommendations from the EPA review of the Research Plan will be transmitted to the NCS Program Office. This transmittal will include suggestions to improve the plan that have minimal impact on cost/burden, additional analyses and data elements needed for the EPA mission (low burden), and additional data collections (adjunct study concepts and ideas that increase both cost and burden). The suggestions will increase the relevancy of the study to EPA's mission and risk assessment process. EPA will work with NCS to encourage changes and will identify Agency and other sponsors to support additional measures and adjunct studies.

There are a number of opportunities for future EPA scientific involvement in the NCS. EPA scientists can work with the NCS on adjunct studies (e.g., exposure validation studies, near-roadway air pollution measurements and modeling to support exposure assessment). EPA scientists also can work with the NCS to develop and/or evaluate innovative methods and technologies. EPA's scientists can continue to provide overall scientific leadership, advice, and oversight to the NCS. In addition, EPA scientists will be able to conduct analyses and modeling of NCS data (as a national probability-based sample).

The EPA members of the ICC are James Quackenboss (NERL), Liz Blackburn (Office of Children's Health Protection and Environmental Education), Nigel Fields (NCER), and Sally Darney (NHEERL), and Kevin Teichman is the EPA lead designee.

Mr. Quackenboss said that more information on the NCS is available on the Web at http://www.NationalChildrensStudy.gov. There is a link on the home page for the Research Plan and interested parties can join the listserv for news and communications on the study by clicking on the link for "E-Updates."

Dr. Sayler thanked Mr. Quackenboss for his presentation and asked if there were any questions. Dr. Haas asked why the study was not looking at biological exposures from tap water. Mr. Quackenboss replied that the study is looking at biological exposures in air to allergens, endotoxins, etc. Many other agents

would be measured at the level of blood tests. He did not have any information on pathogens in water but pediatricians involved in the NCS have suggested that water is not likely to be the cause of most intestinal infections in children. The primary cause is hand transmission of infectious agents.

Dr. Falk commented that CDC is engaged in the NCS. The Biomonitoring Laboratory is heavily invested in it and is providing advice on the biological measurements to be done. He asked if there is a way to factor in the quality of health care to assess the progress of asthma. Mr. Quackenboss responded that the study will consider access to healthcare, utilization of healthcare, and the use of medications. He noted that the study is not a substitute for healthcare.

Dr. Daston asked about the storage of samples and the types and numbers of samples. What samples can be stored? Mr. Quackenboss answered that the NCS is looking for repositories that could handle both biological and environmental samples. The intention is to collect many of the samples (e.g., urine, blood, breast milk, house dust, soil) and prepare them for long-term archival. This will allow researchers to examine the samples more efficiently if an outcome is rare. Multiple locations are needed to store the large number of samples for a substantial period of time. The NCS is relying on the expertise of CDC and NIH in developing the repositories.

Dr. Lambert said that the study was intended to identify the causes of autism, asthma, and other outcomes. He was concerned that there could possibly be so much noise in the data that the link to exposures may not be apparent, and about limitations of any study in its ability to address the original questions. Have the study hypotheses been refined or improved? Mr. Quackenboss responded that the Vanguard Centers were asked to provide experts to help update and refine the hypotheses. The new hypotheses are similar to the original ones but they have been updated to ensure they are current and testable. Mr. Quackenboss was confident that the study will be able to answer most of the original questions. He added that new hypotheses will be generated and addressed as the study moves forward. In terms of limitations, he mentioned that one concern is being able to collect information and samples in a consistent manner in multiple locations and over time, and noted that the Coordinating Center is responsible for training study staff to collect these data.

Additional AA/ORD Remarks

Dr. Kevin Teichman, Acting Deputy Assistant Administrator for Science, EPA/ORD

Before giving his presentation on performance material requests, Dr. Teichman provided some remarks that Dr. Gray did not have time to share yesterday. ORD recognizes that there are three vacancies on the Executive Committee and Dr. Gray has asked the BOSC and the ORD Science Council to suggest potential members. Dr. Gray also is very close to announcing the new Deputy Assistant Administrator for Science for ORD.

Dr. Teichman reported that three ORD staff members—Joel Scheraga, Tom Barnwell, and Anne Grambsch—were among those who received the 2008 Nobel Peace Prize, sharing it with the other members of the Intergovernmental Panel on Climate Change. In December 2007, EPA received the Federal Government's highest honor for strong and effective management—the President's Quality Award for Management Excellence. EPA was honored for its success in integrating management systems identified under the President's five government-wide management initiatives. Dr. Teichman noted that the BOSC helped the Agency win that award.

The EPA Science Forum will be held May 20-22, 2008 in Washington, DC. It will highlight innovative technologies that are key to environmental and economic progress. Dr. Teichman invited the BOSC members to participate in the Forum, which usually has an attendance that exceeds 1,000.

Dr. Teichman wanted to mention two important meetings that had taken place. The Deputy Regional Administrators from all 10 regions met with George Gray, Lek Kadeli, and Kevin Teichman to identify what they needed from ORD to help them make the decisions they must make in the field that impact the environment. The second meeting Dr. Teichman mentioned was the meeting of the SAB with ORD NPDs and other managers to discuss the strategic directions for ORD research. The meeting was held in RTP so that many ORD scientists could attend. The NPDs presented their proposed research directions for the next 5 years and then participated in discussions with the SAB members. This was a good meeting that focused only on the science and not the budget; ORD would like to continue this process in the future. The budget review meeting with the SAB will be held February 28-29, 2008.

ORD is working on the consolidation of several MYPs in an effort to save time and resources of both ORD and the BOSC. ORD is considering how best to accomplish this, given that there is some tension within the programs because it may reduce the visibility of programs that no longer have their own MYP. ORD plans to seek the BOSC's advice on this issue in the future.

The research planning discussions for the 2010 budget took place yesterday morning. It actually started with the October strategic directions meeting with the SAB. Those discussions will inform ORD's planning deliberations. Dr. Teichman is unable to share any of the details on that budget until it becomes public information in February.

ORD has spent considerable time on the Administrative Efficiencies Project (AEP), which consolidates travel and other administrative functions to save resources for the scientific programs.

Dr. Teichman mentioned the NAS efficiency report, noting that he has a slide on that in his presentation. On January 31, 2008, the NRC announced the upcoming release of a report that recommends changes in how the government evaluates the efficiency of research at EPA and other agencies. The report indicated that efficiency should be considered only one part of evaluating a program's quality, relevance, and effectiveness. Evaluations of "process efficiency" should focus on research inputs and outputs, while assessments of "investment efficiency" should gauge how well R&D fits into an agency's strategic plan.

The draft Nanotechnology Research Strategy is finally ready for external review, which will take place in April 2008. The strategy identifies EPA's niche in nanotechnology and its development was coordinated with the efforts of other federal agencies. If the BOSC decides to form a workgroup to address nanotechnology, the members would be provided the strategy as a starting point for them to go forward.

Dr. Lambert asked if EPA was working to inform the public about the EPA staff members winning the Nobel Peace Prize, as well as the President's Quality Award for Management Excellence. It is important that the American public hear this information. Dr. Teichman responded that communications is a high priority and the Agency has issued press releases and posted information on the Web. Dr. Lambert mentioned that the SAB found the October strategic planning meeting to be very instructive and would support this becoming an annual event. Dr. Teichman said that he has talked with Dr. Granger Morgan about making this an annual meeting. Dr. Weiss mentioned that during yesterday's meeting, the Executive Committee discussed the possibility of being included in that SAB meeting. Dr. Teichman replied that the BOSC would be welcome to attend the meeting. Dr. Sayler indicated that he plans to send a letter to Dr. Vanessa Vu about the possibility of having the BOSC Executive Committee participate in that meeting.

BOSC Performance Material Requests

Dr. Kevin Teichman, Acting Deputy Assistant Administrator for Science, EPA, ORD

Dr. Teichman stated that the purpose of the BOSC program reviews are to conduct retrospective and prospective reviews of ORD's research programs, evaluating each program's relevance, quality,

performance, and scientific leadership. In addition, the review includes a rating for the program's past performance for each LTG.

The purpose of the mid-cycle review is to assess progress on ORD commitments made regarding recommendations from the last BOSC program review. ORD uses BOSC feedback from both types of reviews to plan, strengthen, and implement its research programs.

The materials typically provided for a BOSC program review include: FACA background materials; ORD orientation materials; technical background materials, including an MYP, ORD and program technical materials and overviews, posters, staff biosketches, and bibliographies; and performance rating materials, including program performance measures and goals, a bibliometric analysis, the MYP APG chart, partner survey data, and partner use of ORD research presentations.

The typical materials provided for a BOSC mid-cycle review include: FACA background materials; technical background materials, including an updated MYP (or synopsis), progress report, bibliography, and the previous program review report and ORD response; and performance rating materials, including program performance measures and goals, an updated bibliometric analysis, an updated MYP APG chart, and updated partner survey data.

Dr. Teichman identified a number of steps to ensure successful reviews. ORD and the BOSC Executive Committee should agree on the best uniform performance measurement approaches, with the understanding that approaches may evolve over time. ORD and the BOSC Executive Committee should agree on a common set of performance measures if possible. Additional measures may be needed that are program specific. ORD should provide the BOSC subcommittees with **only** the materials the subcommittees need to perform their reviews.

With respect to technical background information and performance rating materials, Dr. Teichman asked the Executive Committee if ORD was providing too much information. He also asked if all the information ORD is providing is valuable. Are the bibliometric analyses, partner document analyses, and surveys of partner opinions and use of ORD products useful?

Some of the additional bibliometric analyses requested during the BOSC reviews include: stratified intramural versus extramural analyses, analyses per FTE, and benchmark values for comparison (across ORD and across other agencies). Dr. Teichman said he did not agree with the stratified intramural versus extramural analyses because when he asks the NPDs to identify the needed research, he wants them to consider it an integrated program—he does not want the NPD to focus on what laboratories and centers can do the work. Research planning should be divorced from which laboratory or center will do the work. In addition, the demands on intramural scientists differ from those on extramural scientists; for example, intramural scientists are required to provide technical support to the program and regional offices. Is this stratified analysis really useful for the review? He also questioned the valued of analyses per FTE because some projects are more resource intensive than others so the productivity per FTE would be quite different among programs even though each of the programs is very important to the Agency. Is an analysis per FTE really useful? With respect to benchmarking for comparison, Dr. Teichman asked if EPA should match any other agency. He said that the state of the research program would have to come into play before ORD could consider such bibliometric add-ons to be important. He added that research conducted in 2002, 2003, and 2004 might be responsible for a 2005 publication so a year-by-year analysis probably would not yield useful information. Dr. Teichman proposed that ORD continue to provide analyses of citation rates and journal impact factors and provide program budget and FTE trend data to enable within program comparisons.

Dr. Teichman noted that partner surveys to assess partner use of ORD products and satisfaction must be done carefully. They could be designed to obtain feedback by program (MYP) or by LTG. ORD could

use a refined survey instrument with both common questions across ORD and customized questions for each program. The survey would be distributed to representative samples of partners from EPA program and regional offices. He warned that the scores from those individuals in the program and regional offices whose projects were not addressed probably will be lower. Perhaps the survey should be distributed to those at the highest level in an office because those individuals are the ones who worked with ORD to prioritize the research based on the available budget. The surveys should be timed to inform the BOSC reviews, which means they may have to be done on a 2-year cycle. Dr. Teichman cautioned that this may overload the partners with too many requests for feedback.

Dr. Teichman stated that the measure of ORD's success is the achievement of environmental outcomes. This means that individual and local environmental decisions are informed by sound science, EPA regional offices implement national policies in scientifically defensible ways, and EPA program offices set national policies based on strong science. Additional measures of ORD's success are quality, relevance, and performance (PART) and efficiency (NAS Efficiency Study).

The NAS Efficiency Study found that EPA is leading the effort to determine the most appropriate approaches for measuring the efficiency of federal research programs. The NAS collected information from OMB, EPA, other federal agencies, and private entities about how these organizations would measure efficiency. The report on the study will be available in spring 2008, and it will include findings about current approaches, conclusions, and recommendations. Although he cannot be certain, Mr. Phillip Juengst, who was involved with the NAS study, anticipated that the report will recommend that efficiency and effectiveness should be assessed jointly through independent peer review. Annual efficiency measures should track those areas of importance/concern identified through the peer review. The implication for ORD and the BOSC is that there may be a more explicit focus on efficiency in review charge questions in the future.

Dr. Teichman concluded by identifying some steps to ensure successful BOSC reviews. ORD and the BOSC Executive Committee should agree on the best, uniform performance measurement approaches. They also should agree on a common set of performance measures, if feasible, with the understanding that additional performance measures may be program specific. ORD should provide the materials the subcommittees need to perform their reviews, but only what they need. He noted that the goal is to optimize the use of ORD and BOSC members' resources.

Dr. Sayler thanked Dr. Teichman for his presentation and said he was not certain how to measure efficiency. Will EPA provide the BOSC some metrics that can be used to measure efficiency? Dr. Teichman responded that the BOSC will be provided the NAS study report, which should be helpful. Mr. Juengst stated that the study has examined what other agencies use for efficiency measures and some examples are cost/publication and variance in achievement of milestones and cost. There are pluses and minuses to each one so he hopes that the NAS will narrow down the list of metrics and provide the BOSC with some guidance on assessing quality, performance, and efficiency. Dr. Henderson asked if the metric of efficiency is productivity per unit dollar or per unit time. Mr. Juengst replied that cost per outcome is used by OMB; however, OMB and others are aware that it is very difficult for research organizations to use such metrics. Some agencies are using time as a proxy for cost. Hopefully, the NAS report will identify the metric that makes the most sense.

Dr. Henderson agreed with Dr. Teichman that the stratification of intramural and extramural publications is not necessary. It is important to have an integrated research program. Dr. Demerjian asked if EPA, as a regulatory agency, will have one set of metrics that will be used for the entire Agency or if ORD will have a different set of metrics. Dr. Teichman expects that ORD will be evaluated differently from the rest of the Agency. Mr. Juengst agreed.

Noting that outcome is the bottom line, Dr. Lambert asked if ORD is quantifying the importance of the outcome; for example, graying at a slower rate versus reducing the incidence of asthma. Mr. Juengst commented that the program offices are being asked to capture the outcomes and ORD is looking at the extent to which partners are using ORD's products. Dr. Lambert noted that the distribution of information to the public to prevent or improve disease states could have a big impact.

Dr. Duke said he liked the idea of partner citing of ORD research. When will that be implemented? Mr. Juengst responded that this had been done manually using a contractor for the Drinking Water Research Program. Over the past 6-12 months, NCER has been working to develop a tool that will automate the search process. The tool is being tested now and probably will be ready this spring. The tool will search regulatory documents on EPA's Web Site and identify how many times these documents cite ORD research publications.

Dr. Daston commented that he was uncomfortable with the efficiency analysis. ORD is providing a foundation for making better decisions. He was concerned that the tool may distract ORD from producing the information the Agency needs. He compared the two programs that he recently reviewed—the Human Health Risk Assessment (HHRA) Research Program and the Computational Toxicology Research Program. The first program is mature and the latter is in its infancy. It is not appropriate to use the same measures for these two programs. The Computational Toxicology Program may yield some great tools, but that is years away. He is concerned that efficiency analysis will pull the Agency away from long-term, higher risk research. Dr. Teichman responded that, like the rating tool scores need an accompanying narrative, the efficiency analysis also may need to be accompanied by a narrative.

With respect to the materials requested by the subcommittees for BOSC reviews, Dr. Sayler commented that the subcommittee chair should control what is requested from EPA and should weigh each request by asking EPA what is readily available. He noted that the chairs should not request anything that is not necessary to do the reviews.

Dr. Swackhamer suggested that the Executive Committee discuss some of the proposals Dr. Teichman made in his presentation. She agreed that there should be a common set of metrics with the ability to add program-specific measures. She did not have enough experience with these reviews to comment about the amount of materials provided to the BOSC. She asked if the other members could comment on this. Dr. Sayler stated that a subcommittee should not request something unless it is absolutely necessary. Dr. Swackhamer thought the list of materials Dr. Teichman cited was adequate. The MYPs are necessary but they always seem to be in draft form. Dr. Teichman replied that he has no problem with the MYP being a draft as long as it is publicly available. He commented that the PART reviews drive the timing of the MYP updates. The MYPs are living documents and will be updated regularly. The most important point is that there is an MYP available to the public.

Dr. Sayler commented that there are reasons that the subcommittees have requested stratified intramural and extramural bibliometric analyses. It helps the subcommittee analyze the in-house core capabilities and expertise and the impacts of a decline in intramural or extramural funding. Dr. Sayler added that although he understands the reasons for this request, he does not necessarily think it is essential for the review.

Dr. Sayler asked if there were any additional questions for Dr. Teichman. Dr. Swackhamer asked about the next steps. Should the BOSC work with ORD to develop common metrics? Dr. Teichman said that the Executive Committee can provide advice to the subcommittees that they carefully consider their requests for information and make sure that the information is really necessary. Dr. Teichman has received complaints from the NPDs because different subcommittees request different information.

Dr. Teichman, Mr. Juengst, and Ms. Kowalski will report back to the BOSC on the data mining tool at the next meeting.

Future Discussions/Future Business

Dr. Gary Sayler, Chair of the BOSC Executive Committee

Dr. Sayler indicated that the Executive Committee did not complete its discussion of Workgroup 2 and would continue that discussion at the next meeting. Dr. Daston liked the idea of the BOSC suggesting topics for review but he thought the Executive Committee should spend more time discussing potential topics and prioritize them as a group. The list then could be submitted to Drs. Teichman and Gray and they can provide feedback to the BOSC regarding those items that would be most helpful to ORD. Dr. Sayler agreed that this would be a good approach. Dr. Demerjian thought it might be good to select a topic that was multimedia and multipollutant, such as biofuels. The Executive Committee could review how EPA is working across the Agency to address this issue. Dr. Sayler thought biofuels would be an appropriate topic. He suggested discussing this more at length at the September meeting. Dr. Teichman mentioned that Dr. Gray serves on the Biomass R&D Board and 62 EPA employees volunteered to help develop the biofuels research strategy. He agreed this is a very important topic and the President has set ambitious goals to reduce the nation's reliance on fossil fuels.

Dr. Sayler reminded the members that the next Executive Committee meeting was scheduled for May 5-6, 2008, in Gulf Breeze, Florida. The meeting will be 2 full days. The date for the September meeting has not been determined yet but it usually is held in the first 2 weeks of September. Dr. Lambert mentioned that the SAB meets at the end of September. That meeting may be of interest to the BOSC because it will focus on science advisory roles. Ms. Kowalski will contact the members to determine their availability for the September meeting.

Dr. Sayler asked Dr. Henderson to serve as the vettor for the Computational Toxicology Subcommittee Report and asked Drs. Falk and Weiss to vet the Global Change Research Program Mid-Cycle Review Report. He then asked Dr. Falk to serve as the vettor for the NERL Subcommittee Letter Report. Drs. Henderson, Falk, and Weiss agreed.

Dr. Sayler mentioned that it may be necessary to schedule a conference call in mid to late March. This call will focus on the review and approval of the NCER, NERL, and Computational Toxicology Reports. Dr. Henderson said that she is unavailable the week of March 16.

At the May meeting, the Executive Committee will review the Global Change Report and the HHRA Report.

Dr. Swackhamer asked if the date for the May meeting could be changed to May 6-7, so that the members would not have to travel on Sunday. The members found the date change acceptable so the meeting was changed to May 6-7, 2008.

In closing, Dr. Sayler stated that the Executive Committee will discuss Dr. Teichman's suggestions for a common set of performance measures and the best, uniform performance measurement approaches at a future meeting. He then adjourned the meeting at 12:10 p.m.

Action Items

- Dr. Swackhamer will make the requested revisions to the EDCs Mid-Cycle Review Report and submit it to Ms. Kowalski.

- Ms. Kowalski will distribute the final EDCs Mid-Cycle Review Report to Dr. Daston who will confirm that the changes requested by the Executive Committee have been made to the report.

- Dr. Sayler will prepare the transmittal letter for the EDCs Mid-Cycle Review Report and submit it along with the final report to Ms. Kowalski.

- Dr. Henderson will examine the Air Research Mid-Cycle Review Report, particularly the apparent recommendations on page 10, lines 5-6; page 11, lines 7-9; page 15, lines 4-7; and page 15, line 39. She will reword these as suggestions or highlight them as recommendations. She also will incorporate the editorial comments from Drs. Ryan and Giesy.

- Dr. Swackhamer will provide a sentence regarding the recommendation that the Air Research Program provide information for the ROE to Dr. Sayler (she also will add a corresponding recommendation in the SAB report on the ROE review). Dr. Sayler will incorporate that sentence into the transmittal letter for the Air Research Mid-Cycle Review Report. Dr. Sayler will submit the final report and the transmittal letter to Ms. Kowalski.

- Dr. Philbert agreed to revise the NCER Standing Subcommittee Letter Report in response to the Executive Committee's comments.

- Drs. Duke and Haas will provide some suggestions to Dr. Philbert concerning how to revise the NCER Standing Subcommittee Letter Report.

- Dr. Philbert will submit the revised NCER Standing Subcommittee Letter Report to Ms. Kowalski for distribution to the Executive Committee.

- Dr. Landis will revise the Technology for Sustainability Program Review Report by adding the recommendation that the Agency should continue to develop a sustainability definition and create a framework for developing metrics for sustainability as part of this research program. He will send the revised report to Ms. Kowalski and she will send it to Dr. Demerjian to confirm that the changes have been incorporated.

- Dr. Sayler will prepare a transmittal letter for the Technology for Sustainability Program Review Report and submit it and the final report to Ms. Kowalski.

- Dr. Henderson agreed to serve as the vettor for the Computational Toxicology Subcommittee Letter Report.

- Dr. Falk agreed to serve as the vettor for the NERL Standing Subcommittee Letter Report.

- Drs. Falk and Weiss agreed to vet the Global Change Research Program Mid-Cycle Review Report.

- Ms. Kowalski will work with Dr. Sayler to develop a 2-page template to capture information from the presentation on the program and the MYP that will accompany the draft report when it is

submitted to the Executive Committee for review. This 2-pager is intended to provide the members background information on the program.

- ✍ Ms. Kowalski will revise the rating tool guidance to clarify the sentence on page 2: "All really means all." The revision will explain that this refers to the fact that the program must be meeting all of its goals and not most of its goals.

- ✍ Executive Committee members should send their suggestions for potential workgroup topics to Dr. Sayler and Ms. Kowalski. There will be time to discuss these and other suggested workgroups at the September meeting and a list of potential workgroups will be developed and submitted to Drs. Teichman and Gray for their consideration and feedback.

- ✍ Dr. Teichman, Mr. Juengst, and Ms. Kowalski will report back to the BOSC on the status of the data mining tool at the next meeting.

- ✍ Ms. Kowalski will schedule a conference call in mid to late March to review and approve the revised NCER Standing Subcommittee Letter Report, the NERL Standing Subcommittee Letter Report, and the Computational Toxicology Letter Report.

- ✍ The date for the May Executive Committee meeting was changed to May 6-7, 2008.

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BOARD OF SCIENTIFIC COUNSELORS

37th EXECUTIVE COMMITTEE FACE-TO-FACE MEETING
AGENDA
January 24-25, 2008

Renaissance M Street Hotel
1143 New Hampshire Avenue, NW
Washington, DC 20037
Tel: (202) 775-0800

Thursday, January 24, 2008

8:00 a.m. – 8:30 a.m.	Registration	
8:30 a.m. – 8:45 a.m.	Welcome and Introductions - Review of Sept. Mtg. Minutes - Overview of Agenda	Dr. Gary S. Sayler, Chair, Executive Committee
8:45 a.m. – 9:00 a.m.	BOSC DFO Remarks - Administrative Issues	Ms. Lori Kowalski, Office of Research & Development (ORD)
9:00 a.m. – 9:30 a.m.	AA/ORD Remarks	Dr. George Gray, Assistant Administrator for ORD
9:30 a.m. – 10:15 a.m.	ORD Response to BOSC Safe Pesticides/Safe Products (SP2) Report	Dr. Elaine Francis, National Program Director, ORD
10:15 a.m. – 10:30 a.m.	Break	
10:30 a.m. – 12:00 p.m.	ORD Responses to BOSC Mid-Cycle Reports: - Human Health - Eco - Drinking Water	ORD National Program Directors Dr. Hugh Tilson, NIEHS Dr. Rick Linthurst, ORD Dr. Audrey Levine, ORD
12:00 p.m. – 1:00 p.m.	Lunch	
1:00 p.m. – 2:30 p.m.	Subcommittee Draft Reports: (1) Endocrine Disrupting Chemicals (EDC) Mid-Cycle Draft Report Presentation - Discussion	Dr. Deborah Swackhamer, Subcommittee Chair Executive Committee
	(2) Particulate Matter/Ozone (Air) Mid-Cycle Draft Report Presentation - Discussion	Dr. Rogene Henderson, Subcommittee Chair Executive Committee

	(3) NCER Standing Subcommittee Draft Letter Report Presentation - Discussion	Dr. Martin Philbert, Subcommittee Chair Executive Committee
2:30 p.m. – 2:45 p.m.	Public Comment	
2:45 p.m. – 3:15 p.m.	Break	
3:15 p.m. – 3:45 p.m.	Subcommittee Draft Reports (Cont'd) - Revised Technology for Sustainability Program Review Draft Report Presentation - Discussion	 Dr. Wayne Landis, Subcommittee Vice-Chair Executive Committee
3:45 p.m. – 4:45 p.m.	Subcommittee Updates: <u>Mid-Cycle Review Subcommittees:</u> - Global Change Mid-Cycle - Land Mid-Cycle <u>Program Review Subcommittees:</u> - Human Health Risk Assessment Program Review - Homeland Security Program Review <u>Standing Subcommittees:</u> - Computational Toxicology - National Center for Environmental Research (NCER) Next Steps - National Exposure Research Lab (NERL)	 Dr. Cliff Duke, Subcommittee Vice-Chair TBD Dr. George Daston, Subcommittee Chair Dr. Gary Sayler, Subcommittee Chair Dr. George Daston, Subcommittee Chair Dr. Martin Philbert, Subcommittee Chair Dr. Ken Demerjian, Subcommittee Chair
4:45 p.m. – 5:15 p.m.	BOSC Performance Material Requests	Dr. Kevin Teichman, Acting Deputy Assistant Administrator for ORD
5:15 p.m.	Adjourn	

Friday, January 25, 2008

8:30 a.m. – 9:00 a.m.	Rating Tool Guidance	Dr. Gary Sayler, Chair Executive Committee
9:00 a.m. – 9:30 a.m.	Workgroup Update Executive Committee	Dr. Gary Sayler, Chair
9:30 a.m. – 10:00 a.m.	ORD Update	Dr. Kevin Teichman, Acting Deputy Assistant Administrator for ORD
10:00 a.m. – 10:30 a.m.	National Children's Study	Dr. James Quackenboss, ORD
10:30 a.m. – 10:45 a.m.	Break	
10:45 a.m. – 11:15 a.m.	SAB Activities	Dr. George Lambert, SAB Liaison to the BOSC
11:15 a.m. – 12:00 p.m.	Future Discussion/Future Business - Meetings in May/Sept 2008 - Mid-Cycle Reviews in 2008 - Future Work	Dr. Gary Sayler, Chair, Executive Committee
12:00 p.m.	Adjourn	