

**Summary Minutes of the US Environmental Protection Agency
Science Advisory Board
Review of the Draft SAB Panel Report on EPA's Regulatory
Environmental Models Guidance
Public Teleconference Meeting
April 26, 2006
1:30 pm – 4:00 pm (Eastern Time)
Meeting Location: Via Telephone Only**

Purpose of the Meeting: The Meeting was held to allow for the Chartered SAB to review and approve the subject draft report. The meeting agenda is in Attachment A.

Members Participating in the Meeting:

Dr. M. Granger Morgan, Chair	Dr. Gregory Biddinger
Dr. Trudy Ann Cameron	Dr. Baruch Fischhoff
Dr. A. Myrick Freeman	Dr. James Galloway
Dr. James Johnson	Dr. Phil Hopke
Dr. Cathy Kling	Dr. Jill Lipoti
Dr. Michael McFarland	Dr. Jana Milford
Dr. Rebecca Parkin	Dr. Kathleen Segerson
Dr. Deborah Swackhamer	Dr. Thomas L. Theis
Dr. Rob Stavins	Dr. Joan Rose
Dr. Gene Matanoski	Dr. Rogene Henderson
Dr. Valerie Thomas	Dr. Lauren Zeise

Others Participating in the Meeting:

SAB Staff: Dr. Jack Kooyoomjian, DFO; Tom Miller, DFO, Dr. Vanessa Vu, Director; Dr. Kathleen White, DFO; Dr. Anthony Maciorowski;

EPA Staff and Public: See Attachment B for a list of those who contacted the DFO noting their interest.

Public Commenters: None

MEETING SUMMARY

Wednesday, April 26, 2006

This meeting was announced in the *Federal Register* at FR 71 18326-18327) (see Attachment C of the physical file and on the SAB website at.

Mr. Thomas Miller, SAB Designated Federal Officer, convened the meeting and identified those on the call. He noted that: 1) the meeting was an official meeting of the Chartered Science Advisory Board, chaired by Dr. Granger Morgan; 2) the meeting

complies with requirements of the FACA and EPA policy for expert advisory committees; and 3) the SAB members participating in this meeting had submitted updates to their confidential statements of financial interest and the Deputy Ethics Official for the SAB Staff Office had determined that Members do not have “conflict of interest” or “appearance of impartiality” issues within the meaning of the relevant ethics and conflict of interest requirements that apply to this advisory activity.

Mr. Miller stated that Member’s responsibilities during this meeting were to evaluate the draft SAB Panel report and decide whether the report:

- a) adequately addressed the Agency charge questions;
- b) is clear and logical; and
- c) conclusions drawn or recommendations made are supported by the body of the Panel’s report.

Mr. Miller noted that SAB proceedings provide an opportunity for public observation and participation and that participation can be through providing written comments to the SAB or by making short oral statements during the public meeting. Mr. Miller noted that for this meeting, no members of the public have requested time for oral statements nor have any written public comments been received.

Mr. Miller then introduced the SAB Chair, Dr. Granger Morgan, who carried out the agenda.

A. REVIEW OF THE DRAFT PANEL REPORT ON EPA’S REM GUIDANCE

Dr. Morgan welcomed the participants and noted the focus of the meeting was to review the draft report from the REM Panel. (See attachment D - *Review of Agency ‘Draft Guidance on the Development, and Application of Regulatory Environmental Models and Models Knowledge Base’ by the REM Guidance Review Panel of the EPA SAB*).

Dr. Morgan then introduced Mr. Pascual, EPA Office of Research and Development, and Chair of the Council for Regulatory Environmental Modeling (CREM) to make comments on behalf of the Agency.

Mr. Pascual thanked those who had provided the vision to pursue this effort from within EPA, the SAB and its staff for their work. He stated his opinion that the draft report thoroughly and fully answered the agency’s charge to the SAB. He noted that EPA takes the recommendations in the draft report seriously and that staff are already moving forward to respond to what they heard in the Panel’s review meetings and read in the draft report. He offered three examples where EPA was already reacting:

- 1) The “Guidance”: EPA will be considering the SAB advice, along with advice of the NAS that is now looking at the issue of best practices for modeling even more broadly, in an integrated fashion and using insights to improve the final guidance.

- 2) The “Knowledge Base”: They are moving to increase the interactions with outside groups that will make it easier to integrate across various groups that are working on such models. In this, the Agency is restructuring to use global and non-proprietary technologies that will allow all interested parties easier access.
- 3) Agreeing with the Panel that the Guidance and the Knowledge Base will affect more than just those who do modeling, EPA is poised to begin an effort to help inform modelers, analysts, managers and stakeholders about REM so that they can better understand and use the results of modeling in their roles. The effort will begin with a workshop in November 2006.

Dr. Morgan then asked Dr. Thomas Theis, Chair of the SAB REM Guidance Review Panel to comment. Dr. Theis noted that there are three areas where multiple SAB Members’ comments on the draft report are similar. He identified the three areas and suggested how he would address each:

- 1) Members noted that the transition from the Introduction to the Body of the Report was rough. Dr. Theis will edit the document to integrate some historical background on EPA’s activities under the Council for Regulatory Environmental Modeling and also include information on the Agency Charge for this current SAB effort.
- 2) Many Members believe the Letter to the Administrator is too long. He noted that he had struggled with this during drafting and that one of the things giving the impression is that the introductory material takes up a half page before the substantive information comes out. He also noted that the letter was double spaced. He will attempt once again to shorten the letter. The final letter will only be single spaced and that should help.
- 3) Many Members commented that urging EPA to provide consistent resources for the REM effort needed to be in the body of the report as well. The Panel gave this comment serious consideration and even though this is also a view expressed in reports by the SAB, believed it was important to say in this effort. He will add information on this to the body of the report.

Dr. Morgan then asked the SAB Lead Reviewers to comment on the draft report. Attachment E provides a compilation of the written comments of Board members on the draft report. Members generally deferred to those comments and during the meeting only mentioned specific comments that they believed to be in need of highlighting.

- a) Dr. James Galloway stated that he believed the report was an excellent job and he deferred to his written comments with no further comments to offer.

- b) Dr. Michael McFarland agreed with the quality of the draft report and in light of the encouraging response from Mr. Pascual felt he did not need to emphasize anything further from his written comments.
- c) Dr. Trudy Cameron noted the many line edits she had provided and highlighted several issues of significance, including: i) the need to clarify the use of the term bias (page 53) which refers to a specific statistical concept (she suggested “apparent advocacy” as the terminology to use); ii) the implication that intrusion into modelers’ time by graduate students justified anonymity for those who do modeling; and iii) the need for caution in suggesting the privatization of MKB – this is a case of a public good that will not likely be supported by outside groups who do not have sufficient incentive to provide the goods.
- d) Jana Milford focused on her general comments and stated that more work was necessary to point out that the guidance should make it clear that it applies to more than just fate and transport modeling. Members had varied opinions about how clear this was in the report. Some thought that the guidance should note that certain models might not be able to conform to the guidance. Her second issue noted the need for more attention to how to address uncertainties that are difficult to quantify (e.g., scenario uncertainties in forecast model applications). Dr. Theis noted that this issue was discussed carefully by the Panel and that the Panel report attempted to make the point that the guidance should apply more broadly than just the fate and transport area.
- e) Dr. Gregory Biddinger largely deferred to his written comments which attempt to highlight places in the report where initial articulation of advice is strong and then it seems to become diffuse as the explanation goes forward. He emphasized that EPA should discuss what constitutes a stakeholder under different conditions that prevail from model development to model application. They are not necessarily the same stakeholders.
- f) Dr. Lauren Zeise noted that the report was well done and emphasized three points. i) the letter might point out that as uncertainty analysis gets more complex, EPA might need to develop new risk management frameworks that can accommodate such analyses better than current frameworks do; ii) the need to clarify the “Post Application Audit” issue and possibly addition of a separate box for this function as well as its placement in the overall figure; and iii) the possibility of clarifying the “structural model uncertainty” issue by giving it a separate treatment that clarifies its distinctiveness within overall uncertainty. Members also discussed whether or not the draft report’s handling of uncertainty suggested a “dumbing-down” of the analysis so it could be understood by risk managers who are usually not model practitioners. They want to ensure that this tone is not conveyed in the final report.

Dr. Morgan then called on other SAB Members to point out specific issues that they feel need to be addressed during this meeting. Comments mentioned by specific members included:

- a) Dr. Rebecca Parkin emphasized the need to clarify the identify of who are included in the group referred to as stakeholders.
- b) Dr. Gene Matanoski noted that the report introduction should clarify that the SAB role over time in model development has been as an advisor and not as co-workers in developing models and model guidance with EPA.
- c) Dr. Valerie Thomas agreed with the need to have clear discussion of the need for stable resources for EPA's modeling efforts in the body of the report and not just the Executive Summary. She also asked that the report be clear in distinguishing between what this draft report advises and the advice given in the previous "SAB Modeling Resolution of 1989." Also it would be good to note how the Agency has moved forward relative to advice in the past SAB advisory efforts on modeling.
- d) Dr. Joan Rose pointed out that modeling efforts for fate and transport modeling for microorganisms is in its infancy. She noted the need to discuss the issue of modeling efforts that are in their "infancy" and those that are mature in their development and application.
- e) Dr. Vanessa Vu, SAB Director, noted that Appendix D on Panel Formation was not necessary because that issue is thoroughly discussed on the SAB Staff Office Website.
- f) Dr. Granger Morgan reiterated his written comments that the level and sophistication of the treatment of uncertainty should be appropriately matched to the problem at hand, and to the way the results will be used. He argued that whenever uncertainty is an important element in a problem, it should at a minimum be acknowledged and receive some basic quantitative analytical treatment. He also suggested that the report should call for an expanded discussion of model uncertainty.

ACTION: Dr. Morgan then noted that his sense of the Board's consensus based on the discussion was that the report meets the objectives stated in the charge; that Board Members have suggested many modest clarifying edits, along with several substantive changes, and that all this could be accomplished by the Panel Chair, with the DFO's assistance, and then the report could be read again by the Lead Reviewers for conformance to suggested edits in the Member comments and then sent on to the Administrator. Dr. Hopke made a motion that incorporated these points and it was seconded. Dr. Morgan asked Board Members to vote on the motion by noting any objection to the motion as made. No dissent was given and the Chair declared that the motion had passed. The Report is approved subject to the conditions on editing and final reading by the Lead Reviewers in the motion.

B. TOPICS FOR THE SAB 2006 ANNUAL MEETING AND WORKSHOP

Dr. Morgan then introduced the final topic for the meeting noting that each year the SAB conducts an annual meeting in December and that it is normally focused on a workshop topic of the Board's choosing. Dr. Morgan referred to the candidate topics below for Member consideration. He noted that the intention for today was to discuss the pros and cons of each topic and to decide on how to go forward with planning.

Workshops are part of the SAB's efforts to advance and keep pace with complex technical and emerging issues, and they provide a forum for Board and Committee members to interact with EPA and external scientific experts and discuss environmental areas of interest to EPA. Past Workshops have focused on:

- (a) **December 2003-** Short, overview sessions on a variety of topics including: *control of transboundary air pollutants, emerging contaminants, invasive species, nanotechnology, and genomics.*
- (b) **December 2004-** "Nanotechnology, Biotechnology, and Information Technology - Implications for Future Science" This was a more in-depth exploration of the nanotechnology topic that was discussed in the overview sessions during the December 2003 workshop mentioned above.
- (c) **December 2005-** "Science for Valuing the Protection of Ecological Systems and Services" which discussed the progress and advancements developed on this issue by the SAB Committee for the Valuation of Ecological Systems and Services.

Topics that have been suggested as candidates for the SAB 2006 annual meeting are (Member discussions are included with each topic):

- a) The SAB is establishing an *Ad Hoc* Committee to evaluate the extent of environmental problems presented by **reactive nitrogen** and to make recommendations toward a more integrated approach to nitrogen research and risk management. The SAB could focus its workshop on nitrogen to kick off this initiative.

Members discussed whether this topic was as narrow as it seems and agreed that it had the potential to be broader than it appears. Some believed it was not a good topic and others suggested it would be a critical topic for the future. Dr. Galloway who will be the Chair of the SAB "Nitrogen Panel" noted that the panel itself was only now in the process of being formed and that it would not likely be ready to organize a December workshop. The topic was deferred to that group's establishment.

- b) The Board is embarking on a new study to assist the Agency in identifying and building on lessons learned from past **responses to major natural and man-made environmental disasters** (e.g., WTC, the anthrax incident on Capitol Hill,

Hurricanes Katrina and Rita). As part of this effort, the Board could hold a workshop inviting outside experts from the private and public sectors to discuss and learn from their programs for dealing with environmental threats.

Members discussed the importance of the issue, whether it could include things such as bird flu and HIV, noted that it was timely, wondered if our efforts could be deep enough given the amount of research and other activity that is already going forward in this area, noted the importance of learning from other sectors activities in this area, and noted the need for a significant component of the activity to focus on not just evacuation from impacted areas but the need to consider the needs that have to be satisfied to allow people to return to these areas. Dr. Morgan argued that the focus should be learning how other public and private organizations prepare for and deal with disasters. He suggested that the focus not be on EPA's recent experiences with WTC, the anthrax incident on Capitol Hill, Hurricanes Katrina and Rita. Members concluded that the project is timely and warrants continued consideration. The focus is likely to be on learning from other sectors outside EPA of their experience and plans for preparing and reacting to such events.

- c) In December 2003, the SAB sponsored a mini-session on global trans-boundary air pollutants. The SAB could hold a workshop to allow in-depth discussions of this topic and to explore the implications of transboundary pollutant transport on EPA's science and research needs.

Members discussed the scope of the project and considered whether it was a global issue or whether the real issues of interest to the SAB would be the US effects of global transboundary pollution. Dr. Hopke noted that very little was being done on the issue and thus it is premature for the SAB to focus on this issue for now. The issue will be deferred for now.

- d) There has been considerable advancement in the science of risk assessment and its use in environmental policy-making. Advances have occurred in understanding and evaluation of many of the specific components included in assessments and in how these components are integrated. The NRC, GAO, EPA, and other independent organizations have evaluated EPA's risk assessment processes and these have been helpful in moving EPA's practice forward over the years. In spite of all this evaluation and improvement, we still have many examples of assessments that are embedded in strong controversy (e.g., PFOA, dioxin, arsenic). Many have suggested that it is necessary to step back and look at EPA's risk assessment practices within the context of how it is used in support of EPA's mission. This is often referred to as the science-policy interface and it reflects the hard reality that science is influenced by the legal structure of policy making as much as science influences policy making itself. The dilemma is that there is no clear line that separates science from policy. The SAB could hold a workshop to discuss the interface between science and science policy choices as a precedent to a

possible exploration of ways to make quantum improvements, not incremental and disconnected ones, in risk assessment.

Members discussed the issue with several noting strong support for the topic because of ongoing issues in the NAAQS area, because of its fit to the SAB role and the difficulty panels often have of discerning where their science focus lies and policy takes up; and how the recent EPA risk assessment staff paper might relate to the project. Others reflected concern that the topic was much too broad as stated. The project needs to have a refinement in its focus to narrow the scope. There is also a possibility that “b” and “d” might be able to be combined in some way. Members will continue to work on refining the project.

Dr. Morgan will work with SAB Staff to refine projects “b” and “d” and then decide on how to move forward. They will keep Board Members informed as this goes forward.

The meeting was adjourned by the Designated Federal Officer.

Respectfully Submitted:

/ Signed /

Thomas O. Miller
Designated Federal Officer
US EPA Science Advisory Board

Certified as True:

/ Signed /

Dr. M. Granger Morgan
Chair, EPA Science Advisory Board

Attachments:

- A Meeting Agenda
- B Table of Interested Public (including EPA)
- C FR Announcement (in physical file only)
- D Draft REM Panel Report
- E Compilation of SAB Member Written Comments on the Draft

ATTACHMENT A

**US Environmental Protection Agency
Science Advisory Board
Review of the Draft SAB Panel Report:
*Review of Agency 'Draft Guidance on the Development, Evaluation, and Application of
Regulatory Environmental Models' and 'Models Knowledge Base'***

Agenda

Public Teleconference Meeting

April 26, 2006

1:30 pm – 4:00 pm (Eastern Time)

Meeting Location: Via Telephone Only

Members of the public may obtain the call in number at 202-343-9999

Wednesday, April 26, 2006

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|----------------|--|---|
| 1:30 pm | <u>Convene the Teleconference Call</u>
<u>Announcements, Summarize Agenda,</u>
<u>Attendance</u> | Mr. Thomas Miller, Designated
Federal Officer |
| 1:40 pm | <u>Welcome and Introduction</u> | Dr. Granger Morgan, SAB
Chair |
| | a. Comments by EPA | To Be Determined
EPA ORD National Center for
Environmental Research |
| 1:50 pm | <u>Review of Draft Report</u>
<u>Review Panel</u> – REM Guidance Review Panel
<u>Chair</u> - Dr. Thomas Theis
<u>Lead Reviewers are:</u> | |
| | 1) Dr. Gregory Biddinger
2) Dr. Trudy Cameron
3) Dr. James Galloway
4) Dr. Michael McFarland
5) Dr. Jana Milford
6) Dr. Lauren Zeise | |
| 3:00 pm | <u>Disposition of the Draft Report by the Board</u> | Chair and Members |
| 3:15 pm | Discussion of Candidate Topics for the 2006 SAB
and Members
Annual Meeting/Workshop | Chair |
| 4:00 pm | <u>Adjourn</u> (time approximate) | |

ATTACHMENT B

Public Requests for REM Meeting Information

No.	Name	Organization
1	B. Sachau	NA
2	Gina Williams	SBC Global
3	Noha Gaber	US EPA
4	Patt Phibbs	Bureau of National Affairs
5	Susan Reith	US EPA
6	Beth Eliason	State of Vermont
7	Namsoo Suk	State of New Jersey
8	John Holmes	NAS / NRC
9	Brian Hennesey	US EPA
10		

ATTACHMENT C

<http://www.epa.gov/fedrgstr/EPA-SAB/2006/April/Day-11/sab5324.htm>

ATTACHMENT D

Review of Agency 'Draft Guidance on the Development, and Application of Regulatory Environmental Models and Models Knowledge Base' by the REM Guidance Review Panel of the EPA SAB)

http://www.epa.gov/sab/pdf/rem_draft_02-24-06.pdf

ATTACHMENT E

April 26, 2006

Compilation of Member Comments on the Draft REM Report

A. LEAD REVIEWERS:

1. Dr. Gregory Biddinger:

Other than the exceptions noted below, the SAB Review of Agency Draft Guidance on the Development, Evaluation and Application of Regulatory Environmental Models and Models Knowledge Base addressed the Agency charge questions in a clear and logical manner and the conclusions and recommendations drawn were supported.

Cover letter

1. The concern raised regarding adequate resources in the 2nd paragraph does not seem to have come from a response to the Agency guidance. As well the draft SAB report does not have a section in the table of contents on this point. Was this based on discussions with the agency during meetings? Personally I can believe it is true but it should be supported somehow.
2. Paragraph 5 recommendations around problem specifications and stakeholders seems out of place. See comments below under charge question 1. This paragraph needs to be modified to create alignment with importance of recommendation provided in section 1.2 of draft report.

Charge question 1.

1. Suggest that the first ten lines of the general comments section 1.2 be moved to the front of the section as an introductory paragraph.
2. The remainder of section 1.2 actually raises the need to expand their model guidance from general models to include site-specific considerations and also to raise the role of stakeholders to a level of central importance. This section should be renamed to be more explicit regarding its content. Something like “Expanded Guidance Scope or Boundaries” is more appropriate.
3. The alternative Figure 1 discussion does not carry through to the letter to the administrator. The discussion in the 5th paragraph (page 2 of letter , lines 18-23) of the cover letter does not convey the importance that is provided in section 1.2 and 1.3. It is handled a bit better in Paragraph 5 (page two of summary , lines 10 to 16). In essence the report recommends an expanded scope for their guidance from development of general models to include the broader considerations of selecting and adapting models for site or problem specific applications. This is an important and global recommendation that does not carry through. These are minor changes but expect the messages to be much stronger if made.
4. The recommendation that stakeholders play a central role should be discussed in further detail. There needs to be guidance on how to select appropriate stakeholders dependent on whether the model being developed has general

applications versus specific. Suggest a few sentences recognizing the agency will have to include a discussion of what constitute a stakeholder under different conditions of development or application from national policy to local permit decisions.

5. Section 1.2 makes point about importance of peer review (Page 9 lines 10-11) through out the model development/application process. The agency makes the same point in Appendix C of their guidance and graphically presents the point in figure C1.1. Suggest you recognize that in conjunction with this point.

Charge question 2

1. Section 2.2 under Goals and methods raises a number of points related to the agency's need to expand their focus or scope in drafting this guidance (or guiding principles). The SAB Review comments suggest recognizing the following
 - a. Model users may be those that simply use the output and not run the models
 - b. Modelers other than in a regulatory context should be an intended audience
 - c. The guidance needs to cover a broad range of modeling types other than just environmental models

It is not clear to me that there is value in making this guidance be so encompassing that it covers all audiences. This document seems to me to be more in line with previous Framework documents written for Ecological Risk Assessment. That document set the groundwork for a whole series of subsequent documents including separate primer for managers on how to use the output of ERA's and critical issue papers on topics such as uncertainty. I wonder if the panel is asking the agency to do more with this single document than is appropriate. They are charged to focus regulatory environmental models and not the other models listed. Maybe a more appropriate recommendation would be to plan and describe in this document a series of continuing guidance that will follow covering other audiences and model types. It might be better for them to write strong guidance for a narrower audience and then expand in subsequent work once they have a solid basis to work from.

2. Section 2.4 notes the need for documentation during the development of the model not just when it is complete. I would agree with that point and would suggest that you link this point with your recommendation on peer review through out the model development process. It clearly would aid such integrated peer reviews.

Charge question 3.

1. Section 3.2 in the last paragraph on page 24 makes the point of need to discuss the use of qualitative assessments tools such as expert judgement to test model appropriateness before moving to more quantitative tools. The agency does make a note of qualitative approaches under section 3.1.3.2 of their report covering the topic of model corroboration. Seems appropriate to recognize that and build from there on what more you would like to see in the guidance.

2. The point in section 3.4 on need to provide some discussion in this guidance about linking models to create a larger modeling tool is well taken. I would also suggest that this might be a good example of where a more detailed guidance document on this specific topic might be worth recommending. This would give them the option of providing high level guidance here and more rigorous guidance in a following document.

Charge Question 4 – Still reviewing

1. Section 4.0 included many good recommendations and lots of interesting and useful suggestions for approaches and references. Many of these good points may deserve more explicit definitions as “recommendations” and bolding in the text. The following are a few, but suggest that the authors revisit this text and make sure some key points are not left with less emphasis than is warranted.
 - a. In the 3rd and 4th paragraphs (page 29) of section 4.1 the point is made that the guidance needs to direct focus on other sources of uncertainty in the decision-making process than just the modeling. The discussion provided suggests that the guidance should direct the modeler should consider the needs of the decision-maker and relevant stakeholders in determining how much uncertainty is acceptable in model design and execution. This seems to beg a specific recommendation
 - b. Later in section 4.1 (page 31 lines 19-22) the review suggests the guidance should include a discussion about propagations of uncertainties when working with multiple models. This is a very important issue and in regulatory analysis very often the real situation. This discussion is worth expanding, but if not at a minimum I suggest it needs more emphasis as a recommendation.
 - c. There is a general recommendation at the end of section 4.1 but it seems to me that many of the good points earlier in the section are lost in the generality. The review panel may want to revisit and redraft to capture some of the above recommendations more explicitly
 - d. In section 4.2 the point about confusion and lack of clarity between sensitivity analysis and uncertainty analysis is both important and well described. Unfortunately no explicit recommendation is made. This could be as simple as bolding lines 23-25 on page 32.
 - e. Section 4.3 suggests that uncertainty analysis needs more complete treatment in section C.6 and specifically there is little guidance on how to evaluate uncertainty in model parameters. But no recommendation is given. A more explicit recommendation seems warranted
2. The use of case study examples seems like a worthwhile addition both for the guidance and for the MKB. As noted above (see charge question 2 #1) it seems to me that the development of guidance for Regulatory Environmental Models could follow a similar pattern as that for Ecological Risk Assessment. In the case of the ERA guidance documents there were 2 volumes developed that included a number of complete and detailed case studies of the application of ERA's. The REM Guidance could also follow such a series approach and you might want to consider not only that they include a few illustrative examples but also they develop guidance in future using detailed applications of modeling to support regulatory decisions and use them to highlight how to do the problem formulation, model design, execution, and quality analysis plus the communication of modeling results.

- a. As well it might be worth considering that the MKB has a series of white papers on the various tools to assess model sensitivity and analysis, and also include white papers on critical technical issues around modeling such as communication of results.

Charge Question 5 –

See comment above about the value of considering white papers on types of models, tools for analysis of modeling sensitivity and uncertainty and also white papers on critical issues.

Charge Question 6 – No comments

Charge Question 7 – No comments

2. Dr. James Galloway:

Thank you for the opportunity to serve as a Lead Reviewer of the *Draft Guidance on the Development, Evaluation, and Application of Regulatory Environmental Models and Models Knowledge Base* prepared by the Regulatory Environmental Modeling Guidance Review Panel of the EPA Science Advisory Board. My overall impression is that the panel has done an excellent job in thoroughly reviewing the report and in the process has of great service to the agency. My comments therefore are more focused on how the information is presented rather than its quality.

Following are my response to my three charges as a lead reviewer.

1. Have the original charge questions to the SAB Panel been adequately addressed in the draft report? It is my assessment that the original charge questions to the SAB Panel are adequately addressed in the draft report. The responses to each of the seven charge questions are clear and extensive. The panel has been thorough in not only reviewing what was written but in also suggesting alterations or additions to the text and the supporting figures.

2. Is the draft report clear and logical? In general, the draft report is well-written and clearly sets out the panel's recommendations. I do recommend that following improvements. First, at the end of each of the sections dealing with a specific charge question, there should be a summary of the panel's recommendations. Second, the Executive Summary should state each charge question along with the summary from the body of the report. Third, the letter to the Administrator is about 3 pages, which in my mind is too long. It would be more effective if it were reduced in length by about a page. Lastly, as noted in the report, Appendix C has not been highly edited given the individual nature of the responses. Given the diffuse nature of the information provided, the panel might wish to consider condensing the key points from the Appendix and merging them into the body of the report. It would make the overall report shorter, and make the information in the report more centrally located.

3. Are the conclusions drawn and/or recommendations made by the panel supported by information in the body of the draft report? It is my assessment that the panel's recommendations are supported by the information in the report.

In summary, I commend the panel for doing an excellent job on the review. It is thorough, well-written and should be of great value to the agency.

3. Dr. Michael McFarland:

General Comments: In general, the SAB draft report is well written, logical and appropriately referenced. The SAB draft report provides a clear and comprehensive response to each of the seven charge questions posed by the Agency. In all of its responses, the SAB Panel furnishes the Agency with a number of useful and pragmatic recommendations that, if implemented, would result in considerable improvement in the scientific defensibility of the Agency's use of model derived information in regulatory decision-making.

The SAB Panel is to be commended in its highlighting of the Agency's scientific accomplishments in preparing the "Draft Guidance on the Development, Evaluation and Application of Regulatory Environmental Models and Models Knowledge Base", which included acknowledging the Agency's responsiveness to earlier SAB advice on model formulation, development and implementation. Moreover, in recognizing the range of deficiencies in the draft guidance, the Panel has eschewed the common practice of merely accentuating the document's technical limitations and has, in all instances, provided the Agency with practical steps that would substantively improve the Agency's modeling activities and those decisions that are supported by model output.

The following are my specific responses to the quality review charge questions. It should be noted that, as a non-modeler, my technical comments should be seen in the light of a generalist whose knowledge of the models and modeling terminology referenced in the draft document is somewhat limited.

Response to Charge Questions

1. Are the original charge questions adequately addressed in the draft report? The SAB Panel's responses to the original charge questions are adequately addressed in the draft report. In formulating its responses, the Panel has demonstrated a broad and practical understanding of a range of technical issues germane to the Agency's generation and use of model-derived information in support of regulatory program decisions. Moreover, the Panel has furnished a number of detailed and pragmatic recommendations in its response to each of the charge questions. Finally, an overarching and valuable recommendation offered by the SAB Panel is the reformulation of Figure 1. In my opinion, the improvements highlighted in alternative Figure 1 represent substantive opportunities for the Agency to establish a scientifically defensible framework for future model formulation, development and implementation.
2. Is the draft report clear and logical? The SAB draft report provides a clear and logical basis in identifying and describing those scientific, technical and programmatic issues that have the potential to undermine the validity of using models and model-derived information to support Agency decisions. The SAB draft report cover letter and

executive summary are well written and highlight those salient issues that Agency senior management should consider in ensuring the scientific and regulatory defensibility of decisions that are supported by modeling data and associated information. The main body of the report provides clear, comprehensive and logical responses to each of the charge questions. Where appropriate, the SAB Panel has supported its charge question responses with practical examples, peer-reviewed references and Panel member modeling experience.

3. Are the conclusions drawn and/or recommendations made supported by information found in the body of the report? The SAB Panel's draft document has identified and described a number of important conclusions focused on enhancing the value and reliability of the Agency's model-derived information as well as a range of practical recommendations formulated to address its current use and limitations. The SAB Panel is to be commended for clearly supporting each of its conclusions and recommendations within the main body of the report. The SAB Panel has provided detailed descriptions of the broad range of scientific, technical and programmatic challenges facing the Agency with regard to its current modeling programs. Finally, the Panel's recommendations describe practical approaches for addressing a number of critically important cross-Agency modeling issues and concerns including: 1) uncertainty quantification and communication, 2) integration of appropriate levels of peer review, 3) systematic model formulation and development, 4) model transparency and 5) ensuring model output is based on the best available science.

4. Dr. Jana Milford:

General Comments: Due to time constraints, I focused my review on the panel's review of the Draft Guidance. I did not closely review the panel's comments on the Models Knowledge Base. With a few exceptions, I found the draft report to adequately address the charge questions and to be generally clear and logical, and found the recommendations to be supported by information in the body of the report. Overall, I feel the report could be improved by redrafting, to make the recommendations and conclusions more direct. This is most important in the letter to the administrator and the executive summary. I did not try to suggest editorial changes, but tried to point out in my comments the places where I felt improvement was especially needed. Two significant substantive concerns I have about both the Draft Guidance and the panel's review are that (1) more attention needs to be paid to the question of whether the Guidance adequately addresses (or should address) models other than pollutant fate and transport models, and (2) more attention needs to be paid to how to address uncertainties, such as scenario uncertainties in forecast model applications, which are relatively difficult to quantify.

Letter to the Administrator: p. 1, line 32. I did not see the back-up for the "concern" that "the REM vision is not matched by a commensurate, and steady, allocation of resources." This seems like a very important concern, which warrants clear and open discussion of the signs or consequences of this lack of sufficient resources, and the reasons for it. The fact that the panel discusses in the introduction to its report the recommendations it made in the 1980's on regulatory modeling underscores the concern, but only in a very indirect way. If there is a problem here, couldn't it be discussed more directly?

p. 2, lines 10-16. The point that the Draft Guidelines are not accessible to many in its potential audience is important. This paragraph should be rewritten to state this more

clearly and directly, and to recommend that the Draft Guidelines be rewritten to be made more widely accessible, not to recommend that the Agency “clarify” how the document should be used.

p. 2, lines 25-31 and p. 3, lines 1-9. The recommendations made in this paragraph are important, but not clearly or directly phrased. Could the letter state more directly that the Guidelines need to provide more context, examples, and recommendations on appropriate uncertainty analysis and communication of uncertainties?

Executive Summary

p. 1, lines 19-22. Same comment as above on Letter, p. 1, line 32.

p. 1, lines 24-27 and p. 2, lines 1-8. Same comment as above on Letter, p. 2, lines 10-16.

p. 2, lines 29-31 and p. 3, lines 1-9. Same comment as above on Letter, p. 2, lines 25-31 and p. 3, lines 1-9.

p. 3, lines 3 and 10. It’s not clear what the panel means by “practicable”. Is the term used to mean accessible, or useful, or ...?

p. 3, line 21. The ES needs to explain why “framework” needs to be redefined.

p. 3, line 27. What is meant by “purveyors”?

The question of how well the Draft Guidance extends to models other than pollutant fate and transport models, which is discussed on p. 18, is important, and warrants mention in the ES.

Report

p. 7, lines 1-2. The panel leaves us hanging. What was the outcome of the SAB’s 1989 model resolution? If it’s worth mentioning the resolution, isn’t it worth summarizing the Agency’s response (or lack thereof) over the ensuing 17 years?

Charge Question 1. Best Practices. I found this section of the report to adequately address the charge question, to be clear and logical, and to provide adequate support for the recommendations and conclusions made.

Charge Question 2. Goals and Methods.

p. 16, lines 26-27 and p. 17, lines 1-15. The discussion in this paragraph seems to relate to the concern expressed in the Letter and Executive Summary that the Draft Guidance is not likely to be very accessible to many “users” of model results who are not modelers. I think this is a serious concern and warrants fixing, e.g., to expand the use of illustrative examples in the Guidance, rather than merely clarifying how different audience members might use the Guidance.

p. 18, lines 6-20. The panel notes (and I agree) that while the Guidance could have been meant to apply to a wide variety of models, it seems to have been developed based

primarily on literature, experience, and prior recommendations for pollutant fate and transport models, as opposed to economic models or engineering process models. I think this point warrants further consideration and elaboration in the panel's review. Are the Best Practices identified in the Guidance appropriate or even applicable for models other than pollutant fate and transport models? Or put another way, would the Guidance be very different if other types of models had been more fully considered? The panel recommends that the Guidance "articulate the broad range of model types to which it is to apply" and "ensure that the guiding principles ... reflect this diversity of model types." However, I think it may be difficult to develop concise, comprehensive, and understandable guidance that covers the full breadth of models EPA employs. Would it make more sense to recommend that the Draft Guidance the panel reviewed be represented as applicable to a more limited range of models (e.g., pollutant fate and transport models and their close relatives), with separate guidance developed for other types of models, if necessary?

Charge Question 3. Graded Approach. I found this section of the report to adequately address the charge question, to be clear and logical, and to provide adequate support for the recommendations and conclusions made.

Charge Question 4. Advice for Decision-Makers.

p. 31, lines 16-17. I'm glad the panel identified "scenario uncertainty" as an important source of uncertainty in modeling that should be clearly identified in the Draft Guidance. But doesn't this particular source of uncertainty warrant further discussion by the panel and in the Draft Guidance? EPA's applications of models (including pollutant fate and transport models) are often made in forecast mode (e.g., using REMSAD to examine whether the Clean Air Interstate Rule will suffice to bring Pittsburgh into attainment with the PM NAAQS), where huge uncertainties are associated with future economic, regulatory, and physical conditions. Quantitative uncertainty analysis techniques that are tractable for model parameters and inputs developed for historical conditions, may not work well for "scenario uncertainties." Yet if these scenario uncertainties are significant, a complex and expensive QUA that focuses only on model input uncertainty would have little meaning for decision-makers. The panel suggests something along these lines on p. 39, lines 16-17, when it recommends that "the REM Guidance be clear on the types of model uncertainty that most QUA tools address." However, I think the point needs more explicit articulation and emphasis. Additionally, the panel might be able to significantly assist EPA by pointing the Agency to best practices for dealing with scenario uncertainty. My colleague, Roger Pielke, Jr., argues that a large part of the reason we academic modelers have had such a difficult time getting practitioners who have real decisions to make to utilize formal uncertainty analysis techniques is that often fail to address the most critical uncertainties in real-world decisions – those having to do with uncertainty in forecasts of socio-economic and technological trajectories.

p. 32, lines 2-7. I'm not sure what the panel means by the recommendation that the Guidance "advise modelers to begin model development or use only after they have obtained an awareness of how a decision maker plans to use the information on uncertainty that they will be providing." Is the point that modelers need to understand how uncertainty in model results factors into decisions about a particular issue, and take that into account in selecting or developing and applying a model? In any case, could the recommendation be phrased more directly?

Charge Question 5. Identification and Structure of Optimal Information. This section of the report is clear and adequately responds to the charge question.

5. Dr. Lauren Zeise:

This report is well done. The original charge questions to the SAB Panel were adequately addressed in the draft report. Overall, the draft report is well constructed, clear, logical, at just the right level of detail for the type of document reviewed, and the quality of the commentary is excellent. The conclusions drawn and recommendations made are supported in the draft report text.

Specific, mostly editorial comments

The letter makes the important point that the use of increasingly complex quantitative uncertainty analysis without a sophisticated framework for decision-making and communication may only make decision making more challenging. It then emphasizes the report's practical advice for guidance to the modeler, which is fitting for the SAB panel report. However, I wonder whether the letter would be the place to point out to the Administrator the need to develop risk management frameworks that might be better able to cope with the results of uncertainty analyses. The report takes the existing decision-making as a given, but perhaps the letter need not. In this transmission letter from the SAB chair and REM Panel chair the observation could be made that this appears to be an area where efforts are sorely needed.

The end of the Introduction to the Panel report needs a punch line to tie the REM report to the series of recommendations and bring the reader back to the issue at hand, the review of the REM report.

The Panel stresses the importance of post application audits and recommends the addition of a section of its own to model application. Alternative Figure 1 on page 14 shows the audit on the public policy process side, as part of a policy observation box, with an arrow leading into the problem identification and stakeholder boxes. While this is a bit of a contradiction with the text, it is a logical spot to refer to it. But it could have its own box on the Model Development and Application side of the figure, perhaps with a dashed arrow leading into it, with arrows going from it to model identification and development boxes, since there would be also be a significant science effort to the audit.

Regarding the discussion at the end of page 29, the panel takes as a given the current decision making framework and does not take on the issue that work on decision-making frameworks would enable better use of uncertainty information in decision-making. The panel report calls for communication between modelers and risk managers and stakeholders regarding how they view scientific uncertainty and would like to see expressed and that should help produce more effective uncertainty assessments. However, a general coordinated and formalized approach toward use of uncertainty information by decision makers seems needed, beyond the problem specific approach suggested by the Panel. This may be a bit beyond the scope of the Panel review though.

Letter, Page 2, line 3. would add "advocacy groups" and "general public" to the list, or use the groups named in the asterisk to Alternative Figure 1.

The Panel makes the important observation that the complexity of the optimal modeling framework depends on the problem specification and resource constraints and goes beyond Figure 2 in the REM report. The sentence on page 8 at lines 18-20 is a bit hard to take in. I think it may be better to italicize “for the problem and available resources” than “the best available, practicable science,” to emphasize the point being made.

Page 9, line 10. “encourages the document to urge” - wording a bit awkward

Page 11, lines 1-2. Suggest adding another sentence indicating the nature of the clarification is that the Panel is seeking.

Page 18, line 12. Suggest adding in “ecological” and perhaps “fate and transport” and take out “scientific” which is overly broad.

The report gives a fairly comprehensive treatment to model uncertainty. The advice on the other three sources of uncertainty listed on page 31 is more limited. Structural model uncertainty is addressed at different places in the Panel report. The Panel’s message/advice on treatment of structural model uncertainty in the REM report may be more effective if placed in a separate section.

In the Panel report, it probably would be better to define model (structure) uncertainty as something like “structural model uncertainty.” The term model uncertainty is being used to mean this but also the overall uncertainty, and perhaps in one place model input uncertainty.

Page 39, line 20, the word “necessarily” seems to be missing. Mismatches of observations and model simulation can signal problems in the modeling effort.

p. 25, lines 16-17. unclear if square bracket US EPA is a placeholder to remind writer to spell out a title.

6. Dr. Trudy Cameron:

It is desirable, to the extent possible, to require a standardized method for documenting and archiving the myriad different models used in formulating environmental policies. However, I am somewhat concerned that there will always be a percentage of models that cannot easily be shoe-horned into a standard format. Perhaps it would be sensible to allow for non-conforming models to be flagged as such and to permit variances from standard documentation protocols whenever the benefits from standardization do not seem to outweigh the costs. I have in mind the difficulty of adapting a protocol to an atypical model. For example, it is likely that the attributes that convey a conceptual description of an economic model might not correspond exactly to the attributes that convey a conceptual description of a model of fate and transport. Will there be an “escape clause” that permits sufficiently non-conforming models to be reported differently, if necessary? One can only waste so much energy forcing a square peg into a round hole.

Details:

The Glossary might be improved by including not just definitions of terms as they are used in the MKB, but explanations where these same terms have different meanings in particular disciplines, so that any potential confusion is cleared up when this is the case.

p.4, line 19: “meaningful” is never a very illuminating adjective. “...the allocation of sufficient resources...” would be better.

p. 6, line 10: “identify key areas [needing additional] study”

p. 6, line 15: What are these “[model]development and application skills”

p. 6, line 18: if models used now are not personal computer-based models, what are they? Supercomputer-based? Are mainframes still the rule? Unix workstations?

p. 8, line 16: Make it clear that there is a z-direction (if there is one).. Merely mentioning “... the x- and y-directions) in the uncertainty versus model complexity curve” is confusing.

p. 8, line 18: “...Panel believes that when a model[‘s] complexity is ...”

p. 8, line 21 “..whether the guidance [that has been] provided [does in fact aid] the modeler in finding...”

p. 9, line 11: Define QAPP in the text, the first time it is used. Readers who forget the definition after its first use can refer to a glossary.

p. 9, line 13: not just after the model[‘s] application.

p. 9, line 14: Why would crucial technical errors or omissions be difficult or impossible to rectify after the project is over? Is a model only ever presented as a fait accompli?

p. 9, line 23: The Alternative Figure 1 represent[s] the same general logic...

p. 10, line 7: there should probably be a hyphen in “model-based” as an adjective for decision making...

p. 10, line 14: most people mean “costs” when they refer to “economics.” Economists prefer to reserve the term “economics” as a shorthand for “the study of the allocation of scarce resources among competing end uses.” If you mean “costs,” use “costs.”

p. 10, line 26: “appropriate [temporal and spatial] scales, [user acceptance of the model], and very importantly, the degree of accuracy...”

p. 12, line 1: by “model calibration,” do you mean the same thing as “ground-truthing with empirical data” (as in using statistical techniques with data to estimate unknown parameters that may merely be given assumed values in other instances)?

p. 12, line 13: likewise, does “parameterization by calibration” mean “empirical estimation of model parameters”?

p. 12, line 23: by “post-auditing,” do you mean ex post validation via forecasting or backcasting of predicted values, achieved by estimating a model based on a subset of the data and using it to predict, out-of-sample, some realized outcomes that have actually already been observed?

p. 19, line 27: “the current terminology used to describe [“the] graded approach[”] needs to be clarified.

p. 20, line 24: The “or not” is rarely necessary. “It is unclear whether this is assumed to be part of the overall modeling project documentation.”

p. 22, line 16: “...be introduced earlier in the document[,] before the discussion of model development, as [an example of an] overarching [concept that is relevant to] all of the modeling stages.

p. 22, line 24: “...or that screening models are used[, where appropriate,] instead of more[-

]complex models.

p. 23, line 6: “i.e. what is the simplest [construct] to be considered as a [“model”] in the REM Draft Guidance... Models Knowledge [B]ase...”

p. 23, line 23: “This level of deeper model evaluation [would also] be appropriate when [attempting to transfer a model] to unique or extreme [circumstances, relative to those wherein it has previously been used.]

p. 24, line 8: “potentially litigious applications” sounds strange. How about “using models in applications where the results may be contested in a court of law.”

p. 24, line 20: “relative reduction factors and ensemble modeling” may not be terms that are globally familiar to all readers. As an econometrician, they are foreign to me.

p. 24, line 26: by “its ability to replicate historical situations” do you mean “within-sample predictive validity”? Or do you mean out-of-sample “backcasting”?

p. 26, line 7: “Just because individual modeling components are behaving properly does not necessarily mean that the full system will provide authentic overall analyses.” Perhaps use “Just because the separate components that can be linked together to form an overall model each seem to be performing properly does not necessarily mean that the overall model will make reliable predictions.”

p. 26, line 8: perhaps use “countervailing errors”

p. 26, line 17: perhaps use “can be mutually offsetting” rather than “can counterbalance each other”

p. 26, line 20: “[However,] the fundamental flaws in the model[‘s] formulation [may cause it] to respond incorrectly to [other simultaneous] changes in the inputs...”

p. 29, line 20: “...and are not intended as a substitute for the [sometimes] hard task of selecting the ‘right’ answer. [A degree of regulatory discretion may still be required.]

p. 30, line 12: “To [some stakeholders,] expressions of uncertainty can be [interpreted] as an indication that experts “don’t know.”

p. 30, line 26-27: Is uncertainty defined as the degree of statistical precision in the estimated model parameters (embodied in the parameter variance-covariance matrix)?

Sensitivity analysis seems to concern things such as the selection of a functional form for the model. However, what is meant by “model factors”? This term is unfamiliar to me.

p. 31, line 20: Do “implications” surround things? Perhaps you could just say “propagation of uncertainties in each component through a set of linked models” (since linked models have been introduced previously).

p. 31, line 24: “too[-]brief advice”

p. 31, line 26: How do you “perform a problem formulation”? Perhaps just “Much more emphasis must be placed on robust and iterative problem formulation. This process must involve modelers, decision-makers, and stakeholders. More emphasis must also be placed upon accurately conveying model results using non-technical (and often non-quantitative) language that is fully accessible to all interested parties.”

p. 33, line 10: “...thereby identifying the uncertainties that [may] matter.”

p. 34, lines 9-12: There is duplication of the sentence beginning “It would be very useful to have a “Box” example. The two versions have different endings, so it is not clear which one was intended to be employed.

p. 35, line 16 “Bay[e]sian”

p. 36, lines 16 and 20: “proscriptive” means “specifically forbidden”, or something to that effect. I believe you intend to use “prescriptive”?

p. 36, line 18: “e.g. [for a] modeler within the regulatory community...”

p. 36, line 23+: “For example[,] the Panel is aware of the extensive uncertainty analysis While it is clear that this one example should not be taken to [define a universal standard for] QUA, the MKB would provide....such examples with [each instance described by] the

nature of the QUA,.... This would provide at least some [prototypes] that model users and decision makers could [consider () beyond the cited statistical references]).

p. 37, line 4: The appeal of QUA is that it can be used to provide quantitative estimates of the “degree of confidence” [to be placed in] model results [when they are used] as a component of regulatory decisions. Nevertheless, [QUA] results should be presented with some caution. It might be tempting [to attribute] a high degree of confidence [to an] uncertainty analysis [if it is a] highly elaborate or complex analysis. [However,] the validity of the QUA is of course dependent on the quantity and quality of the information [employed in] the analysis. The choice of [an] appropriate QUA method....effort to conduct [] various types of QUA. As compared to the REM....., the guidelines [for QUA] do not contain a similar set of “best practices” [concerning how to evaluate, present, and incorporate] model uncertainty [into] decision-making.

p. 37, line 17: ...recommendations [] to provide a model-user/decision-maker...

p. 37, lines 26-28: This is too hard to understand. I am not persuaded that massaging the data can “avoid or cancel out systematic biases in the model formulation”. What is meant by the distinction between “observed (measured) conditions” and “absolute predictions”.

p. 37, line 28: “A third [possible] approach [for] dealing with uncertainty is [to use] “ensemble modeling”...” Given the quotations around “ensemble modeling,” it seems that this is intended to be the initial description of these methods. However, the subject was already mentioned on page 24, without a definition. The order of these events should thus probably be changed.

p. 38, line 2: When you refer to a “composite” of the results, is this actually some sort of meta-analysis of the range of possible predictions across the range of possible models?

p. 38, line 4: “... [may be] worth considering for applications or decisions involving extreme cost [or the reduction of very large] risks.” Do you actually mean that they should be used when the benefits do not so vastly exceed the costs that the choice is a no-brainer, even if benefits and costs are inaccurately measured? Or are you thinking only about the types of regulations that involve a safety standard (as defined by current science) and the only question is how to achieve this designated standard at the lowest cost to society?

p. 38, line 4: “These [candidate] approaches could be included, among others [as part of] the REM Guidance to provide decision-makers [with some] practical examples of methods [for] incorporating uncertainty in the decision framework.

p. 38, line 12: “...to the decision-maker (and [to the] public/stakeholders).should [probably include] a range of [illustrative] examples []. Again the MKB may be useful as an [archive for] such examples.

p. 38, line 17: As the analyst/modeler and [the] decision[-]maker are usually not the same individual, it is important [that any results should be accompanied by] the key assumptions and caveats [embodied] in the analysis.

p. 38, line 21-22: “activities that [may] be most beneficial ...[it is] of the [the case that] only a relatively small subset of inputs is responsible for a majority of the variance in a model[‘s] output.

p. 38, line 25: “Broader approaches [to] risk communication....”

p. 39, line 9: “uncertainties arise as a result of [the models] that produced the data...”

p. 39, lines 10-11: “...of comparing environmental data (collected at a particular point in time and space) to a model prediction based on...”

p. 39, line 22: “...concept to decision-makers who may [be inclined to discredit] modeling results if the comparisons between observations and [model predictions] are less than perfect.”

p. 39, line 26: “In some cases[,] these uncertainties [may actually] be more significant than the uncertainties [introduced by] the modeling itself.

p. 41, line 21: "...and basic [instructions] for obtaining and using the model."

p. 42, line 7: "The information [solicited] in the current data entry sheet [covers] most of the critical elements..."

p. 42, line 10: "...subcategories of information should [probably] be added to the data entry sheet."

p. 42, line 14: "1. Model Name [and Acronym]"

p. 42, line 16: "3. Contact Information [for Model Custodian]"

p. 43, line 10: "access, download, and use [an already-compiled and] executable version of the model."

p. 43, line 12: "...must be obtained or licensed [to permit] use of the model."

p. 43, line 15: "section of the data entry [process], the Panel believes..."

p. 42, line 21: "...explicitly ask for this information as [a specific item in] the data entry sheet.

p. 45, line 1: "... that were identified [during] these evaluations should be reported..."

p. 45, lines 4-5: "...Benchmarking studies in which the model's predictions and/or its accuracy are compared with [those/that of] other models."

p. 45, line 12: This seems an odd use of the term "criteria." Do you mean "characteristics"?

p. 45, line 23: "...not appropriate for models that address economic activity, behavior, and emissions [outputs]." What kind of "behavior" is implied in this statement? Do you mean the behavior of households, or firms? Do you mean adaptation by firms in the face of changing relative prices as a result of regulation (e.g. input substitution)? By models that "address" economic activity, do you mean computable general equilibrium (CGE) models that capture not only the initial impact of regulations, but also the subsequent rounds of effects as changes are propagated through markets that are interconnected?

p. 46, line 8: Is the intention in this passage to encourage a data-entry format that invites model proprietors to be ambitious in defining the broadest possible "market" for their models.

p. 46, line 21: due to concerns regarding [threats to "drinking water quality at the tap"] from accidental contamination [(e.g. the Walkerton incident in Canada) or terrorist activity (e.g. Homeland Security)...].

p. 47, line 23: "and [should direct] site users to specific examples.... In the public record and[or in] the peer-reviewed scientific literature.

p. 48, line 18: ...could reconstruct and rerun that [same] version of the model at a later time...

p. 48, line 27: The form might provide fields for "supercedes X," with a link to that older version of the model.

p. 51, line 26: "useful advice", rather than "useful advise"

p. 52, line 7: "...for the documentation effort [] very few of the terms in the Data Dictionary [are] repeated there...."

p. 53, lines 6-9: This last sentence seems really awkward. Perhaps it could be two sentences. It runs on.

p. 53, lines 13, 16: Rather than using the word "bias" which also denotes a very specific statistical concept, would it be possible to use the notion of "apparent advocacy"?

p. 24, line 24: Has the term "preconceptual bias" been invented at this point in the review document? Or is it standard usage in some discipline other than those with which I am familiar? Just as Amazon.com offers reader reviews and ratings, along with some information about the experience of the reviewer (I believe), this database could also offer opinions about models. If the name of the reviewer is not given, perhaps just some identifying information about job category and professional experience could be elicited to

accompany the opinion.

p. 59, line 23: “As a result, [it is difficult to obtain (from this tool alone) a] sufficient level of detail about scales of data used and assumptions made during the formulation of any specific model in the MKB.

p. 61, line 6: “developed their own [clearinghouse] for models”

p. 61, line 14: “developing common model documentation [protocols]...”

p. 61, line 25-26: “may be necessary for the Agency to provide additional [incentives (or penalties)] as part of their plan to encourage w3hat is currently a voluntary effort by modelers to put their [models] in the MKB.

p. 62, line 3: Perhaps the job would be better described as that of an “archivist” rather than a librarian.

p. 63, line 12: “The level of detail [about what?] provided by each model....”

p. 63, line 24: “was not identified with the [keyword] search using the phrase....”

p. 64, line 28: “[However, a real understanding about] how a given model works and what are its specific strengths and weaknesses would appear to require....

p. 65, line 4: “return link from [the] exit disclaimer page [actually sends] the user to the [keyword] search page.”

p. 65, lines 6-8: [Perhaps these navigational inefficiencies are merely an artifact of the somewhat bewildering array of models and their varying characteristics.]”

p. 65, line 24: [The MKB currently limits contact information to that for a single responsible individual. It does not provide any suggested format for comments. Neither does it provide for open dialogue or discussion of different users’ modeling experiences.] This seriously limits the Agency’s ability to adapt the MKB and improve its utility {Why?} The lack of an open forum also limits [opportunities for] model developers [to take advantage of feedback from model users...]

p. 66, line 11: “...and as such should clearly follow the [principles established] in the Guidance on Environmental Models.”

p. 66, line 14: “If such a model selection tool is developed, it will likely be used early in the life of a project. [At this stage, it would be difficult to identify specific needs or to assess the tradeoffs among these different needs in a way that would facilitate a ranking of models.]”

Incomplete references are noted in the document. I assume that these will be supplied.

p. 73, lines 20-23: This is too jargon-laden. What are “process issues”? What is “kinetic resolution”? “...should take/assume a secondary posture”? What is a secondary posture? Perhaps it would be best to describe “first-order problems/issues” and “second-order problems/issues” (or something to that effect).

p. 79, line 22: “how model results have [fared] in actual decision-making.”

p. 80, line 11: “considered to be preferred or acceptable alternatives to preferred models?” This needs to be fixed. It makes no sense this way.

p. 80, line 15: “beyond its scope” {beyond the scope of what?}

p. 80, line 24: “As indicated in the [Panel’s] Report...”

p. 81, line 6: “The top page of [the] CALPUFF model developer’s website....” Do websites have top pages, or main pages?

p. 82, line 16: “Guideline[s] on Air Quality Models” ?

p. 82, line 30: “...is intended for use on [geographical] scales from tens of meters[, to hundreds

of kilometers,] from a source. However, it does not mention....”

p. 83, line 1: "...a simulation range that does not include important short-term phenomena..."

{Is an accidental spill always a short-term phenomenon?}

p. 83, line 5: "As indicated in the Panel's report, especially important information [about models] that should be [archived] in the MKB includes (i)..."

...past evaluation[] (especially cross-evaluation) studies... [more-detailed] and [more-consistent] information needs to be included in the MKB. {Or, do you mean more exactly conformable information?}

p. 83, line 14: The role of the EPA as the "model contact" is not clear for the feedback forum.

{What does this mean?} The appropriate or desired role of the model contact[,] as either an

internal (Agency) or external (public) interface for the model[,] should be made clear....

{I'm

not sure what this means.}

p. 83, lines 24-26: "it is not unusual for busy modelers to get phone calls from graduate students

wanting help running complex environmental models for thesis projects." {What are we to impute about the relative social values of the time of the "busy modelers" and the

"graduate

students"? Is this a presumption that graduate theses represent ventures with no redeeming

social value?} This passage suggests that model developers are not responsible for

explaining

their models (at least somewhere) at a level that can be understood by graduate students.

Even if

modelers are "busy," some of them enjoying public funding in order to develop their

models. In

these circumstances, especially, there is some obligation to create a useful product that can be

readily understood by others with adequate training or experience.

p. 84, line 1: "The [write-up] on [the] IPM..."

...This is sufficient as long as the appropriate items are covered [in] sufficient depth.

... Page 2-5 of the IPM Model Documentation begins a section....is determined). This section could be simplified and incorporated into the MKB to {bring the reader one level further down in detail} {What does this last bit mean? Could it be expressed differently?}

p. 84, line 24: Why does the fact that IPM is entrenched in the Air Office imply that it would be "unlikely to attract 'new model developers'"? How is 'new model developer' defined?

p. 84, line 31: "A high[ly] spatially resolved model..."

p. 85, line 9: What is meant by "time step." Does this mean "degree of time disaggregation" or "periodicity of the time-series information"?

p. 85, line 17: "...outside the scope [of what?]."

p. 85, lines 20-22: [However, two aspects of the documentation of the IPM are currently inadequate: (a) there should be a better forum for feedback concerning uses of the model outside

Agency applications, and (b) there should be a better way to collect suggestions from external users for updating or improving the structure of the model.]

p. 86, line 4: "...very helpful [if one goal is to eliminate duplication of effort. Processes represented in the model are well-documented] in the MKB and the associated ..."

p. 86, line 16: "...limitations [on] the [model's] use [as a consequence of] these assumptions...."

p. 87, line 13: "...describing the [model's] conceptual basis..."

p. 88, line 13: Is the "Scientific Editor" envisioned as being the same person as the "Librarian" mentioned earlier (or the "Archivist" I suggested above)? Are resources available to have multiple specialists minding the MKB?

p. 88, line 24: If there are vast numbers of accesses to a particular model description in the MKB, this may indeed serve as an incentive for the model's proprietors to update the information in the MKB. However, if there are only a few accesses, this information may serve as a disincentive. Perhaps if accesses are lower than some threshold, this information is not very helpful to the goal of encouraging regular updating.

p. 88, line 28: "The user community may provide a very effective policing mechanism to maintain model quality, especially when money is at stake." {Please elaborate a little. Whose money is at stake? Are costs to be borne by the user community? By the public (consumers, workers, investors)? If self-policing is to be relied upon, it is necessary to determine who gains, and how much, by this policing, as well as who bears the costs of this policing.

p. 89, lines 3-4: The report should tread very cautiously in suggesting that the MKB should be privatized. This is a public good that has value to individual users, but this value is probably not commensurate with the fixed costs of maintaining the whole MKB system. This is why public goods, in general, are sources of market failure. Even a "non-profit organization" does not necessarily have a sufficient incentive to provide public goods.

B. OTHER BOARD MEMBER COMMENTS:

Dr. Myrick Freeman:

I have read the Draft SAB Panel Report on on the agency's Draft Guidance. In my judgment, the answers to the three charge questions for reviewers are "Yes, Yes, and Yes."

I did note three minor editorial changes:

p. 5, line 23-4: the reference to 2 1/2 decades, apparently since 1989. By my count this would be 1 1/2 decades.

p. 34, line 8: I think "distribution" should be singular.

p. 37, line 24: "is to use of the ..." should be either "is the use of ..." or "is to use the ..."

Dr. James Johnson:

My biggest concern of the report is that the introduction section leaves the reader hanging. At a minimum it should include the footnote on page 1.

The second concern is the use of calibration in the text and corroboration in alternate figure 2.

Dr. Cathy Kling:

I've read the review panels report on the "Draft Guidance on the Development, Evaluation, and application for Regulatory Environmental Models and MKB." This is a very well done review. It is clear and comprehensive.

I have a single comment that the committee is welcome to take or leave:

I found the commentary in the introduction section entitled "Background Material" to be odd and somewhat out of place. It read to me as complementing the agency on taking the advice of the SAB, and of being self-congratulatory about the importance and impact of the SAB's previous work (the material about the EEC's Modeling Resolution). I'm not sure what connection there is between this section and the remainder of the report.

Again, I think the overall report is very well done. I especially like the material concerning the treatment of uncertainty and the role of models in decision making.

Dr. Granger Morgan:

Overall the review looks to me to be in very good shape.

I am concerned that the current discussion in the review suggests that whether and to what extent a model should incorporate an analysis and treatment of uncertainty should be entirely driven by the analytical sophistication of the decision makers and the extent to which the current regulatory decision framework allows for a consideration of uncertainty. While I certainly agree that these factors should be a consideration in the choice of the level and nature of the treatment of uncertainty that is undertaken, I do not believe that they should completely dominate.

If a problem involves considerable uncertainty it should not be completely ignored or suppressed simply because decision makers are not sophisticated in thinking about uncertainty, or will be bothered to learn that there is uncertainty. Such suppression is a recipe to keep naive decision makers naive, and inadequate regulatory decision frameworks, inadequate. Followed strictly, such advice would slow, or perhaps even begin to reverse, the dramatic progress the Agency has made over the past three decades in thinking about and dealing with uncertainty.

Rather, I would like to see the discussion on pages 29 and 30 (and in the executive summary) reworked to indicate that while the level and sophistication of the treatment of uncertainty should be appropriately matched to the problem at hand, and to the way the results will be used, whenever uncertainty is an important element in a problem, it should at a minimum be acknowledged and receive some basic quantitative analytical treatment. I do very much agree that analytical sophistication for its own sake should be avoided.

I like the distinction that is drawn between different kinds of uncertainty on page 31 of the SAB draft review. To my quick reading of the EPA document itself, I did not see any serious discussion of what to do about "model (structure) uncertainty." I urge the review panel to suggest that some discussion of this topic be included in the EPA document. In many cases, this source of uncertainty swamps all others, and yet is not considered or discussed, even in qualitative terms.

Finally, I ask the review committee to take another look at Figure C.5.1. The pie diagram does not make sense to me given the shape of the response surface shown. Also, it looks to me like the orientation of the plane in Figure C.5.2 should be rotated to correspond to the slope of the response surface. At the moment it is not properly aligned, making it very hard for a reader who does not already understand, to figure out what is intended.

Dr. Kathleen Segerson:

I have only very small comments on the draft SAB Panel Report: (1) The Introduction provides background information on the Modeling Resolution, but doesn't explicitly link that effort to the current efforts under review. I suspect that the current effort grew out of the recommendations on p. 6, but that is not stated explicitly. Providing some context linking the two efforts would be helpful.

(2) I particularly applaud the report's discussion of uncertainty, including the need to identify how the information about uncertainty will be used and the distinction between sensitivity analysis and uncertainty analysis. A small comment on this latter issue: on p. 32, lines 25-26, the report states that "the discussion in Section C.5.5 relating to Monte Carlo analysis currently reads more like a discussion of uncertainty analysis, rather than sensitivity analysis." Perhaps this statement needs more explanation, since many economists (myself included) view Monte Carlo analysis as a form of uncertainty analysis.

(3) The report notes in several places that the criteria and discussion included in the EPA draft documents seem to focus on models for pollution fate and transport and exposure. It notes the need to consider other models, such as economic models designed to predict behavior and the resulting emissions or other environmental impacts. I would agree that the modeling guidance and knowledge base need to include these other types of models, which can be important in regulatory as well as other settings. I would add another category of models that might also be considered for inclusion, namely, ecological models. There is increasing interest in the ecological impacts of EPA actions (see the CVPESS work) and a need for ecological models (e.g., ecological production functions) that can predict, for example, how a given water quality change will affect a fish or insect population.

(4) I think the question of the selection criteria to be used in deciding what to include (or not include) in the MKB is key. The SAB Panel report notes the need to identify criteria (p. 63) but doesn't suggest what those criteria should be. Can the panel give EPA any advice on this?

(5) The Panel notes the need to provide incentives to encourage the voluntary effort by modelers to put their models in the MKB (p. 61). Does the Panel want to recommend that this be a requirement for models developed under EPA funding (e.g., STAR grants)?

(6) A minor editorial comment: In several places, the word "however" is used as a conjunction (synonymous with "but" in the middle of a sentence) rather than as an adverb (e.g., p. 2 line 21-22). I've always thought that this is not grammatically correct.

Dr. Deborah Swackhamer

1. Have the original charge questions to the SAB Panel been adequately addressed in the draft report? The Charge Questions have been addressed very well by the committee's report, and in fact in many cases they have gone beyond the Charge Questions (this isn't necessarily bad, just an observation).

Is the draft report clear and logical? The report is generally clear and logically organized. I found the Letter to the Administrator to be too long – it is the same length as the Exec Summary, and has the same tone, where in fact they should be oriented to different audiences. The Exec Summary would benefit from having a sentence or two that says that the Committee was asked to address 7 charge questions. The introduction would greatly benefit by telling the reader that there are 7 charge questions and that the report is organized to address each of them in subsequent chapters. The chapters themselves (esp 1-7) would benefit from having the recommendations summarized up front; there is a tendency for the report to meander.

4. Are the conclusions drawn and/or recommendations made by the panel supported by information in the body of the draft report? Absolutely. This is a very well done and thorough report. The recommendations and discussion are supportive of the overall effort, yet highly constructive. Each recommendation is fully discussed in the body of the report.

Dr. Valerie Thomas:

1. Where charge questions adequately addressed? Yes.

2. Is the draft report clear and logical? The Introduction of the Draft Report presents the 1989 SAB Modeling Resolution recommendations. However, there is no clear discussion of the extent to which the EPA has achieved these resolutions. Nor is there discussion of whether the current draft report is a reprise of that Resolution or is focusing on different issues. This makes the draft report unclear; it is difficult to find the logical connection between the Introduction and the rest of the report.

The connection needs to be made between the 1989 SAB Modeling Resolution, the resulting developments at EPA, and the current SAB review. The one small connecting link is on p. 9 lines 2-3: "the Panel finds that the Agency has been responsive to previous SAB advice on modeling practices." What does "the Agency has been responsive" mean? That the Agency followed all the recommendations? Some of them? Which ones? Or simply that the Agency responded to the Modeling Resolution with a letter or comments?

In at least some cases, the draft report goes farther than the 1989 Modeling Resolution. For example, recommendation 3 of the Modeling Resolution, on model validation (p. 6 line 6), does relate to the discussion of Model Post-Audit (p. 12) although the Post-Audit discussion addresses models of system change, which seems to be beyond what was considered in the 1989 Resolution.

It would be helpful to have a clearer statement of whether the EPA and the SAB have now moved beyond the recommendations of the 1989 Modeling Resolution, or whether EPA and SAB are still working to address those issues, or whether this draft report addresses a largely distinct set of modeling issues.

pp. 54-55. The discussion of "inclusion of additional information on model performance" (p. 54 line 20 - p. 55 line 5) is not clear. The meaning of p. 54 lines 2-4 is not at all clear; perhaps these paragraphs should be cut.

3. Are the conclusions and recommendations supported by information in the body of the draft report? The draft report states (p. 1, lines 19-22) that "the panel is concerned that the REM vision is not matched by a commensurate, and steady, allocation of resources on the part of the Agency. It is therefore recommended that the Agency provide a meaningful commitment of resources to the REM initiative." No information in the body of the draft report addresses the allocation of resources to the REM initiative. In Appendix C, there is the suggestion of the need for oversight and for a Scientific Editor, on p. 89, there is the suggestion that EPA might be better off turning the MKB over to the private sector. If this Appendix C discussion is the basis for the recommendation for more resources, it should be moved up into the main body of the draft report.

Dr. Robert Twiss:

I concur in the REM report (with deference to conclusions that might be raised in the call).