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OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

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

Subject: Review of Draft Agency Guidance for Conducting External Peer Review of Environmental Regulatory Modeling

Dear Ms. Browner:

In response to the January 1989 Report of the Science Advisory Board (SAB) entitled "Resolution on the Use of Mathematical Models by EPA for Regulatory Assessment and Decision-Making," (EPA-SAB-EEC-89-012), an ad hoc Agency Task Force on Environmental Regulatory Modeling (ATFERM) was created under the Risk Assessment Council. ATFERM encompasses all offices, regions, and laboratories within EPA, and represents the first time modeling activities have been coordinated at this scale within the Agency. The SAB was asked to review the draft document entitled "Agency Guidance for Conducting External Peer Review of Environmental Regulatory Modeling," (January 26, 1993 draft), one of the first products of ATFERM which support better management of model development and application.

Concurrently, and in response to the March 1992 Report on the Expert Panel on the Role of Science at EPA, "Safeguarding the Future: Credible Science, Credible Decisions," (EPA/600/9-91/050), a Council of Science Advisors (CSA) was established within the Agency. The first major task of the CSA was to develop an Agency Policy on Peer Review. This policy eventually will consist of a general peer review guidance. The modeling guidance has been developed ahead of the general peer review guidance; thus, it refers to a document on general peer review that the SAB cannot evaluate. For this reason, the SAB went beyond the charge of reviewing the guidance on peer reviewing models, and has made comments on the general peer review process.

This review by the Modeling Peer Review Subcommittee (MPRS) took place on March 3-4 at the Environmental Engineering Committee (EEC) meeting in Washington, DC. During discussions on March 3, 1993, it was pointed out that peer review of models is just one initiative in the general area of model use within

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the Agency. This review has focused on a portion of this overall program, specifically peer review. Thus, some of the more general comments on models, included here for completeness, may be more appropriate for other components of the modeling initiative.

1. Charge

The charge to the SAB's EEC/MPRS was stated as two questions and a list of issues:

a) How well does the guidance address its goals of being a resource for Agency managers implementing external peer review of environmental regulatory modeling?

b) Does the guidance provide the proper balance between being too restrictive versus not providing enough detail?

The specific issues addressed included the following:

a) Key elements of a modeling peer review;

b) Modeling framework for addressing peer review;

c) Relationship of peer review to the over all process of model development and application; and

d) Model-specific peer review mechanisms and criteria.

2. Model Peer Review Process

In general, the subject manual represents a good balance between over prescriptive and under prescriptive guidance for external peer review of modeling. The authors correctly recognize that guidance often becomes de facto regulations, and appropriately stress that this guidance should not be construed as rigid. The authors are encouraged not to yield to the temptation to specify more prescriptive guidance that would lose the flexibility necessary to allow peer review of the range of regulatory models used by the Agency.

The authors also correctly identify many of the concerns associated with implementing such a comprehensive external peer review process. In particular, the document points out the concerns associated with slowing the regulatory process and the need to plan the external peer review process early in the activity. It is possible for the process to be abused to stifle activity within the Agency. The authors may want to consider techniques designed to avoid this potential problem. The Agency needs to establish some reasonable time frames to complete reviews, as well as checks and balances within the review process.

3. Application of Review Process

The guidance specifies that external peer review is generally relevant to model development and may be used on a case-by-case basis to applications of models. The application of complicated environmental models is subject to errors, even if the development of the model has been thoroughly peer reviewed. These errors may be more severe than those encountered in the development of models. Some common examples of application problems include improper input data, improper boundary condition specification, poor documentation of inputs and assumptions, the applicability and appropriateness of using default values, documentation and justification of adjusting model inputs to improve model performance, and exercising the model outside the range of its validity.

While there are applications that should be peer-reviewed, the guidance should document reasonable rationales where peer review is unnecessary. These rationales could include common and routine calculations. Guidance on applications that should require external peer review might include applications on which costly decisions are based or applications that may end in litigation. This would include non-routine model applications which have significant impacts that are run by states or their contractors under the direction of EPA. An example of this would be the application of complex photochemical grid models used in State Implementation Plan (SIP) development. Guidance also might be offered on how stake-holders who are not satisfied with potential model applications can have input into whether or not the external peer review process occurs. Guidance should also be given as to what constitutes adequate model performance.

As emphasized by the SAB's EEC/MPRS, it is essential that applications that will have a significant impact also be subjected to peer review. An example pointed out by the SAB's Executive Committee included an entire category of applications that will have hundreds of millions of dollars of impacts that will not be covered by the peer review process as it is presently envisioned. These are the applications to develop the SIPs for nonattainment areas for the criteria air pollutants. For most of the criteria pollutants, this exercise consists of applying a routine dispersion model, but for ozone, it involves the application of a complex photochemical grid model that is essentially a research project. The model runs are not made by the EPA; they are made by the state agencies or their contractors. However, the EPA dictates which model to use, and EPA (OAQPS and the Regional Offices) does not actually "turn the crank," they control the process. These applications should be included in the peer review process, because they involve the use of a highly sophisticated, complex model which lacks adequate performance evaluations.

It is further noted by the SAB's Executive Committee, with regard to the SIPs, particularly with regard to ozone, that decisions are being made in the absence of sufficient input data. In these cases, EPA allows the use of "default" values in lieu of actual input data, and that the evaluation of this practice needs to be included in the peer review process.

The SAB's EEC/MPRS believes that when models are used in the regulatory decision-making process, there is a role for peer review to insure that model results are not misused, and that the decision is consistent with the modeling effort. Although the use of models has been divided into three stages in the guidance (development, application, and use in decision making), in actuality, the use of models is often a continuum across these stages, which are not distinct. The guidance attempts to have the scientific basis of potential future regulatory decisions for which a model may be used reviewed in earlier stages (e.g., model development). This is a risky approach, as it may be impossible to predict how the model will ultimately be used in the decision making process. It is more prudent for the Agency to have a review on the use of models at this last stage (regulatory decisions), as well as earlier stages, to insure that the use of models is appropriately incorporated into the decision-making.

4. General Peer Review Process Closure

There is clear omission in the guidance on what should happen after the external peer review process is completed. While this subject may be generally applicable to Agency-wide peer review processes, it also is necessary to include it in the model peer review guidance. It should address how the issues raised in the peer review process will be resolved. An impartial third party is necessary to review the proposed resolution. This impartial third party could be senior management, CSA, or a continuing form of ATFERM, so long as they are expert in the issues raised by the review. To expedite the development process, the third party should be within EPA.

5. Documentation

Documentation of the entire peer review process is extremely important. Without documentation of the review(s) and the response(s) to the reviewer comments, there is neither rigor in the process nor evidence that the review actually occurred or was taken into account. There is a need in the guidance document to specify a standardized approach to documenting the review process, especially the resolution of reviewer comments.

6. Adequacy of Review Criteria

It is not clear that the elements of the peer review process are suitable for all of the peer review mechanisms listed in the guidance document. Specifically, one external peer review process involves the use of peer-reviewed scientific journals that should not be constrained to the elements posed in the guidance document. Also, the journal review process may require much more time (sometimes one to two years) than the Agency schedule can allow. Clearly, this mechanism cannot give the complete answers to the questions posed in the elements of the peer review process, even though it is the most accepted form of external peer review. The Agency should try to reconcile the differences and describe how this mechanism should be used to achieve the desired end-product.

Specific guidance may be required on what constitutes a peer-reviewed journal or what constitutes a qualified audience in a technical workshop. Guidance could also be provided on what constitutes a "qualified" peer reviewer and what mix or diversity of scientific backgrounds is required for an adequate review. It should also be stressed that qualified peer reviewers will be different for development and application reviews. For the former, modelers may only be required, but for the latter, scientists and engineers familiar with the specific domain, source emissions and data analysis experts may also be required. Finally, guidance should be provided on the number of reviewers (it probably should be a minimum of three) that are required to give a balanced review.

7. Adequacy of Review Elements

It is not clear that the extensive peer review elements that are defined in the guidance are equally important or that the list is complete. Models are, at best, mathematical simplifications or estimations of the current state of understanding associated with the processes and effects of interest. The most important element to the review process is the verification of the model against available data in the range of conditions of interest. It is not clear that other elements are important if the model does not accurately estimate the processes and effects. The ability of the model to estimate the results over a wide range of conditions (so that the agreement between predicted and observed values is unlikely to be due to compensating errors) is the key measure of success of modeling without compensating errors (the issue of compensating errors is a serious problem with some air quality models) and should be an important part of the peer review process.

Specific items that should be added to the review elements follow.

a) **"Model purpose/objectives"**: is the model needed, i.e., has the model selection process overlooked an existing code that can perform the same function (with or without modification)? It is important that the Agency not duplicate efforts.

b) **"Major defining and limiting considerations"**: (1) what are the important parameters and their quantity (e.g., temporal and spatial scales), and the effects of other parameters on these (e.g., temperature effects) and (2) is the conceptual model correct?

c) **"Theoretical basis for model"**: (1) evaluation of scientific foundation of modeling approach and equations, (2) identification of shortcomings of modeling approach (e.g., missing processes, restrictive dimensionality, over-simplification of processes), (3) is there a better (or simpler) modeling approach which could satisfy objectives and have less limitations, (4) is the level of scientific understanding consistent with the modeling objectives, (5) what equations are solved

and do they capture the natural system, and (6) stability and application of the solution?

d) **"Parameter estimation"**: (1) what is the sensitivity of the results to the estimation or variation in parameters and (2) what are the boundary conditions and (3) are they appropriate?

e) **"Model performance measures"**: (1) has the model conserved mass (model should have a mass balance check), (2) has model uncertainty been adequately addressed, (3) what criteria will be used to determine adequate model performance, and (4) if model performance is not adequate, what criteria will be used to encourage modelers to document and justify adjustments, rather than arbitrarily "adjust" inputs to improve performance?

f) **"Model documentation and users guide"**: (1) is the model documentation and level of complexity consistent with the educational background of proposed users and (2) was the model tested by someone other than the model developer. Verification tests should be included as part of the documentation?

8. Agency Task Force on Environmental Regulatory Modeling (ATFERM)

The ad hoc Agency Task Force on Environmental Regulatory Modeling (ATFERM), created under the Risk Assessment Council, responds to the January 1989 Report of the Science Advisory Board (SAB) entitled "Resolution on the Use of Mathematical Models by EPA for Regulatory Assessment and Decision-Making," (EPA-SAB-EEC-89-012). Since ATFERM represents the first time modeling activities have been coordinated at an Agency scale, the SAB supports the concept of ATFERM. Unfortunately, ATFERM is to complete its mission within 12 months. A model-coordinating activity within the Agency is needed on a continuing basis.

9. Recommendations

a) Some form of ATFERM should continue to exist after the 12-month initial time period is complete. A model-coordinating activity within the Agency is needed on a continuing basis. This recommendation was initially made in the SAB's modeling resolution (EPA-SAB-EEC-89-012) , and was repeated in a more recent review on usage of computer models in the hazardous waste and Superfund programs (EPA-SAB-EEC-91-016). One function of ATFERM would be to monitor the effectiveness of the model peer-review process.

b) The steps of the general peer review process, including (1) a documented response to the review comments, (2) an independent evaluation of the review comments, and (3) the documented response

to insure that the review comments were satisfactorily considered, need to be adequately addressed. The final step should be an internal (within EPA) function to expedite the review process in order not to slow model development. This closure step could be performed by senior management, CSA, or a continuing form of ATFERM, so long as they are expert in the issues raised by the review.

c) The introduction of the guidance on modeling peer review needs to include a discussion on model types and codes used within the Agency. Specifically, the discussion should address the variety of model types used within the Agency, including those for air, surface water, groundwater, multimedia, and the codes for associated activities such as risk assessment and Monte Carlo simulation. This discussion should also include a description of the types of applications for which these models can be used. There needs to be an indication as to how the peer review process accommodates this diversity of models.

d) The focus on the guidance for modeling peer review is on model development, but equal emphasis also needs to be placed on review of model applications. Such emphasis should not imply that all model applications need external peer review, but for those applications that do require external peer review, the current guidance is inadequate. Routine calculations or model applications that follow standard operating procedures would not normally require external review. Applications where external review would be considered include: situations where multimillion dollar decisions are based on model results (e.g., hazardous waste site remediation and SIP development using complex photochemical grid models) or model results where future litigation is anticipated, and these should include those applications run by states and their contractors under the direction of EPA.

e) The SAB's EEC/MPRS recommends that when models are used in the regulatory decision-making process, there be a role for peer review to insure that model inputs (and default values) are valid and justified, adjustments to inputs to improve performance are documented and justified, that model results are not misused, and that the decision be consistent with the modeling effort.

f) The peer review process early in the modeling activity should include assessment of the need for a new model, where model development is anticipated. An important role of ATFERM is to reduce the amount of duplication that exists within the Agency, especially in the area of model development.

g) In the paradigm on external peer review, there needs to be more emphasis on documentation of the whole process.

h) Some guidance needs to be provided as to what constitutes adequate model performance.

i) ATFERM has made a good attempt not to be overly prescriptive;. Specific information that might be added include: (1) profiles for typical reviewers, (2) required number of reviewers (minimum of three), and (3) when Beta testing is necessary.

j) EPA should consider making it a requirement to peer-review all models.

We are pleased to have had the opportunity to be of service to the Agency. We trust that these comments will help in your guidance of this important program, and look forward to your response.

Sincerely,

Raymond C. Loehr

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ABSTRACT

The Modeling Peer Review Subcommittee (MPRS), along with its parent Environmental Engineering Committee (EEC) of the Science Advisory Board (SAB) has prepared a letter report on its March 3 and 4, 1993 review of the draft, entitled "Agency Guidance for Conducting External Peer Review of Environmental Regulatory Modeling." This draft guidance was prepared by an ad hoc Agency Task Force on Environmental Regulatory Modeling (ATFERM), which was created under the Agency's Risk Assessment Council.

The MPRS found that, in general the guidance provides an appropriate level of detail in the guidelines for specific elements to be addressed by the reviewer, but that more detailed guidance is needed on the mechanics of the review process. The MPRS cited an omission as to what should happen after the external peer review process is completed, in order to address issues raised in the peer review. However, the Agency was urged not to become overly prescriptive, as to the specific details of the model peer review where the guidance could become de facto regulation.

The MPRS stressed the importance of documenting the entire peer review process. Among the recommendations made, the MPRS also stressed that specific guidance was needed on what constitutes a "qualified" peer reviewer, that the model should be verified against available data over the range of conditions of interest, that there is a role for peer review to insure that model results are not misused and that the decision is consistent with the modeling effort. The MPRS also recommended that some form of the ATFERM should continue to exist, that a model-coordinating activity within the Agency is needed on a continuing basis, and that the Agency should consider making the peer-review guidance into policy.

Key Words: Environmental Regulatory Modeling, External Peer Review, Models, Peer Review,

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