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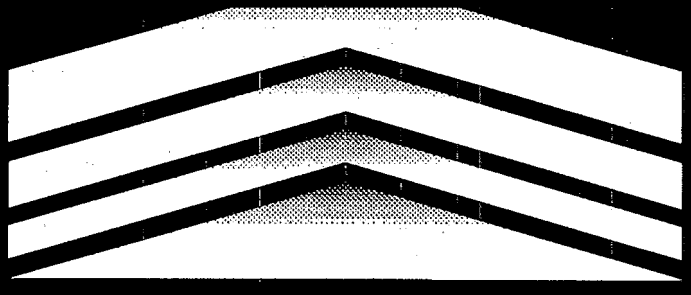
Report of the Agency Task Force on Environmental Regulatory Modeling

Guidance, Support Needs, Draft Criteria and Charter



Agency Task Force on
Environmental Regulatory
Modeling

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

APR 25 1994

MEMORANDUM

SUBJECT: Transmittal of the Report of the Agency Task Force on Environmental Regulatory Modeling

FROM: Steve Cordle, Co-Chair
Office of Research and Development (8401)

Larry G. Reed, Co-Chair
Office of Solid Waste and Emergency Response (5204G)

THROUGH: Gary J. Foley
Acting Assistant Administrator
Office of Research and Development

Elliott P. Laws
Assistant Administrator
Office of Solid Waste and Emergency Response

TO: Robert M. Sussman
Deputy Administrator

This memorandum transmits the final report (attached) of the Agency Task Force on Environmental Regulatory Modeling (ATFERM) for your consideration and approval. The report is also being transmitted to the Science Policy Council's Steering Committee so that its recommendations may also be addressed by that Council.

The report includes conclusions and recommendations for improvement in the development and use of modeling as well as a guidance document which will help ensure the scientific integrity of the use of models. In addition, the report recommends and ATFERM requests your approval for the establishment of a permanent Committee on Regulatory Environmental Modeling (CREM) which will liaison with the Science Policy Council and will require new resources.

Background

In 1992, the Assistant Administrators of the Offices of Solid Waste and Emergency Response and of Research and Development, recognizing the importance of the use of modeling in environmental decision-making, requested the formation of an Agency-wide task force to address modeling issues and needs. The Science Advisory Board had previously issued a resolution on modeling which described the need for improvement in the development and use of modeling. In response to the Assistant Administrators' request, EPA's Deputy Administrator established an ad hoc Agency Task Force on Environmental Regulatory Modeling (ATFERM).

Since that time, the Task Force members, representing most of the Agency's programs and regions, have developed a number of products, issue papers, conclusions and recommendations. These products are based on the Task Force's original charge to address "acceptability criteria for model use,..Agency requirements for peer review,..expansion of training and technical support" and the "advisability of establishing a permanent Agency-wide Expert Panel on Environmental Modeling".

Contents

Section I of the report describes the status and need for training and technical support for modeling. Section II contains a draft set of "acceptability criteria" for models.

Section III of the report contains the final version of the "Guidance for Conducting External Peer Review of Environmental Regulatory Modeling". The Guidance provides a resource for EPA managers who utilize modeling and who are responsible for implementing peer review. The Guidance has been reviewed by the Science Advisory Board, the Council of Science Advisors, and, at your request, the Assistant and Regional Administrators. You have been asked, in a separate memorandum, to transmit the final version of the Guidance Agency-wide.

Section IV, described below, contains a proposal and draft charter for a permanent group on environmental modeling.

Recommendations for a Permanent Group

The Task Force requests that you consider and approve its recommendation to establish a permanent group, or Committee on Regulatory Environmental Modeling (CREM), as described in Section IV of the report. The Committee's purpose is to provide the Agency with consistent yet flexible modeling guidance and tools to support environmental decision making.

The Task Force recommends that the chair of the permanent Committee be a liaison to the Steering Committee of the Science Policy Council. As described in Section IV of the report, the Task Force also recommends that the executive secretariat and staff for the permanent Committee be placed in the Office of Research and Development and that an initial sum of $300,000 be available through a pro-rated percentage of the Agency's Headquarter's programs and its Regions. The proposed operating plan for the first two years is also found in Section IV, Appendix II.

Along with approving the establishment of the Committee, we are asking you to appoint its chair, in your role as Chair of the Science Policy Council.

Please respond with your approval and/or questions regarding the proposal. If you need additional information or desire a briefing, please notify either of us.

Attachment

cc: Agency Task Force on Environmental Regulatory Modeling
Science Advisory Board Executive Committee
Assistant Administrators
Regional Administrators
Science Policy Council Steering Committee

FINAL REPORT

From The

AGENCY TASK FORCE ON

ENVIRONMENTAL REGULATORY MODELING

To The

DEPUTY ADMINISTRATOR

March 1994

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INTRODUCTION AND SUMMARY

Purpose

This report from the Agency Task Force on Environmental Regulatory Modeling (ATFERM) presents the Task Force's conclusions and recommendations on how environmental models and modeling activity can be improved to produce greater contributions to U.S. EPA's regulatory mission. In addition, the report contains three products which will help ensure the scientific integrity of the use of models.

Background

Although environmental simulation models have been used to support decision-making in EPA for many years, their use has accelerated in concert with the ready availability of personal computers and the demand of decision-makers for quantitative answers. At the same time, the number of trained modelers has not kept pace. Consequently, the Agency and others have become increasingly concerned about consistency and quality in model development, selection, and application. For instance, the Science Advisory Board expressed its concerns in "Resolution on Use of Mathematical Models by EPA for Regulatory Assessment and Decision Making" in 1989 (SAB-EEC-89-012).

Since model-supported decision-making can have enormous environmental and economic ramifications, EPA took action. The Assistant Administrator for Research and Development and the Assistant Administrator for Solid Waste and Emergency Response jointly requested the Deputy Administrator, as the Chair of the former Risk Assessment Council, to establish a task force to examine the issues.

In March 1992, the Deputy Administrator approved the creation of an ad hoc "Task Force on Environmental Regulatory Modeling," charging it to "...complete within 12 months a recommendation to the Agency on specific actions that should be taken to satisfy the needs for improvement in the way that models are developed and used in policy and regulatory assessment and decision-making." In the same memorandum, the Deputy Administrator asked the Task Force to "...report on the advisability of establishing a permanent Agency-wide Expert Panel on Environmental Modeling." In addition, the following are the areas were to be addressed:

- Acceptability criteria for model use, generally and in particular circumstances
- Formal technical and policy guidance on model development
- Agency requirements for peer review and for documentation of models prior to use
- Expansion of training and technical support activities for EPA personnel who oversee model applications

Activities

With a 12-month timetable and the constraint that all Task Force members were volunteering their time while carrying on all of their normal duties, the Deputy Administrator's charge was broken down into four objectives: (1) draft a set of "acceptability criteria" for models; (2) assess the need for technical support for model users; (3) draft guidance on external peer review of modeling; and (4) decide whether a permanent, agency-wide panel on modeling was needed.

Task Force members divided up into subgroups to address each of the four objectives. Monthly teleconference meetings were held to track progress, discuss key issues, and exchange comments on each of the products being developed. By June of 1993 draft documents presenting the Task Force's conclusion on the first four objectives were prepared and circulated for comment. From July 1993 through October 1993 each of the four documents was refined. Table 1 lists the Task Force membership and identifies which members contributed to each product. The full text of each report or product is included in this report.

Summary of Conclusions from the Report

Major Conclusions

The four sections of this report contain many conclusions. Below is a summary of the major conclusions. In addition, each section may include recommendations based on those conclusions.

Training and Technical Support Needs

There is a need to support those models developed and used to further specific program objectives. Such support could come from Agency technical experts or by training that makes use of the latest technologies. (Page I-4)

Personnel responsible for model use or interpretation need to be properly trained in the exercise of that responsibility. (Page I-2)

More technical support needs to be provided to model users in general, so that these decision-support tools can be fully exploited. (Page I-8)

Technical support can be provided in the form of training, direct help to users, and information transfer. (Page I-1)

Short-term technical support needs could be met by panels of experts (or forums) until more formal support programs are needed and instituted. (Page I-4)

Table 1: ATFERM Members, 1992-1993
(Alphabetically, by last name)

Co-Chairs:	Steve Cordle; Co-Chair; ORD
	Larry Reed; Co-Chair; OSWER
Members:	Bob Ambrose; ORD/ERL-1,3
	Tim Barry; OPPE
	Barbara Brown; Region I
	David Burden; ORD/RSKERL-1
	Dorothy Canter; OSWER
	Alan Cimorelli; Region III-3
	Mimi Dannel; Region VI-1*
	Michael Firestone; OPPTS-3*
	Rick Johnson; OARM
	Russell Kinerson; OW-2,3
	Will LaVeille; ORD
	Felix Locicero; Region II
	Mary Lou Melley; OSWER-**
	Don Miller; Region VII
	Linda Ross, Region II-■
	Zubair Saleem; OSWER
	Mark Tedesco; Region II
	Joe Tikvart; OAR-1,2,3
	Wayne Valentine; Region II-■
	Luanne Vanderpool; Region V-2*,1
	Thomas Wadell; Region I
	Richard Walentowicz; ORD-2
	Joe Williams; ORD/RSKERL-■
	John Yearsley; Region X-3
	Larry Zaragoza; OSWER-3

Key:

1 = Training and Technical Support
2 = Model Use Acceptability Criteria
3 = Peer Review

1* = Training and Technical Support Leader
2* = Model Use Acceptability Criteria Leader
3* = Peer Review Leader
** = Task Force Coordinator
■ = Designated Representative

Model Use Acceptability Criteria

Model code acceptability should be judged on the basis of appropriateness, accessibility, reliability, and usability. (Page II-5)

There is a need for a "Model Information System" which lists models that meet the acceptability criteria. (Page II-7)

Once a collection of acceptable models is assembled, there is a need for a process to periodically assess the models being used to support rule-making decisions and regulatory impact assessments. (Page II-8)

Agency Guidance For Conducting External Peer Review Of Environmental Regulatory Modeling

Peer review is an important tool in EPA's campaign to document the quality and credibility of the science upon which its regulatory and policy decisions are based. (Page III-2)

Not all managers who must consider the utility of peer reviews are aware of their importance. Many of those who are aware do not have a clear description of the procedures by which peer review can be carried out successfully. In particular, guidance on external peer review is needed now. (Page III-1)

There is a need to begin external peer review as early in the model development phase as possible, in order to maximize its value. (Page III-3)

External peer review of a model's applicability needs to be conducted well in advance of any decision-making that depends upon the model's results. (Page III-4)

Information gathered from the peer review of scientific issues is critical in understanding the uncertainties and usefulness of a model in regulatory decision-making. Therefore, such information needs to be available to the decision-maker before decisions based on the model are made. (Page III-4)

Proposed Charter For A Committee On Regulatory Environmental Modeling

There is an increase in the use of computerized environmental models to support EPA policy and regulatory decision-making. (Page IV-1)

Improper development, application, and use of models will undercut EPA's sound science objective and abuse the potential of models as decision-making tools. (Page IV-1)

There is a need for a centralized focus -- such as an Agency council on regulatory environmental modeling -- to promote the goal of providing EPA's senior policy-makers with

a set of well-developed, well-documented, and well-understood modeling tools to support environmental decision-making. (Page IV-2)

Summary of Products and Recommendations

Sections 1 through 4 of this report present the Task Force's findings and recommendations on each of the four objectives discussed above, in "Activities". Each presentation is divided into four parts -- background, problem statement, recommendations, and full text. Here is a very brief summary of each product.

"Training and Technical Support Needs" asserts that a coherent, multi-faceted program of technical support should be developed throughout the Agency. Program offices, regions, and laboratories all have responsibilities in this area.

"Model Use Acceptability Criteria" establishes four criteria for determining when an environmental regulatory model may be acceptable for Agency use.

"Agency Guidance For Conducting External Peer Review Of Environmental Regulatory Modeling" describes when external peer review of modeling may be appropriate. It sketches the general process of model development and application, showing the points at which external peer review can be applied. It also lists specific elements of an external peer review process that can be adapted to each particular review exercise.

"Proposed Charter For A Committee on Regulatory Environmental Modeling" describes and recommends that a body be created by the Deputy Administrator and/or the new Science Policy Council (SPC) that would be charged with carrying on the work begun by the Task Force. Several options and recommendations for placing the Committee within EPA's organizational structure are offered, together with an examination of its staffing needs and initial budget.

SECTION I - TRAINING AND TECHNICAL SUPPORT NEEDS

Introduction

The field of environmental modeling is extremely dynamic. New models are constantly being developed and existing models updated. In addition, many program areas are evolving, resulting in changes in the type and number of models utilized by program staff. These factors, along with many others, contribute to the increasing need for technical support.

The purpose of this report is to identify critical areas of technical support needs and to suggest ways of meeting these needs.

This report assumes that an Agency goal is to equip personnel involved in conducting or evaluating environmental modeling with the tools required to thoroughly understand and execute these models. In order to provide adequate technical oversight, proficiency in modeling and interpreting model output is needed.

Technical support generally falls into three categories: training, direct support services, and information transfer. In the sections to follow, each of these areas will be described along with suggestions for providing the necessary services. Attention must be given to determining what mix of training and technical support is appropriate for each office. Information is also presented regarding the specialized resource needs of environmental modeling.

Training

Myriad environmental models are currently used for decision making in various Agency programs. In recent years, the use of personal computer software has made complex models more accessible and more efficient for the user. It can be argued, however, that the ready availability of software in the absence of proper training can be counter-productive. While this view may seem elitist at first, the analogous situation of making a GC/MS (gas chromatograph/mass spectrometer) available to an untrained chemist seems absurd. Because environmental models are available to nonspecialists, the educational and training needs required to responsibly operate the software and interpret the results must be considered.

Basic Educational Requirements

Generally, a quantitative, interdisciplinary background is most helpful as a starting point in environmental modeling. Specific areas to focus on include mathematics, physics, chemistry, soil science, fluid mechanics, geology, and hydrogeology. Education in these environmental sciences and engineering is an important step to becoming an effective model user. However, it is difficult to specify an exact program since educational programs evolve over time.

Recommendation: The Agency should ensure that personnel responsible for model use or interpretation have an adequate background education. Quantitative, interdisciplinary academic training is most helpful as a starting point in environmental modeling.

Professional Short Courses

Short courses can effectively introduce the new user to model theory, methods of application, and realistic case studies. Since they usually last from two to five days, these courses provide time-efficient, intense, focused contact between users and model experts. Short courses are most effective if the user has the appropriate background education requirements; they cannot substitute for basic education in a discipline.

Historically, short courses have been offered directly by EPA research and program offices, by universities, and by consulting firms. Unfortunately, the cost of university and consulting firm courses is often prohibitive for State and Federal employees. Typical registration costs are $600 - $1,200 for a 3-4 day course.

Recommendation: A model that is intended for wide use by States or the regulated community should be supported by EPA-sponsored professional short courses. In situations where development of an EPA-sponsored course is not feasible, adequate training and travel funds should be allocated for EPA personnel to attend university or private sector courses.

Self-study Programs

A self-study program may be the most flexible alternative because it can be pursued at the user's convenience. The effectiveness of such a program depends on the student, time commitments, the available model documentation and bibliography for the underlying theory, as well as other informational materials.

Self study programs can be offered in a variety of formats. For example, videotaped lectures have been utilized by some programs. However, it is sometimes difficult to maintain the necessary level of concentration throughout the lecture due to the nature of the material. As a result, while the cost is fairly low and distribution is simple, a video course may not provide a highly effective learning environment. A more interactive system, such as computer-based tutorials, may prove to be a more viable self-study format, even though the initial development cost could be significantly higher than a video presentation.

Recommendation: Each program area should evaluate the degree of model use and determine the most effective methods of providing self-study courses, such as video taped lectures or interactive, computer-based tutorials.

Satellite Transmission of Courses

Training courses transmitted via satellite are currently offered through the Office of Air Quality Planning and Standards (OAQPS). During calendar year 1993, approximately 500

hours of programming have been broadcast. It is expected that 100 Regional and State facilities will eventually be capable of receiving the courses following an initial investment of roughly $9,000 for the downlinking equipment.

Transmission costs are currently $2,500 per day for use of the uplinking facilities and approximately $500 per hour for satellite time. However, the system is converting to the use of compressed digital signals, and transmission costs are projected to drop to $100 to $125 per hour. Given the large audience which can be reached, the use of satellite courses is extremely cost effective. In addition to cost considerations, satellite viewing of training courses may be more conducive to learning than some self study methods since they offer the opportunity for interaction with other students as well as the trainer.

Recommendation: The Agency should continue to support and investigate the expanded use of satellite training courses.

Direct Support Services

Often, the Regions and States need individualized ad hoc assistance for particular model applications. Direct support may include activities such as software consultation, providing advice on data needs, or assisting with model output interpretation. This type of assistance is essential for the day-to-day operation of programs which utilize environmental modeling.

Integrated Model Evaluation System (IMES) and Exposure Models Library on CD-ROM

ORD's Integrated Model Evaluation System (IMES) is available to users as an aid in selection of appropriate fate and dispersion models. This is a PC-based system which helps select suitable models in the various media (air, surface water, ground water, non-point source, and multi-media) for a user's particular scenario or site. The system assists the user in selection by matching model capabilities to site characteristics and information needs. It also contains an extensive database on model applications, validation, and features.

The Exposure Models Library on CD-ROM is an extension of the IMES. The disc (with a storage capacity of close to 600 MB) allows for an efficient, cost effective, and environmentally sound distribution mechanism of the various models (and their documentation and user manuals) used in EPA programs. It contains many of the models described in the IMES and includes source code as well as sample input and output files.

Recommendation: The Agency should continue the support of IMES and the Exposure Models Library as both a tool in model selection and a vehicle for training on initial modeling concepts.

ORD Technical Support

Historically, model distribution and much technical support has been provided by ORD field offices. For example, the Corvallis, Oregon, field office of ERL-Newport supports EPA marine plume models and answers general questions on mixing zone theory. The Center for Exposure Assessment Modeling in Athens, Georgia, offers support for a variety of widely used exposure assessment models. The Center for Subsurface Modeling Support (CSMoS) at the R. S. Kerr Environmental Research Laboratory (RSKERL) in Ada, Oklahoma provides ground water and vadose zone modeling software and technical support to public agencies and private companies throughout the nation.

Models developed by these and other ORD offices are tools to assist in developing sound public policy and support programs' missions. If the models are misapplied or their results are misinterpreted, unsound program and policy decisions may result.

In the past, ORD technical support and model distribution were often provided by both Agency and contractor staff. Recent concerns have been raised about the use of contractors to provide EPA advice in response to user calls. As a result, in some laboratories, on-site contractor support is no longer used and some technical support activity has been discontinued.

Recommendation: Program offices that develop models should also provide for their proper use.

EPA offices (Office of Research and Development, Office of Administration and Resources Management, Office of Acquisition Management, and Office of Inspector General) should develop and agree upon appropriate contract guidelines and contract vehicles for providing model user technical support services.

Technical Assistance Panels

Technical assistance panels (TAP) are composed of Agency and contract personnel with specialized areas of expertise. The Surface Water Assessment Technical Team or SWAT Team is one such TAP. The SWAT Team, funded by the Total Maximum Daily Load (TMDL) program, provides short-term expertise to EPA Regions, States and local governments that are developing TMDLs. The Regional TMDL Coordinator communicates all requests for assistance to the Headquarters contact. Then, the Headquarters contact determines which SWAT Team member would be most suitable for the particular application. The estimated annual budget for the SWAT Team is $100,000.

The user community originally suggested this concept. So far, customers have been very pleased with the response time and the results.

Recommendation: Other program areas should be encouraged to explore the benefits of establishing panels of experts that could provide short-term technical support.

Technical Forums/Centers

The Superfund and RCRA Technical Support Project (TSP) uses two Regional Forums, seven Technical Support Centers and an Environmental Response Team to provide direct scientific and engineering technical assistance to regional Superfund and RCRA staff. TheTSP is funded and managed by OSWER's Technology Innovation Office (TIO).

TSPs provide a wide range of support: site visits, the development or review of sampling plans, the review of contractor work plans and reports, data interpretation, development or evaluation of remedial alternatives, and the development or review of model applications.

The Engineering Forum and the Ground Water Forum are composed of regional technical personnel. While neither is focused specifically on modeling, ground water modeling is one of the concerns of the Ground Water Forum. The two Forums serve as communication networks for technical information transfer between the Regions and the Centers. They work to improve technical consistency among the regional Superfund and RCRA programs and are a source of technical information for the regions, holding semi-annual meetings and monthly conference calls.

The Technical Support Centers provide technical assistance in response to regional requests. Questions or other brief requests are phoned directly to the appropriate Center by EPA staff project managers. More substantive requests (while usually initiated through a phone conversation) require a written technical assistance request. Since the project began in 1987, the TSP had responded to over 1,400 requests for technical assistance at Superfund sites.

Recommendations: Program areas other than Superfund and RCRA should explore the benefits of establishing a similar technical transfer/technical support organization.

To facilitate the formation of additional forums, the Agency should identify broad categories of environmental models that support local, State and Federal environmental regulations. Such categories might include ground water, surface water, air, and multimedia models. For those categories where needs for technical assistance and for exchange of information are identified, Regional technical forums should be encouraged.

Information Exchange

In the dynamic field of environmental modeling, new models continue to be developed while existing models are updated. In addition, many program areas are expanding, resulting in changes in the type and number of models utilized by program staff. As a result, there is an increasing need for information exchange. The following tools are among those which may be used to facilitate this exchange.

Technical Guidance Manuals

Technical guidance manuals for each program area are essential for providing information about models. Distribution of guidance manuals is a common method of providing information to the States and the general public. The primary drawback is that the available manuals are often out of date.

Recommendation: Technical guidance manuals are essential tools for technology transfer. The resources necessary for updating these manuals should be provided. These manuals should be incorporated with the IMES and Exposure Models Library CD-ROM.

Bulletin Board Systems

Bulletin Board Systems can be a cost effective means of providing a variety of services. For example, a number of models can be downloaded from a bulletin board system in a matter of minutes, while obtaining these models by mail can take several weeks. Bulletin boards are also often used for notifying the modeling community of training opportunities and the availability of recent publications. Users can access bulletin boards directly via modem or indirectly via local area networks (LANs) that connect to them.

Recommendation: Use of interactive Internet nodes, as well as electronic bulletin board systems should be encouraged as a means for distributing information such as model availability and training opportunities, thus providing access to the public as well as Federal and State personnel.

Technical Library

Professional publications and journals also play an important role in information transfer. Given the high cost of dues, many government employees, both Federal and State, do not maintain memberships in professional societies or personally subscribe to trade publications. However, it is imperative that Agency personnel remain abreast of developments in their fields.

Recommendation: Since an adequate university library is not always available or convenient, the Agency should compile a list of professional journals and periodicals which should be available at every EPA library.

Clearinghouses

The Office of Air Quality Planning and Standards Model Clearinghouse is the focal point for reviewing specific proposed actions which involve interpretation of guidance on the use of air quality models or deviations from that guidance. The Clearinghouse functions within the organizational structure of EPA and communicates with the Regional Offices. Any

coordination with State and Local agencies or individual sources on Clearinghouse activities is the responsibility of the Regional Offices. This is handled in three ways:

(1) The Clearinghouse, at the request of a Regional Office, reviews the proposed use of a "non-guideline" model for technical soundness and national consistency.

(2) The Clearinghouse screens State implementation plans for adherence to modeling policy, identifies and recommends resolutions.

(3) The Clearinghouse communicates significant decisions involving the interpretation of modeling guidance to regulatory model users through an annual "Clearinghouse report" that identifies significant decisions and the circumstances involved. This report serves to improve consistency in future decisions and is a source of technical information for the Regional Offices.

Recommendation: Clearinghouses similar to the Office of Air Quality Planning and Standards Model Clearinghouse should be encouraged. This clearinghouse serves an important function by providing guidance that merges the technical and policy aspects of model applications.

The ORD Integrated Model Evaluation System (IMES) is another example for a centralized model information system applicable to all media models. It contains information on model validation studies/status, uncertainty analyses, an extensive bibliographic database, and details of model applications.

Recommendation: The IMES should be further enhanced to incorporate the acceptability criteria (discussed elsewhere in this report), and could be considered (to models) as analogous to the way IRIS (Integrated Risk Information System) is to chemical compounds.

The Agency should adopt guidelines for preparing reports on model applications and for formulating policies requiring such reports to be prepared and made available through a clearinghouse or technical library.

As stated under "Technical Forums," the Agency should identify broad categories of environmental models that provide support for local, State, and Federal environmental regulations. An inventory of applications should be developed which defines and implements the paradigms appropriate to each of the categories. Distribution of this inventory of applications could be accomplished via a clearinghouse and/or through EPA libraries.

Joint Federal Interagency Model Clearinghouse

Numerous Federal agencies (e.g., USGS, USACE, USDA, etc.) support the development, distribution, and use of environmental models because they are important scientific tools which enhance the understanding of environmental problems. For instance, the U.S. Army

Corps of Engineers identified mathematical models of ground water flow and contaminant transport as essential to designing remedial actions for contaminated sites. The U.S. Army Corps of Engineers prepared a report which characterizes the technical capabilities in modeling. It identifies three stages of producing a site-specific model of the processes that control ground water flow and contaminant transport. In addition, the National Research Council recently recommended developing a research program focused on the application of ground water modeling in support of remediation efforts by the Corps.

Recommendations: Since many Federal agencies utilize environmental modeling it is recommended that the concept of a Joint Federal Interagency Model Clearinghouse be explored. This clearinghouse would be responsible for model distribution and would direct the user to the appropriate Agency and office for technical support.

Resource Needs

Adequate resources, including technical personnel and computer hardware and software, are required to support applications of a reasonable set of environmental regulatory models within the Agency. At present, the availability of technical personnel and computer hardware and software varies from Region to Region and program to program. Therefore, a review of the existing resources throughout the Agency is necessary. In addition, the resource needs of the model user community should be identified and options for meeting those needs should be developed.

Minimum requirements for computer hardware and software should be developed and a suitable contract vehicle made available for procuring those products. The requirements and equipment should be routinely evaluated to ensure that the equipment reflects the current technology.

Recommendation: The Agency should conduct a requirements survey and identify options for filling the needs of model users; such needs include technical personnel and computer hardware and software.

Immediate needs for technical support may be addressed by intra-Agency teaming as has been the case in the implementation of the SWAT team for TMDL development.

SECTION II - MODEL USE ACCEPTABILITY CRITERIA

Introduction

The use of mathematical models for environmental decision making has increased significantly in recent years. Modeling has become an important methodology in support of the planning and decision-making processes involved in environmental management. Within the U.S. Environmental Protection Agency (EPA) environmental models are being used to support rule-making decisions and regulatory impact assessments.

One of the questions managers continue to ask when models are utilized is "Is this an EPA-accepted model?" This question is also asked by model reviewers. The response that a model code has previously been used does not fully answer the question. Model codes are accepted or rejected on a case-by-case basis. Except for the Office of Air Quality Planning and Standards (OAQPS), there really is no formal mechanism to evaluate model acceptability nor is there a list of EPA-accepted models. Without the establishment of a set of model code selection criteria and a process to evaluate model codes, users and decision-makers will continue with re-evaluations and uncertainty about the acceptability of models being applied and the results therefrom. These constant examinations are redundant and introduce inconsistencies.

A comprehensive set of criteria for model selection could reduce inconsistency in model selection. A process to identify acceptable model codes categorized by application niche (and potentially to identify those that are preferable and those that are redundant) will ease the burden on the Regions and States applying the models to their programs. The Science Advisory Board (SAB) has also voiced similar concerns about the Agency's application and use of models.

In 1988, the SAB (SAB-EC-88-040, SAB-EC-88-040A) recommended that EPA formalize mechanisms for the review and acceptance of environmental models for all media. SAB's "Resolution on Use of Mathematical Models by EPA for Regulatory Assessment and Decision-Making" (SAB-EEC-89-012) reiterated this recommendation and made as one of its main points: "There is a need for a central coordinating group within the EPA to assess the status of environmental models currently used or proposed for use in regulatory assessment and to provide guidance in model selection and use by others in the Agency".

Clearly, development of a mechanism to determine acceptability of environmental models is only one aspect of improving the Agency's use of environmental models for regulation. Establishment of acceptability criteria, establishment of model documentation requirements, and identification of application niches are other steps that need to be taken. The issue of the appropriate application of a model, that is, the selection of models that satisfy the particular scenario and the match between model capabilities, site characteristics and information needs, is a related but separate issue that must be determined on a case-by-case basis. Model code may be deemed acceptable generically, yet its application in a particular situation can be

unacceptable. For example, a model code's acceptability is determined within the context of a particular application niche (or niches); outside of that niche the model may not be acceptable. Even within an appropriate application niche, a large discrepancy between the model's data requirements and the available site data would suggest that the model may not be the best choice for the specific situation. Finally, selection of an acceptable model for a particular situation does not prevent the misuse of the model during its application.

Definitions

The definition of "model" is somewhat ambiguous. The term is used variously as a synonym for conceptual model, mathematical model, computer model and simulation models. The term "model" may apply to either a computer code without site-specific data, or to the representation of a specific system using such a generic code, together with pertinent data. For this report, a ***model*** is defined as a non-unique, simplified, mathematical description of the physical system, coded in computer programming language together with a quantification of the simulated system (in the form of boundary conditions, system and process parameters, and system stresses). The generalized computer code (software) usable for different site- or problem-specific simulations is referred to as a ***model code*** or ***generic model.*** A ***Conceptual Model*** is an interpretation or working description of the characteristics and dynamics of a physical system. The ***Application Niche*** of a model code is the particular prototype physical system or set of defining conditions for which the model code is scientifically defensible. The objective of code ***Verification*** is to check the correctness and accuracy of the computation algorithms used to solve the governing equations, and to assure that the computer code is fully operational. Verification of a model code is separate from verification of a model application. ***Model application verification*** involves testing the accuracy and predictive capabilities of the calibrated model on a data set independent of the data set used for calibration.

The objective of ***Validation*** of a model is to determine how well the mathematical representation of the physical processes of the model code describes the actual system behavior. Given the uncertainties of conceptualization and parameter estimation inherent in environmental modeling, models are never literally validated, instead they are invalidated. ***Calibration*** is the process of adjusting model parameters within physically defensible ranges until the resulting predictions give a best possible good fit to observed data.

Approaches Considered

Several programs of the Agency including the Office of Air Quality Planning and Standards (OAQPS) and the Office of Solid Waste and Environmental Response (OSWER) have considered the issue of model acceptability criteria and approaches to the question of model selection. From these initiatives, much can be learned.

Air Quality Models

OAQPS has developed air quality models suitable for regulatory application. OAQPS, in response to the requirements of the Clean Air Act and in response to comments to include other models in its Guideline on Air Quality Models, developed some criteria (published in March 1980 Federal Register notice) which additional models had to satisfy before they would be considered by the Agency. This is a mechanism by which non-EPA models can be considered for inclusion in the Guidelines. Solicitation of new, improved models is continuous. Under this program, models submitted to the Agency for consideration and evaluation must meet the following criteria.

1. The model must be computerized and functioning in a common FORTRAN language suitable for use on a variety of computer systems.

2. The model must be documented in a user's guide that outlines the appropriate theory upon which it is based, identifies the mathematics of the model, data requirements and the program operating characteristics at a level of detail comparable to that available for currently recommended models.

3. The model must be accompanied by a complete test data set including input parameters and output results. The test data must be included in the user's guide as well as provided in computer-readable form.

4. The model must be useful to typical users. Such users should be able to operate the computer program(s) from available documentation.

5. The model documentation must include a comparison with data or with other well established analytical techniques.

6. The developer must be willing to make the model available to users at reasonable cost or make it available for public access through the National Technical Information Service; the model can not be proprietary.

Submittal of models for consideration also requires specific information on any related documentation concerning past applications and performance of the model. Models are organized into several categories and subjected to intensive evaluations by category or application niche. The evaluation process includes statistical measures of model performance in comparison with measured air quality data and, where possible, peer review. When a single model is found to perform better than others in a given category, it is recommended in the Guidelines on Air Quality Models for application in that category as a preferred model.

If no model is found to clearly perform better through the evaluation exercise, then the preferred model is selected on the basis of other factors such as past use, public familiarity, cost or resource requirements, and availability. The models not specifically recommended for use in a particular category are summarized in a separate index of the Guidelines; these

models must be subjected to a case-specific evaluation before they can be used for regulatory applications. Other models may be used but require justification on a case-by-case basis using consistent pre-established model evaluation procedures.

It must be emphasized that these criteria represent the minimum requirements for Agency consideration. Models meeting these criteria then undergo evaluation by the Agency's experts and a judgement on their acceptability is made.

OSWER Assessment Framework

During the past few years, The Office of Solid Waste and Emergency Response (OSWER) has pursued activities related to improving the management of modeling in the Superfund and RCRA programs. Products of this effort have included the "Ground-Water Modeling Compendium", the "Assessment Framework for Ground-Water Model Applications", and a survey of model use in the waste management programs. The Assessment Framework addresses the use and review of ground-water model applications. It contains a series of assessment criteria focus on the activities and thought processes that should be a part of a model application. Within the Assessment Framework are factors related to model code selection. Relevant criteria include:

The reliability of the model code should be assessed including a review of:

- Peer review of the model's theory (or the publication of the theory in a peer-reviewed journal)
- Peer reviews of the model's code
- Verification studies (evaluation of the model results against laboratory test, analytical solutions, or other well accepted models)
- Relevant field tests (application and evaluation of the model to site-specific conditions for which extensive data sets are available)
- The model's (code) acceptability in the user community as evidenced by the quantity and type of use.

The usability of the model code should be assessed including the availability of:

- The model binary code
- The model source code
- Pre- and post- processors
- Existing data resources
- Standardized data formats
- Complete user instruction manual
- Sample problems

- Necessary hardware
- Transportability across platforms
- User support
- Key assumptions

Acceptability Criteria

Before an environmental model code is used as a planning or decision-making tool, its credentials should be established through a systematic and detailed examination of the generic model relative to a comprehensive set of selection criteria. Model selection is more than just choosing the "best" model of a physical system. The selection process must also take into account such real-world constraints as available resources for the project. Acceptability must be determined within the context of the appropriate application niche and modeling objectives (e.g. screening study or detailed investigation).

A selected model must first accurately represent the significant features of the physical system being considered. Passing this test, the next aspect of model selection is the cost and effort required for implementation, which must be balanced against the potential benefits to be achieved by the model. There is obvious tension between an optimal technical representation of the physical system and the cost of implementation, as increasing model resolution (fineness of temporal and spatial scale of model prediction) and model accuracy usually involve increased expense and effort. A model selection decision of acceptability must reflect both the characteristics of the site and pollutant and also reflect available resources and acceptable levels of uncertainty.

Proposed criteria for models code acceptability are presented below. These criteria are generic; it is anticipated that the criteria will be refined for specific media (air, surface water, ground water). While many of the elements in the set of criteria are objective, other elements are more subjective. Appropriate performance measures need to be established for the subjective criteria. The criteria fall into four broad categories: Appropriateness (is the model code appropriate for the physical system being described?), Accessibility (what is the availability of the code?), Reliability (credibility, verification, validation, and performance evaluations), and Usability (relating to the functional and operational attributes of the code). A draft report prepared for ORD (Current and Suggested Practices in the Validation of Exposure Assessment Models, Office of Health and Environmental Assessment, September 30, 1987) considered ways to evaluate and rank reliability of models in more detail than is appropriate here.

1. Appropriateness

    a. What is the model's application niche? Why was this model code developed? What programmatic questions are the model code attempting to answer?

b. What are the strengths, weaknesses and applicability of this model relative to its application niche? How does this model perform relative to other models in this application niche?

2. Accessibility

a. Is the model code (source code and executable, compiled version) available free or at a nominal cost? If model results will be used to form expert opinions, all parties should have access to the source code of the model.

3. Reliability

a. Has the theoretical basis for the model code been peer reviewed?

b. Have the algorithms and methods of solution of the model code been peer reviewed? Have the program structure and program logic of the model code been peer reviewed?

c. Has the model code undergone verification testing (evaluation of model results against laboratory tests, analytical solutions, synthetic test data sets, or other well accepted models)?

d. Has the model code been applied and tested against relevant field data?

e. What is the model code's acceptability in the user community? Does there exist a number of successful applications of this model code? Have successful peer-reviewed applications of this code been published?

f. How well does the model code perform in terms of accuracy, bias and precision?

g. How well does the model code perform in terms of convergence, stability of solution algorithms, and the absence of terminal failures?

4. Usability

a. Is the model code well structured and internally documented? Where possible, self-explanatory parameter, variable, subroutine, and function names should be used.

b. Is full model documentation available? Good documentation should include:

i. Model description (including intended application niche(s), theoretical framework, underlying assumptions, and limiting conditions)

ii. Model input data definitions, descriptions, and format requirements

iii. Type and format of output data provided

iv. Description of routines, source listing

v. Complete execution instructions, error message explanation, trouble-shooting guide and description of hardware requirements

vi. Sample model runs (input data sets and output results)

vii. Code verification and validation information.

c. Is user support available for this model code (including user training and continuing support and development of the model code)?

d. What kinds of data are required for running the model? To what extent are these data available? How critical to the model is the quality of the data?

e. Are pre- and post-processors available for this model code?

g. How tedious are the model setup and input preparation processes?

h. What computational resources are required to run the model code? How computationally efficient is the model code (i.e. What is the achieved numerical accuracy versus memory requirements and code execution time)?

Information about the various models' codes their application niche(s) their capabilities and data requirements, and how they satisfy the acceptability criteria could be compiled and incorporated into a "Model Information System." This system would be an updated source of model information accessible to EPA staff, State staff, and contractors (possibly via an electronic bulletin board). Information on new models and on revisions of existing models should be added to the information system as such information becomes available. Potentially there would be a separate database for each media (air, surface water, groundwater) with cross references to a database for multimedia models.

The "Model Information System" should build on already existing databases and resources such as the databases developed by the EPA-sponsored International Ground Water Modeling Center, EPA's Integrated Modeling Evaluation System (IMES), EPA's Center for Exposure Assessment Models (CEAM), and EPA's Center for Subsurface Modeling Support (CSMOS). Such a Model Information System should be an cross-program effort; its overall management could be the responsibility of a permanent Agencywide Environmental Modeling Committee.

Conclusions and Recommendations

Environmental models are increasingly being used to support regulatory decisions and impact assessments. There is a continuing need to improve the approach to modeling for environmental decision-making by the EPA and to reduce the potential for environmental model misuse. The issue of model acceptability for regulatory use is one of the more critical aspects of understanding and considering model use in the Agency.

There is a strong need for the Agency to provide guidance to users and decision-makers for selecting environmental models to support planning and decision-making efforts of the Agency. The set of criteria for model acceptance proposed in this report is the foundation for such guidance. Creation of a "Model Information System" that includes information on models (air, ground water, and surface water) and how the models satisfy the points of the acceptability criteria is a necessary adjunct to establishing the criteria. A set of criteria without any readily accessible source of model information would be of little value. The Agency should institute a group (permanent Agencywide Environmental Modeling Committee) to establish model acceptability criteria (including performance measures) and a "Model Information System".

There is also a need for the Agency to systematically assess environmental models being used to support rule-making decisions and regulatory impact assessments. While establishing a model code evaluation process is relatively simple conceptually, it is logistically complex and staff-intensive. Establishment and implementation of such a process would require a level of commitment considerably beyond that required to establish a "Model Information System". Careful consideration of the appropriateness and resource requirements of any evaluation process is needed. Following establishment of acceptability criteria and the Model Information System (MIS), the permanent Agencywide Environmental Modeling Committee should consider the issue of implementing a model code evaluation process and upgrading the MIS.

NOTE

The following Guidance has been updated since April 24, 1994 when it was transmitted to the Deputy Administrator, to reflect the latest (June 7, 1994) statement regarding EPA's Peer Review Policy.

SECTION III - AGENCY GUIDANCE FOR CONDUCTING EXTERNAL PEER REVIEW OF ENVIRONMENTAL REGULATORY MODELING

I. INTRODUCTION

According to EPA's Peer Review Policy Statement dated June 7, 1994, (see attachment):

> Major scientifically and technically based work products related to Agency decisions normally should be peer-reviewed. Agency managers within Headquarters, Regions, laboratories and field components determine and are accountable for the decision whether to employ peer review in particular instances and, if so, its character, scope, and timing. These decisions are made in conformance with program goals and priorities, resource constraints, and statutory or court-ordered deadlines. For those work products that are intended to support the most important decisions or that have special importance in their own right, external peer review is the procedure of choice. Peer review is not restricted to the penultimate version of work products; in fact, peer review at the planning stage can often be extremely beneficial.

By contrast, the policy specifically excludes "non-major or non-technical matters that Agency managers consider as they make decisions."

Clearly, environmental models (i.e., fate and transport, estimation of contaminant concentrations in soil, groundwater, surface water and ambient air, exposure assessment) that may form part of the scientific basis for regulatory decision-making at EPA are subject to the peer review policy. However, it cannot be more strongly stressed that peer review should only be considered for judging the scientific credibility of the model including applicability, uncertainty, and utility (including the potential for mis-use) of results, and not for directly advising the Agency on specific regulatory decisions stemming in part from consideration of the model output.

The purpose of this guidance is to provide a resource for those program managers responsible for implementing the peer review process. More specifically, this guidance is provided as an aid in evaluating the need and, where appropriate, conducting external peer review related to the development and/or application of environmental regulatory modeling. This specific guidance for modeling has been prepared to complement general peer review guidance currently being developed by the Agency's Council of Science Advisors (Council). Thus, Section II (framework for peer review) and Section IV (peer review mechanisms and general criteria) reflect the latest Council guidance, and will be revised in the future as Agency-wide guidance on peer review evolves.

The relationship of external peer review to the process of model development and application, including consideration of peer review at various stages in the process is described in Section III of this guidance.

Section V concerning "Documentation of the Peer Review Process" has been included in response to comments from the Agency's Science Advisory Board who cited the need for more detailed guidance on the mechanics of the review process.

The specific elements of what could be covered in an external peer review of model development and application are presented in Section VI of this guidance. These elements are not meant to be prescriptive or limit the nature of peer review, but rather are intended as an aid to improve the thoroughness and consistency of peer review.

To reiterate one of the major recommendations in the March 1992 report commissioned by former Administrator William K. Reilly re: "Safeguarding the Future: Credible Science, Credible Decisions (The Report of the Expert Panel on the Role of Science at EPA)":

> "Quality assurance and peer review should be applied to the planning and results of all scientific and technical efforts to obtain data used for guidance and decisions at EPA, including such efforts in the program and regional offices. Such a requirement is essential if EPA is to be perceived as a credible, unbiased source of environmental and health information, both in the United States and throughout the world."

In conclusion, this document is intended to provide guidance to program managers in their efforts to consider, and apply where appropriate, external peer review to environmental regulatory modeling. The guidance contained in this document must not be construed as rigid requirements.[1]

II. FRAMEWORK FOR PEER REVIEW OF ENVIRONMENTAL REGULATORY MODELING

Peer review can be an important tool in assisting the Agency to document the quality and credibility of the science upon which its regulatory and policy decisions are made. Modeling to provide the scientific support for environmental regulatory decision-making at EPA can be thought to conceptually involve three stages including: (A) model development; (B) model application; and (C) consideration of modeling results in decision-making.

External peer review, as discussed in more detail below, is generally relevant to the first stage of model development and may be relevant in appropriate cases to the second stage of model application. Although external peer review is not directly germane to the regulatory or policy decision itself, it is important at this third stage to bring forward information regarding prior peer review comments and the Agency's response related to model development and/or application. This information may aid the decision maker in interpreting

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[1] The guidance set out in this document is not final Agency action. It is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the guidance provided herein, or act at variance with the guidance, based on an analysis of specific circumstances. The Agency also reserves the right to change this guidance at any time without public notice.

and weighing the utility of modeling results along with all the other considerations (e.g., field data; risk, cost, and benefits information; requirements to use best available technology; environmental justice issues; etc.) in reaching a regulatory decision.

Broader guidance regarding the applicability of peer review, as discussed in the Introduction, is currently being developed by the Council of Science Advisors. As this broader guidance develops and evolves in the future, the framework for external peer review of environmental regulatory modeling, as discussed below, will be revised.

A. Model Development

Models are developed for a variety of reasons, including:

1. use as research tools to explore new scientific issues;

2. simplification and/or refinement of existing model paradigms or software;

3. use as screening tools; and

4. to estimate compliance with regulatory requirements (e.g., National Ambient Air Quality Standards).

This guidance document, by its terms, does not directly address models developed for reasons other than to support regulatory decision-making (e.g., research tools). Models developed expressly for and used exclusively within a research program should be subject to essentially the same review process as other research results (e.g., informal critique by scientific colleagues, formal appraisal by senior scientists and managers, publication in refereed journal, etc.). However, if the purpose of a research model is expanded in the future to develop scientific information for Agency decision-making, then the program manager should consider arranging for reassessment of the model in accordance with the guidance presented below.

From a general scientific perspective, a well-conceived model is one that provides an acceptable mathematical approximation of a physical, chemical, biological, social or economic system. Model development frequently touches on the interface involving the state-of-the-art in several areas including: (1) the technical and scientific understanding of processes and mechanisms; (2) applicable solution techniques (e.g., analytical, numerical); (3) computer science and technology; and (4) the Agency's need for scientific decision-support tools. The goal of model development is to provide methods which can be applied to improve Agency analysis and decision-making. As such, the development of environmental models cannot be performed in a scientific vacuum. There must be a coherent class of applications in mind against which the appropriateness of the science can be judged.

At the model development stage, a key step is to define and compare to existing models, the set of conditions under which the use of a model is scientifically defensible - this is known as

the "application niche." Peer review of model development would be expected to include evaluation of the application niche, along with consideration of uncertainty and other areas of model performance. Approaching peer review from this perspective should help the decision maker understand the limitations of the scientific basis of the model and confidence in its results. It is only with this firm knowledge that the Agency can develop sound regulatory and policy decisions.

External peer review of major technical issues related to environmental regulatory modeling is generally a lengthy process. This is precisely why external peer review should be identified as an important and integral aspect of an action plan for model development. At first glance external peer review might be expected to slow down the process. However, initiating peer review at early stages may, in fact, save time by redirecting misguided initiatives, identifying alternative approaches, or providing strong technical support for a potentially controversial position.

B. Model Application

The middle stage, model application, begins with examining the stated application niche and its applicability to current needs and/or exploring whether a model can be tailored to fit a new niche. For existing models, especially models developed outside of EPA, peer review may be appropriate to the extent that either: 1) new information becomes available which calls into question the appropriateness of the previously defined application niche; or 2) a model might be considered for application outside the niche for which it was originally developed.

Peer review of a model's applicability should, where possible, be planned well in advance of any decision-making involving use of the model's results. In this way, the formation of "sound science" is distinct from the regulatory decision in which it is considered. The results of such a peer review can aid in the ultimate judgment by a decision maker to consider whether or how to use a particular model's result in the regulatory process.

Normally, the first application of a model should undergo peer review. For subsequent applications, a program manager should consider the scientific/ technical complexity and/or novelty of the particular circumstances as compared to prior applications (also see Section IV-B). Peer review of all similar applications should be avoided because this would likely waste precious time and monetary resources while failing to provide the decision maker with any new relevant scientific information upon which to base a regulatory or policy selection. Nevertheless, a program manager may consider conducting peer review of applications upon which costly decisions are based or applications which are likely to end up in litigation.

As an alternative to peer review of model application, the Office of Air Quality Planning and Standards has developed a formal review and acceptance procedure through rulemaking to evaluate the utility of alternative models for a particular application.

C. Environmental Regulatory Decision-Making

The final stage involves consideration of modeling results in the decision-making process. This stage may include consideration of: (1) selecting among available models and assumptions/standard defaults; and/or (2) whether/how to consider modeling results in the regulatory process. Information previously derived from peer review of scientific issues may provide key information for the decision maker in understanding the uncertainties and utility (and potential for mis-use) of modeling results. When possible, public discussion of the scientific and technical underpinnings associated with the earlier stages of model development and/or application in advance of the final stage of regulatory decision-making is expected to reduce criticism regarding the Agency's use of "sound science."

Environmental regulatory and policy decisions also involve other scientific and non-scientific factors, and are by law, required to be made by the responsible Agency decision makers. Thus, such decisions are not appropriate subjects for scientific peer review. Rather, the process of **public comment** is frequently employed by the Agency at this stage.

III. RELATIONSHIP OF EXTERNAL PEER REVIEW TO THE PROCESS OF ENVIRONMENTAL REGULATORY MODEL DEVELOPMENT AND APPLICATION

The Agency's peer review policy notes that "properly applied, peer review not only enriches the quality of work products but also adds a degree of credibility that cannot be achieved in other way. Further, peer review early in the development of work products in some cases may conserve future resources by steering development along the most efficacious course." Since this subject guidance focuses on the role of external peer review, its relationship to other levels of peer review can best be understood by considering where external peer review may fit into the total process of environmental regulatory modeling. The following paradigm is meant to illustrate the general process:

Step 0: The program manager within the originating office (AA-ship or Region) identifies elements of the regulatory process which would benefit from the use of environmental models. A review/solicitation of currently available models and related research should be conducted. If it is concluded that the development of a new model is necessary, a research/development work plan would be prepared.

Step 0b: (optional) The program manager may consider internal and/or external peer review of the research/development concepts to determine whether they are of sufficient merit and whether the model is likely to achieve the stated purpose.

Step 1: The originating office develops a new or revised model or evaluates the possible novel application of model developed for a different purpose.

Step 1b: The program manager may consider external peer review of the

(optional) technical or theoretical basis prior to final development, revision or application at this stage. For model development, this review should evaluate the stated application niche.

Step 2: Initial Agency-wide (internal) peer review/ consultation of model development and/or proposed application may be undertaken by the originating office.

Model design, default parameters, etc. and/or intended application are revised (if necessary) based on consideration of internal peer review comments.

Step 3: External peer review is considered by the originating office.

Model design, default parameters, etc. and/or intended application are revised (if necessary) based on consideration of external peer review comments.

Step 4: Final Agency-wide evaluation/consultation may be implemented by the originating office. This step should consist of consideration of external peer review comments and documentation of the Agency's response to scientific/technical issues.

(Note: Steps 2 and 4 are relevant where there is either an internal Agency standing or ad hoc peer review committee or process).

A program manager may decide that peer review (step 2 -internal, and step 3 - external) should take place at more than one time during the processes of model development and model application (i.e., optional steps 0b and/or 1b). This decision would depend on the nature and complexity of scientific issues that are presented.

Additionally, a program manager may also consider the utility of employing the broader concept of peer involvement -- that is, to augment staff efforts by soliciting subject-matter experts from outside the program.

Based in part on the results of a scientific peer review of model development and application, as well as other non-technical issues, the program manager would be responsible for advising the decision maker as to the consistent, equitable, and appropriate use of the model and its output for environmental regulatory purposes.

IV. MECHANISMS AND GENERAL CRITERIA FOR CONDUCTING EXTERNAL PEER REVIEW

The mechanisms and general criteria for conducting external peer review presented below are based upon generic peer review guidance currently being developed by the Council of

Science Advisors. As this broader guidance develops and evolves in the future, this Section will be revised.

A. Peer Review Mechanisms

Mechanisms for accomplishing external peer review include, but are not limited to, the following:

i. Using an ad hoc technical panel of at least three scientists;

ii. Using an established external peer review mechanism such as the Science Advisory Board or Scientific Advisory Panel; or

iii. Holding a technical workshop.

Qualifications for peer reviewers will likely vary for model development versus model application. For the former, the emphasis may be toward modelers, while for the latter, the emphasis may be toward scientists with technical expertise in other disciplines (e.g., statistics, field monitoring, etc.).

New models, or significant modifications and/or new applications of established models, should be considered for publication in refereed journals. However, this step should be supplemental to and not a substitute for the peer review mechanisms presented above.

B. General Criteria

General criteria to be considered for determining when and by what mechanism to initiate an external peer review of the development and/or application of environmental regulatory models include:

i. Use of model results as a basis for major regulatory or policy/guidance decision-making;

ii. Significant investment of Agency resources;

iii. Inter-Agency or cross-Agency implications/applicability;

iv. Treatment of a new scientific issue; or

v. Novelty and/or complexity of the science.

V. DOCUMENTATION OF THE PEER REVIEW PROCESS

It is important to prepare documentation for each peer review conducted and make this available to the decision maker along with the modeling results. The record should include the following information:

A. Identity of the peer reviewers, their relevant expertise, and their institutional affiliation;

B. Questions/issues posed to the peer reviewers;

C. Reviewer comments, either as a collection of individual statements or as a consensus statement; and

D. Agency response to peer review comments including rationale.

VI. SPECIFIC ELEMENTS OF EXTERNAL PEER REVIEW FOR ENVIRONMENTAL REGULATORY MODELING

This Section of the guidance addresses the specific elements that should be considered to provide the Agency with consistent scientific/technical external peer review of environmental regulatory model development and/or application.

Such elements could include, but are not limited to:

A. Model Purpose/Objectives

The first step in evaluating a model used for environmental regulatory purposes is to clearly understand the broad context in which a model is intended to be used.

i. What is the regulatory context in which the model will be used and what broad scientific questions is the model intended to answer (e.g., evaluating the range of human respiratory exposure resulting from air toxics release from a power plant)?

ii. What is the model's application niche (i.e., the particular physical, chemical, and/or biological system and set of defining conditions for which the model is expected to be scientifically defensible)?

iii. What are the model's strengths and weaknesses? How well does the model fit its intended application niche compared to existing models and available data sets? It is important that the Agency avoid duplicating prior efforts.

B. Major Defining and Limiting Considerations

With a clear understanding of the broad purpose and objectives of a model in a regulatory context, the scientific context needs to be addressed.

i. Which processes are characterized by the model (e.g., transport, diffusion, chemical reactions, removal mechanisms, etc.)?

ii. What are the important temporal and spatial scales? Is the grid resolution appropriate for the problem?

iii. What is the level of aggregation?

C. Theoretical Basis for the Model

Once the regulatory and scientific contexts of a model have been defined, the basis for problem solving must be formulated.

i. What algorithms are used within the model and how were they derived? What is the mechanistic basis?

ii. What is the method of solution (numerical, analytic)?

iii. What formulations are used for those processes which are parameterized?

iv. How does the basis for problem solving compare to existing models? What is the scientific rationale?

v. What are the shortcomings of the modeling approach (e.g., missing or over-simplification of key processes, restrictive dimensionality, etc.)?

D. Parameter Estimation

Parameter estimation may be based on case specific data or in their absence, on default values. In the latter case, it is important to understand how parameter defaults were established.

i. What methods were used for parameter estimation?

ii. What data were available for parameter estimation?

iii. What methods were used to estimate parameters for which there were no data?

iv. What is the reliability of parameter estimates?

v. What are the boundary conditions and are they appropriate?

E. Data Quality/Quantity

All models require the input of various types and amount of data. Models may also rely on experimental data to help shape their computational algorithms. In large measure, the utility of a model for regulatory purposes depends on the quality, quantity, and spatial and temporal adequacy of data used in its design and in support of its application.

Questions related to model design include:

i. What data were utilized in the design of the model?

ii. How can the adequacy of the data be defined in terms of quality, quantity, and spatial and temporal applicability taking into account the regulatory objectives of the model?

Questions related to model application include:

i. What kinds of data are required to apply the model?

ii. To what extent are these data available and what are the key data gaps?

iii. Have data quality objectives been defined? If so, are they scientifically defensible?

iv. Is the quantity of data sufficient to address the likely variability? What statistical analyses were performed and are they appropriate?

v. To what extent are the data suitable with regard to estimating spatial and temporal effects?

vi. Do additional data need to be collected and for what purpose?

F. Key Assumptions

The applicability of a model depends on the adequacy of its basic underlying assumptions.

i. What are the key assumptions?

ii. What is the basis for each key assumption and what is the range of possible alternatives?

iii. How sensitive is the model toward modifying key assumptions?

G. Model Performance Measures

The most basic test of a model's adequacy is to understand how well its results compare with real world measurements.

i. What criteria have been used to assess model performance?

ii. Did the data bases used in the performance evaluation provide an adequate test of the model in terms of applicability to the modeling niche?

iii. How accurate can the model be expected to perform? Does the model exhibit any overall bias throughout the range of its predictions? Bias is an important test of the model's formulation since intrinsic system uncertainty is not present.

iv. How well does the model address, distinguish, and report variability and uncertainty in its output? Which parameters and key assumptions are most significant in determining the model's variability and uncertainty?

v. How does the model perform relative to other models in this application niche?

H. Model Documentation and Users Guide

The utility of model for regulatory purposes depends on the availability of a clear documentation report and a comprehensive users guide. Do these cover:

i Model applicability and limitations?

ii. Data input?

iii. Interpretation of results? and

iv. Documentation of the model code and other key aspects such as verification testing?

I. Retrospective

A retrospective analysis of the "big picture" may sometimes reveal insights that an analysis of individual components of a model may miss.

i. Does the model satisfy its intended scientific and regulatory objectives?

ii. Is there any available scientific evidence to suggest changes to either the model design and/or key parameters and assumptions prior to its use for regulatory purposes?

iii. How robust (i.e., not overly sensitive toward small changes in modifying key assumptions or input data) are the model predictions?

iv. How well does the model output quantify the overall uncertainty resulting from limitations/simplifications in its design; use of standard assumptions; availability of supporting data; etc.?

v. What key research is necessary to refine or improve the model and/or the data bases upon which it relies?

The elements provided above are not meant to be prescriptive or limit the nature of external peer review. Rather the purpose for their inclusion is to provide modeling-related guidance for peer review protocols which will be consistent with more general guidance being developed by the Council of Science Advisors.

Attachment 1: "Peer Review and Peer Involvement at the U.S. Environmental Protection Agency" dated June 7, 1994

PEER REVIEW AND PEER INVOLVEMENT AT THE U. S. ENVIRONMENTAL PROTECTION AGENCY

This document establishes the policy of the United States Environmental Protection Agency (EPA) for peer review of scientifically and technically based work products that are intended to support Agency decisions. Peer review is presented in the context of the broader concept, peer involvement.

BACKGROUND

The report "Safeguarding the Future: Credible Science, Credible Decisions"[1] focused on the state of science at EPA. The panel of experts who prepared the report emphasized the importance of peer review, especially external peer review, and the need for broader and more systematic use of it at EPA to evaluate scientific and technical work products. Their specific recommendation regarding peer review reads as follows:

> "Quality assurance and peer review should be applied to the planning and results of all scientific and technical efforts to obtain data used for guidance and decisions at EPA, including such efforts in the program and regional offices. Such a requirement is essential if EPA is to be perceived as a credible, unbiased source of environmental and health information, both in the United States and throughout the world."

In response to this recommendation, then-Administrator Reilly directed staff to develop an EPA-wide policy statement, which he issued in January, 1993. The paragraphs below preserve the core of that earlier statement while updating it to specify the role of the Science Policy Council in guiding further implementation of the policy. Effective use of peer review is indispensable for fulfilling the EPA mission and therefore deserves high-priority attention from program managers and scientists within all pertinent Headquarters and Regional Offices.

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[1] EPA/600/9-91/050, March 1992.

PEER INVOLVEMENT AND PEER REVIEW

EPA strives to ensure that the scientific and technical underpinnings of its decisions meet two important criteria: they should be based upon the best current knowledge from science, engineering, and other domains of technical expertise; and they should be judged credible by those who deal with the Agency. EPA staff therefore frequently rely upon peer involvement -- that is, they augment their capabilities by inviting relevant subject-matter experts from outside the program to become involved in one or more aspects of the development of the work products that support policies and actions.

One particularly important type of peer involvement occurs when scientifically and technically based work products undergo peer review -- that is, when they are evaluated by relevant experts from outside the program who are peers of the program staff, consultants, and/or contractor personnel who prepared the product. Properly applied, peer review not only enriches the quality of work products but also adds a degree of credibility that cannot be achieved in any other way. Further, peer review early in the development of work products in some cases may conserve future resources by steering the development along the most efficacious course.

Peer review generally takes one of two forms. The review team may consist primarily of relevant experts from within EPA, albeit individuals who have no other involvement with respect to the work product that is to be evaluated (internal peer review). Or the review team may consist primarily of independent experts from outside EPA (external peer review).

POLICY STATEMENT

Major scientifically and technically based work products related to Agency decisions normally should be peer-reviewed. Agency managers within Headquarters, Regions, laboratories, and field components determine and are accountable for the decision whether to employ peer review in particular instances and, if so, its character, scope, and timing. These decisions are made in conformance with program goals and priorities, resource constraints, and statutory or court-ordered deadlines. For those work products that are intended to support the most important decisions or that have special importance in their own right, external peer review is the procedure of choice. Peer review is not restricted to the penultimate version of work products; in fact, peer review at the planning stage can often be extremely beneficial.

SCOPE

Agency managers routinely make regulatory and other decisions that necessarily involve many different considerations. This policy applies to major work products that are primarily scientific and technical in nature and may contribute to the basis for policy or regulatory decisions. By contrast, this policy does not apply to nonmajor or nontechnical matters that Agency managers consider as they make decisions. Similarly, this policy does not apply to these ultimate decisions.

This policy applies where appropriate, as determined by the National and Regional Program Managers, to major scientifically and technically based work products initiated subsequent to the date of issuance. Peer review should be employed to the extent reasonable to relevant work products that currently are under development. This policy does not apply to the bases for past decisions, unless and until the relevant scientific and technical issues are considered anew in the Agency's decision-making processes.

Except where it is required by law, formal peer review (as distinguished from the Agency's normal internal review procedures) should be conducted in a manner that will not cause EPA to miss or need extension of a statutory or court-ordered deadline. Agency managers still may undertake peer review if it can be conducted concurrently with necessary rulemaking steps.

LEGAL EFFECT

This policy statement does not establish or affect legal rights or obligations. Rather, it confirms the importance of peer review where appropriate, outlines relevant principles, and identifies factors Agency staff should consider in implementing the policy. On a continuing basis, Agency management is expected to evaluate the policy as well as the results of its application throughout the Agency and undertake revisions as necessary. Therefore, the policy does not stand alone; nor does it establish a binding norm that is finally determinative of the issues addressed. Minor variations in its application from one instance to another are appropriate and expected; they thus are not a legitimate basis for delaying or complicating action on otherwise satisfactory scientific, technical, and regulatory products.

Except where provided otherwise by law, peer review is not a formal part of or substitute for notice and comment rulemaking or adjudicative procedures. EPA's decision whether to conduct peer review in any particular case is wholly within the Agency's discretion. Similarly, nothing in this policy creates a legal requirement that EPA respond to peer reviewers. However, to the extent that EPA decisions rely on scientific and technical work products that have been subjected to peer review, the remarks of peer reviewers should be included in the record for that decision.

IMPLEMENTATION

The Science Policy Council is responsible for overseeing Agency-wide implementation. Its responsibilities include promoting consistent interpretation, assessing Agency-wide progress, and developing recommendations for revisions of the policy as necessary.

The Science Policy Council will oversee a peer-review work group, which will include representatives from program units throughout EPA to effect a consistent, workable implementation of the policy. The work group will assist the programs in (1) formulating and, as necessary, revising standard operating procedures (SOPs) for peer review consistent with this policy; (2) identifying work products that are subject to review; and (3) for each major work product, selecting an appropriate level and timing of peer review.

In assisting the programs, the work group will take into account statutory and court deadlines, resource implications, and availability of disinterested peer reviewers. The group will work closely with Headquarters offices and the Regional Offices toward ensuring effective, efficient uses of peer review in supporting their mission objectives. However, the Assistant Administrators and Regional Administrators remain ultimately responsible for developing SOPs, identifying work products subject to peer review, determining the type and timing of such review, documenting the process and outcome of each peer review, and otherwise implementing the policy within their organizational units.

Because peer review can be time-consuming and expensive, Agency managers within Headquarters, Regions, laboratories, and field components are expected to plan carefully with respect to its use -- taking account of program priorities, resource considerations, and any other relevant constraints as well as the policy goal of achieving high-quality, credible underpinnings for decisions. External peer reviewers should be chosen carefully to ensure an independent and objective evaluation. The affiliations of peer reviewers should be identified on the public record, so as to avoid undercutting the credibility of the peer-review process by conflicts of interest.

This policy is effective immediately. The peer-review work group mentioned above will identify the focal point to whom comments and questions should be addressed and, from time to time, will provide further information about implementation activities.

APPROVED: 
CAROL M. BROWNER, ADMINISTRATOR

DATE: JUN 7 1994

SECTION IV - PROPOSED CHARTER FOR A PERMANENT COMMITTEE ON REGULATORY ENVIRONMENTAL MODELING

Rationale For A Permanent Group

Problem Statement

EPA decision-making is supported by a growing number of computerized environmental models. Use of such models has been prompted by the increasing complexity of the environmental programs EPA manages; by the fact that task-specific data almost invariably are incomplete and sometimes unobtainable within the constraints of technology, time, and other resources; and by the sophistication of the regulated community. Use of such models has also been fueled in part by wider access among Agency personnel to desktop computers capable of running such programs.

While the value of computerized environmental models to EPA's policy and regulatory decision-making is indisputable, the widespread and informal employment of highly sophisticated, often narrowly focused models can lead to misuse and misinterpretation. Such failings undermine EPA's commitment to sound science. This must be avoided.

To that end the following issues require attention and action at the highest levels within each Office:

- The Agency needs a formal internal process by which to judge the quality and acceptability of environmental models;
- EPA needs a recognized body Agency-wide to perform or confirm such judgments;
- The Agency needs a standard methodology for model development;
- The evolution and life-cycles of models utilized by EPA should be defined and managed consistently; and
- The level of experience and the type of training needed to properly use and interpret a model should be known and documented.

A permanent Committee on Regulatory Environmental Modeling is proposed to guide and facilitate these and related efforts.

Ad Hoc Task Force

EPA management recognizes the importance of these models and their appropriate applications. The Science Advisory Board issued its modeling resolution in 1989. In response, the Assistant Administrators of the Offices of Solid Waste and Emergency Response and of Research and Development requested formation of a task force on environmental modeling. In March 1992, EPA's Deputy Administrator established an ad hoc Task Force on Environmental Regulatory Modeling.

The Task Force was charged "to complete within twelve months a recommendation to the Agency on specific actions it should take to satisfy the needs for improvement in the way that models are developed and used in policy and regulatory assessment and decision-making."

During the timeframe, the Task Force developed products on:

- Agency Guidance for Conducting External Peer Review of Environmental Regulatory Modeling
- Acceptability Criteria for Model Use
- Technical Support Needs

Permanent Group for Environmental Modeling

The Deputy Administrator also requested the Task Force to "report on the advisability of establishing a permanent Agency-wide Expert Panel on Environmental Modeling." In response to this request, the Task Force has developed the following proposal of establishing a permanent group as well as language for a draft charter.

The Task Force recommends establishing a permanent group to focus on environmental modeling. To address the unmet needs of the Agency, the permanent group should have the following attributes:

Authority/ Autonomy	• Speaks for Agency on inter-Agency modeling activities • Coordinates with all offices and regions • Coordinates with other Agency-wide science groups (e.g., Science Advisory Board, Risk Assessment Forum, Council of Science Advisors, etc.) • Develops policy options for consideration by the new Science Policy council (SPC)
Visibility	• Reports to the SPC through its Steering Committee
Resources	• Has committed and available resources to support activities

In developing the draft charter, the Task Force reviewed lists of elements found in existing charters. The elements included in the draft charter for the permanent group on environmental modeling are based on a review of the:

- Risk Assessment Forum Charter
- Environmental Monitoring Management Council Charter
- Council of Science Advisors Interim Charter
- Charter of the former Risk Assessment Council

The Risk Assessment Forum Charter was the primary model for drafting the environmental modeling charter.

Draft Proposed Charter

U.S. Environmental Protection Agency
Committee on Regulatory Environmental Modeling

Charter

Purpose

The Committee on Regulatory Environmental Modeling (CREM) is established to promote consensus on mathematical modeling issues and to ensure that this consensus is incorporated into appropriate modeling guidance.[1] The purpose of the Committee is to provide the Agency with consistent yet flexible modeling tools to support environmental decision making. To fulfill this purpose, the Committee assembles modeling experts from throughout the Agency to study and report on these issues from a cross media perspective.

Scope of Activity

CREM Activities may include:

- providing expertise to the EPA in developing Agency-wide positions on modeling issues;
- providing a central point of focus to address cross media issues that are beyond the purview of any single program office; and
- promoting consistency in model development and application in order to eliminate duplication, confusion, and uncertainty, thus empowering personnel to develop sound scientific input for consideration in environmentally-related decision-making.

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1 As used in this Charter, the terms "modeling" and "model(s)" are limited to the regulatory environmental context. Other modeling activities such as those associated with economics and demography are outside the scope of CREM.

Responsibilities

Responsibilities of the Committee on Regulatory Environmental Modeling are defined to accommodate the dynamic nature of model development, technology, and advances in environmental management. Responsibilities include:

Agency Positions:

- developing and articulating the Agency response to significant modeling issues
- facilitating resolution of modeling issues
- identifying Agency modeling priorities and long term strategies for the Agency
- developing modeling guidance for adoption by the Agency

Cross Media:

- responding to and addressing concerns regarding the determination of levels of confidence in a wide range of models in different media
- facilitating modification and application of models to address health and ecological risks that are not chemical specific

Consistency:

- participating in Agency review and peer review of modeling efforts
- promoting scientific integrity of the modeling process across the Agency
- promoting consistency in model guidance, testing, and evaluation
- promoting continuity in the technical support and distribution of models
- promoting the establishment of protocols for post audits of applications

Agency Expertise:

- responding to requests from the Deputy Administrator, Assistant and Regional Administrators, and the SPC
- promoting continuity in the availability of modeling information
- identifying issues appropriate for the Committee on Regulatory Environmental Modeling

Empowering EPA Personnel

- encouraging the development of easier access to and use of models as well as training and technical support
- promoting more common interfaces for setting up model runs
- promoting a repository for model application and use within the Agency

Membership

The overall composition reflects a balance of scientific disciplines and Agency experience. Selection of members is based on experience and expertise in environmental modeling and underlying disciplines, such as groundwater, drinking water, hazardous waste engineering, exposure assessment, surface water, air dispersion, information systems, and computer software. The Committee on Regulatory Environmental Modeling has representatives from each of the major programs and regional offices.

Criteria

Members should satisfy one or more of the following criteria:

1. The member should have an advanced degree(s) in engineering, science or mathematics, and/or an established record of peer-reviewed publication on model development or application, and/or substantial experience in utilization of models.

2. The member should have at least three years of actual (i.e., "hands-on") experience with mathematical models. The experience should involve activities that include developing, reviewing, or using models or model applications.

3. The member should have at least three years' experience in working with environmental issues.

4. The member should have knowledge of the organizational structure of EPA, its science policies, and Regional operations.

Membership Term

Members must be appointed by an Assistant Administrator or a Regional Administrator who commits to support participation by the member. The membership term is two years. Members may serve multiple terms without limit.

Organization

Reporting/Authority

The Committee on Regulatory Environmental Modeling is established by the EPA Deputy Administrator in his role as Chair of the Science Policy Council (SPC). The Committee reports through the SPC's Steering Committee. Amendments to the charter must be approved by the SPC.

The Committee reports are referred to the SPC for consideration of policy and procedural issues. Committee products or recommendations become Agency policy upon acceptance and concurrence by the Deputy Administrator as Chair of the SPC.

Chair

The Chair of the Committee is appointed by the Deputy Administrator in his role as Chair of the SPC and serves as liaison to the SPC's Steering Committee.

Executive Secretariat

The Executive Secretariat for the Committee works under the direction of the Chair and manages and directs staff members to assure that all logistical and operational needs are met.

Meetings

The Committee on Regulatory Environmental Modeling meetings are held on a regular basis, at least quarterly. Meeting summary reports are reported from each meeting to the SPC. An agenda is distributed by the Committee staff at least one week before each meeting, along with any papers to be reviewed at that meeting.

Subcommittees or work groups may be formed by the Committee to accomplish short term tasks or address ongoing issues. The Chairpersons of such subcommittees, working with the Committee staff, are responsible for processing their reports and for timely presentation to the full Committee on Regulatory Environmental Modeling.

Procedures for the Committee on Regulatory Environmental Modeling

Decisions

Decisions on issues are the result of consensus from members of the Committee and its subcommittees and work groups. Decisions of the Committee are submitted to the SPC through it Steering Committee (hereafter abbreviated as SPC/SC) for concurrence.

Selecting Committee Issues

New issues are proposed at any time by any member and may also originate from the SPC/SC.

The Committee is responsible for developing a yearly operating plan that specifies tasks, activities, and products and is consistent with the Agency Strategic Plan.

Each year, the Committee presents the operating plan and budget to the SPC for review and approval.

Products

Processing Committee Products

The Chairperson of each subcommittee or work group is responsible for developing and adhering to an approved work plan. The subcommittee or work group coordinates with the Committee staff throughout development of the project and briefs the Committee at regular intervals.

Reviewing Products

Products, their peer review comments, and their responses are submitted to the SPC/SC for evaluation of programmatic and regional impacts.

Distributing Products

Completed Committee products are transmitted to the SPC/SC and disseminated by it throughout the Agency.

In general, draft products are available to non-participants only with the approval of the Committee on Regulatory Environmental Modeling.

Public Participation

Committee meetings are not required to be open to the public, but the Committee may sponsor public workshops, as appropriate.

APPENDIX I

Options And Conclusions

In response to the Deputy Administrator's request to "report on the advisability of establishing a permanent Agency-wide Expert Panel on Environmental Modeling," the Task Force developed the following options to analyze the advantages and disadvantages of establishing a permanent group.

Bases on this analysis, the Task Force concluded and recommends that a permanent group be established.

Options for Task Force Continuation

Option	Advantages	Disadvantages
No Permanent Group	No apparent resource commitment No organizational changes	Continued inconsistency and duplication of current efforts No EPA body to develop standards and guidance for the Agency No consistency in model development No cross media perspective
Ad Hoc Group	Formal EPA body to focus on modeling issues Convene when needed Identify objectives and tasks to accomplish within a specific timeframes	Timeframe limits issues that can be addressed No ongoing Agency group to provide expertise or focus Unable to establish and move toward long range goals
Permanent Group	Formal EPA body to focus on modeling issues Ongoing Agency support and expertise Continuity in Agency guidance and standards Focus on cross media issues Promote quality science	Requires resource commitment

Options for Placement of Committee

After concluding that a permanent group is the best alternative for addressing modeling needs within EPA, the Task Force examined two options for placement of the group within the Agency's structure: (1) a technical panel under the Risk Assessment Forum ; and (2) a Committee on Regulatory Environmental Modeling reporting directly to the Science Policy Council.

The Task Force concluded that an SPC-related Committee is the better option based on the following advantages: (1) the focus is not limited to risk assessment issues; (2) SPC is able to provide an Agency-level policy review of modeling issues; and (3) SPC provides a cross-media basis for coordination of intra-Agency and inter-Agency modeling activities.

Options for Placement of Executive Secretariat

The Task Force examined the following options for the placement of the Executive Secretariat and support staff: (1) AA-ship of the Chair; (2) ORD AA's office; and (3) rotation among the AA's Offices.

The Task Force prefers option (2), the ORD AA's office, since a similar science group, the Risk Assessment Forum, is placed there.

Resources

The Task Force recommends providing the Committee on Regulatory Environmental Modeling with two full time equivalent (FTE) positions and $300,000 for its first two years.

The rationale, a proposed estimated budget, and a descriptions of the projects are discussed below in Appendix II.

Source of Resources

The Task Force examined a number of alternatives for the source of funding for the Committee on Regulatory Environmental Modeling, including (1) the Administrator's budget; (2) pro-rated percentage of resources from all AAs and RAs; and (3) the AA-ship of the Chair.

The Task force prefers option (2), the pro-rated percentage of resources from all AAs and RAs, since it reflects the widespread use of models across the Agency.

APPENDIX II

Resources

A resource commitment is necessary to the successful establishment of any Agency-level modeling group. Resources will support the permanent assignment of an executive director and staff and may also provide for contractor assistance.

The Task Force examined the resources of the Risk Assessment Forum which, nine years ago, initially required $140,000 and 1.5 full time employee (FTE) position. Today its current resources are one million dollars and nine FTE.

The Task Force recommends providing the Committee on Regulatory Environmental Modeling with two full time equivalent (FTE) positions and $300,000 for its first two years.

The proposed estimated budget is as follows:

Fiscal Years 1994 through 1996

1. PC&B for two full time equivalent (FTE) positions with additional funds for travel and other administrative costs

   The Committee on Regulatory Environmental Modeling, with its workgroups and/or panels will address the following initiatives:

   Refine the model acceptability criteria, peer review it, secure approval, and distribute as Agency guidance.

   Examine the Air Program's model management program and identify any aspects which could be instituted Agency-wide.

   Distribute the External Peer Review Guidance prepared by ATFERM. Work to promote widespread awareness and acceptance of the guidance.

   Prepare strategic and tactical plans for future Council activities, including an analysis of the resources necessary to achieve them.

2. Funds for contracts and/or Inter-Agency Agreements to support:

   An inter-program workshop to present the Task Force's findings and to continue the dialogue about model use within the Agency. The workshop would also provide program offices with the opportunity to present information on their use of modeling and modeling issues.

   $40,000

Initiation of the development of an Agency inventory of environmental regulatory models which relate to EPA's programs, meet the draft criteria standards now set, and have identified technical support, documentation, and training. Include in this inventory the Air Program's approved models.

$95,000

Establishment of a communications and awareness program regarding the modeling products available.

$35,000

Survey of current modeling technical support and training programs. Identify alternatives for improving such support, particularly in light of new technologies. Care must be taken to ensure the proper mix of technical support and training for each program office, since the most effective combination may vary between offices. Development of a long-term strategy and a short-term action plan for an Agency initiative on technical support for modeling. Implementation of some short-term activities where feasible.

$130,000

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C 20460

MAR 2 1992

OFFICE OF
THE ADMINISTRATOR

MEMORANDUM

SUBJECT: Task Force on Environmental Regulatory Modeling

FROM: F. Henry Habicht
Chairperson, Risk Assessment Council
Deputy Administrator

TO: Assistant Administrators
Regional Administrators

The Environmental Protection Agency uses numerous computer models to support decision-making. These models originate from a number of sources and have a wide variety of users. In 1989, the Science Advisory Board (SAB) issued a resolution on modeling, citing the need for improvement in the way that decision-making needs are factored into the model development process and in the way that models are applied in actual decisions. The Offices of Solid Waste and Emergency Response and of Research and Development have examined these issues and concur with the SAB.

To respond to these needs, the Risk Assessment Council is creating an ad hoc Agency Task Force on Environmental Regulatory Modeling. The purpose of the Task Force will be to complete within 12 months a recommendation to the Agency on specific actions it should take to satisfy the needs for improvements in the way that models are developed and used in policy and regulatory assessment and decision-making.

In its deliberations, the Task Force should explicitly consider and develop where appropriate the following:

- acceptability criteria for model use generally and in particular circumstances
- formal technical and policy guidance on model development
- Agency requirements for peer review and for documentation of models prior to use
- expansion of training and technical support activities for EPA personnel who oversee model applications

I encourage the ad hoc Task Force to examine and evaluate any other activities that seem appropriate. In particular, the Task Force should report on the advisability of establishing a permanent Agency-wide Expert Panel on Environmental Modeling. Such a panel could assume the responsibility for updating the criteria, guidelines, and requirements, and for overseeing the adequacy of training and technical support activities.

Please designate a representative to serve on the ad hoc Agency Task Force. Ensure that the representative you designate for the Task Force has the education and experience described on the attached list of criteria. The Task Force will convene within six weeks and is expected to complete its assignment within twelve months.

This is a high priority initiative, affecting our ability to make correct and defensible regulatory decisions. Help to ensure its success by selecting an appropriate representative for the ad hoc Task Force, and by supporting the results of its efforts including consideration of a permanent Expert Panel.

Please provide the name of your designated representative to Asa R. Frost, Jr., Director of OSWER Information Management (OS-110, FTS 260-6760) within three weeks of the date of this memorandum.

Attachment

Your work with each other and outside experts can have historic implications - Many thanks

ATTACHMENT

CRITERIA FOR MEMBERSHIP
IN THE RISK ASSESSEMENT COUNCIL AD HOC TASK FORCE
ON ENVIRONMENTAL REGULATORY MODELING

1. The member is to be appointed by an Assistant Administrator or a Regional Administrator.

2. The member should have an advanced degree(s) in engineering, science or mathematics, and/or an established record of peer-reviewed publications on model development or application, and/or substantial experience in utilization of models.

3. The member should have at least three years of actual (i.e., "hands-on") experience with mathematical models. The experience should involve activities which include developing, reviewing, or using models or model applications.

4. The member should have at least three years' experience in working with environmental issues.

5. The member should have knowledge of the organizational structure of EPA, its science policies and Regional operations.

6. The member should be clear on the intended level of detail of the study and be prepared (i.e., have the ability and the time) to support the technical effort, as well as the willingness to travel occasionally. Specifically, the member should be prepared and make available at least a time commitment of 5% of work time during the period of the study.

United States
Environmental Protection
Agency

Office of the Administrator
Science Advisory Board
Washington, DC 20460

EPA-SAB-EEC-89-012
January 1989

Report of the Environmental Engineering Committee

Resolution on Use of Mathematical Models by EPA for Regulatory Assessment and Decision-Making

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C 20460

January 13, 1989

EPA-SAB-EEC-89-012

OFFICE OF
THE ADMINISTRATOR

Honorable Lee M. Thomas
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D. C. 20460

Dear Mr. Thomas:

The Environmental Engineering Committee of the Science Advisory Board has prepared the attached resolution for your consideration on the use of mathematical modeling for regulatory assessment and decision-making. This is the second time the Science Advisory Board has acted on the issue of modeling; a 1984 letter called the Agency's attention to this important concern.

Over the last few years the Environmental Engineering Committee has reviewed a number of EPA environmental modeling studies. In doing so, the Committee has noted a number of problems in the development and implementation of models within the Agency that were common to modeling efforts sponsored by a variety of offices. The Committee believed that these common problems would be best called to the Agency's attention through a more general resolution on modeling.

Drafts of the resolution were presented and widely discussed at a series of Committee and Executive Committee meetings during 1988. For instance, an earlier draft of the resolution was quoted at length in the Radiation Advisory Committee's recent report on the sources and transport of radionuclides. While encouraging the overall approach of quantitative risk assessment and modeling for environmental decision-making, this Committee noted a number of common problems in the use of models by the Agency. The following items summarize the main points that are addressed in the attached resolution:

1. There should be a better balance between field and laboratory data collection efforts and modeling analysis for effective environmental assessment;

2. Models for regulatory assessment and decision-making which incorporate state-of-the-art scientific understanding of the environmental processes involved should be developed and used;

3. There should be better confirmation of models with laboratory and field data;

4. Sensitivity and uncertainty analysis of environmental models and their predictions should be conducted to understand level of confidence in model predictions, as well as to identify key areas of future study;

5. An Agency-wide task-group to assess and guide model use by EPA should be formed;

6. There should be an increased effort to hire and support engineers and scientists with modeling development and application skills;

7. There is a need for systematic management of model use within EPA and a careful review of emerging technologies such as personal computer-based models and expert systems; and

8. Peer review at various levels should be coordinated to ensure proper development and application of models.

The resolution identifies a number of ways in which the use of models by the EPA can be improved. The Committee believes that successful implementation of these recommendations will require the establishment of a formal institutional mechanism with responsibility for review, oversight and coordination of model use in EPA.

We are pleased to have had the opportunity to be of service to the Agency, and look forward to your response on this issue.

Sincerely,

Raymond C. Loehr, Chairman
Executive Committee
Science Advisory Board

Richard A. Conway, Chairman
Environmental Engineering Committee
Science Advisory Board

Mitchell J. Small, Chairman
Modeling Resolution Subcommittee
Science Advisory Board

Attachment: Modeling Resolution

cc: John A. Moore
Donald G. Barnes

ABSTRACT

The Environmental Engineering Committee (EEC) of the Science Advisory (SAB) has prepared a resolution on the use of mathematical modeling for regulatory assessment and decision-making. The main points that are addressed in the resolution are as follows: 1) There should be a better balance between laboratory and field data collection; 2) Models should be developed and used which incorporate state-of-the-art scientific understanding of the processes involved; 3) There should be better confirmation of models with laboratory and field data; 4) Sensitivity and uncertainty analysis should be conducted; 5) An Agency-wide task-group should be formed to assess and guide model use by EPA; 6) EPA should hire and support engineers and scientists with modeling skills, 7) Model use needs systematic management at EPA; and 8) Peer review of models should be conducted at various levels.

Key Words: models, mathematical models, modeling resolution.

NOTICE

This report has been written as a 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 a balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency; hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency or of other Federal agencies. Any mention of trade names or commercial products do not constitute endorsement or recommendation for use.

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of the

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RESOLUTION ON THE USE OF MATHEMATICAL MODELS BY EPA FOR REGULATORY ASSESSMENT AND DECISION-MAKING

by the

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Science Advisory Board
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INTRODUCTION

The use of mathematical models for environmental decision making has increased significantly in recent years. The reasons for this are many, including scientific advances in the understanding of certain environmental processes, the wide availability of computational resources, the increased number of scientists and engineers trained in mathematical formulation and solution techniques, and a general recognition of the power and potential benefits of quantitative assessment methods.

Within the US Environmental Protection Agency (EPA) environmental models which integrate release, transport, fate, ecological effects and human exposure are being used for rule making decisions and regulatory impact assessments. This report is directed to the development and validation of such models, an issue which was first addressed in December 1984 by Norton Nelson, Chairman of the Executive Committee of the SAB. In a letter to the EPA Administrator, William Ruckelshaus, it was recommended that a systematic effort of model validation be initiated, including an identification of the appropriate balance between monitoring and modeling. It was further recommended that the relative utility of exposure modeling approaches be evaluated in the form of case studies in various media including model validation and uncertainty analysis.

The Environmental Engineering Committee reaffirms and amplifies these recommendations, based on review of a number of integrated environmental modeling studies during the past few years. Examples include a review of the report, "Comparison of Risks and Costs of Hazardous Waste Alternatives: Methods Development and Pilot Studies" (SAB-EEC Report, July 1985); a review of the Code for Transport in the Unsaturated Zone (FECTUZ) and its potential use for determining whether a waste is hazardous for listing decisions (SAB-EEC-88-030); a review of risk-based regulations for alternative disposal and reuse options for sewage sludge (SAB-EEC-87-013, SAB-EEC-87-015); a review of the Underground Storage Tank (UST) Release Simulation Model (SAB-EEC-88-029); and a review of the draft risk screening analysis for mining wastes (SAB-EEC-88-028). While encouraging the overall approach of modeling for environmental decision-making by EPA and acknowledging the progress made by various offices within the Agency, the committee noted a number of problems in the development and application of models, including: the increased reliance on models rather than background data collection and analysis, an inadequate level of laboratory and field validation for models employed, a lack of studies quantifying the uncertainties associated with model predictions, and concurrently, the potential misuse of particular uncertainty analysis techniques. The following resolutions address these issues, and identify the need for an institutional mechanism within EPA to ensure their implementation.

RESOLUTIONS

1. **A balanced program of field and laboratory data collection and modeling analysis is required for effective environmental assessment.**

The realistic characterization of an environmental problem requires the collection of laboratory and field data - the more complex the problem, the more extensive and in-depth are the required studies. In some cases involving more complex issues, future projections of environmental effects, larger geophysical regimes, inter-media transfers, or subtle ecological effects, mathematical models of the phenomena provide an essential element of the analysis and understanding. However, the models cannot stand alone; adequate data are required. Indeed, a major function of mathematical models is as a tool to design field studies, interpret the data and generalize the results.

A number of recent studies of integrated exposure and risk reviewed by the committee have exhibited an over-reliance on models at the expense of the acquisition of needed data. This trend should be reversed.

2. **Mathematical models for regulatory assessment and decision-making should incorporate, to the extent possible, the state-of-the-art scientific understanding of the environmental problem.**

Mathematical models should ideally be based on a fundamental representation of the physical, chemical and biological processes affecting environmental systems. In the regulatory domain, there may be a need to sacrifice model complexity and rigor because of inadequate process insight, the need for computational efficiency, or because of a lack in available supporting data. There should not, however, be too ready a willingness to abandon fundamental, scientific approaches simply because the required research and data are too difficult to obtain in a short time-span. If this were done, two undesirable results would likely occur. First, an improperly formulated model can lead to serious misjudgements concerning environmental impacts and the effectiveness of proposed regulations. In this regard, a bad model can be worse than no model at all. Second, by accepting an improperly formulated model, the use of a weak scientific approach can become institutionalized within the Agency, and the opportunity to motivate the needed research and data collection can be lost. Rather, shortcomings in process understanding and available data should serve as an incentive for research and data acquisition to improve the foundations for models.

It must be recognized that research and data acquisition to support state-of-the-art model development and validation is a long-term, iterative process involving many scientific and engineering disciplines. A commensurate, long-term commitment to support this effort is required from the Agency.

3. **There is a need for models used in regulatory applications to be confirmed with laboratory and field data.**

There are a number of steps needed to confirm the accuracy and utility of an environmental model. As a preliminary step, the elements of the basic equations and the computational procedures employed to solve them should be tested to ensure that the model generates results consistent with its underlying theory. The confirmed model should then be calibrated with field data and subsequently validated with additional data collected under varying environmental conditions. After the particular regulatory program has been implemented, field surveys and long-term monitoring should be conducted for comparison with model projections. The stepwise procedure of checking the numerical consistency of a model, followed by field calibration, validation and *a posteriori* evaluation should be an established protocol for environmental quality models in all media, recognizing that the particular implementation of this may differ for surface water, air and ground water quality models. It is also recognized that the degree and extent to which the process of validation is conducted for a model depends on the significance of the environmental issue and the consequence of an erroneous decision concerning the problem.

It is recommended that EPA establish a general model validation protocol and provide sufficient resources to test and confirm models with appropriate field and laboratory data.

4. **Sensitivity and uncertainty analysis of environmental models and their predictions should be performed to provide decision-makers with an understanding of the level of confidence in model results, and to identify key areas for future study.**

A number of methods have been developed in recent years for quantifying and interpreting the sensitivity and uncertainty of models. These methods require careful application, as experience with uncertainty analysis techniques is somewhat limited, and there is a significant potential for misuse of the procedures and misinterpretation of the results. Potential problems include the tendency to confuse model uncertainty with temporal or spatial variation in environmental systems, the tendency to rely on model uncertainty analysis as a low-cost substitute for actual scientific research, and the tendency to ignore important uncertainties in model structure when evaluating uncertainties in model parameters. To address the latter issue, sensitivity analysis of a broader nature is required, considering the impact of

alternative model assumptions and omitted processes. As is the case for model validation, the extent to which sensitivity and uncertainty analysis should be performed depends upon the importance of the environmental issue and the relative role of the model in determining the regulatory decision.

Consideration of model sensitivity and uncertainty should be included in all modeling studies. The implications of errors in model structure, as well as errors in model parameters, should be evaluated to determine possible effects on the ultimate regulatory decision.

5. There is a need for a central coordinating group within the EPA to assess the status of environmental models currently used or proposed for use in regulatory assessment, and to provide guidance in model selection and use by others in the Agency.

In the selection of mathematical models for regulatory applications, a thorough understanding of the capabilities, limitations and degree of validation of available models is required. There have been instances where a model developed for a particular purpose was used in a new application without the appropriate steps taken to properly adapt and validate the model in the new problem setting. Conversely, there are cases where available computational programs for models have been ignored and new, but similar, procedures developed at unnecessary effort and expense. Recognizing the need for improved model selection and use, the Sources, Fate and Transport Subcommittee of the SAB Research Strategies Committee (SAB-EC-88-040, SAB-EC-88-040A) recommended that EPA formalize mechanisms for review and acceptance of environmental models for all media. Methods such as those used by the EPA Office of Air Quality Planning and Standards (EPA-450/2-78-027R) were recommended. This would involve identifying tested or recommended models for particular media or environmental settings, establishing procedures for demonstrating the acceptability of alternative models, and instituting a Model Clearinghouse to compile and test models, conduct periodic workshops to ensure consistency in modeling guidance, and promote the use of the most appropriate models and data bases. The Subcommittee also indicated the need to identify currently applied models where improved validation is needed, and to develop a priority list for these validation efforts.

To address the issues of model validation and model selection and use within the EPA, we suggest the establishment of a task-group on mathematical models for environmental quality assessment. Such a group would evaluate the state-of-the-art of models in each of the media, as well as emerging multi-media models, evaluate environmental models used by other government agencies, and provide oversight for model development, validation and application within the EPA. The group would also rank current models

as to their relative importance and need for further validation studies. This Agency-wide task-group should be established as soon as possible.

6. **EPA must hire and support engineers and scientists with appropriate model development and application skills.**

This issue is closely linked to the recommendation of the SAB Research Strategies Committee that EPA increase the numbers and sharpen the skills of the scientists and engineers who conduct environmental research (SAB-EC-88-080). Modeling is not a separate discipline, rather it is a particular skill that is part of the overall environmental science and engineering approach to problem-solving. There has been a tendency to allocate the development of models to the computer specialist, who frequently lacks the understanding of the basic equations and their significance to the environmental problem. Similarly, there has been a tendency to presume that the users of models need not understand the basis for the models. This is incorrect. The proper development and application of models requires engineers and scientists trained in the fundamental principles of the environmental transport problem and computational methods, so that they can develop and work with the model in an informed manner, not just as a black box which is manipulated to obtain numerical output. Note that often the most critical and effective application of models is made by users not involved in the development of the model, as they are more likely to question and challenge the implicit perspectives and assumptions of the model approach. As such, skilled model developers and model users are both required for effective problem-solving.

The Agency should increase its efforts to hire and retain engineers and scientists who are qualified in the area of model development and model use, having both broad and problem-specific skills. The EPA should support their efforts through the program of the Agency task-force on modeling discussed in the previous resolution.

7. **The need for a systematic management of model use within the EPA is heightened by the introduction of new computer systems and modeling technologies.**

The wide availability of personal computers has brought increasing numbers of models to an increasing number of potential users. As a result, the problem of ensuring code validity and proper model use is that much more difficult. Special challenges are also raised by the growing technology of knowledge-based expert systems. Expert systems allow the automation of a wide range of scientific analysis and inference, and are currently being developed for a variety of environmental engineering

problems. EPA should require strict review and critique of expert systems, recognizing that they can, in many ways, be treated like other environmental models. They are tools to aid the decision-maker, they must be rigorously confirmed with field data prior to regulatory application, they require a careful consideration of model sensitivity and uncertainty, and they require trained users familiar with both the fundamental physical principles of the environmental system being considered and the way in which the expert system uses this information to arrive at its recommendation for a design or regulatory decision.

The recommended EPA task group on modeling should pay particular attention to emerging technologies, such as personal computer-based models and expert systems. Careful review, oversight and validation are needed for these beneficial, but relatively untested approaches to environmental modeling.

8. **Peer review at various levels is required to ensure proper model development and application.**

Peer review is an essential element of all scientific studies, including modeling applications. Peer review is appropriate in varying degrees and forms at different stages of the model development and application process. The basic scientific representation incorporated in the model should be based on formulations which have been presented in the peer reviewed scientific literature. Ideally, the model itself and initial test applications should also be presented in peer-reviewed papers. However, this is not always possible given the pace of scientific development and regulatory need. Peer review panels are thus often required to review the scientific capabilities of proposed models and their intended applications. These expert panels should include some combination of internal Agency staff and outside experts. Innovative approaches to model review should be considered, such as the use of "round robin" reviews in which the same modeling task is addressed by a number of independent groups, or the use of benchmark data-sets for testing model accuracy.

The recommended EPA task group on modeling should identify the needs for peer review of models and establish procedures for coordinating the necessary peer review panels.

SUMMARY

The resolutions presented in this report address critical issues that must be confronted to improve the use of models by the EPA. These issues include the need for a better balance between data collection and modeling, the use of state-of-the-art models, the need for model confirmation and sensitivity and

uncertainty analysis, the need for a central coordinating group to provide oversight and guidance on model use within the Agency, the need for more scientists and engineers with modeling skills, the need for review of new modeling technologies, and the need for peer review of model development and application. Many of the recommendations in this report can be implemented by individuals and individual offices within the EPA. This will undoubtedly lead to a more effective use of models by the Agency. The Committee believes, however, that a full and successful response to these resolutions will require the establishment of a formal, institutional mechanism which can promote better review and coordination of model use throughout the EPA. The actual structure of this group and its relationship to previous or ongoing initiatives is an issue that requires further consideration by the Agency. It is hoped that these resolutions will provide further motivation and direction for this effort.