

July 30, 1999

EPA SAB-EC-ADV-99-011

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

Subject: Advisory on the “White Paper on the Nature and Scope of Issues on Adoption of Model use Acceptability Criteria”

Dear Ms. Browner:

The Environmental Models Subcommittee (EMS), hereinafter referred to as the “Subcommittee”, met February 23 and 24, 1999 to review the draft “White Paper on the Nature and Scope of Issues on Adoption of Model Use Acceptability Criteria”. The Subcommittee conducted this review in order to provide the Agency with advice and insights on the adequacy of this proposed approach to evaluating regulatory environmental models with respect to their ability to produce defensible, scientifically-based and high quality results that meet EPA’s needs.

The review meeting was conducted in public session under the provisions of the Federal Advisory Committee Act (FACA). EPA provided the Subcommittee with the “White Paper” before the meeting and briefed the Subcommittee during the meeting. The Subcommittee was impressed with the depth of knowledge exhibited and the level of cooperation shown during the presentation and briefing, and has prepared this letter and the accompanying report. The letter summarizes EMS’ key findings and recommendations. The attached report provides a more complete description of the Subcommittee’s advice.

Charge 1: Please comment on the adequacy of this approach for helping model developers explain their models clearly, articulate major assumptions and uncertainties, identify reasonable alternative interpretations, and separate scientific conclusions from policy judgments.

The “White Paper”’s general approach and the specific points raised in it are very constructive and can provide the basis for a more effective and consistent process of model development and application across the Agency. The issue of distinguishing scientific conclusions from policy judgments is not directly addressed in the “White Paper”, but the recommended protocol for model validation may be of assistance to model evaluators in this regard. It is often tempting for modelers who have come to “believe” in the results of their efforts to promote these scientific conclusions within the realm of policy. The “White Paper”’s

protocol places great emphasis on the primary role of “task specification” in directing how a model should be evaluated. Specification of the task for which the model is to be developed is the prerogative of the decision maker(s); it is his/her obligation to specify in detail, as appropriate, the terms and conditions to be fulfilled by the model. Provided there is adherence to this aspect of the protocol, i.e. , task specification, separation of scientific conclusions and assumptions should be successfully seen to be entirely separate from policy judgments.

The Subcommittee suggests that the Agency might consider positive incentives to the Program Offices and Regions that develop models to encourage them to report, document and exchange information on their model Quality Assurance (QA) procedures. They should also be encouraged to report the successes they have achieved through effective model use, and the lessons learned. This could be accomplished through use of a highly visible and accessible web page, where offices are given the opportunity to self-report their methods and procedures for ensuring that models contribute effectively to decision support.

Part of the struggle to coordinate model evaluations across the Agency seems to be the lack of a common nomenclature. The models acceptability “White Paper” could help this situation by defining key terms, and then using these definitions consistently throughout the document as well as in its future work.

Charge 2: Is this proposal comparably useful for models for health and for ecological risk assessments as well as for pollution prevention? If not, please identify special needs for any of these general areas.

The basic principles for developing and evaluating different environmental models are the same for health and for ecological risk assessments as well as for pollution prevention. However, the proposal is written generically and would be strengthened by including specific references to these other applications in order to make it clear that the “White Paper” is *not* restricted to fate and transport models. One potentially important difference between exposure models and those developed for pollution prevention analysis is that the sphere of pollution prevention lies principally within the private sector where the same degree of willingness to submit models to an examination of structure, complexity, and uncertainty may not always be present.

The “White Paper” emphasizes that even though models are evolving from simple models to estimate exposure results to those designed to perform more complex risk assessments, EPA provides no guidance about how to deal with more complicated situations. Obviously, it is important that the scale and complexity of ecological models used in risk assessment be compatible and consistent with the scale and complexity implied by regulatory needs.

Charge 3: Please comment on the adequacy and utility of the proposal for helping decision-makers, other risk managers (e.g., assessors and their managers), and the public

- i. understand models used in a regulatory context**
- ii. evaluate the appropriate use for the results from models in decision making**
- iii. understand the “unseen” aspects of the modeling including choices made during regulatory use and the rationale for those choices**

The “White Paper” addresses the need to consider these aspects. However, in its current form, it lacks the broader view of what needs to be included and the associated steps required for implementation. EPA model development can benefit greatly from targeted stakeholder participation to obtain insight into the range of applications, available data and constraints that exist in different locales throughout the United States.

The discussion in relation to model use and evaluation in the Office of Air (OAR) might be particularly useful to help others understand model use in a regulatory context. OAR appears to have addressed many of the issues raised in the “White Paper”. Several of the case studies presented in the report provide examples of the use of models in a regulatory or decision-making context.

Underlying these model-centric themes set out above, EPA needs to ensure that the public, the regulatory community and local decision-makers realize the role that value judgments play in the selection of a model and the way a model is used. Thus, it is important to be very diligent in informing the public, state regulators and local decision-makers on this aspect of models. In the Program Offices, EPA should consider developing educational materials to assist stakeholders in the selection, understanding and use of models that address a program’s mandates. In addition to improving user literacy, this educational outreach should identify the target community for eventual feedback. Tracking model selection and model use by state and local decision-makers will provide a valuable data set to EPA regarding the efficacy of its programs.

Charge 4: Please comment on the utility of the proposal to help those outside EPA understand the Agency’s modeling goals and to help evaluate EPA’s progress toward achieving those goals

In order to help organizations outside the EPA understand the Agency's modeling goals, and allow them to evaluate EPA's progress towards achieving its goals, the information must be accurate, up-to-date and publicly available. The “White Paper” indicates that the CREM will provide guidance to EPA on model evaluation in the form of a protocol. Establishment of a model clearinghouse by the CREM will allow model users to document the model evaluation process, and those outside the EPA will have the opportunity to access this information and understand the Agency’s modeling efforts.

Charge 5: Please comment on the overall utility and adequacy of the proposed “Strategy for Defining Uncertainty in Model Elements (Section 5.1) and supporting “How to” guidances (p.7) for judging model acceptability

While this question generated much discussion among Subcommittee members, none of this undermined its basic response which is that the utility and adequacy of the “White Paper”'s proposed strategy are entirely appropriate.

The “White Paper” should make it clear that (a) uncertainties in a model propagate forward into prediction uncertainty, (b) that decisions be seen to be robust in the presence of such prediction uncertainty, and (c) that procedures are available for ranking the various contributing sources of uncertainty and that steps may be taken to reduce the consequences of the most critical of these, as the model is successively improved over time.

The Subcommittee recognizes the difficulty many will have in grasping the concepts and arguments underlying the discussion of the “White Paper” (as evident in our responses to other Charge Questions). The Subcommittee feels, therefore, that there may indeed be a need for producing written materials expressing these issues in a format more accessible to a wider audience. However, the Subcommittee wishes to record its recognition that the issues of model evaluation are neither trivial nor inherently easy to completely address, therefore great care will be needed to understand and explain them in lay terms.

Charge 6 : EPA welcomes any additional comments or suggestions

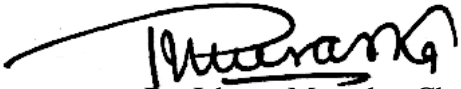
The Subcommittee suspects that when the guidelines for model acceptability are first implemented, there will be a backlog of Agency models whose quality must be evaluated in the broad format recommended by the “White Paper”. The Agency should give consideration to the details of any procedure for clearing this backlog and to the procedure for taking advantage of this opportunity for updating models.

In summary, the Subcommittee finds that the guidance in the “White Paper” is generally useful for addressing the quality and reliability aspects for EPA’s environmental regulatory models. In addition, the Subcommittee finds that model quality issues have been comprehensively addressed. Furthermore, the “White Paper” includes the beginnings of a clarification of how peer review could be interfaced with the majority of more computationally-oriented facets of an evaluation. However, at this point it lacks guidance and information about what needs to be included and associated steps required for implementation to be useful for decision makers and the public (e.g., a communication strategy for obtaining user feedback and establishing a dialog in model development with stakeholders). The Subcommittee suggests that model information be related to the totality of the specific decision-making use, and in this context it should strive to achieve “transparency” in both technical and non-technical respects (e.g., policy decisions). The Subcommittee also recommends that the Agency Program Offices and Regions consider investing in the development of a host of high-quality outreach

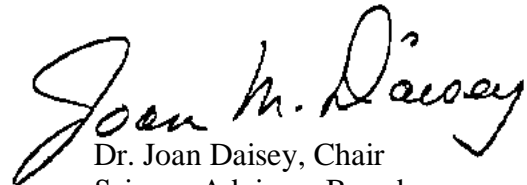
educational materials, tailored to different audiences, on the general topic of models as decision support tools.

The Environmental Models Subcommittee looks forward to continued work with the Agency as it refines its guidance for model acceptability, and we look forward to the response of the Assistant Administrator for Research and Development to the advice contained in this Advisory.

Sincerely,



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



Dr. Joan Daisey, Chair
Science Advisory Board

NOTICE

This report has been written as part of the activities of the Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use.

ABSTRACT

The general approach contained in the “White Paper on the Nature and Scope of Issues on adoption of Model use Acceptability Criteria” and the specific points raised in it are very constructive. The “White Paper” can provide the basis for a more effective and consistent process of model development and application across the Agency. However, there is a lack of a common nomenclature surrounding model application and usage. The models acceptability “White Paper” could help by defining key terms, and then using these definitions consistently throughout the document as well as in its future work. In addition, the “White Paper” needs a broader view of what needs to be included for effective model development and the associated steps required for implementation. EPA can benefit greatly from targeted stakeholder participation to obtain insight into the range of applications, available data and constraints that exist in different locales throughout the U.S. EPA also needs to ensure that the public, the regulatory community and local decision-makers appreciate the role that value judgments play in the selection of a model and the way a model is used. EPA Program Offices should consider developing educational materials to assist stakeholders in the selection, understanding and use of models to address their program’s mandates. Tracking model selection and model use by state and local decision-makers will provide a valuable data set to EPA regarding the efficacy of its programs. The Subcommittee supports the establishment of the Committee for Regulatory Environmental Modeling (CREM) and a model clearinghouse by the CREM. This will allow model users to document the model evaluation process to help others understand. As an additional benefit, it will allow those outside the EPA to access this information and it will provide them with an opportunity to provide feedback.

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1. EXECUTIVE SUMMARY

The Environmental Models Subcommittee (EMS) reviewed the draft “White Paper on the Nature and Scope of Issues on Adoption of Model Use Acceptability Criteria” which has been developed to provide guidance on the development and use of environmental regulatory models at EPA. The Subcommittee addressed six charge questions.

Charge 1: Please comment on the adequacy of this approach for helping model developers explain their models clearly, articulate major assumptions and uncertainties, identify reasonable alternative interpretations, and separate scientific conclusions from policy judgments.

The “White Paper”’s general approach and the specific points raised in it are very constructive and can provide the basis for a more effective and consistent process of model development and application across the Agency. It is often tempting for modelers who have come to “believe” in the results of their efforts to promote these scientific conclusions within the realm of policy. The “White Paper”’s protocol places great emphasis on the primary role of “task specification” in directing how a model should be evaluated. Specification of the task for which the model is to be developed is the prerogative of the decision maker(s); it is his/her obligation to specify in detail, as appropriate, the terms and conditions to be fulfilled by the model. Provided there is adherence to this aspect of the protocol, i.e. , task specification, scientific conclusions and assumptions should be successfully seen to be entirely separate from policy judgments.

The Subcommittee suggests that the Agency might consider positive incentives to the Program Offices and Regions that develop models to encourage them to report, document and exchange information on their model Quality Assurance (QA) procedures. They should also be encouraged to report the successes achieved through effective model use, and the lessons learned. This could be accomplished through the use of a highly visible and accessible web page, where offices are given the opportunity to self-report their methods and procedures for ensuring that models contribute effectively to decision support.

The Subcommittee was concerned that there should be a balance between consistency across the Agency in performing model evaluations, but without being prescriptive in order to achieve such consistency. An effective way to accomplish this would be through the establishment of an entity such as the proposed Committee for Regulatory Environmental Modeling (CREM).

Part of the struggle to coordinate model evaluations across the Agency seems to be the lack of a common nomenclature. The models acceptability “White Paper” could help this situation by defining key terms, and then using these definitions consistently throughout the document as well as in its future work.

Charge 2: Is this proposal comparably useful for models for health and for ecological risk assessments as well as for pollution prevention? If not, please identify special needs for any of these general areas.

The basic principles for developing and evaluating different environmental models are the same for health and for ecological risk assessments as well as for pollution prevention. However, the proposal is written generically and would be strengthened by including specific references to these other applications in order to make it clear that the “White Paper” is *not* restricted merely to fate and transport models. One potentially important difference between exposure models and those developed for pollution prevention analysis is that the sphere of pollution prevention lies principally within the private sector where the same degree of willingness to submit models to an examination of structure, complexity, and uncertainty may not always be present.

Models designed to assess the effects of environmental pollutants on human health and the environment are more complicated than those used to estimate exposure to environmental contaminants. No one model can “do it all”, so a number of models is needed to estimate contaminant concentrations precisely, to assess human exposure and body burden correctly, to establish a reasonable dose-response curve, and to reasonably project the health risk to the exposed population. The “White Paper” emphasizes that even though models are evolving from simple models to estimate exposure results to those designed to perform more complex risk assessments, EPA provides no guidance about how to deal with more complicated situations. Obviously, it is important that the scale and complexity of ecological models used in risk assessment be compatible and consistent with the scale and complexity implied by regulatory needs.

Charge 3: Please comment on the adequacy and utility of the proposal for helping decision-makers, other risk managers (e.g., assessors and their managers), and the public

- i. understand models used in a regulatory context;**
- ii. evaluate the appropriate use for the results from models in decision making;**
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The “White Paper” addresses the need to consider these aspects. However, in its current form, it lacks the broader view of what needs to be included and the associated steps required for implementation. EPA model development can benefit greatly from targeted stakeholder participation to obtain insight into the range of applications, available data and constraints that exist in different locales throughout the United States.

The discussion in relation to model use and evaluation in the Office of Air (OAR) might be particularly useful to help others understand model use in a regulatory context. OAR appears to have addressed many of the issues raised in the “White Paper”. Several of the case studies presented in the report provide examples of the use of models in a regulatory or decision-making context.

Underlying the model-centric themes set out above, EPA needs to ensure that the public, the regulatory community and local decision-makers realize the role that value judgments play in

the selection of a model and the way a model is used. Thus, it is important to be very diligent in informing the public, state regulators and local decision-makers about this aspect of models. In the Program Offices, EPA should consider developing educational materials to assist stakeholders in the selection, understanding and use of models that address a program's mandates. In addition to improving user literacy, this educational outreach should identify the target community for eventual feedback. Tracking model selection and model use by state and local decision-makers will provide a valuable data set to EPA regarding the efficacy of its programs. It is important to reemphasize that educational outreach is not a small task and will require EPA to make a serious commitment of resources. Posting the results of models used in specific applications on the Internet would provide the opportunity for an informed public to view and understand model selection and application in a regulatory context.

Charge 4: Please comment on the utility of the proposal to help those outside EPA understand the Agency's modeling goals and to help evaluate EPA's progress toward achieving those goals

In order to help organizations outside the EPA understand the Agency's modeling goals, and allow them to evaluate EPA's progress towards achieving its goals, the information must be accurate, up-to-date and publicly available. The "White Paper" indicates that the CREM will provide guidance to EPA on model evaluation in the form of a protocol. Establishment of a model clearinghouse by the CREM will allow model users to document the model evaluation process, and those outside the EPA will have the opportunity to access this information and understand the Agency's modeling efforts.

Charge 5: Please comment on the overall utility and adequacy of the proposed "Strategy for Defining Uncertainty in Model Elements (Section 5.1) and supporting "How to" guidances (p.7) for judging model acceptability

While this question generated much discussion among Subcommittee members, none of this undermined its basic response which is that the utility and adequacy of the "White Paper"'s proposed strategy are entirely appropriate.

The "White Paper" should make it clear that (a) uncertainties in a model propagate forward into prediction uncertainty, (b) that decisions be seen to be robust in the presence of such prediction uncertainty, and (c) that procedures are available for ranking the various contributing sources of uncertainty and that steps may be taken to reduce the consequences of the most critical of these, as the model is successively improved over time.

The Subcommittee recognizes the difficulty many will have in grasping the concepts and arguments underlying the discussion of the "White Paper" (as evident in our responses to the other Charge Questions). The Subcommittee feels, therefore, that there may indeed be a need for producing written materials expressing these issues in a format more accessible to a wider audience. However, the Subcommittee wishes to record its recognition that the issues of model evaluation are neither trivial nor inherently easy to address; therefore, great care will be needed to understand and explain them in lay terms.

Charge 6 : EPA welcomes any additional comments or suggestions

The Subcommittee suspects that when the guidelines for model acceptability are first implemented, there will be a backlog of Agency models whose quality must be evaluated in the broad format recommended by the “White Paper”. The Agency should give consideration to the details of any procedure for clearing this backlog and to the procedure for taking advantage of this opportunity for updating models.

2. INTRODUCTION

The Environmental Models Subcommittee (EMS) met February 23 and 24, 1999 to review the draft “White Paper on the Nature and Scope of Issues on Adoption of Model Use Acceptability Criteria”. This review was carried out by EMS in order to provide the Agency with advice and insights on the adequacy of this proposed approach to evaluate regulatory environmental models with respect to their ability to produce defensible, scientifically-based and high quality results that meet the needs of the Agency.

The SAB was provided with a copy of the “White Paper on the Nature and Scope of Issues on Adoption of Model Use Acceptability Criteria” prior to the public meeting. The charge to the Subcommittee contained six questions focusing on the concepts and application of the “White Paper” to facilitate future Agency use of models to inform regulatory environmental decision-making.

Charge 1: Please comment on the adequacy of this approach for helping model developers explain their models clearly, articulate major assumptions and uncertainties, identify reasonable alternative interpretations, and separate scientific conclusions from policy judgments.

Charge 2: Is this proposal comparably useful for models for health and for ecological risk assessments as well as for pollution prevention? If not, please identify special needs for any of these general areas.

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Charge 6 : EPA welcomes any additional comments or suggestions.

3. OVERVIEW COMMENTS AND RESPONSE TO CHARGE

3.1 Overview Comments and Observations

The general approach in the “White Paper” is good and the Subcommittee thinks that the “White Paper” and the specific points raised in it are very constructive, and that implementation can provide the basis for a more effective and consistent process of model development and application across the Agency. The major concerns about the “White Paper” center on public outreach. Many will have difficulties in grasping the concepts and arguments underlying the discussion of the paper, therefore great care is needed when explaining these concepts in understandable terms.

3.2 Responses to Charge Questions

Charge 1: Please comment on the adequacy of this approach for helping model developers explain their models clearly, articulate major assumptions and uncertainties, identify reasonable alternative interpretations, and separate scientific conclusions from policy judgments.

The “White Paper”’s general approach and the specific points raised in it are very constructive and can provide the basis for a more effective and consistent process of model development and application across the Agency. The guidance applies equally well to model users and to environmental analysts in general, not just to model developers. To the extent that CREM can achieve buy-in from various EPA offices involved in model development and use, the effort is more likely to be viewed as enhancing the effort of individual offices, rather than as “yet another” bureaucratic imposition. Thus, the Subcommittee suggests that the Agency might consider positive incentives to the Program Offices and Regions that develop models to encourage them to report, document and exchange information on their model Quality Assurance (QA) procedures. They should also be encouraged to report the successes they have achieved through effective model use, and the lessons they have learned. This could be accomplished through the use of a highly visible and accessible web page, where offices are given the opportunity to self-report their methods and procedures for ensuring that models contribute effectively to decision support.

The Model Evaluation Case Histories in Appendix C of the “White Paper on the Nature and Scope of Issues on Adoption of Model use Acceptability Criteria” provide good examples of how this reporting could be organized and displayed. These case histories, in general, contain the following components :

- a) Regulatory Niche & Purpose (i.e., Task Specification)
- b) Model Selection
- c) Data sources for inputs
- d) Assumptions and inputs based on scientific judgment vs. those reflective of value judgments and policy decisions

- e) Calibration/Validation/Testing
- f) Sensitivity and Uncertainty Analysis
- g) Needs for further research and model(s) improvement
- h) Peer Review

The models acceptability “White Paper” in and of itself will not have much effect on encouraging model developers to “explain their models clearly”, but it is certain that implementation of the paper’s recommended approach to model evaluation (in particular steps 2-4) will have a positive effect. The protocol for model validation set forth in the “White Paper” focuses on five aspects (or steps) of model creation and application: structure, complexity, parameter uncertainty, sensitivity, and quantitative evaluation. The protocol is quite comprehensive, at least for fate, transport, and effects models (those most often used for regulatory purposes), and offers a good framework for model developers to explain their models, and their major assumptions and uncertainties. To be acceptable for specific EPA-defined tasks, the model developer needs to follow the guidance for addressing uncertainty, peer review, and evaluation as the model is being developed (e.g., TRIM.FaTE development). Certainly the model developer will have choices to make among structural (mathematical) representations of certain biological, chemical, toxicological, etc. phenomena (this being step 1 of the “White Paper”’s proposed approach). If the model incorporates only one of the alternative representations, then the justification for its inclusion must be articulated in the model assumptions. If model code allows the user to select from alternative structures, then the model developer must provide guidance for the user on how to make the appropriate selection.

The issue of distinguishing scientific conclusions from policy judgments is not directly addressed in the “White Paper”, but again the recommended protocol for model validation may be of assistance to model evaluators in this regard. It is often tempting for modelers who have come to “believe” in the results of their efforts to promote these scientific conclusions within the realm of policy. The “White Paper”’s protocol places great emphasis on the primary role of “task specification” in directing how a model should be evaluated. Specification of the task for which the model is to be developed is the prerogative of the decision maker(s); it is his/her obligation to specify in detail, as appropriate, the terms and conditions to be fulfilled by the development of the model. Provided there is adherence to this aspect of the protocol, i.e., task specification, separation of scientific conclusions and assumptions should be successfully seen to be entirely separate from policy judgments.

The Subcommittee was concerned that there should be a balance between consistency across the Agency in performing model evaluations, but without being prescriptive in order to achieve such consistency. The Agency should set criteria for what needs to be included in these assessments and provide exemplary examples of how they can be done. However, the steps in the model assessment should not be overly prescriptive. An effective way to accomplish this would be through the establishment of the proposed CREM. Because of the diversity of modeling applications in the Agency, Program Offices and Regions need to be able to select from a menu of useful evaluation tools. However, guidance is definitely needed regarding a framework for the assessment of models. Again we reiterate that the “White Paper” is correct to emphasize that the

first step is task specification, and that full documentation of peer review, performance evaluation, sensitivity analysis and uncertainty analysis is needed. In addition, assessments should also demonstrate the power of the tests used to differentiate between models that are or are not adequate for the specified tasks.

Part of the struggle to coordinate model evaluations across the Agency seems to be the lack of a common nomenclature. The models acceptability "White Paper" could help this situation by defining key terms, and then using these definitions consistently throughout the document as well as in its future work. There seems to be a persistent mix-up of the terms "validation" and "verification". The current use of the term "validation" is an example of the potential for confusion and misunderstanding. In some places it seems to be used for the overall process of assessing the adequacy of a model for a particular application. Elsewhere it is used to refer to the comparison of model results with experimental and observational data. The term "performance evaluation" may be more appropriate for the latter activity. The Agency should also consider maintaining the distinction between model "uncertainty" and modeling "errors". For example, the transcription of mathematical equations into code may very well have errors (that should be corrected if we know about them) but not "uncertainty". The term "verification" is also used to describe these translational errors. The term "uncertainty" could be used to express likelihood or probability to provide a statistical measure of variability or difference between model predictions and real world observations. However, "uncertainty" can only be reduced with the aid of new information when it improves the estimates for parameters used to carry out computations using already developed models. Specific examples of especially confusing terminology appear on p. 27 where the "White Paper" lists "uncertainties" in model tests arising from the range of statistics used in an assessment or "uncertainty" about how a test will be made. The Subcommittee believes "inconsistency" (among analysts), not "uncertainty", was intended here; once a method or particular test has been chosen that decision cannot be "uncertain".

Charge 2: Is this proposal comparably useful for models for health and for ecological risk assessments as well as for pollution prevention? If not, please identify special needs for any of these general areas.

The basic principles for developing and evaluating different environmental models are the same. The "White Paper" captures the major problems of the current practice of model adoption and recommends various ways of improvement. The proposal is useful for health and for ecological risk assessments as well as for pollution prevention. However, the proposal is written generically and would be strengthened by specifically including references to these other applications in order to make it clear that the "White Paper" is *not* restricted to fate and transport models. There are special needs for models which are developed and applied in different domains. In order to comply with environmental and occupational regulations, we have decades of experience in the estimation of contaminant concentrations and their temporal and spatial variations in different media (e.g., air, water, soil, food etc.). Models developed for the prediction of contaminant dispersion may also be components of pollution prevention analyses and health or ecological risk assessments. As such, models to predict contaminant concentrations, while often complex and often exhibiting significant uncertainty, can usually be evaluated using well-established protocols for code validation and comparison with observed laboratory and field data. In contrast the biological and ecological mechanisms involved in risk assessment are much more uncertain and we often lack the ability to define, much less measure, key system outputs and state

variables.

One potentially important difference between exposure models and those applied for pollution prevention analysis is that the sphere of pollution prevention lies principally within the private sector where the same degree of willingness to submit models to an examination of structure, complexity, and uncertainty may not always be present. In such cases, issues related to the proprietary nature of manufacturing, marketing strategies and internal costs may be present, complicating the review process. Such models must accurately capture the nature of the processes under evaluation, but also must be able to accurately assess cost alternatives. They are not typically used directly in support of public regulatory functions, but instead are used in the private sector to justify allocation of resources and to compare the return-on-investment alternatives. Of course these models must ultimately attain the same level of confidence as those developed under EPA or government auspices, if they are to be used to develop public policy, and so must be carefully evaluated. However, the application of the validation protocol may not be as direct and may necessitate different approaches with respect to the format, expertise and background of reviewers used, as well as in the dissemination of results.

Models designed to assess the effects of environmental pollutants on human health are more complicated than those used to estimate distribution of contaminants in the environment. Health effects of pollutants are determined by the contaminant concentration, human exposure, body burden, dose-response relationship and characteristics of the exposed population. Ideally, a good model for health risk assessment should be able to handle all these components with equal precision. However, no one model can “do it all”, so a number of models is needed to estimate contaminant concentrations precisely, to assess human exposure and body burden correctly, to establish a reasonable dose-response curve, and to reasonably project the health risk of the exposed population. The “White Paper” emphasizes that even though models are evolving from simple models to estimate exposure results to those designed to perform more complex risk assessments, EPA provides no guidance about how to deal with more complicated situations. Multi-contaminant, multi-media, and multi-pathway models have been mentioned repeatedly (important for considering exposures), while models for health and ecological risks are multi-endpoint. As noted in the Subcommittee’s earlier Advisory on the TRIM.FaTE model, “Advisory on the Total Risk Integrated Methodology (TRIM)” (SAB, 1998), evaluating such models presents formidable difficulties, especially with respect to the availability of comprehensive field data.

For health risk, a model should be able to assess chronic health effects (carcinogenic and non-carcinogenic) based on long-term integrated exposure while predicting acute health effects based on short-term peak exposure. For ecological risk, all animals and plants in an ecosystem can be affected. The endpoints of health and ecological risks are important factors that should be addressed in the “Model Use Acceptability Criteria”. If the endpoints are not well-defined, it is impossible to evaluate the performance of the model in the conventional “matching history”, although the model’s composition would still be subjected to formal evaluation (as covered in the “White Paper”). Expanding the scope of the proposal to include ecological risk assessment models would also require the development and implementation of procedures that address the ecological scale and complexity of such models. Obviously, it is important that the scale and complexity of ecological models used in risk assessment be compatible and consistent with the scale and complexity implied by regulatory needs.

Charge 3: Please comment on the adequacy and utility of the proposal for helping decision-makers, other risk managers (e.g., assessors and their managers), and the public

- i. understand models used in a regulatory context**
- ii. evaluate the appropriate use for the results from models in decision making**
- iii. understand the “unseen” aspects of the modeling including choices made during regulatory use and the rationale for those choices.**

The “White Paper” addresses the need to consider these aspects. However, in its current form, it lacks the broader view of what needs to be included and the associated steps required for implementation. EPA needs, therefore, to provide the principal guidance on how to develop, select, use appropriately decision-support models and to be aware of their limitations. Models are filled with complex principles, statistics and mathematics. Model parameterization and comparison of model results with field data are usually discussed in terms of probability, scale and levels of uncertainty. The basic language surrounding model evaluation is not common to many state regulators, local decision-makers and the public. The materials addressed in Appendix D of the “White Paper”, for example, will be relevant for decision-makers and risk managers in understanding the important issues in model development, application, and evaluation. But again, it is doubtful that this will be understood by the general public. There should, therefore, be great concern when state and local regulators are attracted to complicated models that generate "hard" numbers under the false belief that the complexity of a model is tantamount to its worth or validity, regardless of the available data or the particulars of a given situation. EPA model development can benefit greatly from targeted stakeholder participation to obtain insight into the range of applications, available data and constraints that exist in different locales throughout the U.S.

Outreach needs to be directed to stakeholder audiences outside of EPA, including state regulators, planners, local decision-makers and the public. As recommended in its Advisory on establishing the CREM “Advisory on the Charter for the Council for Environmental Regulatory Modeling (CREM)” (SAB, 1999a), the Subcommittee strongly suggests that the Program Offices and Regions be charged with this outreach function.

The Agency should consider investing in the development of a host of high-quality outreach educational materials on the general topic of models as decision support tools. These materials should be tailored to different audiences, and ideally would focus on different aspects of decision support models, including such topics as:

- a) what is a model
- b) types of models
- c) the regulatory realities and situations that generate the need for models
- d) how models are developed and tested
- e) how is the validity of a model determined
- f) how models have been useful in previous applications

- g) how to compare models
- h) what are the limitations of models
- i) how have models been misused

Section 3 of the “White Paper” describes how various offices within EPA have applied models in their decision-making. The discussion in relation to model use and evaluation in the Office of Air (OAR) might be particularly useful to help others understand model use in a regulatory context. OAR appears to have addressed many of the issues raised in the “White Paper”. Several of the case studies presented in the report provide examples of the use of models in a regulatory or decision-making context. Perhaps additional case studies might be developed to serve as examples of how models were used to support regulatory decision-making. Otherwise the “White Paper” may not provide general guidance concerning the use of models in a regulatory decision-making context.

Underlying these model-centric themes set out above, EPA needs to ensure that the public, the regulatory community and local decision-makers realize the role that value judgments play in the selection of a model and the way a model is used. EPA is constantly confronted with the task of modeling situations where data are limited and major gaps exist in our process-level understanding. In these situations, there is real controversy over the usefulness of quantitative models vs. indices of risk and the applicability of "worst case" scenarios vs. other scenarios. Different sectors of our society often support vastly different modeling approaches, because the choice of a model may have major consequences on the regulatory climate surrounding their interests. Thus, it is important to be very diligent in informing the public, state regulators and local decision-makers about this aspect of models. The public needs to hear the arguments for simple, worst-case, decision-support models as well as the arguments surrounding the development and use of more sophisticated risk-based models.

In the Program Offices, EPA should consider developing educational materials to assist stakeholders in the selection, understanding and use of models that address a program’s mandates. In addition to improving user literacy, this educational outreach should identify the target community for eventual feedback. Tracking model selection and model use by state and local decision-makers will provide a valuable data set to EPA regarding the efficacy of its programs. The key to this program must be a constant reassessment and refinement of the guidance and communication to users.

It is important to reemphasize that educational outreach is not a small task and will require EPA to make a serious commitment of resources. Education needs to reach beyond Washington to inform those “in the trenches”. National program managers need to ensure that the educational materials are crafted well and also develop mechanisms to assess the materials for coherence, quality and consistency. Posting the results of models used in specific applications on the Internet

would provide the opportunity for an informed public to view and understand model selection and application in a regulatory context.

The background material in Section 3 of the “White Paper” describing the various approaches to modeling issues as understood and implemented by the various offices within the Agency might be particularly useful to help decision-makers and risk managers evaluate the appropriate use of model results, in a general sense. While the issue has been comprehensively addressed, the document provides no guidance on the specific evaluation of models in relation to model quality. However, Section 5 of the “White Paper”, which discusses the nature and contribution of various sources of uncertainty in the modeling process, may be useful in this context of assisting managers to evaluate the results of model applications. It may assist these managers in enhancing their appreciation of the "unseen" aspects of the modeling enterprise. For example, similar issues of model evaluation are outlined in EPA/540R-94-039, including the scientific foundation of model structure, adequacy of parameter estimation, verification, and empirical comparisons; these identify important aspects of the modeling process that are not always obvious to the community of decision-makers.

Charge 4: Please comment on the utility of the proposal to help those outside EPA understand the Agency’s modeling goals and to help evaluate EPA’s progress toward achieving those goals.

In order to help organizations outside the EPA understand the Agency's modeling goals, and to allow them to evaluate EPA's progress towards achieving its goals the information must be accurate, up-to-date and publicly available. The proposal indicates that the CREM will provide guidance to EPA on model evaluation in the form of a protocol. Establishment of a model clearinghouse by the CREM will allow model users to document the model evaluation process, and those outside the EPA will have the opportunity to access this information and understand the Agency’s modeling.

Charge 5: Please comment on the overall utility and adequacy of the proposed “Strategy for Defining Uncertainty in Model Elements (Section 5.1) and supporting “How to” guidances (p.7) for judging model acceptability.

While this question generated much discussion among Subcommittee members, none of this undermined its basic response, which is that the utility and adequacy of the “White Paper”’s proposed strategy are entirely appropriate. However, the Subcommittee does have some recommendations to make. These deal with matters of clarity and the need to be aware of some important gaps in the strategy.

First, as we have already recommended (in our response to Charge Question 1) care should be taken with use of the word "uncertainty" in the “White Paper”. The Subcommittee believes that on several occasions in the paper it would have been more correct to talk of "error", "inconsistency", or "disagreement", as opposed to "uncertainty". We recommend that serious consideration be given to preparing a glossary for inclusion in the final version of the paper.

Second, while the “White Paper” itself acknowledges that attitudes towards "validation" have changed this decade, there is still a need to ensure that the model acceptability guidelines,

when published, are consistent with the contemporary consensus. As presently drafted the paper lacks references to crucial literature published in the last 4-5 years.

Third, the proposed strategy for evaluating models is appropriate and sufficiently comprehensive. However, the steps in the analysis of uncertainty do not extend (explicitly) into the decision context. The “White Paper” should make it clear that (a) uncertainties in a model propagate forward into prediction uncertainty, (b) that decisions be seen to be robust in the presence of such prediction uncertainty, and (c) that procedures are available for ranking the various contributing sources of uncertainty and that steps may be taken to reduce the consequences of the most critical of these, as the model is successively improved over time.

Fourth, if a judgment on the acceptability of a given model is to be made, it will be necessary to make such a judgment on the basis of incommensurate forms of information and evaluative diagnostics, for example, from peer review, on the quantitative uncertainties of model parameter estimates, on the statistics of the overall match of the model's outputs with history, and so on. The Subcommittee is not aware of procedures for facilitating the process of coming to the required, summary judgment and accordingly recommends that the “White Paper” acknowledge this gap clearly.

Last, turning to the charge regarding "How to" guidances, the Subcommittee recognizes the difficulty many will have in grasping the concepts and arguments underlying the discussion of the “White Paper” (as evident in our responses to other Charge Questions). The Subcommittee feels, therefore, that there may indeed be a need for producing written materials expressing these issues in a format more accessible to a much wider audience. However, the Subcommittee wishes to record its recognition that the issues of model evaluation are neither trivial nor inherently easy to understand; great care will be needed when explaining them in lay terms.

The Subcommittee also recognizes that there will be cases when no quantitative modeling effort is warranted. In these situations the effort should stop at the conceptual and perhaps qualitative level of model development.

Charge 6 : EPA welcomes any additional comments or suggestions.

The Subcommittee suggests that when the guidelines for model acceptability are first implemented, there will be a backlog of Agency models whose quality must be evaluated in the broad format recommended by the “White Paper”. Although these models are already in existence (and have been used), future users will still need to know which of them have been evaluated as acceptable. The Agency should give consideration to the details of any procedure for clearing this backlog.

With respect to this backlog of existing models, in particular, implementation of the acceptability guidelines will afford opportunities for updating the theoretical basis of each model (whether it still reflects the state-of-the-science) and the appropriateness of the input data, given contemporary sampling and instrumentation schemes. Again, consideration should be given to the procedure for taking advantage of this opportunity for updating.

The Subcommittee is aware that the Agency's Quality System Management Plan was recently reviewed by the SAB's Environmental Engineering Committee (SAB, 1999b). The well-designed program outline contained in the Models Acceptability White Paper could be extended to serve as the basis of the modeling elements component of the Agency's Quality system.

4. CONCLUSION

The Subcommittee finds that the guidance in the “White Paper” is generally useful for addressing the quality and reliability of models. Model quality issues have been comprehensively addressed. The general approach and the specific points raised in it are very constructive, and can provide the basis for a more effective and consistent process of model development and application across the Agency. Furthermore, it includes the beginnings of a clarification of how peer review could be interfaced with the majority of more computationally-oriented facets of an evaluation. However, at this point the paper lacks guidance and information about what needs to be included and associated steps required for implementation to be useful for decision makers and the public (e.g., a communication strategy for obtaining user feedback and establishing a dialog in model development with stakeholders). The Subcommittee suggests that model information be related to the totality of the specific decision-making use, and in context it should strive to achieve “transparency” in both technical and non-technical respects (e.g., policy decisions).

The Subcommittee recommends that EPA define key terms, and use them consistently throughout the document, and that the “White Paper” include a broader view of what needs to be included for effective model development and the associated steps required for implementation. The Subcommittee also recommends that the Agency Program Offices and Regions consider investing in the development of a host of high-quality outreach educational materials, tailored to different audiences, on the general topic of models as decision support tools. The Subcommittee recommends that EPA seek targeted stakeholder participation to obtain insight into the range of applications, available data and constraints that exist in different locales throughout the United States. EPA should also ensure that the public, the regulatory community, and local decision-makers realize the role that value judgments play in the selection of a model and the way a model is used. The Subcommittee supports the establishment of the Committee for Regulatory Environmental Modeling (CREM) and a model clearinghouse by the CREM to allow model users to document the model evaluation process, and those outside the EPA to access this information and to provide feedback.

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AN SAB ADVISORY ON THE “WHITE PAPER” ON THE NATURE AND SCOPE OF ISSUES ON ADOPTION OF MODEL USE ACCEPTABILITY CRITERIA

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