



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

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MEMORANDUM

SUBJECT: U.S. EPA Science Advisory Board (SAB) Regulatory Environmental Modeling (REM) Guidance Review Panel

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THRU: Daniel Fort */signed/*
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Director
EPA Science Advisory Board Staff Office (1400F)

This memorandum documents the process and the set of determinations used in forming the Science Advisory Board's (SAB) Regulatory Environmental Modeling (REM) Guidance Review Panel. It provides background information on the subject SAB activity and addresses:

- 1) the charge developed for the Panel;
- 2) the type of panel that will be used to conduct the review, the name of the panel, identification of the panel chair, and types of expertise needed to address the charge;
- 3) Identification of parties who are potentially interested in or may be affected by the topic to be reviewed;
- 4) How individuals were placed on the short list;
- 5) Conflict of Interest Considerations;
- 6) How will regulations concerning "appearance of lack of impartiality" under 5 C.F.R. 2635.502 and other ethics factors, apply to members of the Panel; and
- 7) How individuals were selected for the final Panel.

A. Background

The U.S. Environmental Protection Agency's (EPA's) Council for Regulatory Environmental Modeling (CREM) is requesting that the EPA's Science Advisory Board (SAB) provide a review on two EPA initiatives being coordinated by the CREM.

In February 2000, EPA's Administrator formally established the CREM to continue the initiatives toward building consensus and consistency in modeling efforts by the Agency.¹ In February 2003, the Administrator stated her expectations for the CREM to lead EPA in, among other things:

1. providing "guidance for the development, assessment, and use of environmental models," and
2. making "publicly accessible an inventory of EPA's most frequently used models, which will include information on a model's use, development, validation, and quality assessment.

It is with regard to these two items that the CREM is requesting the SAB's REM Review Panel for advice on the charge questions listed below to the Panel.

B. Determinations

- 1) The charge developed for the Panel: The SAB Staff Office, the staff on the CREM, the SAB Staff Office Director, and Chair of the Panel negotiated the following charge.

The CREM seeks SAB advice on the *Draft Guidance and Models Knowledge Base* pertaining to the following charge:

Draft Guidance on Environmental Models:

Charge Question 1: Has EPA sufficiently and appropriately identified the best practices, such that decisions based on models developed and used in accordance with these practices may be said to be based on the best available, practicable science?

Charge Question 2: Has EPA sufficiently and appropriately described the goals and methods, and in adequate detail, such that the guidance serves as a practical, relevant, and useful tool for model developers and users? If not, what else would you recommend to achieve these ends?

¹ U.S. EPA. *Framework for the Council on Regulatory Environmental Modeling*, 2000. Available at <http://www.epa.gov/crem/library/crem%20framework.htm>

Charge Question 3: Has EPA sufficiently and appropriately proposed a graded approach, such that users of the guidance can determine the appropriate level of evaluation for a particular model use. If there are deficiencies in the proposed approach, what would you recommend to correct it, and why?

Charge Question 4: Has EPA sufficiently and appropriately provided practicable advice for decision-makers who must deal with the uncertainty inherent in environmental models and their application? What additional advice should EPA consider in dealing with uncertainty, and why?

A number of researchers recommend a Bayesian approach to help decision-makers incorporate uncertainty into their decisions and to do so in a transparent fashion. Is the use of methods such as Bayesian networks an effective and practicable way for EPA decision-makers to incorporate uncertainty within their decisions and to communicate this uncertainty to stakeholders? If so, how? Are there alternative methods available?

Models Knowledge Base: The SAB previously recommended that the CREM coordinate EPA efforts to collaborate and seek input from model developers and users both inside and outside EPA. One mechanism to implement this collaboration is through a web-accessible knowledge base for environmental models. EPA has developed such a knowledge base to communicate more clearly the data, algorithms, assumptions, and uncertainties underlying each model; to facilitate the use of individual models or the combined use of multiple models; and to enable developers and analysts to more easily identify information needs.

Charge Question 5: The Panel should consider that environmental models will be used by people whose technical sophistication will vary widely. EPA has therefore attempted to cull information about models that broadly serve the needs of all users, using a data template to collect this information. Has EPA identified, structured and developed the optimal set of information to request from model developers and users, i.e., the amount of information that best minimizes the burden on information providers while maximizing the utility derived from the information?

Charge Question 6: EPA has developed a data dictionary and database structure to organize the information it has collected on environmental models. Has EPA provided the appropriate nomenclature needed to elicit specific information from model developers that will allow broad intercomparisons of model performance and application without bias toward a particular field or discipline?

Charge Question 7: To facilitate review for this particular charge question, the panel should focus on three models that represent the diversity of model information housed within the Models Knowledge Base. These models are: (1) *Aquatox*, a water quality model with information found at http://cfpub.epa.gov/crem/crem_report.cfm?deid=74876; (2) *Integrated Planning Model*, a model to estimate air emissions from electric utilities, with information found at http://cfpub.epa.gov/crem/crem_report.cfm?deid=74919; and NWPCAM, an economic model with information at http://cfpub.epa.gov/crem/crem_report.cfm?deid=74918.

Using these three models as examples and emphasizing that EPA is not seeking a review of the individual models, but rather the quality of the information provided about the models, EPA poses the following questions to the Panel. Through the development of this knowledge base, has EPA succeeded in providing:

(7a) Easily accessible resource material for new model developers that will help to eliminate duplication in efforts among the offices/regions where there is overlap in the modeling efforts and sometimes communication is limited?

(7b) Details of the temporal and spatial scales of data used to construct each model as well as endogenous assumptions made during model formulation such that users may evaluate their utility in combination with other models and so that propagation of error due to differences in data resolution can be addressed?

(7c) Examples of "successful" models (e.g., widely applied, have been tested, peer reviewed etc.)?

(7d) A forum for feedback on model uses outside Agency applications and external suggestion for updating/improving model structure?

2) Type of panel that will be used to conduct the review, the name of the panel, identification of the panel chair, and types of expertise needed to address the charge:

The SAB will conduct this review by forming a new panel with expertise in a number of specific modeling areas, and focused on being responsive to the charge questions as listed above. The REM Guidance Review Panel requires a panel composition with broad expertise in model development, use, evaluation and application to address additional aspects of the charge questions. Dr. Thomas L. Theis, a member of the chartered SAB, will chair this review panel. A *Federal Register* notice was published on August 6, 2003 (Volume 68, Number 151, Pages 46602-46604) requesting public nominations for this Panel. The types of expertise and experience in modeling activities sought in the *Federal Register* notice included the following: a) hazardous waste, b) atmospheric transport, transformation and removal, c) groundwater hydrology, d) water quality, e) indoor air, f) multi-media environmental fate and transport, g) environmental management, h) terrestrial and aquatic ecology, i) epidemiology, j) public health, k) sensitivity analysis, l) uncertainty analysis, m) exposure and risk assessment, n) environmental law, o) decision analysis, p) economics, q) computer sciences, r) spatial modeling, s) model documentation, t) nomenclature for environmental models, u) statistics, and v) information quality guidelines, data quality, and quality assurance procedures.

3) Identification of parties who are potentially interested in or may be affected by the topic to be reviewed:

The REM Guidance Review Panel will potentially provide modelers, model users, managers, regulators and environmental decision-makers with information and advice on proper modeling practices. The REM Guidance Review Panel will also potentially provide model developers, users, managers and regulators, as well as a broad swath of decision-makers with information that may be used to illustrate changes necessary to improve modeling practices in a wide variety of disciplines and applications. Interested and affected parties will be: 1) federal, state, and local government agencies, elected officials, and non-government organizations that focus on development, use and application of models for environmental decision-making and policy development (e.g., a variety of federal, state, and local government, environmental, professional, and trade associations, such as the U.S. Department of Energy (DOE), the U.S. Environmental Protection Agency (EPA), the National Institutes of Health (NIH), the Agency for Toxic Substance Disease and Registry (ATSDR), the Environmental Defense (ED - Formerly referred to as the Environmental Defense Fund - EDF), the Natural Resources Defense Council (NRDC), the Sierra Club, the American Society of Civil Engineers (ASCE), the Society for Environmental Toxicology and Chemistry (SETAC), the Electric Power Research Institute (EPRI), the American Chemistry Council (ACC), the American Water Works Association (AWWA), the Water Environment Federation (WEF) and many others who use, develop or in any way rely upon model applications for research, and decision-making, and 2) those involved with the interests of industries and governments that may be affected by policies developed on the basis of analyses conducted using the modeling principles espoused in the guidance or in the advice provided by the Panel. Academic researchers involved with modeling activities will also be interested in this topic. Within EPA, the Agency's Regional Offices may also be interested in the use and application of the modeling principles to guide them on their modeling activities and practices.

4) How individuals were placed on the short list:

Sixty-eight (68) individuals were nominated as candidates for consideration to the REM Guidance Review Panel. On the basis of the candidates' qualifications and availability to participate in the review meeting, the SAB Staff Office identified thirty-five (35) candidates on the "short list." On August 19, 2004 and October 14, 2004, the SAB Staff Office posted notices on the SAB Web site inviting public comments on the "short list" of thirty-five (35) prospective candidates to serve on the REM Guidance Review Panel.

The notice on the Web site stated that the Staff Office would welcome any information, analysis or documentation that the SAB Staff Office should consider in evaluating the candidates on the "Short List", and asked that any advice, observations or comments which would be helpful in selecting the final candidates be provided to the SAB Staff. Comments were received on prospective candidates from four different commenters, representing four different organizational interests on the first posting. *The SAB Staff Office received comments from four commenters (See Attachment #1) on the first posting of the "short list" candidates for the REM*

Guidance Review Panel, but no comments on the second posting.

5) Conflict of Interest Considerations:

For Financial Conflict of Interest (COI) issues, the basic 18 U.S.C. 208 provision states that: “An employee is prohibited from participating *personally and substantially* in an official capacity in any *particular matter* in which he, to his knowledge, or any person whose interests are imputed to him under this statute has a *financial interest*, if the particular matter will have a direct and predictable effect on that interest [emphasis added].” For a conflict of interest to be present, all elements in the above provision must be present. If an element is missing the issue does not involve a formal conflict of interest; however, the general provisions in the appearance of impartiality guidelines must still apply and need to be considered.

Does the charge involve a Particular Matter?

A “particular matter” refers to matters that “...will involve deliberation, decision, or action that is focused upon the interests of specific people, or a discrete and identifiable class of people.” It does not refer to “...consideration or adoption of broad policy options directed to the interests of a large and diverse group of people.” [5 C.F.R. 2640.103 (a)(1)]

The SAB panel’s activity in addressing the *Draft Guidance on the Development, Evaluation, and Application of Regulatory Environmental Models*, and the *Models Knowledge Base* or other background materials pertaining to the charge does not constitute a particular matter in that it does not include matters that involve deliberation, decision or action that is focused upon the interest of specific people or a discrete and identifiable class of persons. The SAB Panel’s activity does not include matters which involve formal parties or extend to legislation or policy making that is narrowly focused upon the interest of a discrete and identifiable class of persons. The REM Guidance Review Panel will provide advice pertaining to broad modeling principles and applications to identify proper and recommended practices in the broad area of modeling to support regulatory decision-making and research and development applications. The REM Guidance Review Panel will provide model developers, model users, regulators, and a wide variety of decision-makers with information that may be used to apply sound fundamental modeling principles and practices toward sound environmental decision-making applications. As such, the advisory panel will consider matters that are directed to the interests of a large and diverse group of people. Thus, the criteria for particular matter concerning specific parties is not met and no financial conflict of interest as defined in 18 USC 208 exists.

6) How will regulations concerning “appearance of lack of impartiality” under 5 C.F.R. 2635.502 and other ethics factors, apply to members of the Panel:

The Code of Federal Regulations [5 C.F.R. 2635.502(a)] states that: “Where an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his household, or knows that a person with whom he has a covered relationship is or represents a party to such matter, and where the person determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter, the employee should not participate in the matter unless he has informed the agency designee of the appearance problem and received authorization from the agency designee.” Further, 5 C.F.R. 2635.502(a)(2) states that, “An employee who is concerned that circumstances other than those specifically described in this section would raise a question regarding his impartiality should use the process described in this section to determine whether he should or should not participate in a particular matter.”

As noted above, the SAB panel’s activity in addressing the REM Guidance Review Panel charge does not constitute a particular matter. There may be some individuals nominated to serve on this panel who have in place, or are applying for, EPA grants, cooperative agreements and contracts broadly related to the underlying methods and practices in the modeling area. Cooperative agreements and contracts may present a different situation and each member was evaluated to determine whether his or her financial interest in existing cooperative agreements and contracts constitutes an “appearance of a lack of impartiality” as defined under 5 C.F.R. 2635.502.

Candidates were evaluated for potential ethics issues using information submitted by each panel member through the EPA 3110-48 form (Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency) and other staff research. To further ascertain whether there was any potentially disqualifying involvement with the topic of the REM Guidance Review Panel activity, which would indicate the appearance of a lack of impartiality, the following five (5) questions were posed to all candidates for the REM Guidance Review Panel activity:

- a) Do you know of any reason that you might be unable to provide impartial advice on the matter to come before the Panel or any reason that your impartiality in the matter might be questioned?
- b) Have you had any previous involvement with the issue(s) or document(s) under consideration, including authorship, collaboration with the authors, or previous peer review functions? If so, please identify those activities.
- c) Have you served on previous advisory panels or committees that have addressed the topic under consideration/ If so, please identify those activities.
- d) Have you made any public statements (written or oral) on the issue? If so, please identify those statements.

e) Have you made any public statements that would indicate to an observer that you have taken a position on the issue under consideration? If so, please identify those statements.

As a result of a review of the EPA Form 3110-48 and the responses to the above (5) questions provided by each prospective REM Guidance Review Panel member, the REM Guidance Review Panel DFO and SAB Ethics and FACA Policy Officer, with the approval of the SAB's Deputy Ethics Official, have determined that there is no appearance of a lack of impartiality on the part of the selectees for the REM Guidance Review Panel.

7) How individuals were selected for the final Panel:

The SAB Staff Office Director - in consultation with the REM Guidance Review Panel Chair - makes the final decision about who serves on the Review Panel during the "Panel Selection" phase. Selection criteria for Panel membership included: scientific and technical credentials and expertise, experience in working with advisory groups, willingness to serve on the Panel, availability to meet during the proposed time, absence of conflicts of interest, absence of appearance of bias and impartiality, and the need to maintain a balance of scientific expertise and scientific view points. Selectees for the REM Guidance Review Panel have backgrounds that include experience with academia, government, research laboratories, and consultant groups.

Accordingly, based on the above specified criteria the membership of the REM Guidance Review Panel includes the following seventeen experts:

1. Dr. Thomas L. Theis, University of Illinois at Chicago (IL) (Chair)
2. Dr. Linfield C. Brown, Tufts University (MA)
3. Dr. Joseph DePinto, Limno-Tech, Inc. (MI)
4. Dr. Panos Georgopoulos, UMDNJ - Robert Wood Johnson Medical School (NJ)
5. Dr. Steven Heeringa, University of Michigan (MI)
6. Dr. Bruce K. Hope, Oregon Department of Environmental Quality (OR)
7. Dr. Alan J. Krupnick, Resources for the Future, Washington (DC)
8. Dr. Randy L. Maddalena, Lawrence Berkeley National Laboratory (CA)
9. Dr. June Fabryka-Martin, Los Alamos National Laboratory (NM)
10. Mr. David Merrill, Gradient Corporation (MA)
11. Dr. Paulette Middleton, Panorama Pathways, Boulder, Colorado (CO)
12. Dr. Mitchell J. Small, Carnegie Mellon University, Pittsburgh (PA)
13. Dr. Douglas G. Smith, ENSR International, Inc., Westford (MA)
14. Dr. James H. Smith, Texas Commission on Environmental Quality (TX)
15. Dr. Richard L. Wetzel, Institute of Marine Sciences, College of William & Mary, Gloucester Point (VA)
16. Dr. Peter Wilcoxon, Syracuse University (NY)

Concurred,

/signed/

Jan. 25, 2005

Vanessa Vu, Ph.D.
Director
EPA Science Advisory Board Staff Office (1400F)

Date

Attachment 1 - Commenters to the Short List

- 1) Mr. Merrill Goozner, Director, Integrity in Science Project, Center for Science in the Public Interest
- 2) Ms. Vickie Patton, Senior Attorney, Environmental Defense
- 3) Mr. David C. Schanbacher, P.E., Chief Engineer, Texas Commission on Environmental Quality
- 4) Dr. Mary L. White, Acting Deputy Office Director, US EPA Region 5, Office of Strategic Environmental Analysis, Chicago, IL