

**NATIONAL EXPOSURE RESEARCH LABORATORY (NERL)
STANDING SUBCOMMITTEE****Conference Call Summary
Wednesday, April 9, 2008
1:00 p.m. – 3:00 p.m. Eastern Time****Welcome**

Dr. Kenneth L. Demerjian, University at Albany, State University of New York, Subcommittee Chair

Dr. Kenneth Demerjian, Chair of the National Exposure Research Laboratory (NERL) Standing Subcommittee and a member of the Board of Scientific Counselors (BOSC) Executive Committee, welcomed participants to the conference call. The Subcommittee has prepared a draft letter report in response to information provided by the NERL Laboratory Director and Associate and Division Directors during a previous conference call and at the face-to-face meeting held in December 2007. The report centers primarily on NERL's goal to develop a unifying theme for exposure assessments. Dr. Demerjian noted that, in response to suggestions from Subcommittee members, he has highlighted the most important items as a bulleted list in the introduction of the draft report. The purpose of this call is for Subcommittee members to discuss these final changes and approve the report, which then will be transmitted to the BOSC Executive Committee. It may be necessary for the Subcommittee to make some revisions to the report in response to comments from the Executive Committee, but Dr. Demerjian expected that any changes would be minimal.

Administrative Procedures

Ms. Susan Peterson, Office of Research and Development (ORD), U.S. Environmental Protection Agency (EPA), Designated Federal Officer (DFO)

Ms. Susan Peterson, Designated Federal Officer (DFO) for the NERL Standing Subcommittee, thanked Subcommittee members for their participation in this conference call. As the DFO for the Subcommittee, Ms. Peterson is responsible for ensuring that the Subcommittee complies with the Federal Advisory Committee Act (FACA).

The BOSC is a Federal Advisory Committee that provides independent, scientific peer review and advice to EPA's Office of Research and Development (ORD) and, as such, is subject to the rules and requirements of FACA. The NERL Standing Subcommittee has been provided with a set of specific charge questions and asked to prepare a report for the Executive Committee's deliberation. The Executive Committee has the authority to evaluate the Subcommittee's report, revise it if necessary, and submit it to ORD. The role of the BOSC is to provide advice and recommendations to ORD; the rights of decision-making and program implementation remain with the Agency.

This is the third conference call for the NERL Subcommittee; the first conference call was held on

November 28, 2007, and the second conference call was held on January 18, 2008. A face-to-face meeting was held December 11–12, 2007, in Research Triangle Park, North Carolina. FACA requires that all meetings and conference calls involving substantive issues—whether in person, by telephone, or by e-mail—that include one-half or more of the Subcommittee members must be open to the public, and a notice must be placed in the *Federal Register* at least 15 days prior to the conference call or meeting. The Subcommittee Chair and DFO must be present at all conference calls and meetings. All advisory committee documents are made available to the public.

Subcommittee members should have received a copy of the draft letter report and a homework form. The homework form covers the time period from January 18, 2008, through April 9, 2008.

Ms. Peterson reported that no requests for public comment were submitted prior to the call, but the agenda allows time for public comment at 1:15 p.m. She will call for public comments at that time, and each comment should be limited to 3 minutes.

Subcommittee Discussion

Dr. Kenneth L. Demerjian, University at Albany, State University of New York, Subcommittee Chair

Dr. Demerjian asked Subcommittee members for their input on the draft letter report.

Dr. Steve Bartell remarked that the current draft report clearly has been carefully edited and reads quite well. On page 2, the second bullet point suggests that “the guidance document should identify and work through one air example and one ecology example.” Dr. Bartell suggested changing this to “the guidance document should identify and work through one human exposure example and one ecological exposure example.” This would be less restrictive because human exposure occurs through routes other than air. Dr. Demerjian and Dr. Doug Dockery agreed with this suggestion.

Dr. Dockery suggested clarification in the second bullet point that the document has multiple target audiences.

Dr. Joseph DePinto pointed out that the bulleted list does not include the recommendation to divide NERL’s Conceptual Exposure Framework document into one document on exposure science guidelines (or guidance document) and another providing a framework for planning and implementing the Laboratory’s research. Dr. Demerjian noted that the second bullet point suggests developing the document first as an EPA guidance document and second as a short paper—a seminal paper on the concept of exposure assessment—suitable for publication in a journal. Dr. DePinto clarified that he specifically was referring to the first paragraph of Section 3 of the draft report (page 9), which suggests that NERL “consider separating the Framework into two core documents. One document should be the NERL/EPA Guidelines to Exposure Science and Research,” and the other (described in the third paragraph) should be “the Framework, which would be focused on describing the practices of NERL in terms of its: (1) mission and goals, (2) management strategy, (3) research and financial planning process, and (4) administrative procedures.” Dr. Demerjian agreed with including this as a third bullet point.

Dr. Bartell commented that a presentation from NERL during the face-to-face meeting indicated that the Conceptual Exposure Framework Document was not intended to be a textbook on exposure research. He recalled the Subcommittee’s earlier conclusions that, first, the Framework Document itself should be used for the stated purpose and, second, a more detailed, textbook-like document would be valuable as a follow-on. Dr. Demerjian recalled the Subcommittee’s earlier conclusion that such a seminal document is lacking in this field. He then asked for clarification that a new third bullet point would suggest that NERL

consider developing a second document that would provide a broad perspective on exposure science. Dr. Bartell agreed that this was his recollection. He noted, however, that one section of the draft report describes the guidance document as the main document for internal and external communication; this is confusing. The draft report should be clear regarding the nature and purpose of both the document intended for planning and implementing the Laboratory's research and the guidance document. In response, Dr. Demerjian characterized the draft report as a review of the Conceptual Exposure Framework Document with the added suggestion that NERL take the lead in developing a seminal scientific paper on exposure science. Dr. Bartell agreed with this characterization.

Dr. Michelle Frey observed that the Subcommittee appeared to be discussing four different documents: a guidelines (or guidance) document, a textbook, a journal article, and a management document. She described the guidance document as an internal document describing NERL's practices in exposure science and how the Laboratory uses exposure science to address the Agency's mission. A textbook or textbook-like document would be intended for the exposure science field as a whole and would describe the principles of exposure science. The Subcommittee also has discussed a refereed journal article, and it is not clear whether this is equivalent to (or is meant to be derived from) the textbook or the guidance document. Finally, a management document would describe how NERL plans and conducts research. Dr. Demerjian had assumed that the management document would be part of the guidance document. Dr. Frey contended that, based on her experience, management information would not fit within a guidance document that is meant for publishing the standard practices and procedures of a field. A guidance document may reflect how protocols fit within the mission of the agency. The manner in which an agency plans and conducts research, however, is a completely different issue; it is entirely internal and not typically published as part of a guidance document. Dr. Demerjian countered that, in NERL's presentation of the Framework Document to the Subcommittee, management guidance was included. Dr. Frey explained her recollection of the Subcommittee's conclusion that NERL has combined two different objectives in the Framework Document and that these two components should be separated. A document for the public would describe, from the perspective of NERL, how exposure science is applied to meet the Agency's mission. An internal document would have an essentially administrative, strategic function.

Dr. DePinto said that this concept is clear in the first two or three paragraphs of Section 3 of the draft report but may not be reflected in the bulleted list. Dr. Frey agreed that the suggestion to separate the Framework Document into two different documents should be clarified in the bulleted list. Drs. DePinto and Frey commented that the notion of a textbook or journal article is a separate issue related to how NERL should disseminate its work to the rest of the community.

Dr. Demerjian offered to create a new bullet point, based on the text in Section 3 of the draft report, to clarify the Subcommittee's recommendation for NERL to divide the Framework Document into two core documents, one regarding the scientific basis for exposure research and one on NERL's management, administration, and strategic planning. Drs. Frey and DePinto agreed. Another Subcommittee member agreed but cautioned that a separate internal document addressing the Laboratory's administration, management, and decision-making must be undertaken very carefully. Dr. Demerjian replied that, even if it will be difficult, he agreed with Dr. Frey that guidance documents generally are technical and do not address the internal administration and management of an agency; they are guidelines to be used by states or research institutions that use particular research and modeling tools. The Subcommittee has discussed the need for such guidelines to stimulate and focus the field and the members advise NERL to take the lead. He clarified that the report will indicate that an internal management document is important but should not be part of the Framework Document. He recalled the Subcommittee's suggestion, as articulated in the draft report, that the guidelines document be supported by one or more peer-reviewed papers; this would be the most successful method by which to obtain acceptance by the scientific community.

Public Comment

Ms. Susan Peterson, ORD, EPA, DFO

Ms. Peterson called for public comments at 1:15 p.m. No comments were offered.

Next Steps

Dr. Kenneth L. Demerjian, University at Albany, State University of New York, Subcommittee Chair

Dr. Demerjian asked Subcommittee members whether they wished to propose any further items for discussion. He added that he has edited the draft letter report to remove redundancy and extract the bulleted highlights; in addition, a technical editor has structured the report in accordance with the BOSC's requirements for letter reports. Dr. Demerjian urged Subcommittee members to take this opportunity to ensure that nothing important has been left out of this draft.

Hearing no concerns regarding missing information, Dr. Demerjian asked Subcommittee members whether he should seek their review and approval of the report once more after making the final changes or simply make the changes and send the draft report to the Executive Committee in time for its meeting in May 2008. Subcommittee members agreed that they did not need to review the report again after Dr. Demerjian makes the final changes.

One Subcommittee member commented that he has tracked minor edits throughout the report and would send this marked up version of the report to Ms. Peterson and Dr. Demerjian. All in all, however, he remarked that the report is in great shape. Dr. Demerjian asked Subcommittee members to send any further edits or comments to him by Friday, April 11, 2008.

Ms. Peterson reminded Subcommittee members to fill out their homework forms and sent them to her.

Dr. Demerjian stated that, after the final report is transmitted to NERL, the Subcommittee will learn whether it will be asked to advise the Laboratory on another issue or to follow up on its consultation regarding the Framework Document. Dr. Demerjian opined that the Subcommittee will be asked to provide further consultation for NERL in the future. NERL staff members were quite interested in obtaining initial feedback from the Subcommittee. For a recent NERL management meeting, Dr. Demerjian said he had provided NERL staff with an unofficial version of the draft report, which seems to have been reasonably well received. NERL will not provide feedback to the Subcommittee, however, until it receives the final report.

Dr. Frey observed, based on information provided at the face-to-face meeting, that one of NERL's major challenges may be the complexities of the Laboratory's planning process, including its interaction with ORD. She wondered if NERL should consider including ORD in a research and development management workshop that would invite administrative staff from other organizations—including private organizations (e.g., the American Water Works Association Research Foundation) that fund research. This may allow NERL to engage in cross-training to learn how other organizations function. Dr. Demerjian agreed and remarked that the first bulleted point in the draft report recommends that NERL communicate the vision of the Framework Document to other ORD laboratories and centers; the report also suggests outreach to other clients. Dr. Frey clarified that she was not suggesting that the Subcommittee make such a recommendation in response to this set of charge questions; rather, this could be something for the Laboratory to consider for the future. She added that NERL has unique issues because of its diversity and its history as a laboratory derived from once-independent laboratories; however, this is part of a global problem.

Dr. Demerjian asked whether the minutes from the BOSC conference calls are part of the public record. Ms. Peterson replied that the minutes are released to the public upon request and also are posted on the BOSC Web Site under the appropriate subcommittee. Dr. Demerjian remarked that the minutes from the previous conference call were very useful in producing the current draft. He asked Subcommittee members to review the minutes from the previous conference call, the face-to-face meeting, and (when available) this conference call and to provide him with any corrections or comments.

Dr. Demerjian thanked all Subcommittee members for their efforts to complete the draft report and expressed his hope that this report will breeze through the Executive Committee review and be sent to Dr. Larry Reiter shortly. When there were no additional comments, Dr. Demerjian adjourned the call at 1:39 p.m.

Action Items

- ✍ Subcommittee members will complete their homework forms for the period from January 18, 2008, through April 9, 2008, and provide them to Ms. Peterson.
- ✍ Dr. Demerjian will modify the second bulleted point on page 2 of the draft report. The section that currently reads “the guidance document should identify and work through one air example and one ecology example” should read “the guidance document should identify and work through one human exposure example and one ecological exposure example.”
- ✍ Dr. Demerjian will clarify, in the second bulleted point on page 2, that the Framework Document has multiple target audiences.
- ✍ Dr. Demerjian will create a new bulleted point, based on text in Section 3 of the draft report, to clarify the Subcommittee’s recommendation for NERL to divide the Framework Document into two core documents: one, a guidelines (or guidance) document, would address the scientific basis for exposure research; the other, an internal document, would address NERL’s management, administration, and strategic planning. Any reference to a peer-reviewed article or textbook should clarify that such a document would be a distinct document supporting the guidelines document.
- ✍ Subcommittee members will provide any further edits or comments on the draft letter report to Ms. Peterson and Dr. Demerjian by Friday, April 11, 2008.

PARTICIPANTS LIST

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**NATIONAL EXPOSURE RESEARCH LABORATORY (NERL)
STANDING SUBCOMMITTEE**

AGENDA

April 9, 2008

1:00 p.m. – 3:00 p.m. Eastern Time

Participation by Teleconference Only

866-299-3188

Code: 2025641077#

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| 1:00 – 1:10 p.m. | Welcome <ul style="list-style-type: none">- Roll Call- Purpose of Teleconference Call | Dr. Kenneth Demerjian
Subcommittee Chair |
| 1:10 – 1:15 p.m. | Administrative Procedures | Ms. Susan Peterson
NERL Standing Subcommittee
DFO |
| 1:15 – 1:25 p.m. | Public Comment | |
| 1:25 – 3:00 p.m. | Subcommittee Discussion <ul style="list-style-type: none">- Summary of Draft Report Progress- Draft Report Discussion- Next Steps and Schedule | Dr. Kenneth Demerjian
Subcommittee Chair and
Subcommittee Members |
| 3:00 p.m. | Adjourn | |