

**36th EXECUTIVE COMMITTEE FACE-TO-FACE  
MEETING SUMMARY****Key Bridge Marriott  
Arlington, Virginia****September 17, 2007****MONDAY, SEPTEMBER 17, 2007****Welcome and Introductions***Dr. James Clark, Exxon Mobil Research and Engineering Co., Executive Committee Chair*

Dr. James Clark called the meeting to order at 8:40 a.m. He welcomed everyone to the 36th meeting of the BOSC Executive Committee. Because the Executive Committee meetings are typically 1 ½ days, the agenda to cover today is quite full. After covering some housekeeping items, such as approval of the minutes of the May meeting and August teleconference and the remarks of the Designated Federal Officer (DFO), Dr. George Gray, Assistant Administrator for Research and Development, will present his remarks. Then, Dr. John Giesy will present the Technology for Sustainability Program Review Report, followed by updates on the Endocrine Disrupting Chemicals (EDCs) mid-cycle review, the Air mid-cycle review, the Global Change mid-cycle review, the Human Health Risk Assessment program review, and the Homeland Security program review. The agenda also includes time for discussing the rating tool, and updates from the standing subcommittees—Computational Toxicology, National Exposure Research Laboratory (NERL), and National Center for Environmental Research (NCER) Subcommittees. These updates will be followed by public comments, an update on the Children's Health Research Centers Workgroup (CEHRC), an update from ORD, and a briefing on the National Research Council (NRC) report on a vision for toxicity testing. The meeting will conclude with a presentation on Science Advisory Board (SAB) activities and a discussion of future business.

***Review of May Meeting Minutes***

Dr. Clark stated that the draft summary for the May 24-25, 2007 meeting was in the notebook. He asked if there were any comments on the minutes. Dr. Henderson said that she had read them and thought they were well done. She did not have any corrections. Dr. Clark said that he also had read them and had no changes. When no additional comments were offered, Dr. Clark called for a motion to approve the May meeting minutes. Dr. Henderson moved to approve the minutes and Dr. Daston seconded the motion. The minutes were approved unanimously by vote of the BOSC Executive Committee.

***Review of the August Teleconference Minutes***

Dr. Clark asked if there were any comments or changes on the draft minutes for the August 6, 2007 conference call. No comments were offered so Dr. Clark called for a motion to approve the minutes. Dr. Daston moved to approve the August conference call minutes and Dr. Sayler seconded the motion. The August minutes were approved unanimously by the BOSC Executive Committee.

Dr. Clark indicated that a number of program reviews and mid-cycle reviews had been completed since the May meeting. The Safe Pesticides/Safe Products (SP2) Research Program Review Report, the Human Health Research Mid-Cycle Review Report, the Drinking Water Research Mid-Cycle Review Report, and the Ecological Research Mid-Cycle Review Report were transmitted to the Office of Research and Development (ORD). He thanked everyone for their efforts in completing these reviews. The face-to-face meetings for the EDCs mid-cycle review and the Air mid-cycle review would be held tomorrow. These meetings are open to the public and Executive Committee members are welcome to attend. Dr. Clark then asked Ms. Lorelei Kowalski to present the DFO's remarks.

### **BOSC Designated Federal Officer Remarks**

*Ms. Lorelei Kowalski, DFO, EPA/ORD*

Ms. Lorelei Kowalski, DFO for the BOSC Executive Committee, welcomed the members to the meeting. She mentioned that Drs. Ryan, Falk, Philbert, Harding, and Swackhamer were unable to attend this meeting, but Dr. Swackhamer will try to call in when possible during the meeting.

Ms. Kowalski stated that the BOSC is chartered as a Federal Advisory Committee and subject to the rules and regulations of the Federal Advisory Committee Act (FACA). Therefore, this meeting was open to the public, and time was designated for public comment. A contractor, Beverly Campbell from SCG, was present to take notes that captured the presentations and discussions. She will prepare the meeting minutes, which will be made available to the public on the BOSC Web Site after approval by the Executive Committee and certification by the BOSC Chair. The Chair must certify the minutes within 90 days following the meeting. Notice of this meeting was published in the *Federal Register*. Ms. Kowalski established an electronic public docket for the meeting on the Federal Docket Management System (FDMS), which can be accessed at <http://www.regulations.gov>. The number to search for this docket is EPA-HQ-ORD-2007-0902. The *Federal Register* notice and the agenda were available to the public on the docket. Ms. Kowalski mentioned that she had not received any requests for public comment prior to the meeting, but there is time set aside at 2:00 p.m. for public comment. As DFO, she worked with EPA's ethics officials to ensure that all appropriate ethics requirements were satisfied for the Executive Committee members. Nevertheless, she asked the members to notify her during the meeting if they have any potential conflicts of interest. Because some members have grants with EPA, potential conflicts of interest arise from time to time. Ms. Kowalski reminded the members that they needed to complete updated confidential disclosure forms and ethics training, which must be done each fall.

Each BOSC member should have received a notebook of materials by mail prior to the meeting. She confirmed that all members present had received a notebook. The notebook included more materials than it has for the past few meetings. Because Dr. Philbert would not be present to provide the update on the NCER Standing Subcommittee, Ms. Kowalski included the agendas for the Subcommittee meetings to give the Executive Committee members an idea of the Subcommittee's progress. There were copies of the draft Technology for Sustainability Research Program Review Report available for those members who did not receive the file that was distributed on Friday. The notebook also included worksheets and travel vouchers, which were to be completed and submitted to Ms. Kowalski, along with members' hotel bills, prior to leaving the meeting. Ms. Kowalski mentioned several other handouts distributed at the meeting, including the FY 2007-2008 projects of the BOSC (including subcommittee activities and program and mid-cycle reviews); a list of Executive Committee member activities (strikethrough indicated that the item had been completed); and a timeline depicting the workload of the BOSC from 2007 to early 2009. Ms. Kowalski reminded the members and other attendees to sign in at the registration desk if they had not done so already.

Dr. Sayler asked about the agendas for the two mid-cycle reviews that would be conducted tomorrow. Ms. Kowalski responded that the agendas were in the notebook under the Mid-Cycle tab near the back. She mentioned that the EDCs Mid-Cycle Subcommittee conference call that was scheduled for Friday,

September 14 had been cancelled because Dr. Swackhamer, the Subcommittee Chair, had a family emergency. Ms. Kowalski indicated that Dr. Glen Van der Kraak would chair the EDCs Mid-Cycle Subcommittee meeting in Dr. Swackhamer's absence, and Dr. Swackhamer would try to attend by telephone.

Dr. Clark mentioned that a handout on the rating tool would be distributed as soon as it was copied. He reported that since the May meeting, he had compiled information on nominations to fill the vacancies on the BOSC Executive Committee and submitted it to ORD. Dr. Clark then welcomed Dr. George Gray.

**Assistant Administrator for Research and Development Remarks**

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

Dr. George Gray thanked the BOSC members for their efforts to help ORD improve its programs. He mentioned that this is Dr. Clark's final meeting as the Chair of the BOSC. He thanked Dr. Clark for his excellent leadership of the Board and for the outstanding effort this past summer in submitting numerous reports to ORD. Dr. Gray said that ORD is working to appoint a new chair. He stressed the importance of the BOSC's reports and stated that ORD is preparing responses to them. He noted that ORD has been trying out some new strategies, and the external advice provided by the BOSC is very helpful to the Agency. Dr. Gray then provided some of his comments on the recently submitted BOSC reports.

The BOSC thought the Human Health Research Program was meeting expectations. The big change in that program since the program review was a focus on Long Term Goal (LTG) 4 and outcomes—doing research that links advances in human health to what EPA does as an Agency. EPA does assessments to project the future and the program offices set standards based on the research conducted by ORD. The Agency needs to determine the benefits that result from implementing the standards and assess the accuracy of EPA's predictions. This information can be used to go back and calibrate the Agency's assessments to improve future predictions. This research will enable the Agency to inform the public of the human health benefits resulting from EPA's programs. If EPA is asking people to make sacrifices or change their behavior to protect the environment then it is very positive when the Agency can report to the public on those benefits. Dr. Gray mentioned that this shift toward outcomes was initially referred to as "accountability," but that term has been replaced by "outcomes," which he believes is a better term. He is very excited about the BOSC's support of this new outcomes focus for the Human Health Research Program. ORD is looking at what can be done retrospectively—to determine if anything useful can be gleaned from the "noisy" health data.

The Ecological Research Program is undergoing a significant change to a focus on decision support and ecosystem services. The program will continue its core research but it will be translated into a form to be used by decision makers within and outside EPA. Dr. Gray believes that this approach—helping decision makers include environmental impacts in decisions—is the future of environmental progress in this country. It will be difficult to achieve much more progress with the Clean Air Act and Clean Water Act. The new focus will lead to better decisions, better choices, and sustainability. One example of this is ORD's work in the Sand Hills area near Fort Bragg, North Carolina. Because the base will be expanding in the future, the population in that area is expected to increase by 40,000 to 50,000. ORD worked with local decision makers to use a modeling tool to do "what if" scenarios to determine what the different decisions would mean with respect to air quality, water quality, and so on. Dr. Gray is very excited about this new direction for the Ecological Research Program and he appreciated the BOSC's support of this strategic shift. He noted that it will be critical to build partnerships as a way to take ORD's expertise and put it to work to make better decisions.

The BOSC thought the Drinking Water Program exceeded expectations. That program went through significant transition since the 2005 program review with the appointment of Dr. Audrey Levine as the National Program Director (NPD). During the past year, Dr. Levine has taken control of the program and

pointed it in a good direction. The program is behind in completing the Multi-Year Plan (MYP), but the plan will be completed as soon as possible. Dr. Gray appreciated the BOSC's suggestion to look at emerging areas such as climate change, water reuse, and nanotechnology. ORD needs to think about how these areas will impact drinking water. ORD has been funding nanotechnology research through the Science To Achieve Results (STAR) Program since 2001. ORD is searching for a niche in nanotechnology and is thinking about the possibility of risk assessment because that is not being addressed by other agencies. He noted that nanotechnology has been coordinated very well among the various federal agencies. Other possible niches for EPA include fate and transport, ecological effects, and human health effects. Dr. Gray mentioned that the Office of Prevention, Pesticides, and Toxic Substances (OPPTS) administers the laws that cover nanomaterials. ORD will continue to consider possible niches and seek advice on this issue from the BOSC.

The SP2 Research Program was considered very successful by the BOSC even though the report included 22 recommendations for improving the program. Dr. Gray viewed this as confirmation that the BOSC wants ORD to benefit from its advice. The BOSC recommended that the program consider model validation and work to gain a better understanding of how well models are predicting health and environmental effects. The program will increase its focus on probabilistic risk assessment, which has been used on the exposure side for 5 to 10 years. The program is moving toward ecological risk assessment and the toxicity side of human health risk assessment. Dr. Gray believes that this is an area in which EPA can provide leadership.

Dr. Gray said that ORD's responses to these reports will be submitted to the BOSC soon.

There have been a few personnel changes in ORD since the May meeting. Dr. Bill Sanders has been named the Director of NCER. He has been managing the Children's Health Program for the past 4 years, but his official title was Deputy Assistant Administrator in OPPTS. Dr. Sanders started his EPA career in Region 5. He came to EPA headquarters when he joined OPPTS, and now he will be directing ORD's extramural research at NCER. Dr. Sanders is very capable and personable and Dr. Gray is confident that he will help ORD get the most out of its grants program. His official start date at NCER is October 1, but he will be attending the ORD Executive Council meeting later this week. Dr. Gary Foley, who currently is the Director of NCER, will be moving to the Office of the Science Advisor where he will lead the Agency's efforts as part of the Group on Earth Observations (GEO), helping EPA move forward in integrating a wide range of information streams to help us better understand the state of our environmental and predict future trends.

Several positions currently are open for applicants—the Deputy Director of NCER, the Chief Scientist in the Office of the Science Advisor, and the Deputy Administrator for Science, ORD. The Agency is casting a wide net to fill these positions, advertising on the Society for Risk Assessment Web Site and in *Science*. He asked the BOSC to encourage qualified individuals to look for these position announcements and apply if they are interested. Because of the time and paperwork involved in filling these positions, he asked that interested parties apply quickly.

Dr. Gray thanked the BOSC for the list of potential candidates to fill the vacancies on the Executive Committee. It is a good group of candidates for the Agency's consideration. Dr. Kevin Teichman and Dr. Gray will discuss the nominees in detail and hope that the new members will be appointed to the BOSC in time to attend the January meeting. Dr. Gray expressed his sincere appreciation for the work that the BOSC has done on behalf of ORD.

Dr. Henderson said that the Ecological Research Program will focus more on decision makers at the local level. How does this fit with the need to set standards? As the Chair of the Clean Air Scientific Advisory Committee (CASAC), she needs information for setting standards. ORD's budget for monitoring the environment and ecological effects is declining. What will be the impact of this decline? Dr. Gray

replied that ORD has an important responsibility to support the decisions made by the EPA program offices and ORD is active in discussions with the program offices. The information used to set standards for ozone is developed, supported, and analyzed by ORD. Several programs focus on decision support, such as Global Change and Sustainability (to some extent). The science generated by ORD can be used in a variety of ways—ORD's goal is to put the science in a form that allows it to be used at different scales; for example, take global circulation models and bring them down to the regional or local levels. In many cases, there is no regulatory standard that ORD is helping support—ORD is trying to put the science to work to improve decisions and choices made at different levels. Dr. Gray noted that monitoring is a bit tricky—there is a point when monitoring ceases to be research and becomes the responsibility of another part of EPA or another organization. The research component of the Environmental Monitoring and Assessment Program (EMAP) is completed, and now the monitoring needs to be implemented. The Agency has come to rely more on the regions for monitoring.

Dr. George Lambert asked if ORD looked at negative outcomes management similar to what the Food and Drug Administration (FDA) does when it looks at the risks of a drug. Dr. Gray agreed that EPA is dealing with serious outcomes and should try to monitor both positive and negative outcomes if possible. The key is trying to extract relevant information from the data that already exist through the Centers for Disease Control and Prevention (CDC), the National Cancer Institute (NCI), and EMAP. Dr. Carol Weiss stated that there is an entire field of study that looks at the effects of science across a range of natural environments. She noted that research is not the only factor affecting air quality and water quality. Research cannot take all the credit or all of the blame. Dr. Gray agreed that there are many factors in play so it is difficult to determine the impact of research. Therefore, ORD has a role to play in looking into the impact of research on outcomes.

Dr. Sayler asked Dr. Gray to elaborate on ORD's interactions with Asia, and China in particular. Dr. Gray said that he visited China about 1 year ago and, following that visit, EPA signed a Memorandum of Understanding (MOU) with China. There are a number of ongoing efforts focused on mercury and particulate control in power plants. Several large U.S. companies have opened R&D facilities in China but there is concern about protecting intellectual property so there have been modest interactions. EPA is active in the Organisation for Economic and Co-operative Development (OECD) and other international organizations. ORD also is involved in the international coordination of efforts on nanotechnology. Dr. Gray commented that the Agency makes a concerted effort to stay engaged in international issues.

Dr. Daston said he thought the outcomes focus of the Human Health Research Program was a good idea but he was concerned about the expense. What resources does the Agency have to invest in this research and how will ORD leverage relationships with other groups? Dr. Gray said that most of the details remain to be worked out. This is one of four LTGs in the Human Health Research Program and the program is trying to figure out how to implement the research. ORD wants to leverage resources and information gathered by other agencies and organizations. ORD wants to find a niche—a unique area to pursue that will help move this forward. Dr. Daston asked if there is some ongoing activity to flesh this out. Dr. Gray replied in the affirmative and said that it is led by Dr. Hugh Tilson, the NPD for Human Health, and Dr. Hal Zenick, the Director of the National Health and Environmental Effects Research Laboratory (NHEERL). This LTG has been developing over a number of years and it is an important part of understanding what the Agency can do to protect human health.

Dr. Clark thanked Dr. Gray for his presentation and for taking the time to respond to so many questions. The next item on the agenda was the presentation of the Technology for Sustainability Program Review Report. Dr. Giesy chaired that Subcommittee and Drs. Clifford Duke and Ken Demerjian were the report's vettors.

**Technology for Sustainability Research Program Review Draft Report**

*Dr. John Giesy, University of Saskatchewan, Subcommittee Chair*

Dr. Giesy, Chair of the Technology for Sustainability Subcommittee, described the draft report that resulted from the program review. He stated that this review was conducted when the Executive Committee was discussing the possibility of changing the wording of one of the four levels of the rating tool from “satisfactory” to “meets expectations.” He indicated that the new terminology of “meets expectations” was well accepted by the Subcommittee. Dr. Giesy did not think that 1 ½ days allowed adequate time for ORD to present the program, discuss the materials provided by ORD, reach a consensus on the rating, and begin drafting a report. He thanked Clois Slocum, the DFO, for her efforts on behalf of the Subcommittee as well as the ORD program staff members, who were superlative. The posters were excellent and the interactions at the meeting were very informative.

The Subcommittee members were Dr. Giesy, Dr. Wayne Landis, Dr. Concepción Jiménez-González, Dr. Earl Beaver, Dr. Martin Abraham, and Dr. Ted Tomasi; Dr. Peter Blaze Corcoran served as a consultant to the Subcommittee.

ORD’s Pollution Prevention and New Technology (P2NT) Research Program is nearing its completion, and a new research program has been created—the Science and Technology for Sustainability (STS) Research Program, which is focused on the issue of sustainability. Although this represents a new research direction for ORD, the STS Program will include a select group of research efforts that had their genesis within the P2NT Program.

The LTGs of the STS Program are as follows:

- ✧ LTG 1: Identify and create scientifically based sustainability metrics.
- ✧ LTG 2: Develop decision support tools that promote environmental stewardship and sustainable management practices.
- ✧ LTG 3: Develop, apply, and demonstrate innovative technologies that solve environmental problems and provide sustainable outcomes.

The Subcommittee assigned an overall qualitative score for the program as well as scores for two of the three LTGs. These scores reflected the quality and significance of the research as well as the extent to which the program is meeting or making measurable progress toward the stated goals—relative to the evidence provided to the BOSC. The Subcommittee’s overall impression was that this is an excellent program that has made many substantial contributions to the science of sustainability. The research staff is first rate, but a critical mass is lacking in some areas. The reorganization provides opportunity to refocus the program elements for maximum impact.

The Subcommittee assigned the overall program a rating of meets expectations, but Dr. Giesy added that some elements of the program are excellent and exceed expectations. Where the program does not exceed expectations, the primary reasons are: (1) some of these program elements are small and lack critical mass, and (2) other elements are in transition. The STS Program has some excellent researchers who are world leaders in their fields and the quality of the research is apparent. The program is doing much with relatively limited resources. In particular, it is leveraging resources by partnering with other agencies, both local and federal, which allows the program to achieve more than it could otherwise. Limited resources have directed the types of studies that have been undertaken by the program. For this reason, the research conducted by the program might not be the highest priority research, or may not move the science forward as rapidly as could be achieved. This resource-driven approach dictates that the STS Program will not be the leader that it otherwise might have the potential to be.

The Subcommittee recommended that the program assure integration and continuity among the elements during the transition. Because the potential impact of the STS Program is limited by the lack of a critical mass and resources, ORD must make as much use as possible of the capabilities across ORD. Much of the work currently being conducted by the STS Program is eclipsed by the magnitude and pace of advancements of the industrial and academic communities. Thus, in developing the MYP, the STS Program must make strategic decisions on where it can make an impact on the overall field. Because the STS Program is sparsely populated and not coordinated with outside efforts, the strategic plan for the program must include an awareness of what is being done outside the Agency, including the efforts of organizations outside the United States, and how ORD can make a significant impact on the science.

Dr. Giesy reported that the Subcommittee did not assign a rating score to LTG 1 because the program has just begun and there has not been adequate time to make much progress on this goal. The Subcommittee did, however, offer a number of suggestions for implementing the program. The development of sustainability metrics is a critical component of the overall effort, because these are the measures that will be used to evaluate the success of all activities. It is unclear, however, precisely how the metrics to be developed within this element will be used in other LTGs, and it also is unclear how the metrics to be developed will be informed by activities in the other LTGs.

The recommendations related to LTG 1 were:

- ✧ Prepare an outline for how metrics for sustainability will be developed. This should include criteria for assessing the utility and predictability of metrics.
- ✧ Coordinate metric development with other LTGs.
- ✧ Determine a strategy of how metrics will be used.
- ✧ Develop an extramural program based on the Technology for Sustainable Environment (TSE) Program that could be crafted to emphasize metrics and how technologies move towards improving the measures.
- ✧ Establish testing protocols to determine if the metrics are measuring the intended functions, if they are consistent in their evaluation, if they are sufficiently independent, and if they can be effectively used to determine if specific actions are driving society to become more sustainable.
- ✧ All of the program elements of the Green Technologies Program are in need of refinement to better address sustainability issues and to demonstrate and articulate the role that it plays in contributing to sustainable outcomes. Some specific suggestions by program element include:
  - People, Prosperity, and the Planet (P3)—Integrate sustainability metrics into the judging criteria.
  - Small Business Innovation Research (SBIR)—Integrate potential impact on sustainability metrics into program solicitations and selections, and into program evaluation.
  - Environmental Technology Verification (ETV)—Broaden the mission to evaluate and verify additional components of the sustainability program and look for opportunities to support emerging markets in trading, offsets, and mitigation.
  - *GreenTech*—Examine carefully the rationale for selection of target areas/technologies to better address market failures and tie outcome measures to sustainable measures and metrics.

- ✧ Identify sustainability targets so that appropriate metrics can be designed and tested.
- ✧ Design critical experiments that allow testing of hypotheses within the realm of defined metrics.
- ✧ Evaluate the predictability of the models and conduct sensitivity analyses.
- ✧ Evaluate the metrics systematically and quantitatively.
- ✧ Better integrate the team throughout EPA so that the team can draw on additional resources that could enhance its effectiveness.
- ✧ Increase interaction between this LTG and the other goals, particularly between LTGs 1 and 2, which are intimately tied together.
- ✧ Use LTG 1 metrics to inform LTG 3 activities.

Dr. Giesy reported that LTG 2 was assigned a rating score of exceeds expectations by the Subcommittee. The program is relatively mature in this area and a great deal of progress has been made. The progress toward achieving this LTG has been excellent and has had a large impact on the field of sustainability. The life cycle assessment (LCA) programs, metrics, and procedures developed under the P2NT Program are relevant and important to the goals of EPA, stakeholders, and the international community. The STS Program is positioned to move these initiatives forward and is encouraged to build on this strength. For LTG 2, the Subcommittee offered the following recommendations:

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

The Subcommittee assigned a rating score of meets expectations to LTG 3. Although the Subcommittee found the overall performance of the STS Program relative to LTG 3 to be meeting expectations, a range of performances was observed. Some program elements were performing at a very high level and would be classified as exceeds expectations. As a whole, the Subcommittee thought that the overall performance was meeting expectations.

The P3, SBIR, and ETV programs have been highly relevant to the mission of the EPA and the elements in these programs should be preserved whenever possible. The relevance and impact of the *GreenTech* program is less apparent and this program needs to be assessed internally to determine if it is serving a function that is not being met already by the private sector and academia. The STS Program could benefit from a more systematic evaluation of the program outcomes, such as tracking of careers of P3 recipients to obtain information that can be used to measure impact as outcome.

The Subcommittee made the following recommendations regarding LTG 3:

- ✧ Improve the solicitation/judging criteria of the P3 program to require a clear statement by students as to effects articulated via sustainability metrics or decision tools.

- ✧ Place more emphasis on measurement.
- ✧ Encourage an increased role in supporting emerging markets in trades/mitigation/offsets (e.g., mercury/greenhouse gases) in the ETV program.
- ✧ Conduct an analysis to determine if there are emerging markets in this trade/offset area that have a barrier surrounding verification issues.
- ✧ Increase the use of sustainability metrics in selection criteria for the SBIR program. Increase linkage of program outcomes to sustainability metrics.
- ✧ Consider redirecting the *GreenTech* program or replacing it with an extramural grants program.
- ✧ Communicate the results of the work effectively to larger industrial enterprises.

Dr. Giesy reviewed the relevance questions in the Subcommittee's charge. He then presented the Subcommittee's findings with respect to the program's relevance. The research undertaken is very relevant. The lack of critical mass, however, makes it difficult for the program to have significant and evident direct public benefits. The LTGs proposed for the STS Program are consistent with the overall EPA Strategic Plan. The proposed STS plan is responsive to the needs of clients, especially in the development of metrics, in LCA, and in green technologies.

Dr. Giesy presented the questions in the charge related to program structure followed by the Subcommittee's findings. In general, the structure appears to be adequate but ORD should assure that there is integration and continuity among the elements during the transition. The existing program elements and the structure proposed for the STS Program in the future is organized around the development of scientifically based sustainability metrics. The proposed structure is well suited for the development of decision support tools that promote environmental stewardship and sustainable management practices. The program as planned will be able to develop, apply, and demonstrate innovative technologies that solve environmental problems and provide sustainable outcomes.

After reviewing the charge questions related to program quality, Dr. Giesy summarized the Subcommittee's findings with respect to quality. The quality of the P2NT research products is excellent and the research being undertaken is appropriate. Where appropriate, elements of the P2NT program are competed and subjected to peer review.

Regarding the leadership the program staff has had in contributing to advancing the current state of the science for tools, methodologies, and technologies that support environmental decision-making, the Subcommittee found that, historically, the P2NT program has been a leader in innovations in the science. Many of the current members of the research staff still are considered global leaders in the field of sustainability. A lack of critical mass, however, has eroded the current impact of the program and probably will continue to do so in the future.

Dr. Giesy presented the charge questions focused on coordination and communication. The Subcommittee found that some of the program elements are independent programs that are not closely coordinated. The P2NT program has engaged many extramural agencies and institutions to leverage research resources and to communicate results, and the publication record of the program is excellent. All elements of the program can improve the tracking of outcomes, successes, and impacts and their communication to the Office of Management and Budget (OMB).

After reviewing the charge questions related to program outcomes, Dr. Giesy said that the Subcommittee found that the program has had a number of significant outcomes, and has influenced the development of

the global science (e.g., LCA); however, other institutions are having a greater impact on the current progress of the science. Some of the Subcommittee members thought it would be impossible for ORD to maintain the leadership in LCA, given the effort invested by other organizations.

### ***Draft Report Discussion***

Dr. Clark asked if there were any questions concerning the draft report. One Executive Committee member asked about the NPD for the program. Dr. Gray replied that there is no official NPD for this program; those responsibilities have been shared by Dr. Alan Hecht and Mr. Gordon Evans. Dr. Clark commented that the lack of a single director for the program may explain why some of the elements are not clearly focused. He then asked about the statement that the program may not be addressing the highest priority research because it has been taking advantage of opportunities to leverage its resources. Is the program doing the best research? Dr. Giesy responded that most of the projects discussed during the review originated because a region or locality approached ORD about doing the project. The Subcommittee found the research to be appropriate, but it is apparent that the program is not choosing its projects strategically. Dr. Clark noted that the question of whether the program is doing appropriate research is important and it is a key aspect of the rating tool. The report did not make it clear that the Subcommittee members thought that the program was funding the right research. Dr. Giesy replied that the program is doing very well with the resources it has, adding that some of its projects have required minimal resources from EPA. Dr. Daston asked Dr. Giesy to identify some of the organizations with which the program has partnered. Are they partnering with European countries working on this topic or large corporations such as Exxon Mobil? Dr. Giesy answered that they are partnering on demonstration projects and green technology development. It was not apparent that the program has made an effort to select a few private-sector organizations that have their own sustainability R&D programs. The program staff members indicated that they interact with such individuals at meetings, but the Subcommittee thought it would be better to have more formal interactions. Dr. Giesy added that one of the Subcommittee members, Dr. Jiménez-González, stated that the private sector has gone far beyond what EPA is doing now, and Europe is actively involved in developing tools.

Dr. Demerjian said that it is clear that the P2NT Program is being phased out and replaced by the STS Program. Does this mean that EPA will no longer do P2 research? He was concerned that the SBIR and ETV programs did not fit into the new STS program.

Dr. Giesy stated that many of the previous elements will be retained in the new STS Program. The focus of the STS Program will be sustainability rather than P2. Dr. Giesy's perception was that this change was made to elevate the program to a higher level—an integrated approach to sustainability that included P2 as well as economics. He mentioned that a number of the programs consolidated under the STS Program were independent and not integrated. SBIR and ETV are not integrated. The program staff pointed out that ORD cannot control the types of proposals that are submitted in response to SBIR solicitations. The Agency just funds the best proposals that it receives.

Dr. Weiss asked about the number of staff supporting the program. Dr. Giesy replied that he did not remember the exact number of full-time equivalents (FTEs) but it appeared to be rather small. The presenters would mention one statistician, one attorney, etc. For many categories there appeared to be only a single individual—there was no depth in the various fields and the staff members work on numerous projects. Dr. Giesy mentioned that some companies have 200-300 people working on sustainability because they are using it to make decisions. Dr. Lambert asked if the staff members worked on sustainability full time. He also asked if the Subcommittee looked at ORD's sustainability Request for Applications (RFAs). This may be an important issue if the Subcommittee thinks the Agency is not getting applications that are on target. Dr. Giesy responded that the Subcommittee did look at the RFAs; one Subcommittee member thought the RFAs should be more focused/specific but ORD thought this

might impinge creativity. Dr. Giesy acknowledged that the program projects are not well integrated, but he recognized that there is a line between targeting RFAs and stifling creativity.

Dr. Henderson asked if the program works with the Health Effects Institute (HEI), noting that HEI has a sustainability research program. Dr. Giesy responded that he did not remember HEI being mentioned in any of the materials, but that does not mean that the program did not interact with HEI.

Dr. Clark stated that the vettors for this report were Drs. Demerjian and Duke. He asked the vettors to provide their comments.

Dr. Demerjian stated that it was clear that Dr. Giesy and the Subcommittee put a great deal of effort into the report. He was not familiar with the Sustainability Program prior to reading this report and it would have been helpful to have more information in the report about the program's mission and vision. Such information would benefit the novice reader. He had some minor edits that he would send to Dr. Giesy. It would be helpful if the section on program background identified what elements of the P2NT program will continue under the STS Program. The report should state that these areas are considered important and will continue under the new program.

Dr. Demerjian thought the report could be improved by adding some examples. When the report makes "hard hitting" statements, it would help to provide some examples. He mentioned several places in the report where examples are needed:

- ✧ Chapter III, page 11, second paragraph, third sentence: "A key component of the development and testing of appropriate metrics is a clear conceptual definition of what is to be measured with a particular set of metrics." Some examples of metrics here would be helpful.
- ✧ Chapter III, page 12, first full paragraph: "The *GreenTech* Program as currently configured might be perceived to be largely irrelevant. Consideration should be given to redirecting the program or replacing it with an extramural grants program." Some guidance or some examples for redirecting the program would strengthen the report.
- ✧ Chapter III, page 13, first sentence under III.2.3 Program Quality, 1. Long-Term Goal 1: "Historically, the STS Program has had a large impact by identifying and creating scientifically-based sustainability metrics." Some examples of the large impact would be beneficial.
- ✧ Chapter III, Page 13, Section III.2.3 Program Quality, 1. Long-Term Goal 1, first sentence: "Some of the algorithms that had been developed have been implemented into standard process simulators." Some examples of the algorithms should be provided.
- ✧ Chapter III, Page 14, Section III.2.3 Program Quality, 3. Long-Term Goal 3, second paragraph: "The science used in the P2NT research is appropriate although in some cases, untimely." Examples of how the science has been untimely would be helpful.
- ✧ Chapter III, page 15, Section III.2.5 Coordination and Communication, 3. Long-Term Goal 3, second paragraph, third sentence: "Some of the work is a duplication of previous or current work being done by others outside of EPA." An explanation is needed here and perhaps some examples of what is being duplicated.
- ✧ Chapter III, page 15, Section III.2.5 Coordination and Communication, 3. Long-Term Goal 3, second paragraph, last sentence: "While not a complete replication, the projects and programs seem to be uncoordinated with those of other agencies." It would be helpful to identify some of the agencies with which the program should coordinate.

Dr. Demerjian asked Dr. Giesy to verify that the statement on page 17, the paragraph on SBIR, third sentence is correct: “The goal of moving to 100 percent cost share needs to be carefully evaluated.” He did not think any agency was moving toward 100 percent cost sharing for their SBIR programs. That would be contrary to the program’s goal of stimulating innovation among small businesses. Perhaps this comment pertains to the ETV program rather than the SBIR program. Dr. Giesy agreed to go back to the program staff to seek clarification on this issue.

Dr. Clark asked for Dr. Duke’s comments. Dr. Duke agreed that some examples would strengthen the report, but overall he thought the report was clear and concise. He suggested that the recommendations be stated in the summary section and not just the body of the report. At least the major recommendations should be highlighted in the summary. He expressed some concern about the first sentence under the Findings and Recommendations using the rating tool terminology. Other members did not share Dr. Duke’s concern about that rating terminology being presented up front. Several thought it was helpful to present the overall impression of the program first, before listing specific recommendations. It was suggested that more text explaining the rating be included in the summary section. Dr. Duke agreed with that suggestion and asked that the recommendations added by Dr. Giesy in the revision be highlighted by using bold type. That will make it easy for EPA to identify the recommendations. Dr. Duke had a number of minor edits that he agreed to send to Dr. Giesy.

Dr. Sayler noted that the report mentions the Sustainability Research Strategy. He thought it would be helpful to include a URL for that strategy so the reader can find it. In response to Dr. Giesy’s comment that the Subcommittee spent a great deal of time discussing the definition of sustainability, Dr. Sayler said that EPA is not the only organization struggling with this definition. Perhaps the Subcommittee should attempt to express its understanding of sustainability. That might be helpful to EPA. Dr. Sayler also asked about the Subcommittee’s basis for the statement on page 14, III.2.4 Program Leadership, 2. Long-Term Goal 2: “The scientists are clearly recognized by the international scientific community as leaders in the development of decision support tools that promote environmental stewardship and sustainable management practices.” Did the Subcommittee base this statement on the number of papers given by program staff at international meetings? He asked that more information to explain the statement be added to the report.

Dr. Sayler also suggested revised wording for the first sentence of the first paragraph under III.2.3 Program Quality, 1. Long-Term Goal 1 (page 13): “Historically, the STS Program ...” Given that the STS Program is new, he did not think it was appropriate to use the word “historically.” Perhaps STS should be changed to P2NT.

Dr. Daston stated that it is clear the program has challenges—it is a small program in a large area and it is being overtaken in scientific leadership by external activities. Adding to these challenges is the fact that there is no legislative mandate that sets goals for the program; it is a forward-looking program that has to define where it will play in the future. Dr. Daston did not see that stated as a recommendation in the report. The program has yet to define what piece of sustainability will be its focus. Can the program serve as a central hub or should it find a niche to fill? It would behoove the BOSC to include this recommendation in the report so that the program can be sustainable. He also said that communication appeared to be almost optional for the program. Communication is essential and should be integral to the program. With respect to the rating tool, he thought the Subcommittee did a good job of applying the tool but he was concerned that grade inflation already was creeping into these reviews. The rating tool was intended to be straight talk to the program and it seems to be getting diluted in the subcommittees’ desire to provide praise to the program. It does not help the program if the BOSC assigns it a rating that is higher than it should be, because then there is no direction for the rating to go but down.

Dr. Henderson agreed with Dr. Demerjian's comments. She thought the report could benefit from more information on the program. She also liked Dr. Duke's suggestion of including the recommendations in the summary of the report. She thought it was odd that there were no general recommendations for LTG 1; when a program is just starting to work on a goal, it is a good time for the BOSC to offer recommendations. The distinction among the general recommendations, specific recommendations, and those under summary assessment was not clear to her.

Dr. Weiss had a comment regarding the rating tool. Although the Executive Committee developed a four point rating tool, no review has included the highest or the lowest of the four ratings—only the middle two ratings have been used by the BOSC. Perhaps the Executive Committee should revisit this issue. The tool also does not state that the rating should be assigned in consideration of the program's resources. The tool was intended to be used to assess progress toward achieving LTGs. Dr. Clark said that this topic will be discussed later in the meeting.

Dr. Clark noted the wording in the report in the last paragraph on page 4 regarding the rating tool. He emphasized that the tool was not developed to accommodate OMB's Program Assessment Rating Tool (PART) reviews. The BOSC agreed to conduct program and mid-cycle reviews of ORD programs to assist ORD in improving its research programs. The rating tool was developed by the Executive Committee to assist the BOSC in providing an overall assessment of the program. It was not developed for the PART review process.

Dr. Clark commented that there are numerous observations in the report that could be reworded as recommendations. He also noted the wording on page 13, III.2.2 Program Structure, B. Specifics for Program Elements, 3. Long-Term Goal 3, last paragraph: "The STS MYP flow of work reasonably reflects...". Dr. Clark emphasized the importance of identifying clear Annual Performance Goals (APGs) and Annual Performance Measures (APMs) that relate the research to outputs and outcomes. The BOSC is looking for clear links between outcomes and goals. If those links are not clear, the report should include a recommendation that the program address this issue.

Dr. Demerjian said he had one additional comment about the report. He was confused by one of the charge questions for outcomes, namely, "How well-defined are the program's measures of outcomes?" He has no idea what the Subcommittee was trying to evaluate with regard to this question. He was not sure what was meant by outcomes.

Dr. Giesy agreed to assemble a list of items to be discussed and decided by the Subcommittee. He did not want to revise the report without input from the Subcommittee members.

Dr. Clark identified the path forward for the Technology for Sustainability Program Review Report. Dr. Giesy will work with the Subcommittee to discuss the Executive Committee's comments and revise the report accordingly. The revised report will be distributed to the Executive Committee for review and the Executive Committee will take a vote to approve the report during an upcoming conference call or the next Executive Committee meeting. Dr. Giesy reminded Drs. Demerjian and Duke to send him their comments, both substantive and editorial. At this point, Dr. Swackhamer had joined the call and said that she had some comments on the report that she would send to Dr. Giesy.

### **Mid-Cycle Review Subcommittee Updates**

#### *Subcommittee Chairs*

#### ***EDCs Mid-Cycle Review Subcommittee***

Dr. Swackhamer, Chair of the EDCs Mid-Cycle Review Subcommittee, said that Dr. Van der Kraak will be chairing the face-to-face meeting tomorrow and that she will be joining as much as possible by

telephone. The materials the Subcommittee has received have been very helpful and well done. The Subcommittee will draft its report this fall so that it can be reviewed by the Executive Committee at its January 2008 meeting. Dr. Clark said that he planned to attend the EDCs meeting.

### ***Air Mid-Cycle Review Subcommittee***

Dr. Henderson, Chair of the Air Mid-Cycle Review Subcommittee, reported that the Subcommittee has held two conference calls. The first call was held in August and it was an administrative call. The second call took place on August 6, and included a presentation on the program's progress by Dr. Dan Costa, the NPD for Air. All of the Mid-Cycle Review Subcommittee members were on the subcommittee that conducted the program review in 2005. She announced that Dr. Costa will not be attending the face-to-face meeting tomorrow but will try to be available by telephone. Dr. Henderson said that she expected the Subcommittee to complete its draft report so that it can be submitted to the Executive Committee for review during the January 2008 meeting.

### ***Global Change Mid-Cycle Review Subcommittee***

Dr. Clark stated that EPA is in the process of identifying members for this Subcommittee. Dr. Duke served as the Vice Chair for the subcommittee that conducted the program review and he has indicated his willingness to serve as a member of the Global Change Mid-Cycle Subcommittee. The face-to-face meeting will be held on January 23, 2008. Ms. Kowalski reported that the DFO for the Subcommittee is Monica Rodia.

### **Program Review Subcommittee Updates**

#### ***Subcommittee Chairs***

### ***Human Health Risk Assessment Subcommittee***

Dr. Daston, Chair of the Human Health Risk Assessment Subcommittee, stated that a Subcommittee has been formed and the Subcommittee DFO is Ms. Joanna Foellmer. The face-to-face meeting will be held November 14-16, 2007. Two conference calls will be held in October to prepare the members for the review. Dr. Daston noted that this program includes the Integrated Risk Information System (IRIS), which is probably the premiere source of risk assessment information on human health. The program also develops tools for risk assessment and is moving the Agency toward more integrated scientific assessments. The Subcommittee's charge was included in the meeting notebook. The report is expected to be completed by the end of the year so that it can be reviewed by the Executive Committee at its January 2008 meeting.

### ***Homeland Security Research Subcommittee***

Dr. Sayler, Chair of the Homeland Security Research Subcommittee, said that the face-to-face meeting, which was originally scheduled for October 2007, has now been scheduled for May 28-30, 2008. The meeting will be held in Cincinnati. Mr. Greg Susanke is the DFO for the Subcommittee. EPA is still working on getting security clearances for the Subcommittee members—about one-half of the members have been cleared. Dr. Sayler noted that this is a large Subcommittee with diverse expertise. The report probably will be available for review by the Executive Committee at its September 2008 meeting.

Dr. Clark said that the BOSC has undertaken an ambitious schedule for fall 2007 and early 2008. As the reports to be reviewed at the January meeting are being finalized, other reviews will be getting underway. He mentioned that volunteers are needed for the mid-cycle reviews of the Land and Water Quality programs.

## **Rating Tool**

*Dr. Clark, BOSC Executive Committee Chair*

Dr. Clark stated that the rating tool provides the BOSC a means of communicating its overall assessment of the program in a consistent manner. He believes that the tool has added to the BOSC's ability to communicate its findings for program and mid-cycle reviews.

He wanted to address Dr. Weiss' earlier comment about the BOSC using only two of the four ratings identified in the tool. Is the tool accomplishing what the BOSC wanted it to accomplish? Is it appropriate for the mid-cycle reviews? Dr. Clark asked for comments about the application of the tool and suggestions for how it could be improved.

Dr. Clark noted that the Ecological mid-cycle review and the STS program review assigned a rating based on the resources available to the program. He noted that the tool language does not say anything about considering the resources when rating a program. The subcommittees have been sensitive to this issue, but that is not an appropriate consideration when applying the tool. The subcommittees can compliment the program for doing so much with so little in the report narrative. For the Ecological mid-cycle review, the Subcommittee assigned the program a rating of meets expectations even though the program was exceeding the Subcommittee's expectations of what could be done with the program's limited resources. He stressed the importance of basing the rating on how well the program is meeting its goals. The report can include a statement that the program probably will not be successful in meeting its goals until it gets additional funding.

Dr. Weiss asked if the goals should be more modest. If the program gets a poor rating because the goals are impossible to achieve with the given resources, then perhaps the goals should be changed.

Dr. Demerjian commented that it is the responsibility of ORD's managers and strategic planners to get the right balance between funding and LTGs. If the goals are not achievable then the ORD managers are allowing the programs to over extend themselves. The managers must determine the research they are willing to invest in and the level they are willing to invest. The BOSC should rate the programs with the understanding that ORD managers have considered resources when setting program goals. A poor rating is really a reflection of management's failure to strike a balance between funding and goals.

Dr. Daston agreed with Dr. Demerjian's comments. The BOSC's job is to evaluate the program as honestly as it can using the rating tool descriptions; ORD management is responsible for forecasting resources and goals as best it can. He commented that, in his company, the goals are set so that 80 percent of the individuals will meet them, 15 percent will exceed them, and 5 percent will not meet them. Goals should be set high enough that they are difficult to exceed but are likely to be met. He suggested tracking ORD management decisions—expecting that some programs would exceed their goals, most would meet their goals, and a few would not meet their goals.

Referring to a comment made earlier by Dr. Duke, Dr. Daston said he was uncomfortable placing the rating assigned by a subcommittee up front. One thing the work group that developed the tool discussed was the need to include a narrative explanation with the rating. Placing it as the first item in the findings of the report provides little incentive for some readers to read the entire report. Including it as part of a narrative requires readers to at least read the Subcommittee's narrative explanation for the rating.

Dr. Sayler said he preferred the rating up front. He suggested that it be accompanied with the narrative explanation. He mentioned that the Drinking Water Mid-Cycle Subcommittee appeared to be somewhat generous with its rating of exceeds expectations because the program had not achieved all of its goals. The Subcommittee, however, agreed that the goals were not met because of the changes recommended by

the BOSC in the program review. That review imposed a great deal of change on the program, particularly how the LTGs were formulated. Therefore, the BOSC program review caused the delay in meeting the program's goals. He stressed that subcommittee members should keep this in mind when conducting mid-cycle reviews.

Dr. Clark mentioned the handout entitled, Guidance for Development of Mid-Cycle Review Reports with Application of the BOSC Program Rating Tool. This handout provides guidance for applying the tool to mid-cycle reviews because the tool was designed for program reviews. For a mid-cycle review, the tool is used to assign a single overall rating for the program's progress since the program review. Dr. Clark said that the guidance is missing an explanation of the review schedule. A program review is conducted by the BOSC every 4-5 years and a mid-cycle review is conducted approximately 2 years following the program review. The guidance handout states that "The rating tool should be used to generate an overall assessment of research program progress towards meeting changes and goals defined as responses to previous program reviews completed by the BOSC and other review committees." Dr. Clark said that this probably should be revised to delete the words "and other review committees." There was general agreement with this suggested change.

Dr. Clark emphasized that a number of factors should be considered when determining the rating, including the bibliometric analysis, the APMs, the LTGs, program outputs, input from clients and stakeholders, and the MYP. He mentioned that the back of the guidance handout contained a checklist of key points.

Dr. Clark asked the members to review the guidance and provide any comments or changes to Ms. Kowalski. He expects that the guidance will be finalized by the January 2008 Executive Committee meeting. Dr. Clark said that he will add wording that addresses the length and format of the mid-cycle review reports, as well as the review timing.

Dr. Weiss stated that the rating depends on how well the program is achieving its LTGs; it is not a critique of the scientists but it can be misinterpreted by the people whose work the subcommittee is reviewing. ORD management needs to explain to them the basis of the rating and that it is not a reflection of their expertise or hard work.

Dr. Lambert suggested including something about the charge questions in the guidance handout. Dr. Henderson said she thought the response to each charge question should be 1-2 pages. Dr. Clark said he will word the report length as guidance rather than as a requirement. He predicted that the tool and this guidance will be discussed by the Executive Committee for many meetings to come, but it is important that the Executive Committee reach consensus on how to apply the tool because it will make the members much more capable of guiding the subcommittees as they apply the tool.

## **Standing Subcommittees Update**

### *Subcommittee Chairs*

#### *Computational Toxicology Subcommittee*

Dr. Daston, Chair of the Computational Toxicology Subcommittee, reported that the next review of the program will be held December 17-18, 2007, in Research Triangle Park, North Carolina. The program is making great progress and it possibly could serve as a model for how a small program can leverage resources and make itself a hub. The program recently was the host for the Science Forum, a large annual symposium. The National Center for Computational Toxicology (NCCT) has a staff of 20 people, and these large conferences really increase the staff reach and effectively publicize the Center's message. When the program was established several years ago, a nice mix of short- and long-term deliverables was identified. The Center has made progress on these deliverables—the staff can take existing data sets and

show how the program can provide useful information. The Center is working on the virtual liver model—a sophisticated computational model to help assess the toxicity of chemicals. The Center also has been successful in filling some very high level Title 42 positions, including the recent addition of Tom Knudsen. During the review, the Subcommittee will get a chance to see the progress the Center has made in staffing up to implement the planned research.

### ***NERL Standing Subcommittee***

Dr. Demerjian, Chair of the NERL Standing Subcommittee, said that the Subcommittee has been established and a face-to-face meeting probably will be held the second week in December. Susan Peterson is the DFO for the Subcommittee. Work will begin on developing a list of charge questions, once the date for the meeting has been set. Currently, there are five individuals on the Subcommittee, but there is the potential to expand should the Laboratory Director's priorities change. The present Subcommittee members were selected following a discussion with Dr. Larry Reiter, the Director of NERL, to ensure that the appropriate areas of expertise would be represented.

### ***NCER Standing Subcommittee***

Because Dr. Philbert, Chair of the NCER Standing Subcommittee, was unable to attend the Executive Committee meeting, Dr. Clark reported that the Subcommittee had two conference calls as well as a face-to-face meeting in July. A third conference call was held on September 11 and another call will be scheduled in October-November to finalize the draft letter report. Ms. Kowalski stated that the Subcommittee's letter report will be vetted at the January 2008 Executive Committee meeting. Dr. Clark stated that, following the January meeting, it might be appropriate to have Drs. Demerjian, Philbert, and Daston discuss their experiences with standing subcommittees and assess the value of establishing additional standing subcommittees. Dr. Daston has chaired the longest standing subcommittee, the Computational Toxicology Subcommittee, so he may have some insights regarding the need for additional standing subcommittees.

Dr. Clark asked if there were any other comments or questions regarding the standing subcommittees. When there were no additional comments, Dr. Clark suggested moving ahead with the Future Business discussion that was to be held at 4:30 p.m.

### **Future Business**

*Dr. James Clark, Executive Committee Chair*

Dr. Clark stated that EPA currently is reviewing nominations to fill the vacancies on the Executive Committee. He reminded the members that his term as well as that of Dr. Anna Harding end on October 31, 2007. EPA hopes to have the new members approved so that they can attend the next Executive Committee meeting, which will be held January 24-25, 2008, in the Washington, DC, area. The May meeting, currently scheduled for May 15-16, 2008, probably will be held at some other location, which has yet to be determined. Dr. Haas suggested meeting at the laboratory in Ada, Oklahoma. Dr. Sayler suggested meeting at the laboratory in Corvallis, Oregon. Dr. Clark stressed that the laboratory should have a programmatic link to the ongoing efforts of the Board. Dr. Haas suggested Ada, which focuses on groundwater, because of the mid-cycle review of the Drinking Water Program.

Drs. Duke and Weiss said that they will not be able to attend the May meeting unless the dates are changed. Dr. Clark suggested that everyone block May 15-16, 2008 on their calendars; once the location of the meeting is determined, the date can be revisited.

Dr. Clark said he hoped to have an Executive Committee conference call before his term ends on October 31. The location of the May meeting and the issue of changing the date can be discussed on that call.

The Land Research Program and Water Quality Research Program mid-cycle reviews will take place in 2008 so subcommittees to conduct these reviews will be established after the January 2008 meeting. It is expected that reports from both of these Subcommittees will be completed by the end of 2008 so that they can be vetted at the January 2009 Executive Committee meeting. Dr. Clark asked if there were any volunteers to chair these Subcommittees. Dr. Sayler asked if the Executive Committee member had to function as the chair and Dr. Clark replied that the chair did not have to be a member of the Executive Committee; for mid-cycle subcommittees, however, it would be very helpful if the chair served on the subcommittee that conducted the program review. There is considerable value in populating the mid-cycle subcommittees with members of the program review subcommittee. Dr. Haas volunteered to serve as Vice Chair of the Land Mid-Cycle Subcommittee. Dr. Clark said the chair of the subcommittee that conducted the program review for the Land Research Program was not a member of the Executive Committee.

Dr. Clark stated that Dr. Herb Windom, a former Executive Committee member, chaired the subcommittee that conducted the program review of the Water Quality Research Program. Dr. Clark thought it would be appropriate to ask Dr. Windom if he would be willing to chair the Water Quality Mid-Cycle Subcommittee.

Dr. Clark asked if there were any new topics that the Board members would like to address. Dr. Demerjian said that he would like to look at nanotechnology. There are many issues associated with nanotechnology and many players, and EPA is trying to find its niche among federal agencies so it may be appropriate for the Agency to seek external advice on this topic. Dr. Demerjian mentioned that Dr. Philbert also is interested in this area. Dr. Teichman commented that there is an interagency group, led by FDA and the National Science Foundation (NSF), which coordinates nanotechnology efforts. EPA participates in this group and most of ORD's work falls under the Land Program, dealing with fate and transport issues. Dr. Teichman suggested that it be a topic for the January meeting.

Dr. Henderson indicated that she is interested in learning more about the one-atmosphere approach. She would like to hear about the Agency's progress on this issue.

Dr. Haas commented that it is difficult for ORD to fund extramural research that targets the specific needs of the Agency. Perhaps it would be helpful for the BOSC to look at extramural vehicles to determine if more flexibility would benefit EPA. Because the Agency must be hands-off with grants, it is difficult for EPA to get the results it needs to meet the needs of the program and regional offices. It is very difficult for EPA to fund good basic research that is of high relevance to EPA's mission. Dr. Clark said that he would work with Dr. Haas to develop a description of this issue. Perhaps the BOSC could prepare a letter report to address it. Dr. Clark also agreed to work with Dr. Demerjian to prepare a paragraph on EPA's role in nanotechnology.

Dr. Weiss suggested looking at other scientific agencies and how they acquire research. The Congressional Research Service did a paper of the different mechanisms used by government agencies. That paper might be a good starting point.

Dr. Clark mentioned that these types of issues have historically been addressed by BOSC workgroups.

Dr. Sayler suggested the topic of bioenergy production and transportation. This is an enormous issue with potential for severe impacts on air, water, and land. He would like to learn more about ORD's role and what the Agency is doing on this issue.

Dr. Lambert proposed the issue of data for inclusion in the Report on the Environment. What can EPA do to encourage other agencies to gather data that will provide a better view of the state of the environment? What can be done to ensure that data can be consolidated and integrated?

Dr. Clark agreed that these were good topics for future work. He will work with the Executive Committee members who suggested them to compile a list of topics for future BOSC business to be submitted to ORD. Dr. Clark then asked the members to consider which of the upcoming reports they would like to vet. Two vetters are need for the program review reports and one for the mid-cycle review reports. Dr. Duke agreed to serve as the vettor for the NCER Standing Subcommittee letter report; Dr. Sayler agreed to vet the NERL Standing Subcommittee letter report. Dr. Daston agreed to serve as the vettor for the EDCs Research Mid-Cycle Review Report and Drs. Ryan and Giesy will vet the Air Mid-Cycle Review Report (Dr. Giesy will be unable to attend the January meeting so he will send his comments to Dr. Ryan before the meeting). Drs. Henderson and Philbert will serve as vettors for the Human Health Risk Assessment Research Program Review Report.

### **Children's Environmental Health Research Centers Workgroup (CEHRC)**

*Dr. George Daston, BOSC Executive Committee Workgroup Member*

Dr. Daston explained that the workgroup is a joint effort of the Children's Health Protection Advisory Committee and the BOSC and it was formed to provide comments on the success of the Children's Environmental Health Disease and Prevention Centers Program. This program is jointly funded by EPA and the National Institute of Environmental Health Sciences (NIEHS) and it has been in existence for 10 years. The review was scheduled at this time because EPA and NIEHS were negotiating the renewal of the program. Dr. Daston mentioned that Dr. Lambert has one of the centers. The workgroup was charged with assessing the Children's Centers' ability to translate the science findings in a manner useful to public decision making. The review was conducted in two phases. First, a case study template was developed by the workgroup and forwarded to the Children's Center investigators, soliciting their participation and agreement to develop up to two case studies demonstrating translation around specific scientific findings. A total of 16 case studies were received and reviewed from nine principal investigators. Secondly, a facilitated 2-hour conversation was held with Center investigators.

The workgroup identified approaches for translating the research results of the Children's Centers that have been most effective in impacting public decision-making processes at the local, state, and federal levels. In addition, findings from the case studies reflect that the majority of the Centers have been effective in the translation of research findings into applied intervention and prevention methods, thereby enhancing awareness and knowledge of environmental risks and risk reduction among children, their families, and health care practitioners.

Dr. Daston said that these Centers are a great investment of research dollars and he would like to see them funded in the future. The Centers have done a good job with basic research and the translation of that research into actionable results. There should be an explicit emphasis on the translational aspect in future grants. The workgroup made a number of recommendations that should be fairly easy to incorporate into the Centers. The successful elements of the program should be retained and funding for the program should be increased by identifying additional partners (e.g., CDC, National Institutes of Health, Housing and Urban Development). It also was recommended that supplemental funding should be provided to those Centers that are more successful on translating the research for use by decision makers so that they can train the other Centers that were less successful. The workgroup also encouraged Centers to partner with pediatric environmental specialty units.

Dr. Clark thanked Dr. Daston for serving on that workgroup. He asked if there were any comments on the report. Dr. Giesy asked if the workgroup discussed what could and could not be done with human subjects. Dr. Daston said the problems encountered previously by EPA were not discussed specifically.

The workgroup did discuss, however, the engagement of the community in the study design to provide ideas and identify aspects of the study design that were unpalatable.

Dr. Lambert said that every spring his Center meets with parent groups and all of the parents praise EPA for being involved with these Centers.

Dr. Daston said that the report of the workgroup is available on the Children's Health Protection Advisory Committee Web Site at [http://yosemite.epa.gov/ochp/ochpweb.nsf/content/CEHRC\\_Findings.htm/\\$file/CEHRC%20Findings.doc](http://yosemite.epa.gov/ochp/ochpweb.nsf/content/CEHRC_Findings.htm/$file/CEHRC%20Findings.doc).

### **Public Comments**

*Ms. Lorelei Kowalski, BOSC Executive Committee DFO*

Ms. Kowalski called for public comments at 2:00 p.m. No comments were offered.

### **SAB Activities**

*Dr. George Lambert, SAB Liaison to the BOSC*

Dr. Lambert distributed the list of advisory projects in the SAB Staff Office Operating Plan for FY 2007. He also handed out a list of proposed projects planned for FY 2008. He reported that Dr. Vanessa Vu is organizing a display for the EPA Science Forum to be held in May 2008 to celebrate the 30th anniversary of the Board. The goal is to communicate to EPA and those attending the Forum the impact that the SAB has had on the Agency. He indicated that a number of federal agencies view the SAB as the gold standard for external peer review.

Dr. Lambert noted that the SAB has completed many projects in FY 2007. The CASAC has been very busy. The CASAC Lead Panel is working on its report; the CASAC Ozone Panel completed its report; the CASAC NO<sub>x</sub>/SO<sub>x</sub> Primary Standards Review Panel completed two letter reports.

The Ethylene Oxide Carcinogenicity Assessment report and the Valuing the Protection of Ecological Systems and Services report are in review. Dr. Swackhamer is chairing the panel reviewing the Report on the Environment (ROE). The panel met in July to review the five chapters. He asked if the BOSC reviewed the ROE. Dr. Saylor said that the BOSC members were invited to provide their comments to him prior to the July meeting. Only Dr. Haas provided comments, which Dr. Saylor communicated to the panel in July. Dr. Lambert noted that there were more data for land than for air, water, and human health, and the usefulness of the ROE to decision makers was questioned recently. The document for distribution to the general population has been written already, but that draft will be circulated to the SAB for input. This document is 50-60 pages and it summarizes the 450-page report. The smaller report is being reviewed by the National Advisory Council for Environmental Policy and Technology (NACEPT).

Dr. Henderson stated that things are moving very fast for CASAC; priority pollutants are being reviewed once every 5 years and previously they were reviewed once every 10 years. There is some thought to having the CASAC not act as a committee of the whole—this means that not every member would be involved with the review of every pollutant. This approach would help the Committee get through its heavy schedule.

Dr. Lambert asked that members notify Dr. Clark or Ms. Kowalski if they are interested in any of these projects.

Dr. Demerjian asked about the difference between a peer review and a consultation. Dr. Lambert replied that a peer review is a complete review resulting in a 2-3 page letter report to the Administrator and a

consultation can result in a short letter report but no report is required. Dr. Teichman mentioned that an advisory and a consultation are the same thing and no report is required.

Dr. Clark noted a couple of items on the SAB project list that the BOSC may want to consider, including ORD Research Strategic Directions (on page 1 of the FY 2008 list), Derivation of Water Quality Criteria for the Protection of Aquatic Life Based on Mode of Action (top of page 3 of FY 2008 list), and Ecological Research Program Strategy and Multi-Year Plan (second item on page 3 of FY 2008 list). Dr. Clark will draft a letter to Dr. Vu and Dr. Granger Morgan, Chair of the SAB, to inform them that the BOSC would be interested in participating in these efforts. Dr. Lambert said he did not think it would be a problem if a few BOSC members wanted to participate in these efforts.

### **ORD Update**

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

Dr. Teichman announced that the SAB meeting on ORD Research Strategic Directions will be held October 4-5, 2007. He has asked each of the NPDs to prepare a 5-page document that explains the strategic directions of his/her program, and no budget restrictions were placed on the NPDs. ORD will add information about sequencing the research efforts. Dr. Teichman pointed out that this is different from the last exercise he assigned the NPDs; previously, he asked each NPD to develop a 3-page document on the strategic direction of the program, assuming a constant budget. The SAB asked ORD to do this.

Referring to the earlier discussion about consideration of budget when using the rating tool, Dr. Teichman said that the ORD Executive Council decides the resources for each program. That budget is reviewed annually by the SAB. The SAB reviews the budget and offers its thoughts to EPA and to Congress. The SAB often comments on the size of ORD's budget and may comment on the allocation of resources among the programs. After the Executive Council decides that a program will receive a budget of \$X, the NPD writes an MYP for \$X. The MYP is written to match the budget assumption. The BOSC reviews the program and the progress it is making in implementing the MYP and achieving its goals. Because this came up earlier in the discussions, Dr. Teichman wanted to clarify the responsibilities of the Executive Council and the NPD with respect to budget.

On October 2, 2007, all Deputy Regional Administrators will meet with the NPDs and Laboratory/Center Directors in Research Triangle Park to inform ORD about what they believe ORD has done well and what could be improved. This is an internal meeting, but ORD intends to build on the feedback it receives.

ORD often is asked to respond quickly to requests from the regions. What can be done to achieve ozone National Ambient Air Quality Standards (NAAQS)? If a new source is added, would the area violate NAAQS? What should the level of compound X be in groundwater? The regions use ORD tools all the time. ORD staff must be up on the science to respond quickly to a wide range of questions from the regions. ORD also works with regions to target emerging issues such as biofuels. Dr. Gray sits on the Biomass R&D Board. ORD is working with Iowa to determine the environmental impacts of using much of the agricultural land to grow corn for ethanol. Regions 5 and 8 are very concerned about these potential impacts.

There will be an ORD Division Directors meeting in late November 2007. Dr. Teichman explained that there are 36 divisions in ORD (e.g., Ada, Gulf Breeze). The purpose of this meeting is to help Division Directors deal efficiently with common problems, such as staffing and succession planning.

On September 19, 2007, the Executive Council will meet and the ORD awards ceremony will be held in the morning. He invited the BOSC members to attend the ceremony if they are in the Washington, DC, area. One of the topics of the Executive Council meeting will be the consolidation of the MYPs. There

currently are 13 MYPs and some ORD managers would like to reduce the number to 8, or possibly as few as 5—one for air, water, land, human health, and ecology. If the number of MYPs is reduced, it will reduce the workload for the BOSC and the ORD staff. Dr. Teichman noted that there is some resistance to consolidating MYPs because it will reduce the visibility of some of the smaller programs.

There have been some changes in personnel at OMB. Mr. Kevin Neyland is the Chief of the Environment Branch at OMB and Janet Irwin is the Chief of the Interior Branch at OMB. There are many new desk officers in the branch. Dr. Teichman and Mr. Jeff Morris have been giving the ORD 101 briefing to the new OMB staff. Dr. Teichman introduced Mr. Morris who was present at the meeting, stating that he is the Associate Director for Science in ORD's Office of Science Policy (OSP). Mr. Morris has acted for Dr. Teichman as the Director of OSP and has helped others rotating in to fill that position in Dr. Teichman's absence from OSP.

Dr. Teichman stated that the OMB examiners have asked a number of questions about the BOSC, such as: Who are the members? Who selects the members? It is clear that the BOSC plays an important role in reviewing ORD's programs. ORD has used the BOSC recommendations to prepare its 2009 budget for submission to OMB.

Dr. Teichman wanted to add some comments regarding the questions that were posed to Dr. Gray in the morning. Dr. Henderson asked a question about monitoring data for NAAQS secondary standards. ORD understands the need for additional data, and ORD can contribute by determining what to measure and how to measure it. These are research questions that can be addressed by ORD; however, it is the responsibility of the Office of Air and Radiation (OAR) to fund regions and states to conduct routine monitoring for data collection. Dr. Saylor had asked about interactions with Asia. Dr. Teichman said he accompanied Dr. Bill Farland to Vietnam to work on dioxin issues. The American government has decided to help fund remediation there to prevent future exposures. Representatives from CDC also participated in this trip to provide guidance on how to prevent birth defects. In addition, ORD's National Risk Management Research Laboratory (NRMRL) is working with OAR to improve the designs of cook stoves used in Asia, often in unventilated situations, to reduce exposure.

Dr. Daston had asked about the resources for researching outcomes. Dr. Teichman agreed that this will be expensive. There are a number of efforts with which EPA is involved that could provide useful data, including the National Children's Study (100,000 children) and the Multi-Ethnic Study on Atherosclerosis (led by the National Heart, Lung and Blood Institute). The Agency will look for similar opportunities to provide some funding to studies conducted by other agencies to add environmental components.

Dr. Clark said he sees a real advantage to consolidating the MYPs, but commented that it has been challenging getting a handle on the current MYPs during the program reviews. It will be even more difficult if the MYPs cover a larger program. It will be a challenge for ORD to help the BOSC understand the program. Dr. Clark asked if there was a specific driver for this consolidation. Dr. Teichman replied that the driver is the transaction cost demanded of the BOSC and ORD staff. Because ORD values the BOSC's reviews, the Agency is trying to strike the proper balance. For example, should there be a separate MYP for mercury? Could other small programs be placed in MYPs of larger programs?

Dr. Saylor asked about the breadth of the Multi-Ethnic Study on Atherosclerosis. Dr. Teichman said that more information on the study is available on the NCER Web Site (<http://www.epa.gov/ncer>).

Dr. Lambert commented that none of the Children's Centers funded by EPA and NIEHS participate in the National Children's Study. Does EPA receive funds for the National Children's Study? Dr. Teichman replied that EPA does not receive any of the resources that go to the National Institute of Child Health

and Human Development (NICHD) for the National Children's Study. EPA provides a small amount of funding for the study and Agency representatives serve on committees associated with the study. EPA considers this an in-kind contribution to the study.

Dr. Clark informed Dr. Teichman that Ada and Corvallis had been suggested as possible locations for the May 2008 meeting. Dr. Daston expressed his concern about visiting some of the smaller laboratories because of the burden the visit places on the staff at these sites. Dr. Clark replied that Dr. Teichman and Ms. Kowalski will take that concern into consideration when selecting the location. Dr. Saylor pointed out that Narragansett is not a large laboratory but he found the site visit to be very illuminating. Dr. Clark said that the BOSC also could consider meeting at one of the EPA regional offices—possibly Region 5 or 8 to discuss the biofuels issue. Dr. Henderson commented that the SAB goes to one region each year. Dr. Lambert asked if ORD found these site visits to be useful to them. Does the Agency have a suggestion for the location of the May meeting? Dr. Clark said that Regions 5 and 8 have a clear link to biofuels. He asked if there is a region that is linked to the one-atmosphere approach and Dr. Demerjian suggested that Regions 1, 2, and 6 may have a link to one-atmosphere. One member suggested the Athens Laboratory and its focus on water quality and surface water.

Dr. Clark summarized the proposed locations for consideration:

- ✧ Ada Laboratory—drinking water
- ✧ Corvallis Laboratory—land and ecological issues
- ✧ Athens Laboratory—water quality, surface water, and modeling
- ✧ Region 7—biofuels
- ✧ Region 1, 2, or 6—one-atmosphere.

Dr. Teichman and Ms. Kowalski will look into these options for the May meeting.

### **ORD Briefing: NRC Report on Vision for Toxicity Testing**

*Dr. Hal Zenick, Director of NHEERL, ORD*

*Dr. Robert Kavlock, Director of NCCT, ORD*

Dr. Hal Zenick asked how many of the Executive Committee members had read the report and Dr. Clark replied that one member present had read it. Dr. Zenick stated the NRC is very excited about this report and plans to distribute it to numerous agencies and Congress. The study was initiated about 4 ½ years ago with the goal of developing a vision and strategic plan for the long-range future of toxicity testing/assessment of environmental agents for evaluating potential human health risks. It was designed as a two-part study. Phase 1 involved the review of relevant aspects of several reports by EPA and others on the topic of toxicity testing and assessment (Interim Report—2006). Phase 2 involved the development of a long-range vision and strategic plan to advance the practices of toxicity testing and assessment of environmental contaminants (Final Report—June 2007). Dr. Zenick noted that the Final Report will be available in the near future.

The overall conclusion of the Final Report is that a transformative paradigm shift is needed to achieve the following design criteria:

- ✧ Provide broad coverage of chemicals, chemical mixtures, outcomes, and life stages.
- ✧ Reduce the cost and time of testing.
- ✧ Use fewer animals and cause minimal suffering in the animals used.
- ✧ Develop a more robust scientific basis for assessing health effects of environmental agents.
- ✧ Recognize that a 10-20 year effort will be needed.

The transformative paradigm shift will focus on toxicity pathways—cellular response pathways that, when sufficiently perturbed, are expected to result in adverse health effects.

The requirements for implementation of the strategy include:

- ✧ Suite of *in vitro* tests, preferably based on human cells or components.
- ✧ Targeted animal tests to complement *in vitro* tests.
- ✧ Computational models of toxicity pathways to support application in risk assessments.
- ✧ Infrastructure to support basic and applied research to develop the tests and pathway models.
- ✧ Validation of tests and test strategies.
- ✧ Human surveillance strategy.
- ✧ Evidence justifying that toxicity-pathway approach is adequately predictive of adverse health outcomes to use in decision-making.

The National Academy of Sciences (NAS) proposal called for: (1) an interdisciplinary research program, (2) intramural and extramural research, (3) high-level coordination, (4) cross-institution and cross-sector linkages, (5) substantial funding, (6) funding and coordination primarily by the federal government, and (7) midcourse corrections.

Dr. Zenick commented that EPA is well suited to serve this role and has discussed with NIEHS the possibility of working together on this.

Regulatory acceptance of the new approach for toxicity testing will depend on several factors:

- ✧ New testing requirements will need to reflect the state of the science and be founded on peer-reviewed research, established test protocols, validated models, and case studies.
- ✧ Policies will be needed to foster development and use of new tests.
- ✧ New test systems and agency guidelines will need to co-evolve.
- ✧ The vision will need to be communicated to all stakeholders in understandable terms.

NRC reached the following conclusions: (1) the paradigm shift will not only improve the current system but transform it into one capable of overcoming current limitations and meeting future challenges, (2) the vision takes full advantage of current and expected scientific advances, (3) it has the potential to greatly reduce animal use and the cost and time of testing, (4) it will lead to much broader coverage—assessment of many more chemicals and end points, and (5) testing will allow assessment of environmentally relevant doses.

Building on the NRC vision, Dr. Gray has had initial discussions with the EPA Administrator and proposed two parallel paths: (1) ensure that relevant, ongoing work is acknowledged; and (2) provide an early appraisal of the report. With respect to the first step, subsequent engagement of NAS has resulted in EPA work being acknowledged in the preface of the report. EPA has developed a program write-up for use by the Chair of the NAS Committee for various speaking engagements (e.g., Tox Forum). The Chair of the NAS Committee visited Research Triangle Park on July 30-31, 2007. EPA is discussing with NIEHS the preparation of an editorial for publication in *Science* or *Nature* that recognizes the efforts and the intent to partner in addressing high-priority research needs.

With respect to building an EPA program, ORD is drafting a White Paper that aligns current work with the NAS paradigm and outlines opportunities and needs. The Science Policy Council is re-establishing the Future of Toxicity Testing Work Group (the inaugural meeting will be held on October 10). This

work group will be charged with scoping a research program based on the White Paper, and examining issues related to regulatory acceptance. EPA is strengthening collaborations with the National Toxicology Program (NTP)/NIEHS and the NIH Chemical Genomics Center/National Human Genome Research Institute (NCGC/NHGRI) through a Memorandum of Understanding.

Dr. Zenick then introduced Dr. Robert Kavlock who completed the presentation.

Dr. Kavlock presented a diagram that provided a snapshot of ongoing, related work. He then focused on an example of relevant research under the Computational Toxicology Research Program involving chemical characterization and toxicity pathways. The ToxCast project is a chemical categorization and prioritization research project designed to create the ability to predict, or forecast toxicity. It is based on drug discovery experience in the pharmaceutical industry and it involves comprehensive use of current technology with more than 400 endpoints explored. The project is being implemented in a phased approach currently anchored to 320 well studied chemicals. Dr. Kavlock stressed that ORD is committed to stakeholder involvement and release of data to the public domain.

Nine contracts have been awarded and one Interagency Agreement (IAG) has been executed providing chemical procurement, biochemical assays, cellular reporter assays and genomics, complex human cell responses, and model organisms. Through these vehicles, EPA has the capacity to screen up to 10,000 chemicals in more than 400 assays by 2012.

Dr. Kavlock explained that Phase I involves more than 300 chemicals, primarily pesticides. The purpose of Phase I is signature development and the estimated cost per chemical is \$20K. Phase I will be implemented in FY 2007-2008. Phase II will involve more than 1,000 chemicals with expanded structure and use diversity. The purpose of this phase is evaluation and extension. The estimated cost per chemical is expected to be \$12K-15K, and the phase will be implemented in FY 2008-2009. Phase III will look at thousands of chemicals for which the Agency needs toxicity data. The purpose of this phase will be prediction and prioritization. The estimated cost per chemical is expected to be \$6K-10K, and the phase will be implemented in FY 2009-2012. ToxCast will deliver an affordable, science-based system for categorizing chemicals. Confidence in the data will increase as the database grows. It will be used to identify potential mechanisms of action as well as refine and reduce the use of animals in hazard identification and risk assessment.

Dr. Kavlock provided some final thoughts for the BOSC. EPA is introducing modern tools into hazard and risk assessment and using approaches endorsed by the NRC vision. The magnitude of the effort to fulfill the vision, however, is more than ORD's current portfolio. EPA should be at the center of this research front and the Agency has cutting-edge tools and expertise available in the intramural program. EPA has access to the scientific community through the extramural grants program and will maintain close, ongoing integration with regulatory clients. The effort must be coordinated across the federal government and internationally with, for example, the NTP, FDA, and OECD. Dr. Kavlock stated that the process can be evolutionary in the short term and revolutionary in the long term.

Dr. Henderson said she is familiar with the NRC report and is very excited about it. She did not think the term "toxicity pathways" was the best terminology, however. They actually are perturbations of normal pathways that may or may not lead to toxicity. Perhaps better terminology would be activation of key pathways. Dr. Zenick responded that he did not know where that term originated, but he agreed that Dr. Henderson had a good point. Dr. Demerjian had a question about the transformation paradigm shift. Did the report try to identify the weakest link and focus on strengthening that weakness? Dr. Kavlock replied that the report was brief and at a higher level—it was proposed as a provocative vision rather than guidance. Dr. Saylor asked about the extended use of animal models. Dr. Kavlock responded that they could use engineered animals that have human traits or cells with human traits, but it will be a long time before the Agency can move away from the use of animals.

Dr. Lambert mentioned that many of the toxicity pathways could actually be detoxification pathways that get overwhelmed. Dr. Zenick noted that this comment related to Dr. Henderson's earlier comment. Dr. Lambert added that the identification of detoxification pathways leads to opportunities for prevention and intervention.

Dr. Henderson asked if high-throughput screening will be used to eliminate inactive chemicals. How do you know how much it takes to overwhelm the organism? Dr. Kavlock replied that reverse PBPK is one way to determine that. He added that it is more difficult to prove a negative so high throughput screening would probably be used for prioritization.

Dr. Clark said it was gratifying to see the growth of the Computational Toxicology Program and its ability to fill this niche. It was very forward-thinking of ORD to establish the NCCT. He thanked Drs. Zenick and Kavlock for their very informative presentation.

Before the meeting was adjourned, Dr. Teichman thanked Dr. Clark for his service on the BOSC and presented him with an engraved clock in appreciation for his efforts on behalf of ORD. Dr. Clark said he had enjoyed his 7 years on the BOSC and that he will continue to serve on the Computational Toxicology Subcommittee. He then adjourned the meeting at 4:01 p.m.

### **Action Items**

- ✧ Dr. Demerjian will send his editorial and substantive edits for the draft Technology for Sustainability Program Review Report to Dr. Giesy.
- ✧ Dr. Duke will send his editorial and substantive edits for the draft Technology for Sustainability Program Review Report to Dr. Giesy.
- ✧ Dr. Swackhamer will send her comments on the draft Technology for Sustainability Program Review Report to Dr. Giesy.
- ✧ Dr. Giesy will assemble the Executive Committee's comments on the draft Technology for Sustainability Program Review Report and work with the Subcommittee to revise the report accordingly.
- ✧ Ms. Kowalski will distribute the revised report to the Executive Committee for review and the Executive Committee will review and approve the report during an upcoming conference call or the next Executive Committee meeting.
- ✧ Dr. Clark will revise the Guidance for Development of Mid-Cycle Review Reports with Application of the BOSC Program Rating Tool. He will delete the words "and other review committees" from the following sentence: "The rating tool should be used to generate an overall assessment of research program progress towards meeting changes and goals defined as responses to previous program reviews completed by the BOSC and other review committees." He also will reword the section that addresses the length and format of the mid-cycle review reports so that it is guidance rather than a requirement. In addition, he will add wording on the timing of mid-cycle reviews and the charge questions.
- ✧ Executive Committee members should send their comments on the Guidance for Development of Mid-Cycle Review Reports with Application of the BOSC Program Rating Tool to Ms. Kowalski.
- ✧ Dr. Haas volunteered to serve as Vice Chair of the Land Mid-Cycle Review Subcommittee.

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- ✧ Ms. Kowalski or another DFO will contact Dr. Herb Windom about chairing the Water Quality Mid-Cycle Subcommittee.
- ✧ Ms. Kowalski and Dr. Teichman will ensure that nanotechnology is a topic on the agenda for the January meeting.
- ✧ Dr. Clark will work with various Executive Committee members to compile a list of topics to be addressed by the BOSC in the future.
- ✧ Dr. Duke agreed to serve as the vettor for the NCER Standing Subcommittee letter report.
- ✧ Dr. Sayler agreed to vet the NERL Standing Subcommittee letter report.
- ✧ Dr. Daston agreed to serve as the vettor for the EDCs Research Mid-Cycle Review Report.
- ✧ Drs. Ryan and Giesy will vet the Air Mid-Cycle Review Report. Because Dr. Giesy will be unable to attend the January meeting, he will send his comments to Dr. Ryan before the meeting.
- ✧ Drs. Henderson and Philbert will serve as vettors for the Human Health Risk Assessment Research Program Review Report.
- ✧ Executive Committee members will notify Ms. Kowalski if they are interested in any of the upcoming SAB activities.
- ✧ Dr. Clark will send a letter to Dr. Vanessa Vu and Dr. Granger Morgan to inform them that the BOSC may want to be involved with the following SAB efforts: ORD Research Strategic Directions (on page 1 of the FY 2008 list), Derivation of Water Quality Criteria for the Protection of Aquatic Life Based on Mode of Action (top of page 3 of FY 2008 list), and Ecological Research Program Strategy and Multi-Year Plan (second item on page 3 of FY 2008 list).
- ✧ Dr. Teichman and Ms. Kowalski will research the following proposed locations for the May meeting: Ada Laboratory—drinking water; Corvallis Laboratory—land and ecological issues; Athens Laboratory—water quality, surface water, and modeling; Region 7—biofuels; and Region 1, 2, or 6—one-atmosphere.

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**36<sup>th</sup> EXECUTIVE COMMITTEE FACE-TO-FACE MEETING  
AGENDA****September 17, 2007**

Key Bridge Marriott

1401 Lee Highway

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Tel: (703) 524-6400

**Monday, September 17, 2007**

8:00 a.m. – 8:30 a.m.	Registration	
8:30 a.m. – 9:00 a.m.	Welcome and Introductions - Review of May Meeting Minutes - Review of August Meeting Minutes - Reports Transmitted to ORD - Overview of Agenda	Dr. James R. Clark, Chair, Executive Committee
9:00 a.m. – 9:15 a.m.	BOSC DFO Remarks - Administrative Issues	Ms. Lori Kowalski, Office of Research and Development
9:15 a.m. – 9:45 a.m.	AA/ORD Remarks	Dr. George Gray, Assistant Administrator for Research and Development
9:45 a.m. – 10:45 a.m.	Subcommittee Draft Reports: - Technology for Sustainability Program Review Draft Report Presentation  - Discussion	Dr. John Giesy, Subcommittee Chair  Executive Committee
10:45 a.m. – 11:00 a.m.	Break	
11:00 a.m. – 12:30 p.m.	Subcommittee Updates:  <u>Mid-Cycle Review Subcommittees:</u> - Endocrine Disrupting Compounds (EDC) Mid-Cycle Review - Air Mid-Cycle Review  - Global Change Mid-Cycle Review	Dr. Deborah Swackhamer, Subcommittee Chair Dr. Rogene Henderson, Subcommittee Chair Dr. James R. Clark, Chair, Executive Committee

September 17, 2007 BOSC Executive Committee Meeting Agenda

	<u>Program Review Subcommittees:</u> - Human Health Risk Assessment Program Review - Homeland Security Program Review	Dr. George Daston, Subcommittee Chair Dr. Gary Saylor, Subcommittee Chair
	<u>Rating Tool</u>	Dr. James R. Clark, Chair, Executive Committee
	<u>Standing Subcommittees:</u> - Computational Toxicology  - National Exposure Research Lab (NERL)	Dr. George Daston, Subcommittee Chair Dr. Ken Demerjian, Subcommittee Chair
12:30 p.m. – 1:30 p.m.	Lunch	
1:30 p.m. – 2:00 p.m.	Subcommittee Update Continued:	
	<u>Standing Subcommittees:</u> - National Center for Environmental Research (NCER)	Dr. Martin Philbert, Subcommittee Chair
2:00 p.m. – 2:15 p.m.	Public Comments	
2:15 p.m. – 2:45 p.m.	Children’s Environmental Health Research Centers Workgroup (CEHRC)	Dr. George Daston/ Dr. Martin Philbert, BOSC Executive Committee Workgroup Members
2:45 p.m. – 3:15 p.m.	ORD Update	Dr. Kevin Teichman, Acting Deputy Assistant Administrator for Science, Office of Research and Development
3:15 p.m. – 3:30 p.m.	Break	
3:30 p.m. – 4:00 p.m.	ORD Briefing: NAS Report on Toxicity Testing in the 21st Century	Dr. Hal Zenick/Dr. Robert Kavlock, Office of Research and Development
4:00 p.m. – 4:30 p.m.	SAB Activities	Dr. George Lambert, SAB Liaison to the BOSC
4:30 p.m. – 5:00 p.m.	Future Discussion/Future Business - Executive Committee Vacancies - Executive Committee Meetings in 2008 - Mid-Cycle Reviews in 2008 - Future Work	Dr. James R. Clark, Chair, Executive Committee
5:00 p.m.	Adjourn	