

**Summary Minutes of the United States Environmental Protection Agency (U.S. EPA)
Science Advisory Board (SAB) Teleconference
March 24, 2010**

Chartered SAB Members: See Roster provided in Attachment A.

Date and Time: March 24, 2010, 1:00 - 2:45 p.m. Eastern Time

Location: By Teleconference

Purpose: To conduct three quality reviews of draft SAB reports.

SAB Participants:

Dr. Deborah Swackhamer, Chair	Dr. Catherine Kling
Dr. David Allen	Dr. Kai Lee
Dr. Claudia Benitez-Nelson	Dr. Cecil Lue-Hing
Dr. Timothy Buckley	Dr. Floyd Malveaux
Dr. Terry Daniel	Dr. L.D. McMullen
Dr. George Daston	Dr. Judith Meyer
Dr. Costel Denson	Dr. Jana Milford
Dr. Otto Doering	Dr. Christine Moe
Dr. Taylor Eighmy	Dr. Eileen Murphy
Dr. John Giesy	Dr. Duncan Patten
Dr. Jeffrey Griffiths	Dr. Steven Roberts
Dr. Rogene Henderson	Dr. Amanda Rodewald
Dr. Bernd Kahn	Dr. James Sanders
Dr. Nancy Kim	Dr. Robert Watts

SAB Staff Office Participants

Dr. Angela Nugent, Designated Federal Officer (DFO)
Dr. Vanessa Vu, Director
Dr. Thomas Armitage
Mr. Aaron Yeow
Dr. Suhair Shallal

Meeting Summary:

The teleconference discussion at the meeting followed the issues and sequence as presented in the agenda (Attachment B).

1. Convene Teleconference

Dr. Angela Nugent, SAB DFO, convened the teleconference and welcomed the group. She noted that four written public comments were received and posted on the SAB Web site and

that three members of the public had requested to make a public statement. She noted that representatives of the Agency not listed on the agenda and members of the public participating in the call would be listed in the minutes of the meeting (Attachment D).

2. Purpose and Review of the Agenda

Dr. Deborah Swackhamer, the SAB Chair, reviewed the agenda.

She reviewed the four questions that are the responsibility of the chartered SAB when conducting a quality review:

1. whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;
2. whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;
3. whether the Committee's report is clear and logical; and
4. whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

She acknowledged written comments were received from members of the chartered SAB on the three draft reports being considered for quality review. Compilations of member comments on each of the draft reports are included in Attachments E, F, and G.

3. Public Comment

Dr. Swackhamer introduced the individuals who had requested public comment. All public comments related to the draft report prepared by the SAB Ecological Processes and Effects Committee (EPEC), a *Review of Empirical Approaches for Nutrient Criteria Derivation*.

Mr. John T. Hall from Hall & Associates provided oral comments on behalf of the Pennsylvania Periphyton Coalition. He supported a weight-of-evidence approach for nutrient criteria, thanked the SAB committee for its work, and urged the SAB to finalize its review document. Mr. Steven A. Hann from Hamburg, Rubin, Mullin, Maxwell & Lupin, P.C., provided comments on behalf of the Pennsylvania Municipal Authorities Association (PMAA). He emphasized the importance of scientific credibility for nutrient criteria as a basis for state development of total maximum daily loads and called for EPA and states to use open and transparent practices to develop nutrient criteria that will withstand scientific scrutiny. Mr. Fredrick Andes of Barnes & Thornburg LLP did not present himself to provide oral comments on behalf of the Federal Water Quality Coalition, but did provide written comments.

4. Quality Review of the Draft Report, Review of Empirical Approaches for Nutrient Criteria Derivation

Dr Judith Meyer, the EPEC Chair, introduced the committee's draft report with a few summary remarks on the nature of the review and the Committee's major conclusions. She briefly described the purpose of the draft guidance that EPA's Office of Water (OW) asked EPEC to review. OW's draft guidance document advanced a stressor-response approach for

deriving water quality criteria for nitrogen and phosphorus, nutrients that are major sources of water quality impairment. EPA's document outlined a five-step process for using statistical analyses to derive numeric nutrient criteria. EPEC responded to seven charge questions. In its findings and conclusions, EPEC recognized the stressor-response approach as a legitimate approach for deriving numeric nutrient criteria, if correctly applied as part of a tiered weight-of-evidence approach. Users may encounter variations, however, when using this approach; these statistical variations may not be relevant to deriving nutrient criteria. EPEC recommended that the guidance document contain more information on supporting analyses that complement the numerical approach EPA. EPEC also recommended that linkages be clearly shown between measured responses and designated uses. EPEC suggested major change in EPA's five-step model, beginning with problem formulation and model development to 1) allow users to consider whether the stressor-response approach is the appropriate approach to use and to 2) prompt users to consider uncertainty appropriately at each step. Dr. Meyer noted that SAB members had provided useful written comments that will assist in revising the final report (see Attachment E for a compilation of members' written comments).

Dr. Swackhamer recognized the lead reviewers, Drs. Claudia Benitez-Nelson, John Giesy, and Duncan Patton, to provide a brief summary of their comments. Comments included the following points:

- The EPEC report provided clear guidance to help EPA improve its draft guidance document
- The EPEC report should provide additional consideration of organic nitrogen, which is bioavailable and important or not focus in such detail on inorganic nitrogen. Dr. Meyer responded that the report will be revised to more clearly describe the context where inorganic nutrients are the dominant form, e.g., with language such as "In systems when inorganic nutrients are the dominant form...."
- The EPEC report should define its use of the term "conservative" where risks are assumed in lack of systems-specific information
- The key conceptual diagram (Diagram 1) in the EPEC report should indicate feedback loops and the conceptual diagram should appear in the body of the report, as well as the Executive Summary
- The EPEC report should cross-walk and cross-reference where responses to charge questions inter-relate.
- The EPEC report should clarify its use of the terms "weight of evidence" and "lines of evidence".

Dr. Swackhamer asked for a motion to dispose of the draft EPEC report. A motion was made and seconded to accept the report, conditional on changes being made by the Chair and DFO to address the comments made by the SAB and provided to the SAB Chair. There was universal approval with no members abstaining.

5. Quality Review of the Draft Review of EPA's Microbial Risk Assessment Protocol

Dr. Jeffrey Griffiths, Chair of the Drinking Water Committee (DWC), introduced the draft Review of EPA's Microbial Risk Assessment Protocol. He also spoke on behalf of Dr. Joan Rose, the Past Chair of the Drinking Water Committee, who co-chaired the review, and who was

not able to participate in the quality review discussion. Dr. Griffiths noted that the DWC concluded that OW's draft document did not fulfill its intended purpose as a protocol and instead should be revised as an introduction to microbial risk assessment. The DWC draft report advises OW to revise its draft document to: 1) reframe it as an introduction to Microbial Risk Assessment; 2) eliminate redundancy; and 3) add examples of microbial risk assessment to illustrate major points. The DWC recommends that OW develop a more advanced document that can serve as a true protocol with steps to follow in developing a microbial risk assessment. Dr. Griffiths also noted that Appendix G in OW's draft document focused on dose-response models that required additional expert statistical review.

Dr. Swackhamer recognized the lead reviewers, Drs. Nancy Kim, Christine Moe, and Eileen Murphy, to provide a brief summary of their comments. Comments included the following points:

- The DWC report appropriately suggests that OW's report be reframed as an introduction to Microbial Risk Assessment.
- The DWC report should emphasize the importance of including examples in OW's revised report to help users determine if microbial risk assessment will be useful for their needs.
- The DWC report should highlight its recommendations more clearly, perhaps by including a section for each charge question that would provide a bulleted list of recommendations.
- The DWC appropriately recommends extensive revisions to the health effects discussion so there will be separate discussions of health effects and dose response.
- The DWC report should clarify that OW should revise the body of its document and its appendices to clarify OW's assessment of the strengths and limitations of each approach described, including statistical methods. The DWC should especially clarify that Appendix G especially requires such revisions.

Other SAB members made additional comments:

- The DWC report should respond consistently to charge questions. Language on page 21 of the Executive Summary differs from language later in the body of the report.
- The DWC report and transmittal letter should communicate more clearly that EPA will need more technical work to develop its existing document into a detailed technical protocol. EPA should invest time in strengthening the information needed for a full protocol.

The SAB Chair noted that SAB members agreed that the DWC document should be revised to: 1) clarify its recommendations regarding the appendices in OW's draft documents; 2) clarify its recommendations related to reframing parts of OW's draft document as an introduction to microbial risk assessment and revising other parts to serve as a separate technical protocol; and 3) ensure consistency in characterizing recommendations in the letter to the Administrator, Executive Summary, and body of the report.

Dr. Swackhamer asked for a motion to dispose of the draft DWC report. A motion was made and seconded to accept the report, conditional on changes being made by the Chair and

DFO to address the comments made by SAB members and after review and approval by the lead reviewers. There was universal approval with no members abstaining.

6. Quality Review of the Draft Report of the Risk and Technology Methods Review Panel

Dr. Jana Milford, Chair of the Risk and Technology Review (RTR) Methods Panel provided an overview of the panel's charge and its draft report. EPA's Office of Air and Radiation (OAR) asked the RTR Panel to review EPA's draft methodologies for assessing residual risks posed by hazardous air pollutants after implementation of Maximum Achievable Control Technologies (MACT) standards. The panel reviewed two case studies (petroleum refining and Portland cement) conducted by OAR to illustrate methods that would be applied to other residual risk assessments. Dr. Milford noted that EPA's residual risk assessment effort was complex and the charge to the RTR panel was correspondingly complex, involving considerations of emissions, exposure modeling, choice of dose-response values for chronic and acute human health risk, and ecological risk assessment.

Dr. Milford summarized several primary findings. The RTR panel was concerned that OAR's initial choice of emissions inputs, based on monitored and not maximum regulated values, because evidence suggests an underestimation bias. The RTR panel also recommends that OAR carefully scrutinize values chosen for acute health effects. The RTR panel supported OAR's approach for ecological risk assessment, but recommended that OAR assessments identify where site-specific ecological characterization may be needed. Finally, the RTR panel recommended that OAR analyze and communicate residual risks in the context of aggregate or cumulative risk.

Dr. Swackhamer recognized the lead reviewers, Drs. David Allen, Timothy Buckley, and George Daston, to provide a brief summary of their comments. She noted that the fourth lead reviewer, Dr. Deborah Cory-Slechta was not able to participate in the discussion but had provided written comments. Oral comments from the lead reviewers included the following points:

- The RTR report should further highlight the difficulty of getting accurate meteorological data and provide recommendations, if possible, for addressing this data gap. Dr. Milford noted that the body of the report addresses this point and that additional language could be added to the executive summary.
- The RTR report should note that EPA guidance on acute risk suggests that the Agency should take the annual average emission and multiply by a factor of 10 but that such data have huge variability. The report should suggest how OAR should address this variability.
- The Executive Summary should "fill in the gaps" on important responses to some of the charge questions.
- The report should highlight the need for more EPA guidance about how to represent cancer and non-cancer hazards to children. Dr. Milford noted that the panel had not taken an in-depth look at this issue. Instead, it suggested that EPA look at the policy of the State of California.

- The report should acknowledge that EPA's preferred practice is to use benchmark doses, where available, rather than using a factor of three when calculating from a LOAEL, instead of a NOAEL.
- The report should better justify its recommendation that the Agency use MACT levels rather than actual emission estimates because of uncertainties and a likelihood that actual emissions estimates can be underestimates. Dr. Milford noted that the panel viewed the MACT standard as the appropriate starting point for analysis (i.e., the Agency should first assess the residual risk based on allowable emissions and then estimate risk based on current emission) and will sharpen communication of its rationale in the transmittal letter and document.

Other SAB members made additional comments:

- The report should clarify key definitions (e.g., residual risk, MACT standards) and explain acronyms.
- The report should include its recommendation concerning particle-bound hazardous air pollutants in the executive summary.
- The report should be formatted to reduce repeated statement of charge questions.
- The report should emphasize the problem of outdated information in the Integrated Risk Information System (IRIS) and IRIS gaps.
- The report should clarify responses to charge questions related to "protocols" to answer the questions more directly.

Dr. Swackhamer asked for a motion to dispose of the draft EPEC report. A motion was made and seconded to accept the report, conditional on changes being made by the Panel Chair and DFO to address the comments made by the SAB and provided to the SAB Chair. There was universal approval with no members abstaining.

Adjourn the Teleconference

The Designated Federal Officer adjourned the teleconference at 2:45 p.m.

Respectfully Submitted:
/Signed/

Dr. Angela Nugent
SAB DFO

Certified as True:
/Signed/

Dr. Deborah L. Swackhamer
SAB Chair

ATTACHMENTS

- Attachment A: Chartered SAB Roster
- Attachment B: Agenda
- Attachment C: FR Notice
- Attachment D: Members of the Public and EPA Representatives who requested call-in information or asked to be identified as participating in the teleconference.
- Attachment E: Comments from Members of the Chartered SAB on Review of Empirical Approaches for Nutrient Criteria Derivation (1-8-10 Draft) -- Compilation as of 3/19/10
- Attachment F: Comments from Members of the Chartered SAB on Drinking Water Committee's Review of EPA's Microbial Risk Assessment Protocol (1-12-10 Draft) -- Compilation as of 3/22/10
- Attachment G: Comments from Members of the Chartered SAB on the draft Report of the Risk and Technology Methods Review Panel (2-17-10 Draft) -- Compilation as of 3/19/10

Attachment A
Roster
U.S. Environmental Protection Agency
Science Advisory Board

CHAIR

Dr. Deborah L. Swackhamer, Professor and Charles M. Denny, Jr., Chair in Science, Technology and Public Policy and Co-Director of the Water Resources Center, Hubert H. Humphrey Institute of Public Affairs, University of Minnesota, St. Paul, MN

SAB MEMBERS

Dr. David T. Allen, Professor, Department of Chemical Engineering, University of Texas, Austin, TX

Dr. Claudia Benitez-Nelson, Associate Professor, Department of Earth and Ocean Sciences and Marine Science Program, University of South Carolina, Columbia, SC

Dr. Timothy Buckley, Associate Professor and Chair, Division of Environmental Health Sciences, College of Public Health, The Ohio State University, Columbus, OH

Dr. Thomas Burke, Professor, Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

Dr. Deborah Cory-Slechta, Professor, Department of Environmental Medicine, School of Medicine and Dentistry, University of Rochester, Rochester, NY

Dr. Terry Daniel, Professor of Psychology and Natural Resources, Department of Psychology, School of Natural Resources, University of Arizona, Tucson, AZ

Dr. George Daston, Victor Mills Society Research Fellow, Product Safety and Regulatory Affairs, Procter & Gamble, Cincinnati, OH

Dr. Costel Denson, Managing Member, Costech Technologies, LLC, Newark, DE

Dr. Otto C. Doering III, Professor, Department of Agricultural Economics, Purdue University, W. Lafayette, IN

Dr. David A. Dzombak, Walter J. Blenko Sr. Professor, Department of Civil and Environmental Engineering, College of Engineering, Carnegie Mellon University, Pittsburgh, PA

Dr. T. Taylor Eighmy, Vice President for Research, Office of the Vice President for Research, Texas Tech University, Lubbock, TX

Dr. Elaine Faustman, Professor, Department of Environmental and Occupational Health

Sciences, School of Public Health and Community Medicine, University of Washington, Seattle, WA

Dr. John P. Giesy, Professor and Canada Research Chair, Veterinary Biomedical Sciences and Toxicology Centre, University of Saskatchewan, Saskatoon, Saskatchewan, Canada

Dr. Jeffrey Griffiths, Associate Professor, Department of Public Health and Community Medicine, School of Medicine, Tufts University, Boston, MA

Dr. James K. Hammitt, Professor, Center for Risk Analysis, Harvard University, Boston, MA

Dr. Rogene Henderson, Senior Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. Bernd Kahn, Professor Emeritus and Associate Director, Environmental Radiation Center, School of Mechanical Engineering, Georgia Institute of Technology, Atlanta, GA

Dr. Agnes Kane, Professor and Chair, Department of Pathology and Laboratory Medicine, Brown University, Providence, RI

Dr. Nancy K. Kim, Senior Executive, New York State Department of Health, Troy, NY

Dr. Catherine Kling, Professor, Department of Economics, Iowa State University, Ames, IA

Dr. Kai Lee, Program Officer, Conservation and Science Program, David & Lucile Packard Foundation, Los Altos, CA

Dr. Cecil Lue-Hing, President, Cecil Lue-Hing & Assoc. Inc., Burr Ridge, IL

Dr. Floyd Malveaux, Executive Director, Merck Childhood Asthma Network, Inc., Washington, DC

Dr. Lee D. McMullen, Water Resources Practice Leader, Snyder & Associates, Inc., Ankeny, IA

Dr. Judith L. Meyer, Distinguished Research Professor Emeritus, Odum School of Ecology, University of Georgia, Lopez Island, WA

Dr. Jana Milford, Professor, Department of Mechanical Engineering, University of Colorado, Boulder, CO

Dr. Christine Moe, Eugene J. Gangarosa Professor, Hubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta, GA

Dr. Eileen Murphy, Manager, Division of Water Supply, New Jersey Department of Environmental Protection, Trenton, NJ

Dr. Duncan Patten, Research Professor , Department of Land Resources and Environmental Sciences, Montana State University, Bozeman, MT

Dr. Stephen Polasky, Fesler-Lampert Professor of Ecological/Environmental Economics, Department of Applied Economics, University of Minnesota, St. Paul, MN

Dr. Stephen M. Roberts, Professor, Department of Physiological Sciences, Director, Center for Environmental and Human Toxicology, University of Florida, Gainesville, FL

Dr. Amanda Rodewald, Associate Professor, School of Environment and Natural Resources, The Ohio State University, Columbus, OH

Dr. Joan B. Rose, Professor and Homer Nowlin Chair for Water Research, Department of Fisheries and Wildlife, Michigan State University, East Lansing, MI

Dr. Jonathan M. Samet, Professor and Flora L. Thornton Chair, Department of Preventive Medicine, University of Southern California, Los Angeles, CA

Dr. James Sanders, Director and Professor, Skidaway Institute of Oceanography, Savannah, GA

Dr. Jerald Schnoor, Allen S. Henry Chair Professor, Department of Civil and Environmental Engineering, Co-Director, Center for Global and Regional Environmental Research, University of Iowa, Iowa City, IA

Dr. Kathleen Segerson, Professor, Department of Economics, University of Connecticut, Storrs, CT

Dr. V. Kerry Smith, W.P. Carey Professor of Economics , Department of Economics , W.P Carey School of Business , Arizona State University, Tempe, AZ

Dr. Herman Taylor, Professor, School of Medicine, University of Mississippi Medical Center, Jackson, MS

Dr. Barton H. (Buzz) Thompson, Jr., Robert E. Paradise Professor of Natural Resources Law at the Stanford Law School and Perry L. McCarty Director, Woods Institute for the Environment, Stanford University, Stanford, CA

Dr. Paige Tolbert, Professor and Chair, Department of Environmental Health, Rollins School of Public Health, Emory University, Atlanta, GA

Dr. Thomas S. Wallsten, Professor and Chair, Department of Psychology, University of Maryland, College Park, MD

Dr. Robert Watts, Professor of Mechanical Engineering Emeritus, Tulane University,
Annapolis, MD

SCIENCE ADVISORY BOARD STAFF

Dr. Angela Nugent, Designated Federal Officer, 1200 Pennsylvania Avenue, NW
1400F, Washington, DC, Phone: 202-343-9981, Fax: 202-233-0643, (nugent.angela@epa.gov)

**Attachment B
Meeting Agenda**

**U.S. Environmental Protection Agency
Science Advisory Board (SAB)
Teleconference
Agenda**

March 24, 2010, 1:00 p.m. to 5:00 p.m. Eastern Time

Purpose: To conduct three quality reviews of draft SAB reports.

1:00 p.m.	Convene the Teleconference	Dr. Angela Nugent <i>Designated Federal Officer EPA SAB</i>
1:05 p.m.	Purpose and Review of the Agenda	Dr. Deborah L. Swackhamer <i>Chair EPA SAB</i>
1:05 p.m.	Public Comments	TBA
1:35 p.m.	Quality Review of the Draft Report, <i>Review of Empirical Approaches for Nutrient Criteria Derivation</i>	Dr. Deborah L. Swackhamer Dr. Judith Meyer <i>Chair, Ecological Process and Effects Committee</i> Chartered SAB Members
2:35 p.m.	Quality Review of the Draft <i>Review of EPA's Microbial Risk Assessment Protocol</i>	Dr. Deborah L. Swackhamer Dr. Jeffrey Griffiths, <i>Chair, Drinking Water Committee</i> Dr. Joan Rose, <i>Past Chair, Drinking Water Committee</i> Chartered SAB Members
3:30 p.m.	Quality Review of the Draft <i>Report of the Risk and Technology Methods Review Panel</i>	Dr. Deborah L. Swackhamer Dr. Jana Milford <i>Chair, Risk and Technology Review Methods Panel</i> Chartered SAB Members
4:30 p.m.	Adjourn the Teleconference	The DFO

Attachment C
FR Announcement

Federal Register: February 22, 2010 (Volume 75, Number 34)]
[Notices]
[Page 7592-7593]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr22fe10-50]

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9114-7]

Science Advisory Board Staff Office; Notification of a Public
Teleconference of the Chartered Science Advisory Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public notice for the chartered SAB to hold a public teleconference on March 24, 2010 to conduct quality reviews of three draft reports.

DATES: The public teleconference will be held on March 24, 2010 from 1 p.m. to 5 p.m. (Eastern Time).

ADDRESSES: The public teleconference will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain general information concerning this public teleconference should contact Dr. Angela Nugent, Designated Federal Officer (DFO), EPA Science Advisory Board (1400F), 1200 Pennsylvania Avenue, NW., Washington, DC 20460; via telephone/voice mail (202) 343-9981; fax (202) 233-0643; or e-mail at nugent.angela@epa.gov. General information concerning the EPA Science Advisory Board can be found on the SAB Web site at <http://www.epa.gov/sab>.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, 5 U.S.C., App. 2 (FACA), notice is hereby given that the EPA Science Advisory Board will hold a public teleconference to conduct quality reviews of three draft SAB Panel reports: (1) The SAB Drinking Water Committee's draft Review of EPA's Microbial Risk Assessment Protocol; (2) the SAB Ecological Processes and Effects Committee's draft Review of Empirical Approaches for Nutrient Criteria Derivation; and (3) the draft Report of the Risk and Technology Methods Review Panel. The SAB was established pursuant to 42 U.S.C. 4365 to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a

Federal Advisory Committee under FACA. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Background: (1) The SAB Drinking Water Committee's Draft Review of EPA's Microbial Risk Assessment Protocol. EPA's Office of Water (OW) conducts microbial risk assessments (MRA) as part of its responsibility for protecting human health and the environment from contaminants in water. OW has requested the SAB conduct a review of the draft ``Protocol for Microbial Risk Assessment for Support Human Health Protection for Water-Based Media'' and provide recommendations on how to improve the overall approach, the applicability of the protocol, the reasonableness of the protocol, the clarity of the protocol, the completeness and robustness of the protocol, and the ease of use of the protocol for conducting water-based

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microbial risk assessments. Background information about this advisory activity can be found on the SAB Web site at http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/MRA%20Protocol?OpenDocument.

(2) SAB Ecological Processes and Effects Committee's Draft Review of Empirical Approaches for Nutrient Criteria Derivation: Nutrient enrichment is one of the leading causes of surface water quality impairment in the United States. The adoption of numeric nutrient criteria in state water quality standards for the protection of aquatic life is a high priority for EPA's Office of Water. EPA's OW has requested SAB review of the Agency's draft Technical Guidance on Empirical Approaches for Numerical Nutrient Criteria Development. This draft guidance would supplement EPA's published technical guidance for developing numeric nutrient water quality by using empirically-derived stressor-response relationships as the basis for developing numeric nutrient endpoints for water quality standards.

Background information about this advisory activity can be found on the SAB Web site at http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/Empirical%20Criteria%20Guidance?OpenDocument.

(3) The Draft Report of the Risk and Technology Methods Review Panel: Section 112(f)(2)(A) of the 1990 Clean Air Act Amendments (CAA) requires EPA to evaluate whether emission standards that were previously adopted under the technology-based, Maximum Achievable Control Technology (MACT) program provide an ample margin of safety to protect public health and prevent adverse environmental effects (taking into consideration costs, energy, safety, and other relevant factors). Within eight years of the promulgation of a MACT standard for the source category, EPA is mandated by the CAA to assess the risks to determine whether additional standards are needed. EPA's Office of Air and Radiation requested the SAB to review the draft assessments which evaluate the potential risks to human health and the environment from two source categories (petroleum refinery and Portland kiln cement) that remain after compliance with MACT. Background information about this advisory activity can be found on the SAB Web site at [http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/RTR%20Risk%20Assessments%20\(P2%2C%20G3\)?OpenDocument](http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/RTR%20Risk%20Assessments%20(P2%2C%20G3)?OpenDocument).

Availability of Meeting Materials: The agenda and other materials in support of the teleconference will be placed on the SAB Web site at <http://www.epa.gov/sab> in advance of the teleconference.

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral information for the SAB to

consider during this teleconference. Oral Statements: In general, individuals or groups requesting time to make an oral presentation at a public SAB teleconference will be limited to three minutes, with no more than one-half hour for all speakers. Those interested in being placed on the public speakers list should contact Dr. Nugent at the contact information provided above by March 17, 2010. Written Statements: Written statements should be received in the SAB Staff Office by March 17, 2010. Written statements should be supplied to the DFO via e-mail to nugent.angela@epa.gov (acceptable file format: Adobe Acrobat PDF, WordPerfect, MS Word, MS PowerPoint, or Rich Text files in IBM-PC/ Windows98/2000/XP format). Submitters are asked to provide versions of each document submitted with and without signatures, because the SAB Staff Office does not publish documents with signatures on its Web sites.

Accessibility: For information on access or services for individuals with disabilities, please contact Dr. Angela Nugent at (202) 343-9981 or nugent.angela@epa.gov. To request accommodation of a disability, please contact her preferably at least 10 days prior to the teleconference, to give EPA as much time as possible to process your request.

Dated: February 4, 2010.
Anthony Maciorowski,
Deputy Director, EPA Science Advisory Board Staff Office.
[FR Doc. 2010-3358 Filed 2-19-10; 8:45 am]
BILLING CODE 6560-50-P

Attachment D: Members of the Public and EPA Representatives who requested call-in information or asked to be identified as participating in the teleconference

Members of the Public

Fredric P. Andes, Esq.
Partner, Barnes & Thornburg LLP

Andrew Childers
BNA

William T. Hall
Hall & Associates

Alan Gates
MitchellWilliamsLaw.com

Steven A. Hann
Hamburg, Rubin, Mullin, Maxwell & Lupin, P.C.

Chris Hornback
National Association of Clean Water Agencies

J. Bart Ruitter
DuPont Engineering Technology

Matthew Todd
API

Representatives of EPA

Ifeyinwa Davis
Paula Dias
Helene Drago
Dave Guinnup
Sarah L. Mazur
Edward Ohanian
Dana A. Thomas
Lester Yuan

**Attachment E: Comments from Members of the Chartered SAB on Review of Empirical Approaches for Nutrient Criteria
Derivation (1-8-10 Draft) -- Compilation as of 3/19/10**

Comments from Members of the Chartered SAB on *Review of Empirical Approaches for Nutrient Criteria Derivation* (1-8-10 Draft)

List of comments received

Comments from Lead Reviewers	2
Comments from Dr. Claudia Benitez-Nelson.....	2
Comments from Dr. Duncan Patten.....	4
Comments from Dr. John Giesy.....	7
Comments from other SAB Members.....	9
Comments from Dr. Terry Daniel.....	9
Comments from Dr. David Dzombak	10
Comments from Dr. Rogene Henderson.....	11
Comments from Dr. Bernd Kahn.....	12
Comments from Dr. Nancy Kim.....	13
Comments from Dr. Cecil Lue-Hing.....	14
Comments from Dr. Eileen Murphy	19

Comments from Lead Reviewers

Comments from Dr. Claudia Benitez-Nelson

Comments on the SAB Review of Empirical Approaches for Nutrient Criteria Derivation. The Science Advisory Board had provided a number of detailed and constructive recommendations for improvement of the Guidance Report on Empirical Approaches for Nutrient Criteria Derivation. These comments will greatly increase the effectiveness of the Guide to local state and tribal water quality managers. I am particularly pleased by the suggested addition of information regarding uncertainty, clarity in defining linkages between cause and effect, and additional frameworks for displaying and analyzing data.

In response to specific Quality review questions:

1. Are the original charge questions to SAB Standing or Ad Hoc Committees adequately addressed?

Yes. The SAB review Committee has provided a number of detailed comments for improving the quality and usefulness of the Guide for local state and tribal water quality managers. These comments are clearly structured and detailed. They include, but are not limited to better descriptions of what is meant by cause and effect, limitations in data, acceptable values of uncertainty, and various alternative models for examining large data sets.

2. Are there any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report.

Yes. I have one major comment in this regard. The SAB Review requests that the following information be added, "The Guidance focuses on total nitrogen and total phosphorus as the primary nutrient stressor 8 variables. Additional consideration should be given to inorganic forms of these nutrients 9 because these forms are the most immediately biologically available." While I agree that knowledge of the various forms of nutrients play an important role in community structure, I disagree that inorganic nutrients are the most "immediately biological available." Over the past decade there have been a number of studies that now show that organic nutrients are both bioavailable and rapidly consumed by a vast number of organisms, even in the presence of high inorganic nutrient levels. Furthermore, there have been links to changes in community structure associated with the various forms, organic versus inorganic, of the nutrients entering the system. As written, managers could easily misconstrue the statement regarding inorganic nutrient bioavailability to mean that organic nutrients are likely unimportant and should not be measured. This would be a great disservice in trying to establish clear guidelines on water quality.

Minor Comments:

The SAB often states that "at the start of the initial problem formulation exercise, a realistic cause and effect conceptual model must be developed." Is there a reason why the SAB avoids the use of the word "hypothesis" throughout the document?

The SAB states at least twice the following, "The initial assessment is the simplest (e.g., minimal ecosystem specific data) and most conservative, and thus will not always provide sufficient certainty for decision-making." I am not sure what is meant by the word "conservative" here. In my mind, the goal of this statement is that

minimal knowledge will result in the establishment of guidelines that have the largest uncertainty. The word “conservative” implies that the answer will be the safest or most traditional choice, whereas there is no such information provided.

3. Is the Committee’s report clear and logical?

Yes. I have only one minor suggested change:

The SAB review states that “The Guidance provides inadequate discussion of the temporal/spatial aspects of data needed to develop relevant stressor-response relationships.” I agree. I would further add a statement at the very beginning of this review document regarding lead/lag times and differences in nutrient concentration versus nutrient load. This is discussed in much more detail near the end of the SAB review (pages 39-40). However the implications of such a discussion should be stated more explicitly in the Executive Summary.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee’s report.

Yes. The SAB Committee provides a number of examples and references supporting their suggestions for modification of the report. The criticisms are well reasoned and appropriate.

Comments from Dr. Duncan Patten

Chartered SAB quality review questions

1. Were the original charge questions to SAB Standing or Ad Hoc Committees adequately addressed?

The EPEC more than adequately addressed the charge questions posed by the authors of the “Nutrient Criteria” report. The charge questions posed by the Office of Water often had several parts and dealt with specific components of the report. The charge questions also often went beyond being questions but rather asked for the review committee to suggest what should be written in the particular component of the report (see comments below).

2. Are there any technical errors or omissions in the report or issues that are inadequately dealt within the Committee’s report?

The committee appears to have thoroughly covered the necessary the technical aspects of the report to the point of suggesting major revisions. These suggestions often posed improved technical approaches to determining stressor/response relationships, etc.

3. Is the Committee’s report clear and logical?

To address each Charge Question, the committee took a three step approach which made their report very clear and logical. This three step approach included first a description of the general weaknesses or problems in the report related to the charge question, second it more fully described what was meant by the more general issue, and third it summed up the response section with a list of key recommendations. The authors of the Nutrient Criteria report will have no problem understanding what they will need to do to improve the report as they rewrite it.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee’s report.

As explained in the prior response, the approach taken by the committee in addressing each section and charge question allowed the committee to build on the problems they found by developing more in depth explanations based on the science of the issue.

Comments on the letter to the Administrator.

The letter clearly lays out the problems with the Nutrient Criteria Report. In the first paragraph the letter lists three requests from OW relative to the Report. The second paragraph identifies a set of problems that need to be addressed in a revision. In the last sentence of the second paragraph, the letter says that “improvements in the Guidance are needed prior to its release”. This statement comes after a litany of major problems which seems to beg a more emphatic word than “improvements”. Perhaps some statement along the lines of “reorganization and rewriting in

the Guidance is needed....” would better summarize the findings of the committee. For example should statements like the one used on Page 16, line 10 “recommends that EPA restructure and revise the Guidance...” be used in this letter?

The third and fourth paragraphs of the letter should clearly pick up on the three requests from OW. The first request is covered in paragraph three, while the second and third requests are covered in paragraph four. These might be presented as separate paragraphs or bulleted.

Is there some wording from page 3, lines 19-28 that might be also used in letter to administrator?

Other Comments on review of Nutrient Guidance Report

As pointed out in response to SAB quality review question 1 above, the committee was requested to do more than just review and critique the accuracy and science behind the materials presented in the guidance document. In some cases (e.g., Charge Question 5) the committee is asked to suggest materials that should have been developed in the process of preparing and writing the report. For example “*What approaches would you recommend that could effectively address indirect pathways of adverse effects? What recommendations do you have to address the effects of confounding variables and uncertainty in the estimated relationships?*” These questions beg the review committee to rewrite, or at least suggest major revision. This seems to imply the authors realize they did not do a complete job to start with, and in a sense, are passing the buck to the review committee.

This appears to be the case, or close to being the case, with several of the charge questions. Take for example in Charge Question 1. They ask: “What suggestions do you have that will improve the utility of the draft document, *Empirical Approaches for Nutrient Criteria Derivation*,” This question should read, “is this document properly written to be readily utilized by the intended audience, and if not, how can this be improved?”

The committee did treat the question as if improvement was a forgone conclusion. This is true throughout. The committee went one step farther and recommended restructuring and revision.

Some random comments on complexity: The emphasis on identifying uncertainty and use of weight of evidence through much of the document are good and very important points. Also, the emphasis on using a multivariate approach emphasizes the complexity of ecosystems which one feels the authors of the Guidance did not fully appreciate. This is also true where the committee points out such things as temporal/spatial aspects of data.

Some more detailed comments:

Figure 1. Figure 1 should be in the body of the text as well as in the Executive Summary.

The suggested revision of the Framework Recommended by SAB in Figure 1 comes close to being an adaptive management approach to the problem. As such, the first box as a new box should have Problem Formation and Goal Development (now combined under conceptual model), and the second box should be Conceptual Model Development. Step 5 in the present recommended framework should have a feedback loop to “consider other methods” because it is a step that evaluates the criteria which may not be appropriate to the method selected. Also, might there also be a feedback loop from Step 6 to new top box with goal setting. There are some points that relate to Figure 1 which might need to be corrected based on this recommendation. For example, Page 8, lines 11-13. Is the development of a conceptual model really the first step in the process? I suggest that identifying goals or reasons for developing the model comes first and this is pointed out above.

Cross-walking through the document. Is there some way of cross-walking between some of the sections so recommendations that primarily fit one charge question can be shown to be of utility elsewhere in the document. This demonstrates the complexity of the issues and the review. For example: In response to Charge Question 1, Improving Utility of the Guidance the committee appears to slip into recommendations that address analytical weakness rather than utility issues, for example, page 4, lines 36-43. How does this statement relate to improving utility of the Guidance for the various users? The same appears to be true for recommendation on page 5, lines 1-22 and may be true elsewhere in this section and elsewhere. Another example is on Page 10, lines 27-31. This recommendation under selecting stressors and response variables seems somewhat appropriate to improving utility of the document. Actually, many if not most of the recommendations will improve the “utility of the document”.

Ensuring corrections are tied to identified problems. For example Page 13, line 34. The committee points out that the conceptual problem associated with selecting nutrient concentrations as stressor variables should be addressed in the Guidance. They point out what the problem is but have they suggested a correction. In this case, the next recommendation (#6) actually may be meant to do that, but if so, it may not be that clear?

The committee should carefully revisit many of the identification of problems to make sure that “corrections” have been suggested. In most cases the summary of findings relative to each Charge Question does this, so I doubt whether there are many situations with this as an issue, but if SAB is going to recommend a “restructure and revision”, then the OW will need all the help they can get.

I did not find other issues of import later in the report that haven’t been mentioned above.

Comments from Dr. John Giesy

1. Were the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed?

Yes. The charge questions were addressed specifically in the report.

2. Where there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report

No. The report was free of technical errors and comprehensive. All issues were dealt with adequately and the report give clear and specific direction for improvement of the utility of the guidance document

3. Was the Committee's report is clear and logical?

Yes. The report is well organized, logical and well written. It is easy to follow and the direction is clearly presented and should help EPA improve the utility of the document.

4. Were the conclusions drawn or recommendations provided [are] supported by the body of the Committee's report?

Yes. The conclusions and suggestions for improvement of the document were supported by the discussion provided in the body of the report.

Specific comments:

The report is very well written with no issues of syntax or grammar and free of typos. Very well done.

Page 12 L 15 Unless this is the terminology used in the Guidance or if the intent is to suggest an actual weighting of the various information and or inputs to the decision process, it is suggested that the committee consider using the term "lines of evidence" which is more consistent with agency terminology in guidance.

Page 12 L 42 I suggest using terms such as great, greater greatest to denote magnitude since it is confusing to use "high" then also use Higher in the context of position in the hierarchy.

Page 12 L 42 Here the term "lines of evidence" is used. I suggest harmonizing the terms throughout the report and being consistent with terms used I the Guidance.

Page 13 L 1 Suggest replacing "reduces" with "decreases"

Page 13 L 4 Now "weight of evidence" is used again

Page 17 L 34 Should "Analysis" be "analyses"?

Page 24 L 13 replace “low” with “small” or “few”

Page 24 L 14 change “also reduces” to “is also less”

Comments from other SAB Members

Comments from Dr. Terry Daniel

SAB Review of Empirical Approaches for Nutrient Criteria Derivation

1. **YES**, the original charge questions to the SAB Ecological Processes and Effects Committee were adequately addressed.
2. **NO**, there do not appear to be any substantive technical errors or omissions or issues that are inadequately dealt with in the Committee's report.
3. **YES**, the Committee's report is clear and logical.
4. **YES**, the conclusions drawn and recommendations provided are supported by the body of the Committee's report.

EPEC is to be commended for a very comprehensive and insightful review and for presenting detailed and useful suggestions for revisions of the subject guidance document. The review document is quite long (40 pages) and in several places redundant, with a number of the same points and even the same phrases repeated in several sections. The repetition is less bothersome in the Executive Summary (albeit 10 pages is rather long for a summary) and the repetition in the main body seems mostly a product of the overlap in the charge questions. The length and complexity of the review (and of the executive summary) suggest that the cover letter may need to play a stronger role in bringing forward the most important findings and recommendations.

The suggested enhancements of the "framework" (Figure 1 in the Executive Summary) seem especially important and useful. The enhanced framework reinforces the recommended "tiered" process, increases attention to uncertainty, and makes the consideration of incorporating methods other than and in addition to the empirical (statistical) stressor-response method in a weight-of-evidence approach more explicit. In this context, the role of uncertainty at the different levels/tiers of analysis is appropriately emphasized throughout the review. However, the role that uncertainty plays at each level of the tiered analysis might be carried somewhat further. For example, at the highest tiers in the analysis the "level" of uncertainty might be rather low, as the Conceptual Model is mostly based on well-established general principles of aquatic systems. The type of uncertainty that is of most concern here is about how well the selected conceptual model fits the specific stressors and ecological systems under consideration. The types of uncertainty that are of most concern at later tiers is different, especially as specific nutrient criteria are being articulated and quantitative precision is rather high, and the levels of uncertainty are likewise quantitative and precise. Uncertainty at higher levels is more difficult to assess, but it is very important as it may cascade down through the analysis, in effect multiplying the uncertainty in the later tiers of the analysis.

Comments from Dr. David Dzombak

1. Comment on whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed.

The charge questions were adequately, indeed comprehensively addressed.

2. Comment on whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report.

I found no technical errors or omissions in the report, or issues that were inadequately addressed.

3. Comment on whether the Committee's report is clear and logical.

The report is very clearly written and is well organized. I commend the committee on a job very well done. I just have a few minor comments for consideration by the committee to improve the clarity of the letter to the Administrator and the Executive Summary.

(a) Letter to the Administrator, line 35: begin a new paragraph with "EPA's draft ..."

(b) ES, p.xiii, line 29: The committee emphasizes several times in the document that "EPA more clearly articulate how the Guidance fits within the Agency's decision-making and regulatory processes and, specifically, how it relates to and complements EPA's other nutrient criteria technical guidance manuals and documents", as stated on lines 7-9 of p. xiii, for example. I suggest that the committee consider re-stating this important recommendation as the first bullet under the response to Charge Question 1. I note that it is given as the first bullet in the detailed response to Charge Question 1 on page 4 of the report.

(c) ES, p.xiii, lines 36-38: The statement about Figure 1 should be linked better and perhaps merged with the statement that precedes it.

4. Comment on whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

The conclusions and recommendations are adequately supported by detailed discussion in the body of the report.

Comments from Dr. Rogene Henderson

Review of Empirical Approaches for Nutrient Criteria Derivation
Rogene F. Henderson

1. Whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed.

The report was quite clear in stating each charge question and addressing it with specific comments.

2. Whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report.

I am not an expert in this field but I did not note any technical errors or omissions.

3. Whether the Committee's report is clear and logical.

The report appeared logical to me.

4. Whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

The recommendations were supported by the body of the report. The letter reflects the major points made in addressing each charge question as described in the Executive Summary.

Comments from Dr. Bernd Kahn

The review is impressively well written; I found no problems with it.
Bernd Kahn March 2010.

Comments from Dr. Nancy Kim

1. Were the original charge questions to the SAB Committee adequately answered?
Yes.
2. Were there any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report?
No.
3. Was the Committee's report clear and logical?
Yes. The responses to the charge questions and subsequent recommendations were well laid out and easy to follow.
4. Were the conclusions drawn or recommendations provided supported by the body of the Committee's report?
Yes.

Comments from Dr. Cecil Lue-Hing

Review of SAB Ecological Processes and Effects Committee's (Committee) Report on EPAs guidance document, "Empirical Approaches for Nutrient Criteria Derivation (the "Guidance").

In its charge to the SAB, the EPA requested that the Committee: 1) comment on the technical merit of the methods and approaches described in each section of the Guidance; 2) recommend other approaches that might be considered to improve the Guidance; and 3) offer suggestions to improve the quality of the Guidance for state and tribal water quality scientists and resource managers. The Committee was also asked to respond to seven charge questions posed by EPA.

The original SAB Committee consisted of 11 members, and was later augmented by an additional six consulting members to conduct the review.

General Comments

The Committee's report represents a strong critique of the EPAs Guidance document with respect to - its technical content, clarity, limitations in its empirical approach, the high degree of uncertainty inherent in some of the derivations, and some of the statistical approaches used.

Opinion

It is the opinion of this reviewer that the SAB Committee adequately addressed the four quality review questions posed by EPA:

1. That the original charge questions to the SAB Committee were adequately addressed
2. Technical errors/omissions in the report were adequately dealt with in the Committee's report
3. The Committee's report is clear and logical, and
4. The conclusions drawn and recommendations provided are supported by the body of the Committee's report

After a careful review of the document, I fully support the Committee's report, its responses and recommendations.

Specific Comments

The Committee structured its responses around the 7 charge questions posed by the EPA, developed findings for each question and provided recommendations in support of the findings.

The Committee's review resulted in 89 findings, including findings of deficiencies, and 64 recommendations.

Herewith is a listing of the charge questions, and a brief account of some of the resulting findings and selected recommendations.

Charge Question #1. Improving the utility of then Guidance

Here the Committee developed 5 findings and 13 recommendations for charge question #1

Some Findings:

- The scope, limitations, and intended use of the Guidance should be more clearly identified
- Substantial revision of the document is needed to facilitate identification of the most scientifically defensible approaches to deriving numeric nutrient criteria
- The absence of a direct causative relationship between stressor and response is one of the most serious issues raised by the Committee.

Some Select Recommendations:

- EPA should specify how the Guidance is to be used in combination with other EPA nutrient criteria technical guidance manuals
- In the Guidance, EPA should address the importance of: 1) establishing linkages among designated uses, measured responses, stressors, and measures, of stressors; and 2) relating measures of responses directly to deleterious effects on designated uses
- In the Guidance, EPA should emphasize that the document does not address downstream effects of nutrient enrichment, which are intended to be the focus of a separate future document

Charge Question #2 – Selecting stressor and response variables

Here the Committee developed 12 findings and 6 recommendations to charge question # 2

Some Findings:

- In the guidance, further discussion of potential response variables appropriate for nutrient effects on detritus-based systems is warranted (e.g., how macroinvertebrate populations dependent on detritus may respond).
- The Guidance focuses primarily on TN and TP as the primary nutrient stressor variables. Some distinction should be given to inorganic N and P because these forms are the most immediately biologically available.
- In many regions N and P are often co-limiting to plants and microbes and stressor-response relationships based on only one nutrient are weak. Nevertheless, nutrients (N and P) may be the primary factor controlling productivity/biomass.
- The Guidance provides little discussion regarding the temporal/spatial aspects of data needed to develop relevant stressor-response relationships.

Some Select recommendations

- The Guidance should be revised to elaborate upon the coupling of response variables to designated uses and the importance of ecological relevance of the stressor-response relationship
- The Guidance should consider including inorganic N and Inorganic P as nutrient stressor variables because these forms are the most immediately biologically available.
- The basic conceptual problem associated with selecting nutrient concentrations as stressor variables should be addressed in the Guidance (i.e., nutrient concentrations directly control only point-in-time, point-in-space kinetics, not peak or standing stock plant biomass).

Charge Question #3 – Approaches to demonstrate the distribution of and relationships among variables

Here the Committee developed 8 findings and 13 recommendations to charge question #3

Some Findings:

- Additional methods for exploratory data analysis should be described in the Guidance
- The examples provided in the Guidance do not demonstrate a strong nutrient stressor linkage to beneficial use impairment
- The Committee emphasizes the importance of choosing the biological endpoints (i.e., response variables) that respond specifically to nutrients.
- Clear guidance is needed for identifying when and how the statistical methods and visualization techniques should be used. The strengths and limitations of the methods should also be identified

Some Select Recommendations:

- The Guidance should be revised to include additional methods for exploratory data analysis.
- The Committee recommends that the Guidance be revised to clearly indicate the statistical assumptions and uncertainties that should be taken into consideration when using methods described in the document.
- The Guidance should contain a quantitatively based weight-of-evidence framework using multiple methods and then combining them into figures and tables for visualization.

Charge Question #4 – Methods for assessing the strength of the cause-effect relationship

Here the Committee developed 7 findings and 7 recommendations

Some Findings:

- Experimental validation of causal relationships between nutrient and response variables should be approached with caution
- It is not clear why information from mechanistic models was not included in Section 2 of the Guidance.
- Additional discussion of conceptual model selection (with specific examples) would be helpful

Some Select Recommendations:

- Mechanistic models should be discussed in the Guidance as one way of supporting the stressor-response relationship
- Experimental validation of causal relationships between nutrient and response variables should be approached with caution because a number of factors can affect the response of a system to nutrient enrichment
- The discussion of conceptual models should be expanded to address various criteria for model

Charge Question #5 – Statistical methods to analyze the data

Here the Committee developed 25 findings and 10 recommendations

Some Findings:

- The statistical methods in the Guidance require careful consideration of confounding variables before being used as predictive tools

- As previously noted, because plant biomass is driven by nutrient supply rates (mass loads), a potential conceptual problem exists with the selection of nutrient concentration (often used in the Guidance) as a stressor variable
- The Guidance lacks sufficient discussion of the importance of variable selection and data characteristics to ensure useful implementation of the statistical procedures
- In the Guidance, more information must be provided regarding regression assumptions, limitations, and diagnostic procedures.
- Statistical rigor is essential to the development of scientifically defensible criteria. Simplistic application of approaches in the Guidance can lead to stressor-response relationships with poor predictive power and result in inappropriate numeric nutrient criteria.

Some Select Recommendations:

- The Guidance should indicate that response variables must in all cases have biological relevance and be associated with designated uses
- The Guidance should contain more information on approaches that address multiple factors, such as a stratified (or hierarchical) approach that considers other attributes known to be important such as canopy, habitat, multiple nutrients, etc.
- The Committee emphasizes that EPA should provide guidance on the degree of relationship (indicated by R^2 , residual analysis, and other evidence) needed to establish sufficiently predictive stressor-response relationships for numeric nutrient criteria development

Charge Question #6 – Evaluating the predictive accuracy of stressor-response relationships

Here the Committee developed 21 findings and 5 recommendations

Some Findings:

- The Committee finds that a clear framework and criteria for statistical model selection is needed in the Guidance
- With regard to validation, nutrient criteria should result from weight-of-evidence from the application of multiple empirical approaches considering multiple response variables and other approaches as appropriate
- The concept of “best fit” needs elaboration in the Guidance
- The Guidance should contain additional information to assess the closeness of root-mean-square predictive error (RMSPE).

Some Select Recommendations:

- The Guidance should be revised to provide much more detailed model validation guidance
- Subsection 4.1 of the Guidance should be revised to make it more consistent with other EPA guidance on development, evaluation and application of models
- Subsection 4.2 of the Guidance should be revised to provide an expanded discussion of uncertainty. This section should address both qualitative and quantitative estimates of uncertainty as well as bias
- Subsection 4.3 of the Guidance should be revised to address inaccuracies associated with linear stressor-response functions

Charge Question #7 – Evaluating candidate stressor-response criteria

Here the Committee developed 11 findings and 10 recommendations

Some Findings:

- A major uncertainty inherent in the Guidance is accounting for factors that influence biological responses to nutrient inputs
- Numeric nutrient criteria developed and implemented without consideration of system specific conditions (e.g., from a classification based on site types) can lead to management actions that may have negative social and economic and unintended environmental consequences without additional environmental protection
- EPA should consider addressing the use of probabilistic modeling (using the distribution of data in the model and re-sampling or simulating a new distribution) to better determine significant stressor-response relationships
- The Guidance does not adequately address the important issue of continued monitoring and assessment for adaptive management
- The direct and indirect effects of best management practices should be captured in setting numeric nutrient targets and evaluating responses to target reductions

Some Select Recommendations:

- The Guidance needs to clearly indicate that then empirical stressor-response approach does not result in cause-effect relationships; it only indicates correlations that need to be explored further.
- EPA should avoid using “biased” databases (i.e., that do not contain the range of data necessary to fully characterize a system of interest) to develop stressor-response relationships
- The Guidance should caution users about potential problems associated with using the overall regression to predict conditions that might result after implementing different nutrient criteria
- The Committee recommends that EPA frame uncertainty according to some key issues including: - what are the goals of the decision makers (e.g., what are the designated uses and when are they impaired?), and what amount of uncertainty is required to make that decision?

Comments from Dr. Eileen Murphy

Ecological Process and Effects Committee:

Charge 1: whether the original charge questions to SAB Standing or Ad Hoc Committee was adequately addressed:

A significant comment throughout the review is that the stressor-response approach (and the framework included in the EPA draft document) is only one approach that can be used deriving numeric nutrient criteria. The Committee stresses, in particular, the important of mechanistic models. However, it is stated in the EPA draft document that the stressor-response approach is one of three approaches that states can use for development of numeric nutrient criteria and that this particular document focuses just on stressor-response. The other two approaches are the reference condition approach and mechanistic modeling approach. Therefore, I think that the Committee MAY have gone beyond the charge given to them. It is stated in the introduction that "...the use of nutrient stressor-response relationships to derive nutrient criteria is one of the recommended approaches in USEPA nutrient criteria guidance." I did not get the impression that EPA is suggesting that states consider only stressor-response approach, but that it is one tool available to them and the guidance document will help them with it. Many of the Committee's comments involved development and use of mechanistic models. However, the EPA draft document specifically states that it is guidance only for the stressor-response approach, and that other approaches may be used as well but are not described in this document. Therefore, I wonder if the comments suggesting more details on mechanistic modeling are beyond the purview of the particular charge?

Under the charge requesting suggestions to improve the utility of the draft document for states and other stakeholders: Not sure that the alternate framework presented by the Committee is an improvement over the one provided in the draft USEPA report. For states working on this issue, I think the original framework in USEPA document can remain intact, and the excellent suggestions made by the Committee can be addressed within that framework. Given the complexity of the issue in general, the simpler the framework, the better for stakeholders.

Charge 2: whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report:

I thought the report was exceptionally well-written. The technical information presented was valuable and pertinent.

Charge 3: whether the Committee's report is clear and logical:

Yes. Organization of the report and justification for opinions rendered were clear and logical throughout.

Charge 4: whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report:

The Committee provides ample justification for its recommendations. My only question is whether or not the Committee may have gone beyond the charges provided to them.

Attachment F: Comments from Members of the Chartered SAB on Drinking Water Committee's Review of EPA's Microbial Risk Assessment Protocol (1-12-10 Draft) -- Compilation as of 3/22/10

**Comments from Members of the Chartered SAB on *Drinking Water
Committee's Review of EPA's Microbial Risk Assessment Protocol (1-12-10
Draft)***

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Comments from Lead Reviewers

Comments from Dr. Nancy Kim

1. Were the original charge questions to the SAB Drinking Water Committee adequately addresses?

Yes. The original questions were addressed.

2. Were there any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report?

No. I did not identify any.

3. Was the Committee's report clear and logical?

Yes. However, I have one suggestion for the committee to consider. The letter, executive summary and the report suggest in several places how EPA should proceed in finalizing the document. One point is made that the document is not a protocol, but an introduction to microbial risk assessment. My impression is that the committee generally favors finalizing this document as an introduction and that EPA subsequently develop a protocol in a series of white papers or as another document. In some places, the document makes this recommendation, in other places it seems to offer options without favoring one option over the other. If my impression is correct (the committee favors finalizing this document as an introduction with a detailed protocol to follow), the report should probably be consistent in its presentation of options. It could provide more than one option, but state that it prefers one (for examples, see page 39, end of first complete paragraph and page 30, end of first full paragraph).

4. Were the conclusions drawn or recommendations provided supported by the body of the Committee's report?

Yes.

Editing suggestions. Most of these are minor comments although a few are more substantive.

Letter to the Administration

1. p.2, line 9. I did not find the word concision in the dictionary. Suggest changing the word to conciseness.

2. P.2, line 27. Add the word formulation after the word problem to be consistent with other entries in the review.

Executive Summary of the report.

1. p. 9, line 14. Rewrite of sentence beginning with however. However, the Agency has done a tremendous amount of work on the MRA document and is commended for its leadership in this area. This completion serves...

2. p. 13, line 17. Additional information about this bullet is needed to improve its meaning and clarity.

Body of the report.

1. p. 17, line 4. Suggested revision. Attempts should be made to condense the document to make it more concise....
2. P. 18, line 6. Remove the word discussed at the end of the sentence.
3. P. 18, line 8. I would remove the first sentence of this paragraph. To a reader who was not involved in the detailed review, this sentence appears to be speculative and not necessary for the Committee to make its point.
4. P. 18, line 19. Placing the recommendations in this paragraph in a list, rather than as a long sentence, would highlight the contents and improve readability.
5. P. 18, line 23. Suggested rewrite of sentence. Appendix G should be placed in the document as a separate chapter and undergo a technical statistical review (see response to charge question 4).
6. P. 19, line 13. Add the word a between formulate and problem.
7. P. 19, lines 17 through 21. I found the use of the word protocol in these lines confusing and a reader could interpret this paragraph as being inconsistent with one of the major conclusions and recommendations of the review. The committee concludes that this document is not a protocol and appears to recommend that this document be finalized quickly and a detailed protocol be developed subsequently. However, in this paragraph of the report, the document suggests adding a step by step protocol. I suspect that the word protocol in this paragraph is a missed edit from earlier versions of the committee's report.
8. P. 20, line 11-14. I recommend reviewing the language in these lines since it seems somewhat contradictory to the language in other places that recommends taking many of the appendices and incorporating them into different chapters of the document rather than just capturing the general principles from the appendices.
9. P. 20, line 27. Remove second "of types" at end of line.
10. P. 23, lines 7 and 12. The sentence beginning with "The chapter has a good, concise..." in line 7 and the sentence beginning with "Overall, this chapter is concise..." say the same thing. They should be combined or one removed.
11. P. 23, line 15. Suggested rewrite of sentence, "Exposure assessment is often very venue- and microbe-specific and previous EPA MRA examples, such as that performed on *Cryptosporidium*, could be included here."
12. P. 24, line 3. Suggest replacing the word soft with another, more specific word.
13. P. 24, line 8. Suggested addition. "...i.e. where there is direct contact with raw untreated or with insufficiently treated water."
14. P. 24, line 17. Suggested insert. "...preventing or minimizing human exposure..."
15. P. 24, line 21. The words processes and process are used together. Perhaps the sentence would be clearer if rewritten slightly.
16. P. 25, line 17. Comma needed after ...outbreak).
17. P. 25, line 18. At the end of the sentence, "on this regard" could be replaced with "about this".
18. P. 25, line 22. Change "to occur" at end of sentence to "occurring."

19. P. 25, line 25. Could the logic in the sentence “Pathogens in treated water supplies are far more likely to occur episodically than otherwise because they occur with such a low frequency” be clarified?
20. P. 27, line 15. Suggested edit. Change the end of the sentence from “the needs for data” to “data needs.”
21. P. 27, line 19. Suggest starting a new paragraph with the sentence beginning with “A more thorough discussion...”
22. P. 27, line 27. Something appears missing after the parenthetic. The sentence doesn’t flow.
23. P. 30, line 24. Change data ...is to data...are.
24. P. 30, lines 16 through 20. The last two sentences in the paragraph seem to disrupt the flow and impact of the paragraph. One suggestion is to reverse the order of the last two sentences, but I am not sure that will fix it or that might change the meaning.
25. P. 34, line 10. Suggest replacing the words such information with human health effects information to improve clarity.
26. P. 36, line 24. Suggest starting a new paragraph with sentence beginning firstly. Consider starting remaining paragraphs in this section with secondly, etc.
27. P. 37, line 13. If the committee would like EPA not to use the words static and dynamic, that should be recommended rather than considered.

Comments from Dr. Christine Moe

Comments on DWC Review of EPA's Microbial Risk Assessment Protocol

Christine Moe

March 22, 2010 (World Water Day)

SAB reviewers are asked to comment on:

1. *whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;*
2. *whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;*
3. *whether the Committee's report is clear and logical; and*
4. *whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.*

The USEPA developed a draft *Protocol for Microbial Risk Assessment to Support Human Health Protection for Water-Based Media* dated July 2009. This document consists of an Executive Summary and five chapters (Ch. 1 Introduction; Ch 2. Planning & Scoping and Problem Formulation; Ch 3. Exposure; Ch 4. Human Health Effects; Ch 5. Risk Characterization). The document also has seven appendices.

1. Addressing the charge questions:

The EPA asked the DWC to address five charge questions that focus on whether the whole microbial risk assessment (MRA) protocol is useful and then whether each of the subject chapters needs improvement. The DWC report starts with an Executive Summary, followed by an Introduction, and then five sections - with each section of the report addressing a charge question. It would be helpful to list all the charge questions in the Executive Summary and perhaps also in the Introduction of the report so that the reader has an overview of the scope of issues that will be addressed by the report.

The Charge Questions from EPA are complex and often involve multiple questions. Overall, the DWC report does a good job addressing each charge question and makes very specific recommendations that should be helpful in revising the document. The only instances where the charge question is perhaps not completely addressed is:

- Question #2, parts "b" through "f" (page 20-21). It is not clear if EPA is just listing bullets "a" through "f" as examples only, or whether the EPA is asking the DWC to comment on these examples. The DWC report comments briefly on bullet "a" (environmentally-based microbial pathogens) on page 22 (lines 21-26) but not on the other examples.
- Question #4 – The DWC does not really comment on the specific dose-response models mentioned in the charge ("advanced and validated threshold, empirical or mechanistic models"). Nor does the DWC comment on other exposure routes ("inhalation and dermal routes") or "in vitro" dose-response protocols.

2. Technical errors, omissions, issues inadequately dealt with:

Overall, the DWC report is very good about raising additional issues that should be included in the MRA protocol. Almost every section of the report includes valuable suggestions about issues for additional consideration.

The DWC report recommends that the EPA add more examples of actual EPA microbial risk assessments to the document (Executive Summary, pg 9. Line 24). This is an important recommendation that should be taken a step further. Not only should the EPA add more examples of MRAs, but for each of these examples, the EPA should explain the strengths and weaknesses of the MRA, where there were information gaps that needed to be addressed by further research, where there were needs to develop better analytical tools or models, etc. Examples are an important way not only to show how to develop an MRA, but also how the results of the MRA were used (or not used) by the Agency for decision-making.

Pg. 29, lines 1-2: Is the DWC suggesting that the MRA protocol should discuss the issue of viable, but non-culturable organisms? This is left as a question in the text.

3. Is report clear and logical:

Overall, the report is quite clear. However, like most documents written by multiple people, this report could benefit from some minor editing and re-organization. There is some **repetition** in the report that could be removed by some re-organization. Examples of this are:

- The report comments several times that the MRA Protocol is not really a protocol (pg. 21 line 28 – pg 22 line 4) and should be re-named and that perhaps there should be two documents – an introduction to MRA document followed by an advanced MRA document or series of white papers.

It is difficult to follow the report's **recommendations on the appendices**. There are times when the report recommends that the materials from the appendices should be added to the body of the report. Yet, the report also recommends putting more advanced and detailed discussions in a second more advanced MRA document or set of white papers (Page 18). There are specific recommendations on page 18, but these are hard to follow. Appendix G is mentioned several times in the report (see also pg 30) – so it is clear that the DWC is concerned about the material in this chapter, but it may be beyond the scope of the DWC review to give more specific guidance on this.

It is very helpful when the report makes specific recommendations, and these should be presented in the form of bullets so that they are easy to identify (such as in the Executive Summary on page 9). It may be helpful to have a summary list of recommendations at the end of each section of the report (e.g. section 5.3 on pages 39-40). Other places where bulleted lists of recommendations could be useful are:

- Pg. 26 – there is a discussion about several omissions that the DWC recommends that the MRA protocol address in the chapter on exposure.

- Pg. 32 – 34: the DWC raises a number of important issues that should be included in the Health Effects chapter of the protocol. It would be helpful to have a summary of the recommendations for this chapter

Minor editing is needed in the following areas:

- Pg. 27, lines 26-29
- Pg. 28, lines 12-14: It is important to use more precise terminology in these sentences. I suggest revising as follows: “The estimates of human infective dose used in developing the dose-response relationship have uncertainty associated with the dose. Freshly-harvested oocysts were used as the inoculum in the human challenge studies and are often used in disinfection studies, yet the age of oocysts in an environmental sample can vary widely, ...”
- Pg. 28, line 26
- Pg. 29, line 4: should specify analytical methods for detecting microorganisms in water
- Pg. 32, lines 1-4: This paragraph seems disconnected from the previous text. Is the DWC referring to the need for further animal studies for certain pathogens?
- Pg. 35, lines 4-12: It seems more logical to move this paragraph on susceptible subpopulations to the following section 4.4.

4. Are conclusions and recommendations supported by the body of report:

The conclusions and recommendations in the report seem to be logical extensions of the body of the report. It would be helpful to make sure that they are easier to find by adding a summary to the end of each section that highlights the main conclusions and recommendations.

Comments from Dr. Eileen Murphy

Drinking Water Committee's Review of EPA's Microbial Risk Assessment Protocol
March 24, 2010
Eileen Murphy Comments

Charge 1: whether the original charge questions to SAB Standing or Ad Hoc Committee was adequately addressed:

The charge questions were addressed adequately with one exception. Charge 4 was broken down into five sections. The first two followed the charge directly ("4.1 Scientifically accepted dose-response models" and "4.2. Animal dose-Response Models") The next three are not part of the charge at all – "4.3. Human Health Outcomes, 4.4. Susceptible Populations and 4.5. Quality of Life." While the points raised in these three sections were valid, they were not related to the actual fourth charge question, which was specifically about models.

The response to Charge 4.1 did not cover "models...which should be included as tools for determining human dose-responses from waterborne exposures via oral, inhalation, and dermal routes...". The MRA itself does not go into these topics, and the DWC did not cover it in this section.

Charge 2: whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report:

No overt technical errors appeared in the report.

Charge 3: whether the Committee's report is clear and logical:

The report clear and logical and easy to follow. The report being reviewed by the DWC was very long, representing a challenge for addressing the charges in a logical way. By presenting the charges by chapter, they kept the flow clear and logical.

Charge 4: whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report:

Yes. Examples were provided in most instances.

Other:

P. 21, lines 5-8: the recommendation to eliminate "wordiness" is vague. Maintain the suggestion that the draft undergo a robust technical edit.

Recommendation is unclear: p. 22, lines 11-14: not sure how the committee is suggesting that the document be divided – specifically, the "advanced and detailed discussions for inclusion in a second" document and several white papers. Not sure what the purpose of the white papers would be or if they would be useful to stakeholders for MRA.

Comments from other SAB members

Comments from Dr. Rogene Henderson

1. Whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed.

The report was quite clear in stating each charge question and addressing it with specific comments.

2. Whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report.

I am not an expert in this field but I did not note any technical errors or omissions.

3. Whether the Committee's report is clear and logical.

The report appeared logical to me.

4. Whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

The recommendations were supported by the body of the report. The letter reflects the major points made in addressing each charge question as described in the Executive Summary.

Comments from Dr. Bernd Kahn

The review is well done; here are some suggested corrections:

p.2, 1.32: Insert comma after 'events'.

p.2, 1.34: Delete 'and' and replace with period. Begin next sentence with 'Finally,'.

p.2, 1.5: Insert comma after 'Again'.

p.7: Insert acronyms and explanation for 'HACCP' and 'ILSI'.

p.10, 1.6: Replace 'though' with 'through'.

p.10, 1.12: Replace 'its role' with 'their roles'.

p.10, 1.18: Replace 'occur with' by 'result from'.

p.12, 1.20: Delete 'as a separate chapter' (said earlier in sentence); also p.18, 1.20.

p.18, 1.9: Insert 'were' after 'changes'.

p.18, 1.16: Delete 'However' (this sentence repeats the previous one).

p.19, 1.13: Insert 'the' before 'problem'.

p.19, 1.17: Previously, the Committee recommended eliminating 'Protocol' from the title; here it seems to offer an alternative,

p.24, 1.25 and 27: Delete these parentheses.

p.27, 1.13: Delete the two commas.

p.27, 1.27: One or more words seem to be missing before 'is found'.

Bernd Kahn March 2010

Comments from Dr. Judith Meyer

1. Whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;

Yes, they have been addressed clearly.

2. Whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;

In general the report is quite thorough. I have only one concern, which is with the recommendation that additional statistical review (e.g., p. 12, lines 3-4, but also in other places) is needed. I would have thought that this review committee would have been augmented with this additional expertise. I read the statement as saying that the committee didn't have the expertise to evaluate the statistical section. Perhaps that is not what was meant. Are you calling for statistical review or a rewriting of the statistical section by an expert? I would have thought review is what this committee has done. Clarification is needed.

3. Whether the Committee's report is clear and logical;

Yes, the document is clearly written and easy to follow.

4. Whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

Yes, although (p. 12) some further justification for the recommendation to move around all the appendices is needed. Is it because having that information in an appendix makes it seem less significant than it is?

Editorial comments

1. Letter, p. 2, line 9: I don't think "concision" is a word – conciseness. Also on p. 9, line 18.

2. Interagency microbial risk group is mentioned in letter, but I don't think I saw it elsewhere in the document. I have no idea what agencies are involved. And it is strange that it is in the letter but nowhere else (unless I missed it).

3. p. 14, lines 11-12: does this imply that the previously mentioned MRAs were quantitative?

4. p. 30, line 24: data ARE available, not is

5. p. 31, line 15: Although I have no idea what a gnotobiotic piglet model is, I think the references to the various studies that have been done with it need some specific citations to the literature so this suggestion can be more useful to the reader. There are several other references to useful studies in the same paragraph; yet there are no citations for any of them. Citations are needed!

6. p. 36, lines 10-11: is the cost benefit analysis part of the risk management? If so, that should be clarified.

7. p. 39, line 2: need to BE clearly...

Comments from Dr. Duncan Patten

1. Are the original charge questions to SAB Standing or Ad Hoc Committees adequately addressed?

The original charge questions are well covered by the report, although in many cases they were not questions but rather "requests" (see comments below).

2. Are there any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report?

There appear to be no technical errors or omissions, although this is not an area of my expertise and others can better answer this.

3. Is the Committee's report is clear and logical?

There is some inconsistency in how the committee responds to the charge questions. In some places they as in Charge question 1, the committee responds to separate restated components of the question and in others, such as Charge question 3 they respond without restating the question. Consistency would help....

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

As far as I can tell, yes.... the recommendation for developing a new document with actual protocol steps and using this one as background is fully justified and appropriate.

Other comments: There should be some consistency between what is requested as stated in letter to administrator, and what the charge questions request, although as pointed out below, some of not questions but requests. The committee uses a general set of requests in the letter and Executive Summary that do not wholly cover the charges.

I've brought this issue up in other requests for review and do so here. When SAB is requested to review a document and the EPA office requesting it uses charge questions, they should use questions rather than requests. For example, in Charge Question 3, the Charge Question "requests" the review committee to suggest what additional material should be in the report rather than asking for critique of what is in the report and then addressing omissions if necessary. These types of Charge "Questions" appear to be an admission of the authors of the original report that they have not fully done their homework and are asking the review committee to help them rewrite the report. Suggestions for how to rewrite and what to include in a revision should result from a review of a fully complete and documented draft which may have need of improvement.

Comments from Dr. Amanda Rodewald

Overall I thought that the Drinking Water Committee did an excellent job in addressing the charge questions and preparing a clear and concise report.

4. are the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;

Yes, the committee provided detailed responses to all charge questions. I make two observations that the committee may want to consider.

First, in Section 1.4 (page 19, lines 9-10), the reports states that “*The strength of the document, explaining the principles of MRA, may also be its weakness **if the document is intended to be a protocol***” [bold emphasis in original document]. I noticed, however, that the first charge question described that the intent of the Protocol was to “*provide a comprehensive and robust suite of approaches, tools, methods, and procedures...*” – a description that seems more far-reaching than a straightforward and streamlined protocol. Given this, it might be appropriate to explain the principles of MRA. My guess is that the committee’s response reflects the more detailed information they received at the meeting regarding the purpose of the Protocol.

Second, the response to Charge Question 2 seemed comparatively thin, but this likely is a consequence of the inclusion of some recommendations in section 1.

5. are there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee’s report;

No, the report looks great. I only have one minor suggestion. On page 2, line 32, the phrase “for example” seems misplaced.

6. is the Committee’s report is clear and logical;

Yes, the Committee clearly and concisely responded to the charge questions. My only comment here is that the paragraph on page 22, lines 21-26, could be more explicitly linked to the charge question and to the previous paragraphs.

7. are the conclusions drawn or recommendations provided are supported by the body of the Committee’s report.

Yes.

Comments from Dr. Stephen Roberts

Comments on the SAB review of EPA's Microbial Risk Assessment Protocol
Steve Roberts

1. The Executive Summary should concisely and faithfully capture the salient points of the panel report. It does not accomplish this well, in my opinion. In the Executive Summary, panel recommendations are presented as bullets, whereas in the main body of the report they are bulleted in some places and simply appear in the narrative in others. The organization of presentation of topics is different as well, compounding the difficulty in comparing the Executive Summary with the main body of the report.

For example, the response to charge question 1 is covered on page 9 of the Executive Summary and pages 15-20 of the main report. The Executive Summary has four bulleted recommendations in response to this charge question, while the main report has seven (pages 16, 17, 18, and 20). Among these, only three are the essentially the same. The response to charge question 2 resulted in one bulleted recommendation in the Executive Summary – “The Committee recommends formatting all the diagrams in the chapter to the standard logic-diagram format.” (page 10). The response to this charge question in the main report also has one bulleted recommendation, which is different: “The title of the document should be changed to eliminate the suggestion that this is a detailed, step-by-step process.” (page 22). This recommendation does appear in some fashion in the Executive Summary, but it is included in the response to charge question 1. Recommendations in response to charge questions 3 and 4 are presented entirely in narrative form in the main report and are captured with varying degrees of success in bullets in the Executive Summary. The principal recommendations in response to charge question 5 are presented in narrative form in the main report and bullets in the Executive Summary. Additional recommendations (primarily editorial) are presented in bulleted form in the main report and are absent from the Executive Summary. All of this is potentially confusing. I recommend re-evaluation of the Executive Summary and the format of the main report. Conclusions and recommendations should be presented in a way that can be more readily understood by the reader, and the Executive Summary should more clearly reflect the content of the main report.

2. It is apparent that the panel is unhappy with Appendix G in particular, but the problem(s) are not clearly articulated in the report, in my opinion. Comments in various places in the report suggest that Appendix G is:

- A. Poorly written, as suggested by the recommendation that it be reviewed by a “technical editor” (page 9).
- B. Inaccurate, as suggested by the recommendation that it requires “statistical expert technical review” (page 9) by “an engaged, broadly-knowledgeable expert in statistical methods” (page 11) with regard to “accuracy in its description of the extant literature and methods” (page 18).
- C. Incomplete, as implied by the statement “It is apparent that individuals ensured that their favorite methodological approaches were included ...”
- D. Inappropriate for this document, as suggested by the recommendation that it be “included in a second more advanced MRA document and/or separate white papers.” (page 12).

Perhaps the Appendix suffers from all of these, but I think that the report would be more helpful if the deficiencies are more clearly described with examples.

3. Overall, the report seems responsive in answering the charge questions. The response to charge question 2 may have been less than what the Agency was seeking, however. This charge question asks for suggestions to enhance or expand guidance to allow users to prepare and conduct risk assessments for a broad range of types of risk management questions, and several types of EPA uses of MRA are identified (pages 20 and 21). Presumably the intent of identifying these uses was to prompt the panel whether additional or expanded guidance is needed so that risk assessments to support each of these uses can be conducted. That question wasn't answered. The response instead is very general (change the title of the document; clarify when stakeholders should become involved; change diagrams; incorporate novel pathogens and routes; page 22) and I suspect may not be the kind of information that was sought.

Editorial suggestions:

1. pg 10, line 3: replace "which" with "that"
2. pg 10, lines 13-14, "the greatest variability to risk assessment is in defining the exposure." Suggest re-phrasing to something like "the greatest source of variability in risk is from exposure."
3. pg 10, line 23: Shouldn't "risk management" really be "risk assessment"? I'm not sure how indicator organisms would be used in risk management.
4. pg 11, line 8: Suggest deleting "engaged".
5. pg 11, lines 8-10, "It is apparent that individuals ensured that their favorite methodological approaches were included in the analysis in Appendix G ...": This looks like unnecessary speculation to me. If the statistical methods presented are incomplete, simply say that and ideally provide examples of important methods left out of the discussion.
6. pg 12, lines 19-20 [also pg 18, lines 19-20]: "separate chapter" appears twice; one should be removed
7. pg 19, line 13: Should read "formulate the problem"

Comments from Dr. James Sanders

1.. Were the original charge questions to SAB DWC adequately addressed?

Yes, the DWC addressed each question.

2. Were there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report?

To the extent that I have looked, no.

3. Was the Committee's report is clear and logical?

For the most part, yes. However, I do have one overall comment.

There seems to be a disconnect between the DWC's desire and recommendation that the EPA should get this report out quickly, and the many recommendations for what appear to be extensive changes, even suggestions that whole sections be moved around or used to develop several stand-alone white papers. The recommended revisions don't appear to be ones which will be quickly done, unless the OW has been working in the background on such revisions. Also, the DWC states that the report is well written, but often refers to its verbosity. To me, the two are incompatible, aren't they?

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report.

Yes, the DWC has discussed its recommendations carefully, and provide examples of possible changes and direction.

Attachment G: Comments from Members of the Chartered SAB on the draft Report of the Risk and Technology Methods Review Panel (2-17-10 Draft) -- Compilation as of 3/19/10

Comments from Members of the Chartered SAB on the draft *Report of the Risk and Technology Methods Review Panel (2-17-10 Draft)*

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Comments from Lead Reviewers

Comments from Dr. David Allen

Summarized below are my responses to the charge questions regarding the Draft SAB Review of EPA's "Risk and Technology Review" document:

Question: Are the original charge questions to SAB Standing or Ad Hoc Committees adequately addressed?

Response: The charge questions are adequately addressed.

Question: Are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report?

Response: One of the issues addressed by the report is whether acute exposures can be adequately characterized by estimating the exposures associated with a 10-fold increase in the annual average emission rate (either actual or allowable). In general the report is supportive of this approach. For example on page 25 (Executive Summary), the panel states "...in the absence of chemical- and site-specific data, the use of the 10X screening assumption for petroleum refineries seems reasonable". Yet later in the document (Pages 85-87), the panel provides extensive discussion surrounding data that indicate that petroleum refineries can have episodic emissions that may be 1000 times annual average emissions, and these emissions may somewhat understate the true emission maxima, since the facility self reporting of episodic emissions discussed by the panel are time averaged. For example, if a facility reported a shut down episodic emission of X pounds over a 24 hour period (one shut down event), the hourly episodic emissions reported by Allen and co-workers (references cited by EPA and the panel) would be reported as X/24. Actual maximum hourly emissions would be higher since episodic emissions are, almost by definition, not constant. Given these data, it is unclear why the panel was supportive of the 10X assumption. This should be further clarified.

The panel also notes that the NEI "actual" emission estimates appear to be biased low (page 43, lines 17-19), and the panel should therefore make clear whether their recommendation for handling acute emissions is a 10X factor on actual or allowable emissions.

At several points in their review, the panel notes the uncertainties associated with performing dispersion modeling based on meteorological data that is remote from the facility undergoing residual risk analysis. For example, in the petroleum refinery case studies, the meteorological data that were used came from Galveston Island. The panel notes the uncertainties that this can introduce, but this point deserves increased emphasis in the Executive Summary and possibly in the letter to the Administrator.

Question: Is the Committee's report is clear and logical

Response: In general, the report is clear and logical, however, two structural changes could improve the clarity of the report:

1. The report both praises the EPA's efforts in the RTR document (e.g., page 14, lines 1 and 2), and raises multiple substantive issues. For the most part, the panel is supportive of the modeling tools and frameworks used by the EPA, but is critical of

- the input data into the models (e.g., meteorology and emissions data). More clearly differentiating between uncertainties associated with modeling frameworks and required model data would improve the clarity of the report.
2. A roughly 80 page report has an Executive Summary that runs to almost 20 pages. The Summary should be condensed.

A few minor clarifications would also be valuable

3. Page 59, line 1, it is not clear why the emissions are implausible
4. Page 69, line 10, and at several other points in the document (Page 74, line 30), the panel makes very specific recommendations that need justification. (e.g., “if [the dose response value] was developed more than 7 years ago, a literature review should be performed” – why 7 years?)

Question: Are the conclusions drawn or recommendations provided supported by the body of the Committee’s report?

Response: With the exceptions noted under the second question, the recommendations are supported by the body of the report.

Comments from Dr. Timothy Buckley

1. Whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;

In general, the subject report was responsive to the charge questions. However, within the Executive Summary, the following points of clarification are suggested.

Charge Question #1:

- As I read the first charge question, EPA is looking for advice on the usefulness of a variety of means for evaluating emission estimates. My read of the Review Panel's report is that they answered a slightly different question which is what is the best method for estimating emissions for purposes of risk assessment. The charge question is oriented toward the process of evaluation whereas the Panel response is oriented toward the outcome of the analysis.
- Within charge question 1A, EPA asks for suggestions as to "ways that we can develop similar analyses for other HAPs and source categories" as they have done with benzene. I do not see that the Panel provided a response to this particular question.
- Charge question 1B asks whether "the approach used to estimate dioxin and furan emissions from Portland cement facilities represent the best available methodology . . ." I suggest the following edits to the Panel's response to provide a more direct response.

Executive Summary (pg 16): The Panel recommends that residual risk assessments be conducted using the current source-specific National Emission Standard for Hazardous Air Pollutants (NESHAP) allowable emission rate in combination with each facility's maximum permitted production rate. It is the Panel's assessment that this approach provides the best available methodology because . . . This should be done whenever NESHAP emission limits have been set for specific hazardous air pollutants. In particular, using estimated emissions that exceed the NESHAP limit is not appropriate for the residual risk assessment. Because allowable limits were not modeled for dioxin and furan (D/F) emissions from Portland cement facilities, the Panel does not believe the approach used in the case study represents the best available methodology in support of a residual risk analysis. There is no need to estimate D/F emissions for Portland cement facilities, when allowable limits exist.

Charge Question #2:

- Within the Executive Summary (ES), the report does not provide a response to the question whether EPA's analyses support the practice of "using facility-supplied meteorological data . . .". [the Panel justifies their lack of response on page 63, footnote 10]
- I suggest the following edits to the ES (pg 19) to sharpen the Panel's response to the charge question relating to "(4) omitting atmospheric chemistry from modeling, (4) omitting deposition from modeling".

The results of the Agency's analysis of omitting HAP *decay* and deposition in risk assessments do support this practice and could be applied to other source categories. However, the same can not be said for atmospheric chemistry since it is possible that secondary HAP *formation* could be

significant for some source categories. Further sensitivity studies of secondary HAP formation would be required to rule out the necessity of including complex photochemical modeling for future HAP risk assessments.

- For the question “(5) using block centroids as surrogate exposure locations for these case studies?” it is unclear how the Panel’s ES recommendation differs from what EPA provided in their analysis Section 4.8 and Appendix M.

Charge Question #4A.

- Within the ES, I do not see a clear or direct response to EPA’s charge question: “Does our process of estimating inhalation exposures adequately support regulatory rulemaking?”

2. Whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee’s report.

No technical errors were observed in the Panel’s report. Omissions are identified above relating to specific charge questions.

3. Whether the Committee’s report is clear and logical.

The report was clear, logical and well written.

4. Whether the conclusions drawn or recommendations provided are supported by the body of the Committee’s report.

The report recommendations were will supported by the body of the report.

Comments from Dr. Deborah Cory-Slechta

Comments on Risk and Technology Review Risk Assessment Methodologies

First, it was clear from reading the charge questions that this Committee was presented with a very broad and multi-faceted set of charge questions to address. I congratulate the Committee and its Chair for producing in this document, a response that in general does a commendable job in responding to the question. Comments that I have are actually very brief.

1. If possible, I would highly recommend changing the title of this document/review which makes little obvious sense. It could use some clarification and brevity, but this may be outside the purview of the committee.
2. In general, the document does provide answers to the set of charge questions that were posed, albeit with some unevenness. That unevenness in some cases directly reflects the difficulty of the question and the lack of any clear options with which to address it. However, one section which stood out a bit, at least to this reviewer, was the response to charge question 3a, in particular the sections entitled “Analysis of Unassessed HAPs’ and ‘Incorporation of HAPS lacking dose-response Values’. The responses in these two sections seem rather vague and there is what appears to be more ‘filler text’ than concrete advice. This again may reflect the absence of any particular advice that can be given, but perhaps that ought to be directly stated.
3. Recognizing all too well the difficulty of extracting the most salient points from such a broad set of charge questions and to accommodate all of those within the prototype 2 page letter, the one point that didn’t appear to make the executive summary was the extent of cautions about the TRIM model.
4. P. 88, lines 11-19. It seems a very major conclusion to state that summing acute hazard quotients by target organ would not be necessary. It is based on the preceding phrase that simultaneous release under adverse meteorological conditions would be very unlikely. Certainly some reference or support for that rationale should be provided given that multiple effects on the same target organ should be of significant concern in the context of cumulative risk.
5. Some other corrections/clarifications:
 - p. 44, lines 14-15: ‘using revised emission data that were revised...’
 - p. 62, line 10 ‘permitting to utilize five years...’
 - p. 69, line 10, ‘developed more than 7 years ago...’ what is the basis for a figure of 7 years?
 - p. 70 lines 28-29 through p. 71, lines 1-2. This needs re-writing, the point(s) are not clear.

Comments from Dr. George Daston

Overall, I found this report to be well written, with the conclusions largely supported by the information contained in the review. It is clear that the review panel has a great deal of expertise in risk assessment methodology and their comments will improve an already good process developed by EPA staff.

I was asked to address four specific questions as part of the quality review.

1. whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;
2. whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;
3. whether the Committee's report is clear and logical; and
4. whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

Question 1: The charge questions posed to the review panel were all adequately addressed in a very transparent way. Responses and recommendations were organized in a way that makes it clear which recommendation addresses which charge question.

Question 2: I found no technical errors or omissions in the report, but there are two recommendations that should be justified a little more fully. The first is the recommendation on p. 21 (second paragraph) and pp. 72-73, that the issue of children's hazard be represented as an additional uncertainty in the dose-response assessment for non-cancer and cancer hazards. Some justification is provided for why genotoxic carcinogens might be evaluated with a child-specific assessment factor, but the justification for how EPA should characterize and quantitate this uncertainty is inadequately described. I believe that there is EPA guidance on how to evaluate cancer dose-response for risk in children; the review panel should evaluate whether this is adequate for the risk evaluation methods described here, and if so, should recommend that it be followed. As for non-cancer dose-response, it is also my understanding that EPA has developed guidance, at least in some contexts (e.g., chemicals regulated under the Food Quality Protection Act) for how to evaluate risks to children's health. Again, I would expect that this would be the procedure recommended by the review panel unless they have explicit reasons to recommend something different.

The discussion of AEGLs and other acute guidance values on p. 22 and pp. 74-76 and ACGIH TLVs on p. 70 recommends that EPA incorporate an additional uncertainty factor of 3 to these values to cover the instances in which those values are based on LOAELs. In effect, the factor of 3 covers the uncertainty in the LOAEL-to-NOAEL extrapolation. I do not think this is the best recommendation that could have been made. Modern risk assessment practices at EPA (e.g., for IRIS assessments, use benchmark dose methodology to calculate a point of departure for risk assessment, a procedure that renders moot the LOAEL-NOAEL extrapolation. I believe that this would be a preferred approach. Furthermore, it should be a reasonably easy matter to determine which guidance values are based on LOAELs such that any adjustments could be limited to these.

Question 3: I found the report to be clearly and logically presented. It was a pleasure to read.

Question 4: In all but one instance, I found the conclusions of the report to be well documented and supported. The only conclusion that I have concern about is the one regarding the use of maximum allowable emission levels (MACTs) vs. emission estimates based on actual data (pp. 42-50). The reason given is that the reported emission values can be uncertain and may in some cases be underestimates of actual emissions. While I appreciate the desire to be conservative, I believe that the review panel is making a recommendation that does not serve the desired purpose of the residual risk calculations. My understanding is that the purpose of the evaluations is to determine whether emission control technologies are doing their job, and if so whether (and how much) risk still exists to the public or environment. This purpose is best served by using the estimates of emissions, however imperfect. It is possible to identify at least some of the conditions under which emissions are underestimated, and these can be accounted for, at least partially. Evaluating residual risks by using pre-established MACT levels does serve a purpose, but it is really an evaluation of whether currently the MACT levels are adequate to reduce emissions to levels with negligible risk, a distinct question from what was posed.

Comments from other SAB members

Comments from Dr. Rogene Henderson

1. Whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed.

The report was quite clear in stating each charge question and addressing it with specific comments.

2. Whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report.

I am not an expert in this field but I did not note any technical errors or omissions.

3. Whether the Committee's report is clear and logical.

The report appeared logical to me.

4. Whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

The recommendations were supported by the body of the report. The letter reflects the major points made in addressing each charge question as described in the Executive Summary.

Comments from Dr. Bernd Kahn

SAB-RTR Review

The review is excellent. A few comments follow:

p.1, l.20: On line 12, 'with' is in place of the colon before 'Case'; also p.13, l.7, and p.29, l.6.

p.12: Missing acronyms include

- HQ p.92, l.23
- MTBE p.52, l.17
- NIOSH p.75, l.7
- OSHA p.76, l.8
- POM p.52, l.10
- STEL p.75, l.5
- TEQ p.55, l.22

p.24, l.10: Skip line for new paragraph; also p.81, l.27.

p.31, l.17: Who is the 'we'?

p.58, l.1: Useful models are reported in early EPA NESHAP studies for the same radioactive effluent from coal-fired power plants and from elemental phosphorus plants, for which findings are summarized in Report EPA 520/1-84-022-1/2 in Volume 2, Sections 4 and 6, respectively. The radioactive isotopes of interest are gaseous Rn-222 and Po-210, and particulate U-238, Th-232 and radioactive progeny. Note, however, that the radioisotope specific activity of deposited or near-ground airborne particles may be essentially the same as in the ambient soil.

p.65, l.21: Although local deposition has only minor impact on distant chronic exposure, air scavenging by rain washout has been shown to be important in radioactive effluent studies for the air-to-ground pathway with regard to chronic exposure via food and feed and for acute exposure associated with rainfall.

Comments from Dr. Nancy Kim

1. Were the original charge questions to SAB Committee adequately answered?
Yes.
2. Were there any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report?
No.
3. Was the Committee's report clear and logical?
Yes. I thought that section 4.0 was well laid out and organized. Section 3.0 seemed somewhat long.
4. Were the conclusions drawn or recommendations provided supported by the body of the Committee's report?
Yes.

Comments from Dr. Judith Meyer

1. Whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;

They are adequately addressed.

2. Whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;

Not that I could discern.

3. Whether the Committee's report is clear and logical;

In general yes.

a. p. 13, line 27 -30: I think a clarification of what is meant by "residual risk" is needed; how does a residual risk assessment differ from ordinary risk assessment? It seems that the two terms are used interchangeably at several points in the document, so I am confused. It is finally explained on p. 29, but some explanation is needed much earlier in the document. It seems as though when the term "risk" is used in this document, the panel really means the "residual risk" that is specific to the Clean Air Act requirements. If so, that needs clarification.

b. This is a very long and detailed report with many recommendations. The recommendations are often buried in the text. Did the panel consider highlighting or bulleting them? It may not be feasible, but it would make finding recommendations easier.

4. Whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

In general, yes.

a. p. 21: Define ATSDR MRL when first used. That recommendation in the Executive Summary comes out of the blue with no explanation of context.

b. p. 84: The recommendation with respect to particle-bound HAPs seems important enough to be included in the Executive Summary, yet it is not there (unless I missed it). The potential importance of particle bound HAPs identified in the discussion of the ecological risk assessment, further enhance the importance of this observation and recommendation and make it even more important to include in the Executive Summary.

Editorial comments

1. Letter, p. 2, line 14: spell out HAP when first used

2. p. 13, lines 17-18: Details of the quality review process are not usually a part of these reports. That sentence could be eliminated, especially in the Executive Summary. Too much detail!

Lines 25-26: Don't need the sentence that begins with "The responses that follow...." It is obvious.

3. p. 22: Define LOAEL and NOAEL when first used. Also it is not clear what the difference is between AEGL-1 and AEGL-2; and between ERPG-1 and ERPG-2.

4. p. 26, lines 27-28: some examples of the kinds of site characteristics you have in mind would make this recommendation less vague.

5. p. 41: Don't repeat the entire charge question including the background information! It makes the report have too many redundancies. I suggest eliminating the previous section where

ALL charge questions are listed, and instead put each charge question at the beginning of each section where it is answered. It doesn't need to be in both places, and it is easier for the reader to follow if the question is just before it is answered.

6. p. 86, lines 1-2: these are printed over in my pdf, so I have no idea what they say.

7. p. 92, line 27: the "prior studies" require a citation.

8. p. 94: Although it is valuable to have this list of references, it is really bizarre to have them listed in the text of the report. In general, I found the use of footnotes for citations unusual for an SAB report. Why not just have a literature cited section at the end of the document, and cite (author, date) in the text rather than using footnotes.

9. p. 100, line 15: "IN Harris county..."

10. p. 97, line 24: Somewhere in the response to this charge question, reference needs to be made to the existence of an appendix with more detailed editorial comments on the risk characterization section. This would be a good place to do that.

Comments from Dr. Amanda Rodewald

The committee prepared a very thorough report that contains a tremendous amount of useful information.

1. are the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;

As a whole, yes. However, there were times when it felt that the reader had to intuit the actual answer based upon the information presented in the response (e.g., response to Charge 1A). I think that some reorganization would improve the usefulness of the responses (see comments in #3 below).

2. are there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;

No.

3. is the Committee's report is clear and logical;

In some places, the organization of (not content of) the text made the document confusing and difficult to read. I highlight examples below:

In the Charge Questions section, I was confused by the placement of the text boxes that contained the charge questions 1A – 1D. At first it seemed that the text on pages 32 (lines 26-31) and 33 (lines 1-24) might be in response to the charge question 1A that *followed* on page 33 lines 25-30. The same is true for the subsequent charge questions. I spent time trying to sort out what I was reading (i.e., questions and responses?), and I did not completely figure it out until I saw Section 4.0. I think both the text boxes and the unusually long charge questions (9 pages) contributed to my confusion.

The structure of "Recommendations related to Charge 1A" (page 51) was a bit awkward given that the first actual recommendation was not articulated until page 53. Perhaps the recommendations can precede the justification/critique. Also, if the actual recommendations were bolded or otherwise highlighted, the reader would not have to search for them.

Likewise, in the panel response to Charge Question 1B (page 55), it seemed as though the question was not directly answered. The response included a lot of important and useful information, but the reader needed to synthesize the information in order to construct a concise answer. Perhaps the question can be succinctly answered in the initial sentence or two and then the elaboration/supporting details can follow the answer.

In the panel response to Charge Question 1C (p. 58), the first question was not answered until the middle of the second paragraph (line 12). I suggest leading with the answer and then supporting that position in subsequent text.

These same comments can be applied to other response sections. Overall, I think that a concise answer should lead the response and that can be followed by support. In the current document, I perceived the answers to be buried in text and difficult to quickly extract. The response to Charge Question 3A (page 68) and 3B (page 74) are great examples of first providing the simple answer and then qualifying it.

4. are the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

Yes.