

has similar capabilities with respect to evaluating the impacts on ecological systems.

*Charge Question 2a:* Does the 3MRA modeling system provide a tool for performing national risk assessments that facilitates consistent use of the science and provides a mechanism for reproducing results?

*Charge Question 2b:* Does the 3MRA modeling system provide decision-makers sufficient flexibility for understanding the impacts on potential chemical exemption levels by allowing varying measures of protection based on the number of receptors and/or number of sites protected, types of human and ecological receptors, and distance?

*Charge Question 2c:* Does the 3MRA modeling system provide appropriate information for setting national risk-based regulations for the waste program?

### Modeling System Evaluation

In response to the SAB recommendation that substantial evaluation of the modeling system is essential to building confidence in the system, the EPA focused significant efforts to ensure the scientific integrity of the 3MRA system and its results during system development and post-development. The EPA designed and implemented rigorous quality assurance and quality control procedures for software development, data collection, verification testing, and peer review on the scientific components of the system.

The EPA implemented specific steps to build a level of confidence in the system to ensure that the system will present a reasonable estimate of nationwide risk for a national-level assessment.

First, the overall technical approach and each science-based module included in 3MRA have been peer reviewed. Teams of peer reviewers (at least three per module) provided critical feedback about the science-based modules. All told, over 45 independent experts reviewed the science modules to ensure that the theoretical concepts describing the processes within release, fate, transport, uptake, exposure, and risk components were adequate representations of the processes to be evaluated.

Second, all software components and databases underwent a series of tests to verify that the software and data were performing properly. At the heart of this protocol is the requirement that each component of the modeling system include a designed and peer reviewed test plan that is executed by both the model developer and a completely independent modeler (*i.e.*, someone

who did not participate in the original model development). These procedures, test plans, test packages, and test results are fully documented and available to the public.

Third, a comprehensive data collection approach was developed to parameterize the modeling system in accordance with the site-based approach described in the assessment methodology. This data collection plan described the general collection methodology for the major types of data (for example, facility location, land use, soil characteristics, receptor locations), including quality assurance and quality control procedures and references for data sources. Fourth, the 3MRA modeling system has undergone a comparison analysis with EPA's Total Risk Integrated Methodology (TRIM) that is currently under development. The objective of the model comparison effort was to increase confidence that the 3MRA modeling system produces estimates consistent with other multimedia models.

While complete validation of a modeling approach would be the ultimate proof for a multimedia system like the 3MRA, the EPA did not find a multimedia data set to compare with the system's predictive outputs. In addition, the model comparison study was conducted using an actual industrial site where environmental monitoring data for mercury representing the relationship between contaminant source and environmental concentrations were available (albeit an incomplete set of observational data). Finally, a formal program focusing on sensitivity and uncertainty analysis for high-order modeling systems has been initiated at ORD. The early focus of this program is the investigation of parameter sensitivities and system uncertainties within the 3MRA modeling system. A supercomputer has been configured to allow exhaustive experimentation with the 3MRA system in Monte Carlo mode. Initial results of these efforts have been documented.

*Charge Question 3a:* Is the software development and verification testing approach implemented for the 3MRA modeling system sufficient to ensure confidence that the modeling results reflect the modeling system design?

*Charge Question 3b:* Given the thorough evaluations that EPA has implemented using the available data resources and technologies, while also recognizing the real world limitations that apply to validating the 3MRA modeling system, have we reasonably demonstrated through methodology design, peer review, quality control, sensitivity analyses, and model

comparison, that the 3MRA modeling system will produce scientifically sound results of high utility and acceptance with respect to multimedia regulatory applications?

### 3MRA Modeling System Documentation

In response to significant comments regarding the lack of clarity and transparency associated with documentation of the earlier modeling system the EPA has devoted significant time and resources to correcting this limitation. The 3MRA represents a comprehensive risk assessment capability and as such integrates the science from all contributing disciplines. Documentation is necessarily voluminous. In preparing the current documentation our intent is to provide different levels of presentation depending on the intended audience. The EPA has prepared a significant number of reports and documents at various levels of technical complexity that describe the 3MRA modeling system and the related HWIR application.

The review documents consist of a four volume set of documents, providing a comprehensive overview of the 3MRA modeling system. These documents are intended to be the primary means by which the general public would become familiar with the 3MRA system and are also intended to provide the level of information necessary for a risk assessor to make an informed decision regarding the applicability of the 3MRA modeling system to specific risk assessment problems.

*Charge Question 4:* Has the EPA made substantive progress, relative to 1995, in designing and preparing documentation for the 3MRA modeling system? Does the SAB have additional suggestions for improving the presentation of the comprehensive set of materials related to this modeling system?

*4. Development Plan Document Available:* For the purpose of enough understanding about the 3MRA modeling system to nominate candidates, the reader may find the ORD/OSW Integrated Research and Development Plan for the Hazardous Waste Identification Rule (HWIR), 1998 helpful. This document introduces the policy and technical issues shaping the development of the 3MRA modeling system. This document is available at: <http://www.epa.gov/epaoswer/hazwaste/id/hwirwste/risk.htm>.

*5. SAB Request for Nominations:* Any interested person or organization may nominate qualified individuals for Membership on the Subcommittee.