Regulatory Models and the Environment: Practice, Pitfalls, and Prospects

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June 2008

This study was funded by the EPA Office of Research and Development, with additional funding by the US Department of Transportation. Preparation of this manuscript was supported in part by Interagency Agreement DW-89-93058201-1 with Lawrence Berkeley National Laboratory through the US Department of Energy under Contract No. DE-AC02-05CH11231.

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Abstract: Computational models support environmental regulatory activities by providing the regulator an ability to evaluate available knowledge, assess alternative regulations, and provide a framework to assess compliance. But all models face inherent uncertainties, because human and natural systems are always more complex and heterogeneous than can be captured in a model. Here we provide a summary discussion of the activities, findings, and recommendations of the National Research Council's Committee on Regulatory Environmental Models, a committee funded by the US Environmental Protection Agency to provide guidance on the use of computational models in the regulatory process. Modeling is a difficult enterprise even outside of the potentially adversarial regulatory environment. The demands grow when the regulatory requirements for accountability, transparency, public accessibility, and technical rigor are added to the challenges. Moreover, models cannot be validated (declared true) but instead should be evaluated with regard to their suitability as tools to address a specific question. The committee concluded that these characteristics make evaluation of a regulatory model more complex than simply comparing measurement data with model results. Evaluation also must balance the need for a model to be accurate with the need for a model to be reproducible, transparent, and useful for the regulatory decision at hand. Meeting these needs requires model evaluation to be applied over the "life cycle" of a regulatory model with an approach that includes different forms of peer review, uncertainty analysis, and extrapolation methods than for non-regulatory models.

Key words: regulatory models, evaluation, uncertainty analysis

Introduction

Models have a long and illustrious history as tools for helping to explain scientific phenomena and for predicting outcomes and behavior in settings where empirical observations may not be available. But it must be recognized that all models are simplifications in which complex relationships are reduced, some relationships are unknown, and ones perceived to be unimportant are eliminated from consideration to reduce computational difficulties and to increase transparency. Thus, all models face inherent uncertainties because human and natural systems are always more complex and heterogeneous than can be captured in a model. The challenge, then, is to deal with these complexities to the extent possible and to provide models useful for their purposes.

This paper looks at a specific aspect of computational modeling, the use of environmental models in federal regulatory activities, particularly at the US Environmental Protection Agency (EPA). EPA uses models to support decision making and engages models for retrospective, current, or prospective evaluations. Obtaining a comprehensive set of measurements to support a decision is often impracticable for EPA in terms of time and resources and may be technically or ethically impossible. This means that EPA must often use model results to augment and assess measured data. The results of models can become the basis for decisions, such as initiating environmental cleanup and regulation. In sum, models help to inform and set priorities in environmental policy development and implementation by providing the regulatory the ability to summarize and evaluate available knowledge needed for regulatory decisions, assess alternative regulations, and provide a framework to assess compliance.

In the sections below, we provide a summary discussion of the activities, findings and recommendations of the National Research Council's Committee on Regulatory Environmental

Models.[1] The committee's detailed analysis and recommendations are contained in *Models in Environmental Regulatory Decision Making* (1). We begin with a summary of the committee's task and describe the role of models in environmental decision making at EPA, emphasizing the diversity of applications at the agency. Using a review of the array of environmental regulatory model uses and the inherent characteristics of computational models, we describe the committee's guidance and principles for the use of models. We conclude with a look ahead at the challenges for environmental regulatory models.

Study Scope and Basic Concepts

Study Charge

Recognizing the importance of models in regulatory decision-making, EPA established the cross-agency Council for Regulatory Environmental Modeling (CREM) in 2000 to promote consistency and consensus within the Agency on computational modeling issues. Its scope includes issuing modeling guidance and enhancing both internal and external communications on modeling activities. CREM requested that the National Research Council (NRC) produce a report on the use of environmental and human health models for decision making. The motivation for this study was to provide better guidance and strengthen modeling activities across the agency. The task statement agreed to by EPA and NRC asked the NRC study committee to assess evolving scientific and technical issues related to the selection and use of computational and statistical models in decision-making processes at EPA. The task statement also asked the committee to (a) provide advice concerning the development of guidelines and a vision for the selection and use of models at the agency (b) consider cross-disciplinary issues including those related to model use, peer review, and uncertainty and (c) assess scientific and technical criteria that should be considered in deciding whether a model should serve as a reasonable basis for environmental regulatory activities.

Study Scope

To help differentiate environmental regulatory models from other models, the committee defined an environmental regulatory model as

> "a computational model used to inform the environmental regulatory process. Some models are independent of a specific regulation, such as water quality or air quality models that are used in an array of application settings. Other models are created to provide a regulation-specific set of analyses completed during the development and assessment of specific regulatory proposals. The approaches can range from single parameter linear relationship models to models with thousands of separate components and many billions of calculations."

This definition takes in a broad set of environmental models used in the implementation of EPA's regulatory mission. This set includes model use in the setting of emissions and environmental standards; the characterization of pollutant fate, transport, exposure, dose, and risk of adverse affects; the development of mitigation plans; and other regulatory-related activities.

Trends in models use

Over the past 25 years, there has been a vast increase in the number, variety, and complexity of computational models available for regulatory purposes, including at the EPA. Models have expanded capabilities and sophistication through advances in computer technology, data availability, developer creativity, and increased understanding of environmental processes. Demand for models has expanded as the participants in regulatory processes--Congress, EPA, Office of Management and Budget (OMB), stakeholders, and the general public--called for improved analyses of environmental issues and of the consequences of proposed regulations. Demands have also increased as policy makers have attempted to improve the ability of environmental regulatory activities to achieve the desired environmental benefits and reduce implementation costs.

While the demand for models has grown, the conceptualization of what a model is has shifted in recent years, especially among those closest to the modeling process. Models are viewed less as truth-generating machines and much more as tools designed to fulfill specific tasks and purposes (2). It is important to consider why the transition from regarding models as "truth" to regarding models as "tools" might have occurred. As regulators have become more experienced with the use of models, they also appear to be gaining an appreciation and awareness of the inherent strengths and limitations of models. The transition to regarding models as tools as opposed to truth machines derives also from efforts by modelers to educate decision makers to recognize that even though models can play an important role in regulatory analysis, models cannot provide "*the* answer," which is often what the regulatory process demands.

Fundamental Characteristics of Models

All models are simplifications of the systems or relations they represent. Simplifications in models produce two types of uncertainties (3). One uncertainty is in the values of key parameters, which are uncertain because of a lack of knowledge and a natural variability. The second uncertainty is in the structure of the model itself. Model uncertainty relates to whether the structure of the model fundamentally represents the system or decision of interest.

Another result of the simplifications inherent to models is that spatial and temporal attributes of processes represented within a model can never be resolved fully against observations. Chave and Levin (4) highlight the intractability of this problem, noting that there is no single correct scale at which to study the dynamics of a natural system. At one end of the spectrum, a model that lumps multiple processes and scales into a few parameters might not simulate at a high enough resolution to represent all critical processes or at scales that capture system heterogeneities. At the other end of the spectrum, an extremely detailed model might not capture large-scale features.

Such features of models create an inability to ever fully validate or verify numerical models of natural systems (5). Fundamentally, natural systems are never closed, and model results are never unique. For example, any match between observations and model results might occur because the model is correct but might also occur because processes not represented in the model canceled each other. One can never truly verify that the combination of model formulation and parameters resulting in a good match between observations and results could not be obtained with another combination of model formulation and parameter values.

Further, all regulatory model applications incorporate assumptions and default parameters, some of which may include science policy judgments (6,7). Because modelers can never find data sufficiently complete to fully develop a model, assumptions and defaults are unavoidable, but can also have a large impact on modeling results. Models are commonly used to predict conditions into the future or under environmental conditions different from those for which the models were developed, so the assumptions and defaults are subject to debate. Further, the policy settings for regulatory models are framed by more than scientific, technological, and economic issues. Factors related to public values and social and political considerations enter into the modeling process and influence modeling assumptions and defaults.

Although it is critical to identify and understand these fundamental uncertainties and limitations when using environmental regulatory models, these characteristics fail to provide justification for avoiding the use of models. When they make effective use of existing science and are transparent to stakeholders and the public, models can be very effective for assessing and choosing among alternate environmental regulatory activities and communicating with decision makers and the public.

Model Use in Environmental Regulatory Activities

Environmental regulatory models are used in a wide range of regulatory activities, including strategic planning, rulemaking, and implementation. Most of EPA's major regulatory activities rely on models and encompass a diversity of uses (several examples are shown in Table 2-2 of *Models in Environmental Regulatory Decision Making* [1]). The types of models integral to environmental regulation at EPA include structure-activity models, anthropogenic and natural emissions models, fate and transport models, exposure models, dose models, human health-effects models, environmental and ecosystem impact models, and economic impact models. Ultimately, environmental regulatory modeling activities stem from underlying statutory mandates and are overseen to various degrees by an array of internal and external review processes. In order to set the stage for our evaluation of environmental regulatory modeling, we briefly discuss here the regulatory settings for model use; the types of models used, and the policies that set the regulatory context for model use. An in-depth discussion of these topics is contained in the committee's report (1).

Phases of Regulatory Activities and Model Use

There are many points in the regulatory process where models can be applied. The committee report described six general phases in the regulatory process and considered how model use varied during these different phases (1). These phases are: (1) strategic planning, (2) rule-making, (3) delegation and permits, (4) compliance, (5) enforcement and (6) post hoc evaluations. Understanding how a particular regulatory setting drives model use makes clear how regulatory needs determine modeling objectives and highlights the separate modeling responsibilities of EPA, state and local governments, and other regulated parties. The strategic planning phase uses models to help identify environmental problems of present and future importance and to guide data collection. In general, EPA and its federal and state partners perform much of the modeling used to support regulation, while being informed by research from academics and other organizations. The rule-making phase encompasses the tasks of regulatory design and promulgation. The modeling activities at the rule-making stage can be more extensive than nearly any other phase. EPA is responsible for performing most of the model analyses, although other stakeholders may submit model analyses and comments on the agency's modeling analyses. Many environmental statutes, such as the Clean Air Act and Clean Water Act delegate important roles, including modeling, to states and tribal governments. States may further delegate some responsibilities for compliance modeling to local agencies, and often engage private consultants to perform part of the modeling analyses required under state delegated programs. Other statutes, such as the Toxic Substances Control Act, Safe Drinking Water Act, and Food Quality Protection Act, require EPA or the states to permit an activity. Permits, which might be required for the construction of a point emissions source or the introduction of a chemical into commerce, require modeling that is carried out by a government agency or by the permittee with subsequent review by a government agency. Finally, models are used in compliance and enforcement and in post hoc evaluations. EPA has received periodic requests from Congress to report on the aggregate costs and benefits of its regulations, which requires substantial modeling. Modelers outside of federal agencies, including those in academia, also contribute post hoc analysis of environmental regulatory activities.

Types of Regulatory Models

Models used in environmental regulatory activities can be categorized according to how they describe the processes that translate human activities and natural systems interactions into environmental impacts. Figure 1 shows an illustration of the pathways from activities to emissions to impacts. These individual components represent the relationships between human activities and emissions, emissions and concentrations, concentrations and exposures, and exposures and impacts. The figure provides an approximate categorization of how computational models used in environmental analysis have historically been grouped, in particular, as economic, environmental, and human health models. Although the categories of models shown in Figure 1 are not specific to environmental media, the models that fit into each category tend to be further subdivided by environmental media or other characteristics. For example, the generic category of environmental fate and transport models can be subdivided further into various types of subsurface containment transport models, surface-water quality models, and air quality models (8,9).

It should be noted that EPA's regulatory activities that rely on modeling are typically a subset of the full system summarized in Figure 1. Only the most important regulatory assessments, such as some of those done for federal rules that have major economic impacts, include a simulation of processes from activity to health impacts and costs. These are the rules that generate a need for benefits and costs assessments of environmental regulation, for which the modeling effort can be enormous. A recent example of such an analysis is the regulatory impact assessment (RIA) for the control of air pollutant emissions from non-road diesel engines (10).

Variability in Modeling Effort

The level of modeling effort dedicated to environmental regulatory applications varies greatly. Taking this variability under consideration is important for developing findings and recommendations related to model development, evaluation, and application. At one end of the spectrum are applications that involve a small investment in resources and modeling effort. Leaking underground petroleum storage tanks number in the hundreds of thousands, and preliminary screening for EPA's leaking underground storage tank program typically relies on a relatively simple analytical modeling approach using default parameters (11). These state-run programs may spend as little as $500 for site assessments. The new chemicals program under the Toxic Substances Control Act (TSCA) requires EPA to review approximately 2,000 new chemicals per year and issue decisions on up to 20-30 chemicals per day (C. Fehrenbacher personal commun., EPA Office of Pollution Prevention and Toxics, February 23, 2006). Because of these demands, the agency relies on the quantitative structure-activity relationship (QSARs) models that use a chemical's structure to predict physical and chemical properties and environmental fate and transport behavior when these data are not available. At the other end of the spectrum, EPA may spend years or even a decade assessing the health and environmental consequences of some environmental pollutants and involving extremely detailed models in the process. Under the Clean Air Act, EPA is required to review the National Ambient Air Quality Standards every 5 years. This requires major investments of resources and may take many years of assembling background information and performing detailed analyses, including modeling. Somewhere between these two extremes are the programs that require intermediate levels of modeling effort, such as Total Maximum Daily Load (TMDL) programs for water quality and the State Implementation Planning (SIP) process for air quality analysis. EPA estimates that 3,000-4,000 TMDLs, with a wide array of resource requirements, will be needed annually for the next 8 to 13 years to meet current deadlines (12). While some TMDLs require extensive data collection and modeling, at least one state has proposed using a non-modeling approach for catchments with little or no data (13). The SIP process can be a major undertaking requiring development of emissions inventories and analysis of control options. Each local area out of attainment must submit a plan for each pollutant. For example, there are currently 116 counties out of attainment with the current 24-hour $PM_{2.5}$[1] standard (14).

Policy Factors Impacting Model Use

Ultimately, environmental regulatory modeling activities stem from the underlying statutory mandates. Examples of the legislative language that give rise to modeling are given in Table I. These enabling statutes and OMB oversight of modeling activities have imposed specific requirements on what is modeled and how regulatory decisions are supported through modeling. Because the results of models can impose important costs on regulated parties and the public at large, EPA's evaluation of models used for regulatory design and promulgation (the rule-making phase from above) is the most heavily constrained by legislative requirements, regulatory review, and legal challenges. In general, these models require multiple layers of review, including formal scientific peer review, notice and comment processes, and intra-agency

[1] $PM_{2.5}$ refers to a subset of particulate matter collected by a sampling device with a size-selective inlet that has a 50% collection efficiency for particles with an aerodynamic diameter of 2.5 μm.

review. Interested parties are also provided with an opportunity to make challenges both to the agency and in court to ensure that the model is reliable.

Implications and Recommendations for Regulatory Modeling

Modeling is a difficult enterprise even outside of the potentially adversarial regulatory environment. When the demands of regulatory accountability, transparency, public accessibility, and technical rigor are added to the challenges typically encountered in modeling, the demands on modelers grow. Moreover, the committee emphasized that models cannot be "validated" (declared true) but instead should be evaluated with regard to their suitability as tools to address a specific question. As discussed above, scientific advances will never make it possible to build a perfect model that accounts for every aspect of reality or to prove that a given model is correct in all respects for a particular regulatory application. These characteristics make evaluation of a regulatory model more complex than simply comparing measurement data with model results. Evaluation also must balance the need for accuracy with the need for a model that is reproducible, transparent, and useful for the regulatory decision at hand. The committee observed that meeting these needs requires a "life cycle" model evaluation, which includes different forms of peer review, uncertainty analysis, and extrapolation methods than for non-regulatory models. It also implies that users and others are provided the ability to understand a model's conceptual basis, assumptions, input data requirements, and life history.

Life Cycle Model Evaluation

Model evaluation is the process of deciding whether and when a model is suitable for its intended purpose. In current practice, evaluation comprises more than merely a test of whether history has been matched. It is not a strict verification procedure of comparing model results to observations but is a process that builds confidence in model applications throughout a model's life and increases the understanding of model strengths and limitations. This requires that model evaluation be a multifaceted activity involving peer review, corroboration of model results with data and other information, quality assurance and quality control checks, uncertainty and sensitivity analyses, and other activities. It is important note that the term “corroboration” emphasizes that the relationship between theory and data is more complex than is sometimes supposed in discussions of model testing and "validation" among scientists. We further note that the term “juxtaposition” also conveys well what the committee envisions in the model evaluation process. Hattis (15) points out that the concept of juxtaposition in place of validation goes back to at least the 1970s when Lakatos (16) demonstrated that data alone can never defeat a theory[2]. Juxtaposing models and data fosters a process of sorting out the reasons for the apparent contradictions between model results and observations and, when appropriate, adapting the model to conform to observations. Even when a model has been thoroughly evaluated, new scientific findings may raise unanticipated questions, or new applications may not be scientifically consistent with the model’s intended purpose. Models may evolve through multiple versions that reflect such new findings, new objectives, and improved algorithms, requiring additional evaluation.

To discuss model evaluation in more detail, the NRC committee characterized the life stages of a model and described the various elements of model evaluation at these different stages. The discussion is organized around four stages in the life cycle of a regulatory model—problem identification, conceptual model development, model construction, and model application (see Figure 2). Models begin their life cycle with the identification of a need for a model and the development of a conceptual approach, and proceed through building of a

[2] Lakatos (1970) shows that advocates of a theory can always defend against apparently contradictory data, at least for a while, by attacking the accuracy of the data themselves or supporting theories that make the data relevant to the main theory at issue, or by making ad hoc adaptations of theory. And sometimes data that appear to refute a theory are later found to be wrong or irrelevant for some good reason.

computational model and subsequent applications. Evaluation of a regulatory model throughout its life stages means that model evaluation should not only be part of the review activities that often occur before the public release of a model but should continue throughout regulatory applications and revisions to the model. The need for such a long-term perspective on model evaluation is emphasized by noting the many long-lived regulatory modeling approaches (e.g., MOBILE model for estimating atmospheric vehicle emissions, UAM air quality model, and the QUAL2 water quality models) that have had multiple versions and major scientific modifications and extensions in their multiple decades of existence (17, 18, 19).

For environmental regulatory models, the NRC committee recommended the development of a life-cycle model evaluation plan commensurate with the regulatory application of the model (for example, the scientific complexity, the precedent-setting potential of the modeling approach or application, the extent to which previous evaluations are still applicable, and the projected impacts of the associated regulatory decision). Some plans may be brief, whereas other plans would be extensive. Although the committee did not make organizational recommendations or recommendations on the level of effort that should be expended on any particular type of evaluation, it recognizes that the resource implications for implementing life-cycle model evaluation are potentially substantial. However, given the importance of modeling activities in the regulatory process, such investments are critical to enable environmental regulatory modeling to meet challenges now and in the future.

The sometimes contentious settings in which regulatory models are used may impede EPA's ability to implement the life-cycle evaluation process. Even high-quality models are filled with components that are incomplete and must be updated as new knowledge arises. When a model that informs a regulatory decision has undergone the multilayered review and comment processes, the model tends to remain in place for some time. This inertia is not always ideal: the cumbersome regulatory procedures and the finality of the rules that survive them may be at odds with the dynamic nature of the science of modeling and the goal of improving models in response to experience and scientific advances. It is important that EPA institute best practice standards for the evaluation of regulatory models. Best evaluation practices may be much easier for EPA to implement if its resulting rigorous life-cycle evaluation process is perceived as satisfying regulatory requirements, such as those of the Information Quality Act. To further encourage life-cycle evaluation of models that support federal rule-makings, alternative means of soliciting public comment on model revisions need to be devised. For example, EPA could promulgate a separate rule-making that establishes an agency-wide process for the evaluation and adjustment of models used in its rules. Such a programmatic process would allow the agency to provide adequate opportunities for meaningful public comment at important stages of the evaluation and revision of an individual model, without triggering the need for a separate rule-making for each revision. A more rigorous and formalized evaluation processes for models may result in greater deference to agency models by interested parties and by reviewing courts. Such a response could decrease the extent of model challenges through adversarial processes.

Peer Review

Peer review is an important tool for improving the quality of scientific products and is basic to all stages of model evaluation. However, one-time reviews, of the kind used for research articles published in the literature, are insufficient for many of the models used in the environmental regulatory process. More time, effort, and variety of expertise are required to conduct and respond to peer review at different stages of the life cycle. This is especially true for long-lived regulatory models or complex models with important regulatory implications. Peer review at the model development stage might focus on the translation of theory into mathematical algorithms and numerical solutions, whereas peer review at the model application stage might focus on the adequacy of the input parameters, model execution, and stakeholder involvement. Recognizing that model evaluation may occur separately during the early stages of a model's life, as well as again during subsequent applications, helps to address issues that might arise when a model is applied by different groups and for different conditions than those for which the model was developed.

The committee recommended that peer review should be considered, but not necessarily performed, at each stage in a model's life cycle. Some simple, uncontroversial models might not require any peer review, whereas others might merit peer review at several stages. Appropriate peer review requires an effort commensurate with the complexity and significance of the model application. When a model peer review is undertaken, EPA should allow sufficient time, resources, and structure to assure an adequate review. Peer review for some regulatory models should involve comparing the model results with known test cases, reviewing the model code and documentation, and running the model for several types of problems for which the model might be used. Such a comprehensive evaluation is beyond that typically conducted, but it can be crucial to the quality of complex models. Because many stakeholders and others interested in the regulatory process do not have the capability or resources for a scientific peer review, they need to be able to have confidence in the evaluation process. This confidence is dependent on a transparent peer review process, adherence to criteria provided in EPA's peer review guidance, and documentation of all peer reviews and response of the agency.

Retrospective Analysis of Models

EPA has been involved in the development and application of computational models for environmental regulatory purposes for as long as the agency has been in existence. Its reliance on models has only increased over time. However, attempts to learn from prior experiences with models and to apply these lessons have been insufficient. The committee recommended that EPA conduct and document the results of retrospective reviews of regulatory models not only on single models but also at the scale of model classes, such as models of groundwater flow and models of health risks. The goal of such retrospective evaluations should be the identification of priorities for improving regulatory models. One objective of this analysis would be to investigate systematic strengths and weaknesses that are characteristic of various types of models. A second important objective would be to study the processes (for example, approaches to model development and evaluation) that led to successful models and model applications. In carrying out a retrospective analysis, it might be helpful to use models or categories of models that are old by current modeling standards, because the older models could present the best opportunities to assess actual model performance quantitatively by using subsequent advances in modeling and in new observations. The discussion of groundwater model retrospective analysis of Bredehoeft (20, 21) demonstrates that generalizing prior experiences with models does not necessarily imply the commitment of a great deal of modeling resources but could instead rely on the experiences of veteran modelers to provide fundamental insights.

The Role of Probability in Communicating Uncertainty

Assessment of uncertainty in model outputs is central to the proper use of models in decision making. Probability provides a useful framework for summarizing uncertainties and should be used as a matter of course to quantify the uncertainty in model outputs used to support regulatory decisions. However, the committee considered the use of probability to quantify *all* uncertainties to be problematic. This is especially true if uncertainty analysis is used to reduce large-scale analyses of complex environmental and human health effects to a single probability distribution or to a single number. For example, it is insufficient to know that the mean expected benefits exceed the mean expected costs to determine whether a proposed policy should be adopted. Although it is hard to argue with the principle that regulations should do more good than harm, there are substantial problems in reducing the results of a large-scale study with many sources of uncertainty to a single number or even a single probability distribution. The committee contended that such an approach draws the line between the role of analysts and the role of policy makers in decision making at the wrong place. In particular, it may not be appropriate for analysts to attach probability distributions to critical quantities that are highly uncertain, especially if the uncertainty is itself difficult to assess. Further, the notion that reducing the results of a large-scale modeling analysis to a single number or distribution is at odds with one of the main themes of the committee's findings, that models are tools for helping make decisions and are not meant as machines for producing decisions. In sounding a cautionary note about the difficulties of both carrying out and communicating the results of probabilistic uncertainty analyses, the committee was are trying to avoid the outcome of having models (and a probabilistic uncertainty analysis as the output of a model) make decisions.

In developing its recommendations, the NRC committee noted the wide range of possibilities available for performing model uncertainty analysis. At one extreme, scenario assessment and/or sensitivity analysis could be used. For example, a scenario assessment might consider model results for a relatively small number of plausible cases (for example, "pessimistic," "neutral," and "optimistic" scenarios). In some cases, presenting results from a small number of model scenarios or sensitivity analyses will be adequate for addressing uncertainty (for example, cases in which the stakes are low, modeling resources are limited, or insufficient information is available). Such a deterministic approach is easy to implement and understand though it does not typically include information corresponding to conditions not included in the assessment and whatever is known about each scenario's likelihood.

At another extreme, all model uncertainties could be represented probabilistically, and the probability distribution of any model outcome of interest could be calculated. However, in assessing environmental regulatory issues, these analyses generally would be quite complicated to carry out convincingly, especially when there are model uncertainties (what to include/exclude) or when uncertainties in critical parameters are very large or when the parameter uncertainty is difficult to quantify. Such problems are compounded when models are linked into a highly complex system, for example, when emissions and meteorological model results are used as inputs into an air quality model. In practice it will be necessary to make strategic choices about which sources of uncertainty justify such treatment and which sources are better handled through less probabilistic means, such as consideration of how model outputs change as an input varies through a range of plausible values. Hybrid approaches are one means to communicate the results of the analysis. These include approaches in which some unknown quantities are treated probabilistically and others are explored in scenario-assessment mode by decision makers through a range of plausible values. More importantly, the effective use of complex uncertainty analysis and communication of the results of such an analysis in environmental regulatory activities require a high level of interaction with the relevant decision makers to ensure that they have the necessary information and understanding about the nature and sources of uncertainty and their consequences.

In some applications, the main sources of uncertainty will be among models rather than within models, and it will often be critical to address these sources of uncertainty. Though in some cases this can be handled probabilistically, a scenario assessment approach is particularly appropriate for showing how different models yield differing results, especially when there are few alternative models or the models are resource intensive to implement.

Future Issues

Models are at the nexus of science and policy and will continue to play central roles in future environmental regulatory activities. Their development and use in the future will be challenged and informed by the expanding systems of environmental and human observations. Vast new measurement programs in fields as diverse as genomics to earth observation systems at scales from the nano to the global pose significant opportunities for modeling. Although observations alone can influence policy, the analysis of this information with models will allow the full realization of the value of these measurement programs. Model use in the future will also be challenged to incorporate new science and modeling technologies into the activities. The potential to incorporate greater understanding of environmental and human processes, such as the creation of airborne particulate matter from gaseous precursors and the physiological and pharmacokinetic absorption, disposition, metabolism, and excretion of a chemical in the body, is already offering great improvements to modeling capabilities. Further, the use of integrated modeling approaches can enable an assessor to describe computationally in a coupled framework the relationships depicted in Figure 1—from source emissions and human activities to adverse outcomes. However, pursuing larger and more-sophisticated models can make them difficult to evaluate and more impenetrable to the public and decision makers. Other modeling technologies and applications, such as object-oriented programming languages, attempt to improve transparency and build a stronger bridge between the public and decision makers through the use of user-friendly graphic simulation software and group model-building activities.

Finally, the use of models in the regulatory process in the future also will be affected by changing perspectives of decision makers and others on the most effective way to incorporate their results into the regulatory process. Two strategies that result from this changing perspective are the increased recognition of weight-of-evidence and adaptive management strategies. Although definitions and methods for carrying out such concepts vary, they all incorporate a perspective that models cannot be used to define a once-and-for-all, precise “bright line,” for example, between attainment and nonattainment of ambient environmental standards. Consistent with the basic finding of this NRC committee, both of these approaches appropriately recognizes that models are not “truth generators”, but rather a part or a tool in a dynamic regulatory process.

Closing Points

Models have a prominent future in the environmental decision-making process because they provide insight and information that clearly outweighs their inherent imperfections. The imperfect nature of modeling means that models will always need improvement through the integration of new scientific understandings and data. However, advances in science, no matter how great, will never make it possible to build a scientifically complete model or prove that a given model is correct in all respects. In addition, a more complete model is not necessarily a better suited for policy making. The successful use of new discoveries about environmental processes and human impacts is dependent on a holistic approach to generating data *and* interpreting the meaning of such data. Computational models will continue to provide linkages for interpretation, but as science gets more complex, it can easily become more isolated from nonscientists, whose mistrust of science might increase. Ultimately, this can seriously damage the scientific endeavor. Thus, it is incumbent on both scientists and nonscientists to develop a strong communication bridge. Scientists need to find ways to express their findings to nonscientists. Nonscientists also have an obligation to seek more in-depth understanding of science. Finally, both scientists and nonscientists need to resist the temptation of expecting models to provide simple answers to the complex questions of the interrelationships of humans and the environment.

References

(1) NRC (National Research Council). 2007. Models in Environmental Regulatory Decision Making. Washington DC: National Academy Press.

(2) Beck, M.B., J.R. Ravetz, L.A. Mulkey, and T.O. Barnwell. 1997. On the problem of model validation for predictive exposure assessments. Stoch. Hydrol. Hydraul. 11(3):229-254.

(3) Morgan, G. 2004. Parameter and Model Uncertainty in Models for Regulatory Decision Making: Problems and Opportunities. Presentation at the Third Meeting on Models in the Regulatory Decision Process, December 2, 2004, Washington, DC.

(4) Chave, J., and S.A. Levin. 2003. Scale and scaling in ecological and economic systems. Environ. Resour. Econ. 26(4):527-557.

(5) Oreskes, N., K. Shrader-Frechette, and K. Belitz. 1994. Verification, validation, and confirmation of numerical models in the earth sciences. Science 263(5147):641-646.

(6) NRC (National Research Council). 1994. Science and Judgment in Risk Assessment. Washington, DC: National Academy Press.

(7) EPA (U.S. Environmental Protection Agency). 2004 An Examination of EPA Risk Assessment Principles and Practices. EPA/100/B-04/001. Office of the Science Advisor, U.S. Environmental Protection Agency, Washington, DC. March 2004.

(8) Schnoor, J.L. 1996. Environmental Modeling: Fate and Transport of Pollutants in Water, Air, and Soil. New York: Wiley.

(9) Ramaswami, A., J.B. Milford, and M.J. Small. 2005. Integrated Environmental Modeling – Pollutant Transport, Fate and Risk in the Environment. Hoboken, NJ: J. Wiley.

(10) EPA (U.S. Environmental Protection Agency). 2004. Final Regulatory Impact Analysis: Control of Emissions from Nonroad Diesel Engines. EPA 420-R-04-007. Assessment and Standards Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency [online]. Available: http://www.epa.gov/nonroad-diesel/2004fr/420r04007a.pdf [accessed Nov. 9, 2006].

(11) Weaver, J. 2004. Modeling Leaking Underground Storage Tanks. Presentation at the First Meeting on Models in the Regulatory Decision Process, March 18, 2004, Washington, DC.

(12) NRC (National Research Council). 2001. Assessing the TMDL Approach to Water Quality Management. Washington DC: National Academy Press.

(13) George, J. 2004. State Perspective on Modeling in Support of the TMDL Program. Presentation at the First Meeting on Models in the Regulatory Decision Process, March 18, 2004, Washington, DC.

(14) Bachman, J. 2006. Presentation on Proposal PMcoarse NAAQS. AAQTF Meeting Summary and Decisions, February 28-March 2, 2006, Bethesda, MD [online]. Available: http://www.airquality.nrcs.usda.gov/AAQTF/Documents/Washington_Feb_2006/Draft_Minutes.pdf [accessed Nov. 6, 2006].

(15) Lakatos, I. 1970. Falsification and the Methodology of Scientific Research Programs. In: Criticism and the Growth of Knowledge, pp. 91-196. (Lakatos, I. and Musgrave, A., Eds.). Cambridge University Press, Cambridge, UK.

(16) Hattis, D. 2000. Draft risk analysis ideals. Human and Ecological Risk Assessment, Vol. 6, pp. 913-919.

(17) Scheffe, R.D., and R.E. Morris. 1993. A review of the development and application of the Urban Airshed model. Atmos. Environ. B-Urb. 27(1):23-39.

(18) Barnwell, T.O., L.C. Brown, and R.C. Whittemore. 2004. Importance of field data in stream water quality modeling using QUAL2E-UNCAS. J. Environ. Eng. 130(6):643-647.

(19) EPA (U.S. Environmental Protection Agency). 2003. Users Guide to MOBILE6.1 and MOBILE6.2: Mobile Source Emission Factor. EPA420-R-03-010. Office of Transportation and

Air Quality, U.S. Environmental Protection Agency, Ann Arbor, MI [online]. Available: http://www.epa.gov/OTAQ/models/mobile6/420r03010.pdf [accessed Nov. 16, 2006].

(20) Bredehoeft, J.D. 2003. From models to performance assessment: The conceptualization problem. Ground Water 41(5):571-577.

(21) Bredehoeft, J.D. 2005. The conceptualization model problem-surprise. Hydrogeol. J. 13(1):37-46.

ACKNOWLEDGEMENTS

The authors acknowledge the expertise and dedicated efforts of the NRC's Committee on Models in the Regulatory Decision Process, upon whose report this paper is based. The members of this committee were: Chris Whipple (chair), M. Bruce Beck, Clayton Clark, Robert Clemen, Judith Graham, Louis Gross, Winston Harrington, Philip Howard, Kimberly Jones, Thomas McKone, Naomi Oreskes, Spyros Pandis, Louise Ryan, Michael Stein, and Wendy Wagner. This study was funded by the EPA's Office of Research and Development, with additional funding by the US Department of Transportation. Preparation of this manuscript was supported in part by Interagency Agreement DW-89-93058201-1 with Lawrence Berkeley National Laboratory through the US Department of Energy under Contract Grant No. DE-AC02-05CH11231. The authors would like to acknowledge these agencies as well as staff in EPA's Council for Regulatory Environmental Modeling and staff of the NRC Board of Environmental Sciences and Toxicology. Finally, the authors would like to acknowledge the many individuals that made presentations to the NRC study committee.

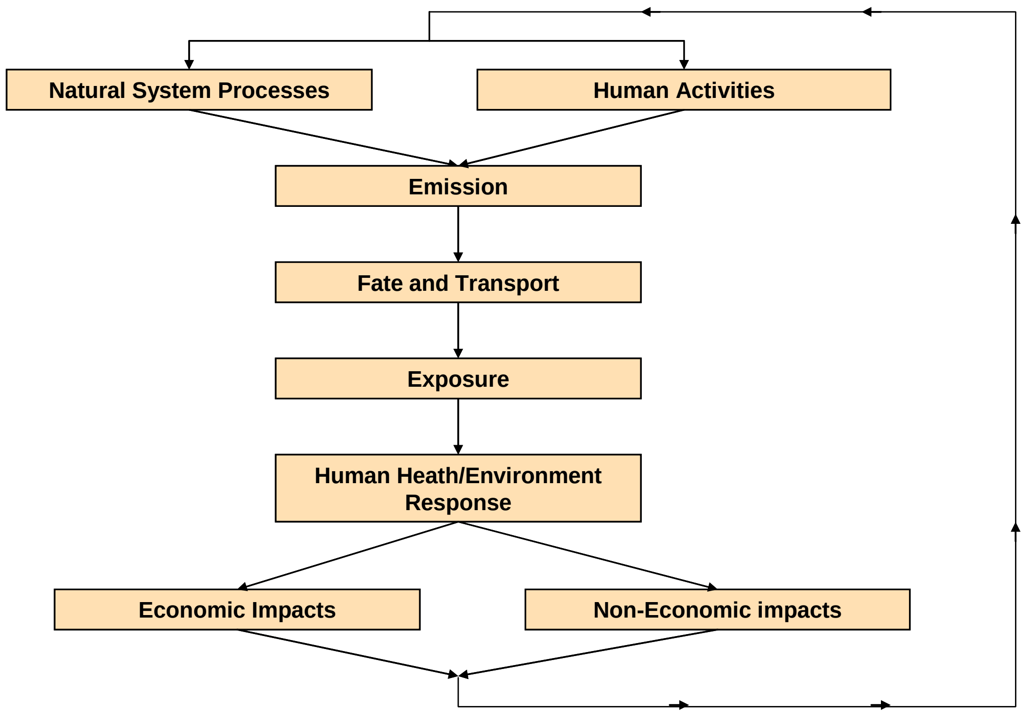

FIGURE 1 Basic modeling elements relating human activities and natural systems to environmental impacts. (1)

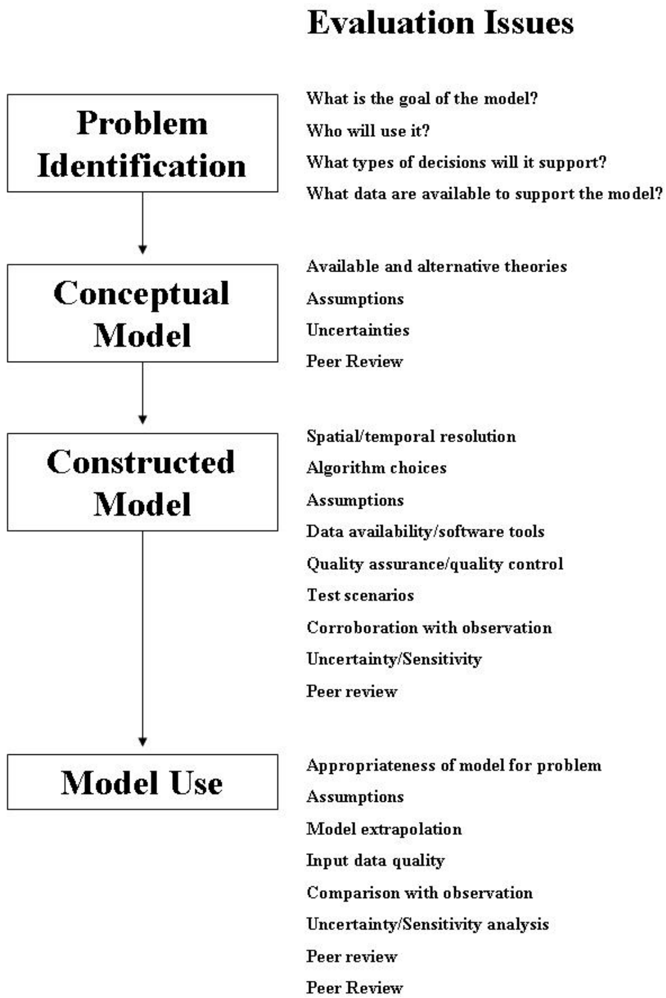

FIGURE 2 - Stages of a model's life cycle**.** Though reducing a model's life cycle to four stages and displaying this in a unidirectional fashion is a simplified view, especially for models with long lives that go through important iterations and modifications from model use to model development, it makes discussion of model evaluation more tractable. (1)

TABLE I Examples of Substantive Legislative Directions for EPA Models

	General Directions
Toxic Substances Control Act, 15 U.S.C. § 2605(a)	Authorizing regulatory action on existing toxic substances "if the administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities presents or will present an unreasonable risk of injury to health or the environment").
Clean Air Act, 42 U.S.C. § 7409(b)(1)	NAAQS for criteria pollutants must "protect the public health," "allowing an adequate margin of safety."
Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136a(c)(5)(D)	Allows pesticides to be registered only if the administrator finds that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."
Clean Water Act, 33 U.S.C. § 1313(c)(2)(A)	The objective of the Act is to "restore and maintain the chemical, physical, and biological integrity of our Nation's waters." Water quality standards set by statute "shall be such as to protect the public health or welfare . . ."
	Specific Directions
Food Quality Protection Act of 1996, 21 U.S.C. 346a(b)(2)(C) and (D)	"In the case of threshold effects … an additional ten-fold margin of safety for the pesticide chemical residue shall be applied for infants and children" . . . with additional legislative specifications for the types of information that must be used in conducting the risk assessment.
Safe Drinking Water Act, 42 U.S.C. § 300g-1 (b)(3)(B)	"The Administrator shall, in a document made available to the public in support of a regulation promulgated under this section, specify, to the extent practicable: i) each population addressed by any estimate of public health effects; ii) the expected risk or central estimate of risk for the specific populations; iii) each appropriate upper-bound or lower-bound estimate of risk …"
Resource Conservation and Recovery Act, 42 U.S.C. § 6924(g)(10).	Requiring (for example) the Administrator to "complete a study of hazardous waste managed [with specific types of treatment processes] . . . to characterize the risks to human health or the environment associated with such management" "[n]ot later than five years after March 26, 1996."

Source: 7.