

US EPA ARCHIVE DOCUMENT

**Summary of the  
45th EXECUTIVE COMMITTEE FACE-TO-FACE MEETING**

**Hilton Garden Inn  
Washington, DC**

**October 18-19, 2010**

**MONDAY, OCTOBER 18, 2010**

**Welcome and Introductions**

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

Dr. Gary Saylor, Chair of the Executive Committee of the Board of Scientific Counselors (BOSC), called the meeting to order at 8:38 a.m., and welcomed the BOSC members to the 45th face-to-face meeting of the Executive Committee. He stated that all Executive Committee members would be in attendance, noting that Dr. Charles Haas would arrive by mid-morning.

Review of July Executive Committee Meeting Minutes

Dr. Saylor asked if there were any comments on the draft minutes for the July 12-13, 2010, Executive Committee meeting. When no comments were offered, Dr. Saylor called for a motion to approve the minutes. Dr. Martin Philbert moved to approve the minutes without any changes and Dr. Ken Demerjian seconded the motion. The minutes for the July meeting were approved unanimously by the BOSC.

Review of August Executive Committee Teleconference Minutes

Dr. Saylor asked if there were any comments on the draft minutes for the August 25, 2010, Executive Committee conference call. When no comments were offered, Dr. Saylor called for a motion to approve the minutes. Dr. John Tharakan made a motion to approve the minutes without any changes and Dr. Barry Ryan seconded the motion. The minutes for the August teleconference were approved unanimously by the BOSC.

Overview of Agenda

Dr. Saylor gave a brief overview of the meeting agenda. The morning of Day 1 included the remarks from the Designated Federal Officer (DFO) for the BOSC, the remarks from the Office of Research and Development (ORD), and several presentations on informatics, data mining, and knowledgebase—the Department of Energy (DOE) Systems Biology Knowledgebase R&D Project, ORD's Health and Environmental Research Online (HERO) Database, and ORD Data Mining Techniques. The afternoon session included three presentations on research program performance evaluation, including STAR METRICS, Overview of ORD Evaluation Techniques, and Exploring New Approaches for Evaluating Research Effectiveness. The day concluded with a discussion of the informatics, data mining, and program performance evaluation presentations.

Day 2 began with the ORD Update, followed by a presentation of the new Safer Products for a Sustainable World (SPSW) program. The morning also included time for public comment and an update

on the ORD response to the BOSC Decision Analysis Letter Report. The meeting concluded with an open forum discussion on the future activities and role of the BOSC, followed by a discussion of future business and the next Executive Committee meeting. Dr. Sayler asked if there were any questions or additions to the meeting agenda and there were none.

### **BOSC DFO Remarks**

*Mr. Greg Susanke, BOSC Designated Federal Officer, ORD, U.S. Environmental Protection Agency (EPA)*

Mr. Susanke, the DFO for the BOSC Executive Committee, welcomed the BOSC members to the meeting and thanked them for their participation. He explained that the BOSC is a federal advisory committee that is subject to the requirements of the Federal Advisory Committee Act (FACA). Mr. Susanke reviewed the procedures that are required for all BOSC meetings. He stated that the BOSC provides independent, scientific peer review and advice to EPA's ORD, and it is his responsibility as the DFO to ensure compliance with all FACA rules.

In compliance with FACA requirements, all BOSC meetings are open to the public and time has been designated on the agenda for public comment. Mr. Susanke noted that although he received several requests for the agenda and materials, no requests for comment were received prior to the meeting. Time has been set aside on Tuesday's agenda at 11:30 a.m. (EDT) for public comment. He asked that comments be limited to 3 minutes each. An ORD contractor, Beverly Campbell from The Scientific Consulting Group (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 and via the public docket 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* on September 30, 2010. Mr. Susanke 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-2010-0817. The agenda was made available to the public in the docket and meeting materials are available upon request. As the DFO, Mr. Susanke ensures that the Executive Committee members receive annual ethics training and complete confidential financial disclosure forms. He asked members to notify him immediately if any potential conflict of interest arose during the meeting deliberations. He then asked if any member had a potential conflict to declare.

Mr. Susanke reminded the BOSC members and other participants to sign in at the registration desk if they had not done so already, and mentioned that Denise Hoffman from SCG was at the desk to help with any logistical needs.

### **ORD Remarks**

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

Dr. Hauchman greeted the BOSC members and welcomed them to Washington, DC. He noted that Dr. Paul Anastas, the Assistant Administrator (AA) for Research and Development, was unable to attend the meeting, so he would provide some comments on what has been happening in ORD since the last BOSC meeting. Dr. Kevin Teichman will be in attendance on Tuesday to present the ORD Update, and provide more detail on the reorganization of ORD's research programs. Dr. Hauchman said he was excited about working with the BOSC to shape its new role as ORD moves forward with its new programs.

Dr. Anastas has come to ORD with a strong vision and high expectations. He has articulated a path forward for ORD that includes four major thrusts: (1) strengthening interactions with the program and

Regional Offices, (2) engaging in Integrated Transdisciplinary Research (ITR), (3) catalyzing sustainable technological innovations, and (4) communicating effectively about ORD's work and its impact.

Dr. Hauchman explained that ORD is vigorously moving forward to strengthen interactions with the Program and Regional Offices. Region 7 recently has taken over from Region 6 as the lead Region for ORD. Dr. Anastas and the ORD staff are actively working to engage the Regions in the research process, which includes the long-term ITR as well as more targeted research and technical support. All of these areas are included in the discussions with the Regional and Program Offices.

Dr. Teichman will elaborate more tomorrow on the ITR thrust. Dr. Hauchman reported that ORD now has interim National Program Directors (NPDs) for four primary research areas—Bob Kavlock for SPSW, Jennifer Orme-Zavaleta for Safer and Sustainable Water Resources, Rick Linthurst for Sustainable and Healthy Communities, and Dan Costa for Air, Climate, and Energy—and two additional areas—Becki Clark for Risk Assessment and Jon Herrmann for Homeland Security.

Dr. Hauchman stated that the Drinking Water Research Program BOSC review scheduled for fall 2010 had been cancelled because of the reorganization of ORD's research programs. ORD has been focusing its energy on standing up these new programs and did not want to expend energy looking back at a program that was undergoing such a significant change.

ORD intends to expand its use of EPA's Title 42 authority to bring in experts to help ORD move forward with implementing ITR. Dr. Hauchman explained that EPA was granted Title 42 authority a number of years ago to bring world-class scientists to the Agency to strengthen EPA's research and development programs. A number of federal agencies use Title 42 authority, including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the National Science Foundation (NSF). As the first 5 years of EPA's Title 42 program drew to a close, the Agency asked the National Research Council (NRC) to conduct an independent evaluation of EPA's program and offer suggestions for strengthening it. Dr. Hauchman distributed copies of the report, *The Use of Title 42 Authority at the U.S. Environmental Protection Agency*, which was prepared by the NRC following its review.

EPA has authority to hire 30 world-class scientists and engineers under Title 42, and the Agency has filled 12 of those positions. One of the recommendations in the NRC report was for EPA to be more flexible on the requirement that all Title 42 hires must have a doctoral degree. Dr. Hauchman noted that there were some highly qualified applicants for the 12 positions that have been filled who were not considered because they did not have doctoral degrees. The NRC also recommended that EPA establish a search committee to oversee recruitment, promote diversity in the process, evaluate applicants' credentials, and recommend the most qualified applicants to a selection committee. Another NRC recommendation was for EPA to advertise the positions widely on appropriate Web sites, in appropriate journals, through scientific and engineering societies, and by contacting highly competent people in the relevant disciplines. In addition, EPA should form a selection committee to determine the best candidate and forward the recommendation to ORD management. NRC also recommended that the BOSC or Science Advisory Board (SAB) review EPA's Title 42 program every 5 years to ensure it is being used for the intended purpose and achieving the desired goals.

Dr. Hauchman said that he had been involved with the Title 42 hiring process at the National Exposure Research Laboratory in Cincinnati, and the Title 42 hires have exceeded every expectation of the Agency. Dr. Dennis Paustenbach asked about the source and the term of the hires. Dr. Hauchman replied that they come primarily from academia and the term appointments are for 5 years, but they are renewable. Dr. Demerjian commented that EPA has filled less than one-half of its Title 42 positions. Is that a good track record? Dr. Hauchman did not have a benchmark with which to compare EPA's record, and he explained that the hiring process had been slowed until certain issues were addressed. Now, the Agency is working hard to catch up and fill the positions.

Other federal agencies have had Title 42 programs much longer than EPA. Dr. Sayler mentioned that he had testified at the NRC review on behalf of the BOSC. He cited the mention of Title 42 hires in many of the BOSC program review reports and how these individuals were critical to the programs. Dr. Henry Falk stated that CDC has been using this authority for the past 10 years. He emphasized the importance of using the authority carefully and advised EPA to make sure to follow an appropriate process.

Dr. Paustenbach asked if the new program areas are just a rearrangement of existing ORD staff and assignment of a new focus. Dr. Hauchman responded that the new programs represent a consolidation of the programs with a refocusing of research as appropriate to better meet Agency needs. Dr. Dan Costa, for example, who has been serving as the NPD for the Clean Air Research Program, will now be directing the Air, Climate, and Energy Research Program. Dr. Hauchman mentioned a slide that Dr. Teichman had presented to the SAB to show the tangled connections between ORD's existing 14 research programs and the Administrator's 7 priorities. With this reorganization, ORD is consolidating its programs so that they align well with the Administrator's priorities. For example, the Drinking Water and Clean Water Research Programs are being combined; this will allow the new program to take a systems level approach and pursue national linkages.

Dr. Haas asked if the new NPDs will be given budget authority. Dr. Hauchman replied that ORD intends to give the NPDs more budget authority. He explained that ORD uses a matrix management system in which the seat of power has been in the hands of the Laboratory and Center Directors. ORD wants to balance that power. The new NPDs will have more staff and budget authority, but this has not been implemented yet.

Dr. Paustenbach said that he did not recall seeing the slide to which Dr. Hauchman referred. He commented that ORD seems to undergo a reorganization with the appointment of each new Administrator. Does the staff find this confusing? Dr. Hauchman replied that Administrator Jackson has laid out clear priorities that make sense to ORD, and she is emphasizing a focus on community-based risk assessment and environmental justice. Dr. Hauchman said he would ask Dr. Teichman to include the slide linking ORD's existing programs to the Administrator's priorities in his presentation on Tuesday.

The third area emphasized by Dr. Anastas—catalyzing sustainable technological innovations—will be addressed in Dr. Teichman's presentation on Tuesday. Dr. Anastas has appointed Dr. Peter Preuss as the Chief Innovation Officer, and there have been a number of activities in the area of technological innovation.

The fourth thrust in the ORD path forward is communicating effectively about ORD's work and its impact. The communications staff has been extremely busy working to improve ORD communications. For example, they have launched *Science Matters*, a newsletter devoted to sharing the innovative environmental and human health science being conducted at EPA. The newsletter includes GEMS—Great Environmental Moments in Science—which are several sentence, easy-to-understand descriptions of the research being conducted by EPA scientists, why it is being conducted, and its impact. ORD also has developed a new communication strategy, and launched an impact initiative and a new award for staff members making impacts with their research.

Dr. Sayler commented that EPA had an important opportunity to communicate with the public about what the Agency was doing to address the oil spill in the Gulf of Mexico, but there was little in the press about EPA's activities. Was there a reason that EPA was not more visible following the oil spill?

Dr. Hauchman responded that EPA was not the lead agency for the response; nevertheless, the EPA Administrator was on camera numerous times in the weeks after the spill and she recently has been appointed by President Obama to chair the Gulf Coast Ecosystem Restoration Task Force. Dr. Hauchman agreed that EPA did not get as much recognition of its role in responding to the oil spill as it deserved, but the Agency is proud of its efforts.



Environmental justice (EJ) is one of the Administrator's priorities and this area is getting a boost in this administration. The Administrator appointed Lisa Garcia as her Senior Advisor for Environmental Justice. EPA's Plan EJ 2014, which is available on the Web (<http://www.epa.gov/compliance/ej/resources/policy/plan-ej-2014.html>), outlines five cross-Agency focus areas: (1) incorporating environmental justice into rulemaking, (2) considering environmental justice concerns in EPA's permitting process, (3) accelerating compliance and enforcement initiatives, (4) supporting community-based action programs, and (5) fostering administration-wide action on environmental justice. Dr. Hauchman pointed out that there is a science thread that runs through several of these areas; for example, ORD is getting involved with the Program Offices to assist them in considering EJ in the rulemaking process. ORD is developing science-based tools to bring information to the work groups that are developing the regulations. Tools development is one of the three sections of Plan EJ 2014. It focuses on developing the scientific, legal, and data and information foundation that supports EJ analysis, community work, and communications and stakeholder engagement. Dr. Anastas and the ORD staff are working with Region 7 on this focus area to build a strong scientific foundation for conducting disproportionate impact analysis, particularly methods to appropriately characterize and assess cumulative impacts. These efforts will help to ensure that EPA brings the best science to decision making around EJ issues.

Dr. Hauchman noted that EJ is an important component of the Sustainable and Healthy Communities Program led by Rick Linthurst. The National Advisory Council for Environmental Policy and Technology (NACEPT) has been charged with advising EPA on the development and deployment of innovative technologies that EPA, states, and communities can use to identify, measure, and reduce the risks faced by EJ communities and other vulnerable populations. There are efforts underway to institutionalize EJ within the Agency under this administration.

Dr. Hauchman said his remarks would not be complete without mentioning hydraulic fracturing, which is such a hot issue. EPA is in the final stages of drafting a research plan on hydraulic fracturing and it soon will be presented to the SAB. The Agency has conducted a series of public meetings on the topic and will sponsor several hydraulic fracturing workshops. The research plan includes an extramural component as well as intramural research that will address groundwater and fate and transport issues, analytical methods development, and health effects. EPA is leveraging the efforts of DOE, the U.S. Geological Survey, and the Agency for Toxic Substances and Disease Registry (ATSDR).

Dr. Ken Olden commented that hydraulic fracturing has significant EJ implications so it is a good opportunity for the Agency to incorporate broad thinking in the regulations and policies for hydraulic fracturing. He asked if the EJ efforts are limited to EPA or if other agencies were participating. Dr. Hauchman replied that there is an interagency effort on EJ. Devon Payne-Sturges is EPA's representative on the interagency effort. Dr. Hauchman stressed the importance of the involvement of other federal agencies. Dr. Olden commended EPA for taking steps to institutionalize EJ within the Agency; he noted that considerable work was done under the Clinton administration but it did not get institutionalized. He added that the political and career leadership of EPA are aligned on this issue, making it an opportune time to act.

In response to a question about ORD's role in working with the Regions on ITR, Dr. Hauchman stated that ORD funds two positions in every Region—the Regional Science Liaisons (RSLs) and the Superfund and Technology Liaisons (STLs). The RSLs will play an important role in communicating Regional research needs and developing research plans.

Ms. Marie Zhuikov asked if the communication strategy mentioned by Dr. Hauchman was for ORD or EPA. Dr. Hauchman responded that it was an ORD communication strategy. Ms. Zhuikov asked if the strategy could be shared with the BOSC. Dr. Hauchman said that it had not been released to the public but he would check to find out if it can be distributed to the BOSC.

Dr. Sayler thanked Dr. Hauchman for responding to the BOSC's questions and then introduced the next presenter.

## **INFORMATICS / DATA MINING / KNOWLEDGBASE SESSION**

### **Information Technology and Advances in Knowledgebase Development: DOE Systems Biology Knowledgebase R&D Project**

*Bob Cottingham, Biosciences Division, Oak Ridge National Laboratory*

Mr. Cottingham stated that his presentation focused on a project he has been working on for the past 18 months. He emphasized that the system has not yet been built but the concept has been developed and there are plans to build it. The report from the May 2008 workshop *Systems Biology Knowledgebase for a New Era in Biology* noted that, historically, projects were developed in isolation resulting in isolated data and methods. The vision was to create an integrated community informatics resource to enable a broader and more powerful systems biology research effort. The objective was to develop an implementation path toward the vision of the DOE Systems Biology Knowledgebase (Kbase).

Mr. Cottingham explained that biological research projects are becoming larger and more complex, both experimentally and computationally; it is clear that we cannot continue to do this the same way we have done in the past. There is an increasing need to cooperate and standardize, and technological advances continue to produce exponentially more and diverse types of data. A new kind of computational infrastructure is needed for the overall scientific effort to be productive and successful.

The Kbase mission is to:

- ✧ Provide a large-scale, open community computational capability for systems biology research data management and analysis.
- ✧ Promote openness and sharing of data, code, and computational infrastructure.
- ✧ Address problems of large-scale data management and processing.
- ✧ Utilize computational techniques required for community effort at data integration, open development, and large-scale resource sharing, and to meet other research community policies and objectives.

Mr. Cottingham defined Kbase as a cyberinfrastructure consisting of a collection of data, organizational methods, standards, analysis tools, and interfaces representing a body of knowledge. The DOE Systems Biology Knowledgebase will be focused on areas of systems biology relevant to DOE missions in energy and the environment, yet also would be widely and easily applicable to all systems biology research. The systems biology modeling framework calls for open-access data and information exchange. It should allow data generators seamless submission and incorporation of diverse data; therefore, scientific concepts need to be standardized. The system has to be accessible to others with flexible user interfaces and easy data retrieval. There should be user standards and advisory committees, value-added analysis for users, as well as training, tutorials, and support. In addition, Kbase should be developed using open-source software and tools.

Kbase would differ from other systems in a number of ways. It would integrate across projects and laboratories, and imply a community research effort. It would employ a more standardized approach and a more mature software engineering approach. In addition, it requires more involvement of non-informatics researchers. Mr. Cottingham identified some of the reference models for Kbase, including: Linux (open source development); iPhone, Google, and Facebook Applications; Google Maps cloud computing with smart phone application; and Wikipedia (shared community reference resource and contribution).

The guiding principles for Kbase are: (1) science drives Kbase development; (2) community effort is required to integrate data and methods across multiple laboratories to improve research productivity; (3) open access—data and methods are available for anyone to use with perhaps a limited embargo policy; (4) open contribution—data and source code are managed in an open environment and can be contributed by anyone with an editorial/peer review process; and (5) data and methods are distributed—Kbase is not a single, centralized, monolithic system. Kbase-recommended policies will be developed under a consensus governance model in which the scientific community is actively engaged in governance and in developing and driving Kbase goals and objectives.

Mr. Cottingham presented a series of slides that showed the progression of a model of the earth, starting with a model from the 15<sup>th</sup> century, moving to a satellite image, and then to an annotated satellite image with street names. The last slide in the progression represented layers of data that had been integrated such as the GPS coordinates with features (satellite image, the road names, and the business addresses and functions). This transition in views of the earth over five centuries today integrated with map and business information that is searchable and can dynamically provide the latest updated information and analyses such as driving directions is analogous to what Kbase strives to achieve in representing current knowledge and perspectives on biological systems to support research.

The Kbase user interface capabilities will include: (1) curation, not just data, including models and representation of scientific concepts; (2) analysis, including ability to compare methods and inventory of results; (3) simulation, including ability to modify and improve models; (4) prediction based on simulation and analysis to form new hypotheses; and (5) experimental design and comparison between prediction and results. Mr. Cottingham stressed that the user interface must be simple so that it can be used with minimal training. It must be understandable for all researchers, not just computationalists. The user interface must enable discovery (new research direction) and engage all researchers so that they will contribute. He stressed the importance of clarifying the role of non-informatics research users of Kbase. Ultimately, the success of Kbase should be measured by how well it advances research. This includes accessibility and support of the scientific method.

For Kbase to succeed it must have focused scientific goals and strong community involvement. Scientists need to see the path to success and be committed to it. Kbase's success also will depend on a cultural change from individual to community science. It will require significant effort toward assessing quality of experimental data, establishing experimental protocol and standards, and tracking provenance of data, including analytical processes.

With such a system in place, a researcher who obtained a field soil sample (including roots) and environmental measurements could return to the laboratory where the sample is prepared for multiple assays. Overnight, genomics, transcriptomics, proteomics, metabolomics ... run automatically producing full data sets. Standard analyses are run along with new modifications being tested. The next morning, the researcher arrives to review the results. Kbase could allow identification of constituents relevant to pathways of interest (intra-, extra-, and inter-cellular); display pathways and constituents; and allow simulations to observe the predicted effects of genetic or environmental modifications.

Clearly defined scientific objectives are critical to Kbase success. It is better to have some focused near-term success and to have objectives that are clearly defined, feasible to develop, and achievable. It also is prudent to have objectives that will actually be used by a sub-community and make an impact, rather than attempt to do everything at once. It is better to have strong community involvement where some researchers see the path to success, are committed and involved, and see benefit in the result. In addition, it is preferable to avoid the tendency to merge 10 specific goals into 3 big bloated ones; prioritize the 10 and keep them well defined.



To help the audience envision what Kbase could do, Mr. Cottingham likened it to using Google Maps on a smart phone to locate the nearest Starbucks. The system has to recognize that Starbucks is a business, that the name of the business is Starbucks, what it produces, and where it is located on a map given the address. It also has to identify the different paths that can be taken to get there. He asked the audience to imagine a similar experience navigating the results of an experiment. Mr. Cottingham said that Kbase is technologically possible but its implementation will require the scientific community to work together.

Four community workshops, with 80-100 participants at each, have been conducted (Supercomputing Workshop in November 2009, Plant and Animal Genome XVIII in January 2010, DOE Genomic Science Grantee Workshop in February 2010, and Joint Genome Institute (JGI) Users Meeting in March 2010.

A Kbase System Development Workshop with 80 participants was held in June 2010. This workshop identified the scientific objectives by focusing on experimental workflows, determining the computing system requirements, and the computing system design (how to build a system to meet those requirements). On Day 2 of the workshop, scientists were asked to: (1) define a long-term measure for science in their area; (2) define six to eight key objectives that could be reached in the near-, mid-, and longer term; (3) prioritize these objectives from high to moderate to low; (4) develop a detailed implementation strategy for the high priority objectives; and (5) work together (biological scientists with computer scientists, and data management and partner scientists) to develop a correspondingly detailed computer architecture implementation strategy. Tasks, milestones, and deliverables were established for each scientific objective and requirements.

To illustrate what was included in the implementation plan, Mr. Cottingham identified the Kbase science objectives in three key areas: microbial sciences, plant sciences, and microbial community sciences (metagenomics). The long-term goal for the microbial sciences area is to rapidly, reconstruct metabolic and regulatory pathways for 100 to 1,000 microbes with comparative reconstructions at 90% accuracy for growth and phenotypic characteristics. From Year 1 to Year 3, data will be integrated with the genomic function—experimental data represented to inferred knowledge about genes and genomes. From mid-Year 1 to Year 5, metabolic networks will be reconstructed, predicted, and manipulated—new experimental data will be integrated and metabolic reconstructions will be created automatically. From Year 2 to beyond Year 5, automatic inference of gene expression and regulatory networks will be enabled, and networks will be extended to include additional experimental data types. Mr. Cottingham provided similar information for the other two key areas.

The June workshop also focused on the Kbase infrastructure (e.g., a cloud cluster as a test bed for storing experimental data). The output of the workshop was the implementation plan, the estimated cost for the system, and a list of tasks that could be partnered with other organizations. Mr. Cottingham commented that those involved in this effort are beginning to realize the importance of sharing responsibilities in developing Kbase and working together with others (e.g., DOE's JGI and Office of Advanced Scientific Computing Research, National Center for Biotechnology Information, and NSF-funded iPlant Collaborative) to reach this goal.

Five pilot projects, initiated in September 2009 and completed in September 2010, were conducted to determine how the system would work. These projects included:

1. Development of a Microbes-On-Line metabolic modeling interface for analysis and visualization within the Google Framework (Google-like Application for Metabolic Maps [GLAMM])—Adam Arkin, Lawrence Berkley National Laboratory (LBNL).
2. Prototyping a Service Oriented Architecture (SOA) for storing and accessing biology data in a cloud computing environment—Ian Gorton, PNNL.
3. Development of semantic technologies to ease, speed up, and improve scientific workflows in systems biology—Kerstin Kleese van Dam, PNNL.

4. Development of JGI Metagenomic analysis pipelines for HPC and cloud systems—Victor Markowitz, LBNL.
5. Benchmarking bioinformatics analysis programs on HPC and cloud systems—Folker Meyer, Argonne National Laboratory.

DOE will build on the work conducted in the prototypic examples developed in these pilot projects.

Mr. Cottingham identified some Kbase architectural milestones. From Year 1 to Year 2, the computational platform will be developed (federated system from cloud to high performance computing [HPC]). Operational support and maintenance will begin in Year 1 and extend beyond Year 5. Other tasks that will be initiated in Year 1 include data workflow services (including data access and searching), core Kbase services (application programming interface and tools for analysis), and user environment (including linking to community analysis programs).

The Kbase cloud system infrastructure includes: (1) six Scientific Data Centers and the Kbase Core Data Center with gigabit Ethernet interconnect and petabyte storage capacity, (2) HPC resources linked with existing Advanced Scientific Computing Research facilities, and (3) cloud compute resources to support commodity data parallel applications and virtualization of work environments.

Mr. Cottingham mentioned that the Kbase Implementation Plan is on the Web at [http://www.sc.doe.gov/ober/kbase\\_plan.pdf](http://www.sc.doe.gov/ober/kbase_plan.pdf). He suggested that the BOSC members interested in the project read the 20-page Executive Summary of the plan.

In closing, Mr. Cottingham acknowledged the efforts of Susan Gregurick, the DOE Program Manager for Computational Biology and Bioinformatics in the Office of Biological and Environmental Research, and Brian Davison, Chief Scientist in the Biosciences Division at ORNL. More information about Kbase is available on the Web at <http://www.systemsbiologyknowledgebase.org>.

### Discussion

Dr. Sayler thanked Mr. Cottingham for his presentation on Kbase and asked about the computing capacity required to build the system. Mr. Cottingham replied that this project moves beyond the current state in which computing is done on individual computers to a world where there are thousands and eventually hundreds of thousands of computers working on the computation.

Dr. Philbert stated that the epigenome is not static but changes with time. Is this being built into the system? Mr. Cottingham replied that this was discussed at the workshop and we know it will have to be done in the future to model biology. At this point, however, the project is just taking baby steps.

Dr. Olden commented that the scale and complexity of the database will have to match the scale and complexity of biology, and the system will have to be hypothesis driven. This is beyond the level of complexity for genomics or anything else being done now. Mr. Cottingham responded that this project is an attempt to build a model that represents how the world works, and then test the model to see how well it works. Many pathways are not understood now; as new discoveries are made, they will be added to the model. Over time, the model will become richer and do better simulations. It will allow scientists to create hypotheses, conduct experiments, and verify if the model's predictions were valid.

Dr. Demerjian mentioned that because of the stochastic nature, weather forecasting models can predict only so far into the future. Will Kbase hit that wall as well? Mr. Cottingham replied that there are systems in biology that are very stochastic; nevertheless there is value in building models and determining what can be modeled accurately. Dr. Sayler commented that Kbase is not just a single model; it is an architecture that will allow scientists to use their own models. This is a whole new strategy for managing

data and information. Mr. Cottingham noted that there is a lack of experimental standards in biology; these standards are needed so that data can be combined, compared, and analyzed. Dr. Haas thought standardization would be based on good ontology and metadata definitions. He asked if EPA could build such a system at this time. Do you have to understand all of the uses of the data in the future or can that be added later? Mr. Cottingham responded that the system will allow definitions to be updated and the tools will take all of that into account. He added that the technology to build Kbase exists today.

Dr. Philbert stated that if the model assumes standardized conditions then the model is studying the biology in those conditions. How would the system account for the fact that biology adapts to environmental changes? Mr. Cottingham pointed out that experiments do not include all possibilities. It is okay to use the model to make a prediction under certain conditions; then someone must validate the model by determining the accuracy of the prediction by conducting an experiment at which point the model would either be validated or need to be modified or improved to encompass additional conditions.

Dr. Falk asked about DOE's commitment to completing the development of Kbase. Mr. Cottingham said that he could not speak for DOE, but there was an allocation of \$10 million for this project in the Fiscal Year (FY) 2011 budget request so that the first phases could be initiated. There could be up to seven groups working together on different aspects of the system. By Year 3, most of the tasks described in this presentation will have been fleshed out. He mentioned that comparable systems attempted in the past at the NIH were funded at the \$50 million level. Dr. Philbert pointed out that the \$50 million is just a fraction of the total real cost of the system. Mr. Cottingham replied that the green computing paradigm of the future will harness the computing power of thousands of computers distributed at many different locations rather than one energy-intensive high-speed computer with several hundred thousand processors.

### **Health and Environmental Research Online (HERO) Database**

*Debra Walsh, Deputy Director, National Center for Environmental Assessment (NCEA), ORD, EPA*

Ms. Debra Walsh explained that the HERO Database is a comprehensive system to identify, compile, characterize, analyze, and prioritize scientific studies. HERO is part of NCEA's effort to revamp the lengthy air quality criteria documents into the more succinct Integrated Science Assessments (ISA), which complements the change in the National Ambient Air Quality Standards (NAAQS) review process. HERO also is being used in development of the Integrated Risk Information System (IRIS) Assessments and the Provisional Peer Reviewed Toxicity Values Assessments.

HERO facilitates complete, sustainable, and effective assessment development, houses citations and study data from the scientific literature, includes studies in EPA's priority areas, and allows efficient and intelligent information extraction and synthesis. In addition, HERO assures the highest scientific integrity in data quality, employs advanced searching and screening techniques using advanced algorithms, utilizes rapid and comprehensive information retrieval, and provides transparency to stakeholders and the public.

The HERO Database system has a public website (<http://cfpub.epa.gov/ncea/hero/>) that allows users to search the more than 350,000 references used in NCEA assessments. In the future, users will be able to view detailed data extracted from key studies (methods, results, effect estimates, etc.), and generate pre-defined reports to print or save. HERO also has an EPA portal that offers the same capabilities as the public site plus full-text PDFs of the references, literature searching (searches multiple databases simultaneously), screening queries to categorize and sort studies, and analysis tools (visualization, clustering, classification, and more). HERO's internal tools include the ability to insert citations and generate reference lists automatically (LitCiter), data entry screens with quality control/quality assurance (QC/QA) features incorporated (LitExtractor), document management for version control (audit trail), and management dashboard for real-time reporting.

Emerging technologies—such as federated searching, discovery interfaces, and deep Web searching—are used for the literature search and screening for HERO. A federated search is the simultaneous searching of multiple databases. Discovery interfaces using appealing design, relevancy ranking, and faceted navigation make for a compelling user experience. Deep Web searching involves scouring the vast repository of underlying content that evades traditional search methods. A wide net is cast to ensure comprehensiveness; then, data and text mining tools are used to screen and tag citations. Techniques such as visualization, clustering, theme mapping, and classification are used to help sort citations. Upon import into the HERO Database, metadata identifying scientific discipline, pollutants examined, health outcomes, etc., are added.

Once the references are in the HERO Database, LitCiter can be used to link citations in an assessment or bibliography to the full citation in the HERO Database. This software is similar to EndNote. Using the HERO ID, a hyperlink is created in the document with the proper format. When readers click on a link in the published document, they are taken to the HERO Database, where they can see the full citation and associated data.

In addition to comprehensive literature searches of peer-reviewed journal articles in multiple disciplines, NCEA routinely imports new studies as they are published for priority pollutants (an “Evergreen” process). During assessment development, new studies are identified by other scientists and the public. Scientists then evaluate the studies using clearly defined criteria. **Informative studies** are well-designed and properly implemented, with methods and results thoroughly described. **Highly informative studies** provide evidence on mode of action or potential susceptibility to effects, reduce uncertainty or exposure error, or offer innovative methods or designs. **Policy-relevant studies** may include those conducted at or near relevant concentrations. Citations from all studies are included in the database for transparency and accessibility. Study data extracted from key studies are analyzed and used in assessment development.

Scientists extract data from policy-relevant studies to use for cross-study analysis. Compelling figures, such as the Forest Plot presented by Ms. Walsh, show the study results at a glance. Ms. Walsh explained that the figure presented was from the recent Particulate Matter ISA draft showing respiratory outcomes from epidemiologic studies. Links in the online PDF bring the reader to the full extracted data in the HERO Database. Synthesizing the data this way demonstrates consistency and coherence across studies. The easy-to-understand graphic distills complicated scientific data for use by policy makers, including the EPA Administrator, as well as the public.

In closing, Ms. Walsh summarized the features of the public Web site, the EPA portal, and the internal tools. The public HERO site includes LitSearch and LitReporter to search citations and extracted data. The EPA portal includes LitSearch, LitLibrary, LitScreener, LitExtractor, LitAnalyzer, and LitStorage, allowing EPA users to access the full-text PDFs of the references, extract data for key studies, and analyze data across studies. The internal tools include LitCiter, LitDoc, LitSmart, and LitDash, which allow users to insert references, generate and format bibliographies, manage document versions, and other tasks. Ms. Walsh noted that the EPA portal is accessible via the Internet to those with a password-protected account.

### Discussion

Dr. Saylor thanked Ms. Walsh for her presentation and asked if there were any questions. Dr. Philbert asked if the system could identify which of the references in the Database were written by EPA investigators and EPA grantees. Ms. Walsh replied that the system did not yet have that capability. HERO is built on an Oracle Enterprise platform and it is accessible throughout NCEA. They are working to expand access within EPA. Dr. Philbert recommended adding the ability to identify EPA-sponsored studies in the HERO Database; this would be a simple add on and it would provide valuable information to ORD.



Dr. Demerjian asked how many years of literature are covered by HERO. Ms. Walsh responded that some of the references were published in the 1970s and some may be even older. Dr. Demerjian said that he thought there might be some papers missing from the Database. Ms. Walsh pointed out that HERO includes only those references cited or reviewed for assessments developed by NCEA such as the ISAs (formerly Air Quality Criteria Documents [AQCDs]). They will expand coverage to other pollutants like the IRIS chemicals. She noted that a user can search by the scientist's name, keyword, reference type, assessment, chemical, or other parameters. The search can be limited to only those references actually cited in the assessments, which is a subset of the references that were reviewed, or it can be limited to certain years.

Dr. Saylor noted that because the public cannot access the EPA portal, they will not be able to see how EPA extracted the data. Ms. Walsh replied that the public user will be able to see the extracted data once the data are all entered. The extracted data can be provided to the public because they are being extracted by EPA. Public users also can import the extracted data so that they can analyze them with their own software tools. In addition, the Web site allows users to submit feedback so if a scientist finds that the data for his study was extracted incorrectly he can notify EPA so that the Database can be corrected. HERO will benefit EPA researchers as well as those outside the Agency; NCEA hopes this will serve as an incentive to get researchers to submit their data in a format that will allow their import into HERO.

Dr. Paustenbach asked if the full text of the government documents included in HERO would be available to the public. Ms. Walsh replied that there would be links to the full text provided for all EPA documents and any journal articles that are open source to make them available to the public users. Dr. Paustenbach asked if full text of books and book chapters were included in the system. Ms. Walsh said that NCEA has purchased and scanned books and book chapters so the full texts of these references are available through the EPA portal. Dr. Paustenbach asked if foreign publications were included. Ms. Walsh responded that there are a number of foreign references, but only those that were used in the assessments. She added that HERO links to Google Scholar, so if a reference is in HERO that will be noted in Google Scholar. Ms. Walsh mentioned that HEROnet can be used to provide SAB members access to full text of the references when they are reviewing a report or document. The links to the full text are embedded in the electronic document, and the SAB members are given a password to access HEROnet for the review.

Dr. Olden commented that HERO is a very important public resource. Is the Office of Management and Budget (OMB) aware of the Database? Ms. Walsh replied that OMB was briefed on HERO in September 2010 in Research Triangle Park. She noted that HERO was developed using funding that already was being used to fund a contractor to do similar work. HERO was created with a limited budget and marginal staff. Dr. Olden asked if EPA would continue to revisit and incorporate data as the science evolves. Ms. Walsh affirmed that would be the case. In fact, as a result of working with the National Center for Computational Toxicology (NCCT), more computational toxicology data have been added to the Database. She explained that NCEA started populating HERO with epidemiologic data because the weight of evidence for ISAs relies heavily on epidemiologic data.

Dr. Philbert emphasized that HERO is an incredibly useful tool and it was developed with minimal resources. It appears that the Agency invests very little to develop tools such as HERO that are useful to EPA and others right now; much more seems to be invested in developing tools that might be useful in the future. He thought there was an imbalance that EPA needs to address. Dr. Philbert specifically requested that his comments be included in the minutes.

Dr. Susan Cozzens said that she was concerned that HERO was developed apart from the EPA Library. This tool should be made available throughout EPA; if it is not, the Agency is not maximizing the effective use of its resources.



## Measuring ORD's Research Impacts

Myles Morse, National Center for Environmental Research (NCER), ORD, EPA

Mr. Myles Morse stated that ORD is using a portfolio of tools to measure research impact. These include:

- ✧ Surveys
- ✧ Case studies
- ✧ Program Office testimonies
- ✧ Bibliometrics and expanded bibliometrics
- ✧ Data mining and Decision Document Analysis (DDA)
- ✧ Expert reviews
- ✧ Economic analyses
- ✧ Anecdotal success stories, etc.

He noted that bibliometrics should never be used as the sole tool to identify the scientific impact of a program's research.

ORD has been using bibliometric citation analysis as one measure of research impact for a number of years. It is used to indicate the impact on the external scientific community and the quality of the program's outputs—through high citation of the papers by the scientific community and publications in top-tiered journals. ORD's citation data are compared to the Thomson Reuters benchmarks in Essential Science Indicators (ESI) and Journal Citation Reports (JCR) impact factors for highly cited papers and high-quality journals.

Highly cited publications often are cited in decision-making documents, and these papers provide evolutionary "proof of sound science" because other scientists verify and build on that research. The citation process confirms the validity of the science and builds the foundation for scientific consensus. Both the cited and citing publications then are cited by policy makers who use the findings in rulemakings and other decision documents. Research results typically are used for decision making only after this "proof of sound science."

Citation analysis is used and accepted by most scientific research organizations around the world. It is used by many federal agencies, non-profit research institutions, and academia. In a 2008 review of research impact assessment tools entitled, *The Return on Investments in Health Research: Defining the Best Metric*, the Canadian government concluded/recommended that impact evaluators must recognize that multiple indicators and metrics are required for any evaluation. The report identified 70 preferred indicators and metrics of impact after evaluating more than 300 different metrics. Of the 70, there were only three recommended indicators of quality: relative citation impact, highly cited publications, and publications in high-quality outlets.

DDA or Decision Document Analysis was designed to identify the impact of research on a stakeholder's policy and rulemaking decisions. Bibliometrics are used to focus or refine the population of publications to be analyzed in one component of the DDA to reduce the number of publications examined and the associated cost.

There are a number of additional metrics being considered by ORD, including:

- ✧ **Capacity Building - Academia:** # of students graduated in science, math, and engineering fields; # of research positions funded; amount of additional funding leveraged; and use in curricula.
- ✧ **Industry:** # of patents/patent applications; # of jobs created; and additional funding leveraged.
- ✧ **News Media:** # of media outlets; # of consumers reached; and caliber of outlets reached.
- ✧ **Collaborations:** with international academic entities, industry, and others (can be quantified).
- ✧ **Tangible Research Outputs:** models, sensors, analyzers, data sets, methods, etc. (can be quantified).

- ✧ **Measurable Health/Environmental Quality Impacts:** monitored contaminant reductions; decrease in hospital admissions; decrease in mortality, etc.

The 2009 DDA for the Endocrine Disrupting Chemicals (EDCs) Research Program identified 227 government decision documents that cited EDCs program publications. These 227 decision documents cited 175 EDCs publications 444 times. The numbers and different types of decision documents identified in the analysis included:

- ✧ **70 Federal Documents:**
  - 12 Rulemaking/Regulatory documents
  - 13 Risk Assessments (including 5 IRIS Assessments)
  - 9 Policy Making documents
  - 29 Technical/Guidance documents
- ✧ **7 ATSDR Toxicological Profiles**
- ✧ **35 State Documents:**
  - 15 Rulemaking/Regulatory documents
  - 5 Risk Assessments
  - 11 Policy Making documents
  - 4 Technical/Guidance documents
- ✧ **122 International Documents:**
  - 8 Rulemaking/Regulatory documents
  - 28 Risk Assessments
  - 2 Policy Making documents
  - 2 Guidelines documents
  - 1 Strategy
  - 81 Technical/Guidance documents

Some examples of the decision and policy documents that cited the EDCs Program publications included:

- ✧ USEPA Aquatic Life Ambient Water Quality Criteria - Nonylphenol
- ✧ USEPA Drinking Water: Preliminary Regulatory Determination on Perchlorate
- ✧ U.S. Environmental Protection Agency. Fish Short-term Reproduction Assay Test Protocol – Fathead Minnow. Fish Screening Assay Protocol, 2007.
- ✧ California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (OEHHA). Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), Notice of Addition of Documents and Information to OAL Notice File No. Z-07-0619-02, Amendment to Title 22, California Code of Regulations, Section 12805, Specific Regulatory Levels: Chemicals Causing Reproductive Toxicity [Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Di(*n*-butyl)phthalate (DBP)], December 7, 2007.
- ✧ Australian Government, Department of Health and Ageing, National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Existing Chemical Hazard Assessment Report. Diisononyl Phthalate, June 2008.

Drilling down even deeper, the analysis examined why the decision document cited the EDCs Program publication. For example, the Australian Government's Existing Chemical Hazard Assessment Report on Diisononyl Phthalate cited the EDC Program publication Swan SH, et al. Decrease in anogenital distance among male infants with prenatal phthalate exposure. *Environmental Health Perspectives* 2005;113:1056-

1061. This decision document cited the Swan paper finding that urinary MBzP concentration was inversely related to AGI (anogenital index, anogenital distance normalized for body weight).

The Swan paper was named “2009 Paper of the Year” by *Environmental Health Perspectives*, and it was cited by Senator Diane Feinstein in senate testimony on the US Consumer Product Safety Improvement Act of 2008. In addition, the Swan paper was cited in the phthalate regulations of California, Vermont, and Washington, and it is cited in bills in more than 20 additional states that are considering phthalate regulations. Beyond state regulations, the Swan paper was cited by more than 20 countries, including the European Union, Japan, Canada, Brazil, and Australia, in their phthalate regulations.

An analysis of the first and second generation citations revealed that researchers from 124 different institutions directly cited the Swan paper, and 1,432 different institutions cited papers that directly cited the Swan paper (second generation), showing the exponential reach of that single paper.

Mr. Morse described four additional examples of metrics used to measure the impact of ORD research. The first example was the Ecovative Design Small Business Innovation Research (SBIR) Award: Growing Mushrooms for Insulation & Packaging. Ecovative Design received a total of \$295,000 from EPA (\$70,000 for the Phase I SBIR and \$225,000 for the Phase II SBIR). Using that funding, the company developed two new products—Greensulate and Ecocradle. Eighteen new jobs were created, \$6 million of venture capital funds were leveraged, and the company was named the “2011 Technology Pioneer” by the World Economic Forum. The Ecovative Design products use mushroom roots to bind agricultural byproducts (e.g., rice hulls) and produce biodegradable building construction materials, insulation, and green packaging material. The products require only one-tenth of the energy needed to produce their petroleum-based counterparts, and the transportation impacts are reduced because local materials are used in production.

The second example to demonstrate additional metrics for measuring research impact was the 2008 People, Prosperity, and the Planet (P3) award to the University of California-Davis for development of a biodegradable plastic produced from municipal wastewater. Using the \$85,000 EPA investment, the student team formed the Micromidas Company 1 year after the P3 award to commercialize a production process for biodegradable plastic from municipal sewage. The company now employs 26 professional staff members, and was able to leverage \$3.6 million of venture capital funding. Micromidas has negotiated contracts with several wastewater treatment plants, and a number of companies (e.g., Nestles, Pepsi) are interested in the plastic. In addition, Micromidas was selected as one of the “Top 50 Water Innovation Leaders” by the Artemis Project.

The third example was the 2005 Oberlin College P3 award for the development of a real-time system that can motivate people to conserve energy and water. Using the EPA investment of \$85,000, the student team was able to develop the Building Dashboard, which resulted in up to a 56% savings in energy and water. The students formed Lucid Design Group to produce the Building Dashboard, and the company now employs 18. Lucid Design Group was able to leverage \$6 million of venture capital funding, and the Dashboard has now been installed at more than 100 large institutions. The company was selected as a Category Finalist for the 2010 Adobe MAX Awards. The Building Dashboard has resulted in real savings of energy and water; in one dormitory where the Dashboard was installed, students’ reduced energy and water use saved the university more than \$5,100 in just 2 weeks.

The fourth example of additional research impact metrics was the 2007 P3 award to the University of Virginia (UVA) to develop The Learning Barge, a floating field station/classroom to teach people how to make the Elizabeth River swimmable and fishable by 2020. Using the \$85,000 EPA investment, the student team was able to build the Learning Barge, which hosted more than 6,500 visitors in its first year, and more than 6,000 K-12 students were booked to visit it next year. The project was able to leverage funding from industry, institutions, and private contributions from the American Institute of Chemical Engineers (AIChE) and the American Institute of Architects (AIA).

The U.S. Coast Guard trained inspectors during the design/construction phases of the barge, and more than 34 UVA students were involved in its construction. Operation of The Learning Barge created seven jobs, and local industries and businesses partnered after the launch to form an advisory committee for maintaining it. The Learning Barge is the world's first floating wetlands classroom, and the curriculum was developed by top-notch science coordinators and teachers.

Mr. Morse pointed out that there is only \$50,000 of funding available to conduct bibliometric and DDA analyses for ORD. The EDCs DDA cost about \$35,000, and the Thomson Reuters subscription to InCites costs about \$45,000, so it is clear that more funding is needed to conduct these types of analyses.

EPA is considering joining the Science & Technology for America's Reinvestment: Measuring the Effect of Research on Innovation (STAR METRICS) project, which is a new initiative to monitor the impact of federal science investments on employment, knowledge generation, and health outcomes. This is a multi-agency effort led by the White House Office of Science and Technology Policy (OSTP), NIH, and NSF. When it is operational, STAR METRICS will measure the impact of research on jobs, patents, publications, citations, and business start-ups. It is based on a highly successful pilot program that includes seven research institutions, and it is now being extended to more universities (60 institutions already have expressed interest in taking part in the project). The first phase will use university administrative records to calculate the employment impact of federal science spending through the American Recovery and Reinvestment Act (ARRA) and agencies' existing budgets. The second phase will measure the impact of science investment in four key areas: (1) economic growth will be measured through indicators such as patents and business start-ups; (2) workforce outcomes will be measured by student mobility into the workforce and employment markers; (3) scientific knowledge will be measured through publications and citations; and (4) social outcomes will be measured by long-term health and environmental impact of funding.

Mr. Morse closed his presentation with a short video on the Micromidas example.

#### Discussion

Dr. Sayler thanked Mr. Morse for his presentation and asked if there were any questions. Dr. Sayler then asked if Micromidas had received any patents for its technology. Mr. Morse responded that he assumed that the process was patented but he did not know for certain. Dr. Paustenbach asked about the number of P3 awards made each year. Mr. Morse replied that EPA has made 350 P3 Phase I awards since 2004—which is about 60 awards per year. The Agency has made only 6 P3 Phase II awards each year, but last year EPA issued 14 Phase II awards. He mentioned that NCER is trying to formalize the funding for P3 as well as expand the program.

Dr. Sayler asked why ORD is not making the videos and other information on these successes more available to the public through outlets such as the Discovery Channel. Mr. Morse replied that because ORD does not have the funds to pay such outlets to run the videos they would have to do it voluntarily.

Referring to the DDA as an example of data mining, Dr. Cozzens asked if ORD would say that publications not cited in rulemaking documents had no impact. Mr. Morse responded that the DDA does not imply that program publications that were not cited in decision documents did not have an impact. All of the publications contribute to the knowledge base and build the science foundation on which EPA bases its decisions. ORD uses the data mining tools to search for the citation of program publications in EPA rulemaking documents. ORD uses bibliometrics to identify a highly cited subset of the program publications for the broader DDA search to identify decisions documents beyond EPA that cite the program publications (e.g., citation in state regulations, foreign government regulations, other federal agency guidelines and risk assessments). This is a method ORD is using to reduce the number of publications for the broader search to reduce the cost of the analysis. Dr. Cozzens commented that if only a portion of the program bibliography is searched, the DDA results are really just examples. Mr. Morse



replied that the entire program bibliography is searched for use in EPA decision documents. A subset of the bibliography is searched for use in decision documents beyond EPA (other federal agencies, states, other countries).

## RESEACH PROGRAM PERFORMANCE EVALUATION SESSION

### STAR METRICS

*Dr. Stefano Bertuzzi, Office of Science Policy, Office of the Director, NIH*

Dr. Stefano Bertuzzi opened his presentation by stating that it was not an NIH presentation. The Science and Technology for America's Reinvestment: Measuring the Effect of Research on Innovation, Competitiveness and Science (STAR METRICS) project is a multi-agency venture led by NIH and NSF under the auspices of OSTP. It is a partnership between science agencies and research institutions to document the outcomes of science investments to the public. One of the major benefits of STAR METRICS is that a common empirical infrastructure will be available to all recipients of federal funding and science agencies to quickly respond to state, congressional, and OMB requests.

EPA has been engaged with STAR METRICS and has been involved with shaping the project as it develops. Dr. Bertuzzi said that his presentation would explain why the STAR METRICS tool could be very helpful to EPA, how the tool works, and what it can do for EPA and other agencies.

In 1950, the Federal Government was basically a non-player in research and development (R&D), but since then, the government has invested considerable resources and made a tremendous contribution to R&D. Even adjusted for inflation, the government is spending more now on non-defense R&D than ever before (more than \$60 billion/year).

As federal budgets get tighter, the public scrutiny of government spending increases. Basically, the public and Congress want to know what the American people are getting for their investment in R&D. NIH has been faced with questions like: With the doubling of the NIH budget, why hasn't there been a doubling of the number of scientific publications? Why haven't there been more cures? What are the benefits of mapping the human genome?

One of the questions that the new NIH Director asked when he accepted the position was: What is the impact of NIH research on health and the economy? Dr. Bertuzzi mentioned a recent article in *Science* entitled, "What Science is Really Worth," by Colin Macilwain. Research advocates say that spending on science is one of the best ways to generate jobs and economic growth, but as Colin Macilwain points out in his article, the evidence behind such claims is patchy. The goal of STAR METRICS is to connect the patchiness by developing tools that can help federal agencies, Congress, and others determine the economic impact of the government R&D investment.

It is clear that the administration is watching and there are some clear themes: (1) investment in science (ARRA, National Academy of Sciences April 2009 speech); (2) openness and transparency (data.gov, open.gov); (3) evidence-based policy (joint memorandum on "Science and Technology Priorities for the FY 2010 Budget"); and (4) accountability (ARRA Reporting Guidelines).

The July 21, 2010 Orszag-Holdren memorandum on priorities for the FY 2012 budget stated that: "Agencies should support the development and use of "science of science policy" tools that can improve management of their R&D portfolios and better assess the impact of their science, technology, and innovation investments." STAR METRICS is one way to measure this impact, and it will help agencies that are competing for the federal resource pool put forth compelling arguments to justify their proposed budgets. Dr. Bertuzzi noted that there also is strong international interest in measuring the impact of science and research, and Japan, for example, has shown considerable interest in the STAR METRICS project.



There is a complex link between inputs and outcomes. The inputs (federal funds for research) are easily measured but they contribute to a knowledge pool rather than directly produce services, so there is seldom a linear relationship between inputs and outcomes. There are measures for outputs as well as outcomes, but it is difficult to associate causation of an outcome (e.g., better health, employment, better policies, sales, and national competitiveness) with a particular input. Dr. Bertuzzi stated that STAR METRICS is not the “silver bullet,” but it will provide more information than is available now and it is a step in the right direction.

The steps for building an empirical framework include: (1) start with scientists as the unit of analysis because science is done by scientists—need to identify the universe of individuals funded by federal agencies (PI, co-PI, research assistants, graduate students, etc.); (2) include a full description of input measures; (3) include a full description of outcomes (economic, scientific, and social); (4) combine inputs and outcomes; and (5) create appropriate metrics that capture all dimensions of science investments.

Dr. Bertuzzi asked Dr. John Voeller, OSTP (who joined by telephone), if he had anything to add. Dr. Voeller said that he had spent many years studying the data system of the Federal Government. If the grant of an NIH scientist, for example, is not renewed, he no longer exists in the federal system. That scientist could have failed to receive a follow-on grant because his research was inferior or he could have left research to start a biotech company. If the later scenario is true, the federal contribution is significant and should be captured in some way, but the process is daunting.

STAR METRICS is being implemented in two phases. Phase I involves the development of uniform, auditable, and standardized measures of the impact of science spending (ARRA and non-ARRA) on job creation, using data from research institutions’ existing database records. No personally identifiable information (PII) will be collected in Phase I. Phase II involves the collaborative development of measures of the impact of federal science investment on: (1) scientific knowledge using metrics such as publications and citations, (2) social outcomes using metrics such as health outcomes measures and environmental impact, (3) economic growth using metrics such as patents, new company start-ups, and other measures), and (4) workforce outcomes using metrics such as student mobility and employment.

STAR METRICS is a strategic collaboration between the Federal Government and research universities and institutions. The universities and institutions are being asked to voluntarily submit data (based on existing records) that will be assembled to assess the number of jobs created by federal research dollars. The project will begin with existing data, which already are collected for financial purposes, to limit the burden on investigators of collecting and reporting the information.

Once an agency funds an investigator, the grant receives a code and the information for that grant feeds into three systems: the human resources (HR), procurement, and subcontracting systems. The HR system captures valuable information, including all of the individuals who charge their time to the grant. The procurement system tracks the use of vendors through the DUNS number. The subcontracting system captures data on grant funding provided to contactors. There also are jobs supported by the indirect costs of the grant, which are captured by STAR METRICS.

Creating jobs, however, is clearly not the only goal of science, so STAR METRICS has to go farther. In Phase II, data to assess the impact of federal research dollars on scientific knowledge, social outcomes, economic growth, and workforce outcomes will be collected.

The STAR METRICS pilot identified systemic and idiosyncratic data issues. The data are relatively clean, but anomalies exist that will need to be coded in the next stage. Standardized reports are created through drop-in code. Universities can create the reports in about an hour, and job estimates can be returned within 24 hours. The Vice President’s office has been briefed on and has approved the STAR METRICS pilot approach and timeline. The approach is aligned with the ARRA Section 1512 guidance,

which calls for recipients to use payroll and financial data in calculation of estimates. OMB, the Council of Economic Advisers (CEA), and science agencies have been briefed on the STAR METRICS pilot project. Dr. Bertuzzi stated that people have been pleased with the pilot—there has been no added burden on the investigators; the initial burden, which is not significant, falls on the administrative staff but after the initial effort the process is highly automated. The universities participating in the pilot have appreciated the reports they have received from the system.

Dr. Bertuzzi identified the 14 data elements requested in Phase I:

- ✧ Information on Individuals and Awards (7 data elements): de-identified employee identification number, unique award number, recipient account number, overhead charged, occupational classification, proportion of earnings allocated to award, and FTE status.
- ✧ Information on Overhead (1 data element): proportion of overhead associated with salaries (from indirect cost rate proposal).
- ✧ Payments to Vendors (4 data elements of which 1 is redundant): unique award number (redundant), recipient account number, vendor DUNS number or ZIP Code, and vendor payment amount).
- ✧ Subcontracts and Sub-awards (4 data elements of which 1 is redundant): unique award number (redundant), recipient account number, sub-award recipient DUNS number or ZIP Code, and sub-award payment amount.

Dr. Bertuzzi presented three tables generated by STAR METRICS that report the jobs supported by federal science funding. The first table identified the total number of FTE jobs and positions during the current period and the change from the previous period; these numbers also were reported for faculty, undergraduate students, administrative staff, post-graduates, graduate students, and technical support staff. The second table identified the number of FTE jobs by industry (all industries; accommodation and food service; administrative and support and waste management; arts, entertainment, and recreation; construction; educational services; health care and social assistance). The third table identified the FTE jobs supported by overhead.

To illustrate the information available to the universities participating in the pilot program, Dr. Bertuzzi showed a map that presented fuzzed data for the local economic impact of federal funding received by the University of Massachusetts-Dartmouth.

Dr. Bertuzzi mentioned that more information on the STAR METRICS project is available on the Internet at <https://www.starmetrics.nih.gov>. The Research Institution Participant Guide is available at <https://www.starmetrics.nih.gov/Star/Participate>.

The goals of Phase II are to:

- ✧ Develop a platform that can transparently and accurately relate inputs and outputs/outcomes.
- ✧ Describe the intricate and flexible dynamics of how discovery and innovation translate into four broad categories of impact: (1) knowledge (e.g., publications, citations), (2) economic (e.g., patents, spin off companies), (3) workforce (e.g., employment, student mobility), and (4) social (e.g., health, environment, energy).
- ✧ Combine authoritative input and output data from several disconnected sources.

- ✧ Interact and interface with ongoing experiments in this arena, such as VIVO and the Brazilian Lattes Platform.
- ✧ Track funded scientists throughout their careers.

Dr. Bertuzzi stated that a practical application of Phase II would be to capitalize on the possibility of automating part of the progress reports, with the new Research Performance Progress Report (RPPR). The information could be absorbed from the researcher's Web page, which contains an RDF or XML tag indicating that it is acting as a researcher identifier. This page could be a personal Web page, an institutional Web page, or a Web page on the proposed Open Researcher and Contributor ID (ORCID) service (<http://www.orcid.org>) or on any other service.

With respect to measuring economic impact, Dr. Bertuzzi posed the following questions: How do university researchers affect regional innovation? What are the impact pathways? As an example of what STAR METRICS offers to answer such questions, he presented a diagram that identified Caltech PIs and the many organizations and firms with which they interact (e.g., Medtronic, University of California, Belkin International, Second Sight, and Alfred Mann Foundation). The next diagram showed the impact pathways identifying the sources of the links (e.g., student graduation, inventor mobility, and direct collaboration).

Implementation of Phase II will involve: (1) determining what data should be collected and from what sources, (2) gathering input from all STAR METRICS stakeholders. The STAR METRICS Consortium will make decisions on what data to collect and move forward with Privacy Impact Assessment (PIA) and Paperwork Reduction Act (PRA) requirements for Phase II.

Dr. Bertuzzi emphasized that the system will be sustained only if the users find value in the product. The questions that will be addressed in evaluating the system are:

- ✧ How does this advance scientists' reporting burden reduction?
- ✧ How does this advance individual scientist connectivity within the scientific community (e.g., interdisciplinary research)?
- ✧ How does this help the university in its portfolio and asset analysis?
- ✧ How does this reduce administration burden?
- ✧ How does it advance knowledge management?
- ✧ How does this help federal agencies reporting to the public and to Congress?
- ✧ How does this help agency planning?

Dr. Bertuzzi presented a tentative timeline for Phase II. From October to November 2010, activities will focus on engaging stakeholders on data elements to be collected in Phase II. Specifically, there will be meetings with professional societies (e.g., Association of American Universities, Association of Public and Land-grant Universities, Association of American Medical Colleges), a meeting with developers of the Lattes database (a curriculum and institutions database of science and technology areas in Brazil), and a meeting with the developers of VIVO software (for national networking of scientists) in October. A technical workshop/Webinar will be held in November 2010, to obtain input from the stakeholders' perspectives. A pilot project could possibly be launched in January 2011. PIA and PRA will be submitted in March 2011, and full implementation and evaluation would take place in 2012.

Dr. Bertuzzi closed his presentation with a quote from Galileo: "I pursue the light of science, and its benefit." He then asked if Dr. Voeller had anything to add. Dr. Voeller commented that when the participating universities in Phase I provided the information on their federal funding, they submitted

information on their grants from all federal agencies, not just NIH and NSF. In fact, there also was information on funding from states, foundations, and other sources. Dr. Voeller also mentioned that through topic modeling, STAR METRICS can be used for discovering opportunities for collaboration within minutes rather than weeks.

### Discussion

Dr. Falk thanked Dr. Bertuzzi for such a clear presentation. He commented that although he understands the motivation behind STAR METRICS, he thought that trying to assess the benefits of research by looking at employment in the first year of a grant was problematic. Scientific research outcomes happen over time, not immediately after a grant is awarded. It might be better to look at the 10 years since the NIH budget was doubled to see what effect that has had on jobs. Dr. Falk was concerned about the short-term basis because it is not representative of the real payoff. Dr. Bertuzzi was in complete agreement with Dr. Falk's comments and he pointed out that it is for that very reason that Phase II is essential. Nevertheless, the government wants to know how many jobs were created from ARRA funding, and it is better for the scientists and agencies to make this determination to avoid under reporting. That will happen in Phase I. With regard to looking at the impact of doubling the NIH budget, that may be possible using the data in STAR METRICS because some universities are submitting data for the past 10 years.

Dr. Voeller mentioned that he has been following the money in six universities in the pilot to determine how they spent their money. He has found that for every \$1 of NIH funding invested, \$3.5 are spent by the university, which is a 3.5:1 multiplier. Dr. Philbert expressed some concern about the credibility of that multiplier, because it would be difficult to determine what the university would have spent regardless of the source of the funding. He noted that universities respond to market pressures. Dr. Bertuzzi agreed that STAR METRICS is not about multipliers. It is about tracking jobs and how the money is spent. Dr. Philbert expressed his concern about associating the \$3.5 of expenditures with the grant funding. Dr. Bertuzzi responded that STAR METRICS just provides the data; it is up to others to analyze the data and assess the impact.

Dr. Saylor stated that NSF examined R&D investment in the United States and found that six or seven states capture two-thirds of the federal R&D funding. This is a strange dynamic—some states can assimilate the dollars better than others. The doubling of the NIH budget did not result in a corresponding increase in funding for junior faculty; rather, researchers stayed longer in post-doc positions. How can you factor that in? A 3.5:1 multiplier would not be adequate in some states. Dr. Bertuzzi replied that STAR METRICS cannot provide all the answers, but it is an attempt to move forward in the right direction and provide more rigor in collecting such information. Dr. Voeller mentioned that there will be a meeting on Friday, October 22 at which they will seek input from those who receive federal funding for research. One goal of this meeting is to identify potential difficulties and how to avoid them. This is a bottom-up rather than a top-down approach; the researchers will inform the project. Dr. Voeller also noted that the European Union wants to build EU STAR based on STAR METRICS.

Dr. Paustenbach asked about the BOSC's role with respect to STAR METRICS. Should the BOSC offer comments or recommendations? He expressed his concern about EPA's involvement in STAR METRICS. He noted that, in the past, EPA had tried unsuccessfully to quantify theoretical deaths avoided (lives saved). He did not think the Agency was ready to pursue this. Dr. Olden said he thought it could be done and that such a system was overdue. He offered two comments. First, it is important to get information from users (i.e., industry and government); right now, it appears that the information is coming from the providers (universities). Second, the data could be queried to determine how to improve the translation of basic science to societal benefits. How might we do a better job and make a greater impact on society? Dr. Bertuzzi responded that they are trying to involve users and obtain input from them. He also agreed with Dr. Olden's second point, adding that it is important to understand how knowledge travels from basic discovery to useful positive outcomes. He stressed the importance of capitalizing on what the government has done, and pointed out that Phase II will be shaped by input from



the scientists because they decide what to measure. Dr. Bertuzzi said he did not think doing nothing was an option. The government has to start building the infrastructure to help federal agencies assess the impact of their research.

### **Overview of ORD Evaluation Techniques: Past and Present**

*Mya Sjogren, Performance and Accountability, ORD, EPA*

Ms. Mya Sjogren identified some key activities related to performance evaluation. She mentioned that ORD has been using internal organizational scorecards to track the performance of the Laboratories and Centers. Ms. Sjogren also reported that the Agency is contemplating becoming a partner in the STAR METRICS project. Although the administration has not yet issued specific guidance on performance evaluation, measures such as those in STAR METRICS should be useful. Ms. Sjogren commented that the Obama administration's goal is to build a performance management evaluation system in which outcomes matter.

Past and current methodologies for assessing performance include: (1) BOSC reviews of program quality, relevance, and scientific impact of the research; (2) partner surveys that provide stakeholder feedback on the utility and timeliness of EPA research; (3) bibliometric analysis, which quantifies the impact and influence of EPA publications in the broader scientific community; (4) decision document analysis or DDA, which is a type of bibliometric analysis that assesses the extent to which partners use EPA research in policy and regulatory decisions; (5) Annual Performance Measures (APMs) that track the on-time completion of research outputs; and (6) organizational scorecards, an internal tool for tracking the annual progress of ORD's Laboratories, Centers, and Offices.

The BOSC conducts reviews of ORD research programs to assess whether ORD is conducting the right research and whether it is being conducted well. The BOSC provides feedback on the relevance, timeliness, and utility of ORD's research. The BOSC recommendations are used by managers to improve research program performance. The Long Term Goal (LTG) ratings used in the reviews were developed under the past administration's PART system to report progress to OMB and Congress.

Since 2008, ORD has launched six partner surveys and received consistent feedback from stakeholders on its performance. The NPDs and the BOSC have indicated that the surveys are not particularly useful for assessing program performance. Therefore, ORD is not currently utilizing partner surveys.

APMs track the on-time completion of research outputs, and the Laboratories and Centers report on APM progress each quarter. Ms. Sjogren noted that ORD created APMs in response to the Government Performance and Reporting Act (GPRA) of 1993.

EPA has tracked *highly cited* and *high impact* measures to assess the influence and impact of ORD's papers. The *highly cited* publications are those papers that meet the top 10% threshold as determined by Thomson Reuter's *Essential Science Indicators (ESI)*. *High impact* papers are those that appear in high impact journals (i.e., journals that are cited frequently and are considered to be the world's leading journals for their impact and influence in the global research community). The highly cited and high impact measures are not widely used by the NPDs. The BOSC has provided mixed feedback on the appropriateness and usefulness of bibliometric measures. The BOSC Clean Air Subcommittee praised the bibliometrics report and relied heavily on bibliometric measures in the review of that program. The BOSC Human Health Subcommittee, however, found the analysis difficult to interpret because of the comingling of intramural and extramural publications. That Subcommittee thought the analysis should be modified or discontinued. EPA is currently exploring the suitability of co-location and co-authorship analysis as another component of bibliometric analysis.

Ms. Sjogren noted that ORD is seeking the BOSC's feedback on appropriate bibliometric measures for assessing program performance and impact.



DDA, a type of bibliometric analysis developed by ORD, has been used to systematically quantify and assess the use (citation) of EPA research in Agency decision documents (regulations, Records of Decision, risk assessments, policy guidelines, technical guidance, etc.). The DDA also indicates what EPA research is cited by external stakeholders and partners (state and local governments, other federal agencies, foreign governments), the research products most commonly cited, and the types of decision documents (regulations, policy, risk assessments, technical guidelines) that cite EPA's research the most. Only part of the DDA analysis is comprehensive; the part that examines citation of program publications by government and other organizations outside of EPA has focused on a subset of the program's publications. Ms. Sjogren explained that the second component of the DDA analysis has not been performed on the programs' complete bibliographies because they are labor intensive and therefore costly.

Since September 2007, ORD has been taking "baby steps" with scorecards. The Laboratory/Center/Office (L/C/O) 2008 and 2009 scorecards were a bottom-up approach, but scorecards were not utilized in 2010. The goal for 2011 is to accelerate and strengthen use of scorecards as a performance management tool. Feedback will be collected from L/C/O senior leaders and it is likely that the scorecards will include some common measures. External experts will probably be engaged to provide scorecard training. It is anticipated that the scorecards will assess performance in the following categories: (1) science impact—deliver relevant, responsive science that serves as the backbone of EPA decision-making; (2) operations—manage resources and operations efficiently and effectively; and (3) capacity—improve capacity to achieve the Agency's mission.

Ms. Sjogren stated that EPA has been engaged in the interagency STAR METRICS project. This effort is a voluntary collaboration of federal agencies and research institutions working to document outcomes of federally funded science investments. It is coordinated by OSTP in collaboration with NSF, NIH, DOE, and EPA. The two goals of STAR METRICS are to: (1) collect data to develop uniform, standardized measures that assess the impact of science spending on employment, using data from research institutions' existing administrative records; and (2) collect data to develop measures of the broader impact of science investment on scientific knowledge (using metrics such as publications and citations), social outcomes (using metrics such as health outcome measures and environmental impact factors), workforce outcomes (using metrics such as student mobility and employment), and economic growth (using metrics such as tracking patents and new company start-ups).

In closing her presentation, Ms. Sjogren pointed out that a suite of measures and tools are employed to assess ORD's performance. Finding appropriate measures for research is a challenge and BOSC feedback on this topic is appreciated. Input would be particularly valuable for identifying appropriate bibliometric measures. She noted that the STAR METRICS project provides EPA an opportunity to partner with other R&D agencies struggling to accurately assess the impact of their research. If successful, STAR METRICS would allow ORD and other R&D agencies and institutions to move beyond relying on anecdotal evidence to convey research success and impact.

#### Discussion

Dr. Saylor thanked Ms. Sjogren and asked if there were any questions. Dr. Cozzens asked what was being required of EPA to participate in the STAR METRICS project and what EPA will obtain from its participation. Ms. Sjogren replied that EPA is sharing information on its grants so that the Agency can analyze and learn the impacts of the extramural component of EPA's research. In addition, EPA's participation helps shape the data to be included in the system. Each partner in the STAR METRICS project must contribute \$500,000 per year for the next 5 years (a total of \$2.5 million). EPA has argued that because the Agency's R&D budget is considerably less than those of the other partners, EPA should not have to contribute the full amount. The Agency also is arguing that HERO should count as an in-kind contribution from EPA. Ms. Sjogren noted that this is still in negotiation.

Dr. Cozzens pointed out that STAR METRICS is collecting information only on extramural grants. EPA will need the same information on its intramural research to assess its programs. Ms. Sjogren responded that the intention is to include intramural research in the future, and Dr. Cozzens asked how they would go about collecting that information. Ms. Sjogren answered that they would start with the investigators. Dr. Sayler asked if this would include investigators at the Regional laboratories as well as the ORD laboratories. Ms. Sjogren replied that it would make sense to include all EPA laboratories. Dr. Sayler asked if the EPA investigators would be asked to provide the same information that is being collected from the universities, and then he asked how much that will cost. Ms. Sjogren said she did not have an estimate for what it would cost to collect the intramural data.

Dr. Cozzens commented that the universities participating in STAR METRICS are getting significant information from STAR METRICS that allows them to benchmark their performance against other universities. The universities are getting this information at minimal to no added investment (about 1 day of effort), so it offers enormous returns for them. She did not think, however, that the information EPA would gain from STAR METRICS would be worth the required investment of \$500,000 per year. She also pointed out that the \$500,000 investment would not cover the additional cost of collecting and submitting the information on the intramural research investments. Dr. Sayler said he thought HERO should be considered as an in-kind contribution for EPA.

Dr. Falk asked if ORD has discontinued the partner surveys indefinitely. He thought they were useful to obtain information from ORD's customers and stakeholders. Ms. Sjogren responded that ORD may consider using surveys again in the future but they would be redesigned and a different approach may be used. She thought the BOSC may be able to provide some advice on how to redesign them and possible new approaches. Dr. Falk responded that he was glad to hear that ORD would consider future surveys.

Dr. Paustenbach thought it may be unfair to hold ORD to the same publication requirements as a university. ORD has a different mission and that should be taken into consideration. He said that he would like to see the budgets, FTEs, initiatives, and timeframes for the programs before the BOSC offers its advice.

### **Exploring New Approaches for Evaluating Research Effectiveness: A Case Study**

*Dr. Audrey Levine, Drinking Water Research Program NPD, ORD, EPA*

*Dr. Dorothy Miller, Recent AAAS Fellow to ORD*

Dr. Dorothy Miller explained that the presentation would describe a case study using bibliometric-based analyses to evaluate research effectiveness in the Drinking Water Research Program (DWRP). It includes a discussion of bibliometric-based approaches and their strengths and weaknesses.

The purpose of the case study was to:

- ✧ Analyze the research productivity of the DWRP from 1999 to 2009—quantity, quality, and focus of the research portfolio, and evaluation of the research trajectory and lifecycle.
- ✧ Establish tools to evaluate research impact—informing Agency decisions and advancing scientific discourse in the broader community.
- ✧ Evaluate alternative metrics for elucidating research effectiveness—to optimize resource alignment and workforce planning, and target communications.

Dr. Levine stated that the DWRP has approximately 170 FTEs with an annual budget of \$47 million, which includes about \$4 million for Science To Achieve Results (STAR) grants. The program includes staff in three ORD laboratories: National Risk Management Research Laboratory (NRMRL), National

Exposure Research Laboratory (NERL), and National Health and Environmental Effects Research Laboratory (NHEERL).

The LTGs of the DWRP are to: (1) characterize risks associated with drinking water sources, treatment, distribution, and use (health effects/exposure and assessment tools); and (2) control, manage, and/or mitigate potential health risks (source water/water resources, drinking water treatment systems and residuals, and water distribution/storage/infrastructure systems). The thematic areas of the program include: Exposure/Health Effects, Source Water/Water Resources, Treatment, and Distribution Systems, and Assessment Tools.

The approach used for the case study involved identifying research products, primarily peer-reviewed publications (both intramural and extramural) for a specific time period and context. The information was entered into a bibliographic database using inputs from the DWRP and augmented using Thomson Reuter's Web of Science. Analyses were conducted that included the research landscape, classification of research outputs, citation mapping, use of the products in decision making, discipline diversity, and future directions.

Some examples of the questions posed and how they were addressed include:

- ✧ What is the current discipline make up within the research program? How has this changed over time?
  - Mapped research program's discipline expertise for different years using publication outlets as representative of researchers' disciplines.
- ✧ Are research products used in Agency decision making?
  - Used publication citations to indicate whether the program was the "go to" source.
- ✧ Are DWRP scientists using the research program products?
  - Examined the transition of research ideas between research program scientists (both intramural and extramural) as represented by histogrammic citation patterns, counts, and links.
- ✧ Are DWRP products used by the broader scientific community?
  - Used citation counts to indicate adoption and propagation of research ideas.
- ✧ Can "linker" scientists and groups in the research program be identified?
  - Examined co-authorship of publications to assess integration across Laboratories/Centers/Divisions/Groups.
- ✧ Can ORD develop metrics that can be used to help improve research effectiveness?

The first step was to build and clean the dataset. To build the bibliographic database, a publication list was obtained from the Laboratories and Centers. Records for each publication were retrieved from external databases (Web of Science, PubMed, Scopus) to ensure consistency. An Endnote library was generated and the library was parsed into thematic "buckets." The data were extracted and converted to ISI format so that they could be submitted for analysis. A number of challenges were encountered in building the dataset, including inconsistent record keeping across the Laboratories and Centers and the fact that new publications are added all the time so keeping the dataset current is labor intensive.

A number of parameters were considered in collecting and categorizing the research products. The time period for the study was bounded by the research life cycle (2-, 5-, 10-, and 15-year periods). The areas evaluated covered the breadth and depth of the program (both LTGs and all research themes). The types

of research products included peer-reviewed journal publications (papers, review articles, communications, etc.), conference proceedings and papers, and other items (government reports, book chapters, “grey literature,” computer programs, methods, and tools). The research products came from the intramural and extramural research funded by the DWRP. The majority of the products were journal articles (79%) and conference proceedings (14%).

A sort of the DWRP products by theme/year indicated that most of them were under the Exposure/Health Effects theme, and this was true for each year in the study period. Up until 2008, most of the products focused on chemical contaminants rather than microbes, but this reversed in 2009.

The DWRP’s discipline expertise was mapped using the publication outlets to represent the various disciplines. This was done to determine the current discipline make up within the program and to determine how this has changed over time. Can this information be used to retrospectively evaluate program performance and prospectively evaluate research capability? Can it be used to identify workforce planning opportunities? The two primary disciplines identified from the mapping diagram were environmental science and technology and biomedical science, and this was true for the products in 2001 as well as in 2005 and 2008. Dr. Miller noted that the proximity of the dots on the mapping diagram means a greater number of interactions.

Dr. Philbert expressed some concern about the utility of the discipline maps. They do not make sense to most people, and the mapping is based on the discipline of the journals in which scientists publish rather than the actual disciplines of the program scientists. Dr. Miller replied that the diagram helps identify the major outlets used to communicate with the broader scientific community. Dr. Haas thought it was a long stretch to assume that the journals were an adequate indicator of the disciplines of the program scientists and then to use that information to identify the disciplines needed to supplement the existing pool of expertise. For example, many engineers publish in *Environmental Science & Technology (ES&T)*, but that journal probably contains many of the products in the biomedical science theme. Dr. Levine agreed and commented that this should not be over-interpreted.

Dr. Miller pointed out that not all journals were covered in the analysis. Web of Science does not cover the *American Water Works Association Journal*, for example, and many DWRP papers are published in that journal. Dr. Levine mentioned that a snapshot such as the discipline map could be helpful in determining if ORD is communicating its science through the appropriate journals. Dr. Cozzens stated that the journals in which the program publishes are more indicative of the audiences being reached by the program rather than the disciplines of the program scientists.

The DWRP products were distributed among some key areas related to the Safe Drinking Water Act (SDWA), including: arsenic, disinfection byproducts, Contaminant Candidate List (CCL), Unregulated Contaminant Monitoring Rule (UCRM), Long Term 2 Enhanced Surface Water Treatment Rule (LT2), and Lead & Copper Rule (LCR).

To assess if research products were used in EPA decision making, all research products in the portfolio relevant to the Long Term 2 Enhanced Surface Water Treatment Rule (LT2), including microbial methods, monitoring and indicators, source controls, disinfection efficacy, and epidemiology studies were identified. The citations of these products in rule and secondary products (e.g., guidance manuals) were determined and mapped with the research timeline. Most of the LT2 cited references were journal articles, followed in order by reports, methods, and conference proceedings. The highest number of LT2 references cited was in 2000, and the number declined each year through 2005 (there was an increase, however, from 2003 to 2004). The LT2 was published in the *Federal Register* in January 2006.

A histographic citation map and timeline was used to determine if the DWRP scientists are using the program products. The map showed the transition of research ideas between the DWRP scientists as represented by histographic citation patterns, counts, and links (one program scientists citing another).



Citation counts were used to assess whether the research products were being used (adoption and propagation of ideas) by the broader scientific community (program scientists cited by non-program scientists). Data for the top five cited publications on the map were presented, including Local Citation Score (LCS) and Global Citation Score (GCS). It was noted that one of the publications had a high GCS but an LCS of 0, which means that it was not cited at all by program scientists but was highly cited by the broader scientific community. Dr. Levine commented that the histographic citation map helps identify seminal publications.

Dr. Haas commented that the histographic citation map does not show the effect of the program products on rulemaking; it simply indicates publications that are highly cited by program scientists and/or scientists outside the program. He thought, however, some useful information for program management could be gleaned from the map.

A co-author map was generated to identify “linker” scientists and groups within the DWRP. Such a map is designed to help the program understand how ORD’s scientists are working with the scientists in the extramural program. The co-author map also provided information on the integration across ORD Laboratories, Centers, Divisions, and Groups.

In closing, Dr. Levine stated that retrospective analyses provide an opportunity to evaluate research effectiveness. Interpretation of the data requires careful consideration of the context for the research (decision support, technical and scientific advancements, and applications), classification of research products, and timeframe. The research drivers can be used to inform metrics of effectiveness and resource decisions, including regulatory and policy decisions, and advancing the state of the science. There is an opportunity to develop dynamic metrics capitalizing on advances in information technology to help ORD optimize resource use and effectively prioritize research efforts.

#### Discussion

Dr. Haas commented that he did not think other organizations had done such analyses and he asked what ORD would use to benchmark the results against. Dr. Levine replied that there would be no benchmarks, but such analysis might be useful to determine if the program is publishing in the appropriate journals.

Dr. Tharakan asked how publications that covered more than one thematic area were parsed into the thematic buckets. Dr. Levine replied that such papers were placed in multiple thematic buckets. Dr. Cozzens mentioned that similar analysis could be done across various government agency programs if STAR METRICS is fully populated.

Ms. Zhuikov said that the focus of this analysis appears to be scientists communicating with scientists, but it does not determine if the products are communicated to the affected audiences. That information would be useful to ORD. Dr. Miller responded that they attempted to look at diffusion of information but had little success. Ms. Zhuikov suggested that ORD examine news media stories and circulation. She mentioned that there are companies that track topics covered by the news media.

Dr. Demerjian stated that the BOSC Clean Air Subcommittee carefully examined the bibliometric analysis report when reviewing the Air Research Program and found it to be very helpful and understandable. It was well received by the Subcommittee members. If the bibliometric-based information included in Dr. Levine’s presentation (histographic citation mapping, co-author analysis) had been submitted to the Subcommittee, it would have received a negative reaction. The diagrams are too confusing and there are no benchmarks to gauge whether the results are good or bad.

Dr. Falk asked Dr. Levine if she was better informed about the DWRP after conducting the case study. Did you get the answers to the questions posed at the beginning of the study? Dr. Levine responded that the list of measures is not final. The case study was presented to the BOSC to facilitate discussion.



Perhaps such analysis could be used to help ORD decide when to disinvest in an area. It also provides a baseline against which progress can be assessed in the future.

Dr. Paustenbach applauded the idea of stepping back and assessing whether ORD is doing the research that it is supposed to do; however, he thought EPA should use a different paradigm. He suggested looking at the users—EPA Administrator, Program Offices, Regions, states, Congress, OMB, and other clients. ORD should ask its clients what they need to make decisions. Dr. Paustenbach was concerned that ORD scientists were doing work that piqued their research interest and they were capable of doing rather than the work that is needed to answer the questions of the decision makers. The real question to ask is not how many times a paper was cited but rather is the client getting the information he needs when he needs it to make a decision. Dr. Levine responded that the program interacts a great deal with the EPA Office of Water and the Regions to get input on what they need and how they use ORD products. Dr. Paustenbach suggested looking at SAB advice to the Administrator to determine if there have been times when the SAB has indicated that there is not enough information to select a specific number or answer a specific question. Dr. Sayler noted that another metric would be when the Agency does not get sued over a regulation because the data are sufficient.

Dr. Olden pointed out that it is important to consult the end user, but sound science is the primary driver. Dr. Paustenbach commented that ORD can do sound science that is not the right science needed to inform the decision maker. For example, a cost-benefit analysis often is not conducted. The decision maker needs that information. Dr. Levine agreed that economics and cost-benefit analysis are important.

### **Discussion of Informatics/Data Mining and Program Performance Evaluation Sessions**

*Dr. Susan Cozzens, BOSC Executive Committee*

Dr. Cozzens stated that Dr. Sayler asked her to respond to the presentations on this topic. She has a program evaluation background; she started as a bibliometrician and has since moved into broader ways to assess research. The questions she asked herself about these presentations were: Does EPA's work on research program evaluation reflect the state-of-the-art and does the state-of-the-art answer EPA's questions? Can the BOSC recommend any additional methods to assist ORD in evaluating the impact of its research programs?

Dr. Cozzens indicated that she saw elements of state-of-the-art program evaluation in the presentations so it appears that ORD is on the right path. The primary approach appears to be expert panel reviews and that is by far the best and most widely used approach. The panel's experience and knowledge are crucial for assessing the research. These review panels receive information from the programs being evaluated and it appears that ORD sometimes struggles to provide some of that information.

Dr. Cozzens recommended that ORD and the BOSC determine what information should be provided for expert panel review and then develop internal management systems that automatically collect that information in a standardized format across ORD. She noted that EPA is not the only agency struggling with collecting such data. ORD should seek input from users about the usefulness of its products. Dr. Cozzens pointed out that there is no global state-of-the-art on gathering this information and there is no good systematic way to obtain this information from stakeholders.

Another means of measuring impact is by analyzing publicly available information. Dr. Cozzens was glad to see that ORD has moved beyond citation counts. Although it appears that many in Washington, DC, are interested in mapping bibliometric-based data, most people do not like such diagrams. They find them confusing and difficult to understand. She added that such maps give answers to a different set of questions than those answered by citation counts.

Dr. Cozzens stated that it is more common to identify the field of the program and then look at the role of the program rather than the type of analysis presented by Dr. Levine. Dr. Cozzens commented that

today's discussion illustrates that there is a small community of professionals who have perfected these techniques and know how to interpret the results. Many people try to use the tools but most do not know how to apply them. She pointed out that a real evaluation study would be quite expensive and would involve more intense data gathering, such as interviews of program scientists and users.

Under all of the data, ORD needs to have a model of how it thinks the program works. The models currently are underdeveloped to accomplish what EPA is trying to do, but it is promising that the Agency is experimenting with such techniques.

### Discussion

Dr. Saylor asked if the BOSC members had any comments or questions on this topic. Dr. Falk said he recently did a survey of epidemic investigations. He read 452 papers and synthesized the information, which was very time consuming. At what point do you link the decisions made with the key scientific papers? He pointed out that computer mapping can only go so far.

Dr. Cozzens replied that someone did a study of research knowledge and its utilization. They divided the information into time slices and looked at the journals. The study found that there was periodization, but it requires an analyst who knows the technical field and who is comfortable with mapping techniques. Dr. Cozzens stressed that the maps by themselves are not very useful. She noted that co-author analysis probably is not a good approach for ORD, because it really is just looking "under the lamp post."

Dr. Falk asked what measures the BOSC could use that are both quantitative and useful for the program reviews. Dr. Katherine von Stackelberg asked about the approach ORD uses to make decisions on changing research directions. She could not see the connection between the information presented by Drs. Levine and Miller and making decisions about the direction of the research program or the types of disciplines that are needed for the program.

Dr. Haas commented that some of the information resulting from the DWRP case study would likely be more useful to the NPD managing the program than the BOSC subcommittee conducting a program review. For example, the NPD could examine why some papers were not cited at all or why other papers were highly cited by EPA scientists but not outside scientists. Such information could be useful to the NPD.

Dr. Falk reiterated Dr. von Stackelberg's comment about having difficulty seeing how this information would be useful for the program reviews. Dr. Saylor noted that the information provided for BOSC reviews is being analyzed by experts in the field who know the best papers and leading authors, so he agreed that the information would be more useful to the NPDs. Dr. Haas said that it might be more appropriate for the BOSC to determine whether ORD has valid internal procedures in place to assess research impacts.

Dr. Cozzens asked those who had chaired BOSC subcommittees to comment on what questions the subcommittees could not answer and what information would have helped to answer those questions. Dr. Saylor replied that for past program reviews, the subcommittees have received long lists of publications, biosketches of the investigators, lists of programmatic awards, and various other materials. Many of the subcommittees wanted to separate the intramural and extramural publications and their associated bibliometric data. He did not agree with that approach, however, because both are components of the research program being reviewed. A great deal of unanalyzed data was provided to the subcommittee so wading through the information to do the review was problematic. The bibliometric report was one of the many items provided to the subcommittee to assess the program. Although that report did not answer all of the questions, it did address some of them.

Dr. Philbert noted that the main point is: How does the BOSC determine if the research that ORD is doing is the right research and that ORD is doing it right? The analysis presented by Dr. Levine is just replacing counting citations with counting how much the researchers are citing each other. That still does not help us determine whether ORD is doing the best quality science that is needed to answer the Agency's questions. Dr. Falk commented that it is appropriate to rely on expert review—the subcommittee members are experts in appropriate fields and their advice will be valuable. To the extent that it is possible, however, it would be beneficial to provide some clear evidence of impact that is not dependent on the judgment of the subcommittee members. Dr. Philbert suggested that perhaps more thought should be given to the questions for the review.

Dr. Demerjian commented that the Agency's mission is clear and usually the goals of the programs are clear. For example, the goal of the Clean Air Research Program is to demonstrate that the air standards are adequate to protect health and the environment or that they are inadequate and need to be changed to improve air quality and health outcomes. The other part is how to mitigate the impacts of air pollution and meet the standards. The program has done little to address this part. The program does not focus on whether the system can actually meet the lower standard. EPA should look at whether the new standard is achievable and what science is needed to achieve it. There are huge economic consequences to even a small tightening of a standard. Referring to the STAR METRICS project, Dr. Demerjian stated that if the country was not in a recession, little thought would be given to how many jobs are created by federally funded research.

Dr. Olden stated that NIH was mandated by Congress to develop a system to evaluate its research investments, and an office was created within NIH to accomplish this. He agreed that such information does not indicate whether an organization is doing the right research. How does an organization know that it is doing the right science? Dr. Philbert responded that universities are part of the free market system; they hire people to do research. If NIH or another federal agency provides funding for that research, that is an indication that the university is doing the right research. Dr. Olden commented that just because NIH or another agency is supporting a research project does not mean that it is the right research. When he came to the City University of New York, he suggested that they make a conscious effort to determine what they think would be the most important investments in public health and then market those priorities to NIH and other funding sources. He thought EPA's efforts to assess research impact were fine; the information is useful. It is appropriate for ORD to provide the BOSC evidence that they are publishing their research results in good journals and that the research is being cited and used in policy and other decisions. He thought EPA was doing as much as any other agency or organization to assess the impact of its research.

Dr. Philbert pointed out that there is a difference between good science and useful research. NSF does great science because it has intrinsic value, NIH does research for discovery, but EPA has a different role. It is a regulatory agency that is implementing standards to protect public health and the environment. The Agency must evaluate great science and figure out how to apply it to environmental protection. This should have a profound impact on how outcomes are measured. NSF simply grinds out good science and lets others figure out how to use it. Dr. Olden agreed but stated that an agency knows it is doing the right science by looking back at what it has done.

Dr. Saylor thanked Dr. Cozzens for her comments on this subject and recessed the meeting for the day.

## **TUESDAY, OCTOBER 19, 2010**

The meeting reconvened at 8:38 a.m., and Dr. Saylor welcomed Dr. Teichman who would be providing the ORD Update.

Before Dr. Teichman gave his presentation, he extended his sincere thanks to Dr. Sayler for his 7 years of service to the BOSC and for chairing the Board for the last few years. On behalf of EPA, Dr. Teichman presented a gift to Dr. Sayler as a token of the Agency's appreciation for his commendable service.

### **ORD Update**

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

Dr. Teichman explained that the beginning of his presentation, *ORD's Strategic Directions and the Administrator's Priorities*, was the one that he gave to the SAB in April 2010. He wanted to share it with the BOSC and discuss the possible role that the BOSC could play in helping ORD shape its new research directions.

The Administrator's guiding principles are: (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. The Administrator's priorities are:

- ✧ Improving Air Quality
- ✧ Assuring the Safety of Chemicals
- ✧ Cleaning Up Our Communities
- ✧ Protecting America's Waters
- ✧ Taking Action on Climate Change
- ✧ Building Strong State and Tribal Partnerships
- ✧ Expanding the Conversation on Environmentalism and Working for Environmental Justice.

Dr. Teichman highlighted some recent exemplary EPA accomplishments in each of the Administrator's priorities. One of those accomplishments was the new NAAQS process. In May 2009, EPA reintroduced the development of staff-level documents describing its NAAQS policy assessments. These documents lay out the policy-relevant science from ORD's ISAs, the results of OAR's Risk and Exposure Assessments, and staff recommendations for whether and how to revise the NAAQS. The Clean Air Scientific Advisory Committee (CASAC) reviews these documents before their final publication. ORD's contributions include: (1) development of the ISAs, which address both health (primary) and welfare (secondary) NAAQS; (2) support of much of the research informing these assessments (e.g., the finding that smaller air particles affect the cardiovascular system, while larger air particles impact on the lungs; the research showing that reductions of ambient particulate matter lead to increased life expectancy); and (3) the HERO database.

Referring to a diagram that depicted the relationships among science, research, and environmental policy, Dr. Teichman stated that research is only a subset of the environmental science and engineering work of EPA. There are about 1,500 scientists and engineers in ORD and about 6,000 scientists and engineers at EPA. In addition, environmental policy is not just regulation; there are other ways to do environmental policy. Science is the backbone of EPA programs, but many other factors also come into consideration with policy decisions, such as public values and perceptions, costs, benefits, state/tribal/local implementation issues, and environmental statutes.

Dr. Teichman wanted ORD researchers to think of their programs in terms of the Administrator's priorities, so he tried to link the programs to the priorities. He presented a diagram that showed the links between ORD's 14 research areas (i.e., Air, Drinking Water, Water Quality, Land Preservation and Restoration, Safe Pesticides and Products, Homeland Security, Human Health, Ecosystem Services, Human Health Risk Assessment, Global Change, Endocrine Disrupting Chemicals, Computational Toxicology, Nanotechnology, and Science and Technology for Sustainability) and the Administrator's seven priorities. Once he got beyond air and water, the links became more complex and the diagram ultimately resulted in almost 98 arrows between the two lists to show the connections.



The touchstones for the meeting with the SAB were:

- ✧ This is a strategic planning meeting—not a budget meeting.
- ✧ We will be discussing strategic plans for ORD **research**, not EPA **science**.
- ✧ To get where you want to go, you need to know where you are.
- ✧ Arraying the current ORD research areas by the Administrator’s priorities is a “work in progress.”

The presentation included a crosswalk of the current ORD research activities and strategic directions with the Administrator’s priorities. For brevity, Dr. Teichman presented only one example of this crosswalk—Assuring the Safety of Chemicals. Examples of ORD’s current activities in this area include:

- ✧ Creating virtual models of the human liver and embryo (and other organs in the future) that integrate toxicity pathways and predict chemicals risks.
- ✧ Conducting research to understand which nanoparticle properties may cause risk, and how green chemistry and other approaches can be used to develop safe nanomaterials.
- ✧ Developing and implementing methods for the next-generation of human health risk assessments.
- ✧ Researching effects, exposures, and risk-management options related to perfluorinated chemicals and other toxic substances and pesticides.
- ✧ Helping to characterize and reduce exposure to EDCs by creating new exposure-assessment and risk-management tools; and developing standardized protocols to screen and test chemicals for their potential endocrine-mediated effects.
- ✧ Developing ecosystem-service models for integrated pest management and pesticide fate and transport.
- ✧ Developing ecological probabilistic models to assess risks (i.e., spatially explicit, population-level) to wildlife populations and non-target plants from pesticides, toxic chemicals, and multiple stressors.

The vision for Assuring the Safety of Chemicals is for EPA science to lead the sustainable development, use, and assessment of chemicals. Some suggested strategic directions and examples of anticipated accomplishments include:

- ✧ Provide smarter and more efficient testing, risk assessment, and risk management options.
  - Provide much higher throughput tools for the prioritization and screening of chemicals based on exposure and toxicity pathways.
  - Support research into alternative product formulations using green chemistry and green engineering principles, leading to the design of safer chemicals/products.
- ✧ Enhance and leverage existing relationships and create new ones with industry, academia, non-governmental organizations (NGOs), and other agencies in the United States and other countries to speed up and share data generation, life cycle assessment, and green chemistry/safety-by-design approaches.
  - Develop new approaches for assessing risks, by integrating computational toxicology approaches into risk prediction for new and existing chemicals at the screening stage.

Dr. Teichman’s presentation to the SAB included more than 50 slides. That presentation is available to the BOSC and others who are interested on the SAB Web Site.

Dr. Teichman charged the SAB to address the following questions:

- ✧ To what extent do ORD's suggested strategic research directions address the Administrator's priorities by providing the scientific information needed to inform environmental decision making, especially decisions made by Program and Regional Offices?
- ✧ Which key research areas should ORD leverage by working with other (non-ORD) science programs across EPA? Which key research areas should ORD leverage by working with the science programs of other federal agencies?
- ✧ Which areas should receive increased emphasis in ORD's research program over the next 5 years? Which areas should receive decreased emphasis over the next 5 years?
- ✧ Are there strategic research directions that ORD should pursue differently or undertake as it draws upon its unique expertise to conduct ITR?
- ✧ Where can research on socioeconomic best contribute to ORD's ITR efforts?
- ✧ Where can ORD apply lessons learned from environmental research to protect human health, and from human health research to protect the environment?

The SAB provided a letter report that addressed these charge questions to the EPA Administrator on July 8, 2010. The Administrator replied by letter on September 27, 2010. In brief, the SAB thought that ORD needed to clarify how it plans to develop and use ITR before the Board could provide appropriate advice on strategic directions related to ITR.

Dr. Teichman acknowledged that ORD is grappling with defining ITR. He used near-roadway research as an example to define ITR. EPA is trying to determine the best location for nitrogen oxides (NO<sub>x</sub>) monitors. The highest concentrations of NO<sub>x</sub> are near roadways, but the effects are on populations. Should the monitors be located near the roads or near the high population areas affected by the emissions? Will barriers along roads reduce exposure to NO<sub>x</sub>? Addressing these questions requires EPA to work with those who site roadways as well as those who construct housing, schools, and shopping centers. Many schools and shopping centers are located near major highways for easy access. ITR means involving the other federal agencies, affected communities, city planners, and others in the research planning and implementation.

Dr. Teichman then described ORD's planning/budgeting process, starting from where the Agency currently is with the Fiscal Year (FY) 2012 President's budget request for EPA research. From October to November 2010, OMB conducts its review of the FY 2012 budget. The budget is submitted to Congress in February 2011. The SAB review/comment and congressional deliberations on the budget occur from March to September 2011. The Appropriations Bill is approved by October 2011 or Congress passes a continuing resolution. Long before the FY 2012 budget is approved, work has begun on the FY 2013 budget. ORD will conduct its FY2013 annual planning from February to June 2011, and the EPA Budget Forum will be in July 2011. The FY2013 budget will be submitted to OMB for review in August 2011.

At the most recent SAB budget review meeting, *Future ORD-SAB Interactions on Strategic Directions*, Dr. Teichman was joined by Dr. Peter Preuss, ORD's new Chief Innovation Officer. Dr. Teichman described ORD's path forward as set forth in the April 2010 memorandum from Dr. Paul Anastas, AA for ORD:

- ✧ "To ensure **close and continual dialogue with our Program and Regional partners**, I will be tasking the National Program Directors, together with the Office of Science Policy, to develop **mechanisms for engagement** of these partners in time for the fiscal year 2012 ORD research program planning and on into the future."

- ✧ “ORD will be fully engaged in **Integrated Transdisciplinary Research (ITR)**, which is defined as the process to develop sustainable solutions to environmental problems by engaging partners who transcend traditional scientific disciplines throughout each stage of the research process.”
- ✧ “I will be looking to encourage development of **sustainable technological innovations** by supporting internal entrepreneurial research projects through an internal competitive seed grant program, external partnerships for innovation, and catalyzing the private sector to develop approaches to facilitate sustainable technology implementation across the technology life-cycle.”
- ✧ “To **communicate this message as ‘One ORD,’** I have tasked our Communication Team across ORD to work with the Executive Council to systematize the identification, inventorying, collection, translation, and dissemination of **ORD’s contributions and impact.**”

Because creating and developing sustainable solutions to improve human health and the environment is a core mission of ORD and offers great opportunities, Dr. Anastas formed a small group to continue to develop, encourage, facilitate, and enable new ideas throughout the ORD research program and move ORD’s program in the direction of innovative, sustainable solutions to environmental problems. This group will be headed by Dr. Preuss, who has been appointed the Chief Innovation Officer. Dr. Preuss reports directly to Dr. Anastas on these matters. Dr. Preuss’ team is a small one, composed of people with diverse backgrounds, working to craft new and innovative approaches that will further ORD’s impact and EPA’s mission.

ORD will encourage divergent thinking, i.e., thinking that is not limited by today’s constraints, but instead focuses on “**disruptive**” **ideas and solutions** with the potential to transform environmental protection strategies. In addition, this team will promote the **creative application of new tools** for environmental and public health protection. The innovation team also will work with ORD scientists to help **identify and eliminate barriers to innovation.**

ORD has announced an opportunity for scientists in ORD to apply for **internal innovation grants.** ORD will begin to use **online networking tools to foster collaboration** among scientists both in EPA and other organizations. ORD also will pilot the use of open, collaborative innovation platforms, which **engage a much broader, diverse group of people** in environmental problem identification and formulation, and in the joint development of innovative solutions.

The goal of the ORD-SAB meeting was to discuss how best to obtain future input on ORD strategic priorities, independent of budget constraints. The questions for discussion included: What are some possible approaches to/formats for these discussions? What materials would the SAB need to prepare for these discussions? What has been most helpful in the past? What has not? What would be most helpful in the future?

The research groupings currently being considered as part of ORD’s path forward are: Sustainable and Healthy Communities; Safe and Sustainable Water Resources; Safer Products for a Sustainable World; and Air, Climate, and Energy plus Human Health Risk Assessment and Homeland Security. Dr. Teichman mentioned that ORD is referring to these groupings as “4 plus 2.”

Following the rule of keeping things simple, Dr. Teichman stated that the SAB advises ORD on “are we doing the right science.” The BOSC advises ORD on “are we doing the science right.” He noted that ITR is doing the “right science the right way.”

In seeking the BOSC’s input on ORD’s strategic directions, Dr. Teichman posed the following questions for the BOSC to discuss: What role can/should the BOSC play in these discussions? What are some possible approaches to/formats for these discussions? What materials would the SAB and BOSC need to prepare for these discussions? Are there strategic research directions that ORD should pursue differently or undertake as it draws upon its unique expertise to conduct ITR?

Dr. Teichman mentioned that the SAB would like to meet jointly with the BOSC the next time (probably late spring/early summer 2011) the SAB reviews ORD's strategic directions. He then asked if the BOSC members had any questions or comments.

### Discussion

Dr. Sayler noted that this is an excellent opportunity for the BOSC to redefine its advisory role and to establish a new focus. There also is an opportunity to strengthen interactions with the SAB. He mentioned that the number of program reviews has declined significantly so the BOSC has more time to devote to other topics. He added that the nature of the program reviews may change in the future.

Given the new 4 plus 2 groupings, Dr. Haas asked if the next questions for the NPDs to address would be what type of expertise, personnel, and resources are needed to carry out the tasks in the portfolio. With regard to the groupings, he thought that Homeland Security could fall under Sustainable and Healthy Communities.

Dr. Teichman responded that Dr. Haas was correct about Homeland Security falling under Sustainable and Healthy Communities. It could fall under Safe and Sustainable Water Resources as well. He noted that there is nothing magical about the 4 plus 2 groupings, and those are still being deliberated within ORD. He thought it would be necessary for ORD to identify priorities in each of these areas before identifying the people and expertise needed.

Dr. Sayler asked how much of ORD's budget is allocated to statutory directives. Dr. Teichman replied that there is no specific percentage of the budget dedicated to short-term statutory directives *per se*. ORD needs to engage in research along a continuum that extends from high-risk, game-changing research to technical support. Targeted research also must be included. ORD must figure out the best mix and it may vary for each of the six areas. To ensure that ORD achieves the proper balance, it is important to involve others outside the Agency in thinking this through. Dr. Sayler asked if the Regions are included in the planning. Are their needs being addressed? Dr. Teichman responded that ORD is working with the Regions. He has spent time with two counterparts, Bill Rice (Region 7) and Larry Starfield (Region 6), but there will be more visits to the Regions by ORD senior management. The Regions must be part of the process. Dr. Olden asked if ORD has engaged in interdisciplinary planning and discussions to develop the research initiatives. Dr. Teichman confirmed that such planning and discussions have occurred within EPA; for example, the Office of Chemical Safety and Pollution Prevention (OCSPP) and other offices worked with ORD on the SPSW area. Now, EPA needs to go to other federal agencies, communities, and affected industries to get their input. The goal is to involve more and more stakeholders as the initiatives develop.

Dr. Paustenbach thought Dr. Teichman's slide about the different roles of the SAB and BOSC was clear. ORD can seek the BOSC's input on "doing the science right" either in the beginning at the planning stage or at the end after the research has been conducted or both. Are there different mechanisms for the BOSC to provide input to ORD? Perhaps the BOSC members could e-mail ideas to Dr. Sayler and then he can share them with ORD. Dr. Paustenbach was concerned that ORD was not capitalizing on the brain trust assembled in the BOSC. Dr. Teichman commented that ORD has been using the BOSC to review how well the science was done and to offer suggestions for how ORD could plan as well as conduct research better.

Dr. Demerjian noted that the program reviews also looked at whether ORD was doing the right science. He serves on CASAC, and they have identified issues for decades that do not seem to get solved; NO<sub>2</sub> measurement is an example. Addressing many problems requires measuring the right things. No one has clearly identified what specifically needs to be addressed before the Agency can move forward. The legacy costs for maintaining the Clean Air Act, Clean Water Act, and other legislation have risen but the public is getting less and less benefit from these efforts. There are places that still have not met ozone



standards and the scientists cannot figure out why. Our nation is about to embark on a standard that pushes the country to what is basically the summertime background levels in many urban areas. The NO<sub>x</sub> standard will be based on a model, not a measurement. Is it worth spending millions of dollars to meet a new standard when there is a possibility that there will not be much benefit? Dr. Demerjian expressed his concern that the Agency is still working on the same problems that it was working on 30 years ago.

Dr. Teichman agreed that there are longstanding issues that require many years of research to find a solution; mixtures of pollutants is an example. If the monitors are inadequate, ORD can work to develop a better monitor; however, it is the states and the Office of Air and Radiation (OAR) that pay for and locate the monitors. Perhaps ORD can advise OAR and the states on where to locate the monitors to achieve the intended health and ecological benefits.

Dr. Teichman noted that ORD needs to look for ways to do things more efficiently; HERO is a good example. High-throughput screening is another example, and it will help EPA address the many chemicals that could be regulated under the Toxic Substances Control Act (TSCA).

Dr. Teichman said that he was one of 50 scientists who visited Washington, DC, schools to talk to the students interested in science, technology, engineering, and math. Dr. Teichman's talk focused on what his generation had done to improve the environment, and then he shared a list of problems that will be left for the next generation to resolve. He noted that both lists were robust.

Dr. Cozzens asked if the SAB can provide adequate advice on whether ORD is doing the right science. Dr. Teichman mentioned that the SAB has recruited a number of BOSC members to serve on its Board. As ORD grapples with ITR, it would be helpful to have a BOSC representative on the SAB, particularly at the meeting where ORD's strategic priorities are being discussed. The BOSC should be involved earlier in the program development, and a joint meeting seems to make sense.

Dr. Sayler asked how EPA identified the critical issues for research. ITR is more nested with other agencies and stakeholders. Is there a systematic approach to get to a sensitivity analysis? Dr. Teichman replied that value of information (VOI) must be a large part of establishing priorities, but this cannot just be what ORD, the Program Offices, and Regions think is valuable. If the states, consumers, and other stakeholders do not use the tools or products developed by ORD, then they were not valuable. He was not sure that there would be a systematic way to quantify those inputs, but he emphasized that it is important to have them involved in the process.

### **Discussion of BOSC Consultation on ORD Research: Safer Products for a Sustainable World**

*Mr. Jeff Morris, NPD for Nanotechnology, ORD, EPA*

Mr. Jeff Morris stated that his presentation should provide the BOSC with an understanding of how ORD has worked with other EPA offices to formulate the problems SPSW will address. The BOSC also will understand the research area/science question framework SPSW will use to support EPA's application of integrated evaluation strategies to chemicals. In addition, he will present ORD's path forward to implement SPSW. The discussion following his presentation should focus on determining the best way for the BOSC to provide consultative input into the formation and initiation of the SPSW Program.

Mr. Morris provided the Agency context for SPSW. To help lead America toward an environmentally sustainable future, EPA faces two major challenges: (1) making more, faster, and smarter decisions, guided by science, on the problems facing us today; and (2) anticipating tomorrow's problems by identifying and applying approaches that better inform and guide environmentally sustainable behavior. In 2009, Administrator Jackson articulated the following principles for chemicals reform:

- ✧ EPA must review all chemicals against risk-based safety standards.
- ✧ Responsibility for providing information should rest with industry.
- ✧ Special consideration should be given to vulnerable groups.
- ✧ When chemicals fall short of the safety standard, EPA must have clear authority to take action.
- ✧ Encourage innovation in green chemistry and sustainable processes.
- ✧ EPA's safety assessments must be resourced properly, with industry contributing its fair share.

SPSW focuses ORD's chemicals-related research on the development of approaches that enable transformative (rather than incremental) improvements to how EPA and other stakeholders make environmental decisions related to chemicals. EPA will do this by:

- ✧ Putting in the hands of decision makers tools that inform sustainable chemical/material design and use (e.g., green product "dashboards").
- ✧ Providing methods for much faster screening and prioritizing of many more chemicals than is currently possible.
- ✧ Providing the scientific knowledge and tools to effectively understand real-world risks (cumulative risk, population vulnerability, etc.).
- ✧ Developing assessment approaches that are tailored to specific decision contexts (i.e., using enough information [but no more than necessary] to make timely decisions, and more of them, that are scientifically defensible).
- ✧ Considering where impacts may occur throughout a chemical's life cycle.

Mr. Morris explained that "chemicals" refer to intentionally produced or manufactured chemicals, particles, and materials as well as the products into which they are incorporated.

Dr. Paustenbach asked if there was any connection with the European Union's REACH (Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals) effort. Mr. Morris replied that he and Bob Kavlock have worked closely with their European colleagues and they all agree that the current chemical situation is not sustainable. That agreement is driving REACH as well as this change to SPSW—agencies can no longer look at chemical impacts in isolation, rather they need to look at the whole life cycle.

Dr. Sayler mentioned that industry has large databases that contain information on chemical effects, toxicity, and other characteristics. Can EPA get access to those databases by working closer with industry in collaboration rather than as a regulator? Dr. Kavlock responded that EPA has obtained data from the pharmaceutical industry but he did not think there was the same volume of information available from the industrial chemicals industry. He noted that obtaining those data is not an easy task.

Dr. Falk stated that the SPSW research appears to be similar to what existed before. What is the real game-changer here? Mr. Morris replied that the game-changer is the integrated evaluation strategies; these will be transformative because they will help ORD focus its effort where it is needed most, based on only as much information as is required for particular decision contexts and how much uncertainty can be tolerated. Another transformation will take place when those making chemicals use these strategies for green chemistry and other pollution prevention approaches.

Continuing with his presentation, Mr. Morris stated that within an overall context of improving the environmental sustainability of chemicals, materials, and products, SPSW will better integrate current ORD research related to: computational toxicology, EDCs, nanotechnology, next-generation risk assessment, pesticides decisions, and TSCA chemical decisions.

Closer integration of ORD's chemicals-related programs to address common science questions will be more efficient, better coordinated both within SPSW as well as across ORD, and will focus a critical mass of ORD resources and expertise on the Agency's highest-priority science needs for chemicals.

SPSW research will support **integrated evaluation strategies and smarter, context-relevant chemical assessment and management** to benefit not only pesticide and industrial chemical regulation for existing chemicals, but also to enhance green chemistry opportunities for the design and use of new chemicals. SPSW also will support **community-level decision making** specific to those contaminants of highest priority and concern to individual localities and communities. Better approaches to chemical testing, assessment, and management also will lead to better **air toxics, drinking water, hazardous waste, and remediation-related** regional and local decision making. Mr. Morris commented that SPSW is the methods and tools development program that will inform community-based assessments and support the other programs (Safer and Sustainable Water Resources; Sustainable and Healthy Communities; and Air, Climate, and Energy).

Dr. Olden commented that agriculture and urbanization are two big challenges. The systems currently used to provide services to urban populations are not sustainable. Eighty percent of Americans live in urban areas and the population is aging, which makes it more vulnerable to exposures. Is EPA thinking about what can be done to change health outcomes in urban populations? Mr. Morris responded that cumulative risk, complex mixtures, and population vulnerability are issues that are priorities at EPA. ORD has started looking at how the SPSW research could inform decision-making at the community level. Thought has been given to extracting a "chemical slice" of the urban environment to determine what might be driving the health-related outcomes. This effort would require close collaboration and integration with the Sustainable and Healthy Communities Program.

Dr. Haas asked if there was an ecological component to SPSW. Mr. Morris replied that the program is looking at the implications of chemicals to non-human organisms, but there is not an ecosystems research component. That research would fall under the Sustainable and Healthy Communities Program. Dr. Kavlock added that the tools developed by SPSW will be applicable to both health and the environment. Mr. Morris stressed that the interconnection of the programs makes it important for the BOSC to look at the ORD program as a whole.

Dr. Demerjian noted that nanotechnology research is included in SPSW. Is that research on how nanomaterials affect human health and the environment or research on how nanotechnologies might help society deal with sustainability issues. Mr. Morris said that it is the first focus rather than the latter; however, ORD is conducting both types of research.

Mr. Morris stated that developing SPSW as an ITR program requires partner participation in problem identification as well as problem formulation and analysis. This information was provided to ORD senior scientists who are working to develop key science questions. That is the point ORD is at now. The next step is for the partners to review these questions and provide feedback. Partners then will participate in analyzing the portfolio of existing ORD Programs to identify gaps and alignments. Partners also will assist in identifying stakeholders and will participate in stakeholder engagement. ORD will develop a new portfolio to address partner-identified problems and key science questions in consultation with partners and external stakeholders.

Dr. Tharakan asked if partners included communities affected by contaminants. Mr. Morris responded yes. The Regions have established relationships with local communities so the Regions will work with ORD to develop the process and then the Regions will reach out to the communities. Dr. Tharakan asked where the BOSC and SAB come into this process. Dr. Teichman replied that now is the time for the BOSC and SAB to get involved in this process. ORD is trying to identify strategic priorities and formulate its research portfolio now, and ORD wants the BOSC to contribute to this effort. Mr. Morris

said that ORD will be meeting with the partners next Monday to focus on how to move outside the Agency to involve external stakeholders.

There is EPA-wide collaboration on SPSW. In May 2010, ORD sponsored a problem-formulation workshop that was attended by OCSPP; Region 6 (ORD Lead Region); Office of Water; OAR; Office of Solid Waste and Emergency Response; Office of Policy, Economics, and Innovation; Office of Children’s Health Protection; Office of the Science Advisor; Office of the Chief Financial Officer; and Office of Environmental Information. The workshop participants raised a number of chemicals-related issues, including: grouping and prioritizing chemicals, chemical-specific effects, dose-response, persistence, intelligent testing, mixtures and source apportionment, cumulative risk, quantification of dose-response relationships (especially low dose), decision support with little “usable” data, translational science/technical support, alternatives analysis approaches, prioritizing data needs, properties that drive exposure and hazards, green chemistry, intelligent chemical design, exposure in conjunction with toxicity data, more efficient and reliable assessment methodologies, biomonitoring data, life stages/children, and technology transfer.

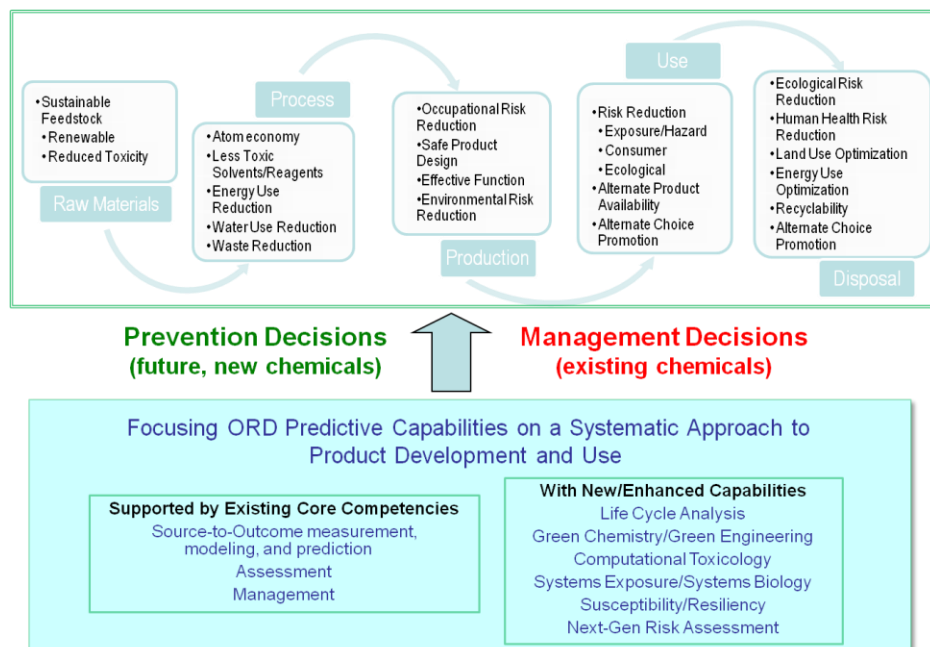
At the May workshop three SPSW research areas were identified: (1) Developing the Scientific Knowledge, Tools, and Models for Integrated Evaluation Strategies; (2) Improving Assessment and Informing Management for Chemical Safety and Sustainability; and (3) Targeting High-Priority Research Needs for Immediate and Focused Attention. Mr. Morris noted that integrated evaluation strategies will be applied in the risk assessment part of ORD and beyond to others in the Agency making decisions. The assessment and management of risk are being combined in one research area, so that those responsible for managing risk have to talk with those responsible for assessing risk. Can we identify the high priority areas for decision makers and use the tools/approaches developed to make more targeted selections?

Referring to Exhibit 1, Mr. Morris stated that the chemical life cycle at the top of the diagram identifies opportunities to inform decision making across the life cycle. Dr. Sayler asked if this would be done by EPA and industry or just EPA. Mr. Morris answered that this would have to be an EPA-industry partnership. EPA would develop the tools and approaches needed to inform industry decisions.

The bottom box in the diagram identifies the core competencies required to inform decisions in the chemical space. He noted that the new-enhanced capabilities come by bringing together the chemical expertise from across ORD.

Dr. Tharakan suggested changing the word “reduction” to “elimination” and use of the term “cradle to cradle” rather than “cradle to grave.” Mr. Morris agreed stating that “elimination” would be more in line with the program’s goals.

**Exhibit 1. Considering Sustainability Across Chemical Life Cycles**





An SPSW view of an integrated evaluation strategy for chemicals is provided in Exhibit 2. The objective is to develop science information to inform the integrated evaluation strategy. How can we develop enough information to make decisions without doing too much work and wasting resources? The strategy is divided into the testing approaches and the assessment and management approaches. The problems to apply to testing and then assessment are developed by the decision needs. Inputs from testing go through assessment to inform management decisions.

The testing approaches including evaluating properties, screening, targeted testing, and integrated modeling. As you move down the testing approaches the resource requirements increase but the residual uncertainty decreases.

Dr. Haas asked if the diagram addresses the fact that chemicals embedded in a product can change during its life cycle. Mr. Morris replied that this would be considered in property evaluation. Dr. Haas then asked where use and disposal patterns fit in. Mr. Morris responded that if EPA thinks a decision can be made based on property evaluation, then how those properties change throughout the life cycle must be considered. Fate and transport also must be considered in properties evaluation.

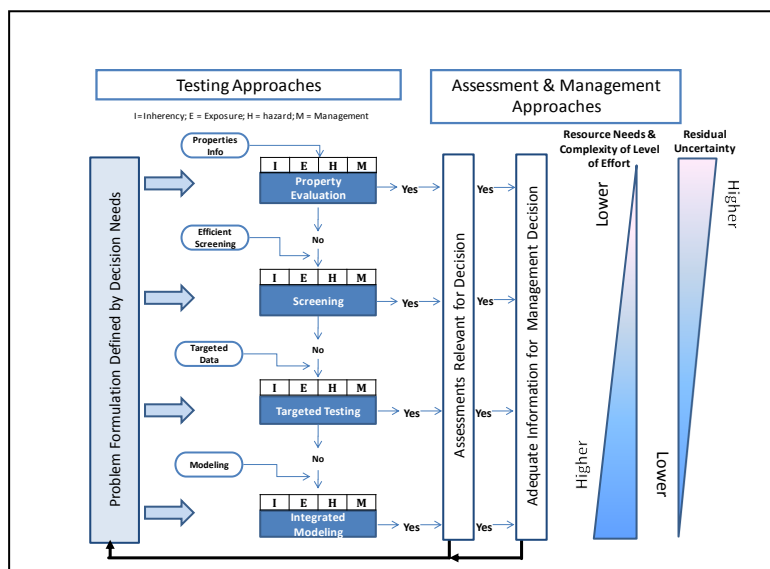
Dr. Haas asked how this diagram differs from one ORD would have presented 5 years ago. Dr. Kavlock responded that one difference is the scale of what ORD is trying to do. ORD will not be limited by the number of chemicals and toxicity pathways; thousands of chemicals and hundreds of toxicity pathways can be examined and that will help target testing approaches. He noted that one goal is to reach the point of understanding the toxicity pathways and what tests are needed to understand the effects.

Dr. Sayler said he thought the integrated modeling box should be at the top rather than the bottom. Dr. Kavlock explained that there will be models in each of the blue boxed areas. The last box, Integrated Modeling, is the “Cadillac” level of tests that would be run.

Dr. Demerjian commented that characterizing raw nanomaterials is straightforward but characterizing them in the product stream and then determining how they get into the environment is much more complex. Each product would be a study in and of itself. Mr. Morris agreed. If you think some characteristic at the property evaluation stage would affect toxicity, are you willing to make the decision with high uncertainty? If not, then you would go to the screening stage, using high throughput assays to identify those with high concerns. Are you now willing to make the decision with medium uncertainty? If not, then go to targeted testing and estimate the risk. The uncertainty is reduced but this requires more resources. In cases where the stakes are high, ORD may be forced to look at complex models for systems biology to reduce the uncertainty.

Dr. Kavlock commented that ORD probably will need additional expertise in life cycle assessment (LCA) to help with the development of a higher throughput LCA. He pointed out that this is only a framework; as ORD receives proposals, more details can be added and gaps can be filled.

**Exhibit 2. SPSW View of an Integrated Evaluation Strategy for Chemicals**



Dr. Barry Ryan asked how ORD will know when there is enough information. Typically, it is whatever information the Agency has prior to the deadline for a regulation. Mr. Morris responded that social sciences play a role in determining when there is enough information to make a decision. He added that this approach will not work until the Agency deals with the social science, regulatory, and administrative aspects of decision making.

Dr. Paustenbach was concerned that ORD did not have the resources to implement the SPSW Program. He thought it was overly ambitious for ORD to undertake this program without additional resources. He questioned whether much of this work should be done by the regulated community. Dr. von Stackelberg commented that SPSW appears to affect all of the other programs, and it seems like it is the philosophical beginning rather than just one of the programs. Shouldn't ORD start with this and then build on it? She agreed with Dr. Paustenbach that this appears to be too ambitious. The concept sounds good but a different organization may be needed. Dr. Haas suggested starting from the product rather than the chemical. Develop product models, grouping products together based on how they behave and their use. Dr. Paustenbach thought a massive simplification of the program was needed. What are other agencies, universities, and institutions doing to fill in pieces of this puzzle? ORD cannot possibly do all of this alone. Mr. Morris agreed that this is a big undertaking but it seems much more doable than running full batteries of tests on the 80,000 chemicals in commerce.

Research Area 1 of SPSW is developing the scientific knowledge, tools, and models for integrated evaluation strategies. This research is needed because there are more than 200,000 chemicals registered in REACH, and 75,000 chemicals in TSCA, and relatively few have been thoroughly evaluated for safety. The goal of this research area is to develop the scientific knowledge, tools, and models needed to improve our understanding of their environmental impact. Integrated evaluation strategies will inform assessments of risk or impact to humans and the environment. The SPSW solutions are to:

- ✧ Inform green chemistry and green engineering practices, leading to the design of safer chemicals and products.
- ✧ Understand chemical and chemical-mixture life cycles.
- ✧ Create innovative models to predict biologically effective exposure and internal dose.
- ✧ Develop much higher-throughput tools for the prioritization and biological screening of chemicals based on exposure and toxicity pathways.
- ✧ Link predictive pathways with in-life effects using smarter testing.

Research Area 2 is improving assessment and informing management for chemical safety and sustainability. This research is needed because assessment approaches are not keeping up with decision-making needs. The goals of this research area are to: (1) integrate state-of-the-art science into next-generation risk assessment approaches; (2) produce assessments that are more responsive, timely, and relevant to decision makers; and (3) facilitate management decisions with assessments that reduce uncertainty in risk estimates and achievable management outcomes. The SPSW solutions are to:

- ✧ Integrate computational toxicology and exposure approaches into chemical risk prediction, where appropriate, at all tiers of assessment.
- ✧ Apply new data, methods, and principles for next-generation risk assessments, including developing the science and the tools for conducting the most challenging risk assessments.
- ✧ Improve technologies for managing risks and catalyzing solutions.

Dr. Paustenbach commented that this is exactly what ORD needs to do—develop a computer model that would indicate the likelihood that suspected impacts would occur for a given chemical. This would be a great accomplishment. With the information available from REACH there should be enough data to

make predictions about classes of chemicals. Dr. Sayler agreed that this would be a good foundation for the program. Dr. Paustenbach viewed this as an extension of the screening process used by the pharmaceutical industry for decades. No private company or university would develop such a tool, so this would be a valuable contribution from EPA.

Dr. Olden said he had a different take on the program. ORD is trying to look at the bigger picture and develop a scientific basis for environmental decision making. The information needed for decisions is not product or chemical specific. ORD is trying to identify fundamental information and tools needed to make decisions regardless of the product. He agreed that this framework is complex, but it is a complex problem. In the long run, this research program will provide more than a product by product assessment. ORD should take its time and be logical in designing a program that ultimately will answer important questions for environmental decision making.

Dr. von Stackelberg asked about the resources that will be allocated to this program. Even if ORD's entire budget were dedicated to this effort, ORD may only achieve progress in a few areas. Mr. Morris said that approximately 25% of ORD's resources will be dedicated to the SPSW Program, but he will have a better idea of the resources available for the program a year from now.

Research Area 3 of SPSW is targeting high-priority research needs for immediate and focused attention. This research is needed because EPA has needs *today* for decision-support applications and tools. The goal is to establish infrastructure and transdisciplinary teams to rapidly respond to specific needs that include agency partners' targeted research priorities. The SPSW solutions are to:

- ✧ Identify, on an annual basis, the highest-priority research for specific chemical management needs that can best be provided by SPSW in a timely manner.
- ✧ Identify opportunities for integrating outputs of Research Areas 1 and 2 into the targeted needs of the Agency's chemical management programs.
- ✧ Determine how effective SPSW research has been in: (1) providing timely technical consultation and targeted testing results to EPA partner offices; and (2) transforming traditional evaluation, assessment, and management practices.

Dr. Sayler said he saw a lot of commonality between Dr. Paustenbach's comments and those of Dr. Olden. Dr. Falk, however, thought they had two very different perspectives. Dr. Paustenbach is saying that ORD should identify much quicker, more innovative ways to assess risk and toxicity, and he agrees with Dr. Paustenbach that this would be a significant accomplishment. Dr. Olden, on the other hand, is talking about transforming the way the Agency makes assessment and management decisions; this is a huge, aspirational goal. ORD needs to decide whether to design the program narrowly (Dr. Paustenbach's view) or broadly (Dr. Olden's) view. Dr. Falk said he would hesitate to make such a huge leap at the present time. Dr. Paustenbach concurred, stating that developing the model would bring about the next incremental change. The program should focus on achieving these incremental breakthroughs as steps toward the ultimate goal articulated by Dr. Olden.

Mr. Morris responded that it appears that ORD came to the BOSC at the right time. ORD is just getting started with standing up SPSW and will be working to accomplish this over the next year. Referring to the SPSW timeline, Mr. Morris stated that the SPSW portfolio development would extend from now until October 2011.

Mr. Morris closed his presentation by posing the following questions: What is the best way for the BOSC to provide consultative advice as ORD develops SPSW? What is the best way for ORD to keep the BOSC informed about SPSW? He added that BOSC input will be sought on the other programs as well.

Dr. von Stackelberg asked how SPSW is integrated with the other programs. She still thought this needed to be the foundation rather than one of the programs. The model Dr. Paustenbach described does not apply only to this program; it seems to be the foundation that contributes to them all.

### **Public Comment**

*Dr. Gary Saylor, BOSC Executive Committee Chair*

At 11:30 a.m., Dr. Saylor called for public comments. No comments were offered by those in the room or on the telephone. Mr. Susanke added that, as of this morning, there were no public comments submitted through the docket.

### **Discussion of BOSC Consultation on ORD Research: SPSW (Continued)**

Dr. Olden expressed his sincere appreciation to Mr. Morris and Dr. Kavlock, stating that this research is very important. Even if the pathway is not yet clearly defined, ORD is heading in the right direction. This was a very good presentation.

Dr. Teichman said that he had to leave to return to EPA for a meeting. Referring to Dr. von Stackelberg's comment about SPSW forming the foundation, Dr. Teichman commented that the other NPDs would probably think the same thing about their programs. Each of the four programs track on all the others and there are clear linkages. He agreed that the end goal is to improve environmental decision making and hence public health, but ORD has to reach this goal iteratively. This is a framework for reaching the ultimate goal. Once the portfolio is fleshed out, the roles of other organizations will become clearer. Dr. Teichman stated that EPA's research budget is only about 7% of the Federal Government's environmental budget. Therefore, ORD is not the only organization responsible for filling the data gaps. He found today's discussion meaningful and the comments to be thought provoking. He looked forward to future discussions of the new programs with the BOSC over the next 12 months.

### **Update on ORD Response to BOSC Decision Analysis Report**

*Dr. Fred Hauchman, Director, OSP, ORD, EPA*

Before beginning his presentation, Dr. Hauchman distributed two handouts to the BOSC members. The first was the *Communication Strategy for EPA Research* and the second was the Plan EJ 2014, both of which were mentioned in his presentation on Monday. He noted that the *Communication Strategy* was very brief and was intended to be at a high level.

Dr. Hauchman said that he would have liked to report to the BOSC that ORD is in high gear implementing the recommendations that were contained in the Decision Analysis Report, but that is not the case. ORD has been making some progress in this area, but most of the focus has been on the reorganization of the research programs. Nevertheless, Dr. Hauchman has some progress to report and wanted to identify some challenges that ORD is facing.

As background, Dr. Hauchman explained that following a presentation to the BOSC on the use of VOI approaches for prioritizing research, the Executive Committee decided to form a workgroup to provide advice to ORD on this topic. He noted that a number of the BOSC program review reports included recommendations on developing better, more systematic methods for prioritizing research. Dr. Hauchman read some of these recommendations from the Global Change, Ecological, and Safe Pesticides/Safe Products (SP2) Program Review reports. He commented that with the reorganization of the research programs and development of the research portfolios, this is an opportune time for ORD to pursue the decision analysis tools.



A workshop was held in Cincinnati in spring 2009. The workgroup developed three case studies to organize discussions around the topic, examined different decision analysis approaches, and prepared a report that was submitted to the Executive Committee and then ORD. That report contained the following recommendations:

- ✧ Use of decision analysis techniques to support research prioritization within ORD is feasible and recommended.
- ✧ Leadership is necessary and required.
- ✧ Engage staff in the effort.
- ✧ Resist the impulse to rely on one piece of software or an outside vendor or contractor to implement use of these techniques.
- ✧ Define expected benefits (quantitatively).
- ✧ Work through this effort by selecting pilot studies to try out the use of decision analysis approaches.

Responding to these recommendations is posing some organizational challenges. It has become clear that ORD needs to develop internal expertise in decision analysis, and Dr. Anastas is supportive of this effort. There have been some discussions about using a decision analysis approach to prioritize research for the SPSW Program.

Dr. von Stackelberg said that she had spent some time with the SPSW team thinking about how to apply decision analysis approaches in prioritizing research for the new program. This is an ambitious undertaking that will require EPA staff to approach decisions differently. She pointed out that decision analysis approaches evaluate different pieces of information that go into decision making in a single framework in standardized units. Dr. von Stackelberg said she is excited about working with ORD to move forward on these recommendations and is willing to help in implementing the pilots.

Dr. Sayler asked about the next steps. Dr. Hauchman responded that he will provide the BOSC a formal response that lays out where ORD plans to go with decision analysis. He appreciated the BOSC's report and thought it was what exactly what ORD needed. The nature of the BOSC's future involvement in this area remains to be determined.

Dr. Hauchman reported that NCER is incorporating decision analysis into its review of research proposals. The BOSC report is getting some traction and ORD is looking at moving forward on some other things; for example, NCEA is looking at using decision analysis for prioritizing chemicals for assessments. There are other opportunities within NCEA being considered as well.

There are plans to recruit someone with appropriate expertise to focus on decision analysis and how it can be piloted within ORD. Dr. von Stackelberg commented that once ORD has staff members who are vested in decision analysis, it will help in the efforts to employ it successfully and then institutionalize it within the Agency.

### **Executive Committee Open Forum**

*Dr. Gary Sayler, BOSC Executive Committee Chair*

Dr. Sayler explained that this time had been set aside on the agenda for an open discussion of what the BOSC will be doing in the foreseeable future. The BOSC members need to provide feedback to EPA on the presentations (e.g., knowledgebase, data mining, alternative bibliometric-based measures) they have seen and offer suggestions for future activities.

Dr. Von Stackelberg said that she had not been on the BOSC very long so she had little experience with program reviews. Since she joined the Board, her role has been to provide high-level consultative advice on key issues identified by ORD. For example, she has provided advice on decision analysis approaches. Dr. Cozzens has offered some general advice on bibliometrics and program evaluation techniques. Does it make more sense for the BOSC to provide advice on key topics rather than conduct program reviews? Dr. Saylor thought that was a reasonable suggestion.

Dr. Hauchman pointed out that this is an opportunity for the BOSC to do more than retrospective reviews of ORD programs. The BOSC can work with the SAB to help ORD shape its new research programs. He noted that the BOSC's charge does not limit the Board's work to retrospective reviews. There is a vital role for the BOSC to play in shaping major programs and identifying their logical components. He sees the BOSC's current role as helping guide the ORD programs and, at some future date down the road, reviewing those programs retrospectively to assess ORD's progress.

Dr. Demerjian commented that with the new programs, air, climate, and energy are being combined. He agreed that these areas belong together but was concerned about whether the programs can be fully integrated. The demands on each program are different; if the Agency lists CO<sub>2</sub> as an air pollutant, this will create a huge demand on the climate group. The resources for these programs have been disparate in the past, and Dr. Demerjian was concerned that each area would not receive adequate attention.

Dr. Falk stated that this meeting has been very different from the previous BOSC meetings he has attended. When the BOSC was conducting program reviews, the subcommittees were responsible for the in-depth analysis of the programs. The BOSC Executive Committee's role was to review, edit, and approve the reports for submission to ORD. Unlike previous meetings, the members have exhibited considerable passion about the topics discussed—it is clear they have some strong opinions about these issues. This meeting, however, has been less structured. If future BOSC meetings continue to function using this model, their success will depend on choosing the right topics and then structuring the discussion.

Dr. Saylor asked that the BOSC members send him their comments via e-mail on what topics they think the Board should cover, any cross-cutting themes, the structure of the meetings, and other any other issues or suggestions. Dr. Saylor will forward that input to Mr. Susanke who will provide it to the next BOSC Chair.

Dr. Haas thought it would be good for the BOSC to provide input in the research planning stage rather than only review ORD program retrospectively. Should the BOSC establish four subcommittees for the four major research programs? Dr. Saylor suggested that Dr. Haas submit that comment via e-mail.

Dr. Cozzens asked if ORD was directing the BOSC to terminate the retrospective program reviews. She did not think the BOSC could provide advice on whether ORD was doing the science right without conducting retrospective reviews. Therefore, she recommended that the BOSC continue the retrospective program reviews even as the Board adds new activities.

Mr. Susanke said that the mid-cycle progress report for the Homeland Security Research Program will be presented at the spring BOSC meeting. He thought the BOSC should meet jointly with the SAB before the BOSC decides to establish four workgroups that correspond to the four major programs. The SAB meeting is scheduled for Tuesday and Wednesday, March 22-23, 2011. Perhaps several of the BOSC members could attend that meeting to discuss what a joint meeting of the SAB and BOSC would entail. Dr. Saylor asked why the SAB would be involved in determining the BOSC's future activities. Mr. Susanke replied that the focus of that joint SAB-BOSC meeting will be "is ORD doing the right science," which historically has been under the purview of the SAB. The BOSC's focus has been retrospective program evaluation.

Dr. Cozzens commented that even though there appears to be a great deal of work for the BOSC, the Board should not abandon the retrospective reviews. This is a key element of program evaluation and the most effective means of determining that ORD “is doing the science right.”

Dr. Sayler pointed out that the BOSC has been given the opportunity to be more proactive—providing input on SPSW, for example, during its formative, planning stage. The BOSC can continue to do the retrospective reviews, but if the Board is to be helpful to ORD during this organizational change, the BOSC must be ready to provide advice on how best to structure and implement these new programs to accomplish their goals. Because of this opportunity, the BOSC will be even better prepared in the future to conduct the retrospective reviews of these programs.

Dr. von Stackelberg stated that the BOSC’s role of assessing whether ORD is “doing the science right” has led to retrospective program reviews. If that role is shifting to whether ORD is “doing the right science,” then that clearly expands the BOSC’s activities beyond retrospective reviews. There has been some frustration expressed in the past during the program reviews because the BOSC did not know how decisions were made and program priorities were established. Are the program reviews useful to ORD? Are they the most effective way to for the BOSC to assess that ORD is doing the science right?

Dr. Sayler pointed out that ITR will require integration with the Regions, communities, and other stakeholders. The BOSC will have to look at how all the partners are participating in the program in future reviews; he noted that embracing the ITR concept will require considerable work. He encouraged the BOSC members to e-mail their ideas to him and Mr. Susanke.

### **Future Discussion/Future Business**

*Dr. Gary Sayler, BOSC Executive Committee Chair*

Dr. Falk asked about the date of the next BOSC meeting. Dr. Sayler suggested that the BOSC could meet March 22-23, 2011, which would allow the members to spend a few hours with the SAB to discuss the process for a more formal, longer joint meeting.

Dr. Paustenbach said it would be helpful if ORD could provide information on ORD’s current skill sets and expertise, ongoing projects, the level of effort for those projects, and the dates that they will expire. This information will help the BOSC and SAB identify gaps that need to be addressed in building the portfolios for the new programs.

Dr. Sayler hoped that the BOSC would recommend that EPA stay engaged with DOE’s Knowledgebase effort, which may yield significant benefits. Dr. Tharakan made a motion to recommend that EPA remain engaged with Knowledgebase and Dr. Demerjian seconded the motion.

Dr. Hauchman stated that ORD is seeking the BOSC’s input on the Board’s future role. That role needs to be clearly defined. There is an opportunity for the BOSC to work with the SAB in shaping the new programs, but he was concerned about mission creep. It is important to understand that the BOSC and the SAB have different roles to play. He wanted to clarify that ORD valued the BOSC’s program reviews; many changes have been made in response to those reviews and the BOSC has had a positive impact on ORD programs. Mr. Susanke added that 89% of the BOSC’s recommendations have been fully or partially implemented, which is a very high percentage. Dr. Hauchman pointed out that this percentage reflects the value of the Board’s contribution. He then thanked Dr. Sayler for his leadership, which has certainly been a factor in the BOSC’s success.

Dr. Sayler mentioned that he had received a letter from a well known scientist complaining about NCER’s grant review process. He noted that the complaint also was sent to Dr. Anastas. Basically, this scientist had submitted a grant application that received high marks in the peer review, and the scientist was told that the grant may be funded pending the results of the relevancy review. The scientist waited

for several months and then contacted NCER to determine why the grant had not been funded. NCER told the individual that the application had been re-reviewed and found to be unacceptable; as a result, the grant was not funded. Dr. Sayler noted that the re-review of grant applications is not uncommon, but perhaps there is an opportunity here for the BOSC to look at NCER's grant review process and offer some suggestions for making the peer review and relevancy review processes more transparent.

Dr. von Stackelberg pointed out that there was an explicit recommendation in the Decision Analysis Report about using a decision analysis approach for grant review; the information collected in the spreadsheets from reviewers could be filtered through a formal evaluation process. This would be rather easy to implement and would enhance transparency.

Dr. Sayler replied that perhaps NCER should explain the current review process at the next BOSC meeting and the Board could offer some suggestions for increasing the transparency of the process.

Dr. Cozzens noted that the next BOSC Chair might appreciate having some of these issues clarified before the next meeting.

Dr. Paustenbach asked if the BOSC was locked into the March 22-23, 2011 date for the next meeting. Mr. Susanke responded that those dates are locked in for the SAB meeting, not the BOSC meeting. The BOSC would not have to meet on those dates if several Board members could attend the SAB meeting for several hours on one of the 2 days to discuss the process and topics for a joint SAB-BOSC meeting. Dr. Sayler noted that if the BOSC Executive Committee meeting overlaps those dates, the BOSC could set aside a few hours on the agenda to meet with the SAB to discuss the joint meeting.

Dr. Paustenbach suggested holding the BOSC meeting on Monday and Tuesday, March 21-22, 2011. The BOSC could meet with the SAB for a few hours on Tuesday, March 22 to discuss the joint SAB-BOSC meeting. Beginning the BOSC meeting on Monday would allow those from the West Coast to fly on Sunday and miss fewer days of work.

Mr. Susanke stated that there will be no BOSC meeting in January. He will work with the SAB to discuss the possibility of meeting for 2 hours with the BOSC on March 22, 2011. The meeting will be held in Washington, DC. He will get back to the BOSC members about the dates for the next Executive Committee meeting. The agenda for the next meeting will include the mid-cycle progress report for the Homeland Security Research Program, discussion of several pilots, and possibly community and tribal risk screening tools. There are plenty of topics to fill the agenda.

Dr. Hauchman noted that ORD will begin the process of briefing the BOSC about the other new programs at the March meeting to solicit the Board's input on the scope of those programs. Dr. Demerjian asked how much time the NPD has been working on integrating these programs. Dr. Hauchman replied that the NPDs were just named in the past few weeks so they have not had much time; however, some of the new interim NPDs have been associated with these programs for a number of years.

Dr. Sayler asked if the BOSC members can communicate amongst themselves about future directions. Because these were more than administrative issues, Mr. Susanke suggested sending ideas to him and Dr. Sayler via e-mail but postponing the discussion of the ideas until the next public meeting.

Ms. Zhuikov asked if ORD wanted comments on the newsletter that was distributed to the members. Mr. Susanke confirmed that ORD would welcome any comments. Ms. Zhuikov asked about the audience and purpose of the newsletter. Mr. Susanke explained that the newsletter was developed for the BOSC to keep the members informed about ORD happenings. It was compiled by pulling articles from the ORD Web Site. If the members find it useful, ORD will continue to provide the newsletter to the BOSC members. Ms. Zhuikov said she thought it provided some useful information; she expressed some



concern, however, about the story on hydraulic fracturing because it skirted the drinking water contamination issue. Dr. Falk mentioned that he thought the newsletter was helpful.

Dr. Paustenbach asked if it would be possible to get the information on the current projects, skills and expertise, level of effort, and other information before the next meeting. Dr. Hauchman responded that he would have to check on that and get back to the BOSC. Dr. Paustenbach thought the BOSC needed that information before the Board could advise ORD. Dr. Hauchman pointed out that the role of the BOSC needs to be clarified to determine whether the Board needs such detailed information.

After thanking the BOSC members for their participation, Dr. Sayler adjourned the meeting at 12:42 p.m.

### **Action Items**

- ✧ ORD will prepare a formal response to the BOSC Decision Analysis Report that lays out where ORD plans to go with decision analysis.
- ✧ The BOSC members will submit comments on the future topics for discussion, cross-cutting themes, structure of BOSC meetings, and any other ideas on future activities to Dr. Sayler and Mr. Susanke before the next meeting.
- ✧ Mr. Susanke will compile the BOSC members' comments on future topics/activities and distribute them to the BOSC members.
- ✧ Mr. Susanke will discuss with the SAB DFO the possibility of meeting for a few hours with the BOSC on Tuesday, March 22, 2011, to discuss the process and potential dates for a joint SAB-BOSC meeting.
- ✧ Mr. Susanke will poll the BOSC members about their availability to meet on March 21-22, 2011 in Washington, DC.
- ✧ Dr. Hauchman will check on providing the BOSC with information on ORD's current skill sets and expertise, ongoing projects, the level of effort for those projects, and the dates that they will expire.

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

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## 45th EXECUTIVE COMMITTEE FACE-TO-FACE MEETING AGENDA

October 18 - 19, 2010

Hilton Garden Inn  
815 14th Street NW  
Washington, DC 20005

### Monday, October 18, 2010

8:00 a.m. – 8:30 a.m.	Registration	
8:30 a.m. – 8:45 a.m.	Welcome and Introductions - Review of July and August Meeting Minutes - Overview of Agenda	Dr. Gary S. Saylor, Chair, Executive Committee
8:45 a.m. – 8:50 a.m.	BOSC DFO Remarks - Administrative Issues	Mr. Greg Susanke, Designated Federal Officer (DFO), Office of Research and Development (ORD)
8:50 a.m. – 9:30 a.m.	ORD Remarks	Dr. Fred Hauchman, Director, Office of Science Policy, ORD
9:30 a.m. – 12:00 p.m.	<b>Informatics/Data Mining/Knowledgebase Session</b>	
9:30 a.m. – 10:30 a.m.	Information Technology and Advances in Knowledgebase Development - DOE Systems Biology Knowledgebase R&D Project	Mr. Robert Cottingham, Oak Ridge National Laboratory U.S. Department of Energy
10:30 a.m. – 10:45 a.m.	Break	
10:45 a.m. – 11:30 p.m.	Health and Environmental Research Online (HERO) Database	Ms. Debra Walsh, Deputy Director, National Center for Environmental Assessment – RTP, ORD
11:30 p.m. – 12:00 p.m.	ORD Data Mining Techniques	Mr. Myles Morse, National Center for Environmental Research, ORD
12:00 p.m. – 1:00 p.m.	Lunch	
1:00 p.m. – 5:00 p.m.	<b>Research Program Performance Evaluation Session</b>	
1:00 p.m. – 2:30 p.m.	STAR METRICS	Dr. Stefano Bertuzzi, National Institute of Health



*Agenda for October 18-19, 2010 Executive Committee Meeting*

2:30 p.m. – 2:45 p.m.	Break	
2:45 p.m. – 3:00 p.m.	Overview of ORD Evaluation Techniques: Past and Present	Ms. Mya Sjogren, Performance and Accountability, ORD
3:00 p.m. – 4:00 p.m.	Exploring New Approaches for Evaluating Research Effectiveness: A Case Study	Dr. Dorothy Miller, Recent AAAS Fellow to ORD  Dr. Audrey Levine, National Program Director for Drinking Water, ORD
4:00 p.m. – 5:00 p.m.	Discussion of Informatics/Data Mining and Program Performance Evaluation Sessions	Dr. Susan Cozzens, BOSC Executive Committee
5:00 p.m.	Recess	

**Tuesday, October 19, 2010**

8:30 a.m. – 9:15 a.m.	ORD Update	Dr. Kevin Teichman, Deputy Assistant Administrator for Science, ORD
9:15 a.m. – 11:30 a.m.	Discussion of BOSC Consultation on ORD Research: Safer Products for a Sustainable World	Mr. Jeff Morris, National Program Director for Nanotechnology, ORD
10:15 a.m. – 10:30 a.m.	Break	
11:30 a.m. – 11:45 a.m.	Public Comment	
11:45 a.m. – 12:00 p.m.	Update on ORD Response to BOSC Decision Analysis Report	Dr. Fred Hauchman, Director, Office of Science Policy, ORD
12:00 p.m. – 12:45 p.m.	Executive Committee Open Forum	Dr. Gary Sayler, Chair, Executive Committee
12:45 p.m. – 1:00 p.m.	Future Discussion/Future Business - EC Meetings in 2011 - Future Work	Dr. Gary Sayler, Chair, Executive Committee
1:00 p.m.	Adjourn	