# 40th EXECUTIVE COMMITTEE FACE-TO-FACE MEETING SUMMARY

**Marriott Courtyard Arlington Crystal City**
**2899 Jefferson Davis Highway**
**Arlington, VA**
**February 9 - 10, 2009**

## MONDAY, FEBRUARY 9, 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 called for comments regarding the September 2008 Executive Committee meeting minutes and there were none. Dr. Martin Philbert moved to accept the minutes, and Dr. Dennis Paustenbach seconded the motion. The minutes were approved unanimously by the BOSC.

Dr. Sayler called for comments on the summary of the December 2008 conference call. He asked that the word "ultimate" be inserted at the end of line 34 on page 4 of the summary. No other changes were requested. Dr. Kenneth Demerjian moved to accept the minutes, and Dr. Henry Falk seconded the motion. The minutes were approved unanimously by the BOSC.

Following approval of the minutes, Dr. Sayler provided a brief overview of the agenda. He highlighted the presentation on coal combustion residue, which is an important topic that recently has caught the attention of several senators. Because Drs. Clifford Duke and Charles Haas arrived following the approval of the minutes, Dr. Sayler confirmed that they did not have any comments on the September meeting and December conference call minutes.

### BOSC DFO Remarks

*Ms. Heather Drumm, EPA/Office of Research and Development (ORD), Subcommittee Designated Federal Officer (DFO)*

Ms. Heather Drumm welcomed the Executive Committee members to the meeting and explained that she was serving as the DFO for this meeting on behalf of Ms. Lorelei Kowalski, who was on detail to the U.S. General Services Administration. Ms. Drumm 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 Ms. Drumm's responsibility as the DFO to ensure compliance with all FACA rules; thus, this meeting was open to the public and time was 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 12:00 noon on Day 2 for public comment. She asked that comments be limited to 3 minutes each. An ORD contractor, Beverly Campbell from SCG, was 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. Drumm established an electronic public docket for the meeting on the Federal Docket Management System (FDMS), which can be accessed at http://www.regulations.gov. The number to search for this docket is EPA-HQ-ORD-2008-0943. The *Federal Register* notice and the agenda were available to the public on the docket. As DFO, Ms. Drumm 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.

Ms. Drumm introduced Ms. Megan Grogard, who will serve as the DFO for the Endocrine Disrupting Chemicals (EDC) and Safe Pesticides/Safe Products (SP2) Subcommittees. She also announced that Mr. Troy Rutkofske, who has been making the travel arrangements for the BOSC members, will serve as the DFO for the Drinking Water Subcommittee.

Executive Committee members should have received a notebook of materials prior to the meeting, and additional materials will be distributed during the meeting. The Subcommittee status table at the end of the materials binder will be discussed during Day 2. Homework sheets also are in the binder; these should be returned to Ms. Drumm with the expense reports as well as any receipts for any expenditures greater than $75.

**ORD Responses to BOSC Letter Reports**

*Dr. Linda Sheldon, EPA/ORD, National Exposure Research Laboratory (NERL); and Dr. Robert Kavlock, EPA/ORD, Director, National Center for Computational Toxicology (NCCT)*

Dr. Linda Sheldon informed the BOSC that she was now the Acting Director of NERL and Dr. Larry Reiter was the Acting Deputy Assistant Administrator for Management, ORD. Dr. Sheldon said she would be presenting ORD's response to the NERL Standing Subcommittee letter report. The Subcommittee, which is chaired by Dr. Demerjian, did not conduct a review of NERL's programs or science; rather, the Subcommittee reviewed a proposed exposure framework. The Subcommittee was asked by NERL to consider the following charge questions:

- ✧ How effective is the NERL exposure framework in describing the elements of exposure science, bridging the understanding of exposure science for both human health and ecological research, and describing the uses of exposure science in furthering the Agency's mission?
- ✧ What are the core areas of expertise that are required to effectively conduct human health and ecological exposure research?
- ✧ How are these areas likely to evolve in the future?
- ✧ How can NERL use the exposure framework as a communication tool to enhance our external communications and develop new partnerships?
- ✧ What are the merits and barriers to conducting the exposure-related collaborative, multidisciplinary research?

Dr. Sheldon explained that the purpose of the exposure framework is to create an identity for NERL. This is an important point because exposure research is a relatively young science, and NERL's divisions have functioned fairly independently of each other with little cohesion. The goal was to bring the collective knowledge and expertise of the NERL divisions together to perform more effective, cross-cutting research that would have greater impact. The intended effect of the exposure framework was to improve strategic planning, organizational development, and communication. The definition and domain of exposure science were introduced in the framework document, as was the need to understand and articulate the difference between human health and ecological research, which is particularly important to NERL as it provides both types of research. Dr. Sheldon pointed out that although models provide the underpinning

of science, they are not the only element. The use of models to understand fate and transport in the environment is useful, for example, but better predictive systems are needed. Additionally, exposure is critical in regulatory-decision making. The Agency must answer three basic questions: (1) Is there a risk? (2) If so, how can it be reduced? and (3) Have the Agency's policies made a difference?

The Subcommittee's overall findings were that the effort and commitment of NERL management in developing the framework was time well spent, and the document has achieved its goals. The framework document offers an opportunity for NERL to provide a leadership role in defining exposure science and its uses, and one of its strengths is the specification of the utility of exposure science. Dr. Sheldon provided a brief summary of the specific recommendations in the areas of structure, technical content, organizational implications, communication, expertise, and collaborative multidisciplinary research.

In response to the recommendation that two documents be developed, NERL elected to retain a single document because it is critical to the structure and integrity of the internal purpose. Journal articles and presentations will be used for external communication of the principles and practices of exposure science. In response to the Subcommittee's comments on technical content, distinctions between exposure science and exposure research were made, separate figures on the source-to-outcome continuum were maintained, and clarifying language was added on several issues. In terms of organizational content, Chapter 4 was substantially revised to align NERL's business as a strategy-focused organization, and the principles of the exposure framework are being used to develop integrated multidisciplinary programs in NERL and across ORD. NERL's planning process is evolving, and a construct for filtering research areas has been included, but a prioritization process has not. To increase internal communication, standard briefings on science principles and application will be conducted, and research planning fact sheets and guides to research planning will be developed. NERL identified partners and clients in the framework and is working with the National Research Council (NRC) on a workshop regarding exposure in the 21st century. An abstract/summary, standard presentation, and frequently-asked-questions guide will be developed and added to the Web site. Collaborative multidisciplinary research is crucial to solve the complex risk assessment process that NERL faces and provides an opportunity for key scientific discovery and advancement. Some promotion and reward structures already are in place, and these will be augmented and strengthened. A formal structured process to evaluate success in conducting collaborative multidisciplinary research will be developed. At that point, researchers will be given the problems so that they can determine what research is necessary. The next steps are to continue working on the responses described above.

Dr. Demerjian noted that NERL addressed many of the issues that the Subcommittee mentioned. The Subcommittee members agreed that exposure science needs a strong advocate, and NERL is poised to be that advocate. The exposure framework is a positive step in this direction. Dr. Demerjian explained that the Subcommittee recommended that two documents be published so that one would serve as an internal document and include internal management processes, and the other one would be appropriate for the public.

In closing, Dr. Sheldon indicated that this framework document will form the structure for NERL, and the BOSC provided useful input.

Dr. Paustenbach asked if the framework document was a scoping document and Dr. Sheldon confirmed that it was. Dr. Paustenbach asked whether the document amended a prior mission statement. Dr. Sheldon responded that this effort was considerably more than a mission statement; it was a matter of getting to a place and direction understood by everyone in NERL. She noted that NERL did not agree with the one published account that defines exposure science. Dr. Sheldon emphasized that exposure science includes more than exposure assessment, illustrating this point using a State Implementation Plan example.

Dr. Barry Ryan commended NERL for the proposed series of articles and asked about the content of these articles. Dr. Sheldon replied that the article published in *Environmental Health Perspectives* is a commentary; the *Environmental Science & Technology* article focuses on defining exposure science. It was suggested that perhaps Dr. Dana Barr of the Centers for Disease Control and Prevention (CDC) could be consulted regarding a definition. Dr. Sayler thought *Environmental Science & Technology* was a good choice for the article, but suggested that NERL also consider submitting an article to *Science.*

Dr. Philbert noted that some people are inhibited by multidisciplinary research and asked whether NERL would provide disincentives for individual research. Dr. Sheldon responded that individual research will continue in conjunction with the multidisciplinary approach; the important issue is to identify what must be done.

Dr. George Lambert stressed the importance of these articles to NERL, ORD, and EPA. He asked if it would be helpful for the BOSC to review and provide input on them prior to submission to the journal. Dr. Sheldon explained that there was not time for the BOSC to provide input on the *Environmental Health Perspectives* article before its publication deadline; however, it may be possible for the BOSC to provide input on the articles that are in preparation.

Dr. Paustenbach asked whether NERL collaborates with the CDC or the Agency for Toxic Substances and Disease Registry. Dr. Sheldon responded that NERL has collaborated with sister organizations and laboratories, but she was not sure whether the CDC was specifically mentioned in the exposure framework. She will determine whether additional partners should be added to the framework.

Dr. Demerjian was concerned about the interface between ecology and water quality. One driver has been reorganization and bringing all NERL laboratories together to address certain issues. He was unsure whether the system would allow NERL to complete the entire process of planning research, which is why the Subcommittee recommended that NERL choose one issue and follow it through the process. Dr. Sheldon acknowledged that NERL had planned to do this, but every problem needed spatially explicit modeling experts. If all of these experts were committed to the first problem, then addressing the next problem would be an issue. Instead, NERL identified the range of necessary actions and divided the expertise to address the various problems.

Dr. Sayler noted that no prioritization process was in place. Dr. Sheldon explained that individual problems were considered based on their increased uncertainty and risk. Dr. Sayler asked whether benchmarks would be established to determine whether to stop or continue research. Dr. Sheldon responded that these benchmarks were mandatory.

Dr. Robert Kavlock, Director of NCCT, provided an overview of the Center's response to its most recent BOSC review. He thanked the Subcommittee for their time and efforts in conducting NCCT's third BOSC review since February 2005; NCCT appreciates BOSC's advice and guidance. The goals of the review were to provide NCCT with advice on the progress it had made during the past year in fulfilling its mission and strategic goals. Particularly, the Subcommittee addressed six charge questions for five NCCT activities: ToxCast™, informatics technology/information management, the Virtual Liver project, developmental systems biology, and arsenic biologically based dose response.

Overall, the Subcommittee was pleased with the progress that NCCT had made toward its goals while "making connections within and outside EPA to leverage the staff's considerable modeling expertise, expanding its capabilities in informatics, and making significant contributions to research and decision-making throughout the Agency." The Subcommittee was pleased that "informatics tools developed by the Center already are being used by program offices, and the program offices are taking advantage of the expertise of the Center in developing critical elements for risk assessment." The Subcommittee specifically recommended that the Center: (1) identify stakeholders and increase their involvement, (2) initiate discussions with risk assessment practitioners, (3) develop effective methods to manage the wealth of data, (4) examine the relevance of ToxCast™ beyond toxicity prioritization to include exposure

paths and ecology, (5) develop detailed milestones and a timetable, and (6) create detailed project plans for virtual tissues (v-tissues).

In response to the recommendations regarding stakeholders and risk assessment practitioners, NCCT will identify and invite key stakeholders to the next BOSC review and participate in the v-tissues workshop (with the European Union) in April 2009, and the ToxCast™ data summit in May 2009, both at EPA. Currently, NCCT is engaging in regular discussions with the National Center for Environmental Assessment and others. Dr. Kavlock pointed out that the team for the Virtual Liver project includes risk assessors. In response to the recommendation regarding data management, NCCT has an extensive suite of interactive databases under development and is consulting with program offices and others about prioritization of data input. To examine the relevance of ToxCast™, NCCT has expanded workgroups to address exposure pathways through "ExpoCast" (the exposure relevance to toxicity signature predictions) and is testing pharmaceuticals in Phase II of ToxCast™ to compare results to known human toxicities. Detailed milestones have been implemented for ToxCast™, v-tissues, and informatics technology/ information management; short- and long-term goals for the Virtual Liver project have been identified; and a detailed project plan for v-embryo has been developed. All of these are detailed in ORD's response to the letter report. Milestones for the arsenic biologically based dose response project have not been developed as a result of significant changes in the plans for this work; this also is described in ORD's response. Currently, NCCT is developing the next ORD Computational Toxicology Research Implementation Plan, which will cover 2009-2012 and reflect the recommendations from the most recent BOSC review; milestones and plans developed as a result of these recommendations will be incorporated. The plan will be presented to the BOSC Computational Toxicology Subcommittee during 2009.

Dr. Sayler noted that Drs. James Clark and George Daston serve on the Computational Toxicology Subcommittee even though they no longer are members of the BOSC Executive Committee. Dr. Sayler indicated that a member of the Executive Committee will be added to the Subcommittee prior to the next review. He asked Dr. Kavlock if he had any thoughts regarding the composition of the expertise of the Subcommittee. Dr. Kavlock responded that the Subcommittee could benefit from additional expertise in computational biology and informatics; he noted that Dr. John Quackenbush's insights have been helpful.

Dr. Paustenbach noted that this program has great potential and he commended Dr. Kavlock for his efforts in directing the program.

Dr. Sayler asked at what point a data set is so large that its size becomes a limiting factor. Dr. Kavlock replied that size and computing power is not the limiting factor; rather, the limiting factor is the personnel to run the computations and understand the relationships. He added that expanding the use of postdoctoral fellows will help.

Dr. Lambert asked whether the pharmaceutical industry was providing information to NCCT in addition to agents. Dr. Kavlock replied that, per the agreement, the pharmaceutical industry will deliver the materials for screening, the preclinical and clinical data available on the human manifestations, and kinetic data on rodents and/or humans. Additionally, the industry has entered a ground-breaking agreement to make the computational toxicology data public. Dr. Lambert asked how the in-house research at various pharmaceutical companies compared to that of EPA in terms of timeliness. Dr. Kavlock responded that it was difficult to determine because these companies do not share their research strategies, but they appear to find EPA's work of value. There are 19 laboratories generating chemical data, and he does not believe that an effort of this scope has been completed in the pharmaceutical industry.

Dr. Paustenbach asked whether there was a genomics group within NCCT. Dr. Kavlock replied that the Center's 22 staff members are computer experts. If the Center requires genomics expertise, it will obtain it via a contract or in collaboration with the National Health and Environmental Effects Research Laboratory (NHEERL).

Dr. Sayler asked whether the number of attendees for the upcoming May meeting was limited. Dr. Kavlock responded that it was an open meeting limited only by the size of the conference room, which holds approximately 300 people. Those who submitted abstracts analyzing data will be given first priority, but NCCT is taking steps to ensure that the various sectors are represented at the meeting.

**Science Advisory Board Activities**

*Dr. George Lambert, University of Medicine and Dentistry of New Jersey, Science Advisory Board (SAB), Liaison to the BOSC*

Dr. Lambert provided information about the SAB "Looking to the Future" meeting held in October 2008. Dr. Duke and Dr. John Giesy of the BOSC were in attendance. Two of the sessions focused on biofuels and epigenetics research, with three to four presentations within each session. Biomass was the focus of the biofuels session, specifically how much should be allocated for fuel and how much for food. It was stressed that each decision affects many other environmental areas, and unintended consequences of decisions must be examined. Because biomass can account for only 20 percent of biofuel, it cannot eliminate dependence on gasoline. When asked what EPA should consider, the experts stressed that the Agency must: (1) build on past research to meet future energy and food production challenges; (2) be involved in critical biofuel decisions affecting the environment; (3) invest in full life-cycle analysis that addresses greenhouse gas and other environmental impacts; (4) invest in research and foster policies that encourage environmentally friendly agricultural practices; (5) provide leadership to develop appropriate models, monitoring, and measurement methods to quantify the environmental impacts of biofuels; (6) invest resources to improve life-cycle, sensitivity, land-use partitioning, and indirect land-use analyses; and (7) support and study the potential for cellulosic ethanol, including the use of grasses for ethanol. Experts also were concerned about increased use of pesticides.

The epigenetics session also was insightful. It is possible to observe epigenetic variations over the course of four generations of male lines with pronounced affects. Epigenetics is an emerging field, and it will have a tremendous impact on toxicology and nutrition. The experts suggested that the Agency focus on neurological effects, schizophrenia, autism, neurodegenerative disease, childhood obesity, diabetes, childhood diseases, and endocrine disruptors. The epigenome can be affected adversely when exposed to new environmental challenges. Dr. Philbert noted that, in terms of the epigenetics of the male line discussed at the SAB meeting, mitochondrial DNA has perfect penetrance through the maternal line.

Dr. Duke, who attended the biofuels session, said that the discussion captured three major issues: (1) land-use impacts, (2) water-use impacts, and (3) the importance of life-cycle analysis to capture these impacts. Current models are not well developed for conducting these analyses.

Dr. Lambert explained that the SAB met in December 2008, to discuss the Board's role under the new Administrator. The minutes of the meeting are available for interested individuals. Three charge questions were formulated during the meeting. The first involves development of advice on priorities, issues, or challenges that the new Administrator should address immediately. This is an opportunity for the Agency to take a leadership role and promote its expertise, science, and agenda within the Federal Government. Suggestions were made for EPA to expand its research base, ensure the integrity of Agency science, ensure its leadership role throughout the Federal Government, and be involved in all environmental issues. It was suggested that a presidential climate-energy-environmental team be developed. Additionally, issues of sustainability and improving the science of cumulative risk assessment are important.

The second charge question called for the development of a plan and a charge for a special Administrator's project for strengthening the science at EPA. The SAB will hold a meeting devoted to this topic on June 8-10, 2009. Dr. Lambert thought this would be a good opportunity for the BOSC to provide input. The third charge question dealt with creating strategies to increase the SAB's effectiveness and efficiency; the BOSC apparently is examining the same issue. A letter to the Administrator derived

from the meeting topics will be available in March 2009. Additionally, an annual EPA budget meeting is tentatively scheduled for April 21-23, 2009.

Dr. Lambert stated that the SAB Operating Plan for fiscal year (FY) 2009 was included in the meeting materials. He noted that the SAB would welcome input from the BOSC on any of its activities. The Operating Plans for the Clean Air Scientific Advisory Committee and the Advisory Council on the Clean Air Compliance Analysis also were included in the BOSC meeting materials.

The Children's Environmental Health Caucus in the U.S. Congress has been renewed and reinvigorated. It is being led by U.S. Representatives Rush Holt and Frank LoBiondo of New Jersey; Representative LoBiondo replaces former Representative Jim Saxton. The first briefing, which will be held after April 2009, will deal with school air quality, prompted by a *USA TODAY*/Johns Hopkins article. The briefing will include Dr. Patrick Breysse of Johns Hopkins who was involved with the article and Dr. Rob McConnell of the Children's Environmental Health Center at the University of Southern California and University of California at Los Angeles (UCLA). Dr. Lambert asked that BOSC members should contact him if they have suggestions about others who should attend the briefing. He emphasized that the caucus informs Congress; it does not lobby. There are approximately 30 caucus members.

Dr. Sayler noted that the SAB did not have a large role in reviewing last year's budget and asked whether the SAB was more involved this year. Dr. Lambert responded that historically, the SAB has been involved in the "fine tuning" of the budget; however, the Board members did not think this involvement had much of an impact on the overall budget and its direction. The new approach is for the SAB and the BOSC to examine strategically a 2- to 4-year timeframe and provide input. Dr. Lambert responded that Dr. Kevin Teichman might be better able to answer that question. Dr. Teichman said that ORD will make a presentation on the FY2010 budget, which still is in deliberation. Although the budget normally is public by this time, the change in administration delayed its release. Last year, the House Committee on Science and Technology did not hear oral testimony from the SAB, but the SAB did send written testimony to the Committee. Dr. Teichman indicated that he has been encouraging the SAB discussions at a strategic level in the absence of budget constraints.

Dr. Philbert re-emphasized Dr. Lambert's comment regarding strengthening the research structure within the Agency. The BOSC National Center for Environmental Research (NCER) Standing Subcommittee views with dismay the pernicious decline in budgetary support. Dr. Philbert noted that the best time to raise money is when things are bad, so that one is first in line when things are good. What can the BOSC, SAB, and partners such as the American Association for the Advancement of Science (AAAS) do to help EPA develop well-articulated arguments and place the Agency in a good position to appropriately expand its research mission once the budget situation changes? Dr. Demerjian noted that it is disconcerting that other science agencies are mentioned in the stimulus package, but EPA is not. Dr. Lambert added that the budget has been flat or declining since 1982. The American public expects the Agency to protect their health, but EPA does not have the budget to accomplish this. The public does not have enough information to understand the issues. Dr. Falk thought that the Superfund and Brownfields projects were included in the stimulus package. Dr. Philbert explained that this funding is not for research and does not affect ORD.

Dr. Sayler reiterated that if an Executive Committee member would like to participate in any of the SAB activities, they should notify him, Ms. Kowalski, or Dr. Teichman. The member would be asked to provide a report on the effort to the BOSC. Dr. Sayler noted that the SAB is attempting to increase its interactions with the BOSC and he thought the Executive Committee should take advantage of these opportunities when possible.

**AA/ORD Remarks**

*Lek Kadeli, EPA, Acting Assistant Administrator for ORD*

Mr. Lek Kadeli noted that a new EPA Administrator had been appointed since the last BOSC meeting. Mr. Kadeli currently is serving as the Acting Assistant Administrator (AA) for ORD, and Dr. Teichman will continue as Deputy AA for Science for ORD. Additionally, Dr. Teichman is serving as the Acting Science Advisor for ORD, and Dr. Larry Reiter is serving as the Deputy AA for Management for ORD. Dr. Reiter will focus on ORD transformation effects to determine how ORD can be more effective. Mr. Kadeli noted that he appreciates the sound advice and wise counsel of the BOSC.

Although transitions can be full of uncertainty and indecision, Mr. Kadeli has spent enough time with Administrator Jackson to determine that this will not be the case. The new Administrator is interested in science, and her first EPA visit following her confirmation was to ORD. The President's stated agenda for the environment presents opportunities for ORD to advance the role of science within EPA. The President expects EPA to uphold three values: (1) science must be the backbone for EPA programs, (2) EPA must follow the rule of law, and (3) EPA's actions must be transparent. Mr. Kadeli believes that ORD will have a major role in supporting the new administration's commitment to science and will continue to rely on the BOSC to provide guidance and expertise.

Administrator Jackson has committed her personal attention to five priority areas: (1) reducing greenhouse gas emissions, (2) improving air quality, (3) managing chemical risks, (4) cleaning up hazardous waste sites, and (5) protecting U.S. waters. EPA's funding in the House version of the stimulus package included investment in a number of these areas. As ORD moves forward in Agency budget discussions and discussions with the Office of Management and Budget (OMB), it is hopeful that the new administration's commitment to science will be tangibly reflected in future ORD resource levels. ORD also realizes that its budget will be designed in the context of the current fiscal challenges. ORD will be engaging the new administration in strategic discussions about the ORD transformation. This includes examining environmental problems and how ORD addresses them as an organization so that ORD can draw on its unique expertise to solve broad problems of national significance and provide the targeted research needed by program and regional offices. ORD is interested in BOSC input regarding the transformation. Dr. Teichman will provide more information and answer any questions regarding this transformation during his presentation.

In this era of fiscal realities and increased program needs, career staff members have been examining how ORD can best serve the Agency's needs. The goal is to move ORD to a "better place" to address these needs. There is considerable work involved in achieving this goal, and it is a healthy sign that ORD is evaluating its role and looking for opportunities to improve itself. Mr. Kadeli noted that an important aspect of success is how ORD engages its stakeholders.

Dr. Paustenbach said that, although he did not know how government transitions occurred between administrations, during industry leadership transitions external experts often perform interviews with the top 20 people in the organization to determine what challenges the new leadership may face. This information is reported to the new president of the organization. During the last 16 years, there have been internal conflicts within ORD regarding its goals and charges. It would be a wonderful accomplishment for the external stakeholders and internal staff to move in the same direction.

Mr. Kadeli explained that a large transition team met and interviewed 150 to 200 staff members within all of the federal agencies. He and Dr. Teichman were interviewed in what he thought could be characterized as an honest, open dialogue. The team members were familiar with the Agency and its challenges and opportunities. The team prepared and provided a report to the new administration. Dr. Falk added that the questions to CDC managers were very focused on what is and is not working. He asked whether the AA is the only position within ORD that requires congressional approval and whether this is standard across the various offices. Mr. Kadeli confirmed that the AA is the only ORD position

that requires congressional approval; each office has one politically appointed position, although some offices may have a second deputy position that is politically appointed. In general, it is the AA positions that require the confirmation process as well as the Administrator and Deputy Administrator of the Agency. Currently, there is no information about who may be appointed to ORD's AA position, but the hope is that the position will be filled within the next 12 months.

Dr. Lambert asked about ORD's perception of receiving increased funding from the stimulus package given the emphasis on science. Mr. Kadeli replied that classic methods to stimulate the economy include projects that have quick outlays. There is a spectrum of projects within the stimulus package, and some of them have quick outlays, whereas others do not. Research generally outlays over a longer period of time. Although it is not confirmed, purportedly some of the projects taken out of the Senate version of the package include grant monies. A $1 billion grants program for graduate students probably would outlay within the first year. Members of Congress are looking for funds that will support their state programs that have been negatively impacted. The hope is that the Science To Achieve Results (STAR) grants program will benefit, as the current budget is approximately one-half of its historical level.

Dr. Sayler noted that the Administrator's five focus areas correlate loosely but not perfectly with ORD's laboratory and center activities. Will these activities be realigned? Mr. Kadeli responded that the current intent of the transformation is not to reorganize ORD; however, at the end of the process it may be determined that there is a more effective alignment. The current structure offers the opportunity to address Agency needs, but the portfolios may need to be adjusted. If the Administrator requires ORD to expand its efforts on a certain program, then realignment will be necessary. The structure will follow as required.

Dr. Demerjian noted that the focus area of greenhouse gases does not appear to be aligned with existing activities. He asked whether this would be a case in which the science is performed by other agencies and EPA assumes a regulatory role. Dr. Teichman responded that EPA is reconsidering the California waiver and will pursue other policies for examining carbon dioxide. The vast majority of resources for the Climate Change Science Program is within other agencies with EPA performing a critical role in assessment that informs policy deliberations. Dr. Demerjian asked if this role could inform a new Clean Air Act. Dr. Teichman replied that reauthorizing the Clean Air Act would take a considerable amount of time and effort. Legislative attention is not under its purview, but ORD will continue to exercise its appropriate authority to address pollution problems.

Dr. Haas asked Mr. Kadeli if he thinks the matrix system of White House-level science committees will continue. He also asked whether EPA is considering the appropriate follow-through activities as a result of the National Academy of Sciences (NAS) report, *Science and Decisions: Advancing Risk Assessment*. Mr. Kadeli responded that the White House science committees probably would continue, at least in the short term. There has not been any indication that the new administration wants to move away from this structure. In terms of the question regarding the NAS report, Dr. Teichman replied that EPA had commissioned two NAS studies, one on cumulative risk with a focus on phthalates and one on the risk assessment process. The latter study determined that the Agency needed to take a more holistic approach. EPA is taking the report very seriously, and it will influence Agency activities.

Dr. Lambert mentioned that Lisa Jackson had been impressed with the SAB model and had left instructions that it be used in New Jersey.

Dr. Sayler thanked everyone for their participation and recessed the meeting at 4:44 p.m.

## TUESDAY, FEBRUARY 10, 2009

Dr. Sayler called the meeting to order at 8:15 a.m., and asked Dr. Teichman to provide the ORD update.

### ORD Update

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

Dr. Teichman explained that he will provide his perspective on the ORD transition. The new Administrator has stated that science must be the backbone of the Agency's decision-making. The first organization that she visited at EPA was ORD, and she currently is the only confirmed EPA appointment. He expressed his hope that the positions of AA and Science Advisor for ORD will be filled as soon as possible.

ORD is committed to EPA's mission, and the Agency is committed to environmental protection. EPA is the only federal agency that addresses both human health and ecological resources, and these two areas influence each other within the Agency. The continuum of work at the Agency includes sources of pollution, outcome, exposure, effects, risk assessment, and risk management. EPA also has the ability to perform intramural research and fund extramural research. Within EPA, ORD is unique. Dr. Teichman said he has discussed the transformation of ORD with the SAB, including embracing an integrated multidisciplinary research approach. This is consistent with the guidance from the SAB that the Agency's research must go "beyond its immediate regulatory needs and address the broad array of environmental problems facing the nation." ORD is ensuring that broad, complex, national needs are being addressed in addition to targeted needs.

Dr. Teichman explained that the buying power of research has decreased over time; therefore, it is necessary to examine ORD to ensure it is as productive and efficient as possible. Because ORD can excel at integrated multidisciplinary research, this approach has been adopted within ORD while continuing to perform targeted research for program and regional offices. Integrated multidisciplinary research can address problems of broad national and international significance, such as climate change, alternative energy, toxicity assessment in the 21st century, and ensuring an ample and safe water supply. While addressing these broad areas, targeted research also must continue. The integrated multidisciplinary approach uses a true collaborative approach to solve problems. More than one discipline is included in this integrated approach, and knowledge is synthesized at all phases. Dr. Teichman illustrated the approach with an example of how to collaborate on the biofuels issue. Additionally, ORD will work with the program offices to determine exactly what they need; this will ensure that ORD's research provides the information necessary to develop regulations. Transformation includes an examination of how ORD transforms itself to plan, conduct, and deliver research in an integrated multidisciplinary approach to complete its mission.

Dr. Philbert thanked Dr. Teichman for this overview. He indicated that ORD's concept of integrated multidisciplinary research had been presented at the previous week's NCER Standing Subcommittee face-to-face meeting, and the Subcommittee members had some questions about it. He noted that academia views multidisciplinary research as integrated research and many of the Subcommittee members thought the terms redundant. How is this approach different than bringing researchers together around a research project? Dr. Teichman replied that this approach brings together those who do the research, address the problem, and implement the solution. There are several areas in which ORD could have better tailored its research if it had used this approach initially. The Office of Water (OW) presents a list of water-related needs to ORD, and the Office of Air and Radiation (OAR) does the same for air needs, but the needs are not integrated across all media. There must be a method in place to address cross-cutting problems.

Dr. Philbert asked about opportunities to scale down the research (i.e., one or two lower level researchers talking to each other rather than at the highest levels). Dr. Teichman responded that the plan is to perform scaled-down research in addition to the integrated multidisciplinary research. Targeted research must

continue, and ORD must have the capability to perform both types of research. For everything to fit together, high-level planning is required.

Dr. Demerjian noted the complexity of the problems that must be addressed; for example, the issue of biomass and how much is allotted to food versus fuel. He asked how EPA has approached such issues and whether the approach has been working. Dr. Teichman responded that interagency collaboration is one method, but—although this is excellent for exchanging information—it is not optimal for planning research. ORD works with the CDC in terms of research on health outcomes and understanding by surveillance. Relationships that have been built with scientists at other agencies are more helpful for research planning than interagency committees.

Dr. Paustenbach asked for clarification about what ORD is transforming into. Dr. Teichman responded that ORD is hoping to adopt the integrated multidisciplinary research approach to integrate the individual offices and laboratories. Dr. Paustenbach was unsure how the BOSC could help with this transformation. He also noted that the agenda of the new administration will bring significant changes. He suggested that EPA is unsure of how to best deal with large problems because its scientists are not trained to think in this manner. Dr. Paustenbach noted that this will be a major transition. There are numerous federal agencies seeking funding. Is there something EPA can do now to influence that funding? Dr. Sayler commented that this is a difficult question to answer because the BOSC advises ORD about what it already is doing.

Dr. Sayler stated that if the integrated multidisciplinary research approach becomes a transformational property across ORD, then the charge questions for BOSC program reviews will need to reflect this. He asked how the BOSC will address and evaluate whether ORD research programs are moving in the direction of integrated multidisciplinary research. Dr. Teichman explained that the SAB examines ORD's strategic directions to determine whether the Office is moving in the right direction; the SAB also ensures that ORD is aware of activities that other agencies are carrying out. This helps ORD determine in which areas it should be working. The BOSC examines whether ORD coordinates with other agencies and groups, is working to break down silos, and accomplishes its goals. ORD will re-train researchers if necessary, and ORD staff members are willing to shift to this new paradigm. Some researchers will continue to perform targeted research, and others will contribute to addressing problems that they have not worked on previously.

Dr. Haas suggested that ORD develop a stronger, more formal program of performing short-term assignments to obtain cross-fertilization. Dr. Teichman responded that there is a move to expand experiences; this will be within another part of ORD or a program office.

Dr. Demerjian said that ORD has a good skills set, which will enable it to handle the transition. He noted that major policy questions, such as about the food supply, do not fall under EPA's purview. He believes that ORD has a set of qualified people who can handle this transition. Dr. Teichman noted that when dealing with major environmental issues, only the issue of climate change cross-cuts the traditional offices. Researchers will be needed to understand the sources, exposures, and effects. These are skills that ORD possesses, and postdoctoral fellows can bridge any gaps. The current workforce can be trained to address new challenges.

Dr. Lambert noted that two of the major topics of the SAB are how to improve the role of the SAB and make the Board more efficient and effective. Former Administrator Stephen Johnson suggested that the SAB look at improving science at the Agency. Dr. Lambert then asked the Agency's view of Ms. Carol Brenner's role. Dr. Teichman replied that the Council on Environmental Quality, Administrator Jackson, and Ms. Browner will need to work together to determine how they can best cooperate with each other.

**Nanomaterials: ORD Research To Inform Environmental Decisions**
*Mr. Jeff Morris, EPA/ORD, National Program Director (NPD) for Nanotechnology*

Mr. Jeff Morris explained that the Agency's Nanotechnology Research Program is a $10-15 million/year program. He reminded the BOSC members that Dr. Randy Wentsel provided an overview of the program last year to the BOSC; today's discussion will provide a decision-support context. There are three key questions that the Program is attempting to address: Are nanoscale particles different as environmental contaminants? If they are different, how will risk be assessed? If they are risky, how will they be mitigated? Context is important. EPA interacts with other groups to develop information to support decisions regarding nanomaterial safety. The Nanotechnology Environmental and Health Implications Working Group coordinates the $60 million investment in nanotechnology safety. The Agency interacts bilaterally with other agencies, such as the Department of Health and Human Services' National Toxicology Program. The Organisation for Economic Co-operation and Development (OECD) considers this an internationally important issue, and industry and environmental non-governmental organizations (NGOs) are part of OECD's nanotechnology effort. Industry also interacts with the Agency through the Office of Prevention, Pesticides, and Toxic Substances' (OPPTS) regulation of new materials. Additionally, EPA and the National Science Foundation (NSF) have established two Centers for the Environmental Implications of Nanotechnology at Duke University and UCLA.

There are several federal sources that inform EPA nanotechnology decisions in a variety of areas (e.g., characterization properties, toxicity, detection, monitoring, fate and transport). These agencies include the National Institute of Standards and Technology (NIST), Department of Defense, Department of Energy (DOE), and so forth. NIST is planning work regarding toxicity, pharmacokinetics, and fate and transport of nanomaterials, and EPA will need to communicate with NIST about these efforts. There is a great deal involved in addressing questions regarding nanotechnology, and addressing these questions is important to EPA's decision process. OECD has coordinated international cooperation, including a testing program. As an example, the United States and Japan will co-lead the effort to investigate $C_{60}$ fullerenes and single- and multiwalled carbon nanotubes. The U.S. effort will focus on ecotoxicology and environmental fate and transport. The goal is to accomplish two objectives. The first is to understand how to test these materials and modify test guidelines to exchange data. The second is to gather a body of information (knowledge base) that is useful to the scientific community.

There are four questions related to environmental decision-making regarding nanomaterials: Which nanomaterials, in what forms, are most likely to result in environmental exposure? What particular nanomaterial properties may raise hazard concerns? Are nanomaterials with these properties likely to be present in environmental media or biological systems at concentrations of concern, and what does this mean for dose response and risk? Can the hazardous properties be changed or exposure mitigated? ORD is examining the risk assessment problem from a life-cycle approach. In the near term, the risk assessment paradigm, however, will not be sufficient because it will take at least several years to develop nanoparticle effects and exposure databases as robust as those currently used for risk assessment.

The vision for ORD's Nanotechnology Research Program is to build an integrated, multidisciplinary team that will foster excellence through partnership and be valued for its contributions to decision support. The goal is that nanotechnology products will be safer and better as a result of ORD's work. Because all EPa program offices likely will be presented with nanomaterial problems, ORD will need to provide these offices with decision-support tools. The challenges will be getting all partners to move in the same direction, finding the right collaborations and building effective networks, effectively leveraging every work hour and research dollar, and creating an excellent program in an uncertain and complex environment.

The nanotechnology research strategy has four themes, each with a variety of key questions and challenges. The themes are: (1) sources, fate, transport, and exposure; (2) human health and ecological

research to inform risk assessment and test methods; (3) risk assessment methods and case studies; and (4) preventing and mitigating risks.

Mr. Morris identified five key points. First, decision-makers need information grounded in reality, and researchers should understand decision-makers' needs. Second, a life-cycle perspective is important. Third, preventing pollution is better than "managing" risk. What information can researchers provide to decision-makers that can prevent hazards and unintentional exposures? Fourth, the best manner to develop an integrated ORD program that functions as a single team, regardless of investigator discipline and laboratory or center affiliation, must be determined. Fifth, the goal is for every ORD nanotechnology investigator to be able to say how his or her research is contributing to nanomaterial safety. What role(s) can the BOSC play to advance this goal?

Dr. Sayler noted that life-cycle analysis is embedded throughout the Program, and the Agency has a long history with this approach. Is life-cycle analysis being considered as a tool to drive integrated multidisciplinary research? Mr. Morris confirmed that it was being used, and added that ORD wants to apply life-cycle analysis approaches to the research questions.

Dr. Duke asked about the role of the UCLA and Duke University centers. Mr. Morris replied that the recently established centers are co-funded by NSF and NCER and were established to address mission-support questions such as fate of nanomaterials in the environment. This research will be complementary to ORD research. ORD will be examining many of the same questions and will meet with the two centers to divide the work. Duke is using mesocosm studies to examine nanosilver.

Dr. Demerjian commented that there can be a variety of exposure routes for nanomaterials as with other pollutants. One exposure route that has been in play for many decades is exposure from gas and diesel motor vehicle combustion. Is there an effort by the health effects community to look at this problem as providing historical perspective of how nanoparticles may be a problem? Mr. Morris replied that the work on airborne particulate matter has been foundational for moving into nanomaterial research, particularly the ultrafine particulate matter work, which has allowed the understanding of potential cardiopulmonary effects. As a result of this, examination of cardio effects is required in the OECD testing program. Additionally, the inhalation route is the route by which nanomaterial exposure likely will occur.

Dr. Katherine von Stackelberg asked for clarification about the number of nanomaterials included in the research efforts. Has ORD decided which specific constituents that it will investigate or will ORD take a broader view, examining those nanomaterials that are likely to result in environmental exposure? Mr. Morris responded that ORD started with a list of 14 possible targets identified by OECD that were likely to be incorporated into products. ORD then identified seven that are of concern to the Agency; the focus may shift, however, if other nanomaterials are deemed to be of concern in the future.

Dr. von Stackelberg noted that there are few measurement tools, so it will be necessary to rely heavily on models. How is the Agency evaluating these models? Mr. Morris explained that ORD's Athens, Georgia, laboratory used its existing environmental fate capability to develop a fate and transport model for $C_{60}$ fullerenes and in parallel developed a sand column study to determine how the $C_{60}$ fullerenes moved through the column. The groups are working in parallel to develop empirical data to test the model; the sand column study is close to completion. The next step will be to open source the fate model.

Dr. von Stackelberg asked whether the NCCT is involved with the integrated multidisciplinary research. Mr. Morris said that the NCCT is involved. For instance, the Nanotechnology Research Program worked with OPPTS to require, for every premanufacturing notice submitted for a carbon material, that the manufacturer submit a 1 g sample to be used in the ToxCast™ program to run ToxCast™ assays on the material.

Dr. Ryan noted that nanomaterials are similar in size but vary chemically. What program is ORD devising to analyze these in multiple media (e.g., sand, soil, food, air)? Mr. Morris explained that the researchers are starting simple, which is why the sand column was chosen. The Program must be focused, because it is an impossible challenge to determine every permutation of all material types across all media in all exposure scenarios. As EPA begins its nanotechnology research, other agencies and countries are performing different studies on the same materials, and all of these entities will share results and develop new research questions based on the results.

Dr. Philbert commented that it is unlikely that humans will be exposed to pristine nanomaterials outside of the manufacturing process. When the materials combine with biology, biology only has a certain subset of responses. The concern is that the pristine nanomaterials that EPA is categorizing will bear no resemblance to the nanomaterials to which people will be exposed in the environment. Mr. Morris acknowledged this but noted while some researchers outside of EPA are testing only on pristine nanoparticles, ORD is first finding out what the particles transform into as they move through environmental media, and then conducting targeted effects research based on fate and transport and exposure findings. Research still is needed, however, on pristine particles in order to understand what particle characteristics (e.g., surface charge, aspect ratio) may induce hazard.

Dr. Philbert asked about the rationale to make an enormous investment in exposing animals to monodispersed carbon nanotubes if they ultimately agglomerate into a noninhalable form. Mr. Morris explained that EPA realized that it could not make this investment, which is why it asked the OECD member nations to share the burden. Collaboration may make it possible to conduct these tests. Currently, it is unknown how informative the research results will be, but if this route is neglected and sound approaches to toxicology are not developed for these materials, then future problems may arise.

### Water Quality Mid-Cycle Draft Report Presentation

*Dr. Herb Windom, Professor Emeritus, Skidaway Institute of Oceanography, Water Quality Mid-Cycle Subcommittee Chair*

Dr. Herb Windom presented the Water Quality Mid-Cycle Subcommittee's draft report to the Executive Committee by telephone. Dr. Windom, who formerly served as a member of the BOSC Executive Committee, chaired the Water Quality Mid-Cycle Subcommittee. He mentioned that Dr. Sayler also served on the Subcommittee. The report is a succinct, mid-cycle review of the Water Quality Research Program; the full BOSC program review occurred in 2006. Six of the seven members of the Subcommittee that conducted the 2006 review also served on the Mid-Cycle Subcommittee. The face-to-face meeting of the Mid-Cycle Subcommittee occurred in September 2008. The seven charge questions were similar to those for mid-cycle reviews of other ORD research programs. The purpose of the mid-cycle review was to determine the progress the Program had made in responding to the previous full program review and provide feedback.

The basic conclusion of the Subcommittee was that the Water Quality Research Program had been responsive to the BOSC's 2006 recommendations. Enhanced transparency was one broad recommendation, and the Program provided several examples of how it had increased transparency. Additionally, the Program has held productive workshops with stakeholders to identify Annual Performance Goals (APGs). The Multi-Year Plan (MYP) also changed in response to the 2006 BOSC program review as well as internal Agency changes. In the 2006 review, the Subcommittee recommended that the Program perform an annual accounting of outcomes. One of the Program's responses to this recommendation was to conduct a bibliometric analysis. Another broad recommendation from the 2006 review was for the Program to reinstate support for exploratory STAR grants. Dr. Window acknowledged that this is a funding issue for the Program. In response to a broad recommendation to increase partnering and collaboration, the Program is collaborating with a number of organizations. Another broad recommendation was to improve the MYP to better communicate Program goals; the revised MYP does a better job of communicating the Program to external clients and ORD. Dr.

Window stated that the responses to the numerous specific recommendations are contained within the letter report.

During the 2006 program review, the Subcommittee highlighted the need to establish a more systematic approach to communicating with clients. In response, the Program established a Water Research Coordination Team, which has improved communication with clients. In terms of the second mid-cycle charge question, the MYP underwent significant revisions since the program review and now includes three Long-Term Goals (LTGs). The Subcommittee thinks that this is a better approach to communicating the Water Quality Research Program, but the members had one concern that Dr. Windom agreed to explain later in his presentation. It is clear that the Program is addressing critical research to meet the regulatory mandates of the Clean Water Act (Charge Question 3). The feedback from the client survey of states, OW, and others indicates that the MYP is responsive to their needs. In terms of Charge Question 4, the Subcommittee thought that the Program was responsive but was concerned about the manner in which the new MYP is divided into three categories. Watershed management falls under LTG 1, and remediation of wastewater infrastructure also falls under this goal. LTG 2 should link to the other LTGs that relate to it. In response to Charge Question 5, the Subcommittee members thought that the Program provides a balance among its three LTGs.

Charge Question 6 concerned whether existing Program Assessment Rating Tool (PART) performance measures provide appropriate and quantifiable indices of progress. The Subcommittee made six recommendations regarding performance measures in the 2006 review; two of the six recommendations were implemented. The bibliometric analysis was one measure, but there were four other measures that were not met. The Program has indicated that it will implement these measures in the future. Dr. Windom noted that investment efficiency also is an issue that needs to be addressed. The final charge question called for the Subcommittee to assign a rating to the Program. The Subcommittee members agreed that the Water Quality Research Program meets expectations. Dr. Windom explained that it would be unreasonable to expect more than this, because the Program has been responding to so many changes and inputs in such a short time period. The Subcommittee identified some areas in which the Program exceeded expectations, including the application of molecular approaches to water quality issues and the development of tools to use weight-of-evidence approaches to assess water quality.

Dr. Sayler stated that Drs. von Stackelberg and Paustenbach had agreed to vet the Subcommittee's report. He asked them to provide their comments.

Dr. von Stackelberg noted that some of her comments may be revisited during the discussion on standardized report formats. She would this report, and all future BOSC reports, to include a table that shows, at a glance, the recommendations, responses, and ratings. She also wanted the report to indicate how the charge questions relate to the recommendations. Dr. von Stackelberg noted that the statement on line 25, page 1 of the report should be included up front to help readers understand the rating. In some areas, it was clear that the Program exceeded expectations, and it is not transparent how the final rating of "Meets Expectations" was reached. A summary table would be helpful to address this issue. In line 13 on page 6, the report states that "an annual accounting using metrics in the six areas suggested has not been achieved"; however, it is unclear whether it was even possible for the Program to achieve these measures. She noted that the sentence regarding APGs on line 4, page 9 was awkward and should be revised. Dr. von Stackelberg agreed to send her suggested editorial changes electronically to Dr. Windom.

Dr. Windom explained that the Water Quality Research Program mid-cycle review was one of the early mid-cycle reviews conducted by the BOSC. Most of the mid-cycle reports prepared at that time were succinct. Therefore, the Subcommittee attempted to keep the report short in accordance with the directions for mid-cycle reviews. The objective of the mid-cycle review is to gauge Program's progress and offer advice and feedback on its performance. Therefore, the Subcommittee did not go into great detail in this report. The members considered ranking the charge questions but were instructed not to do

so. Dr. Windom stated that the Water Quality Research Program has accomplished a great deal since the 2006 program review. The Program has a barrage of items to which it is responding, and the Subcommittee did not want to offer additional recommendations to which they would need to respond. The Subcommittee, therefore, focused on the important points. He emphasized that the Subcommittee members expect that the Program will implement the six PART measures. The Program had two reports to which it needed to respond, and the Subcommittee wanted to minimize the burden by providing advice and direction. The most important item in the mid-cycle report is the restructuring of the Program's LTGs. This is a very positive change that has improved the MYP and its communication of the Program; however, the Program must ensure that watershed research is cohesive under the three LTGs. Dr. Windom noted that the face-to-face meeting for the mid-cycle review lasted only 1 day, which allows limited time to organize the report. Dr. von Stackelberg agreed and noted that she was not calling for additional details but a simplification of the report.

Dr. Paustenbach said Dr. Windom's presentation of the report was clear and well done. Most of Dr. Paustenbach's concerns related to the layout of the report. If the Subcommittee members are convinced that the Program understood the 2006 recommendations, then the rating was not supported by the text. The response indicates that the Program is doing its best given the available resources.

Dr. Windom agreed that the BOSC Executive Committee could provide clearer direction to ensure that the mid-cycle reports are more standardized. He had no problem with providing a rating for each charge question within a summary table. He thought this would be very helpful to ORD's research programs because it would help them identify the areas they are doing well and those that need improvement. This is a legitimate way to look at the Program's progress.

Dr. Sayler stated that this would be discussed during the presentation on standardization of BOSC reports. He will forward the Water Quality Mid-Cycle Subcommittee's report in its current format, which was slightly longer than some of the other mid-cycle reports. Dr. Sayler noted that the some of the Subcommittee mid-cycle reports have indicated that the BOSC does not request a formal response from the program. He asked Dr. Windom whether the Subcommittee expected a response from ORD. Dr. Windom replied that the Subcommittee did not expect a reply; the members were convinced that the Program understands the expectations and they are confident that the Program will move in the right direction. He though requiring a formal response would just add an unnecessary burden.

Dr. Sayler summarized the vettors comments. A different organizational structure for the report would be helpful because it is a very detailed report. There do not appear, however, to be any serious criticisms of the report. Drs. von Stackelberg and Paustenbach will provide their comments to Dr. Windom who will revise the report as necessary. Because there were no substantive changes requested to the report, Dr. Sayler called for a motion to accept the report with the editorial changes of the vettors. Dr. Duke made a motion to approve the report, and Dr. Ryan seconded it. The Executive Committee voted unanimously to accept the report with the minor revisions suggested by Drs. von Stackelberg and Paustenbach. Dr. Sayler reiterated that there is no need for the Program to respond to the mid-cycle report.

**Optimizing the BOSC Review Process**

*Dr. Fred Hauchman, EPA/ORD, Director, Office of Science Policy*

Dr. Fred Hauchman remarked that the topic of his presentation appears to be one of great interest to the Executive Committee and ORD. Many individuals, including members of the BOSC, staff from ORD's Office of Science Policy and Office of Resources Management and Administration, and the NPDs, have been considering this issue for some time. The main questions are: How can the BOSC review process be optimized, and more specifically, does the BOSC have the right information and right volume of information to conduct program reviews? With the transformation of ORD toward integrated multidisciplinary research, it is necessary to ensure that the BOSC reviews can capture this as well as investment efficiency. Dr. Hauchman noted that the charges and materials are similar for each BOSC

review, but a great deal of time and effort are needed to produce the materials and conduct the reviews. The goal is to determine the best use of time for both the BOSC members and the EPA staff.

ORD managers have a great appreciation for the efforts of the BOSC reviewers but are concerned about the uneven engagement of the BOSC members. This uneven engagement could result for a number of reasons, including lack of time, the type of information being provided, or lack of a common understanding of the broad nature of these reviews. Some BOSC members have requested that individual papers be provided, but ORD is concerned that this could lead to detailed scientific discussions, which is not the purpose of the BOSC reviews. ORD staff members have questions regarding the value and presentation of the bibliometric analysis, improvement of the partner surveys, whether partner testimonials are adequately focused, and whether the posters provide the right amount of detail. Additionally, it is sometimes difficult for ORD staff to distinguish specific recommendations in the BOSC reports from general comments or views held by only one reviewer. It would be helpful if the recommendations were presented clearly in the reports.

Dr. Hauchman noted that the BOSC members and EPA staff in attendance are aware of the differences between a full program review and a mid-cycle review. For a full program review, the program is assessed at the LTG level; for a mid-cycle review, the program's progress since the program review is assessed. Dr. Hauchman identified a list of materials that are provided routinely for BOSC reviews. He also displayed a matrix created by Dr. Sally Darney, the NPD for Human Health Research, that illustrates which materials apply to which program assessment charge (relevance, structure, quality, coordination/communication, performance, and leadership). Dr. Hauchman then opened the floor for discussion.

Dr. Sayler pointed out that the list of materials provided for a particular review may be considerably longer than the list presented by Dr. Hauchman. Frequently in these reviews, there is a need to reference the Agency and ORD Strategic Plans. These are available on the Web so they should not be provided in the hardcopy materials. He emphasized that BOSC members just need easy access to these items. Dr. Sayler mentioned that some subcommittees examine the bibliography and biosketches, but others do not. He does not personally find this information particularly useful for the reviews and thought it could be provided on the Web site and not in hardcopy.

Dr. von Stackelberg commented that it is difficult to assess quality. Published articles and reports are good, but it would be more useful for research programs to identify the top 10 seminal publications to which they contributed since the previous review and make these available on the Web site. The seminal papers could be examined to assess the quality of the research. Also, receiving the posters in advance is very useful because it allows the subcommittee members time to formulate specific questions to ask the researchers during the poster sessions in advance. Dr. von Stackelberg thought it would be acceptable to provide the bibliography on the Web site.

Dr. Sayler agreed with the comment regarding the posters. Additionally, linking the posters to the LTGs would help with the evaluation. Dr. Falk indicated that these comments compare to those he received from the Human Health Mid-Cycle Subcommittee. He also noted that there is a great appreciation for ORD staff efforts, and the orientations during the conference calls are helpful. Being provided with 5 to 10 reprints of seminal articles would help with the evaluation of quality, and the bibliometric analysis needs to be summarized to increase its usefulness. Dr. Sayler cautioned that the BOSC reviews are not peer reviews; assessing publications for quality evaluation is acceptable, but the review should not turn into a scientific peer review.

Dr. Duke remarked that, from a practical standpoint, it is useful for Subcommittee members to receive items that are illustrative. Can the program staff select items that illustrate key aspects of the program? He emphasized that the review focus should be on key aspects and not the whole program. He added that it is not practical to review 30 to 40 posters during a review meeting. Dr. Demerjian commented that

dividing the responsibilities for reviewing the posters among the Subcommittee members eases this burden. He added that it may take considerable effort for ORD to simplify the current process, and suggested that an overview poster that ties the research to the LTGs may be an easy solution.

Dr. Ryan stressed that the most important poster is the one providing the overview of the whole program, LTGs, and chief accomplishments. This poster can be supplemented with posters that provide individual examples of what is being accomplished. Dr. Sayler added that the posters should detail the intermediate outcomes. Dr. Ryan agreed that it is not the role of the BOSC to examine individual papers and liked the idea of illustrative examples.

Dr. Paustenbach noted that information about the size and funding of the program as well as its mission should be provided. This will help the reviewers determine whether their expectations are consistent with reality, which will feed into the efficiency question. Dr. Sayler commented that this information often is provided in the program overview provided by the NPD or the Laboratory/Center Director.

Because the Executive Committee members chair the various subcommittees conducting these reviews, Dr. Sayler asked whether they were comfortable with accessing review materials on the Web site. His concern was that some individuals may be reluctant to do so and will only review the hardcopy materials. He stressed that it is the responsibility of the Subcommittee Chair to ensure that all subcommittee members are examining the information for the review. He described an experience he had with a Subcommittee member who relied only on the oral presentations and posters at the face-to-face meeting to analyze the research program. Dr. Duke agreed that it is the responsibility of the Subcommittee Chairs to ensure that the members review the materials in advance of the meeting and request additional information only when it is appropriate. Subcommittee Chairs also must identify when a comment included in a report is not the consensus of the Subcommittee.

Dr. Lambert asked whether ORD had any suggestions on how to improve the reports. Dr. Hauchman responded that ORD staff members have some thoughts about improving the process and the reports. The ORD Science Council currently is being revitalized, which includes Associate Laboratory/Center Directors and the NPDs. ORD may form a group to work with the BOSC EPA staff on this issue.

Ms. Drumm noted that the *BOSC Handbook for Subcommittee Chairs* identifies the Chair's responsibilities. Perhaps ORD and the BOSC need to re-examine the handbook to ensure that it provides adequate guidance, particularly for Subcommittee Chairs who are not members of the Executive Committee.

Dr. Paustenbach volunteered to serve on the BOSC workgroup that reviews the formatting of the BOSC reports. He suggested that this effort is related to the current discussion. Dr. Hauchman responded that ORD appreciates the input.

Dr. Sayler noted that the partner testimonials offered at the BOSC review meetings provide information about which outcomes are considered important. The Subcommittee members would like to see how that information is used and integrated in future planning. Outcomes are being achieved, which is good, but the process goes farther than this, and this should be included in the BOSC reviews.

**Investment Efficiency Discussion**

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

Dr. Sayler explained that this investment efficiency discussion is a follow-on from the December 2008 conference call, during which the BOSC members agreed to define efficiency using the terms "process efficiency" and "investment efficiency." The NRC report, *Evaluating Research Efficiency in the U.S. Environmental Protection Agency*, stated that ultimate outcomes are not effective measures because they take too long and depend on too many outside factors to achieve. Dr. Sayler used the recent BOSC review of the Homeland Security Research Program (HSRP) to illustrate the points found in the NRC

report; although the HSRP was making good front-end decisions, projects below the LTG level were not justifiable given the tools, metrics, and so forth made available to the Subcommittee. The Subcommittee wanted to see what decision process was being used to match the logic models provided on the front-end.

Dr. Sayler referred the Executive Committee members to the lessons learned from the BOSC HSRP review handout under the "Workgroup Updates" tab in the meeting notebook. The last section of the handout includes some questions and concerns regarding investment efficiency evaluation. He noted that these questions could be useful to the Agency in determining the information needed by the BOSC Subcommittees to evaluate investment efficiency. Dr. Sayler went over the questions and noted examples using the recent HSRP review. The HSRP is doing a good job communicating with its end users but is not providing these users with the tools they need because the Program is waiting until the product is "perfect." If these questions had been answered during the HSRP review, the Subcommittee would have been better equipped to evaluate the Program's investment efficiency.

Dr. Haas commented that the academic program accreditation process evolution is a similar analogy. Previously, an external review team examined academic program outputs (e.g., number of students graduated); currently, the focus is on evaluating the process whereby there is a continued assessment and reassessment underway in the program. This may be an appropriate approach to consider for the BOSC. The Subcommittees could assess whether the program leadership has an adequate system in place to make investment decisions and shifts. If there is an internal process for program reassessment, the BOSC review could focus on how decisions are made, whether there is an adequate process, and whether the decisions are being made in an appropriate manner.

In response to a question from Dr. Sayler, Dr. Demerjian explained how he plans to address the investment efficiency question at the upcoming Air Research Program review for which he is the Subcommittee Chair. The LTGs, the achievements of the past decade, and how the Air Research Program is meeting its various challenges will be examined. He will instruct the Subcommittee members to assess investment efficiency using information on the quality of the Program's work, metrics used for monitoring the work, and support of clients. Potential synergisms also will be considered. EPA staff are observing the process and considering components from an operational point of view. Dr. von Stackelberg noted that investment efficiency might be more easily assessed prospectively than retrospectively. A process should be in place up front to define where the programs are headed instead of looking back to determine whether they made the right choices. The BOSC Value of Information (VOI) Workgroup will try to move this dialogue forward.

Dr. Sayler said that ORD needs to frame the investment efficiency questions better for the upcoming series of BOSC reviews. Subcommittee members need to understand these questions and be provided information regarding decision-making strategies for sunsetting programs, making mid-course corrections, and so forth.

Dr. Paustenbach asked whether the efficiency question was related to the OMB PART review questions regarding resource allocation and how EPA leadership determines which efforts should be sunsetted and their resources moved to new priorities. Dr. Teichman replied that he was unsure, because the new Director of OMB has questioned the PART process and its application. This does not indicate that he is not concerned about performance, but accountability in government agencies may not be assessed via the PART process in the future. All of this feeds into the question of what is the best manner to evaluate performance in the government, in particular research programs, which are more difficult to quantify than other government programs.

**VOI Workgroup**

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

Dr. von Stackelberg stated that VOI can be used to support decision-making within the Agency. This Workgroup has heard how the BOSC can help ORD and the members have discussed the hierarchy of decision-making in ORD. The Workgroup is interested in systematizing the use of tools across all levels of ORD decision-making (e.g., leadership, laboratories, centers, research programs). Additionally, there are specific questions asked of ORD from clients. Dr. von Stackelberg referred Executive Committee members to the meeting notebook, which included a summary of a proposed 2-day workshop in conjunction with the National Risk Management Research Laboratory (NRMRL). Day 1, which will be open to the public, will focus on what other agencies are doing in this area and how these approaches can help in day-to-day decision-making. Day 2 of the workshop will be attended by a smaller number, with participants breaking into groups to work on case studies. This information will be gathered and reported to the BOSC. Bringing in outside advice will help implement this approach in a concrete manner. In terms of investment efficiency, once a systematic process for making decisions is in place, it is easier to determine whether resources have been used in the most cost-effective and efficient manner to achieve the LTGs. Drs. Haas and Philbert also are involved in the workshop effort.

Dr. Philbert stated that VOI is a "buzzword" that few individuals seem to understand, but it is clear that there is a highly quantitative exercise that is useful when boundary conditions are known and ample data are available. In many areas in which EPA must make decisions, however, one or both of these elements are missing; therefore, a qualitative method is needed. A lexicon should be developed so that all Agency staff members are using the same terms and applying the same meanings to those terms.

Dr. von Stackelberg noted that VOI is not a matrix-based approach. VOI allows identification of sources of uncertainty in all of the assumptions that feed into decision outcomes. The workshop will address the various levels of tools. There are tools to help with strategic and specific funding decisions.
Dr. Teichman responded that he can describe the criteria behind the strategic funding decisions. ORD starts at a strategic level without budget constraints to allocate resources to various research programs. The NPDs also should be able answer, within their research programs, how they prioritized funding for the various LTGs. Annual decisions must consider the existing workforce and shorter term priorities that may have been introduced. This is a decision-analysis approach rather than a VOI approach because the weighting factors are unknown. It is important to follow through on presidential directives as well as comply with the timelines for Integrated Science Assessments, the congressionally mandated 5-year review of the National Ambient Air Quality Standards, and 6-year review of drinking water regulations. Future issues of broad national significance not captured by existing regulatory structure cannot be neglected either; resources must be allocated to provide information to policymakers who make critical decisions. The efficiency of the integrated multidisciplinary research approach can be addressed by questioning the NPDs as well as information from the prospective SAB reviews and the retrospective BOSC reviews. It also is critical for ORD to work with its partners from the beginning to the end to understand the problem definitions and ensure that the research results provided are useful and feed into regulatory decisions. ORD may need to define its LTGs more specifically so that the partners know what research will be delivered in what timeframe.

Dr. Hauchman said he appreciated the effort of the VOI Workgroup. He is trying to be realistic about the outcome of this effort, but it could be very beneficial and possibly transformational in terms of how ORD does business. He also found Dr. Haas' comment about a new paradigm for BOSC reviews intriguing and will attempt to elaborate on this idea.

Dr. Paustenbach commented that the Agency probably has the skill sets to adopt the five new priorities of the Administrator. Are these priorities different than previous priorities? What can the BOSC do to help ORD address these new priorities? Dr. Teichman responded that the five priorities are aligned with many of the Agency's existing priorities; however, the issue of global climate change did not fall easily into one

program office, which is good because it will move EPA out of its traditional silos. Creating relationships within the Agency that allow decision-makers to have access to all science information ensures that the decision-making in one program office will not negatively impact another program office. The integrated multidisciplinary research approach must be incorporated to address problems. Dr. Teichman remarked that the Administrator's comments were interesting in that science would be the backbone of driving EPA decision-making, and the rule of law would dictate her decision-making. Advisory groups such as the BOSC and SAB contribute to the science backbone, and the Administrator's comments indicate that she will take very seriously the advice and guidance from advisory panels such as the BOSC and SAB.

To address some of the BOSC member's questions, Dr. Teichman presented some information about integrated multidisciplinary research. To best fulfill its mission, ORD must fully employ its unique integrated multidisciplinary capability to address increasingly complex environmental issues. He noted that this vision is consistent with the recommendations of the SAB and testimony of the new Administrator that science must be the backbone for EPA programs. To achieve this vision, ORD must partner closely with program and regional offices, starting from problem definition through the use of research results. In 2008, the SAB stated that the Agency "must undertake a larger program of research that goes beyond its immediate regulatory needs and address the broad array of environmental problems facing the nation."

ORD has many strengths on which to build, including strong scientists, modern laboratory facilities, and a wide range of expertise. ORD also has unique capabilities to approach environmental problems from source-to-outcome, risk assessment/risk management, and health and ecological perspectives. In response to program and regional office partners that increasingly request ORD's time and expertise, the Office provides highly valued technical support. ORD can excel at integrated multidisciplinary research, which must be translated to support environmental decisions. The goal is to utilize this approach for all ORD research while continuing to perform targeted research. Dr. Teichman described how ORD's sustainable water infrastructure research is an example of integrated multidisciplinary research.

ORD's goal is to solve problems of national significance and support its program and regional partners' needs. By focusing on its strengths and using integrated multidisciplinary research, ORD will inform and enable decisions that protect public health and the environment. Producing tangible results that significantly inform environmental policy will establish ORD as the foremost environmental research organization; this recognition will attract supporters and stakeholders needed for support.

Dr. Philbert noted that the focus of this discussion has been internal investments and asked whether there would be an attempt to use this approach for external investments and aligning them with the internal mission. How does this relate to integrated multidisciplinary research? Dr. Teichman explained that it is the responsibility of the NPDs to examine all available tools to meet their goals, including the intramural and extramural programs. The decision-analysis approach should determine how the extramural program can complement the intramural program. He stressed that the decision-analysis approach discussed is not strictly related to intramural programs.

Dr. Philbert noted that a major portion of the extramural research community is isolated from the integrated multidisciplinary research approach, as there is no structural organization requirement for the extramural community funded by EPA to engage in solving these problems. ORD may need to identify structural methods to integrate the extramural research community (e.g., inclusion in center meetings). Dr. Teichman acknowledged that ORD does not want to exclude those in the academic community from providing input. This could be accomplished, in part, through the SAB meetings. Dr. Philbert clarified that the extramurally funded researchers should be engaged. Dr. Teichman responded that NCER has done a good job of engaging its extramural researchers in discussions with intramural researchers and policymakers.

Dr. Sayler noted that ORD already is very committed to integrated multidisciplinary research. Many of the programs and centers demonstrate a high level of integration. The key is to communicate and continue to build on the communications between the various groups.

## Public Comment Period

Dr. Sayler called for public comments at 12:00 noon. No comments were offered.

## Coal Combustion Residue

*Dr. Susan Thorneloe, EPA/ORD; and Mr. Greg Helms, EPA/Office of Solid Waste and Emergency Response*

Dr. Sayler explained that the topic of coal combustion residue is an emerging issue of concern, especially following the large release of coal ash in rivers in eastern Tennessee, which has resulted in a number of law suits. This is an opportunity to examine this issue in a cross-cutting manner to determine the long-term ecological effects. EPA has been engaged in significant work relative to coal combustion residue and Dr. Susan Thorneloe is here to brief the BOSC on these efforts.

Dr. Thorneloe stated that, based on the increased number of calls from the press recently, there is renewed interest in this topic. Changes in air pollution control at power plants have resulted in increased metals in fly ash. The key release route is leaching to groundwater; also of concern is release to surface waters, re-emission of mercury, and the potential for bioaccumulation. ORD is working on this problem with OW, OAR, and OPPTS, as well as the states and regions. The American Coal Ash Association (ACAA) estimated that 125 million tons of coal combustion products, including fly ash, were produced in 2007; 43 percent of this was utilized beneficially, but some uses are not appropriate given the increased metal in the fly ash. There is a range of uses for the material, including mine reclamation, as road base, and so forth. How the material is used or disposed of determines what it may contain. More information is available at the ACAA Web Site (http://www.acaa-usa.org).

Dr. Thorneloe showed an illustration of multipollutant control at a coal-fired power plant and explained that the resultant residues depend on a variety of factors (e.g., electrostatic precipitator vs. fabric filter, hot-side vs. cold-side electrostatic precipitation). Use of selective catalytic reduction causes a difference in chromium residues, and a wet scrubber affects gypsum content. Per *EPA's Roadmap for Mercury*, EPA is committed to developing a report on the fate of mercury and other metals from land disposal and commercial use of coal combustion residues from plants equipped with multipollutant control technologies. There are a wide variety of leach tests, most of which do not address SAB comments. Therefore, ORD worked with the Office of Solid Waste (OSW) to determine which leach test to use. OSW recommended the use of the leach testing framework and probabilistic assessment published in two separate sources (Kosson, et al., *Environmental Engineering Science* 2002;19(3):159-204; Sanchez and Kosson, *Waste Management* 2005;25(5):463-472). The first publication defines the leach test protocol, and the second describes an approach to estimate the release of contaminants. OSW is developing this into SW-846, *Test Methods for Evaluating Solid Waste, Physical/Chemical Methods*.

Dr. Paustenbach asked whether the Toxicity Characteristic Leaching Procedure (TCLP) was used. Dr. Thorneloe replied that a single-point pH test defined whether a material is hazardous; in 2000, EPA made the decision that coal combustion residues would not be subject to Resource Conservation and Recovery Act (RCRA) Subtitle C. Mr. Greg Helms from OSW added that TCLP is used to determine whether waste should be managed as RCRA hazardous. For coal combustion residues, EPA was required to perform a study, report to Congress, and then make a regulatory determination. Much of the data that the regulatory framework was based on was TCLP data because it was available at the time. Although it was decided that coal combustion residue did not need to be regulated under Subtitle C, EPA is moving forward to have it regulated under Subtitle D. Most of the residue is not disposed of in landfills, so TCLP is not the best test. Dr. Thorneloe added that EPA is working with the Energy research Centre of the

Netherlands (http://www.ecn.nl/en), the Netherlands Environmental Assessment Agency, and others to leverage resources. The SAB noted that it is necessary to determine how the laboratory simulation mimics real situations before comparing results.

Four different test methods have been integrated to help understand leaching. A liquid/solid ratio test method is used in conjunction with a column test method to determine whether future problems may result. So far, outputs from the leach testing of coal combustion residues include four reports; two have been released, one will be drafted by summer 2009, and the fourth will be drafted by spring 2010. The first report, *Characterization of Mercury-Enriched Coal Combustion Residues from Electric Utilities Using Enhanced Sorbents for Mercury Control*, found that mercury is strongly retained by coal combustion residue, arsenic and selenium may be leached at levels of environmental concern, leaching does not correlate to total content, and laboratory leach data are comparable to field leach data. The second report, *Characterization of Coal Combustion Residues from Electric Utilities Using Wet Scrubbers*, found that mercury was not of environmental concern, but other metals were of concern. Although gypsum is of less concern because metals are lost upstream with particulate control, there still are more metals than in natural gypsum.

It appears that hexavalent chromium is being formed, which is of major concern, so more research is being done to confirm this and determine the cause. The third report will detail these results. Although only a few metals are of concern with gypsum, there are many metals of concern associated with fly ash. Mercury leaching from fly ash with and without postcombustion nitrogen oxides ($NO_x$) control is below the maximum contaminant level (MCL), and mercury leaching from scrubber sludge is less of a concern following postcombustion $NO_x$ control. Most mercury leaching is below the MCL over a plausible pH range; arsenic leaching, however, almost always is above the MCL, although gypsum has different behaviors in this area. Differences are seen in terms of material classes and leaching potential. The fourth report will include probabilistic analysis of potential release rates based on plausible management practices. The Monte Carlo technique will be used to determine 100-year cumulative release estimates.

A decision-support tool for coal combustion residue management is being developed that will allow users to enter specifics to determine how EPA's data compare with the user's conditions. It is being designed so that users can enter protocols and receive access to available data. Dr. Thorneloe reported that ORD has received positive feedback and this appears to be a method to provide easier access to these data. The next steps include a continued focus on collecting and analyzing coal combustion residues samples, continued support of OSW and development of a leach testing framework for SW-846, and publication of results. ORD also will continue to develop a decision-support tool for coal combustion residue management decisions and work with other program offices to provide support.

Dr. Paustenbach asked about the status of fly ash in road base. Dr. Thorneloe responded that the ACAA Web Site has information about this. Dr. Paustenbach then asked whether ORD's research involved only coal. Dr. Thorneloe replied that the research focused on coal and fly ash.

Dr. Haas commented that he liked the probabilistic approach but was concerned about the 100 year projections. He asked whether microbiological interactions over the timeframe were included. Dr. Thorneloe responded that she and Mr. Helms were entering into discussions with DOE to compare interlaboratory methods, and DOE does not examine any timeframe less than 1,000 years. Methyl mercury is the focus, and as anaerobic conditions are present, microbial activity is a valid concern; she will raise this as an uncertainty. Mr. Helms added that part of the concern regarding microorganisms is generating reducing conditions, and it is difficult to run leach tests under reducing conditions. To address this, geochemical speciation modeling is being considered. Microbial activity has been considered, but it has not been easy to incorporate it directly into the leach testing. Dr. Thorneloe stated that the researchers are open to suggestions regarding how to take this into account.

Dr. Sayler noted that this is the type of data being sought by the Tennessee Valley Authority (TVA), and local communities are concerned about what is being released into the water and air. Dr. Thorneloe commented that no one from the TVA has contacted her specifically, but EPA has On-scene Coordinators helping with the initial response. The Governor of Tennessee, who by training is a physicist and understands the science very well, has been in contact with Dr. David Kosson of Vanderbilt University, who is briefing the Governor on what metals to test for.

Dr. Sayler asked what Dr. Thorneloe would suggest concerning archiving samples. Dr. Thorneloe responded that she will ask her laboratory staff about the archival protocols.

Dr. Lambert stated that the SAB spent 2 days examining emergency response and brought in the train industry, because that industry has tremendous expertise in responding to chemical emergencies and environmental disasters. Did EPA activate its emergency response procedure in this case? Dr. Thorneloe explained that regional personnel would have that information.

Dr. Sayler stated that the BOSC had invited the TVA Vice President for Federal Relations to speak at this meeting. The TVA was interested, but because this meeting occurred during the period of emergency response, TVA thought it would be better to make a presentation at the next BOSC meeting. TVA will provide an overview of clean-up activities and the Authority's perspective on emergency response, analytical issues, and long-term environmental health and ecological monitoring plans. This was a dramatic release, especially when looking at the entire scope of what occurred. Dr. Ryan thought it would be beneficial for TVA to attend the next meeting, especially if the EPA researchers could also be present. Dr. Thorneloe stated that she would be glad to attend if travel funds are available. Dr. Sayler said that the BOSC would hold this option open. Dr. Thorneloe thanked the BOSC for the opportunity to present ORD's coal combustion residue research.

**Subcommittee Updates**

Dr. Demerjian provided an update on the Air Research Program review. Nine candidates for the Subcommittee have been identified, including three from the Subcommittee that conducted the previous review, and there will be a conference call with Dr. Dan Costa, NPD for Air Research, and others to discuss the expertise needed for the review. The charge questions will be formulated during a second conference call with Dr. Costa. The face-to-face meeting is scheduled to occur June 8-10, 2009.

Regarding the NERL Standing Subcommittee, Dr. Demerjian explained that NERL will initiate a request to solicit advice from the Subcommittee when it is needed. When the BOSC receives the written response to the letter report, Dr. Demerjian asked if it could be sent to the Subcommittee members so that they can see the results of their work. He suggested that a postmortem of the process be completed to determine whether it is an effective exercise.

Dr. Sayler explained that Dr. Giesy is in Hong Kong and not present to provide an update on the Science and Technology for Sustainability Subcommittee. Ms. Drumm stated that Mr. Greg Susanke is the DFO for this Subcommittee, and the face-to-face meeting will be held on March 12, 2009, at the EPA Potomac Yard Facility in Arlington, Virginia. The Subcommittee's first conference call will be held Thursday, February 12, 2009.

Dr. Ryan provided an update on the SP2 Mid-Cycle Subcommittee. He and Ms. Grogard discussed soliciting the participation of the majority of the Subcommittee members who served during the last review. The hope is that Dr. Anna Harding will be available to serve on the Subcommittee.

Ms. Drumm stated that the EDCs Subcommittee face-to-face meeting is tentatively scheduled for April 14-16, 2009, with conference calls to be held on March 3 and March 12, 2009. Dr. Glenn Van der Kraak is the Subcommittee Chair, and Dr. Melvin Anderson was the BOSC Executive Committee representative. Dr. Sayler explained that, as Dr. Anderson is no longer a BOSC member, a replacement is

needed for this Subcommittee. Dr. Sayler said he would be willing to serve on the Subcommittee if there is no conflict of interest. Dr. Lambert indicated that he would be interested in participating in the EDCs review.

Dr. Haas explained that Mr. Troy Rutkofske has been designated as the DFO for the Drinking Water Subcommittee. Ms. Drumm reported that the face-to-face meeting is likely to occur in late fall of 2009. Mr. Rutkofske has been speaking with Dr. Audrey Levine, NPD for Drinking Water Research, regarding possible individuals for the Subcommittee and he will be contacting Dr. Haas shortly.

Dr. Philbert provided an overview of NCER Standing Subcommittee activities. The second face-to-face meeting was held February 2-3, 2009, and addressed one charge question with two sub-questions. The Subcommittee members received a great deal of information from NCER. Dr. Philbert stated that the first charge question affects the BOSC Executive Committee in that NCER is asking whether the Executive Committee should help the Center identify research priorities. The second question addresses the VOI discussion. The first Subcommittee report recommended that NCER consider the VOI approach, and now the Center is asking for advice on how to implement the approach. The Subcommittee's letter report will be submitted before the next BOSC meeting. As the Subcommittee members reviewed their previous recommendations, it occurred to them that NCER is laboring under a reduced budget, and perhaps the BOSC should engage in advocacy activities, perhaps with AAAS, to encourage an increase in EPA's research budget under the new administration. The Subcommittee will forward a letter to the Executive Committee regarding this issue.

Dr. Sayler noted that the Executive Committee can discuss the letter after it has been received. He mentioned that many of the academic members of the BOSC Subcommittees think there is a significant need to double EPA's extramural budget. Dr. Teichman commented that ORD is willing to consider all advice from the Subcommittee and would try to respond to this issue. He would work with Ms. Drumm and Ms. Kowalski to ensure that any response is consistent with the BOSC charter. Dr. Teichman pointed out that the SAB reviews the budget, and the BOSC may comment on it. Dr. Lambert added that the SAB examines the budget and the SAB Chair annually testifies before the appropriate congressional committee regarding the SAB view of the budget. The SAB usually recommends an increase in research funds and continuation of STAR grants. Dr. Duke stated that, in terms of outreach to professional societies, there is an association called the Biological and Ecological Sciences Coalition that advocates for research funding in the biological and ecological sciences. Dr. Sayler noted that because ORD's extramural and fellowship funding has been unstable, the academic community does not view EPA as a resource for training the future workforce. As a result, the Agency loses many bright, young individuals.

Dr. Sayler explained that the Computational Toxicology Subcommittee currently is inactive, and ORD's response to the previous report was received recently. Dr. Daston will continue as Subcommittee Chair, but now that Dr. Daston is no longer on the Executive Committee, a new Executive Committee member is needed to serve on the Subcommittee before the next meeting, which currently is planned for September 2009.

**Standard Format for BOSC Reports**

*Dr. Dennis Paustenbach, ChemRisk, Inc., BOSC Executive Committee*

Dr. Paustenbach reminded members that at the last BOSC meeting, Dr. Charlie Menzie presented his report for the Land Research Program review, and the members discussed how they liked the approach and format of that report. Dr. Paustenbach identified six reports to use for benchmark analysis. The goal is to standardize the format so that certain information is in the same location within each report and less text and more specific data are contained within the report. The cover page, credits, and table of contents are acceptable as is, but the executive summary has a different title in each report. It should be called the executive summary and it should describe the charge and provide the overall rating. Dr. Paustenbach

thought there were benefits to a numerical or grade score. There has been some standardization of the charge questions, so perhaps a numerical score could be implemented. As an exercise, Dr. Paustenbach applied grades based on the text of the reports, and these grades did not match the Subcommittees' conclusions. He recommended that the instructions regarding ratings should be made clearer. He suggested that the Subcommittees use bullets instead of paragraphs of text, and that each box in the table have two sentences.

Dr. Paustenbach recommends adding to the reports a section that describes the program or laboratory/center being reviewed. Some of the reports require the reader to refer to previous reports or other documents to understand the current report. This new section would describe the age of the program; any morphing that has occurred over time; a timeline that incorporates budget, directions, full-time equivalents, and so forth; and an organizational chart that describes the structure of the program (the groups that contribute to the research), and some information about each group, including its role, the number of individuals in the group, and its clients and stakeholders. Key interagency interactions and whether or not the program is applying the integrated multidisciplinary research approach also should be included.

The introduction and rating scheme should be standardized. A chapter should be devoted to each charge question and a page limit for each chapter should be provided. He suggested that the ratings could be provided in a table with the charge question in the left column and the rating in the right column. Dr. Paustenbach acknowledged that charge questions currently are not rated individually, but he thought they should be. A new section on investment efficiency would include the set of criteria that the BOSC will establish, a score, and bulleted recommendations regarding how to increase efficiency. A section devoted to recommendations that are outside the original scope and charge of the review also could be incorporated. The final section of the proposed report should contain the overall score. The appendices differ between each report and should be standardized. One appendix could be devoted to a list of 10 major accomplishments as identified by the program or center being reviewed. Other appendices would remain the same (e.g., affiliation of the panel, acronyms). An additional appendix would include a timeline of the original charge and a timeline illustrating when the BOSC and the NPD think that the recommendations have been addressed and accomplished.

Dr. Sayler noted that this format would impact the materials presented to the Subcommittees by the programs. The program under review could organize its presentations and materials in a manner that would help the Subcommittees prepare their reports. Dr. Paustenbach stated that this was his intent.

Dr. Philbert asked whether it is implicit that a score of 75 is needed to be adequate and whether it would correlate to the PART score. Dr. Paustenbach replied that this would need to be discussed and determined. Dr. Sayler explained that when the BOSC was asked to provide ratings for the programs and centers, it studiously avoided numerical ratings for a variety of reasons and instead developed the qualitative descriptions, which do not always translate as expected. He agreed that the descriptors needed to be examined.

Dr. von Stackelberg suggested that the current qualitative ratings could be used with a qualitative statement of "…with the exception of…" following the rating (e.g., "Exceeds expectations with the exception of…").

Dr. Sayler noted that it is necessary to consider to whom the results are being communicated. Is the current approach functional for ORD and the programs? ORD and program feedback regarding whether the ratings are useful is desired. Dr. Duke agreed that the audience is a critical consideration in standardizing an outline for these reports. He added that the primary audience is the program or organization being reviewed. There are some secondary audiences, including the BOSC Executive Committee, which vets and approves the report, and the public. It is necessary for these secondary audiences to read the report without extensive prior knowledge of the program or organization. Dr. Duke

said he had considerable reservations about implementing quantitative evaluations because of the amount of time required to reach consensus on that type of score. He was concerned that this approach might divert the Subcommittee members from their core charge of providing broad program evaluations. Dr. Paustenbach agreed that if a numeric rating is problematic, it should be avoided. He observed that some reports provide an overall rating instead of a rating for each charge question, and other reports provide a rating for each LTG. He thought that this should be standardized regardless of whether a qualitative or quantitative rating is used. Dr. Sayler explained that mid-cycle reviews assign an overall rating for the program's response to the previous BOSC review, and full program reviews assign a rating for each LTG. He also noted that, although standardization is desirable, there must be some degree of latitude because each program is unique. The current format has been an evolution.

Dr. Philbert explained that the National Institutes of Health (NIH) has a long history of performing these types of reviews; individual elements receive scores, and then the panel is asked to examine everything as a whole and provide a score that is not necessarily a mean of the individual element scores but a broad consensus. Numerical scores can be useful if there is a strict understanding of what the numbers mean. Dr. Sayler noted that EPA programs are much broader than discrete NIH grant proposals. He was concerned that the Subcommittees may be overwhelmed with trying to develop numerical scores. Dr. Sayler indicated that both the BOSC Executive Committee and ORD will review Dr. Paustenbach's proposal to determine whether it fits their needs. Although Dr. Sayler was uncomfortable with using numerical ratings, he was open to discussing it further.

Ms. Drumm stated that, for some reviews, the BOSC Executive Committee was provided a fact sheet that gave an overview of the program, which might address Dr. Paustenbach's proposed section on program background. She apologized that this fact sheet was not distributed for the most recent reviews. Dr. Paustenbach thought the fact sheet would be helpful because this information is necessary to answer the question regarding investment efficiency.

Dr. Falk identified three elements of the proposed format that he found to be very positive: (1) standardization, (2) context, and (3) clarity. These three elements would be beneficial regardless of the type of rating used. Dr. Sayler agreed and asked Dr. Paustenbach to forward the proposed format to Ms. Kowalski so that the Executive Committee members could review it. A conference call could be arranged before the June meeting to allow the Executive Committee members time to discuss this further. He suggested that Dr. Paustenbach create one format for the full program review reports and another format for the more concise mid-cycle review reports.

**Future Discussion/Future Business**
*Dr. Gary Sayler, University of Tennessee, BOSC Executive Committee Chair*

Dr. Sayler identified the standardization of the format for BOSC reports as a future business item for the BOSC. The next meeting will be held June 4-5, 2009, in Duluth, Minnesota. He may contact the TVA to determine whether a representative would like to participate in the June meeting. Dr. Sayler also agreed to canvass the BOSC and ORD regarding this possibility. In an effort to schedule the fall meeting, Dr. Sayler asked Ms. Kowalski to poll the BOSC members regarding their availability in September 2009.

The VOI workshop will take place March 30 and April 1, 2009, in the Cincinnati, Ohio, area; the exact location will be determined. Drs. von Stackelberg, Philbert, and Haas will attend, and other BOSC members also are welcome. Ms. Kowalski noted that the VOI Workgroup is not a FACA committee, and individual rather than consensus advice will be provided at the workshop. Dr. von Stackelberg stated that she will provide a report of the workshop to the BOSC. Ms. Drumm stated that NRMRL will provide support for the workshop and BOSC members will be reimbursed for travel to the workshop.

Dr. Sayler mentioned that there are several vacancies on the Executive Committee. He announced that Dr. Paustenbach has agreed to serve as the Chair of the Human Health Risk Assessment Mid-Cycle

Subcommittee. Dr. Duke has volunteered to participate in the Climate Change Science Program review and he served as the Vice Chair of the Subcommittee that conducted the previous review. In response to Dr. Duke's question, Ms. Kowalski replied that it would not be a problem that he would be rotating off of the Executive Committee during the time of the review. Dr. Sayler noted that volunteers are needed to vet the Human Health, EDCs, and NCER Standing Subcommittees' reports. Drs. Philbert and Weiss will vet the Human Health Subcommittee report, Drs. von Stackelberg and Falk will vet the EDCs Subcommittee report, and Drs. Duke and Falk will vet the NCER Standing Subcommittee report.

In terms of filling the vacancy on the Computational Toxicology Subcommittee, Dr. Philbert suggested Dr. Tim Zacharewski of Michigan State University. Dr. Philbert agreed to forward the name to Ms. Drumm.

Referring to a handout provided by Ms. Drumm on the recent expertise and institutional affiliations that were lost as a result of members rotating off of the BOSC, Dr. Sayler pointed out that the Board should maintain a balance in terms of both expertise and institutional affiliation. ORD has developed a good list of names for consideration, and BOSC members are encouraged to submit names as well. The goal is to have the three vacancies filled before the June meeting.

Dr. Philbert asked whether the BOSC intended to form a Subcommittee for the Nanotechnology Research Program. Dr. Sayler did not know whether the Program had requested a subcommittee and he indicated that such a request should go through Dr. Teichman, who will follow up with Mr. Morris about this possibility and report to the BOSC.

In response to Dr. Sayler's request, the BOSC members did not suggest any items for the next conference call or the face-to-face meeting in Duluth, Minnesota.

Dr. Sayler thanked everyone for their participation and adjourned the meeting at 2:50 p.m.

**Action Items**

- ✧ Drs. von Stackelberg and Paustenbach will provide Dr. Windom their comments on the Water Quality Mid-Cycle Review Report.
- ✧ Dr. Paustenbach will e-mail the proposed standard formats for the BOSC full program review reports and the mid-cycle reports to Ms. Kowalski, who will forward the formats to the BOSC members for their review.
- ✧ Dr. Sayler and Ms. Kowalski will determine whether a conference call to discuss the proposed standardized formats is necessary. If necessary, Ms. Kowalski will schedule the conference call.
- ✧ Dr. Lambert will serve on the EDCs Subcommittee.
- ✧ Dr. Sayler will canvass the BOSC and ORD regarding inviting a TVA representative to the next Executive Committee face-to-face meeting.
- ✧ Ms. Kowalski will poll the BOSC members regarding their availability in September 2009 for the fall Executive Committee meeting.
- ✧ Dr. Paustenbach will serve as the Chair of the Human Health Risk Assessment Mid-Cycle Subcommittee.
- ✧ Dr. Duke volunteered to participate in the Climate Change Science Program review.
- ✧ Drs. Philbert and Carol Weiss will vet the Human Health Subcommittee report.

- ✧ Drs. von Stackelberg and Falk will vet the EDCs Subcommittee report.
- ✧ Drs. Duke and Falk will vet the NCER Standing Subcommittee report.
- ✧ Dr. Philbert will forward to Ms. Drumm his suggestion of Dr. Tim Zacharewski of Michigan State University for the Computational Toxicology Subcommittee.
- ✧ Dr. Teichman will follow up with Mr. Morris about the possibility of forming a Nanotechnology Subcommittee and report to the BOSC.
- ✧ BOSC members will submit names to be considered for Executive Committee membership to Dr. Sayler and Ms. Kowalski.
- ✧ BOSC members should notify Dr. Sayler, Ms. Kowalski, or Dr. Teichman if they would like to participate in any of the SAB activities.

All materials that were transmitted during and for this meeting are in the public meeting binder held at the DFO's office.

## PARTICIPANTS LIST

**Executive Committee Members:**

**Gary S. Sayler, Ph.D., Chair**
Center for Environmental Biotechnology
The University of Tennessee

**Kenneth L. Demerjian, Ph.D.**
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
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Skidaway Institute of Oceanography

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**Chika Kato**
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**Aaron Lovell**
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**Jim Rollins, J.D.**
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**Denise Hoffman**
The Scientific Consulting Group, Inc.

B·O·S·C
BOARD OF SCIENTIFIC COUNSELORS

**40th EXECUTIVE COMMITTEE FACE-TO-FACE MEETING**
**AGENDA**
**February 9 – 10, 2009**

**Marriott Courtyard Arlington Crystal City**
2899 Jefferson Davis Highway
Arlington, VA 22202
Phone: (703) 549-3434

**Monday, February 9, 2009**

| | | |
|---|---|---|
| 2:00 p.m. – 2:20 p.m. | Welcome and Introductions<br>- Review of Sept. Meeting Minutes<br>- Review of Dec. Meeting Minutes<br>- Overview of Agenda | Dr. Gary S. Sayler, Chair, Executive Committee |
| 2:20 p.m. – 2:30 p.m. | BOSC DFO Remarks<br>- Administrative Issues | Ms. Heather Drumm, Office of Research & Development (ORD) |
| 2:30 p.m. – 4:00 p.m. | ORD Responses to BOSC Letter Reports:<br>- National Center for Computational Toxicology (NCCT)<br>- National Exposure Research Lab (NERL) | <br>Dr. Robert Kavlock, ORD<br>Dr. Linda Sheldon, ORD |
| 4:00 p.m. – 4:30 p.m. | SAB Activities | Dr. George Lambert, SAB Liaison to the BOSC |
| 4:30 p.m. – 5:00 p.m. | AA/ORD Remarks | Mr. Lek Kadeli, Acting Assistant Administrator for ORD |
| 5:00 p.m. | Recess | |

**Tuesday, February 10, 2009**

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|---|---|---|
| 8:00 a.m. – 8:15 a.m. | Registration | |
| 8:15 a.m. – 8:45 a.m. | ORD Update | Dr. Kevin Teichman, Deputy Assistant Administrator for Science for ORD |
| 8:45 a.m. – 9:30 a.m. | Nanomaterials: ORD Research to Inform Environmental Decisions | Mr. Jeff Morris, ORD |

**Tuesday, February 10, 2009 (continued)**

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|---|---|---|
| 9:30 a.m. – 10:15 a.m. | Water Quality Mid-Cycle Draft Report Presentation | Dr. Herb Windom, Chair<br>Water Quality Mid-Cycle Subcommittee |
| 10:15 a.m. – 10:45 a.m. | Optimizing the BOSC Review Process | Dr. Fred Hauchman, ORD |
| 10:45 a.m. – 11:30 a.m. | Investment Efficiency Discussion | Dr. Gary Sayler, Chair<br>Executive Committee |
| 11:30 a.m. – 12:00 p.m. | Value of Information (VOI) Workgroup | Dr. Katherine von Stackelberg,<br>Workgroup Chair |
| 12:00 p.m. – 12:15 p.m. | Public Comment | |
| 12:15 p.m. – 1:15 p.m. | Lunch | |
| 1:15 p.m. – 2:00 p.m. | Coal Combustion Residue | Dr. Susan Thorneloe, ORD<br>Mr. Greg Helms, OSW |
| 2:00 p.m. – 2:30 p.m. | Subcommittee Updates:<br><u>Mid-Cycle Review Subcommittees:</u> | |
| | - Science and Technology for Sustainability (STS) Mid-Cycle | Dr. John Giesy,<br>Subcommittee Chair |
| | - Safe Pesticides/Safe Products (SP2) Mid-Cycle | Dr. Barry Ryan,<br>Subcommittee Chair |
| | <u>Program Review Subcommittees</u>: | |
| | - Human Health Program Review | Dr. Henry Falk,<br>Subcommittee Vice Chair |
| | - Endocrine Disrupting Chemicals (EDC) Program Review | Dr. Gary Sayler, Chair,<br>Executive Committee |
| | - Air Program Review | Dr. Ken Demerjian,<br>Subcommittee Chair |
| | - Drinking Water Program Review | Dr. Chuck Haas,<br>Subcommittee Chair |
| | <u>Standing Subcommittees</u>: | |
| | - National Center for Environmental Research (NCER) | Dr. Martin Philbert,<br>Subcommittee Chair |
| | - National Exposure Research Lab (NERL) | Dr. Ken Demerjian,<br>Subcommittee Chair |
| | - Computational Toxicology | Dr. Gary Sayler, Chair,<br>Executive Committee |
| 2:30 p.m. – 3:00 p.m. | Standard Format for BOSC Reports | Dr. Dennis Paustenbach,<br>Executive Committee |
| 3:00 p.m. – 3:30 p.m. | Future Discussion/Future Business<br>- EC Meetings in 2009<br>- Future Work | Dr. Gary Sayler, Chair,<br>Executive Committee |
| 3:30 p.m. | Adjourn | |