

**38th EXECUTIVE COMMITTEE FACE-TO-FACE
MEETING SUMMARY**

**U.S. Environmental Protection Agency
Office of Research and Development
National Health and Environmental Effects Research Laboratory (NHEERL)
Gulf Ecology Division
1 Sabine Island Drive
Gulf Breeze, Florida 32561**

May 6-7, 2008

TUESDAY, MAY 6, 2008

Welcome and Introductions

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

Dr. Gary Saylor, Chair of the Executive Committee of the Board of Scientific Counselors (BOSC) called the meeting to order at 8:03 a.m. He welcomed everyone to the 38th face-to-face meeting of the BOSC Executive Committee. He noted that the agenda for the meeting was quite full and mentioned that all of the members were present with the exception of Dr. John Giesy who was participating by telephone and Dr. Ken Demerjian who would be joining the meeting later this morning. He noted that Dr. Martin Philbert would only be able to attend on May 7.

Review of March Conference Call Summary

Dr. Saylor asked the BOSC members if there were any comments on the March 26, 2008, Conference Call Summary. He pointed out that the draft summary was in the notebook. This conference call included approval of a number of reports for transmittal to EPA's Office of Research and Development (ORD). Hearing no comments on the summary, Dr. Saylor called for a motion to approve the summary. Dr. Rogene Henderson moved that the summary be approved; her motion was seconded by Dr. Deborah Swackhamer. The summary was unanimously approved by the BOSC Executive Committee.

Overview of the Agenda

Dr. Saylor referred members to the agenda in the notebook, pointing out that Lorelei Kowalski, the Designated Federal Officer (DFO) for the BOSC Executive Committee, will follow his overview with brief remarks about Federal Advisory Committee Act (FACA) issues. At 8:30 a.m., Dr. Gilbert Omenn, who chaired the National Academies' Committee on Evaluating the Efficiency of Research and Development Programs at the U.S. EPA, will describe the National Research Council's (NRC) January 2008 report entitled, "Evaluating Research Efficiency in the U.S. Environmental Protection Agency." Dr. Omenn will be presenting via videoconference. Following this presentation, Phillip Juengst from EPA's ORD will discuss ORD's implementation plans as a result of the NRC report. Dr. Saylor commented that the BOSC review process already incorporates many of the recommendations in the NRC report.

In reviewing the agenda, Dr. Sayler noted that Dr. George Gray, Assistant Administrator for Research and Development, would be unable to attend and Lek Kadeli, ORD Deputy Assistant Administrator for Management, would present the AA/ORD's remarks. Similarly, Dr. George Lambert, EPA Science Advisory Board (SAB) liaison to the BOSC, would not be attending the meeting and Dr. Martin Philbert, BOSC National Center for Environmental Research (NCER) Standing Subcommittee Chair, would not be present for today's meeting. There are, however, materials in the meeting notebook about their presentations on the SAB activities and the new steps for the NCER Standing Subcommittee, respectively.

Dr. Sayler reviewed a few agenda changes. He said he had a teleconference tomorrow afternoon from 2:00 – 4:00 p.m. He asked Dr. Henderson to chair the meeting in his absence and she agreed. He noted that Dr. Bill Benson, Director of the Gulf Ecology Division, will be providing the ORD Update in lieu of Jeff Morris. Also on tomorrow's agenda is the presentation on nanotechnology by Randy Wentzel, ORD Land National Program Director (NPD). Dr. Sayler mentioned that the CD in the notebook contains the nanotechnology white paper as well as information on this program.

BOSC Designated Federal Officer Remarks

Ms. Lorelei Kowalski, DFO, ORD, EPA

Ms. Kowalski, DFO for the BOSC Executive Committee, welcomed the BOSC members and other participants to the meeting. She stated that the BOSC is chartered as a Federal Advisory Committee and subject to FACA rules and regulations. As the DFO for the BOSC Executive Committee, she is responsible for ensuring that BOSC activities comply with FACA; thus, this meeting was open to the public and time was designated on the agenda for public comment. Although there were public requests for the meeting agenda, no one has offered to make any public comments; nevertheless, at the designated time on the agenda, there will be a call for public comments. An ORD 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.

As required by FACA, a 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-2008-0268. The *Federal Register* notice and the agenda were available to the public on the docket. Ms. Kowalski mentioned that the Government Ethics Office prepared a pamphlet "To Serve with Honor," which is a guide on the ethics rules for Special Government Employees (SGEs) serving on FACA committees. She made the guide available to the BOSC members and provided them the Web URL for the guide.

Each BOSC member should have received a notebook of materials by mail as well as additional materials by e-mail prior to the meeting. In addition to the notebook, each member should have received a copy of the entire NRC Report. The meeting notebook contains several items including: a summary of the NRC Report, three reports to be vetted by the BOSC, meeting presentations, and homework and voucher work sheets.

Ms. Kowalski distributed handouts and tables that listed the activities of the BOSC and its subcommittees. The work load chart described the Fiscal Year (FY) 2008-2009 projects of the BOSC and their status. Another table identified the BOSC subcommittee, workgroup, and vettor activities for each Executive Committee member. The subcommittee status table identified which activities are ongoing and which had been completed. She noted some new activities on this table such as the upcoming Human Health and Endocrine Disrupting Chemicals (EDCs) program reviews and Science and Technology for Sustainability mid-cycle review in late 2008 and early 2009. Dr. Falk has agreed to chair the Human

Health Subcommittee; however, no chairs have been identified for the two other subcommittees. In 2009, there also will be an Air Research Program Review, a Drinking Water Program Review, and several more mid-cycle reviews, so there will be a lot of activities next year.

Ms. Kowalski explained that Dr. Gray was unexpectedly called to Capitol Hill and expressed his apologies for not being able to attend the meeting. Likewise, Dr. Kevin Teichmann will not be participating because he is out of the country on leave. Lek Kadeli will be filling in for Dr. Gray and he is expected to arrive later this morning. In Dr. Teichmann's absence, Dr. Benson will be available throughout the meeting to answer any questions concerning ORD. Ms. Kowalski noted that the teleconference line would be open throughout the two-day meeting and Dr. John Giesy would be participating by phone.

Ms. Kowalski commented that EPA implemented a new travel system in January 2008 and travel for several members for this meeting was processed under the new *GovTrip* system. A new travel information form for use by BOSC members is included in the meeting notebook. Members are asked to use the form and check all of the relevant information regarding travel and send this information to Troy Rutkofske, who is responsible for coordinating the travel arrangements. Once information is entered into *GovTrip*, e-mails are generated automatically. She warned travelers to expect a lot of e-mail correspondence regarding their travel. Fortunately, many of these *GovTrip* e-mails can be ignored because many of them are generated because an approval is made in the EPA travel system. This e-mail traffic indicates that the travel is being processed. Ms. Kowalski recommended that travelers look for the *GovTrip Sabre* travel notification because this provides the traveler's itinerary. She noted that Mr. Rutkofske was provided contact information for BOSC members' assistants so they will be receiving the notifications as well.

With the *GovTrip* system, travelers are able to login online and sign their travel vouchers. Instructions for logging into the *GovTrip* system are available in the notebooks under the voucher sheet tab. Unfortunately, Dr. Philbert continues to have problems with *GovTrip* and he has not been paid for his January 2008 travel yet. Ms. Kowalski stressed that members notify her if they are experiencing problems with the *GovTrip* system. Ms. Kowalski also explained that the government has "city-pairs" airline flight agreements; if city-pair flights are not booked, a separate justification is required. Ms. Kowalski noted that selection of a different carrier to accumulate frequent flyer miles is not adequate justification for taking an alternative, non-city-pair flight. Basically, there are fewer pre-negotiated flights available now.

Dr. George Daston said he also experienced some problems with *GovTrip*. Ms. Kowalski noted that the new system limits the airline flight options for government travelers. She explained that Dr. Daston's flight arrangements would have required him to exit and re-enter security to make his connecting flight. Fortunately, he noticed this problem before traveling and there was time for it to be corrected. Dr. Carol Weiss asked about the *GovTrip* "key code," stating that she did not think she received one. Ms. Kowalski was not familiar with the key code but said she would look into it.

Ms. Kowalski reminded the members and other attendees to sign in at the registration desk if they had not done so already. Again, she noted that the telephone line would be open during both days of the meeting.

National Research Council of the National Academies: January 2008 Report on Evaluating Research Efficiency in the U.S. EPA

Overview of the Report "Evaluating Research Efficiency in the U.S. Environmental Protection Agency"

Dr. Gilbert S. Omenn, Chair, Committee on the Efficiency of Research and Development Programs at the U.S. Environmental Protection Agency, National Academies

Dr. Omenn asked the BOSC members if they had received the prepublication copy of the National Academies Report, a six-page summary of the report, some additional charts, and copies of his slides. Dr. Saylor confirmed that the members had received these items. Dr. Omenn mentioned that the final report would be available in late June 2008.

Dr. Omenn referred the BOSC members to Appendix F, page 78, in the Report that includes the “Draft Proposed Charge Questions for BOSC Reviews” and page 80 that lists the summary assessment charge questions for each BOSC program review. These BOSC questions on page 80 refer to efficiency metrics such as the quality of the program’s research products and the speed at which the products are being produced and the milestones are being met.

Dr. Omenn stated that the National Academies study addressed the following issues:

- ✧ How best to evaluate the efficiency component of performance for R&D at EPA, for response with the Program Assessment Rating Tool (PART) to the Office of Management and Budget (OMB).
- ✧ How to overcome conflict between EPA and OMB.
- ✧ How to achieve a level playing field across the federal agencies and the OMB branches for use of the PART, which is a descendant of the Government Performance Results Act (GPRA).

Dr. Omenn indicated that, under PART, OMB is interested in reviewing all Agency programs with a common framework; he noted that this is more complicated for R&D and basic science programs than for many other agency functions. In conducting the study, the National Academies Committee was sensitive to the conflict between EPA and OMB on PART reviews. By scheduling the initial workshop for this study and having it co-hosted by EPA and OMB on April 10, 2007, the Committee helped facilitate a compromise for at least 1 year. The workshop was attended by more than 20 agencies and was very productive. The third issue was addressed through presentations by many agencies, as well as comments from leaders of industrial R&D programs.

Dr. Omenn’s third slide identified the four questions addressed by the National Academies study:

- ✧ What efficiency measures currently are used for R&D programs?
- ✧ Are these measures sufficient? Are they outcomes-based?
- ✧ What principles should guide development of efficiency measures?
- ✧ What measures should be used specifically for EPA’s basic and applied R&D programs?

His fourth slide described the following classes of metrics:

- ✧ Inputs—funds, personnel, facilities, and consumables that support R&D.
- ✧ Outputs—deliverables (research findings, presentations, publications, exposure methods developed and validated, and facilities built or upgraded).
- ✧ Outcomes—improved knowledge or timely scientific assessment (intermediate); lives saved, habitats protected (ultimate).

Dr. Omenn distinguished between intermediate and ultimate outcomes, emphasizing that the BOSC reviews should focus on intermediate outcomes. The key is determining whether the intermediate outcomes of improved knowledge or timely scientific assessments are used in the regulatory process.

The four main findings of the National Academies study were:

1. Assessment of efficiency must be in the context of quality, relevance, and effectiveness.
2. Efficiency comprises “investment efficiency” or portfolio management, and “process efficiency.”
3. None of nine current metrics is sufficient or outcomes-based; expert review panels are the best mechanism to evaluate both investment and process efficiency.
4. The same methods and standards should apply across all federal agencies—and OMB itself should “part” PART.

With respect to the first finding, the Committee found that efficiency should be integrated into PART and not considered as a separate review component. In the second finding, the Committee determined that both types of efficiency (investment and process) can be evaluated by an expert review panel. None of the nine metrics listed in the National Academies report handout “Common Types of Metrics Proposed by the Agencies, Many of Which Have Been Accepted by OMB”, which was in the BOSC meeting notebook, is sufficient or outcome-based. The Committee concluded that an expert review panel is the best method to evaluate both investment and process efficiency.

Dr. Omenn stated that the key to research efficiency is good planning and implementation. EPA and its ORD have a sound multi-year strategic planning architecture, with annual assessment of progress against milestones. He noted that good portfolio management requires adjustments in response to new science, new priorities, and budgetary realities.

The Committee was encouraged to see research milestones in each of the five goals of the EPA Strategic Plan. Nevertheless, he noted that all research portfolios need timely adjustments, not simple check offs in response to Agency requirements.

All metrics proposed by OMB or accepted by OMB have been based on relatively simple inputs and outputs of the research-management process. Ultimate outcome-based metrics are neither achievable nor valid for this process. EPA’s difficulties in complying with PART Questions 3.4 and 4.3 about efficiency stem from inappropriate demands for outcome-based metrics. Dr. Omenn noted that an “ineffective” PART score can have serious adverse consequences.

Dr. Omenn explained that the points OMB attributes to PART Questions 3.4 and 4.3 can constitute the difference between an acceptable and unacceptable overall PART score. He added that PART Question 4.3 can only be answered if an acceptable score is achieved on PART Question 3.4.

Expert review panels are broader than peer review panels; they include stakeholders, especially downstream users. The use of such panels was recommended by previous Committee on Science Engineering and Public Policy (COSEPUP)/National Academies committees. ORD, the SAB, and the BOSC have gained experience and credibility with such panels for pesticides and drinking water program reviews. Dr. Omenn stated that the Committee recommended proactive use of such panels by EPA and the BOSC.

Dr. Omenn expressed interest in the suggestions BOSC members might have for further use of these panels. Committee members were particularly interested in how process and investment efficiency might be measured by the BOSC in the future.

Dr. Omenn's next slide outlined the rollout of the National Academies report.

- ✧ April 2007 Workshop—a summary of the workshop is included in the report.
- ✧ January 2008—briefings at EPA, OMB, Office of Science and Technology Policy (OSTP), and House and Senate Committees.
- ✧ February 2008—additional briefing for ORD.
- ✧ April 10, 2008—forum convened by EPA and OMB with numerous federal agencies.
- ✧ May 6, 2008—ORD/BOSC meeting.
- ✧ Publication of the formal report is imminent.

Appendix B in the report (page 54) provides a summary of the April 2007 Workshop. Dr. Omenn noted that a summary of the April 10, 2008 forum has been posted on the EPA Web Site.

Dr. Omenn pointed out that the National Academies Committee that worked on the study included three former EPA senior managers and three former OMB senior managers, including him. Committee members included: Linda Fisher, former EPA Deputy Administrator, and Drs. Paul Gilman and Bob Huggett, former EPA ORD Assistant Administrators, as well as T.J. Glauthier and Sally Katzen, who were former senior OMB officials. The Committee also included representatives from U.S. Congressional staff, state agencies, and nonprofit organizations.

Dr. Omenn ended his presentation by asking if the BOSC members had any questions about the study.

Dr. Saylor began the discussion by noting that the SAB has been involved in the review of the National Academies report with respect to PART and some BOSC members provided input to the study. In addition, a former BOSC Chair reviewed the draft report and several BOSC members also serve on the SAB. Therefore, there are a number of BOSC members who are familiar with the report. Dr. Saylor explained that both the SAB and the BOSC use expert review panels but each board conducts its panels differently. Dr. Saylor asked if the BOSC members had any questions for Dr. Omenn.

Dr. Daston appreciated the fact that the National Academies report endorsed the BOSC approach for efficiency measurement, which includes the use of metrics accompanied by narrative statements. He questioned the need, however, for differentiating between the two types of efficiency—process and investment. Is this something that OMB requires or will require?

Dr. Omenn responded that this will be the central PART question in the future. At the April 10, 2008, meeting convened by EPA and OMB, there was a lot of enthusiasm about the complementary nature of these two types of efficiency. With various input and output documentation available, the need for measuring process efficiency has been recognized by many federal agencies. For example, building a research facility or conducting bioassays allows the use of the “earned value management” (EVM) quantitative tool that can track aspects of research programs against milestones (i.e., matching budget and time schedules). Similarly, grant processing can be tracked via EVM. As outlined in Appendix F of the National Academies report, the BOSC apparently seeks this type of information in its reviews—the speed and timeliness of scientific assessments needed for National Ambient Air Quality Standards (NAAQS), for example. A lot of these data and their evaluation reflect the measurement of the research management process. An equally important question, however, is how does the research agenda match the Agency's Strategic Plan or Multi-Year Plan, and what judgments or changes to the research agenda are made in light of new science and/or environmental priorities? A combination of process efficiency and investment

efficiency measurement is needed. This latter efficiency is more difficult to measure because it reflects scientific judgment.

Dr. Omenn commented on the BOSC's use of the four adjectives—exceptional, exceeds expectations, meets expectations, and not satisfactory—to evaluate EPA research program progress (see page 80 in the National Academies report). He considered this an odd four-point scale because an exceptional assessment would be very difficult to meet; exceeds expectations could reflect “hard” or “soft” grading; it is critical to achieve at least a meets expectations rating; and not satisfactory would mean that the research program might “fall off the cliff.” Dr. Omenn admitted that such measures are used in evaluating university faculty. He suggested using the term “needs improvement” rather than not satisfactory because this term sends a more constructive message.

Dr. Daston thanked Dr. Omenn for his comments and stated that the BOSC is still getting used to its four-point rating system. He acknowledged that the creation of the system was the result of a long and difficult negotiation with OMB.

To better understand the concept of investment efficiency and how to measure it, Dr. Omenn recommended that BOSC members review a book by F. Peter Boer entitled, *The Real Options Solution: Finding Total Value in a High-Risk World* that was referenced in the National Academies report (page 35). Dr. Boer has considerable private-sector experience and has developed a risk-adjusted valuation measure for R&D projects.

Dr. Carol Weiss said she liked the distinction between process and investment efficiency but wondered why the word efficiency was included. The use of efficiency conveys the wrong impression about a research program because the real issues are the quality and relevance of the program. She pointed out that efficiency normally relates to economics, not quality. Did OMB require the use of the word efficiency?

Dr. Omenn responded that this was a very insightful comment. Unfortunately, the charge to the National Academies Committee was focused on efficiency. In turn, the Committee did its best, as indicated in the first finding of the report, to ensure that evaluation of the efficiency process begins by assessing the relevance, quality, and performance of the research. He stressed that efficiency is a subcomponent of effectiveness. Dr. Omenn disagreed that efficiency always refers to economics because in this era every research manager must get the most from his/her assigned resources. The efficient use of resources is necessary to achieve high-quality research products. The Committee tried to use efficiency in the context of appropriate use, recognition of benchmarks, and continued improvement.

Dr. Henderson asked if OMB agreed with the use of expert panels providing a qualitative review of investment efficiency. Dr. Omenn replied that Darien Wong, OMB, and Marcus Peacock, EPA Deputy Administrator, who was formerly at OMB, have been generally receptive to the use of expert panels providing investment efficiency reviews. Dr. Omenn also pointed out that investment efficiency is sometimes referred to as research portfolio management.

OMB is looking for process efficiency metrics so it is important, according to Dr. Omenn, for agencies to include these in their expert panel evaluations. He urged the BOSC and ORD to take advantage of this opportunity and capture OMB's approval while OMB is eager to give it and use the term efficiency in conjunction with evaluating the relevance, quality, and effectiveness of research programs. Dr. Omenn pointed out that the BOSC already uses the term “speed” in its ranking narratives and speed can be equivalent to process efficiency metrics.

Dr. Daston asked how OMB views research programs relative to efficiency. Efficiency measures tend to overvalue short-term research at the expense of long-term research. Research that may take 10 years to mature and yield significant public health improvements might be poorly viewed from a process

efficiency perspective versus other research programs that offer an immediate payoff. For example, EPA can conduct numerous Integrated Risk Information System (IRIS) assessments each year and receive high scores whereas the ToxCast Program will take years to yield such results so it will receive much lower scores. In the long term, however, ToxCast may have a huge impact on how EPA prioritizes chemicals for risk assessment. Dr. Daston wondered if these are the types of research programs for which EPA will have to develop different metrics in its discussions with OMB about research program efficiency.

Dr. Omenn replied that researchers need to overcome this risk. OMB agrees that efficiency should not be viewed in isolation. As mentioned earlier, efficiency is one component of a research program along with quality, relevance, and effectiveness. This issue has been raised and endorsed in previous National Academies reports as well. He agreed that it is a challenge to conduct both short- and long-term research programs efficiently. It is the nature of R&D to include a broad range of programs. Some environmental research is tied to the regulatory agenda whereas other research is basic and fundamental. There is an opportunity for the BOSC and EPA ORD senior management to make it clear in the ORD contributions to the Agency Strategic Plan and Multi-Year Plans that there are short, intermediate, and long-term research programs with varying payoffs. There are no guarantees, but the future of EPA research program should not be decided solely on a multi-factorial analysis of the R&D function.

Dr. Weiss appreciated the report's recognition of the inconsistencies among OMB budget examiners in their reviews of federal research programs. Dr. Omenn replied that OMB senior management acknowledged this problem and is trying to address it. He recalled that one OMB EPA examiner heard such criticism during one of the Committee meetings and took it very well. This examiner noted that OMB staff members are trying to figure out better ways of conducting PART reviews.

As a former OMB senior official and long-time university researcher, Dr. Omenn suggested that federal agencies should be allowed to experiment and not be at risk in the first year of implementing new OMB metrics (i.e., process and investment efficiency). There was general agreement among OMB managers and examiners with this approach. OMB officials also agreed that new training was needed and they are looking into how it could be conducted. Dr. Omenn mentioned that OMB has an external advisory committee to assist in addressing these issues.

Based on the National Academies study experience, much of the antagonism about PART reviews between federal agencies and OMB has subsided and OMB is open to a more collaborative approach. He noted that, in some cases, the Committee members thought that OMB was demanding too little from federal agencies. This spurred the high federal agency participation (with more than 20 agencies attending) in the April 10, 2008, meeting, which was co-sponsored by OMB and EPA. As mentioned earlier, there was a lot of enthusiasm at this meeting about the report's findings and recommendations. At least two agencies voiced their acceptance—the National Science Foundation (NSF) and National Institute of Safety and Health (NIOSH)—indicating that they already had the equivalent in their review processes.

Dr. Saylor asked Dr. Omenn for his comments about ongoing BOSC reviews of ORD programs. He explained that, for these reviews, information and data are provided by the program that includes a bibliometric analysis of the program's publications, which combines internal ORD research and extramural Science To Achieve Results (STAR) grant research publications. BOSC reviewers have asked ORD to analyze the intramural and extramural publications separately. Bibliometric analysis is one of the process efficiency tools EPA is using to review research efforts. Dr. Saylor asked Dr. Omenn's opinion about using bibliometric analysis as a process efficiency tool and the integration of intramural and extramural research publications.

Dr. Omenn replied that publications are a useful measure for research performance. There is a varying publication rate in different scientific fields. In ecological research, for example, the publication rate is

lower than that for human health. This may have to do more with the problem being studied rather than the researchers or the journals; it also could be related to the fact that there are fewer journals available in some of these fields.

With regard to integrating intramural and extramural publications, if the program involves both types of research, then the publications should be reviewed jointly. The key question is: how is the science being advanced in these fields relative to the Agency's interests?

Dr. Omenn cautioned that reviewers need to recognize that counting the number of citations of a paper or counting the number of an individual's citations is not sufficient; however, in the context of a review that includes quality, relevance, and performance of research, publication citation analysis is useful.

Based on Dr. Omenn's comments, Dr. Sayler stressed that the BOSC reviews look at the entire research program as a whole and not just the individual contributions to that program. Dr. Sayler continued that efficiency is not an independent issue but is nested within other areas that are being reviewed. The BOSC is conducting reviews across research disciplines within various ORD programs and using narratives to describe the program.

Dr. Omenn asked how the BOSC identifies research programs for review. He wanted to know how the BOSC defines the boundaries for its reviews among the five goals within the EPA Strategic Plan.

Dr. Sayler replied that the BOSC maintains a cyclical review process. ORD research programs are reviewed by the BOSC on a 4-year cycle. Mid-cycle reviews (conducted 2 years after the BOSC program review) also are conducted by the BOSC, which allows the Board to assess mid-term correction strategies for ORD programs. The BOSC conducts reviews of the air, drinking water, water quality, land, human health, human health risk assessment, global change, and other programs. All of these reviews are conducted on a cyclical basis, which consists of an in-depth program review, followed 2 years later by a mid-cycle review. The reviews are conducted by Subcommittees that prepare a report that is reviewed and approved by the BOSC Executive Committee.

Dr. Omenn commented that one part of the Air Program that is particularly suited to interim outcome analysis is the Integrated Scientific Assessments (ISAs), which have replaced the criteria documents. These assessments can be tied to a periodic process that in turn is related to Clean Air Act NAAQS Sections for criteria and hazardous pollutants. Given this process, there should be ample evidence whether these assessments were timely, helpful, and insightful for the air regulatory development process.

Dr. Sayler agreed with Dr. Omenn's assessment and asked Dr. Henderson, who chaired the BOSC review of the Air Program, if she had anything to add. Dr. Henderson agreed with Dr. Omenn's comment. She added that the timing of the BOSC program reviews is designed to precede the PART review. EPA tries to complete the BOSC review prior to the PART review so that the results of the external review can be submitted to OMB for the PART review. Dr. Henderson noted that, for the Air Program, a useful program review metric was the number of citations of Air Program publications in the criteria documents or ISAs.

Dr. Deborah Swackhamer asked Dr. Omenn if the BOSC should include in its reviews an explicit evaluation of efficiency. Dr. Omenn replied that the BOSC should include efficiency in its reviews.

Dr. Swackhammer complimented Dr. Omenn on his Committee's report, stating that it was well done and much needed. Dr. Omenn responded that this was one case where bringing parties together (EPA, OMB, and others) produced a very cooperative dialogue and a useful product.

ORD Implementation Plans

Phillip Juengst, EPA/ORD

Mr. Phillip Juengst provided some information about how EPA is responding to the National Academies report. One of the responses, already mentioned, was the April 10, 2008 EPA/OMB meeting that was attended by nearly 100 representatives from 25 different federal agencies and departments. Marcus Peacock, EPA Deputy Administrator, and Robert Shea, OMB Associate Deputy Director for Management, participated in the meeting as well as panelists from OMB, National Institutes of Health (NIH), NSF, Department of Energy (DOE), National Aeronautics and Space Administration (NASA), and NIOSH. The meeting included in-depth dialogue among the agencies and general agreement with the report's findings and recommendations. As a result of this meeting and other discussions with OMB, there is emerging consensus that agencies should be allowed, as Dr. Omenn suggested, to experiment with developing process efficiency metrics without the risk of lowering the Agency's PART scores and President's Management Agenda scorecard ratings.

Mr. Juengst explained that ORD is trying to determine how to implement both the investment and process efficiency recommendations of the National Academies. Assessing investment efficiency is something that ORD believes is best achieved through existing BOSC reviews. The extent to which ORD programs are investing and managing their resources efficiently to achieve their goals is a critical investment efficiency question. ORD has added a specific charge question to this effect for the upcoming Homeland Security BOSC program review. ORD is looking to the BOSC Executive Committee for more guidance about how to focus on investment efficiency in a more explicit way. What level of detail does the BOSC need from ORD to determine how well ORD is investing and managing its resources? Long-term funding and full-time equivalent (FTE) data have been provided for past reviews. Is this information sufficient?

ORD also is working with OMB to determine how to better measure process efficiency. Of the nine measures identified in the National Academies report (pages 30-32), the one ORD currently is focusing on is the "proportion of research budget consumed by administrative functions (overhead ratio)." A cross-cutting ORD measure that tracks the percent of the budget that is committed to direct science would support current ORD-wide administrative efficiency efforts. It also could be useful to the research laboratories and centers, as well as division directors and branch chiefs. Depending on EPA's negotiations with OMB, ORD may develop such an ORD-wide measure as well as retain other, program-specific process measures. For example, the Land Research Program tracks the response time for the technical center, and the human health program, which has a large grant component, tracks grant processing.

Dr. Henry Falk asked Dr. Omenn about long-term outcomes from human health research programs. At what point should reviewers expect to see results? At what point can reviewers assess a long-term outcome from a human health research program?

Dr. Omenn mentioned an EPA report that was prepared 2-3 years ago that assessed the impact of the Clean Air Act (CAA) on the control of criteria air pollutants, primarily NAAQS pollutants. He emphasized that it is very complicated to determine the effectiveness of the CAA because of the many contributing factors. The number of motor vehicles has changed dramatically since 1970, there are a lot more people in the United States, and the impact of secondary pollutants such as ozone has been more prominent. Nevertheless, the EPA report found that there was a positive benefit-to-cost ratio in terms of public health improvements. This may be a "once in a generation" report. The annual incremental assessments provided by PART would offer only a small contribution to such a report. Nonetheless, such a report provides a framework for what can be identified for intermediate outcomes in a long-term research program.

Dr. Omenn mentioned there is a pending National Academies report on ozone-related mortality that also may provide some illustrative examples. This report focuses on tropospheric not stratospheric ozone. The

regulations for ozone control have been tied to respiratory symptoms even though the complaint most often reported from excessive photochemical oxidants is irritation to the eyes. Breathing problems from ozone have been identified as acute or semi-acute, but they have not yet been linked to mortality. This latest report attempts to determine if ozone causes chronic effects to the lung and the cardiovascular system and whether these effects result in any mortality differences. Although it has not been released, Dr. Omenn understands that the report found that ozone has a negative effect on lung function. The reason Dr. Omenn mentioned this report is that it is an example of another specific assessment not focusing on total air quality that will illustrate the socioeconomic value of specialized research programs. These studies are important to gain public appreciation of long-term research programs. Unfortunately, long-term research programs are not well suited to PART reviews because there are too many factors that can contribute to reductions. It is more reasonable and feasible to focus the assessment on intermediate outcomes.

Dr. Omenn also wanted to respond to Mr. Juengst's comment about the level of detail needed for BOSC reviews. First, there should be an agreement up front between ORD and the BOSC regarding the level of detail needed to conduct the review. This should be a transparent process and OMB should be advised about how it is conducted. Qualifying the scale and timing of a BOSC review is important because questions may arise later about whether specific aspects of a research program were reviewed. There has to be an understanding between those commissioning the research and those conducting the review about what is needed in terms of both scale and scope. OMB should ask similar questions about the structure, context, and efficiency of PART reviews of R&D across agencies and OMB branches; this is what the National Academies Committee had in mind when it suggested that OMB should "part" PART.

Dr. Sayler admitted that the BOSC has struggled with the issue of how much information is enough and how much is too much to address the charge questions. As the BOSC moves forward on efficiency evaluations, there needs to be a clear understanding between the BOSC and ORD about what information is needed for such assessments. For example, the BOSC Homeland Security program review will take place at the end of May and one of the charge questions to the Subcommittee is related to efficiency. Specifically, the question is: how has the program invested and managed resources to achieve the long-term goals of the program? He asked if Dr. Omenn thought this question will allow the BOSC to get to the desired level of information needed to make an efficiency evaluation. This may appear to be more of a process efficiency rather than an investment efficiency question but the investment issue is included. Does this question move the BOSC in the direction it needs to go?

Dr. Omenn replied that in 2002 the NRC released a report entitled "Making the Nation Safer: The Role of Science and Technology in Countering Terrorism." This report was produced by the NRC Committee on Science and Technology for Countering Terrorism, which was co-chaired by Dr. Richard Klausner and Dr. Lewis Branscomb. The report recommended that the United States take advantage of its scientific and engineering strengths to detect, thwart, and respond to terrorist attacks more effectively. The report deals with all types of biological, chemical, psychological, and other research that has been or should be addressed by the Department of Homeland Security (DHS), EPA, or other government agencies. The report was instrumental in establishing two offices within DHS on research and technology development. This report may be useful to the BOSC in conducting its Homeland Security program review. Dr. Omenn noted that Homeland Security deals with many issues so it is difficult to determine whether the efficiency charge question is adequate.

Dr. Cliff Duke mentioned that he represented the BOSC at the April 10, 2008, EPA/OMB meeting on the National Academies report. He stated that there was broad interest and support among participating federal agencies for the ideas expressed in the report. He noted, however, that the support was not universal. The application of the report recommendations go beyond EPA and OMB and will have use for research evaluation in general. The report's focus on outputs and intermediate outcomes will have a lot of application for BOSC reviews. The BOSC has wrestled with how to measure program outputs and

outcomes for several years. Interim outcomes may be very useful for BOSC mid-cycle reviews. The links between the evaluation metrics identified in the report and goal setting were of particular interest to Dr. Duke. He added that the BOSC often is asked for advice on how to word long-term goals for ORD programs.

Dr. Duke mentioned that the BOSC Subcommittees conducting the program reviews often are concerned with resource issues. The new charge question for the Homeland Security program review tries to address this issue by linking managed resources to long-term program goals. This type of question will allow the BOSC to better address program resources and goals in an explicit fashion. Overall, the National Academies report is tremendously useful for anyone dealing with research program evaluation and goal setting.

Dr. Omenn responded that Dr. Duke's comments were insightful because he described what is needed in any comprehensive evaluation upfront—the specification about research program metrics, milestones, and justification that in turn will help set program goals. Defining this type of information upfront should be transparent and it will be useful in future periodic reviews.

Dr. Daston commented that a charge question on efficiency is useful for BOSC reviews but he cautioned against the trap of favoring short-term research and short-term outcomes because they appear to be more efficient. Long-term research could suffer from such an approach. Dr. Daston noted that the Defense Advanced Research Projects Agency (DARPA), the central R&D organization for the Department of Defense (DOD), manages and directs many long-term research programs. DARPA projects provided good examples of high-risk, high-reward efforts that any research institution must have to ensure its longevity. A near-term focus on efficiency could devalue the need for long-term research expertise and experience.

Dr. Daston stressed the need to bring other agencies into these research evaluation discussions. EPA may be the “first among equals” in the amount of peer review its products and programs undergo. He was concerned that the burden of peer review may be impairing EPA's efficiency. In the future, EPA may want to calibrate its peer review efforts with those of other science-based federal agencies.

Dr. Omenn replied that this dilemma between short- and long-term research evaluations will continue but the emphasis should be placed on program goals. A balanced research program that includes both short- and long-term research is necessary, and BOSC reviews should not be project-by-project, but rather on a research program portfolio basis. Using this approach, a portfolio of particularly high-risk/high-payoff projects could be evaluated in the manner that venture capitalists evaluate projects (i.e., expecting only 3 to 5 of 10 projects to produce valuable results and only 1 out of 10 to succeed dramatically; hopefully, the success of the one will pay for investing in the others). The key is to establish the correct evaluation criteria upfront and review the research portfolios accordingly. DARPA's success with long-term research is well known and other federal agencies such as the Department of Health and Human Services (DHHS) and DOE have considered setting up similar programs. Perhaps, EPA should consider establishing a similar long-term environmental research component. Even DARPA, however, has been criticized in the past for moving to short-term work—and not because of PART requirements to assess efficiency.

Dr. Swackhamer asked if the BOSC should be asking specific questions about the program's long-term research investments. The issue is not high-risk research but rather long-term investments for the future. She agreed that focusing on short-term gains provides a bias in the review process. Dr. Swackhamer asked Mr. Juengst about the ORD administrative overhead ratio metric as a process efficiency measure. Is this metric for all of ORD or is it applied on a program-by-program basis?

Mr. Juengst responded that it was being considered as an ORD-wide measure. He explained that ORD is trying to develop a “scorecard” measure that could have multiple applications including meeting PART,

GPRA, and internal quarterly management requirements. He noted that looking at administrative functions as part of the overall budget provides an important evaluation opportunity for ORD management. This would not be a program-specific measure but it would cascade down to the research laboratories and centers. As noted earlier, for OMB PART reviews this ORD-wide measure may be supplemented with program-specific measures such as the grant processing time measure for the Human Health Research Program or the technical support response time for the Land Research Program.

Dr. Sayler asked if ORD considers the overhead ratio a comparative cost measure to be used among federal agencies. Mr. Juengst replied that ORD is trying to work with other federal agencies to benchmark their efforts. DOE, for example, tracks administrative costs as a percentage of its overall research effort and the proposed EPA overhead metric “mirrors” the DOE effort. OMB also is conducting a “quality measure” review for all federal agencies in conjunction with their PART reviews. OMB is interested in having a standardized and defined review process across all federal agencies. Both OMB and EPA want to use standard methods and methodologies to evaluate research programs.

Dr. Chuck Haas asked Dr. Omenn if the National Academies study considered what percentage of EPA’s research should be devoted to preventing or anticipating problems. Clearly, this is long-term research (i.e., research devoted to anticipating environmental problems so they can be prevented). Dr. Omenn responded that this type of research is clearly within EPA’s mission and the Agency should be focused on correcting existing environmental problems as well as conducting research aimed at revealing and preventing future environmental problems.

Dr. Omenn noted that there is an important challenge for peer review—determining what level of effort is sufficient. He pointed to the dioxin research program as an example of a program that was over-reviewed. Environmental research is different from some other types of research because protection of public health and the environment are involved. The important issue is to ensure that the review process includes quality, relevance, and sufficiency.

Dr. Sayler thanked Dr. Omenn for his presentation and remarks.

Computational Toxicology Draft Letter Report Presentation

Dr. George Daston, Chair, BOSC Subcommittee on Computational Toxicology

Dr. Daston explained that this is the third BOSC review of the National Center for Computational Toxicology (NCCT). The first two reviews focused primarily on planning issues but because the Center has done considerable work since its inception, this review focused on the NCCT research programs. Specifically, it focused on the following five NCCT projects:

- ✧ ToxCast
- ✧ Informatics Technology and Information Management (IT/IM)
- ✧ Developmental Systems Biology (Virtual Embryo)
- ✧ Virtual Liver
- ✧ Biologically Based Dose Response (BBDR) Model for Arsenic

ToxCast is a multifaceted program designed to generate biological effects information on a large number of chemicals to determine if there are specific biological interactions with these chemicals that are predictive of their toxicology. If this project is successful, it will be able to add value to prioritizing and assessing chemicals in the EPA pesticides and toxic substances programs.

The Informatics Technology and Information Management (IT/IM) project focuses on the management and query of large complex, datasets. In the short term, this program is trying to develop the ability to query large databases of chemical structures for common toxicological properties. Relational databases of

this type provide novel opportunities for risk assessors to consider the potential biological activity of new chemicals instead of using just production volume to prioritize them for further evaluation and testing.

The Developmental Systems Biology and Virtual Liver projects are very ambitious long-term efforts. Although these projects have long horizons, they have significant potential to improve risk assessment. These projects are trying to model embryonic and liver development as a means to determine the quantitative relationships between a toxicant and a biological system to predict computationally the outcome.

The goal of the Arsenic BBDR Model is to determine the carcinogenic and toxic effects of inorganic arsenic at very low levels. The BBDR model would incorporate a physiologically based pharmacokinetic (PBPK) component to assess the relationship between the concentration of arsenic in drinking water and the dose received by the target organ. BPK models are regarded as a more sophisticated approach to understanding how chemicals are transported and transformed as physiological processes break them down, potentially reducing their toxicity.

The BOSC Subcommittee evaluated these five projects based on the following charge questions:

- ✧ Charge Question 1: Does the scope and involvement of expertise in the project reflect activities consistent with the function of a Center?
- ✧ Charge Question 2: Are the goals and milestones suitably described, ambitious, and innovative?
- ✧ Charge Question 3: Are there significant gaps in the approach that can be pointed out at this point in the evolution of the project?
- ✧ Charge Question 4: Does the work offer to significantly improve environmental health impacts and is the path toward regulatory acceptance and utilization apparent?
- ✧ Charge Question 5: Have appropriate data management and analysis tools been incorporated into the project?
- ✧ Charge Question 6: How would you assess the outreach to other groups in executing the project?

The BOSC Subcommittee's letter report is structured around the answers to these questions. Overall, the Subcommittee found that the programs were doing well but offered some suggestions for improvement. Following is a brief summary of the Subcommittee's findings relative to these questions.

In terms of scope and involvement of expertise, the Center's efforts are broad considering NCCT has only 19 people. The Center has expanded the scope of its projects through collaboration with others both inside and outside EPA. On February 14, 2008, for example, there was an announcement of collaboration between EPA's NCCT and the National Institute of Environmental Health Sciences (NIEHS) and the NIH National Genome Research Institute. This will be a large multiyear collaboration among these three agencies, which takes advantage of the individual expertise and capabilities of each organization, such as high throughput screening analysis, bioinformatics, and computational biology.

The goals and milestones of NCCT's projects are well established. Some of the projects are further along than others; for example, the IT/IM program goals are fairly well defined whereas the Virtual Embryo and Liver projects are new and comparatively less well defined. For these biology developmental programs, the Subcommittee suggested that the Center "think hard" about how the products from these projects will be used.

ToxCast has gotten off to a great start with a dataset of 300 chemicals from the pesticides program. These chemicals were selected because there is extensive toxicology data against which to anchor the high throughput screening analysis and other assays the Center intends to run. The IT/IM project may be one of the most challenging NCCT projects because it requires the incorporation of various datasets prepared by different organizations for different purposes. Nevertheless, this could be a success story for the NCCT because the informatics and databases being developed already are being used by the EPA program offices. The use of these datasets could fundamentally change the way the program offices currently do their job. The remaining three projects reviewed by the Subcommittee are newer and NCCT continues to work on their ultimate outputs.

It may be too early to determine how these programs will significantly improve environmental health and gain regulatory acceptance. Nonetheless, for the IT/IM project, the EPA Office of Pesticide Programs (OPP) already is using NCCT's Toxicity Reference Data Base (ToxRefDB). Initially, the ToxRefDB is being populated with 20 years of toxicology data from pesticide registration studies (OPP's Data Evaluation Records). These records contain high quality, comparable data with significant quality control. ToxRefDB allows OPP to query large databases based on chemical structure to determine the toxicology for closely related analogs.

The data management and analysis charge question is highly relevant to the NCCT projects because computational toxicology is about managing large datasets. For the most part, these projects are making great progress in this area but this is a large and complex effort. Many of the scientists within the Center, as well as two STAR grant recipients, are working on these projects. One of the most challenging things from a management standpoint is coordinating all of these activities.

The last charge question addresses outreach to other groups, some of which was addressed by Dr. Daston in his summary of the responses to the previous charge questions. In addition, NCCT has developed three Communities of Practice (CoP)—chemi-informatics, biological modeling, and chemical categorization and prioritization. The purpose of the CoP is to unite scientists who have a common interest in an area in which NCCT is a center of excellence. External collaborations, such as the one mentioned earlier with NIEHS and NIH, also are indicative of the Center's outreach efforts.

Dr. Daston concluded his remarks by saying that the NCCT projects are progressing nicely and they are indicative of the substantial efforts the Agency is taking to improve the risk assessment and regulatory process.

Dr. Sayler asked if the BOSC members had any questions or comments on the letter report.

Dr. Barry Ryan asked if there will be any intermediate products or outcomes from the Virtual Liver and Virtual Embryo projects. Dr. Daston replied that intermediate products will be forthcoming from both of these programs. He added that the BOSC NCCT review was held in December 2007 just a few months after Dr. Tom Knudsen, who directs the Virtual Embryo project, joined the Center. There has not been sufficient time for project staff to develop intermediate outcomes. Likewise, for the Virtual Liver project, the staff is working on developing intermediate outcomes.

Dr. Henderson asked how the model will deal with compounds that become toxic through metabolic processes. Dr. Daston replied that the Center has not yet solved that problem; however, for the IT/IM informatics databases and the Virtual Liver projects, the staff is trying to structure metabolism. Related to this point, Dr. Haas asked if there is an explicit pathway for validating these models. Dr. Daston replied that this will have to be discussed more with NCCT in the future.

Dr. Robert Kavlock, NCCT Director, explained that the Center is trying to validate the ToxCast, Virtual Liver, and Virtual Embryo models but each validation is different. For the ToxCast model, for example,

validations are traditionally done by looking at available bioassays; unfortunately, the data are available from only one organization so it is difficult to conduct a blind round robin. In creating ToxCast, NCCT is using as much transparency as possible so interested users will understand how the model is designed and operated. NCCT wants to do whatever is necessary to allow these models to achieve acceptance by the regulatory programs. NCCT wants to use the Virtual Liver and Virtual Embryo models to integrate the information generated from ToxCast, starting at the molecular level and building up to cellular networks to describe the biology. The traditional validation approaches are not applicable for these models; scientific consensus will drive their validation.

Dr. Knudsen noted that, for the Virtual Embryo Model, the Center is trying to build a morphogenetic model with data from a variety of species; for the Virtual Liver Model, the Center is building on information from ToxCast and other sources.

Dr. Saylor asked how the computational toxicology programs are related to other Agency-wide efforts, such as the Chemical Contaminants List (CCL) for drinking water or the endocrine disruptor screens. Dr. Knudsen replied that NCCT has a CoP on categorization and prioritization that reaches out to interested Agency users. The Center also has 56 of the 73 chemicals that will go through the first endocrine disruptor screening battery so NCCT already has high throughput data on a variety of those chemicals.

Dr. Henderson was the vetter for the BOSC Subcommittee on Computational Toxicology letter report. She thought the draft letter was well organized and clearly written. She did not have any editorial changes until page 8. She agreed to provide her editorial changes to Dr. Daston.

Dr. Henderson had a question about whether the use of ToxCast would, as the draft letter report implies, lead to the creation of new test methods “that are not encumbered with much of the uncertainty inherent in traditional toxicity tests.” She also asked Dr. Daston to edit the following run-on sentence: “What the project seems to be lacking are a set of analytical objectives necessary for building the relevant use cases that will ultimately inform the process of database construction and this will ultimately determine its utility.” This sentence was in the middle of the first full paragraph on page 9 of the letter report.

Dr. Saylor asked if there were any additional comments on the draft letter report.

Dr. Swackhamer complimented Dr. Daston on the quality of the letter report. She added that the review was in-depth and based on sound reasoning. It also recognized the high quality of the Computational Toxicology Program while also offering suggestions for areas of improvement.

Dr. Daston replied that the quality of the Subcommittee’s review could be attributed to the fact that this is a standing subcommittee that has reviewed the program several times. As a standing subcommittee, the members are more familiar with the NCCT and its projects; this allows the Center staff to provide more detailed information and tailor presentations and data to address the specific charge questions.

Dr. Swackhamer asked about the narrow focus of the charge questions for this review.

Dr. Daston replied that the charge questions resulted from meetings among Dr. Kavlock, Ms. Kowalski, and himself. The questions were focused on what input would be most useful to strengthen the program and what information is needed by ORD senior managers to assess how the program is performing.

Ms. Kowalski added that because this is a standing subcommittee, this review was different from the program and mid-cycle reviews conducted by the BOSC. This review was specifically designed to give feedback to a 3-year-old startup research program. As a standing committee, these reviewers get to know the research program on a more intimate basis and can provide more specific advice and recommendations.

Dr. Swackhamer noted that some of the charge questions seem to be follow-up questions from previous reviews. Is this the case? Dr. Daston confirmed that this was the case. Dr. Swackhamer added that it would have been useful to provide the context of the questions for those who are not on the Subcommittee. Dr. Daston agreed to modify the draft letter report to reflect this issue.

Given the success of the Subcommittee on Computational Toxicology, Dr. Saylor suggested that the BOSC may want to consider creating standing subcommittees for program reviews. He asked Dr. Kavlock if he thought the feedback provided by the Subcommittee was helpful. Dr. Kavlock replied positively, noting that a standing subcommittee offers better continuity across the reviews.

Dr. Saylor concluded the discussion by noting that the draft letter report will be modified based on Dr. Henderson's comments and Dr. Daston will insert the context of the charge questions in response to Dr. Swackhamer's suggestion. Because these changes are editorial in nature, they do not require further review by the BOSC Subcommittee or Executive Committee. Dr. Saylor then called for a motion to approve the draft letter report with the suggested changes. Dr. Weiss moved to approve the draft letter report with the changes and the motion was seconded by Dr. Haas. The letter report was approved unanimously by the BOSC Executive Committee.

Assistant Administrator (AA) for ORD Remarks

Lek Kadeli, Deputy Assistant Administrator for Management, ORD, EPA

Lek Kadeli expressed Dr. George Gray's regrets that he was unable to attend the meeting because he was scheduled to appear before the Senate Oversight Committee. Mr. Kadeli was attending on Dr. Gray's behalf to provide the AA's remarks.

There is an effort within EPA to re-energize program evaluation across the Agency. Program evaluation has been fallow at the Agency for quite some time. Recently, at an EPA Performance Management Council meeting led by Deputy Administrator Marcus Peacock, Mr. Kadeli made a presentation about efficiency measures and PART reviews. In this presentation, Mr. Kadeli was able to describe the "best practices" ORD uses to conduct program reviews via the BOSC. During his presentation to the Council, Mr. Kadeli was able to illustrate how ORD uses outside expert panels to evaluate various programs and how this practice is an important part of the ORD culture. Mr. Kadeli thanked the BOSC members for their continuing efforts toward improving ORD programs through their evaluations.

Mr. Kadeli recognized Dr. Benson, Director of ORD's Gulf Ecology Division, as a rising ORD manager. Dr. Benson spent more than 6 months in ORD Headquarters and successfully supported EPA's Office of Water with work on criteria documents and hypoxia research.

Mr. Kadeli thanked the BOSC for its efforts on the NCER Standing Subcommittee Letter Report, the Air Mid-Cycle Review Report, and the Technology for Sustainability Program Review Report. ORD is in the process of reviewing these reports and will provide responses to them at the BOSC Executive Committee meeting in September 2008.

Mr. Kadeli commented on the Agency's budget for fiscal year (FY) 2009 and the FY 2010 budget planning process. The 2009 President's Budget was submitted in February 2008. There are many factors affecting the 2009 budget including the upcoming November presidential election. Although Congressional committee staffers hope to have a subcommittee or full committee report out by the election, this might not be possible. The House Speaker's Office is playing a strong role in the budget process. It appears likely that the Federal Government will be under a continuing resolution in the fall. Mr. Kadeli projected that an appropriations bill will be out by the end of the calendar year or after the start of the New Year. The lack of an approved budget will put new programs on hold and prevent other

programs expecting increased increments to expand existing programs. Mr. Kadeli concluded his remarks by asking if there were any questions or comments about ORD's FY 2009 budget.

Dr. Swackhamer asked why Dr. Granger Morgan, Chair of the SAB, was not asked this year to provide Congressional testimony on behalf of the Agency's research programs. Mr. Kadeli replied that Dr. Morgan's testimony is normally provided as part of the Agency's Oversight Hearing of the House Science Committee and that hearing has not yet been scheduled. He added that there is no oversight hearing on ORD programs conducted by the Senate Environment and Public Works Committee.

For FY 2010, Mr. Kadeli noted that the Agency's annual planning is nearing completion and the program offices are completing their budget requests. The OMB guidance for 2010, however, does not yet involve federal agency submissions because it is an election year and budgets will change depending on the election results. The 2010 budget likely will be submitted in February 2009 but the new Administration will provide guidance on what is in that budget. For now, EPA is working on identifying cross-program priorities for 2010. For ORD, some of the high priority research areas for 2010 include nanotechnology, climate change, computational toxicology, and biofuels and alternative fuels. Each of these areas has considerable interest across the Agency. Obviously, there are other important research programs and ORD will continue to support them to the extent possible in the 2010 budget process.

Dr. Falk asked about the budget shift that may occur as a result of the cross-Agency interest in these four priority areas. Mr. Kadeli replied that the President's Budget includes projections and based on recent budget submissions these projections have shown a 1-2 percent decline per year. He noted that there are fixed-cost drivers within any budget, such as the annual payroll increase of nearly \$100 million per year, which limit annual budget increases. Of the four areas mentioned earlier, ORD already has invested in three of the areas; only biofuels would be a new investment area for ORD. The increases to be made in these areas would be marginal. Nanotechnology investments, for example, would increase about \$4-5 million. Increases in the range of \$5 million would be a healthy rise given the current limitations of the federal budget. The substantial increases seen in the past, like the \$20 million increase in particulate matter research in the 1995 and 1996 budget, have not been possible in recent years.

Dr. Henderson asked what research programs will decline, given the potential increases in these four cross-Agency priorities. Mr. Kadeli replied that he did not know at this time which programs will receive less funding; ORD has not yet prioritized the other programs for the 2010 budget. In the past few years, ORD has experienced substantial budget cuts in the Ecological Research Program and the Pollution Prevention or Technology for Sustainability Program but he did not know which programs will be affected by future budget cuts.

Dr. Henderson noted that there is a great deal of interest in applying a multi-pollutant approach toward managing air quality. Are there any plans within ORD to move in this direction? Mr. Kadeli replied that the ORD Air Research Program has expanded beyond particulate matter and air toxics and is looking at mixtures rather than single pollutants. Five or six years ago, ORD proposed one atmosphere initiative that did receive Agency support. Dr. Dan Costa, NPD for ORD's Clean Air Research Program, is looking at ways to address air research from a multi-pollutant standpoint. Mr. Kadeli also noted that chemical mixtures are being investigated in the ORD pesticides and toxics programs; this also is the case for ORD research at Superfund sites.

Dr. Ken Demerjian pointed out that NARSTO, a public/private partnership dedicated to improving the management of air quality in North America, will soon be releasing on a report on multi-pollutant assessment of air quality. This report lays out some strategies to be considered in multi-pollutant assessments, which are more complicated than single pollutant assessments. There are potential overlaps in the current controls used for particulate matter/ozone, air toxics, and acid rain precursors; all of these pollutants have some common elements. The NARSTO report has been under development for the past

year and the effort includes participation from Canada, Mexico, and numerous U.S. government agencies, including EPA.

Dr. Sayler asked if ORD is exploring any leveraging opportunities with respect to the four high-priority cross-program initiatives. Mr. Kadeli replied that a number of leveraging opportunities were being pursued by ORD. For example, Dr. Gray is a member of the interagency Biomass Research and Development Board and he chairs or co-chairs a biofuels committee that is attempting to leverage resources across federal agencies. Avoiding duplication across federal research also is one of the drivers of the National Nanotechnology Initiative, in which ORD participates.

Dr. Falk asked how the budget cuts and political issues are affecting ORD. Mr. Kadeli replied that the challenge is to determine how to be successful in spite of resource constraints and political turmoil. ORD is spread out across 13 different locations and it is important to manage ORD's administrative resources effectively. In the past, each laboratory would buy its own version of software without consulting with others in ORD to find out if it or something similar was already available. ORD is now taking a corporate approach toward information technology that has resulted in savings of nearly \$4.5 million. This savings has allowed ORD to provide up to \$2 million to NCCT to initiate new projects.

Mr. Kadeli pointed out that ORD is trying to economize in some areas to allow ORD greater flexibility to focus on its research mission. ORD employs about 400 administrative staff members who support the research programs. ORD management is working with the administrative staff and researchers to determine how best to maintain ORD administrative support while "freeing up" more resources for research. Based on the Office of Personnel Management (OPM) and internal Agency surveys, ORD scientists are generally satisfied with the resources available to them for travel, equipment, etc. The recent Union of Concerned Scientists (UCS) survey, however, offered some different perspectives, which ORD is investigating. The respondent base for the UCS survey may have been smaller than that for the other surveys conducted by or for the Agency. He acknowledged that ORD is going through changes and there is some concern among the staff, but this is a natural response. Mr. Kadeli mentioned that there are some contradictions between the headlines reported on the results of the UCS survey and the actual data from the survey. ORD management is taking a closer look at this information and, as mentioned earlier, investigating the results.

Dr. Henderson pointed out the UCS survey probably included EPA Air Research Program scientists who may not be happy about the recent NAAQS issues. She explained that there has been a lot of interest in making the NAAQS review process more efficient and the Clean Air Scientific Advisory Committee (CASAC) has been working on this issue. Unfortunately, the Agency has decided to replace the former EPA Staff Paper on the NAAQS review process with a policy assessment paper, which is quite different. CASAC expressed its concern about these changes in a January 2008 letter to the EPA Administrator to which it has not yet received a response. This issue has caused a morale problem among EPA's air scientists who work with the CASAC.

Mr. Kadeli speculated that there may be difference among UCS survey respondents dealing with narrow scientific issues versus those dealing with issues where policy and science meet. For example, ORD risk assessment scientists may have larger concerns about policy and science issues than those focusing on more specific scientific problems.

Dr. Sayler thanked Mr. Kadeli for his presentation and dialogue with the BOSC members.

National Exposure Research Laboratory (NERL) Standing Subcommittee Draft Letter Report

Dr. Kenneth Demerjian, Chair, BOSC NERL Standing Subcommittee

Dr. Demerjian explained that this review was created to provide advice and consultation to the NERL on the development and implication of the Laboratory's Conceptual Exposure Framework document. This consultative activity was initially formed as a result of several conference calls between Dr. Demerjian, Dr. Larry Reiter, Director, NERL, Lori Kowalski, and Susan Peterson. These calls involved discussions about what NERL was expecting from the consultation, the development of charge questions, and what kind of expertise was needed for this Subcommittee. Membership in the Subcommittee includes Steve Bartell, Joe DePinto, Doug Dockery, Michelle Frey, and Ken Demerjian. Doug Dockery and Ken Demerjian share experience in exposure assessments, health, and air quality; while the other members have expertise in water, risk assessment, and ecosystems.

The BOSC Subcommittee was briefed by NERL management over the course of a 2-hour teleconference and a 1.5 day meeting in Research Triangle Park, North Carolina, on December 11-12, 2007.

The creation of the NERL exposure framework is significant because it is expected to provide a unifying theme and cohesiveness that will bring the six NERL divisions into a closer working relationship. The charge questions that the BOSC used were designed to help NERL maintain and apply this framework. The BOSC Subcommittee had two teleconferences to review and the drafts of the letter report, which were approved in April, to discuss.

Dr. Demerjian provided an overview of the review in a series of slides.

The Charge Questions included:

1. What is the effectiveness of the NERL Exposure Framework?
2. What are the core areas of expertise that are required within NERL to effectively conduct human health and ecological exposure research? How are these areas likely to evolve in the future?
3. How can we use the Exposure Framework as a communication tool?
4. Please comment on the merits and barriers to conducting the exposure-related collaborative, multidisciplinary research that will be required to successfully address the full suite of risk assessment and risk management activities.

Dr. Demerjian, other Subcommittee members, and NERL managers found the dialogue between the BOSC and NERL representatives to be one of the most useful outcomes of the review. One of the issues facing the Subcommittee was that too many members were trying to evaluate NERL activities rather than provide advice and counsel; it took time to resolve individual agendas. The final product was reasonable and well received.

A summary of the Subcommittee's advice and counsel included:

- ❖ Overall, there was unanimous agreement among Subcommittee members that the Exposure Framework was well worth the effort and time that the NERL management and staff committed to its preparation.
- ❖ The document, which is expected to evolve with time, provides a unifying theme and cohesiveness that will bring the six divisions into closer working relationships.

At the time of this review only senior NERL managers were aware of this framework; it was not “pushed down” to staff. The BOSC Subcommittee stressed that this “pushing down” had to be done; everyone had to “buy into” this process. Upper levels of ORD management also had to buy into this process. This framework also will guide the NERL planning process in the future.

The 10 principal recommendations are summarized as follows:

- ✧ The communication of the vision of the Exposure Framework to the other ORD laboratories and centers to develop a sense of ownership throughout ORD is important and dictates that the document be vetted by the other laboratories and centers before it is finalized.
- ✧ The Framework might be separated into two core documents—one document addressing the NERL/EPA Guidelines to Exposure Science and Research, and the second document describing internal management practices at NERL in implementing the Framework.

Dr. Demerjian pointed out that many of the Subcommittee members had expertise in exposure, yet there is not a single current organization responsible for exposure science. He suggested that the framework be published in a peer-reviewed journal so that researchers outside of EPA could use it to coordinate and unify their future research.

- ✧ The first document should be viewed as an EPA guidance document, founded on best practices and principles for sound exposure research and estimation techniques. This guidance document should be followed up with a peer-reviewed journal article describing the scientific basis of the Exposure Framework. This document should include a detailed description of its target audience. In addition, the document should identify and work through one human health example and one ecology example to truly assess its utility and clearly identify the process and prioritization criteria applied in setting the research agenda.
- ✧ The second document should describe the implementation framework, focusing on NERL practices in terms of: (1) mission and goals, (2) management strategy, (3) research and financial planning process, and (4) administrative procedures. Although it is not in the interest of NERL to write a “management book,” it is important for NERL operations and for staff to have an internally-focused “rule book” of how the laboratory will pragmatically carry out its mandate.

Dr. Demerjian pointed out there was some skepticism about how well this would work; the Subcommittee stressed that NERL needs to be successful at getting the program received by upper ORD management.

- ✧ The Framework document could be strengthened through the addition of a detailed description of its target audience. Indeed, there are multiple audiences that will require somewhat alternative documents. The document should be developed first as an EPA guidance document. Based on the guidance document, a short paper then could be drafted for submission to a journal. The guidance document should identify and work through one air example and one ecology example to truly assess the utility of the document and clearly identify the process and prioritization criteria applied in setting the research agenda.
- ✧ The Framework document has great value in defining the field of “exposure science” for the broader scientific community. In that context, it is important that the document clearly state its goals and audiences in the introduction and be written in such a way that it is sensitive to the broader role it will be playing. This means being very careful and inclusive in how the document defines and explains exposure science and research in Sections 2 and 3 of the document.

Dr. Demerjian explained that the exposure science field has multiple audiences if for no other reason than its multimedia applications; health risk assessment and ecological risk assessments are different. Many of the reviewers wanted to make sure that ecology was getting the proper attention that it should; the reason for this is that the framework primarily uses health-based data. One of the recommendations is that the framework should make the document more generic and treat health and ecology issues equally. The reason Figures 2-3 and 2-4 from the slide presentation were created was to illustrate the source-to-outcome continuum for human health and ecological exposure research.

- ✧ NERL should consider using a single diagram with text highlighting the complexities of media interactions and the differences in the demands of the research disciplines (as outlined in the text box on page 5 of the Framework document).
- ✧ The Framework document needs to further clarify how program areas' responsibilities will be divided among ORD laboratories (e.g., water quality research) under the proposed construct.
- ✧ The Framework should be applied as part of the research planning process, with a follow-up post-audit to assess the effectiveness of the document and help highlight the areas of the framework that need to be strengthened.
- ✧ The Framework document needs to better articulate NERL's partnering goals and agenda. In summary, Dr. Demerjian offered to assist NERL in conducting one of their demonstration studies. He also explained that NERL needed some quick feedback on the consultation, which the Subcommittee provided them in draft form.

Dr. Falk was the BOSC vetter for the draft letter report. Dr. Falk complimented the Subcommittee on its letter, which was clear, well organized, with little duplication. It would be helpful to append some piece of the Framework to the letter to help readers understand the issues. There was a good discussion about the challenges of implementing the Framework and integrating future issues like nanotechnology. There was also a good discussion about the Framework's relationships to bio-monitoring. Much information was conveyed without the benefit of reviewing the Framework document itself.

Dr. Haas asked to what degree the Framework document addresses uncertainty and variability. Dr. Demerjian replied there is section in the document (Appendix D: Example Prioritization Algorithm), prepared by Dr. Frey, that has suggestions for improvements in this area. Dr. Haas explained that he disagrees with the type of analysis presented in Appendix D because there is a large controversy in the scientific community about qualitative or semi-quantitative risk assessments. Dr. Haas suggested that this type of qualitative comparison is fraught with numerous issues.

Dr. Demerjian replied that this was a consultation and that NERL would "take or leave it." If NERL finds that the suggestions are controversial, they can consider not adopting them. Dr. Demerjian did not think that qualifiers should be added to the suggestions.

Dr. Sayler reminded members that this is a BOSC report and modifications can be made. Dr. Sayler asked Dr. Haas what the appropriate modifications for Appendix D would be. Dr. Haas replied that in order for NERL to use the algorithm to prioritize their research, they should consider the value of this information in terms of reduction of uncertainty. Perhaps, the box in Exhibit 2 should be deleted and replaced with text suggesting there are issues with health outcomes and exposure levels and that these two issues need to be balanced.

Dr. Ryan explained that the issue of uncertainty and exposure has been debated within the International Society of Exposure Analysis (ISEA) since 1990. If there is some new material in this framework about this issue, it should be put in the open literature. The Journal of Exposure Science and Environmental

Epidemiology may be the vehicle for releasing this information. Since the circulation for this Journal is small, other more visible journals may be enlisted for such an article. Dr. Ryan asked if NERL researched the literature about this issue.

Dr. Demerjian replied that copies of the framework should have been distributed with the report; unfortunately, the framework is being changed as it goes through various levels of review. The guidance document is available and “ready to go,” however, a published paper still requires some work to bring up all of the available literature done prior to it. Reviewers found that the framework was fundamentally sound, science-wise. Several reviewers suggested that this framework should be a management tool and a pilot study should be undertaken before it evolves any further. Dr. Demerjian stressed again that this was not a review but a consultation and it was hard to keep the Subcommittee focused on giving advice. The Subcommittee strongly suggested that this framework needs to be promoted across ORD. If NERL’s effectiveness will be based on this framework, then they need to convince themselves and educate others such as ORD management, EPA program and regional offices, OMB, etc., that it works and has value. The Subcommittee advised NERL to spend some time on outreach and think through the process.

Dr. Swackhamer commented that she was surprised that the Subcommittee makeup had such a high percentage of consultants (three of the five members were private consultants). Why were consultants used instead of standing committee members? Dr. Demerjian replied that originally the Subcommittee was composed of too many academics and more diverse backgrounds were needed. The final membership provided a good balance and everyone seemed to be satisfied with the selections. Originally, Dr. Larry Reiter wanted a nine member Subcommittee based on the areas he wanted covered; subsequently, it was decided that the Subcommittee could be smaller and grow according to NERL needs; new members could be added as topics were better defined.

Ms. Kowalski explained that balance (i.e., public versus private organizational representatives, geographic locations, etc.) is an important aspect of all FACA nomination packages and an EPA FACA and Ethics attorney reviews all packages for balance and other issues. ORD can look at the composition of this Subcommittee again to ensure there is a balanced membership.

Dr. Demerjian noted that if the Subcommittee is asked to take on another task, the Subcommittee would have to be restructured or augmented in some way. Depending on the charge questions, Ms. Kowalski replied that the Subcommittee could be supplemented with consultants for specific meetings or conference calls. The core Subcommittee membership would be maintained year-to-year but supplemented as needed.

Dr. Swackhamer pointed out that the table in Exhibit 2, Appendix D, may be sufficiently generic to allow readers to put things into bins, which is helpful. She found it helpful to have a prioritization process and asked how other BOSC members felt about getting this prescriptive or if using text rather than a table may be less objective. Dr. Haas explained that there is third dimension on the Exhibit 2 table; the relative cost of adding knowledge. In other words, it could be that uncertainty is high and above the threshold but it will cost an enormous amount of money to get more information; at the least, this is a three-dimensional problem. The bottom line is that qualitative comparisons are flawed.

Dr. Saylor suggested that text could be added to inform readers that the Exhibit 2 table “illustrates one decision support matrix, etc.” to qualify the issue; in other words, make this an explanation rather than a directive about qualitative comparisons. Dr. Saylor added that he did not think it would be necessary to go to the Subcommittee to modify the text accordingly. He explained that he preferred not to return this issue to the Subcommittee for further debate. Dr. Haas agreed to provide some text modifications for the Exhibit 2 table.

Dr. Demerjian noted that Subcommittee members have some strong ideas about issues raised by the framework but he tried to temper these opinions with a request that models be offered rather than directives about how things should be done. NERL asked for advice and the Subcommittee tried to provide it.

At 1:45 p.m. Dr. Salyer suspended the BOSC Executive Committee discussion and asked if there were any public comments on the issues before the BOSC; hearing no public comment, Dr. Salyer resumed the BOSC deliberations.

Dr. Henderson offered some suggestions about how to handle diverse Subcommittee member opinions in consultative capabilities. She suggested a letter might provide the opportunity for members to express their divergent opinions without the need for consensus. Dr. Salyer cautioned members about the use of the term consultation because it has a specific meaning when used by the SAB; he preferred that BOSC members use “advice and guidance,” not consultation.

Dr. Duke asked if the third and fifth principal recommendations on page 2 of the draft letter report were redundant because both talk about target audiences and other similar issues. Dr. Demerjian replied that the difference between the two recommendations is that the EPA guidance document is a subset of the framework document. The EPA guidance document is the “science” piece whereas the framework document is the master plan. Perhaps, the order of the recommendations should be changed with the fifth recommendation replacing the third recommendation. Dr. Demerjian agreed to clarify the fifth recommendation on page 2 relative to the other recommendations.

Dr. Salyer summarized the BOSC changes to the draft letter report as a modification to the Exhibit 2 table and a clarification of the fifth recommendation on page 2. He asked if the committee members were comfortable with the report with these changes. Dr. Ryan asked if a Web site reference could be provided for the Framework document. Dr. Demerjian replied that the EPA guidance document may be internal to ORD and not releasable, and the Framework document is not sufficiently complete to be released. He was not sure if Dr. Reiter was willing to make the draft framework exposure portion of the document available. Ms. Kowalski agreed to talk with Dr. Reiter. Dr. Salyer also asked Dr. Demerjian to change the first page of the draft letter report to “advice and guidance” rather than “consultation.”

Dr. Demerjian read the proposed changes to the Exhibit 2 table and BOSC members were agreeable to the changes. Dr. Salyer asked if there was a motion to accept the changes; Dr. Henderson moved to approve them and the motion was seconded by Dr. Haas; Dr. Weiss abstained from approving the report. The BOSC Executive Committee approved the draft letter report.

Global Change Mid-Cycle Draft Report Presentation

Dr. Clifford Duke, Vice-Chair, BOSC Global Change Mid-Cycle Subcommittee

Dr. Duke explained that Dr. Milton Russell was the chair of the BOSC Global Change Mid-Cycle Subcommittee but was unable to attend today’s meeting, so as vice-chair of the Subcommittee Dr. Duke would be making the presentation and handling the deliberations. The previous program review for the Global Change Research Program (GCRP) was completed in April 2006. The 2008 mid-cycle review was conducted in the context of the questions that guided the original program review.

- ✧ Has the Program done its work well?
- ✧ Has the Program done the right work?

In the original program review, the Subcommittee found positive answers to these two overarching charge questions. Prior to the original review, the GCRP shifted its focus from a series of place-based or

regionally-based assessments to decision support and how to adapt to climate change. Based on these changes, the original review had to look backward and forward based on the program's new focus. The 2008 mid-cycle review was conducted through a series of teleconferences, which included two presentations, and a face-to-face meeting.

The detailed charge questions for the Subcommittee included:

- ✧ Responsiveness to the April 2006 BOSC review recommendations.
- ✧ Clarity of rationale for draft multi-year plan and consistency with advice from BOSC.
- ✧ Consistency of wording of two of three long-term goals with the intended purpose of program.
- ✧ Recommendations regarding design and distribution of a client survey.
- ✧ Appropriate performance metrics for the program.
- ✧ Summary assessment of the review.

The context and considerations for the review included:

- ✧ The institutional setting for the GCRP is unique because it is part of the Federal Climate Change Science Program (CCSP) that is distributed across 12 federal agencies; the GCRP has to respond to the needs of the Federal Program and EPA.
- ✧ The GCRP is focused on the consequences of and the adaptation to potential global climate change; most federal programs are looking at causes of climate change, the GCRP is looking at the effects of climate change on air, water quality, ecosystems, and human health.
- ✧ As noted earlier, the mission and focus of the GCRP changed from place-based to environmental effects and adaptation.
- ✧ As result of its mission, the GCRP is not a traditional ORD or science program.
- ✧ A serious science peer review of the GCRP was not practical given its mission.

The Subcommittee's summary assessment from the 2008 mid-cycle review concluded:

- ✧ The GCRP is doing the right work and doing it well.
- ✧ Given the stretch goals and the challenging recommendations made in 2006, the Subcommittee concluded that a rating "Exceeds Expectations" is appropriate.

Since the 2006 BOSC review, the GCRP has had to respond to one court-ordered mandate to carry out a series of scientific assessments, which the Federal CCSP failed to deliver. The GCRP had to divert resources from their mission functions to conduct these assessments.

With respect to responsiveness to the previous BOSC review, overall the Subcommittee found the GCRP has been very responsive to previous recommendations, given that they were asked to conduct additional work, without extra resources, as a result of the court-ordered mandates. The Subcommittee concluded that the GCRP needs a clear and well-defined framework for establishing priorities in a national context. The Subcommittee found that the MYP should be the vehicle for creating this framework.

The Subcommittee was given a synopsis of the draft MYP for review. The Subcommittee found that the reasons for revising the MYP include: (1) the science is developing rapidly with several important new findings that is changing the nation's perception of the rate and severity of global climate change; (2) external advisory boards, including the BOSC, have been providing input on the GCRP structure and performance; and (3) external events, like the court-ordered mandate, have placed increased demands on the GCRP. The Subcommittee recommended that a clear, up-front statement needs to be added to the MYP explaining what is to be achieved and why. The GCRP needs to describe "what it is about" and "what it is not about."

The Subcommittee was asked to look at the GCRP long-term goal (LTG) 1, their air quality mission; LTG 2, which refers to water quality and ecosystems; and just one of their LTG 3, which refers to the statutory requirements of the Federal CCSP. The Subcommittee found that LTGs 1 and 2 wording were consistent with the primary purpose of GCRP. The key distinction between the LTG wordings is the degree to which they are output- or outcome-based. The Subcommittee recommended the inclusion of a reference to "effective communication of impacts to decision makers" for strengthening outcome-based results. Although researchers cannot determine how their outcomes are used, they can ensure communication of their impacts to decision makers.

Regarding the client survey, the Subcommittee concluded that they did not have sufficient expertise to assist the GCRP in this area. If the GCRP goes forward with a survey, the Subcommittee recommended that the program seek expert advice to assist them. The Subcommittee observed that the diversity and number of GCRP clients make the design of a single survey instrument difficult.

With respect to performance metrics, the Subcommittee cautioned that the metrics need to be designed to respond to the final versions of the MYP and LTGs, both of which remain in draft form. The Subcommittee found that general metrics, such as bibliometric analyses and timely completion of goals, are appropriate. The Subcommittee further recommended that GCRP's role in CCSP is critical—metrics need to be carefully crafted to take into account the GCRP's contribution to the CCSP as a whole, to the EPA mission, and to the broader national community it serves.

The Subcommittee offered three general recommendations that are outlined on pages 7-8 in the draft letter report. Some of these recommendations are similar to those made in 2006. The recommendations are:

- ✧ The GCRP needs to develop a clear, focused mission statement in enough detail that it can "monitor its borders" to forestall extraneous demands and to hold itself accountable to a discrete set of activities.
- ✧ The GCRP should include intramural and extramural elements in research on nonlinear/threshold responses (currently there is only one extramural STAR grant planned that deals with nonlinear responses).
- ✧ The GCRP should make a greater effort in facilitating the "harvest" of program results; this issue deals with the use and communication of program results.

Beyond the charge questions, the Subcommittee made some additional observations. EPA responses to global change are likely to increase demand for GCRP to assist with implementation. If this happens, resources are likely to be diverted from the core GCRP mission; this possibility makes it all the more necessary for the GCRP to have a clear mission statement. It is important for GCRP to state not only what it does do, but also what it does not do. The Subcommittee also observed that GCRP resources are being

constrained by outside influences such as court-ordered mandates; this may justify special consideration of supplemental budgetary requirements for the GCRP.

Dr. Duke identified the other Subcommittee members including Drs. Milton Russell, Rita Colwell, Patrick Mulholland, Claudia Nierenberg, and Ruth Reck. Dr. Duke concluded his presentation by asking BOSC members if they had any questions about the draft letter report.

Drs. Weiss and Falk were the vetters of the draft letter report. Dr. Weiss opened the discussion by commending the Subcommittee for preparing an excellent report. The GCRP is a very complex program that is in an early developmental stage. She agreed with the point that the GCRP needs to have a clear mission statement. A statement that sets boundaries will be needed to fend off extra future demands to the program. Before 2011, if resources are available, it would be useful for the GCRP to expand their intramural research program. Nonlinear effects research is a very important issue in climate change. Dr. Weiss also agreed with the focus on outputs not outcomes and the focus on communicating results to decision makers.

Dr. Weiss is a program evaluator and survey research is one of her areas of expertise. She would be pleased to help GCRP on the design of the survey instrument but as the Subcommittee observed, the wide array of audiences can present difficulty. It might be possible to focus a survey on the responses from audience "A." This audience would be responsible for only one subset of actions; this might be a way to obtain some feedback.

Like Dr. Weiss, Dr. Falk liked the draft report and the Subcommittee recommendations. There were two areas Dr. Falk wanted to discuss. First, he agreed that a survey should be conducted and the approach offered by Dr. Weiss is one way to design it. Second, Dr. Falk stressed the importance of the MYP and LTGs. On page 15 of the draft report, for example, five alternatives are offered for LTG 2. There are some big differences among these alternatives. Given the differences among these alternatives, Dr. Falk wondered whether it was too early for the Subcommittee to conduct its mid-cycle review.

Dr. Duke replied that they asked the GCRP what the process for completing the MYP would be, and they were told that once the MYP is completed it would be offered to the BOSC or SAB for review. Dr. Saylor reminded BOSC members that this was not the first mid-cycle review conducted wherein a MYP was not available. Dr. Haas noted, however, that the big differences among the LTG 2 alternatives limit how the program can go forward. He asked whether the Subcommittee was leaning toward one or more alternatives but had not yet selected one explicitly. Dr. Duke replied that the Subcommittee did not have a preference for an alternative but that the GCRP should think about the implications of each alternative.

Like Dr. Haas, Dr. Weiss wondered if the mid-cycle review may be too soon after the original program review; only 18 months separated the two reviews. Dr. Duke replied that the Subcommittee did not know. Both the program shift prior to the original review and the response to the court-ordered mandates since that review suggested that a mid-cycle would be warranted. Dr. Haas explained that the draft report described the program shifts very well. He still has difficulty with all the LTGs' possibilities because there are too many directions associated with each of the alternatives.

Dr. Saylor asked if the Subcommittee expects a response from the GCRP based on their report. Dr. Duke replied that the Subcommittee did not address this issue. Dr. Saylor suggested that it might be useful to have a GCRP response to the Subcommittee recommendations. Alternatively, Dr. Duke suggested that the MYP review might offer an opportunity to assess their reactions to the recommendations. Dr. Weiss offered that she would be reluctant to ask the GCRP for a response to the Subcommittee review because there were many demands placed on them at this time.

Ms. Kowalski observed that the GCRP wanted BOSC feedback given the reviews the program had undergone. Dr. Duke replied that this was consistent with his understanding of the GCRP request to the BOSC. He pointed out that the Subcommittee was not asked to recommend a specific alternative.

Dr. Sayler asked if the vetters had any further suggestions about the Subcommittee draft report. Dr. Weiss suggested that the statement about a survey could be a little less firm. The focus of a survey on a narrow set of clients might provide some useful information.

Regarding the charge to the Subcommittee, Dr. Duke referred BOSC members to paragraph 2, page 13 of the draft report. He pointed out that it was ambiguous whether ORD requested Subcommittee comment on the alternative phrasings of three LTGs or whether they asked which alternative were the most appropriate for GCRP. Dr. Weiss added that GCRP is trying to develop LTGs in a shifting situation. Dr. Duke noted that the GCRP has combined two separate goals for water and ecosystems into a single goal.

Dr. Sayler asked about the inclusion of the Appendix C: Bibliometric Analysis in the report; he thought it was too long to be included. Dr. John Giesy agreed with his observation. Bibliometric analyses are not normally included in BOSC mid-cycle reports.

Dr. Falk thought that the draft report would be valuable to the GCRP and that it would be worthwhile to determine if their research program had made any decisions about their LTGs. Dr. Duke replied that this might be a good idea but he wondered how the Subcommittee would ask about the status and how the draft report would be changed.

Ms. Kowalski pointed out that the original review actually occurred in September 2005, although the BOSC report was not released until March 2006. It takes several months between the completion of a BOSC program review and approval by the BOSC Executive Committee, and release of the report. Based on the actual meeting date, the GCRP mid-cycle review timing is consistent with other mid-cycle reviews that have been conducted in 2008.

Dr. Sayler asked about the Subcommittee rating of “exceeds expectations”. He wondered if the rating was a unanimous opinion among Subcommittee members. Dr. Duke replied that the decision was based on the original program review recommendations that the GCRP responded to and on the additional demands placed on the program since the original review. The Subcommittee did reach consensus on the “exceeds expectations” rating. Based on the draft report, Dr. Weiss asked why they were not given an “exceptional” rating. Dr. Sayler pointed out that exceptional means the program is meeting all and exceeding some of its goals in terms of the quality of the science produced and the speed at which the results are produced. Unfortunately, after 2 years the GCRP is still undecided about their LTG definitions; thus, they are not exceptional.

Dr. Sayler summarized the changes to the draft report: (1) eliminate the bibliometric analysis; (2) address the issue of a focused survey; (3) edit paragraph 2, page 13 to reduce ambiguity about the charge question; and (4) indicate whether a response is desired from the GCRP about the Subcommittee recommendations. He asked if there was a recommendation from BOSC members to accept the draft report; Dr. Henderson moved to approve the draft report, Dr. Weiss seconded the motion, and Dr. Duke abstained because he was the Vice Chair of the Subcommittee. The BOSC Executive Committee thus approved the draft letter report with the changes identified.

Land Mid-Cycle Review

Dr. Chuck Haas, Vice-Chair, BOSC Land Mid-Cycle Subcommittee

Dr. Haas identified the six members of the Land Mid-Cycle Subcommittee. Besides himself, the members included Drs. Charles Menzie, James Clark, Lynne Haber, Robert Siegrist, and Tim Thompson. Ms. Heather Drumm is the ORD DFO for the Subcommittee. The Subcommittee had two conference calls and will be having a face-to-face meeting on May 8, 2008, following the BOSC Executive Committee meeting. The Subcommittee expects to have an additional conference call following the face-to-face meeting. The Subcommittee plans to have a draft report ready for BOSC Executive Committee review for their September 2008 meeting.

Water Quality Mid-Cycle Review

Dr. Gary Saylor, Vice Chair, BOSC Water Quality Mid-Cycle Subcommittee

Dr. Herb Windom will be asked to chair the BOSC Water Quality Mid-Cycle Subcommittee. Ms. Susan Peterson is the DFO for the Subcommittee. The Mid-Cycle Subcommittee membership is reconstituted from the original water quality program review Subcommittee. The Subcommittee is planning to have a face-to-face meeting with the program representatives on September 23, 2008, in Washington, DC.

Homeland Security Program Review

Dr. Gary Saylor, Chair, BOSC Homeland Security Subcommittee

Dr. Saylor is the Chair of the Homeland Security Subcommittee; Dr. Ellen Raber is the Vice-Chair of the Subcommittee. This is a nine member Subcommittee. Mr. Greg Susanke is the ORD DFO for the Subcommittee. Dr. Saylor pointed out that there has been one teleconference; a second teleconference is scheduled for tomorrow afternoon to discuss the face-to-face meeting with the program representatives. The face-to-face meeting is scheduled for May 28-30, 2008. The Subcommittee expects to complete its review at that time; part of the meeting is closed because of security considerations.

Human Health Program Review

Dr. Gary Saylor, Chair, BOSC Executive Committee

Dr. Saylor noted that Dr. John Evans will chair the Subcommittee again; Ms. Heather Drumm is the ORD DFO for the Subcommittee. A face-to-face meeting is scheduled for the second week in January 2009.

Endocrine Disrupting Chemicals (EDC) Program Review

Dr. Gary Saylor, Chair, BOSC Executive Committee

Dr. Saylor noted that Dr. Swackhamer agreed to Chair this Subcommittee. The Subcommittee will have a face-to-face meeting with the program representatives in February 2009.

National Center for Environmental Research (NCER) Standing Subcommittee

Dr. Gary Saylor, Chair, BOSC Executive Committee

As mentioned earlier, Dr. Saylor noted that Dr. Martin Philbert was unable to attend today's meeting. A conference call and face-to-face meeting are planned for summer 2008; no dates for these activities have been confirmed. A draft charge is being reviewed for this Standing Subcommittee.

Dr. Saylor temporarily adjourned the meeting for a 15-minute afternoon break.

Workgroup Update

Dr. Gary Saylor, Chair, BOSC Executive Committee

Dr. Saylor noted that there were no workgroup activities at this time; so he wanted to open the discussion for possibilities. He suggested that there may be a need for a workgroup to discuss Standing Subcommittees, rather than ORD coming to the BOSC to talk about Standing Subcommittees. Similarly, he suggested that there may be a need for a workgroup on biofuels.

In January 2008 when the issue of biofuels was raised, Ms. Kowalski mentioned that Dr. Kevin Teichman asked if there was interest in forming a BOSC biofuels workgroup because the Biofuels Research Strategy was due to be completed in the Spring 2008. Although she did not know the status of the Strategy, Ms. Kowalski suggested that this might be an initial issue for a workgroup to consider. Dr. Saylor suggested that a workgroup might be formed on the BOSC rating tool, given the NAS report recommendations on efficiency. A workgroup might consider how to address investment efficiency metrics in conjunction with ORD representatives. Dr. Saylor asked BOSC members for comments on these suggested activities.

Dr. Swackhamer admitted that she liked the idea of a Subcommittee to look into the status of the Biofuels Strategy. Dr. Duke seconded that suggestion, although he may have a conflict of interest because his organization received a small EPA grant for a conference they completed on the topic. Dr. Saylor added that within biofuels there are significant air, ecological, and energy input/output issues; depending on the kinds of biomass substrates being utilized, there are significant water and water quality issues. In lignocellulosic materials, there are more water related issues; mercury is tied up in forest products; and there are a lot more materials to consider than found in corn, soybean, or sugar cane.

Dr. Haas noted that Mr. Alan Hecht, Sustainability Director, ORD, made a presentation to the SAB Integrated Nitrogen Committee, on April 10, 2008, about the proposed EPA Biofuel Strategy. The EPA Strategy apparently will be released in June 2008. Dr. Demerjian added that EPA has numerous requirements on biofuels as a result of the Energy and Independence Security Act of 2007 (the new National Energy Policy Act). This effort also will be dependent on the mitigation strategy for greenhouse gases; there are issues dealing with carbon dioxide and nitrogen oxide.

Dr. Saylor asked if any BOSC members were familiar with Dr. Virginia Dale's work on dead zone in the Gulf of Mexico and biofuels. Dr. Swackhamer mentioned that she was the author of a hypoxia report that dealt with the issue; Dr. Randy Bruins, EPA Cincinnati, is doing research in this area. Dr. Saylor noted that there are several BOSC volunteers for this new biofuels workgroup; Dr. Swackhamer will lead the effort and follow up with a status report on the Biofuels Strategy. Ms. Kowalski added that she will check with Mr. Hecht about the status of Strategy. Dr. Daston cautioned that Mr. Hecht may be dealing with the SAB and the BOSC may need to narrowly define their role in any biofuels effort.

Dr. Demerjian pointed out that there were numerous biofuel air and water quality issues. Dr. Saylor noted there may be some unintended consequences from biofuels and this might be where the BOSC could offer some assistance. EPA is getting political pressure to potentially rescind its biofuels requirements because it is driving up food costs. It was proposed that Mr. Hecht be asked to address the BOSC during its September 2008 meeting.

Dr. Saylor asked if any BOSC members might be interested in a nanotechnology workgroup. Ms. Kowalski noted that there will be a presentation tomorrow about the land program nanotechnology effort. Dr. Demerjian stated that there is no clear definition of EPA's role and responsibilities in nanotechnology but he predicts that it will be written into the Clean Air Act (CAA). Many federal agencies are already involved in nanotechnology research. Dr. Randy Wentsel may be able to provide some explanation of what is going on during his presentation tomorrow. Dr. Haas added that NIEHS has a

major nanotechnology effort focused on worker effects. Dr. Saylor noted that the NSF may be creating a National Nanotechnology Center.

Dr. Saylor asked how investment efficiency could be built into future BOSC program reviews. Dr. Duke replied that EPA plans for responding to the NAS report may guide what the BOSC should do in the future. Dr. Weiss liked what the NAS report said about investment efficiency but she did not like the terminology. She did not want to use new words for old concepts. Dr. Weiss suggested that investment decisions should be central issues in BOSC reviews. Dr. Haas noted that evaluating programs was not one-dimensional; efficiency, relevance, quality, and performance should always be considered. Dr. Saylor commented that the BOSC does a good job of evaluating programs relative to quality, relevance, and leadership. The Agency needs help to develop metrics that can be used to address these issues. EPA needs help to quantify these issues.

Dr. Weiss agreed to lead a BOSC workgroup to investigate investment efficiency metrics; Drs. Henderson, Haas, and Demerjian agreed to be workgroup members. Any progress the workgroup makes can be discussed at the September 2008 BOSC Executive Committee meeting.

Ms. Kowalski reminded BOSC members that the Homeland Security Program Review has a charge question about efficiency. There is a lot of uncertainty about what may come out of this review question. Given that the Human Health program review is not until January 2009, there may be an opportunity, during the intervening months, for BOSC members to refine a new charge question on efficiency. As mentioned earlier, a summary of the April 10, 2008, EPA/OMB workshop on the NAS report is available on the Web. This summary may give BOSC members more insights on investment efficiency issues. Mr. Juengst is the ORD official responsible for coordinating the ORD response to the NAS report.

Dr. Saylor asked the BOSC members to revisit what may be possible in these workgroup areas tomorrow afternoon. He noted that there is a Sustainability Mid-Cycle Review in January 2009 that needs a chairperson. Dr. Giesy agreed to be the Chair of the review and asked if the Subcommittee could be restructured. Dr. Saylor agreed to a restructuring of the Subcommittee, adding that ORD will have to assign a DFO as well. Dr. Swackhamer will chair the EDC program review. Dr. James Klaunig will be asked to chair the Human Health Program Review and Dr. Falk will be the vice-chair.

Ms. Kowalski noted that, in the future, as a new cycle of program reviews are started there is an opportunity to include new members as well as use old members who previously participated in relevant program reviews. This approach is being used for the Human Health Program Review. New Subcommittee compositions might be one-third of the Subcommittee from the original members with two-thirds new members; this could help continuity and allow new ideas to be included. Ms. Kowalski also suggested that no one chair more than two back-to-back reviews. Dr. Klaunig, for example, did not chair the Human Health Mid-Cycle Subcommittee; however, he did chair the Subcommittee that conducted the original program review.

Ms. Kowalski explained that there will be five BOSC program reviews in 2009; two in the beginning of the year; two in the summer; and one at the end of the year. During this time, there also will be activities by the Computational Toxicology Subcommittee and the NCER and NERL Standing Subcommittees. Dr. Saylor asked if Dr. Daston should remain as the Chair of the Computational Toxicology Subcommittee. He noted that the BOSC Standing Subcommittees were created in response to requests from the ORD Center Directors who wanted specific guidance and advice. Dr. Daston offered to remain the Chair for another year and rotate off as chairperson at that time.

Dr. Weiss agreed with Dr. Saylor's earlier suggestion that a BOSC workgroup could be created on standing subcommittees. The issue is whether the BOSC wants to be proactive rather than reactive in creating standing subcommittees; for example, should a BOSC Standing Subcommittee on Global Change

be created. Every 2 years, the BOSC reviews programs. He noted that some laboratory and center directors are more aggressive in seeking advice and guidance than others. Dr. Saylor cautioned that creating more standing subcommittees would create a greater work load for the BOSC. Another issue is whether standing subcommittees might overlap, supersede, or feed into formal program or mid-cycle reviews. Alternatively, this could make program reviews go faster if more background information is available. Ms. Kowalski mentioned that she and Dr. Teichman periodically discuss this issue of standing subcommittees for other ORD laboratories and centers, and their office was doing outreach to determine if there was interest in BOSC support.

Dr. Saylor asked about potential dates for the January 2009 BOSC meeting. There is the Human Health Research Program Review the second week of January and the EDC Review in early February 2009. In addition to these reviews, there will be a Presidential Inauguration in late January 2009. Ms. Kowalski agreed to survey BOSC members to determine their availability for a January or February 2009 meeting.

Dr. Saylor asked about BOSC vetters for the upcoming subcommittee letter reports. Ms. Kowalski noted that vetters were needed for the Land Mid-Cycle Review and the Homeland Security Program Review. Dr. Haas offered to be the vetter for Homeland Security but may have a conflict of interest. Dr. Daston offered to be a backup for Dr. Haas if he has a conflict. Dr. Falk also offered to be a vetter for Homeland Security. Drs. Ryan and Duke offered to be vetters for the Land Review. Ms. Kowalski suggested that vetters for the NCER Standing Subcommittee and the Water Quality Mid-Cycle Review be discussed at the September 2008 BOSC Executive Committee meeting.

Dr. Saylor noted that the Committee had covered everything for the day. The meeting adjourned at 4:28 p.m.

WEDNESDAY, MAY 7, 2008

Opening Remarks

Dr. Gary Saylor, Chair, BOSC Executive Committee

Dr. Saylor called the meeting to order at 8:35 a.m. He welcomed everyone to Day 2 of the 38th meeting of the BOSC Executive Committee. He noted that Dr. Philbert would be joining the Committee by phone. He also noted the changes in the agenda. Dr. Benson would provide an ORD Update at 1:00 p.m. and it was possible that Dr. Wentzel might give his nanotechnology presentation by teleconference. Dr. Henderson will chair the meeting from 1:00 p.m. until the end so that Dr. Saylor can participate in a teleconference call.

ORD's Ecological Research Program

Dr. Steve Jordan, NHEERL Gulf Breeze Division

Dr. Jordan is a research ecologist and Special Assistant to the Director of the Gulf Ecology Division. His presentation was on ecosystem services, which is a new direction for EPA's ecological research program. Dr. Rick Linthurst is the ORD NPD for Ecological Research. National assessments are a major step toward accountability for ecosystems. ORD is transferring the technology for these systems to the EPA Office of Water (OW) and the States.

Dr. Jordan pointed out that the ORD Ecological Research Program is large scale, bold, and long term. The vision for the program is to provide a comprehensive theory and practice for quantifying ecosystem services and their value to human well-being. The ERP aims to consistently incorporate this information into environmental decision making. The goal for the program is to transform the way people understand

and respond to environmental issues by clarifying the ways in which management choices affect the type, quality, and magnitude of ecosystem services.

Dr. Jordan described how the drivers, (forces that affect ecosystems) and the stressors, (ecosystem conditions, structures and functions) influence ecosystem services that, in turn, translate into values. Wetland functions such as reactive nitrogen removal purify water. Another function wetlands provide is recharging ground water, which replenishes water supply and protects against drought. Services in turn translate into values. Water purification, for example, reduces treatment costs and improves human and ecological health. Most values have economic dollar values. Water supply services results in a higher health and well-being value for sustainable communities.

Dr. Jordan identified two key findings from the Millennium Ecosystem Assessment (MEA) that greatly influenced the ORD ERP. All humans depend on nature and ecosystems to provide the conditions for a decent, healthy, and secure life. Second, today's technology and knowledge can reduce the human impact on ecosystems but interventions are unlikely to be fully deployed until people stop perceiving ecosystems to be free and limitless.

ERP's role is to provide the science to: (1) clarify this dependence; (2) describe the full range of values; and (3) quantify what is known about the limited versus limitless nature of different services. Dr. Jordan pointed out we know how to preserve and protect these ecosystems but we do not invest in the methods until we realize the cost of not doing so. He offered two quotes from the 2005 BOSC ERP Subcommittee that recognized the ERP as "a comprehensive federal research program" and that asserted "the new research on the provision of these ecosystem services is essential."

Dr. Jordan noted that the National Program Director (NPD) for Ecological Research, Dr. Rick Linthurst, has previously pointed out that EPA's challenge is "to change the economic and human well-being foundation for environmental decision-making relating to ecosystems." Dr. Jordan stated that the MYP for Ecological Research has five LTGs:

1. Effective decision support (this means getting the tools to the decision makers).
2. National mapping, inventorying, and monitoring (these are some of the early projects that the ERP hopes to produce).
3. Nitrogen assessment (this is a national scale assessment of the positive and negative nitrogen effects on ecosystems).
4. Ecosystems assessments (these are selected ecosystems such as wetlands, coral reefs, etc., to look at the ecosystem services provided and their values).
5. Place-based demonstration projects (these are based on specific concerns across the country).

Although the SAB reviewed the MYP in April 2008, it is not yet ready for release.

Dr. Jordan identified some major research questions regarding pollutant-based, ecosystem-based, and place-based ecosystem services. The questions relate to how these ecosystem services change under alternative management scenarios. For nitrogen, specific research questions are: what are the responses and what are the thresholds; for wetlands, what kind of decision support tools are needed to protect and enhance these systems nationally; and for coral reefs, what kind of decision support tools are needed to sustain them?

Dr. Jordan explained that four areas have been selected for place-based projects—the coastal Carolinas, the Willamette Valley, the Upper Midwest, and the Tampa Bay region. There are a number of challenges dealing with each of these projects. He outlined the bundling services that can be offered for specific regions such as the Chesapeake Bay. He described economic benefit indicators such as shoreline protection, aesthetics, fishing, and recreational boating for eight Chesapeake Bay Island sites (Dr. Lisa Wainger’s work). Dr. Jordan provided an overview of ERP activities across eight cross-cutting themes including human health and well-being, landscape characterization and mapping, modeling, inventory and monitoring, decision support, education and outreach, and wetlands and nitrogen. Dr. Jordan is the wetlands coordinator for ERP. One point that has been emphasized by the NPD is the integration of ERP across all of ORD. A hallmark of the ERP is its effort to be comprehensive and inclusive in its work within ORD and across the Agency.

Dr. Jordan displayed a matrix that identified the levels of program integration ERP maintains. The matrix identified ERP LTGs and projects, coordinators for each project, and issues affecting each of the place-based projects. Dr. Jordan displayed a picture of the partners associated with the Tampa Bay Ecosystem Services Pilot Project; Dr. Mark Russell, coordinator for the Tampa Bay Project, called this the “NASCAR slide” because of all the logos of the local partners.

Dr. Jordan outlined ERP timelines that identified 2007–2008 program efforts and the projected program efforts through 2014. In spring 2007, a draft strategy was produced; in July 2007, an internal review of their strategic plans was completed; and in fall 2007, a draft MYP was completed. Detailed research planning was conducted and cross-ORD commitments were identified and made. In April 2008, the SAB reviewed the MYP and by July 2008, the ERP peer reviewed research plans will be complete. From 2008 to 2014, the ERP will conduct their research and deliver products.

Dr. Jordan concluded that the ERP offers a trans-disciplinary, human-centric approach. ORD scientists will focus on the ecological production functions; their implementation plans are the next critical hurdles. He asked if there were any questions about his presentation.

Dr. Haas asked where the locus of EPA economic expertise resided and how economic questions were incorporated into the front end of research efforts. Dr. Jordan replied that the primary economic expertise within the Agency is the National Center for Environmental Economics that is within the immediate Office of the EPA Administrator in Washington, DC. There are economists in the NERL, Cincinnati; and an economist within the Gulf Ecology Division. Economic questions are incorporated into the ERP through a valuation theme that is part of the human health and well-being aspects of the research program.

Dr. Swackhamer asked who served as the ERP Nitrogen Coordinator. Dr. Jordan responded that Jana Compton is the ERP Nitrogen Coordinator. Dr. Jordan also identified himself as the wetlands, nitrogen cross-cell person. Dr. Swackhamer asked if they were dealing with nitrogen nationally—fresh water as well as coastal nitrogen? Dr. Jordan responded positively but acknowledged that the program lacks the research capability to do it all. In the upper Midwest, Dr. Randy Bruins, NERL, Cincinnati, is the lead.

Dr. Daston asked about biofuel runoff into water; was there an ecological component to biofuels? Dr. Jordan replied that this was an excellent question but it was not an issue under investigation at this time. Dr. Swackhamer noted that the University of Minnesota is doing some research in this area.

Based on her CASAC experience, Dr. Henderson noted that when the primary standard for human health was set, data were available; but there was limited data available for the secondary standard. She asked if anyone was working on data for the secondary air standard. Dr. Jordan replied that he may not be able to provide the best answer but water quality criteria data are developed in the water program. Nonetheless, some nutrient criteria research is being conducted within the ERP on estuaries and near coastal waters.

Dr. Sayler closed the discussion noting that Dr. Benson would provide an overview of the Gulf Breeze Laboratory followed by individual presentations by laboratory researchers.

NHEERL Gulf Ecology Division Site Visit

Dr. Bill Benson, Director, Gulf Ecology Division

Dr. Benson welcomed everyone to the Gulf Ecology Division (GED). He said he was very impressed with the caliber of BOSC members and their interest in having a face-to-face meeting at the GED. Dr. Benson expressed his appreciation of the time and effort put forth by BOSC members as an advisory panel to ORD.

Dr. Benson outlined the content of the Gulf Ecology Division presentations. He provided an introduction and overview of the Division, which operates under three MYPs. Each of the Branch Chiefs provided a summary of the research conducted within these MYPs, and covered the studies presented in the poster sessions. A demonstration was scheduled in the safe pesticides/safe products research area, followed by the poster sessions. Then, meeting participants will be divided among three groups: a laboratory tour and two research vessel tours.

Dr. Benson pointed out that the Gulf Ecology Division is within the National Health and Environmental Effects Research Laboratory (NHEERL); Dr. Hal Zenick is the Director, NHEERL. Drs. Julian Preston and Steve Hedtke are the Associate Directors for Health and Ecology, respectively. The health side is reorganizing from five to three divisions; two in Research Triangle Park, North Carolina, and one at the University of North Carolina, Chapel Hill. On the ecology side, there are four divisions—Atlantic Ecology Division (Narragansett, Rhode Island), Mid-Continent Ecology Division (Duluth, Minnesota), Western Division (Corvallis, Oregon) and the Gulf Ecology Division (Gulf Breeze, Florida).

Dr. Benson noted the focus of GED is coastal ecological effects. The GED has 63 staff, of which 40 percent have Ph.D.s. GED is on a 16-acre federally owned island. The island was formed from ballast rock from commercial vessels in the late 1800s. During its first life as a federal facility, it served as a public health service quarantine station. Following this, the station was an oyster research federal facility and a fisheries research facility. With the creation of EPA in 1970, the station became part of the Agency's Office of Research and Development.

Dr. Benson pointed out that the laboratory has 68,000 square feet of work space; 25,000 square feet of laboratory space. GED is a unique ORD research facility with regard to coral research. GED has a year-round sea water and wet laboratory facility, and, as mentioned above, there is a coral research facility for coral culture and exposure. GED has a research fleet including access to the ocean survey vessel named "Bold." The EPA OW maintains Bold. This vessel can sustain Gulf of Mexico hypoxia work for up to 8 to 10 weeks. GED works in three MYPs that include: nutrient and hypoxia under the water quality MYP; ecological assessments and services under the ecological MYP; and predictive ecotoxicology under the safe pesticides/safe products MYP. A demonstration of Web-ICE (Web-based Interspecies Correlation Estimation) developed with and used by the OW and the EPA Office of Pesticide Programs was planned. Gulf Breeze is developing a Cooperative Research and Development Agreement with Proctor and Gamble on Web-ICE.

Dr. Benson displayed a matrix to describe the GED Mission. He explained issues regarding the quality of science and how this impacts EPA needs. GED stresses both the quality of the research as well as the Agency needs that drive the research. GED conducts research, provides advice, and offers leadership through participation in scientific societies and professional groups. Dr. Benson has been the GED Director since 1999; there are two associate directors—Connie Shoemaker, Program Operations, and Kevin Summers, Science. There are three GED Branches—Rick Greene, Chief, Ecosystem Dynamics and Effects Branch; Mace Barron, Chief, Biological Effects and Population Response Branch; and John

Macauley, Acting Chief, Ecosystem Assessment Branch. GED Branches are treated as administrative and disciplinary homes and the work is conducted across research teams. GED seeks stability in administrative issues but ecological problems are dynamic and change with time, and teams are more adaptive to accommodating such changes. Lisa Smith is the coastal services team leader; Michael Hemmer is the ecotoxicology team leader; and Jim Hagy is the nutrients team leader.

Dr. Benson described how GED determines their problem-driven research programs by addressing problems identified in the MYP. GED works closely with the program office to understand the science questions associated with an environmental problem. Once the science questions are understood, GED works on the approaches to address these questions. GED tries to work on strategic products to address relevant problems. GED strives to be responsive to Agency needs and to produce timely results. They work to create short-term, intermediate, and long-term products for their Agency clients. Dr. Benson concluded his remarks by asking if there were any questions; hearing none, he asked Mr. John Macauley to start the GED Branch presentation.

Mr. Macauley reiterated that the research conducted in the branch was developed under ORD's Ecological MYP, which was previously reviewed by the BOSC. Wetlands are the primary focus of the branch. Three projects are underway—one in the Gulf of Mexico assessing wetland conditions from the Rio Grande River to the Florida Keys. Research gathered from this effort will provide the basis for OW to conduct a national wetlands survey in 2011. Another project focuses on developing decision making tools for wetland ecosystem services and coastal wetlands services. The third project is the development of a human well-being indicator that is responsive to ecosystem services. Researchers hope to create an index that is unifying and matters to people. GED also is the lead for one of the place-based studies conducted under ecosystem services—Tampa Bay, Florida. Tampa Bay represents an almost perfect example of human stress on a natural ecosystem. The goal of this project is to develop decision support tools to help Tampa Bay regional resource managers.

GED is conducting research under the water quality MYP. GED was the lead for the National Coastal Assessment conducted from 2000 to 2006. They are completing this work and transferring it to OW. GED is continuing to work on the National Coastal Condition Report. Mr. Macauley concluded his remarks by asking if there were any questions.

Dr. Duke asked for more information on the well-being index and if there any links to the Council on Environmental Quality (CEQ) national indicators initiatives. Dr. Benson replied that Kevin Summers and Lisa Smith are the GED leads on developing a well-being index. He noted that there was a direct connection between the CEQ initiatives and the well-being index. GED is trying to relate ecosystem services and ecosystem effects on human beings; the creation of a well-being index could translate such information into a useful tool for the public as well as decision makers. Working with researchers outside of ORD is a new effort for GED. GED staff are investigating what others have done to figure out how to do it better.

Next, Dr. Rick Greene described the GED water quality research conducted within the Ecosystem Dynamics and Effects Branch. The water quality MYP is under revision; in its current form GED has research efforts in LTGs 1 and 2. Under LTG 1, GED is informing development and application of Water Quality Criteria. Specifically, rapid assessment protocols for coral reef biocriteria are being developed and approaches to establish estuary nutrient criteria are underway. Within LTG 1.2, biological assessment approaches to biocriteria, the goal is to foster development of coral reef biocriteria through focused field and laboratory research, methods evaluation, and communication among Agency partners and interactive implementation with U.S. jurisdictions. Several coral rapid assessment protocols have been developed under this research area. Within LTG 1.3, nutrient criteria, the goal is to develop and demonstrate approaches to establish nutrient criteria for estuarine waters in support of national, regional and state-based Clean Water Act requirements (CWA 304a). Within this research area, several products are been

prepared, such as the nutrient criteria for estuarine waters based on two ORD reports, one prepared by GED for Pensacola Bay and the other by the NHEERL Western Ecology Division (Corvallis, Oregon).

Under LTG 2, watershed management, GED is developing national monitoring frameworks for estuaries and wetlands, and developing Gulf of Mexico hypoxia monitoring and modeling capabilities. Within LTG 2.2, identifying causes of impairment—Gulf Hypoxia, the goal is to develop model applications, data products and other tools to: (1) predict relationships between nutrient loads and hypoxia, (2) quantify sources of error and uncertainty in nutrient load reduction targets, (3) forecast effects of nutrient management actions, and (4) provide defensible options to guide restoration and decision-making. Within this research area, GED has been providing technical support to OW on Hypoxia Task Force activities and has been involved in preparing several peer-reviewed journal articles.

Dr. Greene concluded his remarks by asking for any questions; hearing none, he asked Dr. Mace Barron from the Biological Effects and Population Response Branch to begin his presentation.

Dr. Barron explained that he was going to briefly describe five areas of research in support of the safe pesticides/safe products (SP2) portion of the MYP. The first program is Web-ICE, which was launched in 2007. Web-ICE has modules for both cross species estimation as well as species sensitivity distributions (SSDs). The methodology for Web-ICE was peer reviewed in several journals over the past 3 years.

The second program under SP2 is the development of tools for chemical prioritization and screening. Under this program, small fish screening models for endocrine disrupting chemicals (EDC) are being developed. The sheepshead minnow was the fish species used for these models.

The third program under SP2 is the development of EDC Test Methods. This has been a GED 5-year effort to develop a multi-generation test protocol for invertebrates and estuarine fish for the EPA Office of Science Coordination and Policy. Mysid are used for the invertebrate test and sheepshead minnow for the 9-month estuarine fish test. GED has completed ORD's only invertebrate EDC test method and ORD's first fish two generation EDC test method.

With the completion of some of EDC Test Methods, GED staff and facilities are being redeployed into spatial fish research for the EPA Office of Pesticide Programs. This fourth program area under SP2 is the development of a spatially-explicit, probabilistic ecological risk assessment. A triad approach is being used to develop this spatial fish population model. This approach includes pilot field studies, laboratory density dependence, and model sensitivity analysis.

The last program is the development of spatially-explicit probabilistic ecological risk assessment. Under this program, GED is developing avian population models to assess the pesticide impacts on bird populations. This work is being done under the NHEERL Wildlife Research Strategy. Population models are being built for birds in agricultural landscapes, such as cotton fields. Another aspect of this project is to assess the indirect effects of pesticides.

Dr. Barron concluded his presentation by asking if there are any questions. Between proteomics and these biological models, Dr. Daston asked if there was a need for computation and how well GED was working with the ORD Computational Toxicology Program. Dr. Mace replied that they were collaborating with the NCCT. Dr. Benson said he visited NCCT last week and they specifically requested integration into Web-ICE and the computational approaches used in that model. Dr. Benson pointed out that they have three GED staff working on computational analysis; they have three vacancies in the modeling area for which they are now conducting interviews.

Dr. Sandy Raimondo next spoke about Web-ICE. She explained why and how Web-ICE was developed. Web-ICE estimates acute toxicities, for both aquatic organisms and wildlife. Dr. Raimondo explained that

ecological risk assessments (ERA) are wide-spread across EPA, being performed by at least four program offices: OPP, OW, the Office of Pollution Prevention and Toxics (OPPT), and in the Superfund/RCRA Program at hazardous waste sites. One of the biggest ERA challenges is the limited amount of toxicity data on species. Given the limited amount of data, questions arose such as: are the tested species representative of the communities being protected; are species endangered and in need of population protection; and is there uncertainty in existing species extrapolation methods? To address these questions, GED developed interspecies correlation estimation (ICE) models. These are extrapolation models that estimate acute toxicity for a species, genus, or family from the known toxicity of a surrogate species. Acute toxicity is defined as a LC50 (lethal concentration for 50 percent of test animals [aquatic]) and LD50 (lethal dose for 50 percent [terrestrial]).

ICE is used in ERA for several activities: it populates toxicity databases; allows for species sensitivity comparisons; directs toxicity estimation for endangered species; and provides quantifiable model confidence. Dr. Raimondo described how ICE models are developed. For the terrestrial database, 4,329 LD50 values are available, and for the aquatic database, 5,866 LC50 values are available. The aquatic database is growing; GED hopes to have potentially 20,000 values in the future. Dr. Raimondo presented a table for log-linear models of the relationship between the acute toxicity (LC50/LD50) of chemicals tested in Rainbow trout and Cape Fear shiner fish species. In conclusion, she pointed out that, for Web-ICE, a suite of models was developed for terrestrial and aquatic species and put it into a Web-based application. The application has several different modules such as air toxicity models and species demonstration models. Web-ICE has been under extensive ORD review and was placed on the Internet in mid-2007.

Dr. Raimondo provided a Web demonstration of Web-ICE. Rather than taking questions at this time, Dr. Benson asked participants to hold them for Dr. Raimondo during the Poster Session. Dr. Benson introduced the seven Poster Session Presenters:

1. Tampa Bay Ecological Services Demonstration Project, Marc Russell
2. Application of Proficiency for Chemical Screening and Prioritization, Michael Hemmer and Kimberly Salinas
3. Nutrient Criteria Research at GED, Jim Hagy and John Lehrter
4. Gulf of Mexico Hypoxia, Jim Hagy
5. Web-ICE, Sandra Raimondo
6. Coral Reef Ecosystem Services, Bill Fisher
7. Wetland Ecosystem Research at GED, Virginia Engle

The Poster Sessions continued from 9:50 a.m. to 10:30 a.m., at which time the site and boat tours began. These tours continued until 12:00 noon, at which time the participants broke for lunch.

ORD Update

Dr. Bill Benson, Director, Gulf Ecology Division

Dr. Benson began his remarks by describing personnel changes within the Agency. Within the Office of the Science Advisor (OSA) Dr. Pai-Yei Whung was recently appointed as the Chief Scientist. Dr. Whung has a doctoral degree in Marine and Atmospheric Chemistry from the University of Miami, and a Master's degree in Oceanography. Most recently, Dr. Whung worked at the U.S. Department of Agriculture (USDA). Prior to that, she served at the National Oceanic and Atmospheric Administration (NOAA). Dr. Whung's permanent appointment was effective April 14, 2008.

Other ORD personnel changes include the appointment of Dr. Kevin Teichman as the new Deputy Assistant Administrator for Science. The senior ORD management team is now Dr. George Gray, AA ORD, Dr. Teichman DAA for Science, and Mr. Lek Kadeli, DAA for Management. Jeff Morris was the

Acting Director, ORD Office of Science Policy and has recently been appointed the Nanotechnology Science Policy lead. Jack Puzak has been appointed the ORD Science Information Official and Howard Cantor is the Acting Director, ORD Office of Resources Management and Administration. Two other recent appointments in ORD are Gary Ankley and Bob Devlin as Senior Science Team Leaders.

Dr. Benson asked BOSC members if they were interested in an ORD discussion of the value of information. Since ORD was unable to have such a presentation at this meeting, he wanted to know if there was an interest in scheduling this discussion for the September 2008 BOSC meeting. Hearing a positive response, Dr. Benson agreed that a presentation would be scheduled for the September meeting.

Another item that was not covered during the current BOSC meeting was a status report on the ORD data mining tool. Dr. Teichman was to provide information but was unable to make this meeting. At this time, ORD continues to develop a decision document analysis tool for data mining to access the extent to which ORD products are been cited by EPA decisions and actions. NCER is using a unique software program that takes the 10-year list of program publications and automatically searches EPA's electronic dockets for hits. The data are aggregated to quantify the total number and the percentage of citations.

Two more general announcements that Dr. Benson provided dealt with a National Design Expo (P3) EPA held on the National Mall on April 20-22, 2008, and an upcoming EPA Science Forum on May 20-22, 2008, in the Ronald Reagan Building, Washington, DC. The Science Forum is titled "Innovative Technologies: Key to Environmental and Economic Progress."

Dr. Henderson, who was acting Chair of the BOSC Executive Committee in Dr. Saylor's absence, asked if there were any questions for Dr. Benson. Dr. Swackhamer asked how the impending Administration change will affect ORD. Dr. Benson was uncertain about potential changes. He speculated that ORD would have a flat budget in the future. He suggested that ORD would continue to focus on the key issues to address the important environmental problems faced by the Agency. When budgets are tight, researchers need to focus on working smarter and in partnership. Administrations change regularly and changes are expected and accommodated.

Dr. Henderson asked about OMB's involvement with EPA in the current Administration relative to regulatory issues. Is there any expectation that this may change?

Dr. Benson replied that as Acting Chief Scientist for EPA he dealt with Agency guidance and framework documents such as cancer guidelines, the nanotechnology white paper, and others. The OSA frequently interacted with OMB. The key issue for OMB is to ensure interagency review. This is a give and take process; it involves working with other federal agencies as well as Chambers of Commerce, small business, and others; OMB is in the middle of these deliberations. Dr. Wentzel added that the recent Union of Concerned Scientists survey is an example of the involvement of outside parties in environmental issues. Dr. Benson explained that environmental officials need to develop a relationship with OMB and understand the office's functions.

Dr. Weiss asked about the Science Advisor. Dr. Benson reiterated that Dr. Gray is both the EPA Science Advisor and AA ORD. The OSA has responsibility in several areas: the Science Policy Council, the Risk Assessment Forum, and the Human Studies Review Board. Examples of Science Policy Council activities include: nanotechnology, peer review, risk characterization, genomics, and regulatory environmental monitoring.

Dr. Henderson asked if there were any more questions for Dr. Benson; hearing none, she thanked Dr. Benson for his remarks and introduced Dr. Wentzel, who made a presentation on nanotechnology.

Nanotechnology

Dr. Randy Wentsel, National Program Director, ORD Land Research

Dr. Wentsel noted that he was filling in for Jeff Morris who was recently named the Acting Nanotechnology Science Policy Lead. Mr. Morris reports to Dr. Gray in this new position. Mr. Morris will be filling in for Dr. Gray on the various federal agency workgroups on nanotechnology. Formerly, Mr. Morris worked with the Organization for Economic Cooperation and Development (OECD) on methods development issues. Dr. Nora Savage has been a technical lead in this area and will remain involved. Dr. Savage has been involved in establishing several grants in this field. ORD has an active nanotechnology research team as well.

Dr. Wentsel described why nanotechnology was important. He pointed out that new nanomaterials offer societal and environmental benefits but the impact of these innovations is uncertain. There are significant R&D investments to advance nanotechnology and there is significant Congressional and public interest in nanotechnology and its health and environmental effects. Some of the key issues regarding nanotechnology are: how, if at all, are nano-scale particles different as environmental contaminants; if different, how should risks be assessed; how should risk be mitigated, and how should nanotechnology be used to benefit the environment?

Dr. Wentsel explained that there are many players involved in nanotechnology including: the federal government, state and local governments, international organizations such as the OECD and the International Standards Organization (ISO), universities, and the private sector. Within EPA, ORD and OPPT have been principally involved. OPPT has been involved because of the potential new uses of these nanomaterials. In 2002, EPA ORD started a nanotechnology grants program and, in 2007, ORD started an inhouse research program.

Dr. Wentsel described the four environmental health and safety pillars affecting nanotechnology. These pillars included: the Interagency Nanotechnology Environmental and Health Implications (NEHI) Strategy; the ORD Nanomaterial Research Strategy (NRS), the OECD Testing Program, and the OPPT Nanomaterial Stewardship Program. Dr. Wentsel stated that the NEHI Working Group released a “Strategy for Nanotechnology-Related Environmental, Health, and Safety Research” in February 2008. A matrix within the Strategy (page 49, Table 2) lays out the roles of various NEHI Working Group members with regard to interagency environment, health, and safety (EHS) research needs.

Dr. Martin Philbert asked about the difference between “Coordinating and Contributor Agencies” in Table 2. Dr. Wentsel replied that the Coordinating Agencies identified in the dark triangles in Table 2 are actually the lead federal agencies with the nanotechnology-related EHS research needs. The contributor agencies identified as circles indicate that these federal agencies are contributing in the research area and relying on the leader (i.e., coordinating agency) for guidance. Dr. Philbert noticed that some of the lead agencies identified in the Strategy, such as EPA, the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Occupational Safety and Health Administration (OSHA), do not have a lot of nanotechnology research resources. Given these designated federal leads, he asked if appropriated resources will change for these agencies. Dr. Wentsel replied that there is interest within Congress to expand nanotechnology EHS funding.

Dr. Swackhamer asked if NEHI was a subgroup of the National Nanotechnology Initiative (NNI). Dr. Wentsel replied positively that there are two current EHS nanotechnology strategies, the NEHI Strategy and the January 24, 2008, ORD NRS. Dr. Wentsel also noted that the National Academies are reviewing the NEHI Strategy.

Dr. Haas asked if the strategies consider post-consumer wastes. Dr. Wentzel replied that the ORD NRS includes a Life Cycle Assessment approach. The NRS was peer reviewed 2 weeks ago and the draft NRS is publicly available on the Land Research Program Web Site.

Dr. Philbert asked about nanotechnology definitions. He found the NEHI Strategy focused on man-made materials whereas the NRS included engineered materials. Dr. Wentzel replied that there is a footnote in the NRS that defines terms. The NRS focuses on engineered materials and the NRS peer reviewers agreed with this approach. There are five types of engineered nanomaterials considered in the NRS.

Dr. Wentzel referred to Figure 2-4, page 12, in the NRS as a chart illustrating the various federal sources of scientific information for use in EPA decisions on nanotechnology. He noted that this information was drawn from earlier NNI data.

ORD started preparing the NRS in March 2007, and it was completed prior to the release of the NEHI Strategy. Four research themes were considered within the NRS: sources, fate, transport and exposure; human health and ecological effects; risk assessment methods; and risk prevention and mitigation. The NRS has gone through many reviews including an ORD review, an EPA Science Policy Council review, and external peer review. As a co-lead on the NRS writing team, Dr. Wentzel used the Mercury and Human Health Research Strategies as templates in preparing the NRS. When the NRS was externally peer reviewed, ORD was asked for an implementation plan in conjunction with the NRS. ORD was not able to prepare an implementation plan because the initial priority was on defining the NRS focus.

EPA was one of the first federal agencies in NNI that prepared its own nanotechnology research strategy. The NRS also will help support the EPA OPPT Nanoscale Materials Stewardship Program (NMSP). ORD has research coordination teams usually for a single program office, but for nanomaterials ORD developed a cross-agency team. In the NRS, ORD used a product life cycle to illustrate the interrelationship of the research activities with research products informing risk assessment and management issues. In the NRS, ORD developed Figure 3-2, page 22, to illustrate the relationship of key science questions to risk assessment and management decisions.

Dr. Wentzel outlined the science questions with each of the four NRS themes. For NRS Theme 1: Sources, Fate, Transport, and Exposure, the key science questions are:

- ✧ Which nanomaterials have a high potential for release from a life-cycle perspective?
- ✧ What technologies exist, can be modified, or must be developed to detect and quantify engineered materials in environmental media and biological samples?
- ✧ What are the major processes/properties that govern the environmental fate of engineered nanomaterials, and how are these related to physical and chemical properties of these materials?
- ✧ What are the exposures that will result from releases of engineered nanomaterials?

For the remaining three themes, there is only one science question associated with each. In the external peer review, reviewers found some of these remaining questions too broad, so these questions may have to be expanded in the future. For NRS Theme 2: Human Health and Ecological Research to Inform Risk Assessment and Test Methods, the key science question is:

- ✧ What are the effects of engineered nanomaterials and their applications on human and ecological receptors, and how can these effects be quantified and predicted?

For NRS Theme 3: Risk Assessment Methods and Case Studies, the key science question is:

- ✧ Does Agency risk assessment approaches need to be amended to incorporate special characteristics of engineered nanomaterials?

For NRS Theme 4: Preventing and Mitigating Risks, the key science question is:

- ✧ What technologies or practices can be applied to minimize risks of engineered nanomaterials throughout their life cycle, and how can nanotechnology's beneficial uses be maximized to protect the environment?

Dr. Wentsel next explained how ORD might allocate its nanotechnology resources across the four NRS themes over the next 5 years, 2008 to 2013. If EPA is given the lead in NRS Theme 1: Source, Fate, Transport and Exposure, for example, the majority of its research efforts would be devoted to this theme in the next few years; whereas, if EPA was to be a contributor to NRS Theme 2: Human Health and Ecological Research, then the Agency's resource commitments might be lower in the next few years, building to a greater commitment in the out years. Likewise, for NRS Themes 3 and 4: Risk Assessment and Mitigation, respectively, EPA resource commitments will likely be higher in the out years.

Dr. Wentsel outlined a few key issues ORD is considering in building and managing the new program. These issues include: resource allocations to laboratories and centers, resource changes and shifts over time; and resource management, tracking, and accountability. He described ORD's budget history relative to nanotechnology starting with the FY 2004 enacted budget through the FY 2009 proposed budget. Initially, about \$5 million was taken out of the ORD exploratory research program to support nanotechnology (in the enacted FY 2004 budget). This support was continued through FY 2007, wherein a \$3 million add-on was provided to start an inhouse nanotechnology research program. In FY 2008, ORD received \$8.2 million for nanotechnology and the FY 2009 request is for \$14.9 million.

Dr. Wentsel also showed a breakdown of FY 2008 resource allocations by program projects. He recounted that many of the FTE positions were shifted internally to staff the Nanotechnology Research Program (NRP). In answer to a question about how many employees were from NCER, Dr. Wentsel said that 3.5 people were from NCER and 21 were ORD employees involved in research.

The NRS will guide the management of the nanomaterials research program. Dr. Wentsel emphasized the importance of establishing federal leadership for this initiative. Staff need to function as knowledge sources and the program must visibly provide useful products. The extramural funding that will build up inhouse capabilities will help the ORD develop linkages to universities and consultants. An implementation framework could be linked to existing MYPs with integration across research programs.

Dr. Wentsel envisions a time in the future when, if the program grows to become a \$20-30 million operation, there would be a shift towards consolidation. Dr. Swackhamer asked for more specifics about the practicalities of mapping the NRS to existing MYPs. How can new research needs be added onto needs integral to existing MYPs? Dr. Wentsel acknowledged that the NRS would require shifting people to work on new priorities.

Dr. Henderson commented that most exposures would occur during the manufacturing process and that NIOSH has taken a lead role in human and environmental exposure assessment. Dr. Wentsel responded that the nanomaterials program researchers were more interested in exposures that occur in the disposal of nanomaterials and that the workplace should be investigated by OSHA. To identify the categories of nanoparticles that could be hazardous is one of the program's goals. If certain substances could be eliminated as hazardous through modeling or screening efforts, the scope of future studies could be better defined.

Dr. Haas asked Dr. Wentsel if there were lessons to be learned from initiating the program via the STAR grant process. Dr. Wentsel pointed out that EPA and NSF grantees have done a good job laying the groundwork and giving direction to where additional studies are needed. For example, grantees presented their data on eco effects testing at last year's meeting of the Society of Environmental Toxicology and Chemistry. Valuable linkages are being developed in universities between the nanotech developer and the effects tester. He reiterated that the nanomaterial research program needed to build on the body of basic science knowledge, not redo it.

Dr. Philbert questioned why ORD's Land Research Program was chosen for the NRS when there are other sources of exposure, such as water and cycling through the environment. Dr. Wentsel said that even though the NRS had the "land" moniker that research would cover broad areas and address multiple program office needs. Researchers will be conducting aquatic, atmospheric, terrestrial, and sediment studies. The key is to assemble a critical mass of knowledge and proceed from there. Dr. Philbert applauded the researchers' hazard-identification efforts and their emphasis on ruling out materials that were not hazardous.

If the nano program has the potential to grow to a \$30 million national program, Dr. Swackhamer questioned where the money would come from. She asked whether the FY 2009 budget reflected the necessary FTEs and whether personnel would be shifted from within the Land division or from other parts of ORD. Dr. Wentsel acknowledged that most of the personnel came from the Land Research Program. He emphasized the importance of EPA establishing leadership within several of the themes he presented.

Dr. Henderson asked whether the BOSC should create a nanotechnology workgroup. Dr. Philbert reflected that the NNI is still in its formative stages and until a national strategy has been set, a workgroup would not be of much value. For the January meeting, he suggested an update on models development and on the direction that scientific discovery is leading the EPA. He reported that the document detailing the NNI strategy was almost complete. A NAS panel will be evaluating the document for the overall implications for the entire federal government. Ms. Kowalski confirmed that the BOSC can receive an update in January. Dr. Philbert reiterated that the focus be on intra- and extramural science rather than the administrative strategy.

SAB Activities

Dr. Rogene Henderson, BOSC Vice-Chair

Dr. Henderson outlined the progress of the SAB, referring to the FY 2008 Operating Plan in the BOSC meeting book. Among the completed projects are the ecological risk assessment approach, hypoxia in the northern Gulf of Mexico, and the report on updating methodologies for estimating cancer risk from ionizing radiation. Reports on preparedness for manmade and natural disasters and strategic directions of EPA's research and development program are under finalization. Dr. Swackhamer said that the Report on the 2007 Environment has been completed and submitted to the EPA Administrator.

The Integrated Nitrogen Committee has been quite active. In the past, when setting nitrogen oxides (NO_x) standards, only oxidized nitrogen has been considered. CASAC's Subcommittee, looking at the secondary standards for nitrogen, is now recommending that they include all reactive forms of nitrogen.

The Ecological Research Program Strategy and MYP are being reviewed. Dr. Henderson noted the importance of the influence analysis of air pollution benefits report, pointing out that the uncertainty associated with the benefits of air pollution regulation prevents stricter standards from being set. She reported on CASAC's progress in reviewing the six criteria pollutants on a 5-year basis. Three different face-to-face meeting groups are evaluating the primary and secondary NO_x/SO_x standards. She recognized the excellent job that Ted Russell was doing as chair of the NO_x/SO_x secondary panel. Dr. Henderson announced that the lead review has been completed and that the EPA Administrator has released a

proposed rule for lead standard. A carbon monoxide panel has begun work and another panel is reviewing particulate matter.

Dr. Swackhamer asked for clarification on the difference between the Committee on Valuing the Protection of Ecological Systems and Services (C-VPES) and the Environmental Economics Advisory Committee. Dr. Duke responded that CVPES is an ad hoc committee.

The motion to adjourn the meeting was offered and seconded. The meeting adjourned at 2:43 p.m.

Action Items

- ✧ The draft letter report of the NCCT review will be modified based on Dr. Henderson's comments and Dr. Daston will insert the context of the charge questions in response to Dr. Swackhamer's suggestion. The letter report was approved unanimously by the BOSC Executive Committee.
- ✧ Dr. Demerjian will revise the NERL draft report by modifying the table in Exhibit 2 and clarifying the fifth recommendation on page 2. He will change the first page of the draft letter report to read "advice and guidance" rather than "consultation." The BOSC Executive Committee approved the draft letter report.
- ✧ Ms. Kowalski will talk to Dr. Reiter to see if the draft framework exposure portion of the Framework document could be placed on the Web.
- ✧ Dr. Duke will make the following changes to the GCRP draft letter report: eliminate the bibliometric analysis; address the issue of a focused survey; edit paragraph 2, page 13 to reduce ambiguity about the charge questions; and indicate whether a response is desired from the GCRP about the Subcommittee recommendations. The BOSC Executive Committee approved the draft letter report with these changes.
- ✧ Dr. Swackhamer will follow up on the status of the Biofuels Strategy and Ms. Kowalski will check with Mr. Hecht on the status of the Strategy.
- ✧ Mr. Hecht will be asked to address the BOSC on biofuels during its September 2008 meeting.
- ✧ Dr. Geisy agreed to be the chair of the Sustainability Mid-Cycle Review Committee.
- ✧ Dr. Klaunig will be asked to chair the Human Health Program Review.
- ✧ Dr. Swackhamer will chair the EDC program review.
- ✧ Dr. Daston agreed to remain for another year as the chair of the Computational Toxicology Subcommittee.
- ✧ Dr. Weiss will lead a BOSC workgroup on investment efficiency metrics. Drs. Henderson, Haas, and Demerjian agreed to serve as members of the workgroup. The workgroup's progress will be reported at the September 2008 BOSC meeting.
- ✧ Dr. Haas agreed to serve as a vetter for the Homeland Security Program Review. If he has a conflict of interest, Dr. Daston will serve as the vetter. Dr. Falk also agreed to serve as a vetter for the Homeland Security Program Review.
- ✧ Drs. Ryan and Duke agreed to serve as vettors for the Land Review.

May 6-7, 2008 BOSC Executive Committee Meeting Summary

- ✧ Ms. Kowalski will survey BOSC members to determine their availability for a January or February 2009 meeting.
- ✧ Veters for the NCER Standing Subcommittee and the Water Quality Mid-Cycle Review will be discussed at the September 2008 BOSC Executive Committee meeting.
- ✧ ORD will give a presentation to the BOSC on the value of information at the September 2008 BOSC Executive Committee meeting.
- ✧ The BOSC will receive an update on the NRS and on intramural and extramural nanotechnology research at the January 2009 meeting.

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**38th EXECUTIVE COMMITTEE FACE-TO-FACE MEETING AGENDA
May 6-7, 2008**

Office of Research and Development
National Health and Environmental Effects Research Laboratory (NHEERL)
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1 Sabine Island Drive
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Tuesday, May 6, 2008

7:45 a.m. – 8:00 a.m.	Registration	
8:00 a.m. - 8:15 a.m.	Welcome and Introductions - Review of March Meeting Minutes - Overview of Agenda	Dr. Gary S. Sayler, Chair, Executive Committee
8:15 a.m. – 8:30 a.m.	BOSC DFO Remarks -Administrative Issues	Ms. Lori Kowalski, ORD
8:30 a.m. – 10:00 a.m.	National Research Council of the National Academies: Jan 2008 Report On Evaluating Research Efficiency in the U.S. EPA - Overview of the Report	Dr. Gilbert S. Omenn, Chair, Committee on Evaluating the Efficiency of Research and Development Programs at the U.S. EPA
	- ORD Implementation Plans	Mr. Phillip Juengst, Accountability Team Leader, ORD
	- Implication for BOSC Program Reviews	Dr. Gary S. Sayler, Chair Executive Committee
10:00 a.m. – 10:15 a.m.	Break	
10:15 a.m. – 11:15 a.m.	Subcommittee Draft Reports: (1) Computational Toxicology Draft Letter Report Presentation - Discussion (2) NERL Standing Subcommittee Draft Letter Report Presentation - Discussion	Dr. George Daston, Subcommittee Chair Executive Committee Dr. Ken Demerjian, Subcommittee Chair Executive Committee

11:15 a.m. - 11:45 a.m.	AA/ORD Remarks	Dr. George Gray, Assistant Administrator for ORD
11:45 a.m. - 1:00 p.m.	Lunch	
1:00 p.m. – 1:45 p.m.	Subcommittee Draft Reports (Cont.): (3) Global Change Mid-Cycle Draft Report Presentation - Discussion	Dr. Clifford Duke, Subcommittee Vice-Chair Executive Committee
1:45 p.m. - 2:00 p.m.	Public Comment	
2:00 p.m. – 3:00 p.m.	Subcommittee Updates: <u>Mid-Cycle Review Subcommittees:</u> - Land Mid-Cycle - Water Quality Mid-Cycle <u>Program Review Subcommittees:</u> - Homeland Security Program Review - Human Health Program Review - Endocrine Disrupting Chemicals (EDC) Program Review <u>Standing Subcommittees:</u> - National Center for Environmental Research (NCER) Next Steps	Dr. Chuck Haas, Subcommittee Vice-Chair Dr. Gary Saylor, Subcommittee Vice-Chair Dr. Gary Saylor, Subcommittee Chair Dr. Gary Saylor, Chair Executive Committee Dr. Gary Saylor, Chair Executive Committee Dr. Martin Philbert, Subcommittee Chair
3:00 p.m. – 3:30 p.m.	Break	
3:30 p.m. – 4:00 p.m.	Workgroup Update	Dr. Gary Saylor, Chair Executive Committee
4:00 p.m. – 4:30 p.m.	SAB Activities	Dr. George Lambert, SAB Liaison to the BOSC
4:30 p.m.	Adjourn	

Wednesday, May 7, 2008

8:30 a.m. – 9:00 a.m.	ORD's Ecological Research Program	Dr. Steve Jordan, NHEERL Gulf Ecology Division
9:00 a.m. – 12 noon	NHEERL Gulf Ecology Division Site Visit * Introduction to Gulf Ecology Division * Eco Research Program Poster Session * Water Quality Research Program Poster Session * Tours and Field Demonstration * Safe Pesticides/Safe Products Research Program	Gulf Breeze Laboratory
12 noon – 1:00 p.m.	Lunch	
1:00 p.m. – 1:30 p.m.	ORD Update	Mr. Jeff Morris, Acting Office Director, ORD Office of Science Policy
1:30 p.m. – 3:00 p.m.	Nanotechnology	Mr. Jeff Morris, Acting Office Director, ORD Office of Science Policy
3:00 p.m. – 3:30 p.m.	Future Discussion/Future Business - Meetings in Sept 2008/Jan 2009 - Mid-Cycle Reviews in 2008/2009 - Future Work	Dr. Gary Saylor, Chair, Executive Committee
3:30 p.m.	Adjourn	