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BOARD OF SCIENTIFIC COUNSELORS

BOARD OF SCIENTIFIC COUNSELORS (BOSC)
EXECUTIVE COMMITTEE

Conference Call Summary
March 26, 2008
9:30 a.m. – 12:00 noon EDT

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

Dr. Gary Sayler welcomed the Executive Committee members and others to the conference call and thanked everyone for taking the time to participate. He explained that the purpose of the call was to review and hopefully approve two draft reports—the Human Health Risk Assessment (HHRA) Research Program Review Report and the National Center for Environmental Research (NCER) Standing Subcommittee Letter Report. In addition, there will be status reports on several other reports that are in preparation. The Executive Committee also will discuss the date for the September 2008 meeting. He noted that at least two members could not remain on the call until 12:00 noon so he wanted to cover the discussion and approval of the two reports expeditiously.

Dr. Sayler reminded the members that the next Executive Committee meeting will be held May 6-7, 2008, in Gulf Breeze, Florida. The Mid-Cycle Review of the Land Research Program will be held May 8, 2008, in Gulf Breeze. He asked the Executive Committee members and other participants to identify themselves. A list of participants is attached to this summary. Dr. Sayler then introduced Ms. Heather Drumm, who was serving as the Designated Federal Officer (DFO) for this Executive Committee conference call in Ms. Lorelei Kowalski's absence, to provide the DFO remarks.

DFO Remarks
Ms. Heather Drumm, EPA/ORD/OSP, Designated Federal Officer

Ms. Drumm stated that the Board of Scientific Counselors (BOSC) is a federal advisory committee that is subject to the requirements of the Federal Advisory Committee Act (FACA). As the DFO, she serves as the liaison between the BOSC Executive Committee and the U.S. Environmental Protection Agency's (EPA) Office of Research and Development (ORD) and ensures that all FACA procedures and requirements are met. All meetings involving substantive issues, whether in person, by phone, or by e-mail, must be open to the public. This applies to all group communications that include at least one-half of the Executive Committee members. In addition, there must be time set aside for public comment at each meeting. Ms. Drumm noted that she did not receive any requests for public comment prior to the call; however, there is time on the agenda for public comment at 10:45 a.m. She asked that comments be limited to 3

minutes each. The BOSC Chair and the DFO must be present at all Executive Committee meetings and conference calls. A notice was placed in the *Federal Register* to announce this conference call and it was entered into the federal docket management system (www.regulations.gov, Docket ID EPA-HQ-ORD-2008-0169).

A contractor, Beverly Campbell from The Scientific Consulting Group, is present to take notes during the call. Ms. Drumm asked those speaking during the conference call to identify themselves for the record. A summary of the call will be prepared and it will be posted on the BOSC Web Site (www.epa.gov/osp/bosc) after it is approved by the BOSC Chair. Ms. Drumm has ensured that all ethics requirements have been satisfied, each BOSC member has filed a standard government financial disclosure report, and all members have completed the required ethics training. She asked the members to notify her if any potential conflict of interest arises during the call. The purpose of this call is to discuss and vet the HHRA Research Program Review Report and the revised NCER Standing Subcommittee Letter Report, receive a status report on several other reports, and set a date for the September meeting.

The following items were distributed by Ms. Kowalski to the Executive Committee members via e-mail on March 14, 2008: (1) the draft agenda, (2) the 2-page summary of the HHRA Program, the draft HHRA Research Program Review Report, and (3) the revised NCER Standing Subcommittee Letter Report. On March 21, 2008, the Executive Committee members were sent the draft summary of the January 24-25, 2008 Executive Committee Meeting. Ms. Drumm confirmed that the members had received these items prior to the call. She noted that the 2-page HHRA Program summary was prepared and distributed in response to a suggestion from the January meeting. She added that feedback on the usefulness of the summary would be appreciated.

Dr. Sayler asked if there were any questions for Ms. Drumm and there were none.

Human Health Risk Assessment Research Program Review Report
Dr. George Daston, HHRA Research Subcommittee Chair

Dr. Daston served as the Chair of the Subcommittee and Bruce Allen, Henry Anderson, Richard Corley, John Evans, Mark Utell, and Lauren Zeise served as Subcommittee members. Dr. Daston mentioned that the report was ready for review later than expected because John Evans was unable to attend the face-to-face meeting so he could not help draft the report and another Subcommittee member resigned because he was elected to public office and did not have time to participate in the review.

The Subcommittee's overall impression of the program is highly favorable. There is a clear need for this program within the Agency. The HHRA Program has done a good job of meeting its goals and satisfying its customers within EPA. It provides formal risk assessments to the Agency in the form of Integrated Risk Information System (IRIS) reviews and Provisional Peer Reviewed Toxicity Values (PPRTVs) used for Superfund site cleanups. This program also prepares Integrated Science Assessments (ISAs) on criteria air pollutants and provides risk assessment advice to the Agency. All of these efforts were consolidated under ORD's National Center for Environmental Assessment (NCEA) when ORD was reorganized a number of years

ago. The consolidation of the Agency's risk assessment expertise in NCEA has been beneficial to the program and the Agency—creating a "one-stop shop" for this expertise within EPA.

The program has three long-term goals (LTGs). LTG 1 focuses on IRIS and other priority hazard assessments. The current success criteria for this goal are 16 new IRIS assessments and 50 new PPRTVs per year. There also is an expectation that existing IRIS assessment will be reviewed and updated on a regular basis. LTG 2 is to develop state-of-the-art risk assessment models, methods, and guidance to improve the quality of risk assessments and provide greater support for decision-making. LTG 3 involves updating the ISAs (formerly the Air Quality Criteria Documents[AQCDs]) on a recurring 5-year cycle to include the best and most up-to-date science on the effects of exposure to the criteria air pollutants. The ISAs are used by the Office of Air and Radiation (OAR) as it reviews the National Ambient Air Quality Standards (NAAQS). Dr. Daston noted that LTG 2 is less prescribed than the other two LTGs.

The Subcommittee met by conference call twice in October 2007, and met face-to-face in Bethesda, Maryland, in November. The review covered all aspects of the program and NCEA Director Peter Preuss and his staff provided presentations, posters, and materials that were extremely helpful in conducting the review. The Subcommittee recognized that preparing for the review was a major undertaking and the members very much appreciated the work the program staff put into the review. Since the November meeting, there have been two Subcommittee conference calls to discuss the draft report.

The HHRA Program is very relevant to EPA's mission. The Clean Air Act (CAA), Resource Conservation and Recovery Act (RCRA), Toxic Substances Control Act (TSCA), and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) could not be implemented without this program. IRIS is used by states and other regulators as well as by the private sector. It is viewed as the gold standard in hazard characterization. The IRIS Web Site receives about 8 million visits annually—a testament to its value as an information source.

The program is meeting the goal of 16 new IRIS assessments per year, but many more are needed by EPA and those outside the Agency. The Subcommittee heard from regional officials as well as a consultant who surveyed IRIS users that there is a critical need for additional IRIS assessments. Because of this need, the Subcommittee recommended that NCEA assess what needs to be done to increase the program's ability to produce more IRIS and PPRTV assessments per year. The Subcommittee also recommended that NCEA develop a mechanism to prioritize assessments for updating and a mechanism for retaining assessments in the database that have not been updated within 10 years, particularly when new data on that chemical are limited. NCEA should make this prioritization process available to the general public and take steps to ensure the transparency of decisions made in the process of performing IRIS and PPRTV assessments.

With respect to LTG 2, the program has made strategic choices to concentrate on areas that are likely to bear fruit in ways that will markedly improve risk assessment. The Subcommittee recommended that the program continue to develop ties with the National Center for Computational Toxicology (NCCT) and provide formal input to the Computational Toxicology Research Program on the aspects of its research that will be valuable to the HHRA Program.

The importance of the work under LTG 3 to help the Agency meet CAA requirements cannot be overstated. The program has instituted internal and external feedback mechanisms that ensure the work remains relevant to the Agency's needs. There was some concern about the ISA process because it is new and differs from that used for the AQCDs. The Subcommittee advised the program to closely follow this work to ensure that the ISAs meet the same needs as the AQCDs.

The work of the HHRA Program has been highly responsive to the needs of the program offices and regions. The Subcommittee heard testimonials of program office and region officials who strongly value the work and expertise of the HHRA Program, both in providing risk assessment products and in supporting emergency responses to crises such as the 9/11 terrorist attacks on the World Trade Center and Hurricane Katrina. The risk assessment expertise within the program has been critical in dealing with these and other disasters, but this support has not been captured in Annual Performance Measures (APMs). Because this is such a valuable aspect of the program, the Subcommittee encouraged the HHRA Program to find a way to catalog the important application of the program's expertise in its APMs.

With respect to scientific leadership, the program is internationally recognized as a leader in risk assessment methods development and implementation. The program's products are impressive and the Subcommittee was provided numerous examples of its scientific leadership, including the development of physiologically based pharmacokinetic (PBPK) model applications for IRIS other priority health hazard assessments. The Subcommittee recommended recruiting one or two additional senior scientists, especially for LTG 2 where efforts are underway to integrate emerging technologies into the risk assessment processes. Experienced investigators with proven track records are more likely to move these fields forward and serve as catalysts to junior scientists.

The HHRA Program has done an excellent job of engaging scientists and managers from other ORD programs as well as program and regional offices in its planning. The program also has formed relationships with external groups that facilitate coordination and avoid duplication of effort. This includes a memorandum of understanding with the Agency for Toxic Substances and Disease Registry (ATSDR) that emphasizes the sharing of information on substances being evaluated by both organizations. The HHRA Program also has working relationships with the World Health Organization's International Program on Chemical Safety, the International Agency for Research on Cancer, and the United Nations Environment Programme.

Because PPRTVs are only available on a Web site restricted to use by EPA staff or those who obtain special permission from EPA, the Subcommittee recommended that EPA make the PPRTVs and their supporting documentation publicly available for use in hazardous waste site risk assessment and promote their use where appropriate.

With respect to the summary assessments, the Subcommittee assigned the rating of Meets Expectations to LTG 1. This LTG is highly prescribed and the program is consistently meeting all of its goals. The Subcommittee assigned the rating of Exceeds Expectations to LTG 2. It was clear to the Subcommittee that the program provides real leadership to EPA and others with respect to risk assessment tools and methods. The program is making good decisions about what technologies are ready for routine use in risk assessments that support public health decisions. The Subcommittee assigned the rating of Meets Expectations to LTG 3. This LTG also is highly

prescribed and the program is meeting its goals. The work is exceptional but it received this rating because of the strict definitions of the ratings in the tool.

Discussion of the HHRA Research Program Review Report

Dr. Sayler thanked Dr. Daston for his thorough overview and asked Dr. Henderson, who served as a vettor for this report, to share her comments. Dr. Henderson enjoyed reading the report and thought the recommendations were insightful. The report would be more effective, however, if it was shorter and less repetitive. There was considerable redundancy among the different sections. Dr. Henderson also thought the Summary section was longer than necessary. She mentioned that the ISA process includes the development of a database of studies on each criteria air pollutant. Is that effort part of this program? Dr. Daston replied in the affirmative adding that there was a poster on the topic. It was not emphasized in the report, however, because it is not yet operational. Dr. Henderson stated that she sent her written comments on the report to Ms. Drumm.

Dr. Ryan, who also served as a vettor for the report, stated that he thought the report was well written and that the Summary section gives the reader a good idea of the program's efforts. He suggested that the Summary section could be shortened by moving some of the text to the Introduction. He liked the way Dr. Daston pulled out the recommendations by LTG in today's presentation. The redundancy in the report was of less concern to him; these reports tend to be repetitive because of the charge questions. He cautioned that the program is struggling to meet the current goals of 16 new IRIS and 50 new PPRTV assessments each year, and he thought it would be very difficult to expect the program to increase the number of annual assessments. He also asked for some additional insight into the Exceeds Expectations rating for LTG 2. Are they making progress more rapidly than the Subcommittee expected? Dr. Daston responded that the Subcommittee assigned this rating for a couple of reasons. The program has been tremendously successful in selecting the right technologies to translate into practice. He cited the PBPK modeling guidance and the updated benchmark dose models as examples. Dr. Daston also noted that the quality of the products under LTG 2 has been very good.

Dr. Sayler said he thought perhaps the ratings were too low. He pointed out that Meets Expectations applies to a program that is meeting most but not all of its goals. He thought a rating of Exceptional could be applied to LTG 2. Dr. Ryan agreed that the program is doing exceptional work but thought it was achieving the goals that the Agency expects it to achieve.

Dr. Falk thought it was a good report and that the Summary section was very helpful in understanding the HHRA Program. He also thought the recommendations and ratings were appropriate.

Dr. Sayler agreed that the Summary may be a bit long, but he did not think it needed to be changed just to make it shorter. It is well written as it stands.

Dr. Daston agreed to revise the Summary section by combining the recommendations into a section at the end of the Summary. That should make the section a little shorter and the recommendations clearer. Dr. Henderson said those changes would address her concern. Dr. Ryan asked that the recommendations be linked to the LTGs in the Summary section.

When there were no additional comments and it was agreed that the Executive Committee should vote on the report, Dr. Henderson moved to approve the report with the suggested changes and Dr. Ryan seconded the motion. The HHRA Research Program Review Report was approved unanimously by the Executive Committee.

Dr. Sayler thanked Drs. Daston, Henderson, and Ryan for their efforts with the report.

NCER Standing Subcommittee Revised Letter Report
Dr. Martin Philbert, NCER Standing Subcommittee Chair

Dr. Philbert reviewed the changes that had been made to the report based on the comments from the January Executive Committee meeting. The sixth bullet on page 2 of the draft report was revised for clarification. It now reads: "NCER should consider using an unsolicited grant submission process to encourage generation of relevant scientific questions that do not match exactly the wording of existing Requests for Applications (RFAs)." Also on page 3, the third bullet under Measuring Impacts was revised to read: "NCER should develop case studies of how research funded by the Center facilitates change in tangible indicators of environmental performance ('results'), in addition to how the research is cited, read, and otherwise increases knowledge."

The second paragraph on page 4 under Identifying the Most Valuable Research was revised to read: "One set of inputs to this identification process can be a formal assessment of the estimated value-of-information to be provided by different candidate research endeavors. From a high-level view, NCER and ORD should strive to conduct the highest value research, while also supporting an appropriate amount of research to guard against unknown surprises and to provide information that could be used to deal with as yet unidentified future problems."

Dr. Philbert added a footnote to the table on page 13 under Charge Question #3 to indicate that the time to impact values were estimated by workgroup 3. The estimates were based on the time it takes to do the research and then get through the process of integrating it into regulations and rulemaking. He noted that there were minor editorial changes throughout the report to reduce the strident tone in the previous draft.

Dr. Duke, who served as the vettor for this report, said he thought Dr. Philbert and the Subcommittee did a great job of incorporating the comments. He suggested two small changes on page 7. In the first line of the first paragraph under More Rapid Funding Mechanisms, the words "questions why it would be burdensome" should be deleted. In addition, in the fifth line of that same paragraph, the words "not be burdensome, and indeed could" should be deleted. Dr. Philbert agreed to make these changes.

Dr. Henderson said she had sent her written comments on this report to Ms. Drumm. Her primary concern was that the report did not appear to follow the two questions on the top of page 4 that emerged from "deconstruction" of the charge.

With respect to the footnote added to the table on page 13, Dr. Sayler asked if the members of workgroup 3 were identified in the report. Dr. Philbert replied that they were not and he agreed

to change the footnote to read: "Estimated by the Subcommittee" because the Subcommittee reviewed and approved the table. Dr. Sayler agreed that would address his concern. He then asked if the Executive Committee members were ready to vote on the report. Dr. Duke made a motion to approve the report with the requested changes and Dr. Henderson seconded the motion. The NCER Standing Subcommittee Letter Report was approved unanimously by the Executive Committee.

Feedback on the Two-Page Summary of the HHRA Program
BOSC Executive Committee

Dr. Sayler asked if the members found the two-page summary of the HHRA Program to be helpful in reviewing the draft report. He reminded the Executive Committee members that this was suggested at the January meeting to give the members an overview of the program when reviewing the draft report. Dr. Falk said that he found the 2-pager provided background on the program that he found helpful when reading the report. Dr. Duke agreed, adding that the 2-pager should eliminate the need to provide background information in the review reports, which adds unnecessary length. Dr. Ryan thought the 2-pager was very useful and Dr. Daston concurred.

Dr. Sayler reported to Ms. Drumm that the Executive Committee finds the 2-pager a helpful addition for reviewing the draft Subcommittee reports.

Review of the January 2008 Executive Committee Meeting Minutes
Dr. Gary Sayler, BOSC Executive Committee Chair

Dr. Sayler asked if there were any comments on the summary of the January 24-25, 2008 meeting. Dr. Henderson had a few small edits that she sent to Ms. Drumm. No additional comments were offered so Dr. Sayler called for a motion to approve the minutes. Dr. Philbert moved to approve the minutes with Dr. Henderson's edits and Dr. Duke seconded the motion. The January 2008 meeting summary was unanimously approved by the BOSC Executive Committee.

Executive Committee Updates
Dr. Gary Sayler, BOSC Executive Committee Chair

Dr. Sayler stated that the Executive Committee will be reviewing the report from the National Exposure Research Laboratory (NERL) Standing Subcommittee. Dr. Demerjian, who was unable to make this conference call, is working on that report. Dr. Swackhamer, who also was unable to participate in this call, was charged with revising the Endocrine Disrupting Chemicals (EDCs) Mid-Cycle Program Review Report. Dr. Sayler said these reports will be reviewed at the May meeting in Gulf Breeze.

Dr. Henderson was asked to revise the Air Program Mid-Cycle Review Report. Drs. Ryan and Giesy agreed to vet the revised report. Dr. Sayler reported that both Drs. Ryan and Giesy have approved the revisions that were made subsequent to the January meeting. Dr. Henderson said that the only additional change that needs to be made is the inclusion of a sentence at the end of the report stating that the Air Program does not need to respond to the report. This was suggested at the January meeting. With the approval of the vettors, Dr. Sayler stated that the Air

Program Mid-Cycle Review Report is ready for transmission to ORD. He will prepare the transmittal letter to accompany the report.

Public Comments
Ms. Heather Drumm, EPA/ORD/OSP, DFO

At 10:45 a.m., Ms. Drumm asked if anyone on the call would like to make a public comment. Dr. John Vandenberg from NCEA said, on behalf of the HHRA Program staff, that the BOSC review was very important to the program and the results of the review are used in a variety of ways both inside and outside of EPA. He thanked the Subcommittee for taking time to conduct the review, adding that preparing for these reviews forces the staff to think about all aspects of the program and its impacts. Dr. Vandenberg said that he looked forward to receiving the report. He then was going to comment on a statement that was made earlier about the level of peer review used for IRIS, but Ms. Drumm interrupted him, indicating that this was not the appropriate venue for such a comment. No other comments were offered so the Executive Committee Updates resumed.

Executive Committee Updates (Continued)
Dr. Gary Sayler, BOSC Executive Committee Chair

Dr. Sayler reminded the Executive Committee members that the next meeting would be held May 6-7, 2008 in Gulf Breeze, Florida. There is a tentative agenda for that meeting, which will include field tours. September 18-19, 2008 has been selected as the date for the fall Executive Committee meeting, which will be held in Washington, DC. Dr. Sayler mentioned that the Land Research Program Mid-Cycle Review meeting will be held May 8, 2008 in Gulf Breeze and the Water Quality Research Program Mid-Cycle Review will be held on September 23, 2008 in Washington, DC. Dr. Herb Windom has agreed to serve as Chair of the Water Quality Mid-Cycle Review Subcommittee. The NERL Standing Subcommittee Report and the EDCs Mid-Cycle Review Report will be reviewed at the May meeting.

Dr. Sayler asked if there were any questions or additional topics to cover. Dr. Falk said he had agreed to vet two reports, but he could not remember which ones. Ms. Drumm said that Ms. Kowalski would send the two reports to Dr. Falk for review 2 weeks prior to the May meeting. Dr. Duke stated that one of the reports Dr. Falk was to vet is the Global Change Mid-Cycle Review Report. That report is being revised by the Subcommittee and will be ready for review by the Executive Committee well before the May meeting.

When there were no additional comments, Dr. Sayler adjourned the conference call at 10:55 a.m.

Action Items

- ✍ Dr. Daston agreed to revise the Summary section of the HHRA Research Program Review Report by combining the recommendations into a section at the end of the Summary. He will link the recommendations to the LTGs.

- ✍ Dr. Philbert will make the changes on page 7 that were suggested by Dr. Duke. In the first line of the first paragraph under More Rapid Funding Mechanisms, the words “questions why

it would be burdensome" will be deleted. In addition, in the fifth line of that same paragraph, the words "not be burdensome, and indeed could" will be deleted.

- ✍ Dr. Philbert agreed to change the footnote added to the table on page 13 to read: "Estimated by the Subcommittee" because the Subcommittee reviewed and approved the table and workgroup 3 is not identified in the report.

- ✍ Ms. Drumm will send the changes Dr. Henderson requested to the January 24-25, 2008 meeting summary to SCG so that the summary can be finalized for posting on the BOSC Web Site.

- ✍ Ms. Kowalski will send the two reports that Dr. Falk agreed to vet to him for review 2 weeks before the May meeting.

- ✍ Dr. Sayler will prepare a transmittal letter for the Air Research Program Mid-Cycle Review Report and Ms. Kowalski will submit the letter and the report to ORD.

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BOARD OF SCIENTIFIC COUNSELORS

EXECUTIVE COMMITTEE MEETING
AGENDA
Wednesday, March 26, 2008
9:30 a.m. – 12:00 noon Eastern Time

CONFERENCE CALL
Participation by Teleconference Only

9:30-9:40 a.m.	Welcome and Overview - Roll Call - Purpose of Teleconference	Dr. Gary Sayler, Chair, BOSC Executive Committee
9:40-9:45 a.m.	DFO Remarks	Ms. Heather Drumm, Office of Research and Development
9:45-10:45 a.m.	Human Health Risk Assessment Subcommittee Draft Report - Overview of Draft Report - Discussion	Dr. George Daston, Chair, Human Health Risk Assessment Subcommittee Rogene Henderson and Barry Ryan, BOSC Executive Committee
10:45-11:00 a.m.	Public Comment	
11:00-11:30 a.m.	National Center for Environmental Research (NCER) Standing Subcommittee Revised Draft Letter Report - Overview of Changes to Revised Letter Report - Discussion	Dr. Martin Philbert, Chair, NCER Standing Subcommittee Cliff Duke, BOSC Executive Committee
11:30-11:50 a.m.	Executive Committee Updates - Status of NERL Standing Subcommittee - Status of Endocrine Disrupting Chemicals, Air, and Technology for Sustainability Reports - Suggestions for Potential Workgroups - Date for September 2008 Executive Committee Meeting	Dr. Gary Sayler, Chair, BOSC Executive Committee
11:45-12:00 noon	Action Items/Wrap Up	Dr. Gary Sayler, Chair, BOSC Executive Committee
12:00 noon	Adjourn	