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41st EXECUTIVE COMMITTEE FACE-TO-FACE MEETING SUMMARY

U.S. Environmental Protection Agency
Office of Research and Development
National Health and Environmental Effects Research Laboratory (NHEERL)
Mid-Continent Ecology Division (MED)
Duluth, Minnesota
June 4 - 5, 2009

THURSDAY, JUNE 4, 2009

Welcome and Introductions

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

Dr. Gary Sayler, Chair of the Executive Committee of the Board of Scientific Counselors (BOSC), welcomed the BOSC members to the meeting. He noted that a few of the Committee members were not present, but there were enough members in attendance to provide a quorum. He noted that Dr. Carol Weiss, Harvard University, and Dr. Kenneth Demerjian, State University of New York, were unable to attend the meeting, and Dr. Katherine von Stackelberg, Harvard School of Public Health, will be participating via telephone.

Dr. Sayler asked the members to examine the minutes from the February 9-10, 2009, Executive Committee meeting. Dr. Sayler stated that he had reviewed the summary and did not have any comments. He asked if any of the members had comments or corrections on the minutes. Dr. Dennis Paustenbach, ChemRisk, Inc., said that the minutes were well written; Dr. Clifford Duke, The Ecological Society of America, noted a few typographical errors, which he agreed to send to Ms. Kowalski. When no additional comments were made, Dr. Sayler called for a motion to accept the minutes. Dr. Charles Haas, Drexel University, moved to accept the minutes of February meeting, and Dr. Paustenbach seconded the motion. The minutes for February 2009 were approved unanimously by the BOSC.

Dr. Sayler called for comments on the minutes for the May 4, 2009, Executive Committee conference call. No comments were offered so Dr. Sayler called for a motion to accept the minutes. Dr. Paustenbach moved to accept the minutes, and Dr. Duke seconded the motion. The minutes for the May 2009 conference call were approved unanimously by the BOSC.

Dr. Sayler reviewed the agenda and noted that Dr. Neil Carriker from the Tennessee Valley Authority would be joining the Executive Committee members on their site visit of the laboratory to be held that afternoon. He noted that the agenda also will include time for discussing the format of future BOSC reports.

BOSC DFO Remarks

Ms. Lorelei Kowalski, U.S. Environmental Protection Agency (EPA)/Office of Research and Development (ORD), BOSC Designated Federal Officer (DFO)

Ms. Lorelei Kowalski, DFO, welcomed the Executive Committee members to the meeting. She asked those participating via phone to identify themselves so that their attendance could be captured in the

minutes. Mr. Greg Susanke, ORD, Dr. Greg Sayles, ORD, and Dr. von Stackelberg indicated that they were on the telephone.

Ms. Kowalski reviewed the Federal Advisory Committee Act (FACA) procedures that are required for all BOSC meetings. She stated that the BOSC is a Federal Advisory Committee that provides independent, scientific peer review and advice to EPA's ORD, and it is her responsibility as the DFO to ensure compliance with all FACA rules. As Dr. Sayler noted, Drs. Demerjian and Weiss are not in attendance. Ms. Kowalski announced that Dr. Weiss had resigned from the BOSC because of health issues. Her perspective was helpful to the Executive Committee so it will be important for EPA to find a replacement who has similar expertise.

Ms. Kowalski reviewed the FACA procedures that are required for all BOSC meetings. This meeting is open to the public and time has been designated on the agenda for public comment. She noted that no requests for comment were received prior to the meeting, but there is time set aside at 10:15 a.m. on Day 2 for public comment. She asked that comments be limited to 3 minutes each. An ORD contractor, Beverly Campbell from The Scientific Consulting Group (SCG), is present to take notes that capture the presentations and discussions. Following the meeting, she will prepare the meeting minutes, which will be made available to the public on the BOSC Web Site after approval by the Executive Committee and certification by the BOSC Chair.

As required by FACA, a notice of this meeting was published in the *Federal Register*. Ms. Kowalski established an electronic public docket for the meeting on the Federal Docket Management System (FDMS), which can be accessed at http://www.regulations.gov. The number to search for this docket is EPA-HQ-ORD-2009-0266. The *Federal Register* notice and the agenda were available to the public on the docket. As the DFO, Ms. Kowalski ensures that the Executive Committee members receive annual ethics training and complete confidential disclosure forms. She asked members to notify her immediately if any potential conflict of interest arises during the meeting.

Mr. Lek Kadeli, Acting Assistant Administrator (AA) for ORD, was scheduled to present the ORD remarks, but he was unable to attend the meeting. Therefore, Dr. Kevin Teichman, Deputy Assistant Administrator for Science for ORD, will give that presentation. All members should have received their notebooks prior to the meeting, except those members who were traveling. The notebook contains the minutes from the last meeting and conference call; the original Homeland Security report on CD as a reference for the ORD response to be presented this morning; three draft reports for vetting including the Human Health program review report, the Science and Technology for Sustainability mid-cycle review report, and the National Center for Environmental Research (NCER) letter report; and three fact sheets on the three programs reviewed. Ms. Kowalski asked for the members' feedback on the contents of the fact sheets. She noted that these fact sheets are intended to help the BOSC members vet and review the reports from the program and mid-cycle reviews. The binders also contain homework and voucher sheets, both of which should be submitted to her before members leave the meeting.

Ms. Kowalski distributed three tables, which she creates for each Executive Committee meeting: a listing of all the activities under the BOSC; a listing of all the Executive Committee member activities, including vetting and workgroup activities; and the work chart table that shows the BOSC workload into 2010. She noted that Dr. Martin Philbert, University of Michigan, will be both vetting reports and making presentations at this meeting; the Executive Committee should examine the list of member activities so that responsibilities are better distributed at future meetings. Ms. Kowalski indicated that there were a few requests to participate in the meeting by telephone; therefore, the telephone line will remain open during the meeting. The line will not be open, however, during the site visit. She asked those participating by phone to mute their lines except when speaking, and she reminded participants to sign in at the registration desk if they had not done so already.

AA/ORD Remarks

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

Dr. Teichman stated that there has been a great deal of activity with respect to both of his current positions at EPA. Administrator Lisa Jackson has made it clear that science will be the backbone of her leadership at EPA, and those involved in science in the Agency have been pleased to hear that. The Administrator is not speaking only of the research conducted within ORD, but also the science within the rest of the Agency as well. There are roughly 18,000 EPA employees, of which about 6,000 are classified as scientists. ORD contains only one-fifth of the scientists within the Agency. The Administrator's emphasis on science will include the entire Agency, and will affect how EPA uses scientific results in its policy making. To that end, the Administrator will be testifying on scientific integrity before the Senate Environment and Public Works Committee on June 9, 2009. Dr. Teichman disseminated a memo to the BOSC that was sent to all EPA employees on May 9, 2009, regarding Administrator Jackson's intentions on this topic; he wrote the draft testimony based on this scientific integrity memorandum entitled "Scientific Integrity, Our Compass for Environmental Protection." It is accompanied by a memorandum from the President to the Office of Science and Technology Policy (OSTP) charging that Presidential level recommendations should be developed on how to maximize scientific integrity across all federal agencies.

Dr. Teichman is serving as the EPA representative to the OSTP workgroup that has been formed to address this charge. He has attempted to carry the message of EPA's dedication to openness and transparency as well as scientific integrity to the maximum extent possible. He noted that scientific integrity also relates to how members are chosen to serve on advisory groups, such as the BOSC. Because advisory group members are selected by political appointees, the workgroup wanted to ensure that there will be no political influence on the independence of the scientific review of such panels. Another important issue being discussed by the workgroup is how to ensure that scientists' results are not changed to meet specific policy goals. This includes exerting influence on the research or re-writing of the results in a biased manner. Dr. Teichman stated that once a policy on this issue is developed, it would be in effect throughout the Federal Government. The President asked for recommendations from Dr. John Holdren, White House Science Advisor, within 120 days of the request. The recommendations from the OSTP workgroup are being reviewed now within the Executive Office of the President and subsequently will be disseminated for inter-agency review.

The EPA Administrator also has expressed a strong commitment to openness and transparency in all of EPA's work, not just the Agency's science, and two old processes have been revised to this end. One is the Integrated Risk Information System (IRIS) Process. Dr. Teichman disseminated a May 21, 2009, memorandum that discussed the new process for IRIS health assessments.

Dr. Teichman said he will testify before the House Science Oversight Subcommittee on June 11, 2009, regarding the new IRIS process. He explained that the process has been streamlined, as evident in the diagram in the memo, to attempt to conduct more IRIS assessments than have been done in the past. In this new process, there will be only 23 months from the time a chemical is identified for study and the conclusion of the process. There may be some exceptional cases where a chemical for which there is much scientific controversy takes longer or if there is a need to turn to the Science Advisory Board (SAB) or the National Academies. As part of the new IRIS process, in the interest of transparency, all the written comments from other federal agencies to EPA will be made public. Dr. Teichman noted that this has not been done in the past. This will be useful to peer review panels and to interagency science discussions. The public will be able to comment on the input from other federal agencies, and also see the various inputs into the Agency's decision-making process.

ORD also has revised the process for the National Ambient Air Quality Standards (NAAQS). The recent change from voluminous air quality criteria documents to smaller integrated scientific assessments is

maintained; the goal of having a public meeting at the beginning of the process also has been maintained. The requirement for the Advance Notice for Proposed Rulemaking instituted in the last administration, however, has been removed and replaced with a policy assessment generated by the policy staff in the Office of Air and Radiation (OAR), which will contain recommendations for the Administrator's consideration. This paper will be available for review by the Clean Air Scientific Advisory Committee (CASAC) and the public. Dr. Teichman noted that all of this work has been completed in the Administrator's first 120 days at the Agency.

Dr. Teichman stated that the new Administrator is very intelligent, direct, and committed. He hopes that the political appointee positions throughout EPA will be filled quickly. Robert Perciasepe has been nominated by President Obama to serve as EPA Deputy Administrator. Mr. Perciasepe previously served as Assistant Administrator for Water and then the Assistant Administrator for Air. Positions have been filled in the Office of Air and Radiation (OAR), the Office of Prevention, Pesticides and Toxic Substances (OPPTS), the Office of Solid Waste and Emergency Response (OSWER), and the Office of International Activities. Dr. Paul Anastas is at the stage of "intent to nominate" as the Assistant Administrator for Research and Development. Dr. Anastas is Director of the Yale Center for Green Chemistry and Green Engineering. He served in OSTP in the Executive Office of the President from 1999-2004, most recently as the Assistant Director for Environment. In 1989, he joined EPA's OPPTS where he served as Chief of the Industrial Chemistry Branch. He is considered the "Father of Green Chemistry," a field of scientific innovation designed to meet environmental and economic goals.

EPA recently was voted the sixth best place to work in the Federal Government, up from ninth in 2008. Dr. Teichman has been asked to serve as one of the six task group leaders for the Agency for Toxic Substances and Disease Registry's National Conversation on Public Health and Chemical Exposures; he also has been in discussions with Vietnamese officials about how to reduce dioxin concentration at the Danang Airport.

Dr. Paustenbach commented that the recent changes in the IRIS process appear to be correcting some of the poorly supported decisions that were made in 2008. Dr. Teichman responded that these recent changes were made to create a more streamlined process that would allow for more IRIS assessments to be conducted more quickly. Dr. Paustenbach asked if the complicated flow chart of the IRIS process that was generated in 2008 was obstructive. Dr. Teichman commented that the diagram was not necessarily complicated just because it contained many steps. The issue was that accomplishing the steps in the flow chart would mean that it would take approximately 4.5 years to complete an IRIS assessment. The time needed to complete the steps in the 2009 process is 23 months; reducing the time required to complete an assessment was the Administrator's main motivation for the change. Dr. Paustenbach mentioned that he liked the steps in the 2008 process, but he thought the diagram was complicated. He thinks the 2008 approach was superior to the current streamlined approach; he noted that it may take 3 to 4 years to review some of these chemicals. Dr. Paustenbach also expressed concern about who is allowed to participate in the comment and review process for IRIS assessments. The press coverage made it appear that there was going to be greater constraint on those who could participate in the comment and review process; specifically, it prohibited the participation of anyone from the private sector. Dr. Teichman responded that he did not believe that participation requirements had changed in the new process. There still is a listening session before the peer review meeting, which allows for extensive presentations and is open to the public; this has not changed, and it allows all groups an opportunity to provide their thoughts on a given assessment.

Dr. Teichman noted that he would speak about the Presidential Budget on Day 2 of the meeting. He brought the slides he presented to the SAB on ORD's National Program Directors' strategic research directions and information on the 2010 budget. Dr. Philbert asked whether Dr. Teichman would address the lack of appropriation of stimulus money for ORD. Dr. Teichman replied that he would describe where the stimulus money that EPA received is going.

ORD Response to BOSC Report: National Homeland Security Research Center (NHSRC) *Dr. Gregory Sayles, Associate Director, EPA NHSRC*

Dr. Sayles led the preparation for the BOSC review as well as the development of the response to the BOSC's review of NHSRC. He mentioned that his colleague, Dr. Hiba Ernst, was on the telephone with him to help answer the BOSC's more detailed questions. Dr. Sayles informed the BOSC that the meeting binder contained ORD's detailed narrative response to the NHSRC review. He explained that he would be presenting an overview of that detailed response. He thanked the Homeland Security Subcommittee for its work and engagement with the Program. The process went smoothly and the review was completed in a timely manner. He also thanked Mr. Greg Susanke, the DFO for the Subcommittee, who worked diligently on this review.

The Homeland Security Research Program received positive feedback from the BOSC on all aspects of the Program: relevance, structure, quality, scientific leadership, coordination and communications, and performance and efficiency. The BOSC report offered 23 specific recommendations for the Program, and rated the Program overall, plus Long-Term Goals 1 and 2 (LTG 1 and LTG 2) as meeting expectations. A few additional recommendations were made in the body of the report.

ORD's response to the BOSC report addresses each recommendation, and lists the actions that ORD plans to take in response, as well as the timeline for implementing these actions. The response also contains a summary table of these actions, which serves as the source for Dr. Sayles' presentation. The recommendations and responses are as follows:

- ♦ General Recommendation 1: Expand support of extramural research including STAR and increase collaboration with other organizations.
 - **ORD Response:** In the short term, the Program must focus on urgent research that is difficult to conduct through the STAR Program, but the Homeland Security Research Program would benefit from longer-term extramural research; active collaboration with other agencies could be expanded.
- ♦ General Recommendation 2: NHSRC should explore the use of an acquisition life cycle model for individual research Program elements.
 - **ORD Response:** The Program agrees, and acquisition life cycle models will be investigated for their feasibility in fiscal years (FY) 2010 and 2011.
- ♦ General Recommendation 3: Clarify roles and responsibilities of the Homeland Security Research NPD.
 - **ORD Response:** The Program will continue to pursue relevant responsibilities of Program planning; Multi-Year Plan (MYP) writing; and intra-Program, cross-ORD, and inter-federal coordination.
- ♦ General Recommendation 4: Additional research in behavioral sciences should be considered. ORD Response: The Program is expanding its efforts in this area by indentifying, with client input, a relevant research niche and initiating work.
- ♦ General Recommendation 5A: Establish a program to develop and periodically evaluate the priorities for evaluating research goals.
 - **ORD Response:** The Program will follow the BOSC's ongoing work on using decision analysis tools for prioritization, and may wish to help pilot these; in the interim, the Program will continue to prioritize its research based on the input from clients, threat analysis, and other existing mechanisms, and will seek improvements.

- ♦ General Recommendation 5B: Establish a program for determining product delivery within research programs.
 - **ORD Response:** The Program is making efforts to improve the efficiency of product delivery to clients so that they are increasingly used to improve the clients' capabilities.
- ❖ General Recommendation 5C: Implement a mechanism to gauge the degree to which these priorities are heard and addressed.
 - **ORD Response:** The Program actively pursues feedback from customers on the responsiveness of products; the feedback mechanisms are evolving as refined approaches are developed.
- ♦ General Recommendation 6: Develop a "clearinghouse" of technical information produced by the Program.
 - **ORD Response:** Program products are available in several locations, some for specific end users (e.g., the WaterISAC, and OEM's decontamination portal), and some for the public, including EPA's Science Inventory, and the Program will continue to ensure that products are represented in the existing "clearinghouses."
- ♦ General Recommendation 7: Take a more integrative, systems-oriented approach when evaluating key research objectives.
 - **ORD Response:** The Program is designed and planned using a systems-oriented, "event chronology" approach, and will continue this, but Program managers are open to other systems-oriented ideas.
- ❖ General Recommendation 8: Provide greater explanation in the MYP for the current priorities and how these may change.
 - **ORD Response:** More definitive statements on strategic directions and their likely evolution have been added to the draft MYP.

Dr. Sayler noted that when the Subcommittee discussed Recommendation 6, the members were focusing on the electronic nature of the clearinghouse, and asked if there was a specific plan for comprehensive incorporation of a digital approach (versus print materials) for information processing and sharing. Dr. Sayles responded that ORD interpreted the recommendation to mean that the Subcommittee was interested in having the Program's work searchable and easily accessible, which is the intent of EPA's Science Inventory; however, if another mechanism is necessary, ORD is open to ideas. Dr. Sayler responded that this issue may be revisited during the next review. Dr. Charles Haas, Drexel University, added that ORD relies on WaterISAC as a means of dissemination of information, but clients are not always obvious nor directly known, and they may need to have more detail about the work that is being conducted. Dr. Sayles responded that the information on WaterISAC is not available to the public because it is sensitive material; in general, the Program's products are publicly available through the NHSRC Web site and the Science Inventory. Only a small fraction of the Program's products are exclusively available on WaterISAC.

Dr. Sayles explained that LTG 1 is focused on water security; LTG 1-directed recommendations and responses are as follows:

- ♦ LTG 1 Recommendation 1: Conduct sensitivity analyses on TEVA tools (modeling tools for distribution systems) to determine variance in decisions.
 - **ORD Response:** Sensitivity analyses have been conducted in the past and will continue as needed.
- - **ORD Response:** Direct requests from Program clients require the Program to conduct additional work on the BVA Tool, but this tool is close to maturity, and the tool development life cycle will be examined following the current development efforts.

- ♦ LTG 1 Recommendation 3: Clearer milestones and a more timely release of results for Provisional Action Levels (PALs) are needed.
 - **ORD Response:** PALs are developed as rapidly as funding allows using a prioritized list of chemicals. NHSRC is evaluating mechanisms by which PALs can be released to the user community without releasing sensitive information.
- ♦ LTG 1 Recommendation 4: Examine the CARVER methodology to improve Risk Assessment Methodology for Water Utilities (RAM-W).
 - **ORD Response:** The Office of Water (OW) has responsibility for this activity, and the Program will support OW as needed.
- ♦ LTG 1 Recommendation 5: A comprehensive model verification process should be established to evaluate the predictive capabilities of the advanced TEVA model.
 - **ORD Response:** TEVA modules are tested extensively and their manuals include examples; the Program will continue existing software testing and documentation efforts.
- ♦ LTG 1 Recommendation 6: Effort should be placed on assessment methodologies following detection to decrease the time for public notification.
 - **ORD Response:** Existing and developing TEVA tools will help utilities to interpret signals of detection (CANARY), develop real-time containment and mitigation strategies, and making informed decisions. The Program will continue to develop TEVA tools.
- ❖ LTG 1 Recommendation 7: A cost-benefit analysis methodology, along with a database as a decision-making support tool, should be developed to assist water systems in cleanup prioritization. ORD Response: The proposed approaches are risk management decision tools that are the responsibility of OW, and OW has not requested technical support from ORD in these areas. The Program does not have a role until OW asks for help, but the Program will continue to actively plan decontamination research with OW.
- Dr. Sayler noted that the narrative provided in response to the report does an excellent job of breaking these issues down, and the response is more than adequate on the LTG 1 recommendations.
- Dr. Sayles explained that LTG 2 deals with the Program's responsibilities regarding cleanup of buildings and outdoor areas.
- ♦ LTG 2 Recommendation 1: Accelerate release of products to meet the needs of the clients, recognizing that at times 50 percent solutions with implementation are better than no implementation with 100 percent solution.
 - **ORD Response:** The Program has provided draft products to the end-users and used their feedback to improve on the products, and will continue to communicate urgent research results to clients as they are developed while maintaining high quality standards for the research and the resulting products.
- ❖ LTG 2 Recommendation 2: Customer support surveys should be broadened to include On-Scene Coordinators (OSCs), National Decontamination Teams (NDTs), and other state and local responders. ORD Response: The survey presented included OSCs and NDTs as participants; the most relevant feedback would come from EPA clients including EPA response personnel rather than state and local responders. The Program will improve survey activities to gauge the utility of the Program to EPA clients.

- ♦ LTG 2 Recommendation 3: Identify and test field-ready technology to provide information to the end users.
 - **ORD Response:** The Program created the Technology Testing and Evaluation Program (TTEP) to test technologies according to their vendor specifications. Priority technologies to be tested are selected by stakeholder groups in both LTGs. This recommendation has been met.
- ♦ LTG 2 Recommendation 4: Threat assessment evaluation similar to that employed in LTG 1 should be used for LTG 2 work.
 - **ORD Response:** The Program conducted a threat assessment for buildings early in its tenure, but the Department of Homeland Security (DHS) now has responsibility for these assessments. The Program will continue to coordinate with DHS to receive up-to-date threat assessments and use this information to plan and prioritize the research program.
- ❖ LTG 2 Recommendation 5: Efforts should be focused on evaluating existing commercially available detection systems rather than on the development of new sensors and analytical equipment.
 ORD Response: The Program rarely invests in technology development and supports a program to conduct performance testing of commercially available technologies, the TTEP.
- - **ORD Response:** The Program agrees that exposure guidelines that account for multiple exposure routes and cumulative risk should be investigated; the Program actively partners with CDC on a number of technical issues, including MRA.
- ♦ LTG 2 Recommendation 7: Additional research in technical mitigation and remediation is needed, especially relating to environmental setting and media.

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 - **ORD Response:** The Program is increasing its efforts in mitigation and remediation and recognizes the importance of research in bio-reaerosolization.
- ♦ LTG 2 Recommendation 8: Examine and report on the environmental settings and media that are likely to be impacted by various threat scenarios and the basic research needed to address fate, residence, persistence, and alternative disinfection and decontamination practices.
 - **ORD Response:** The Program will work with the BOSC to better understand and respond to this recommendation during FY09 and FY10.

Dr. Sayles noted that the Program will continue to implement the BOSC's recommendations, finalize the MYP in the next month, and begin a discussion on the future BOSC review.

Dr. Sayler acknowledged that some of the recommendations may have been ambiguous; some of their context was lost over time since the review was conducted. In several cases, the recommendations do not appear to express what was intended; perhaps some conversations about these recommendations outside of the meeting would be helpful. Dr. Sayler stressed the importance of clear recommendations in future BOSC reports.

Dr. Sayles indicated that only a few of the recommendations were unclear. Dr. Sayler asked if the way the recommendations were presented in the report made it easy for Program staff to identify them. Does the Program have any suggestions for a better way to present the recommendations? Dr. Sayles noted that some recommendations were included in the front of the report and others were just in bold font within the narrative of the report. He thought it might be helpful for the BOSC to explain the criteria used in selecting the recommendations that were included in the front of the report. Also, it is unclear why some of the recommendations in the front of the report are worded differently from those in the body of the report.

Dr. Sayler responded that those recommendations moved to the front were considered the more important recommendations. He explained that the language was changed because some recommendations covered the same themes and they were combined and summarized in the list at the front of the report. Dr. Sayles also suggested that recommendations for which an ORD response is not expected should be designated in some way. Dr. Sayler agreed.

Subcommittee Draft Reports: (1) Human Health Program Review Draft Report Presentation

Dr. James Klaunig, BOSC Human Health Subcommittee Chair Vettors: Dr. Martin Philbert and Dr. Carol Weiss, Executive Committee

Dr. Klaunig explained that only four of his nine slides had been transmitted to the BOSC; therefore, he would attempt to summarize what was on the missing slides and send a revised presentation at a later date. Dr. Sayler mentioned that the BOSC members did receive a copy of the report on which the slides were based.

Dr. Klaunig explained that the members of the Human Health Subcommittee were very experienced and hard-working, and they did an excellent job on the review. Virginia Houk, DFO for the Subcommittee, also did an excellent job helping the group to stay organized and produce the report. The Subcommittee conducted the review during four public conference calls and one face-to-face meeting, which was held January 13-15, 2009. The report was finalized during the April 21, 2009, conference call.

The Human Health Research Program (HHRP) has four LTGs:

- ♦ LTG 1: Use of Mechanistic Data in Risk Assessment
- ♦ LTG 2: Cumulative Risk Assessment
- ♦ LTG 3: Susceptible and Vulnerable Populations
- ♦ LTG 4: Developing Tools to Evaluate Risk Management Decisions

The Subcommittee used the following format recommended by the Executive Committee to conduct its review of the HHRP: program relevance; program structure; program quality; coordination and communication; program performance; scientific leadership; summary assessment; and recommendations. This format was used in for each of the four LTGs.

The Subcommittee agreed that the HHRP had matured significantly since the last review and was much more integrated, robust, and responsive to emerging issues. The Subcommittee found the science to be excellent, and the leadership did a commendable job in taking the recommendations from the previous report and organizing the Program. Dr. Klaunig noted that, when assigned the rating, the Subcommittee struggled over the qualifiers for "meets expectations" versus "exceeds expectations."

In terms of summary assessments, LTG 1 is devoted to mode of action (MOA) and quantitative risk assessment. The Subcommittee advised that it is important to demonstrate the value and impact that basic studies of MOA have on EPA's quantitative risk assessments. LTG 1 received a rating of meets expectations. The Subcommittee members thought the Program was performing well.

LTG 2 received a rating of meets expectations. The research program for this LTG remains true to its major research goals, which are cumulative risk assessment and susceptible populations. The planning, organization and research were conducted in a very logical manner; this LTG in particular could benefit, however, from cross-planning with the other LTGs, which was a recommendation of the Subcommittee.

LTG 3 also received a rating of meets expectations. For LTG 3, there was good communication and coordination with other LTGs and EPA programs. The scientific quality was excellent, and in many cases,

there was high productivity due to strong leadership. The reason it did not receive a rating of exceeds expectations is that the programmatic structure was too limited to childhood health instead of examining all life stages, especially the elderly. The Subcommittee noted that the childhood portion also could be expanded.

Before offering any comments, Dr. George Lambert, Robert Wood Johnson Medical School, disclosed that he works at the Center for Childhood Neurotoxicology and Exposure Assessment, which receives EPA funding. When the DFO indicated that he could make a comment, Dr. Lambert read a phrase from the draft report: "programmatic structure was assessed as over-weighting childhood health within its life-stage construct of vulnerability," and stated that he agrees that epigenetics, genetics, disease state, and a full range of age should be covered. He suggested that it might be better to state that the Program is "under-weighting" these other areas rather than state that it is over-weighting childhood health, given that EPA's work on children's health is on the decline.

Dr. Klaunig, who was participating via telephone and was having difficulty hearing because of a bad connection on his cellular phone, asked Dr. Henry Falk to continue this presentation.

Dr. Falk readily agreed that research areas other than childhood health were under emphasized; he confirmed that the Subcommittee was not suggesting that work on children should be decreased. Dr. Lambert thought the wording in the report should be changed so that this would not be misinterpreted by the Agency, and result in a reduction in children's studies. Dr. Sayler asked Dr. Falk to make a note of this revision to the text.

Dr. Falk stated that LTG 4 received a rating of exceeds expectations; the Subcommittee was pleased that various measures of long-term health impacts were being evaluated. Also, the Subcommittee viewed the Report on the Environment very positively, and wanted to see it more broadly distributed and utilized within the Agency.

Dr. Sayler asked if the Subcommittee considered investment efficiency as part of the performance review. Dr. Falk responded that he did not see it treated prominently in the summary. Dr. Sayler stated that "efficiency" falls under the charge question in terms of performance, but it may not have appeared as an issue strong enough to address. Dr. Falk explained that the Subcommittee was very positive about the general trends and the quality of the science, but had a number of specific and programmatically relevant questions, such as the balance between the life stages, linkage with other agencies doing work on human health, and how to incorporate epidemiological and statistical data.

Dr. Sayler explained that because Dr. Weiss had resigned from the Board, Dr. Philbert would be the only vettor for this report. Dr. Philbert said he would send his comments electronically to Drs. Klaunig and Falk following the meeting.

Dr. Philbert did not see an explicit description of how expectations were exceeded for LTG 4. Dr. Falk responded that the Subcommittee members commented on this when reviewing the previous draft of the report. There was an attempt to add some additional information after the last conference call, but it may have fallen short. He thought the Subcommittee members were impressed by the trajectory of the work for LTG 4. Dr. Philbert responded that the report needs to reflect this more clearly.

Dr. Philbert stated that there is a large number of recommendations in each section of the report; did the Subcommittee prioritize these recommendations? Dr. Falk responded that the recommendations were not listed in order of priority; some are programmatic and some are related to the review process. Dr. Philbert recommended that separating these recommendations would make the report easier to read and easier for ORD to grasp what the Subcommittee views as urgent.

Dr. Philbert mentioned that there are several recommendations about the Program's workforce—notably under-staffing in the area of biostatistics and epidemiology—without any detail on how new staff might

be used. Dr. Falk responded that some members wanted to improve the quality and availability of epidemiologic data. Dr. Philbert noted that it was unclear whether the Subcommittee was advocating for keeping the workforce at the same size with a greater percentage of biostatisticians and epidemiologists, or expanding the staff. Dr. Falk responded that the recommendation is to increase that expertise within the Program; the Subcommittee did not offer any opinion regarding how this should be accomplished.

Dr. Philbert asked if the Subcommittee had any suggestions for alternative presentation of the bibliometric data that would have aided the review. Dr. Falk replied that the intramural and the extramural analyses should be separated so that the members could assess the efforts of researchers at the Agency versus outside researchers; the bibliometric data also could be formulated differently so that it could be better utilized. Dr. Philbert responded that the report should explain this more clearly.

Dr. Paustenbach noted that, of the approximately 50 times chemicals have been modeled, the results have only affected rulemaking a few times. Dr. Falk responded that there are a number of places in the report where the potential uses of the models was noted. Dr. Sayler asked Dr. Paustenbach to point out the section in the report to which he was referring so that specific revisions to the document could be recommended. Dr. Falk directed the BOSC members to page 15, where there is a statement asking for a specific example of a risk assessment with results that have changed because of this work. Dr. Paustenbach commented that it would be beneficial for the Program to develop a list of seven chemicals to be addressed, along with a timeline and proposal for these data to impact the way chemicals are regulated. There are many papers published, but this may not have changed any decision-making for regulations.

Dr. Teichman stated that EPA is an applied research agency, and as such, its research should influence policy making. The IRIS assessments have drawn on physiologically-based pharmacokinetic (PBPK) modeling and tried to identify MOA data when available and inform the toxicity assessments. The extent to which this gets combined with exposure and influences policy decisions is out of ORD's control, but he hopes the Agency would look at chemicals that pose the highest risk rather than focus on the academic questions that would not play into policy. Specific examples of how improved MOA data or PBPK modeling inform a toxicity assessment, risk assessment, and eventual policy would be available, as ORD is working on certain pollutant classes because they have regulatory relevance.

Dr. Sally Darney, NPD for the HHRP, said that there were some examples of this in the posters, but they could have been pulled out for the Subcommittee. She noted that it is important to show the lifecycle of a project from conception to outcome. The HHRP can do this in its response to the report in tabular form, identifying where the research was used in the risk assessment or a model was used to assist with community-based risk assessments. There are specific examples of this with cumulative risk; ORD's research was used by OPPTS' science advisory panels. Additionally, in community risk assessment, LTG 3 and LTG 4 address where better indicators of public health are needed. It might be useful for ORD to keep a central record of impacts on decision-making because multiple programs sometimes contribute to a decision.

Dr. Sayler suggested that the report needs a general recommendation that addresses this issue. He asked Dr. Paustenbach to draft and send him an appropriate general recommendation to include in the report. Dr. Sayler will transmit the draft recommendation to Dr. Klaunig or Dr. Falk for incorporation into the revised report. Dr. Sayler will ask Dr. Teichman to ensure that the recommendation is factually accurate. Dr. Teichman agreed, stating that ORD would respond to any recommendation added to the report with specific examples. He mentioned that the computational toxicology effort will provide more and different ways to inform risk assessment decisions.

Dr. Philbert noted that on page 15, concerning LTG 1 and mechanistic data, there is a statement about taking an advocacy role. He asked that this statement be explained further in the revised report.

Dr. Sayler suggested that the Executive Committee postpone voting on this report because the presentation was incomplete and the Subcommittee Chair lost his telephone connection and did not hear all of the comments. Dr. Sayler proposed that revisions and requests for further information be sent to Dr. Klaunig. The Executive Committee can examine a revised report within the next 30 days and hold a conference call to vote on the report. Given the delay in approving and transmitting the report to ORD, Dr. Sayler commented that ORD's response probably will not be presented at the September meeting.

Subcommittee Draft Reports: (2) Science and Technology for Sustainability Draft Mid-Cycle Report Presentation

Dr. John Giesy, BOSC Science and Technology for Sustainability Subcommittee Chair Vettors: Dr. Martin Philbert and Dr. Barry Ryan, Executive Committee

Referring to the copy of the draft report in the meeting binders, Dr. Giesy pointed out that Appendix C contained a table of the Subcommittee's comments on ORD's responses to the 2007 program review. He identified the Subcommittee members, and stated that they did an excellent job on the review, as did the DFO, Greg Susanke. The review was conducted through a teleconference held on February 12, 2009, and a face-to-face meeting held on March 12, 2009.

Dr. Giesy noted that at that the time of the 2007 program review, the Program was in transition, with new leadership, a new focus, and the changes resulting from the transformation of the Pollution Prevention and New Technologies Research Program to the Science and Technology for Sustainability (STS) Program. During the 2007 program review, the Subcommittee members commented that many industry organizations were having more impact than the Program. The STS Program lacked focus and had to manage a number of disparate programs. It was agreed that the reorganized Program could act as a focal group within EPA, providing metrics and direction on how sustainability can be integrated into all of EPA's work.

There were 39 specific recommendations from the 2007 program review, which the Program summarized into seven strategic recommendations, and explained how they had been addressed. At the time of the review, one LTG had not been implemented yet, so the BOSC did not review that goal.

For the mid-cycle review, the STS Program received a rating of exceeds expectations, because although details of some of its plans remain vague, the Program was very responsive to the 2007 program review and has implemented a number of recommended actions. Charge Question 1 asked the BOSC to evaluate the accomplishments and effectiveness of the funded research. Alan Hecht, Director of the STS Program, drafted a white paper to explain some of the Program plans, and the Subcommittee responded positively to the paper. Additional details on the Program plans were provided in a briefing during the first conference call. The Program has changed significantly in the last few years in response to the BOSC recommendations.

Charge Question 2 concerns the clarity of the rationale for the Program, and the BOSC found that the Program's initiatives and rationales were well articulated in the MYP. The BOSC had advised the Program to focus on a single project designed by the Program itself. Biofuels has been selected for this focus; the Program will use it as a case study because it touches on a number of issues, including how the Program works with other groups across the Agency. The Program still will be developing the tools, models, metrics, and methods to assess whether sustainability is being achieved.

Charge Question 3 asked what additional performance metrics, if any, would be appropriate for the STS Program. The Subcommittee received a bibliometric analysis, which demonstrated that the Program is publishing some high-quality, highly cited papers, indicators of quality research. The bibliometric analysis was of limited use by the Subcommittee, however, because these papers were from the old Pollution Prevention Program (P3) and included many extramural researchers. Therefore, the bibliometric analysis was not a good measure of the new Program. There also was some concern that a

focus on publications places too much emphasis on first authors to the detriment of other team members. The user survey, the results of which were provided orally at the face-to-face meeting, also was not of much use to the Subcommittee. There currently is no coordinated mechanism to collect information on the outcomes and impacts of the Program. Mechanisms are needed that track where students and/or post doctorates who have participated in research projects have gone; lists of industrial partnerships and partnerships with other U.S. and international government agencies are needed. A list of outcomes of case studies also would be useful. A metric should be developed that reflects "technology transfer" from the STS Program, tracking whether the Program's work is being used both within EPA and extramurally, and examining proposals to the P3 and Small Business Innovation Research (SBIR) programs to determine if the proposed metrics are being used more frequently. For instance, one measure of success would be the number of times the STS Program is consulted by other programs. The STS Program should avoid the use of soft metrics like number of publications.

Charge Question 4 concerns how the Program can enhance the impact of its research products within and outside of EPA. The Subcommittee members believed that the Program should take a more organized and aggressive role in transitioning from providing support of regulatory functions to enabling the United States to move to true sustainability; the expertise is available within the STS Program to accomplish this. The Program also should enable cooperation and coordinated technology development via partnerships among industry, community stakeholder groups, universities, and governmental agencies and focus on developing metrics and tools that enable sustainability by focusing on protecting human health and the environment while enhancing economic growth.

Charge Question 5 asks whether the focus on biofuels is appropriate given the need to focus on national environmental priorities, and if so, if the STS Program is able to address it properly. The Subcommittee found that biofuels was a good choice; ORD is well situated to have an impact on U.S. energy policy. Focus on the biofuels issue also makes use of limited resources, which was a theme of the full BOSC program review.

Whether other issues of national importance should be the focus of the Program in the near future is the theme of Charge Question 6. The Subcommittee members did not think that there were alternative focus areas that should be considered, but rather that the STS Program can best have an impact by being positioned as a nexus to bring sustainability issues to all policy debates. Some other issues of national concern the Program should work toward in the future include: energy and climate changes, water sources, distribution and quality, land-use policies and urban sprawl, rendering existing buildings and infrastructure more sustainable, and transportation and sustainability scenarios.

Dr. Barry Ryan, Emory University, noted that the enthusiasm expressed by the Subcommittee did not seem evident in the report. The text did not seem to support the rating that the Program exceeded expectations. Some of the positive statements made in the presentation should be included in the report. He added that the report, though responsive to the charge questions, seemed to go beyond the scope of a mid-cycle review, and he cautioned the Subcommittee against "mission creep." Additionally, he thought the report was vague in some areas, and needed some clarification. Dr. Ryan noted these sections in the electronic version of his comments, which he will send to Dr. Giesy.

Dr. Paustenbach asked if the Executive Committee members liked the table format used in the STS report. Dr. Sayler indicated that this will be discussed when the proposals for report format are reviewed. Dr. Giesy said that he would welcome a standard format for the reports. He had questions about what to include in the executive summary and would prefer that the recommendations be listed only once instead of repeated in the executive summary and text. Dr. Giesy added that he likes the table. He agreed that this report did go beyond a typical mid-cycle report but he believes that the BOSC's goal is to help ORD, and in this case, additional content was added because the Program changed so significantly since the program review.

Dr. Sayler asked that the report be revised to reflect the level of enthusiasm for the STS Program and supported by key elements that led the Subcommittee to rate the report as exceeding expectations. Hearing no objections to the specific recommendations for revisions that had been communicated, Dr. Sayler called for a motion to approve the STS Report. Dr. Ryan moved to approve the report, and Dr. Philbert seconded the motion. The report was unanimously approved by the BOSC. Dr. Giesy will incorporate the revisions, Dr. Ryan will ensure that the changes were made and the report will be transmitted to ORD.

Subcommittee Draft Reports: (3) National Center for Environmental Research (NCER) Standing Subcommittee Draft Letter Report Presentation

Dr. Martin Philbert, University of Michigan, NCER Subcommittee Chair Vettors: Dr. Cliff Duke and Dr. Henry Falk, Executive Committee

Dr. Philbert explained that the charge questions submitted to the Subcommittee were an extension of those considered in the previous letter report. The first question asked how NCER should identify high priority areas for its extramural portfolio. NCER proposed that the BOSC Executive Committee serve as a resource to help NCER identify priority areas for RFAs, and the Subcommittee responded that this was a good idea, but not sufficient. The Subcommittee recommended that NCER consider a deliberately managed and diversified portfolio that integrates research into two broad areas. The first area would be targeted research that continually improved priority setting. This area would examine high priority and high risk research versus low priority but very feasible research in terms of the values of each. The second area is research focused on identifying and addressing emerging challenges. The Subcommittee believes that NCER must engage in a protocol of investment and disinvestment. There is an example in the report illustrating how the strategic approach to research can be presented. The Subcommittee thought that these two components of science policy research and emerging issues research should consume about 10 percent of NCER's resources. The prioritization process should go beyond the BOSC Executive Committee; a matrix is included in the report to demonstrate how research can be prioritized by engaging external stakeholders, including international stakeholders. If an area is considered high priority by only EPA, then it would be considered a niche area that would help the Agency address its policy needs. The extramural research program at EPA ought to be very different from that at the National Institutes of Health, and should be targeted to elucidating and promoting Agency needs, reducing uncertainty, and policy making.

The second charge question concerned the fellowship program. NCER manages the Science To Achieve Results (STAR) Fellowship Program and the Greater Research Opportunities (GRO) Fellowship Program. Dr. Philbert noted that despite its name, the GRO Program does not require students to conduct research.

In 2009, the GRO Program provided \$20K per year in academic support and an additional \$8K to support an internship, which is approximately \$46K per student for a 2-year fellowship. There are 10 to 15 new fellowship awards annually. Dr. Philbert explained that the GRO Program evolved from the Minority Academic Institution Award Program. Under the GRO Program there is reduced emphasis on racial and ethnic considerations in awarding the fellowships; however, at the face-to-face meeting, NCER staff indicated that the Program is trying to reach people in underserved institutions. The Subcommittee noted that substantial amounts of money are being awarded to individuals with little or no program capability to track people once they complete their fellowships. The response rates of former fellows are low, and the mechanisms for reporting back to the Agency are onerous and difficult to use. The Subcommittee believes that NCER is missing an opportunity to use available communication tools to collect such information. The Subcommittee recommended a more imaginative rethinking of the GRO and STAR Programs to allow for maximum impact across a large number of participants. More modern approaches need to be taken to keep track of students during and after completion of their fellowships. One idea proposed by the Subcommittee is to build consortia between research intensive universities and traditionally underserved institutions so that a large number of students would have an opportunity for

internships in research. This moves away from the current approach of funding individual students to an approach of funding institutions, which comes with associated administrative costs. The Subcommittee believes that some balance is needed for minimum indirect cost outlays and maximum benefits for students.

Dr. Duke thought the report was both interesting and useful to NCER. He chaired the previous review of the STAR and GRO Fellowship Programs and that report recommended eliminating the GRO Program entirely and replacing it with the type of consortia mentioned in the letter report presented by Dr. Philbert. In response to the earlier BOSC report, EPA indicated that NCER would consider this recommendation. The stated mission of the GRO Program is to stimulate undergraduate education in environmental fields. Expanding outreach efforts for both the STAR and GRO Fellowship Programs to some of the social networking tools available today is an excellent suggestion, as is exploring the use of focus groups to inform the Program. Dr. Duke acknowledged that the consortia may come with significant administrative costs, but he believes that it is an option still worth exploring. In terms of metrics, some of the comments in the letter report were vague, and would be more useful if they were made more specific. He referred to lines 34 and 35 on page 7, as an example of vague comments. He thought the idea of measuring the number of students who complete an environment-related degree program was straightforward. The letter report notes that there is a problem tracking students' outcomes for the STAR and GRO Fellowship Programs. Dr. Duke noted that problems tracking researchers' outcomes were mentioned in the STS report as well, and may be a broader problem within ORD. He suggested that there should be a crossprogram effort to identify and implement successful methods to follow researchers and track outcomes. In closing, Dr. Duke stated that the notion that NCER needs to internalize its prioritizing process is sound, and should be part of the management process.

Dr. Sayler asked if the graduate portion of the GRO Program has been eliminated. Dr. Philbert confirmed that there is no longer a graduate component, because the graduate students are eligible to compete for STAR fellowships.

Dr. Falk stated that the letter report was very good, and he had no substantive issues with it. He suggested that the report be more explicit in its recommendations. Additionally, he thought the report would be more readable if all of the recommendations on emerging priorities, targeted research, and science policy were consolidated in one place. Similarly, on the second issue, on page 6, the words "generally agreed" with the consolidation of the GRO funding implies some reticence; the report should place more emphasis on the points strongly endorsed by the Subcommittee. Dr. Philbert responded that the first question was viewed as binary by the Subcommittee—they were asked if the Executive Committee would be a good resource for helping with priority setting and the simple answer is yes. The additional comments are suggestions for consideration by NCER, as much is unknown about the resources. In subsequent reviews, a more in-depth charge question would be useful. Similarly, some Subcommittee members were disturbed that the graduate component of the GRO Program already had been sunset by the time of the review. The report includes a number of suggestions that the Subcommittee believes will be helpful to NCER, but Dr. Philbert was somewhat reluctant to pull out specific recommendations without participating in another conversation with NCER.

Dr. Sayler confirmed that, at this point, Dr. Philbert's Subcommittee did not have strong enough conclusions from the review of the charge questions to make general recommendations. He pointed out that a letter report does not require a response from ORD, but clarification might be useful. Dr. Philbert responded that recommendations could be pulled out of the report, but the counsel that he was given regarding the previous report was to provide suggestions rather than recommendations so that the Agency would not be required to respond. Ms. Kowalski explained that it is not an EPA requirement to respond to every BOSC recommendation, but it is a best practice within ORD to provide a response to every recommendation from the BOSC whether that recommendation is in a letter or report. Therefore, it is important for ORD to be able to distinguish recommendations from comments and suggestions.

Dr. Teichman agreed that there is a difference between a recommendation and suggestion but he expected ORD to respond to a letter from the BOSC.

Dr. Paustenbach asked if there is a need to encourage more students to enter the environmental sciences, and if it is within the Executive Committee's purview to recommend moving resources from undergraduate to graduate education. Dr. Sayler noted that the first question is not within the Executive Committee's purview, but the second is open for discussion. This report, however, should not address that issue because it was not discussed and analyzed by the Subcommittee, nor did the Agency pose the question. Dr. Philbert said the Subcommittee did discuss the need for an assessment in collaboration with The American Association for the Advancement of Science (AAAS). Dr. Paustenbach suggested that the report include a recommendation for this assessment because it was discussed by the Subcommittee. Dr. Philbert responded that while the social networking tools are important, many times they are out of the control of the Agency. It may be that the Agency builds its own networking site; that is part of the reason why these suggestions are vague. Dr. Haas added that there are other government agencies that have substantial fellowship programs that may be doing a better job of long-term tracking than EPA. Dr. Philbert commented that these other federal programs may be more successful at tracking because institutions rather than individuals are funded and have the institutions have the responsibility of tracking and reporting the results.

Dr. Sayler proposed, because the suggested revisions were minor, that a motion be entertained to approve the NCER letter report with modifications as provided to Dr. Philbert. Dr. Duke made a motion to approve the report, and Dr. Paustenbach seconded the motion. The letter report with revisions was approved unanimously.

Dr. Sayler noted that the Subcommittees should really be called committees, and the reports will be sent to ORD as approved by the Executive Committee of the BOSC. The terminology will be changed in future reports.

Dr. Philbert confirmed that there would be two recommendations in the letter report—one for a needs assessment of the undergraduate and graduate pipelines, and the other for lessons learned; the rest of the comments will remain suggestions.

Site Visit: NHEERL Mid-Continent Ecology Division

Dr. Carl Richards, EPA, Director, MED, NHEERL

Dr. Richards welcomed the group, and explained that the division has two physical locations—Duluth, Minnesota, and a field station in Grosse Ile, Michigan. The Division's mission is to provide leadership in ecotoxicology and freshwater ecology. Because of the location, freshwater is a central focus of the Division's research.

The Division has approximately 86 federal staff members, 33 of which are at the Ph.D. level. Additionally, MED has 12 student contract staff, 34 onsite contract staff, 16 offsite contract staff, and 16 Senior Environmental Employment Program staff. The Division is divided into six branches, but the Division's MYPs and research transcends these branches; the branch divisions are used to implement personnel and budget decisions.

The Division's core strengths are: extrapolative mechanistic criteria, toxic chemical extrapolative modeling, ecosystem analysis/assessment, and large-scale ecosystem modeling. In each of these areas, there are senior scientists, support staff, and the supplies and facilities needed to conduct research activities. All of these areas represent new and emerging science. The Division's strengths play out in the descriptions of the research in five of ORD's MYPs: Ecosystem Services, Water Quality, Land (including nanomaterials), Safe Pesticides/Safe Products (SP2), and Endocrine Disrupting Chemicals (EDC). The Division's role in support of each of these MYPs is described below:

- ♦ Ecosystem Services MYP: The Ecosystem Services Research Program is one of ORD's newest MYPs, and has created many changes for MED. The Division's work in the Environmental Monitoring and Assessment Program (EMAP) of the Great Rivers Ecosystems area involved developing sampling designs and indicators for large rivers using the Missouri, Upper Mississippi, and Ohio Rivers. The Ecosystem Services Research Program is evolving into several components. The Great Lakes nearshore and coastal wetlands is helping the national coastal survey parts of the new Ecosystem Services Program to understand how ecosystem services can be mapped in coastal regions. Regional EMAP (REMAP) is assessment design and indicator research oriented at statelevel needs, which is morphing into an ecoservices concept. The Division's greatest interaction with the Ecosystem Services Program is understanding and modeling services as they apply to surface waters. The Grosse Ile group has a history of doing large, spatially explicit mass balance modeling. The Division is exploring how these models can be extended into new areas. The Great Rivers group is becoming more involved in landscape and watershed assessment. MED also is completing some work with forecasting Great Lakes invasive species effects on ecosystem services
- Water Quality MYP: The Water Quality Research Program employs approximately 20 staff members. The Division has two types of research in this area: the historical connections the laboratory has had in assisting the Office of Water (OW) in the development of aquatic life criteria, and examining watersheds, rivers, and coastal areas. The Division has a program examining the development of nutrient criteria along the biological condition gradient defined over a large spatialscale in coastal wetlands. The Agency is conducting a National Coastal Assessment for the Great Lakes, and the Division is developing the methodology for this study. The Division is working on the Gulf of Mexico Hypoxia Forecasting with a number of partners; MED's contribution involves a spatial modeling group's development of a model for the reduction of nitrogen by percentage. Other projects involve a more toxics-oriented approach. MED is continuing to work with some aspects of Toxicity Identification Evaluation (TIE), identifying chemical associated with toxicity in sediments. Additionally, MED is conducting research support for revision of national aquatic life criteria, including studying multiple routes of exposure (respiratory versus dietary exposure), developing dosimetry models for concentration/time variability, using advanced oxidation processes (AOPs) to assist in the development of criteria for approaching chemicals of emerging concern, and developing approaches for chemicals of emerging concern.
- ❖ Land MYP: The Contaminated Sites Research Program is a small program at the Division that focuses mainly on two projects. The first involves linking residues to effects in aquatic and aquatic-dependent wildlife with a focus on bioaccumulative chemicals and dose effects. The Division has developed the PCBres dataset for this project. The second involves linking chemical concentrations in water and sediment with residues in aquatic and aquatic-dependent wildlife (linking exposure to tissue residue) using biota-sediment accumulation factor models. In addition, MED is involved in the evaluation of testing procedures for the effects of nanomaterials on aquatic life.
- ♦ SP2 MYP: SP2 is a relatively large part of MED's program, employing approximately 22 full-time staff equivalents (FTEs). MED's research in this area includes: developing toxicity pathway-based quantitative structure activity relationships (QSARs) for prioritization within large chemical lists; simulating metabolism to enhance effects modeling (METAPATH); conducting ongoing efforts on the ECOTOX knowledgebase; developing physiologically-based toxicokinetic (PBTK) models for compounds that undergo metabolic biotransformation; developing short-term test endpoints to predict multi-generational effects for aquatic species; conducting linkage of exposure and effects using genomics, proteomics, and metabonomics in small fish models; taking a systems approach to characterizing and predicting thyroid toxicity using an amphibian model; and developing avian population models for risk assessment.
- ♦ EDCs MYP: The EDCs Research Program involves approximately 9 FTEs,. Research highlights include: development of a short-term fathead minnow assay for estrogenic/androgenic disruption;

development of a short-term African clawed frog assay for thyroid activity; development of amphibian-based reproductive and developmental toxicity tests for EDCs (part of U.S.-Japan bilateral agreement), and determination of the effects of confined animal feeding operation (CAFO) pharmaceuticals as EDCs.

Dr. Richards noted that the work he described was possible because MED has a staff of nationally and internationally renowned scientists.

Dr. Sayler asked if MED was involved in the development of the Report on the Environment (ROE). Dr. Richards responded that MED's EMAP efforts were included in the ROE.

Dr. Philbert asked what was meant in this context by multimedia. Dr. Richards responded that the models include inputs from atmospheric deposition, land, or a lake including elements of the hydrosphere and sediments. Dr. Philbert asked if MED was factoring colloidal sediments into its nanotechnology work. Dr. Richards responded that MED is trying to keep nanoparticles in suspension in the laboratory, because conducting tests is a challenge in working with these unique materials.

Dr. Sayler asked if, in addition to computational toxicology, MED has a significant bioinformatics component. Dr. Richards answered that MED does not have a bioinformatics expert on staff, but MED employees interact with such experts in other parts of ORD. He acknowledged that there is a learning process underway.

Dr. Haas asked how ORD's new integrated multidisciplinary (IMD) vision has affected MED. Dr. Richards responded that IMD is part of all of MED's discussions. He noted that IMD still is in the process of being fully defined at MED. There are few changes yet. Dr. Teichman commented that the ecology staff at ORD is ahead of the human health staff in this area. Dr. Janet Keough said that IMD has been MED's mode of operation for some time (in terms of dealing with outside partners) and it is exciting that the whole organization is embracing the idea.

Dr. Lambert asked if MED was conducting epigenetic research with fish. Dr. Richards responded that MED had developed multigenerational tests. Dr. Lambert asked if MED worked with Canada on any research. Dr. Richards noted that MED is involved as an official member of the Upper Great Lakes Lakes Study of the International Joint Commission and some other binational programs. EMAP and the Great Lakes Assessment help coordinate the federal and provincial entities. The stakeholders are involved in this research in the Great Lakes area; MED interacts with Region 5.

Dr. Sayler asked if MED had an early focus on metals. Dr. Richards confirmed that metals were an early focus, but that topic has changed direction and evolved into the study of dietary versus respiratory aspects of metals uptake. He added that metals are no longer a central focus for MED.

The Executive Committee members toured the MED facility for the remainder of the day.

FRIDAY, JUNE 5, 2009

The meeting reconvened on Friday morning and Dr. Sayler called the meeting to order at 8:15 a.m. He then asked Dr. Teichman to provide the ORD update.

ORD Update

Dr. Kevin Teichman, EPA, Deputy AA for Science, ORD

Dr. Teichman distributed two presentations he had presented to the SAB: FY 2010 President's Budget Request for the Office of Research and Development and Strategic Research Directions: 2010-2014. He stated that BOSC members can participate in SAB meetings to learn about the ORD scientists' future plans as well as the President's budget request. The budget was not released in October as occurs in most

years; because of the election, the 2009 budget was not decided until April 2009, and shortly thereafter, a 2010 budget was presented. The budget for 2010 was not yet official at the time of the SAB meeting in April, so Dr. Teichman was unable to share definitive information about it with the SAB. Dr. Teichman explained that his intention is to have an annual meeting with the SAB on strategic research directions for each of the programs and to identify the gaps that should be filled. This SAB meeting would be held in September (outside of the budget cycle) in Research Triangle Park, North Carolina, so the maximum number of EPA scientists can attend.

Referring to the ORD budget trend graph in the strategic directions presentation, Dr. Teichman said it shows the ORD budget trend in nominal dollars and constant 1999 dollars. Although it appears that the research budget has been restored to 1999 levels, over time the buying power has declined considerably. The next diagram shows the ORD budget by type of spending including salary costs (assuming the loss of two people and hiring of one person); if other costs are kept constant, over time the extramural dollars decrease, which means that the organization has a large staff, but not the same amount of extramural resources that it has had in the past. Dr. Teichman wanted the SAB to be aware of these trends, and because the BOSC gives input on strategic directions and how ORD should be evaluated in its performance, he wanted the BOSC to appreciate their significance.

There has been an increase in ORD's budget; however, it is not as large as the increase the Agency has seen overall from stimulus dollars, and EPA has not received as much as other research organizations. Dr. Teichman speculated that this may be because EPA is thought of primarily as a regulatory agency rather than a research organization. The Agency is examining all potential causes and trying to understand the perception of EPA's research program as a science entity to be compared to other science entities in the federal system.

Dr. Philbert asked if there was any way to redress the distribution of American Recovery and Reinvestment Act (ARRA) funds within EPA. Dr. Teichman responded that there are ongoing discussions within EPA and with other federal agencies to get some of these funds devoted to relevant environmental concerns, in which case ORD could provide services to help accomplish the work. Dr. Paustenbach asked if there would be an internal task force to examine why ORD did not receive many research dollars. Dr. Teichman replied that there is not a task force per se, but the ORD Executive Council has been discussing the issue. The IMD approach to research, which involves more stakeholders and outside input, will mean the research will be used by more end users. This will make EPA's research results more available and usable, which may change the perception of EPA as a science agency and lead to an improved budget situation.

Dr. Lambert noted that more than a year ago, the National Research Council (NRC) examined the quality of EPA's science and found it to be of the highest quality, and an excellent return on the monies spent. The SAB held a teleconference a few weeks ago during which it was noted that although Administrator Lisa Jackson has said that science is critical, the science budget is static. SAB members noted the need for increased spending on science, including social science. Dr. Teichman said that he hoped the NRC would find EPA's research to be high quality. ORD has not been very active in the social sciences; there was an environmental and decision sciences component managed by NCER (\$3M) but that was moved to the Office of Policy, Economics, and Innovation. SAB members have said there is much more that can be done in the social sciences research area (economics, decision sciences, and behavioral sciences). EPA should be conducting more work on how its message is received and translated into action at the state, local and personal level. In the second presentation, Dr. Teichman noted that social science is being performed within other research areas.

Dr. Teichman then discussed a one-page paper "Streamlining the BOSC Review Process," which was developed in response to a discussion at the February BOSC meeting about the effectiveness of the BOSC reviews. Dr. Teichman wanted to ensure that the BOSC received all the information it needed to conduct reviews effectively, but was not receiving too much information or items that were not useful. From

ORD's perspective, Dr. Teichman also wanted to ensure that the frequency of reviews is adequate to ensure the quality of the programs without being a burden to the scientists involved in the reviews. The following changes are proposed to streamline the BOSC review process:

- ♦ Materials for BOSC reviews will be posted on the BOSC Web Site rather than sent to members in binders in hardcopy form.
- ♦ ORD will make summary presentations at the BOSC face-to-face meetings to illustrate key aspects of the program under review.
- ♦ ORD will describe how feedback from clients and stakeholders is obtained, used, and integrated into future planning.
- ♦ BOSC Subcommittee Chairs should ensure that members read review materials in advance of meetings, identify when a comment in a report is not based on consensus, and determine if additional information requested by members is necessary to answer the charge questions.
- ♦ Recommendations in the BOSC reports will be identified in bold text.

In addition, ORD recommends the following changes based on discussions with the NPDs:

- ❖ Program reviews should be conducted on a 4-year cycle. The number of years between reviews was dictated by the Program Assessment Rating Tool process used by the Office of Management and Budget (OMB) to evaluate all federal programs. This tool no longer will be used for performance assessment; the nature of the new tool that will be used is not known yet.
- ♦ The routine mid-cycle review should be eliminated; instead, ORD and the BOSC can arrange for discussions between program reviews if either ORD or the BOSC identifies a need for this interaction.
- ♦ Biosketches will be provided only for key research program staff determined by the NPD.
- ♦ Options for modifying the bibliometric analysis to increase its usefulness should be explored; ORD will propose alternatives at a future BOSC meeting.

Dr. Sayler stated that the BOSC most likely would follow the suggestion of discontinuing the mid-cycle reviews unless the Executive Committee members strongly disagree. Dr. Giesy thought it would be useful to eliminate the mid-cycle review with the case-by-case flexibility mentioned. Currently, the reviews are too frequent and intense; outside review is important but a 2-year cycle is excessive. He indicated that he has a number of other comments on the process that he will submit when appropriate. Dr. Falk added that if there were fewer reviews, the BOSC and ORD program staff could give more attention to the full program reviews, and allow more time for discussion.

Dr. Lambert noted that EPA has been praised, especially recently, as the gold standard for peer review within the Federal Government, so the importance of external review for the Agency and other agencies is critical. He agrees that review every 2 years is unnecessary; he has been impressed with the high-quality, constructive opinions that have been put forward in the BOSC reviews.

Dr. Falk commented that the mid-cycle reviews have been a method of gauging how well the program is progressing in response to the program review. If the mid-cycle reviews are eliminated, ORD management would have the added burden of monitoring this progress and deciding if mid-cycle corrections are warranted. Dr. Teichman agreed and noted that he would take that responsibility seriously; he also wanted to keep the option open for the BOSC to initiate a discussion when the members think it is needed.

Dr. Sayler asked if Dr. Teichman had given any consideration to any intermediate measure that could be included in the charge questions, such as a question that was directed toward identifying opportunities for the NPD to note after 2 years whether goals were being accomplished and to alert the BOSC as to where the program stands. Dr. Teichman agreed that approach would be useful.

Dr. Ryan was concerned that 4 years may be a long time to go without external review. He attributed the excessive burden of the mid-cycle reviews in part to "mission creep." He though the mid-cycle reviews could be simplified, perhaps even just a conference call to assess progress and determine if mid-course corrections are needed.

Dr. Teichman asked if Dr. Ryan was suggesting having full reviews on a 3-year cycle, or merely strengthening the recommendation for dialogue at the mid-point. Dr. Ryan confirmed it was the latter, stating that he believed a 4-year cycle was appropriate for the full program reviews.

Dr. Giesy suggested that ORD implement a system in which the BOSC would receive, at the mid-point of the review cycle, a table such as those in recent reports that goes through the recommendations and notes if they have been addressed, are in progress, or will not be done. The program will know that someone will be checking what has been done after 2 years. The BOSC could respond via a letter to ORD. This streamlined approach would remove some of the burden from ORD as well as from the BOSC. The BOSC could request a discussion with the program if it appeared that little progress was being made, or if there were numerous changes in the program. He stressed that flexibility is beneficial. Dr. Giesy thought the requirement of a mid-cycle progress report would be a good compromise. Dr. Haas agreed that a brief progress report at the mid-cycle would be an effective approach.

Dr. Sayler pointed out that the BOSC Executive Committee might not be the appropriate body to examine the mid-cycle progress report; he thought the committee members who conducted the program review should examine it. The committee members are the ones most familiar with the program review report and the recommendations and they are in the best position to provide useful input at the mid-point. Dr. Philbert suggested that the Executive Committee could review the mid-cycle progress report and then refer it to the reviewing committee if there were any concerns or issues.

Dr. Sayler said there appears to be a consensus that eliminating the mid-cycle reviews would be acceptable to the BOSC. A 4-year review cycle with various approaches for intermediate level review as needed by ORD, the program, or BOSC seems reasonable.

Dr. Paustenbach agreed with Dr. Ryan that 4 years is a long time between reviews, noting that reviews are conducted every 6 months in the private sector. He thought a written response, as Dr. Giesy mentioned, to report the program's progress in responding to the program review would be useful. He was concerned that eliminating the mid-point review completely would reduce accountability. He suggested creating a form that could be completed by the program and submitted to the BOSC at the mid-point. Dr. Giesy pointed out that the BOSC review is not the only review of the program. These programs are being reviewed internally on a continual basis. Dr. Sayler added that SAB reviews also are being conducted. Dr. Falk pointed out that the BOSC reviews are not performance reviews; rather they are to provide broad direction to the programs. Given that the mid-cycle reviews will be eliminated, Dr. Falk proposed that two or three members of the Executive Committee be involved in each program review so that several members of the Executive Committee are familiar with the program and the BOSC's recommendations when the Executive Committee reviews the mid-cycle progress report. Dr. Duke supported this suggestion.

Dr. Giesy volunteered to prepare a memorandum to communicate his observations on each of ORD's recommendations to streamline the review process and send it to Dr. Sayler. These changes should yield considerable savings of both cost and time. Dr. Giesy offered some suggestions for the program reviews: (1) shorten the time devoted to the testimonials during the face-to-face meeting; (2) add an extra day to the meeting so that there is more time for poster review, discussion, and preparing a draft report.

Dr. Giesy said he would like the members to complete a draft of the report before the meeting is adjourned, because it is very difficult to get the report drafted once people return to work. He proposed lengthening the meeting to allow adequate time to review the posters and discuss the research with the program staff. It is disrespectful to the researchers to limit these sessions to a cursory glance given the time they have spent on the project and the poster.

Dr. Sayler agreed that this memorandum could be on the agenda for the Executive Committee's next conference call. He stated that the Executive Committee members concur that mid-cycle reviews will be eliminated and a new structure adopted; there will be further discussion of this new structure on an upcoming conference call. He noted that getting the committee members to read the materials prior to the meeting have been problematic. It may help to make writing assignments and require members to bring drafts to the meeting.

Dr. Teichman raised the issue of an overview poster for the LTGs. Does the BOSC find the overview posters helpful? With regard to identifying the most important papers published by the program, the NPDs are hesitant to identify seminal papers, because they do not want to belittle the work of the other researchers in the program whose papers were not selected. He asked if the BOSC has any opinions of these issues.

Dr. Sayler moved to the topic of a standard format for BOSC program review reports. He explained that Dr. Paustenbach drafted some guidance on standardizing the report format. Ms. Kowalski used this draft to develop the guidance that was distributed to the members. With this guidance, the program review reports will include the following sections:

- ♦ Executive Summary: The qualitative rating by LTG would be included in the Executive Summary followed by a standard table with recommendations in bold font. The Executive Summary should be a free-standing snapshot of the outcome of the review process.
- ♦ <u>Introduction and Background</u>: These should be similar to what the BOSC has used before, but slightly more organized and structured, including inter- and intra-agency interactions.
- ♦ Response to Charge Questions: The review process should be organized by charge question rather than the LTGs; the charge questions will be subdivided, as needed, for the LTGs. This format has been effective for past reports.

Some reports include recommendations that are different in terms of their impact on the program; these may be made by a particular committee member, and may not reflect on the strategy of the LTGs, broader areas of research, or the charge questions. Dr. Haas noted that it might be better to distinguish these as "suggestions" rather than "recommendations." He also proposed distinguishing between "recommendations" and "key recommendations." Dr. Giesy thought these terms should be codified, and there should be some basic guidance on the number of recommendations, because the programs have to respond to each one. Recommendations could be defined as major issues relevant to the LTGs, and there should be 10 to 12 maximum, for example.

Dr. Duke said that the Executive Committee should make it clear that the reports should be organized by the charge questions. Giesy recommended that a draft template be provided to the committees. The charge questions would be the major subheadings, and the LTGs would be organized beneath those headings. Dr. Falk was not sure that this structure would be very helpful because there are large differences between the LTGs. Summarizing the discussion, Dr. Sayler stated that the program review reports should be organized by charge questions but, with appropriate justification, could be organized by LTGs.

Dr. Giesy said that he had chaired a subcommittee that organized its report by the LTGs as well as one that organized its report by the charge questions. Both approaches seemed to work but he preferred

organizing by charge questions. This format captures the dialog between the committee and ORD; it also allows comparison and contrast of how the LTGs relate together in a way that is not possible if the report is organized by LTGs. Dr. Sayler called for a motion stating that the default organization of program review reports would be based on the charge questions. Dr. Giesy made a motion to this effect, and Dr. Philbert seconded the motion. The motion passed with one opposing vote.

Dr. Paustenbach asked if the Executive Committee was satisfied with the wording of the charge questions. Dr. Sayler indicated that the topic of the charge questions would have to be dealt with separately from the organization of the reports. Ms. Kowalski commented that the charge questions were being examined by ORD, and this will be a topic of discussion at the September meeting. Dr. Sayler noted that the charge questions were developed to some extent to support the PART process that will no longer be used by OMB. As the new OMB review process is implemented, it may be necessary to revise the charge questions.

Dr. Sayler stated that most of the materials on this topic distributed by Ms. Kowalski are self-explanatory. A basic outline for the reports has been proposed and this matter can be discussed again, if necessary, during the next conference call. Ms. Kowalski asked for suggestions on the appendices; she pointed out that there are some questions in red for the Executive Committee concerning the appendices and investment efficiency. New charge questions on investment efficiency were developed for the Clean Air Subcommittee review. ORD will be interested in the Subcommittee's feedback on the new questions, and this feedback will be reported to the Executive Committee.

Subcommittee Reviews: Mid-Cycle Subcommittees – Human Health Risk Assessment Dr. Dennis Paustenbach. Subcommittee Chair

Dr. Paustenbach said that he had nothing to report on the activities of this Subcommittee. Dr. Giesy pointed out that these should now be called committees rather than subcommittees.

Subcommittee Reviews: Program Review Subcommittees – Clean Air Program Dr. Ken Demerjian, Subcommittee Chair

Dr. Demerjian was not present at the meeting to give the Clean Air Program Review report. Ms. Kowalski stated that there were conference calls on May 21 and May 29, and there would be a face-to-face meeting June 8-10, 2009, in Research Triangle Park. She confirmed that the decisions on report structure would apply to the report of this committee and agreed to provide this information to the NPD of the Air Program and Dr. Demerjian. Ms. Kowalski said that she would be covering the Clean Air Committee meeting for Ms. Heather Drumm, who is the DFO for that Committee.

Subcommittee Reviews: Program Review Subcommittees – Endocrine Disrupting Chemicals Program

Dr. George Lambert, Subcommittee Member

Dr. Sayler stated that this Committee is chaired by Dr. Glen Van der Kraak, and the face-to-face meeting has been scheduled for August 12-14, 2009, in Research Triangle Park, North Carolina. Dr. Lambert noted that Susan Peterson now is the DFO for the Committee; it has taken considerable time to form the Committee. The first conference call was scheduled for June 8, 2009, but it has been rescheduled for July 16, 2009. No materials have been received yet.

Subcommittee Reviews: Program Review Subcommittees – Drinking Water Program

Dr. Chuck Haas, Subcommittee Chair

Dr. Haas reported that the Committee is being formed. The face-to-face meeting is targeted for November 2009. Troy Rutkofske will serve as the DFO for this Committee. Dr. Haas said that he had sent Mr. Rutkofske some names for consideration.

Subcommittee Reviews: Standing Subcommittees – NCER

Dr. Martin Philbert. Subcommittee Chair

Dr. Philbert strongly encouraged Dr. Teichman and ORD to develop charge questions that will generate responses that are helpful to the Program. Dr. Sayler noted that if new members are needed for this Committee, BOSC Executive Committee members could volunteer.

Subcommittee Reviews: Standing Subcommittees – National Exposure Research Lab (NERL)

Dr. Ken Demerjian, Subcommittee Chair

Dr. Sayler noted that a public conference call is scheduled for fall 2009. Susan Peterson is the DFO.

Subcommittee Reviews: Standing Subcommittees – Computational Toxicology

Dr. Gary Sayler, Executive Committee Chair

Dr. Sayler stated that Dr. George Daston had served as the Committee Chair; his service will end after the Program review in September 2009. Dr. Paustenbach has volunteered to join this Committee, and to serve as Chair if Dr. Daston does not wish to continue in that role. Dr. Sayler mentioned that Executive Committee members have been providing names to Ms. Kowalski of individuals with computational toxicology area for inclusion on review committees as well as the Executive Committee. Dr. Paustenbach said he could provide some names as well.

Dr. Ryan mentioned that he had spoken with Ms. Kowalski about his possible conflict of interest because he receives funding from various agencies, but if he is eligible, he would be happy to work on any of the standing committees.

Dr. Sayler asked if Dr. Lambert's presentation could precede Dr. von Stackelberg's presentation, and Dr. Lambert agreed.

EPA Science Advisory Board (SAB) Activities

Dr. George Lambert, SAB Liaison to the BOSC

Dr. Lambert discussed the FY 2009 Operating Plan for the SAB, much of which has been completed. A discussion of EPA's science budget request for FY 2010 was initiated at a meeting in October 2008. The SAB had some concerns that the science budget request did not increase given the new EPA Administrator's emphasis of science. Dr. Lambert noted that funding for human health research go below the 1999 levels. He also mentioned that the human health and ecosystem budget supports the computational toxicology efforts. When Lisa Jackson was the head of the Department of Environmental Protection in New Jersey, she eliminated the Science and Technology Research Division using the rationale that the data needed to make decisions were available and simply had to be mined. There was some concern among the SAB members about this action.

Under planned advisory meetings, the Integration of Science Assessments for Environmental Decisions meeting will be held June 9-10, 2009. The Report on the Environment review is scheduled for 2012. The SAB has been involved with the ROE because there were concerns about the past two reports. The SAB

thought it would be helpful to get involved at the beginning of the process; an ad hoc panel will meet July 14-15, 2009. The EPA Research Directions for 2010-2015 meeting will be held September 23-24, 2009; one-quarter of the SAB members will be rotating off the Board after the September meeting, so Dr. Lambert hopes the SAB will provide some strong direction at that meeting. In 2010, the SAB Environmental Economics Advisory Committee will meet and the Dioxin Reassessment will begin. Dr. Lambert mentioned that there was a meeting held in Indiana to try to address the National Academies' concerns about the dioxin report but he did not attend. The last dioxin report took 5 to 6 years to release.

One of the handouts distributed by Dr. Lambert listed the meetings of the Clean Air Scientific Advisory Committee (CASAC). The last handout deals with meetings scheduled for the Advisory Council on the Clean Air Compliance Analysis; it is accurate as of the beginning of June.

Dr. Lambert stated that the SAB is in the process of identifying its new role. There was a meeting in December 2008 that focused on examining the role of the SAB and it generated a lot of interest in reidentifying how the Board functions.

Dr. Lambert extended an invitation to the BOSC members to attend any of the SAB meetings. Input from the BOSC is welcomed and encouraged. Dr. Sayler added that any member who wants EPA to support their attendance at an SAB meeting should contact Ms. Kowalski. If EPA provides support to attend the meeting, the member would be expected to provide a report on the SAB meeting at a future BOSC Executive Committee meeting. Dr. Lambert thinks that the next year will be critical and that the BOSC and the SAB will have heightened roles. Dr. Giesy said he may be attending the Integration of Science Assessments meeting next week.

Dr. Paustenbach asked what had happened during the past 2 years that would give the SAB a different role. Dr. Lambert responded that Dr. Deborah Swackhamer became the Chair in December 2008, and she is trying to energize the SAB and make sure its role is updated and directed in new and productive ways.

Dr. Giesy added that he thinks that ORD have been very responsive to the BOSC reports, but the Agency has not been as responsive to the SAB reports. Dr. Lambert stated that Dr. Swackhamer is attempting to reverse that trend.

Dr. Sayler informed the Executive Committee members that Dr. Carriker's presentation would be moved to 10:30 a.m.

Decision Analysis Workgroup

Dr. Katherine von Stackelberg, Harvard School of Public Health, Workgroup Chair

Dr. von Stackelberg gave an update on the activities of the Decision Analysis Workgroup. The Decision Analysis: Supporting Environmental Decision Makers Workshop was held March 31-April 1, 2009, in Cincinnati, Ohio, and a summary report from that workshop is being prepared. An outline of that meeting summary was included with the meeting materials, as well as two of the three case studies discussed at the workshop. Dr. von Stackelberg noted that the third case study is relevant to NCER because it is an example of evaluations and prioritizations of proposals in response to RFPs in the STAR Program.

The first day of the workshop was open to the public, and included a number of presentations. These presentations are available online (including PowerPoint and video). The second day of the workshop was by invitation only and it focused on discussion. It was agreed that the methods and software are available to conduct the process but the participants cautioned that this cannot be implemented as a half-hearted effort. It will require a concerted effort to begin the process of institutionalizing these kinds of approaches to support decision making. Dottie Miller from the American Association for the Advancement of Science (AAAS) is working on this effort, and there are a lot of people from all parts of ORD participating in and conducting pilot studies. Dr. von Stackelberg mentioned that there is a current opportunity to move this forward—several members of the transition team were present at the workshop

to learn more about ways to improve decision making. The key to success is communication at the top level of decision makers. Workshop participants suggested that decision makers may need to attend training sessions. There also is a need for liaisons between the technical staff and the decision makers.

The first case study, the Ecological Research Program, is a strategic level MYP. Staff from Expert Choice, using a software product based on the Analytic Hierarchy Process (AHP) as the algorithm, fleshed-out this case study using the LTGs as objectives and the Annual Performance Goals (APGs) as the alternatives against which the objectives could be evaluated. The APGs contribute to the LTGs in various ways and had to be weighted. AHP is a controversial method, but a weighting will have to be done no matter what method is used. EPA prioritizes the LTGs in a way that does not recognize that some of the research underlying other LTGs has to be conducted in order to achieve the first priority, for example.

In Day 2 of the workshop, no consensus was developed and no recommendations were formed, but the common theme that emerged was the use of influence diagrams as a good way to organize complex relationships. This approach has promise, and was widely supported. Ms. Cynthia Stahl, EPA Region 3, has developed an influence diagram linked with a multiple criteria decision model that demonstrates how to link day-to-day activities of researchers at the timesheet level to the larger interconnected logic model using Access, Excel, and Visual Basic.

Dr. Sayler asked if it would be worthwhile to provide a tutorial on this topic for the BOSC. Dr. von Stackelberg thought it would be helpful to invite some of the key workshop participants to give presentations to the BOSC. Ms. Stahl, for example, already has developed some tools to support her decision-making work in Region 3 that would be applicable across other components of ORD. Another option is to invite Dr. Todd Bridges, U.S. Army Corps of Engineers (USACE). The USACE recently went through this process; Dr. Bridges has made a concerted effort to introduce the use of these kinds of approaches for decision making, and he has been quite successful.

Dr. von Stackelberg said that participants also spoke about linking environmental indicators back to decisions, and this is part of what Ms. Stahl does in Region 3 on a day-to-day basis. There must be ways to measure and think about research in terms of outcomes rather than outputs. If scientists are conducting research that is very interesting but not directly related to a decided focus, that research is incidental. Incidental research should not be penalized, but research should be conducted efficiently. If environmental indicators can be linked to decisions, it is easier to evaluate these decisions and demonstrate investment efficiency. Prioritization is key in terms of what research should be conducted within and outside of ORD.

Dr. Sayler asked if that approach could create a situation in which all the research is reactionary rather than exploratory. Dr. von Stackelberg responded that it could, and there had been quite a bit of discussion at the workshop about how to foster innovative research. Such research would be strictly evaluated in a decision model and probabilities and successful outcomes must be designed. She stressed that there needs to be a mechanism that allows ORD to stop research that is no longer relevant. Dr. Sayler noted that this issue was raised in the Homeland Security Program review. The representatives from the armed forces and the National Aeronautics and Space Administration (NASA) that participated in that review indicated that their organizations had developed some guidance for disinvesting in programs that might be useful to EPA. Dr. von Stackelberg commented that this is another opportunity that could be leveraged by EPA.

Dr. Sayler noted that Ms. Kowalski should be involved in the discussion of a future presentation on this topic to the BOSC. Dr. von Stackelberg proposed devoting 2 hours to the topic at an upcoming meeting. She suggested inviting Ms. Stahl, who is the closest to implementation, to make a presentation as well as Dr. Bridges or someone from another agency who has gone through the process. Dr. Sayler stated that he will work with Ms. Kowalski to get this presentation on the agenda for a future meeting. Dr. von Stackelberg stated that in the interim she was working on a report that communicated observations from the workshop and this could serve as the basis for developing BOSC recommendations on this subject.

Future Business

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

Realizing that some members may have to leave before the session devoted to future business, Dr. Sayler wanted to address a few administrative issues. Referring to the table that listed current BOSC member activities as of June 1, he noted that Chairs need to be identified for the Global Change Program Review and the Ecosystem Services Program Review. The face-to-face meetings for these reviews probably will be held in the first half of 2010. Vettors also are needed for several reports.

Dr. Giesy asked about the timing of these assignments and if he was eligible to vet the report for the EDCs program review. In light of the shortage of BOSC Executive Committee members, Dr. Paustenbach suggested that Dr. Giesy's term on the Committee be extended for a year. Ms. Kowalski explained that there are limitations on extending terms based on an Agency best practice. There is a term limit of 6 years to encourage bringing in new people with different ideas. There have been times when there has been justification for extending a member's term on the Board, but the Administration is discouraging that practice unless there is real justification. Therefore, Dr. Giesy may not be able to continue as a member of the Executive Committee, however, he could continue to serve at the review committee level. With regard to timeframes, the Ecosystem Services Program and Global Change Program reviews will be conducted during the first half of 2010. The specific times for the conference calls and meetings will be determined during the next few months. Ms. Kowalski has asked the NPDs for those programs to work out a schedule. The report for the Clean Air Program review should be vetted at the September meeting. The EDCs Program Review has been scheduled for August, so it is not probable that the report will be ready for vetting at the September meeting. The Drinking Water Program Review will be held in November, so that report probably will be vetted in January or February of 2010. The Computational Toxicology Review is in September, so that report will be vetted in January or February of 2010. The Decision Analysis Workgroup product that Dr. von Stackelberg mentioned will be available for review by the end of the calendar year, so that also would be vetted in early 2010.

The following assignments were made:

- ♦ Drs. Ryan and Giesy will vet the EDCs report.
- ♦ Drs. Ryan and Paustenbach will vet the Clean Air Report.
- ♦ Drs. Sayler and Falk will vet the Drinking Water Report.
- ♦ Drs. Haas and Philbert will vet the Decision Analysis Workgroup product.
- ♦ Dr. Falk will serve on the Global Review Subcommittee.

Public Comment

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

Dr. Sayler called for public comments at 10:16 a.m. No comments were offered.

Kingston Project

Mr. Neil Carriker, Tennessee Valley Authority (TVA)

Dr. Sayler mentioned that the Kingston coal ash release occurred in December 2008, and EPA staff made a presentation to the BOSC on this topic at the previous Executive Committee meeting describing EPA's work on coal combustion products. Dr. Sayler expressed the Executive Committee's appreciation to Mr. Carriker for agreeing to come and describe TVA's efforts to address this problem. He noted that EPA has become more engaged in the project in the past few weeks because of Superfund oversight.

Mr. Carriker thanked the BOSC for inviting him to the meeting. He explained that his first few slides provide an overview of the event and the initial recovery activities. The TVA is a federal agency that received appropriated funding until 2003, at which time the Chairman decided that TVA would undergo less Congressional oversight if it did not accept appropriated funding. TVA serves 8 million customers, with power revenues of approximately \$8 billion per year, a portion of which now goes to provide some of the services that used to be funded from appropriated funds.

The incident occurred on December 22, 2008, between midnight and 1:00 a.m. Mr. Carriker was on site by 12:00 noon the next day, and has been on site most days since. The investigation of the cause of the ash pond dike failure will be completed and the results of the analysis will be released shortly. Mr. Carriker noted that three or four different factors contributed to the failure. The pond released 5.4 million cubic yards of coal ash and destroyed three homes; however, no one was injured in the event. Roads, rail lines, and utility lines were damaged, including the rail line that delivers coal to the plant. Debris covered approximately 300 acres and 3 million cubic yards of the ash entered the river. TVA has been dredging at the site since March 19, 2009, and at this point, about 300,000 cubic yards have been removed. Mr. Carriker commented that dredging is very difficult because of all the debris that is mixed with the ash in the river; larger equipment is needed, and TVA is seeking a new contractor.

The plant has a skimmer wall that extends from the surface to approximately 9 feet from the bottom of the river. The incident created a tidal wave that is estimated to have been approximately 28 feet high; it knocked out three sections of the skimmer wall and two 230-ton concrete caissons. The spill also knocked out part of a road and stripped the trees off a nearby island. The flow went across Swan Pond Circle Road, and flowed upstream and downstream from the canal. The ash spill blocked the river flow; flow was diverting around a sand island.

Dr. Paustenbach asked about the height of the failed dredge cell and Mr. Carriker responded that it covered 80 acres and was approximately 60 feet high. Dr. Paustenbach then asked if anyone had conducted a fault tree analysis and Mr. Carriker replied that no such analysis had been done. Dr. Haas asked if a seismic analysis had been conducted. Mr. Carriker responded that a seismic analysis had been done; there was a small seismic event 5 or 6 days prior to the spill, but the analysis by the technical firm does not indicate that it contributed to the event because the seismic activity was approximately 100 miles away. Other factors were more significant, including the fact that the original disposition of ash from the plant was directly into water. There was some initial concern about the design, but it appears to have been correct. A notch was cut in the unfailed section to examine the construction methods.

It appears that there were multiple reasons for the slide and these will be described in the final report that is due out in 2 weeks. That report currently is undergoing review.

The initial response was begin working immediately with the local county emergency management agency, the Tennessee Department of Environment and Conservation (TDEC), Tennessee Emergency Management Agency (TEMA), EPA, USACE, and the U.S. Department of Homeland Security. TVA established a unified incident command center with EPA and state and local agencies. The initial outreach involved ensuring that all neighbors were safe, arranging for temporary housing, setting up a claims center for those who had received damages, and publishing information on the Web site. Operation of the plant was significantly impacted because coal could not be delivered, so the employees met with neighbors to determine and address their concerns.

Mr. Carriker stated that TVA's objectives for the Kingston Recovery Project are to: ensure the safety of citizens and response personnel, keep the public and stakeholders informed of response activities, maximize the protection of environmentally sensitive areas, and return the community to normal conditions.

The options on disposing of this material include moving it via rail to a Class I landfill in Alabama or Georgia. The dredge cells were managed as a Class II industrial landfill. Disposal in a Class I or II

landfill that is permitted and has appropriate drainage will be the short-term solution. The material can be used as structural fill, but it requires the addition of Portland cement to make that feasible, which drives the price up. The other long-term options are dry fly ash collection, mine reclamation, or greenfields.

To date, the project cost has exceeded \$100 million, and the projected cost is between \$600 million and \$1 billion. Mr. Carriker believes that this estimate may be low given that litigation, recovery support, long-term monitoring, and remediation have not been factored in. Fines also will be substantial.

Water, air, ash, and soil were sampled on December 28, 2008; biological sampling began in mid-January. There have been 48,000 real-time PM₁₀ measurements. TVA and the Tennessee Department of Environmental Quality (TDEQ) conducted radiological monitoring. Radioactivity has been a public concern, but there is not much radioactivity in the material (average Ra-226 was 2.5 pCi/g, well below the level of concern).

Arsenic is a big concern with fly ash, and there are some high numbers in the data. It is the only element that is present above EPA remedial action levels.

Water monitoring is being conducted three times per week and after rain events of one-half inch or more. Drinking water is being tested weekly by TDEQ and daily by Kingston. The effects of this event will be experienced for some time, but the material seems to have dropped out of the water fairly quickly; only during high-flow events are high amounts observed in the river.

Long-term issues to be resolved include: offsite transportation and disposal options; public and local expectations for financial support (buying homes and paying realtors' commissions); non-peer reviewed, independent test results and theories; final recovery and remediation costs; property purchase expectations outside affected area; regulations; utilization/beneficial reuse; impacts to present and future plant operations; and environmental remediation and monitoring.

TVA and EPA have agreed to conduct remediation of the Kingston Fossil Plant (KIF) Ash Release under the regulatory structure of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA).

Dr. Falk asked about TVA's long-term plans for disposing of the material before the event. Mr. Carriker responded that the plan was in place to move to dry storage. As a Class II landfill, a closure plan is necessary. Dr. Falk asked about the cause of the failure. Mr. Carriker said he had not seen the report yet but he understood that it was a combination of wet weather, loading material into one of the cells at a high rate, and possibly instability at the base of the system. The geotechnical firm is finalizing its analysis and the report will be released on June 22, 2009.

Dr. Giesy asked if this has triggered EPA's examination of other ash ponds or development of stricter requirements. Mr. Carriker replied that EPA issued a directive to all power companies to inspect all ash storage facilities in early 2009. The direction involves reviewing the stability of all of the sites, the design specifications, and the structural integrity.

Future Discussion/Future Business

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

Dr. Sayler noted that the topics relevant to future business already had been discussed. The next Executive Committee meeting is planned for September 2009, and based on the discussions at this meeting, a few items will be added to that agenda, possibly a presentation on decision analysis.

Dr. Sayler thanked members for their participation and adjourned the meeting at 11:09 a.m.

Action Items

- ♦ Committee members should send revisions and requests for further information on the Human Health Program Review Draft Report to Dr. Klaunig who will revise the report based on recommendations made at this meeting and any additional suggested revisions. The Executive Committee will examine the revised report and vote on the report at a conference call to be held in July.
- ❖ Dr. Paustenbach will draft a recommendation for the Human Health Program Review Draft Report stating that the HHRP should show the lifecycle of a project from conception to regulatory outcome or use in risk assessment.
- ❖ Dr. Giesy will incorporate some of the positive statements made in the meeting presentation into the STS Mid-Cycle Review Draft Report to support the fact that the STS Program was rated as exceeds expectations. Key elements that led to the ranking also should be included. Once revised, the report will be transmitted to ORD.
- ❖ Dr. Philbert will revise the NCER Subcommittee letter report to include the recommendation that NCER collaborate with AAAS to determine if more undergraduate and graduate students need to be encouraged to enter environmental sciences.
- ♦ ORD will propose options for modifying the bibliometric analysis to increase its usefulness at a future BOSC meeting.
- ❖ Dr. Giesy will prepare a memorandum to communicate his observations on each of ORD's recommendations on streamlining BOSC reviews and send it to Dr. Sayler. The memorandum will be on the agenda of the Executive Committee's July conference call.
- ♦ BOSC members should send Ms. Kowalski suggestions on the appendices and the topic of investment efficiency in the outline for the review report format.
- ♦ ORD will report back to the BOSC the Clean Air Subcommittee's feedback on the new charge questions on investment efficiency that were developed for the Clean Air Program Review.
- ❖ Dr. Sayler will add a presentation on decision analysis tools and metrics to the agenda for a future meeting.
- ♦ Drs. Ryan and Giesy will vet the EDCs report.
- ♦ Drs. Ryan and Paustenbach will vet the Clean Air Report.
- ♦ Drs. Sayler and Falk will vet the Drinking Water Report.
- ♦ Drs. Haas and Philbert will vet the Decision Analysis Workgroup product.
- ♦ Dr. Falk will serve on the Global Change Review Committee.

All materials that were transmitted during and for this meeting are in the public meeting binder in the BOSC central files in Washington, DC.

PARTICIPANTS LIST

Executive Committee Members:

Gary S. Sayler, Ph.D., Chair

Center for Environmental Biotechnology The University of Tennessee

Kenneth L. Demerjian, Ph.D. (not present)

Atmospheric Sciences Research Center State University of New York

Clifford S. Duke, Ph.D.

The Ecological Society of America

Henry Falk, M.D., M.P.H.

Coordinating Center for Environmental Health and Injury Prevention Centers for Disease Control and Prevention

John Giesy, Ph.D.

Department of Veterinary Biomedical Sciences University of Saskatchewan

Charles N. Haas, Ph.D.

Department of Civil, Architectural, and Environmental Engineering Drexel University

Dennis Paustenbach, Ph.D., CIH, DABT

ChemRisk, Inc.

Martin Philbert, Ph.D.

Department of Environmental Health Sciences School of Public Health University of Michigan

P. Barry Ryan, Ph.D.

Department of Environmental and Occupational Health Rollins School of Public Health Emory University

Katherine von Stackelberg, Sc.D. (via

telephone)

Harvard Center for Risk Analysis Harvard School of Public Health

SAB Liaison to the BOSC:

George Lambert, M.D.

The Center for Childhood Neurotoxicology and Exposure Assessment Robert Wood Johnson Medical School University of Medicine and Dentistry of New Jersey

BOSC Subcommittee Members:

James E. Klaunig, Ph.D. (via telephone) Chair, Human Health Subcommittee Indiana University School of Medicine

Committee Staff:

Lorelei Kowalski

Designated Federal Officer U.S. Environmental Protection Agency Office of Research and Development Office of Science Policy

Kevin Teichman, Ph.D.

Deputy Assistant Administrator for Science U.S. Environmental Protection Agency Office of Research and Development

EPA Participants:

Meta Bonner, Ph.D (via telephone)
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Research

Heriberto Cabezas, Ph.D. (via telephone)

U.S. Environmental Protection Agency
Office of Research and Development
National Risk Management Research Laboratory

Sally Darney, Ph.D. (via telephone)

U.S. Environmental Protection Agency Office of Research and Development National Health and Environmental Effects Research Laboratory Hiba Ernst, Ph.D. (via telephone)
U.S. Environmental Protection Agency
Office of Research and Development
National Homeland Security Research
Center

Nigel Fields (via telephone)
U.S. Environmental Protection Agency
Office of Research and Development

Alan Hecht, Ph.D. (via telephone) U.S. Environmental Protection Agency Office of Research and Development Science to Attain Sustainability Program

David Herr, Ph.D. (via telephone)
U.S. Environmental Protection Agency
Office of Research and Development
National Health and Environmental Effects
Research Laboratory

Robert Hetes (via telephone) U.S. Environmental Protection Agency Office of Research and Development

Janet Keough, Ph.D.

U.S. Environmental Protection Agency Office of Research and Development National Health and Environmental Effects Research Laboratory Mid-Continent Ecology Division

Patricia Murphy, Ph.D. (via telephone) U.S. Environmental Protection Agency Office of Research and Development

Chris Nollet

U.S. Environmental Protection Agency Office of Research and Development National Health and Environmental Effects Research Laboratory Mid-Continent Ecology Division
Carl Richards, Ph.D.
U.S. Environmental Protection Agency
Office of Research and Development
National Health and Environmental Effects

Research Laboratory
Mid-Continent Ecology Division

Gregory Sayles, Ph.D. (via telephone)
U.S. Environmental Protection Agency
Office of Research and Development
National Homeland Security Research Center

Bradley Schultz (via telephone) U.S. Environmental Protection Agency Office of Research and Development National Exposure Research Laboratory

Timothy Shafer, Ph.D. (via telephone) U.S. Environmental Protection Agency Office of Research and Development National Health and Environmental Effects Research Laboratory

Gregory Susanke (via telephone) U.S. Environmental Protection Agency Office of Research and Development

Other Participants:

Neil Carriker

Tennessee Valley Authority

Contractor Support:

Beverly Campbell

The Scientific Consulting Group, Inc.

Denise Hoffman

The Scientific Consulting Group, Inc.



41st EXECUTIVE COMMITTEE FACE-TO-FACE MEETING AGENDA June 4-5, 2009

Office of Research and Development National Health and Environmental Effects Laboratory Mid-Continent Ecology Division

6201 Congdon Boulevard Duluth, Minnesota 55804 Tel: 218-529-5000

NOTE THAT DULUTH IS IN THE CENTRAL TIME ZONE

Thursday, June 4, 2009

8:00 a.m. – 8:15 a.m.	Registration	
8:15 a.m. – 8:30 a.m.	Welcome and Introductions - Review of February Meeting Minutes - Review of May Meeting Minutes - Overview of Agenda	Dr. Gary S. Sayler, Chair, Executive Committee
8:30 a.m. – 8:45 a.m.	BOSC DFO Remarks - Administrative Issues	Ms. Lorelei Kowalski, Office of Research & Development (ORD)
8:45 a.m. – 9:15 a.m.	AA/ORD Remarks	Mr. Lek Kadeli, Acting Assistant Administrator for ORD
9:15 a.m. – 10:00 a.m.	ORD Response to BOSC Report: National Homeland Security Research Center (NHSRC)	Dr. Gregory Sayles, Associate Director, NHSRC
10:00 a.m. – 10:15 a.m.	Break	
10:15 a.m. – 12:30 p.m.	Subcommittee Draft Reports: (1) Human Health Program Review Draft Report Presentation - Discussion	Dr. James Klaunig, Subcommittee Chair Vettors: Dr. Carol Weiss/ Dr. Martin Philbert, Executive Committee
	(2) Science and Technology for Sustainability Draft Mid-Cycle Report Presentation- Discussion	Dr. John Giesy, Subcommittee Chair Vettors: Dr. Martin Philbert/ Dr. Barry Ryan, Executive Committee

(3) National Center for Environmental Dr. Martin Philbert. Research (NCER) Draft Report Subcommittee Chair Presentation - Discussion Vettors: Dr. Cliff Duke/ Dr. Henry Falk, Executive Committee 12:30 p.m. - 1:30 p.m.Lunch 1:30 p.m. – 5:00 p.m. Site Visit Friday, June 5, 2009 8:15 a.m. – 9:15 a.m. ORD Update Dr. Kevin Teichman, *Optimizing BOSC Reviews Deputy Assistant Administrator for Science for ORD 9:15 a.m. - 9:45 a.m. Subcommittee Updates: Mid-Cycle Review Subcommittees: - Human Health Risk Assessment Dr. Dennis Paustenbach, Mid-Cycle Subcommittee Chair Program Review Subcommittees: - Clean Air Program Review Dr. Ken Demerjian, Subcommittee Chair - Endocrine Disrupting Chemicals Dr. George Lambert, (EDC) Program Review Subcommittee Member - Drinking Water Program Review Dr. Chuck Haas, Subcommittee Chair Standing Subcommittees: - National Center for Environmental Dr. Martin Philbert. Research (NCER) Subcommittee Chair - National Exposure Research Dr. Ken Demerjian, Lab (NERL) Subcommittee Chair - Computational Toxicology Dr. Gary Sayler, Chair, **Executive Committee** 9:45 a.m. – 10:15 a.m. Decision Analysis Workgroup Dr. Katherine von Stackelberg, Workgroup Chair 10:15 a.m. – 10:30 a.m. **Public Comment** 10:30 a.m. – 11:00 a.m. EPA Science Advisory Board (SAB) Dr. George Lambert, SAB Activities Liaison to the BOSC 11:00 a.m. – 11:30 a.m. Dr. Neil Carriker, Tennessee **Kingston Project** Valley Authority 11:30 a.m. – 12:00 noon Future Discussion/Future Business Dr. Gary Sayler, Chair,

- EC Meetings in 2009/2010

- Future Work

Executive Committee