

June 1, 1999

EPA-SAB-EC-ADV-99-009

Honorable Carol M. Browner  
Administrator  
U.S. Environmental Protection Agency  
401 M Street, SW  
Washington, DC 20460

Subject: Advisory on the Charter for the Council on Regulatory Environmental Modeling (CREM)

Dear Ms. Browner:

The Environmental Models Subcommittee (EMS), hereinafter referred to as the "Subcommittee", met February 23 and 24, 1999, to review the draft "Proposed Charter, Council on Regulatory Environmental Modeling", in a public meeting in Washington, DC. The Subcommittee concluded that the draft charter provides adequate and appropriate guidance to help the Agency develop, apply, evaluate and improve, scientifically-based and defensible models of high quality. The Subcommittee also felt that the proposed CREM charter should help the Agency communicate its activities to the public, and it made recommendations for improving the CREM charter.

Further, the Subcommittee supports EPA's proposal to establish the Council on Regulatory Environmental Modeling (CREM) for the explicit purpose of enhancing the scientific defensibility of environmental models and also to promote consistency in the development, use and improvement of models as well as to communicate these activities to the public. The Subcommittee is unanimous that an entity like the CREM is long overdue and encourages the Agency to proceed quickly to implementation. Given the past difficulty within EPA of establishing Agency-wide guidance for model development and use (e.g., the Agency Task Force on Environmental Regulatory Modeling - ATFERM), the Subcommittee strongly urges EPA senior management to establish CREM and support its charter.

This recommendation is consistent with past SAB recommendations and continuing concerns. The SAB has been actively advising the Agency on the use of models in environmental protection for many years dating back to 1989 (SAB, 1989).

The Board recommended that:

- a) EPA establish a general model validation protocol, provide sufficient resources to test and evaluate models with appropriate field and laboratory data, and

- b) EPA form an Agency-wide task-group to assess and guide model use by EPA

We note that the Agency then set up the Agency Task Force on Environmental Regulatory Modeling (ATFERM) in 1992 and that in the resulting report (EPA, 1994 ) ATFERM concluded that the Agency had no formal mechanism to evaluate model acceptability and that a comprehensive set of criteria for model selection was needed to reduce inconsistency in the use of models by the EPA. If implemented this would also ease the burden on the Regions and States who apply the models in their programs. The SAB reviewed the ATFERM report and supported the generic approach to conducting peer review of environmental regulatory modeling, noting that the “most important element to the review process is the verification of the model against available data in the range of conditions of interest” with a discussion of compensating errors and suggesting that guidance be provided concerning adequate model performance (SAB, 1993). The ATFERM report contained acceptability criteria deemed adequate by the SAB. ATFERM also prepared “Agency Guidance for Conducting External Peer Review of Environmental Regulatory Modeling” in 1994 (EPA, 1994) for use across EPA, but the approach was not implemented within the Agency. The SAB therefore urged the Agency to move forward in consolidating its gains in modeling (SAB, 1995). In part as a result of this urging, the Agency conducted the Models 2000 Conference in Athens, GA in December 1997. This conference led to the Models 2000 proposal for the establishment of CREM which the EMS is reviewing in this report. In light of these events, the Subcommittee commends EPA’s proposal for CREM, but it is concerned about EPA’s commitment to the effort and its willingness to follow through and to implement the CREM.

In this Advisory, the Subcommittee focuses on how the Charter promotes the use of science with respect to models, and avoids the policy and management aspects of deciding how to implement a program for evaluating the effectiveness of model use at EPA. However, the Subcommittee strongly recommends that the CREM be given sufficient authority to do its job, as well as the appropriate oversight and support from EPA senior management.

**Charge 1. Comment on the Adequacy of the CREM Charter to Ensure That Models Are Useful, Articulate Major Assumptions and Separate Scientific Conclusions from Policy Judgments**

The first charge to the Subcommittee was to “comment on the adequacy of the CREM Charter for helping the Agency establish a framework to ensure that models developed by the Agency are useful for their intended purpose, articulate major assumptions and uncertainties, and separate scientific conclusions from policy judgments”.

The CREM charter is largely silent on this issue, especially on the separation of scientific conclusions from policy judgments. The Subcommittee therefore encourages the Agency to consider the findings presented in the soon to be published SAB Integrated Risk Project report. It offers a way to integrate the seemingly disparate factors that must be considered in decision-making (e.g., science, economics, policy, public values, etc.). The Subcommittee believes that successful regulatory model development within the Agency requires a clear statement of the

model's designated task. The key for CREM is to collaborate with the Agency Program Offices and Regions to develop policies and procedures to ensure that the regulatory or other needs that stimulate model development and use are clearly stated. Model developers should be required to document the policy and other choices made as they develop EPA models, and likewise model users should describe the choices they make when they apply the model. Users should also describe how these choices affect the model output. These same principles also apply to models developed by others which are to be used by the Agency.

To ensure that regulatory models are useful, CREM should emphasize the role of models in regulatory problem-solving. Models are tools to help solve problems. An emphasis on problem-solving will allow EPA to clearly demonstrate how and why they apply models, and to describe the extent to which EPA models succeed in their assigned tasks. The lessons learned should be systematically documented for use when models are applied in different situations to improve existing models, and for future model development.

In considering how CREM might collaborate with the Agency Offices and Regions to help them implement the policies and procedures CREM develops, the Subcommittee felt that the CREM might work most effectively if it shares the information it collects, and then encourages peer influence to effect change. The documentation and promotion of "Exemplary Case Studies" could be used to highlight the successes of the Agency's activities in developing and applying models. The intent would be to illuminate general modeling principles applicable to other modeling activities beyond the specific case studies and purposes for which the models were originally constructed.

To provide guidance to Agency Program Offices and Regions the Subcommittee felt that an effective CREM needs to actively monitor how well procedures are followed, and) how well do they work. CREM also needs to receive feedback and suggestions from Agency Offices and Regions in order to suggest changes needed to improve modeling procedures to the Science Policy Council for Agency-wide adoption and use. CREM needs good working relationships with Agency Offices and the Regions as well as ready access to information concerning the use of models. Therefore, CREM will need commensurate authority and EPA senior management support to carry out its chartered responsibilities effectively. A similar collaborative process will be useful for making changes to the CREM charter as the Agency learns from implementing these new procedures.

## **Charge 2. Mechanism to Help Assessors and Managers Ensure That "Unseen" Aspects of the Assessment Are Brought Forward**

In the second charge, the Subcommittee was asked to "comment on the utility of the Charter for developing a framework under which a mechanism can be developed to help risk assessors and managers ensure that usually 'unseen' aspects of the assessment are brought forward to make clear to decision-makers and the public choices made during the modeling and (the reasons) why they were made".

The Subcommittee interprets this charge to mean that we are being asked to comment on whether the proposed CREM charter helps promote making transparent the science policy and other largely non-technical choices made during the development and application of an environmental regulatory model. The proposed charter does not address this issue, but CREM could play an important role by providing guidance on how to make clear what are the “unseen” aspects of a model and ensuring that the case studies recommended earlier address this issue. The subcommittee recommends that the CREM help the Agency move towards training EPA staff in the role of models in problem-solving and move away from merely certifying that users have been trained in the use of various software applications..

There are many ways models may be used to support a decision. They may help scientists calculate an estimated risk, economists estimate costs and benefits, pollsters analyze the public’s viewpoints on the issue, etc. To the extent that EPA emphasizes certain factors considered during decision making (e.g., the risk assessment number), and not others (e.g., policy considerations), Agency assessors, managers, and, equally important, the public are not fully informed about how specific decisions are reached. The use of models must be viewed in this broader context. To help promote this recognition, as we have already recommended, CREM could organize its activities around problem-solving assessment issues, such as: Total Maximum Daily Load (TMDL) determinations, wasteload allocations, hazardous waste listing/delisting determinations, site prioritizations, Clean Air Act State Implementation Plan (SIP) approvals, environmental justice assessments, etc. The Agency’s web site might be an appropriate way to do this. The categories for reporting might then include:

- a) Designated task assessment issues and endpoints (which aspects of the problem are considered, which are not)
- b) Problem framing: what are the specific measures used to evaluate these issues and endpoints
- c) State-of-science in understanding the problem and in being able to predict the impact of a decision or regulation
- d) Available data and data needs -- data analysis procedures
- e) Alternative models available for assessment
- f) Basis for choosing a particular model or set of models

These recommendations are similar to those made by SAB’s Environmental Engineering Committee in its Quality Systems report (SAB, 1999).

This would help to put modeling efforts into the broader context of decision support. Again, as the Subcommittee has already recommended, analysts should be encouraged to be very explicit about the broad framing of the problem and the roles of science and value judgments in

determining what to include (and model) and what to exclude.

### **Charge 3. Help Those Outside EPA Understand and Help Evaluate Progress Toward Achieving Agency Modeling Goals**

The third charge to the Subcommittee was to “comment on the utility of the Charter to help develop goals for the use of models, and a mechanism to help those outside EPA understand the Agency’s models, modeling activities and modeling results and to help them evaluate EPA’s progress toward achieving the Agency’s goals”.

The Subcommittee recommends that CREM encourage Program Offices and Regions to collaborate with their constituencies to improve model development and use. The Subcommittee believes this to be an effective way to help those outside EPA understand and evaluate progress toward achieving Agency modeling goals. This function should be made explicit in the CREM charter. An added benefit is that “ownership” will be broadened, and the Agency will be able to build on the work of others. The section in the charter titled “Empowering the Public” is a good start towards this goal, and the Subcommittee endorses its inclusion in the proposed charter. In promoting such outreach CREM should act as a facilitator. It should provide guidance to each Program Office and Region with regard to their seeking feedback from model users, not only within the Agency but also from outside the Agency, (including industry, state and local governments, community groups, academia and environmental organizations). The Agency will, therefore, need to identify clearly the procedures by which Program Offices and Regions can effectively gather feedback from the community of model users.

The CREM should likewise act as a facilitator in demonstrating how to share the information gathered across Agency programs for uses beyond its original intent. As part of this effort, CREM is strongly encouraged to make the completed Action Team White Papers and other products public. In fact, careful consideration should be given to persons from outside the Agency being included as members of these Action Teams. The Subcommittee further recommends that CREM publish examples of models or model applications that fail evaluation tests and how EPA learns from these experiences. The payoff for these activities is that the Agency will be better able to explain and defend its use of environmental regulatory models. EPA will be able to save resources by leveraging the work of others and enjoy greater benefit from the money it spends on model development, use and improvement. The practice of sharing information and cooperation will also help to reduce duplication of modeling effort.

Models are often complex. Therefore, proper training is necessary to ensure effective and proper use. Because resources for formal training are not always available, the Subcommittee recommends that tutorials, examples, and case studies be developed for environmental regulatory models used by EPA. Furthermore, cooperation between EPA, other parts of the public, private and not-for-profit sectors be encouraged to develop and disseminate training materials. To

summarize, CREM should act as a facilitator in promoting Agency outreach implemented through the participation of the Program Offices and Regions. However, the CREM itself should not be charged with performing the function of public outreach.

In addition to the comments in response to the three charge questions, the Subcommittee recommends adding a sentence on page 2 , under Organization -- reporting/Authority, to indicate who can propose amendments to the CREM charter.

In summary, the Subcommittee strongly urges the Agency to charter and employ CREM to develop policies and procedures for the development, validation and use of environmental regulatory models at EPA. The Subcommittee feels that this is necessary and long overdue to ensure that models used by EPA are of the highest quality and that they are scientifically-based and defensible. However, the Subcommittee is not convinced that EPA is fully committed and willing to launch the CREM with the level of senior management support needed for its success.

The Subcommittee believes that a “carrot and stick” approach is the best way for CREM to accomplish its mission. This can be done by providing incentives and support for those who provide input and share their modeling efforts through the CREM. In addition, by instituting a mechanism for full disclosure of modeling activities at the Agency, pressure will be exerted to improve the quality of these activities. Through a well-designed process of highlighting Agency modeling efforts in a unique and distinctive manner, CREM can identify where modeling practices are working well; CREM can also identify gaps and areas that need improvement. To be effective in this important activity CREM must have input and access to information about model development and model use in the Programs and Regions. CREM also will need solid backing of senior EPA management to fulfill its mission. The Subcommittee recommends that CREM be given this necessary authority and management backing to fulfill its mission.

The Subcommittee commends EPA’s proposal for involving the public in this effort. This process can lead not only to a better understanding of EPA’s models, but a better acceptance of models used in regulatory activities. It also provides a way to tap the work done by others, thereby leveraging EPA’s resources.

The EMS looks forward to the opportunity to continue to work with the Agency as it increases its efforts to develop, apply and improve high quality, scientifically-based and defensible regulatory models. We look forward to your response to the advice contained in this Advisory.

Sincerely,

/signed/

/signed/

Dr. Joan Daisey, Chair  
Science Advisory Board

Dr. Ishwar Murarka, Chair  
Environmental Models Subcommittee  
Science Advisory Board

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