



## Department of Energy

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### SENSITIVITY STUDIES TO RESOLVE KEY TECHNICAL ISSUES (KTI)

Reference: Ltr, Schlueter to Ziegler, dtd 7/30/02

The U.S. Department of Energy has developed a position on the use of sensitivity studies to resolve KTIs using a risk-informed performance-based approach. The enclosed position paper on this approach responds to discussions held at the July 2002 Technical Exchange and Management Meeting on KTI Agreement Status.

Please contact April V. Gil at (702) 794-5578 if you have any questions.

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Enclosure:  
As stated

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**U.S. DEPARTMENT OF ENERGY**  
**POSITION PAPER ON USE OF SENSITIVITY STUDIES TO SUPPORT RESPONSES**  
**TO KEY TECHNICAL ISSUE AGREEMENTS**

**Position:**

Resolution of the Key Technical Issue (KTI) agreements is based on documented technical analyses designed to represent the current state of knowledge regarding reasonably expected repository performance, supported by the best information available at the time of the analyses. In keeping with the risk-informed, performance-based approach contained in recent U.S. Nuclear Regulatory Commission (NRC) regulations and guidance, the U.S. Department of Energy (DOE) believes that this resolution should include the use of sensitivity studies supporting risk-prioritization analyses.<sup>1</sup> These supporting sensitivity studies and analyses represent the best available information (data, software, and models) and have provided a sound technical basis for key DOE documents; in addition, these studies and analyses have been conducted by the DOE under appropriate quality assurance (QA) controls and are used to provide insight into a risk-informed, performance-based foundation for closure of KTI agreements. Results from these supplemental studies contribute to the development of a technical argument to support the basis for closing an agreement.

**Issue:**

Yucca Mountain Project programs, products, and analyses that are important to safety or waste isolation, pursuant to 10 CFR Part 63, are conducted in accordance with the requirements of the QA program as contained in the *Quality Assurance Requirements and Description* (QARD). However, to supplement the basis for closure of some KTI agreements, other information and analyses developed under more limited, but appropriate, QA controls have been proposed for use.

The DOE will continue to make proposals to close agreements based on this supplemental information when the results of studies provide a reasonable technical basis and meet the following criteria: 1) the requested information in the KTI agreement has limited significance to risk based on importance to repository system performance or waste isolation (dose during the 10,000 year regulatory period); or, 2) the information is not needed to support the current basis for modeling, including the understanding of uncertainty, that will be relied upon in the Total System Performance Assessment for License Application (TSPA-LA).

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<sup>1</sup> See *Summary Highlights of NRC/DOE Technical Exchange and Management Meeting on Key Technical Issue Agreement Status*, July 23, 2002.

## **Background:**

The DOE has supplied much information, including the TSPA for Site Recommendation (SR) and its supporting documents, to the NRC for consideration. Agreements to provide NRC with this additional information to address KTIs were made by the DOE during a series of management meetings held between August 2000 and September 2001.

Since September 2001, the DOE has completed risk-prioritization evaluations of the TSPA component models as part of the general approach to complete the work needed to close KTI agreements. Specific plans for developing the License Application (LA) and addressing KTI agreements were developed based on consideration of the risk-informed, performance-based provisions of 10 CFR Part 63. The evaluations that were conducted employed the best-available information, using the information that supported TSPA-SR; the *FY01 Supplemental Science and Performance Analyses* (SSPA); and the *Total System Performance Assessment: Analyses for Disposal of Commercial and DOE Waste Inventories at Yucca Mountain, Input to Final Environmental Impact Statement and Site Suitability Evaluation, Revision 00, ICN 01* (SSE/FEIS input report), completed in late FY 2001. This information was supplemented with a report on *Risk Information to Support Prioritization of Performance Assessment Models* in late FY 2002. The results of these evaluations were used to inform DOE management decisions about the priorities for and scope of work to be conducted to support LA submittal and closure of KTI agreements, based on the relative importance of the information to repository system performance and waste isolation.

## **Technical Validity:**

The TSPA model represents the behavior of a complex system with hundreds of parameters, many of which are uncertain or variable or both, and interactions among parameters can be complex and nonlinear. Sensitivity analysis provides a useful and structured framework for examining the sensitivity of the TSPA model results to the uncertainties and assumptions in model inputs. In its simplest form, sensitivity analysis involves quantification of the change in model output corresponding to a change in one or more of the model inputs. In the context of probabilistic models, sensitivity analysis is focused on identification of those input parameters (and their associated uncertainties) that have the greatest influence on the spread or variance of the model results. In general, input variables identified as important in a sensitivity analysis demonstrate significant uncertainty (variance) and are characterized by causing large variations in the output. In the context of TSPA, the goal of sensitivity analysis is to obtain information such as the identity of the variables that have the greatest impact on the overall uncertainty (spread) in probabilistic model outcomes and the key factors that control the separation of model outcomes into higher-dose and lower-dose realizations.

The recent report *Risk Information to Support Prioritization of Performance Assessment Models, Revision 01, ICN 01* (Risk Information report), used essentially the same models and software as the SSPA completed in late FY 2001. Both the SSPA and the Risk Information report were prepared using appropriate controls for configuration management, documentation, checking, review, approval, and document control to assure that the calculations are correct and based upon the best available input. Although some of the data and software are not qualified and some models are not completely verified, their use was based upon sound scientific and technical judgement and it is reasonable to use them now to inform our decisions.

Further, the results of these sensitivity analyses are consistent with the results of the TSPA-Viability Assessment and TSPA-SR, and continue to demonstrate overall system performance that is well below post-closure regulatory limits. The latest TSPA results in the SSE/FEIS input report (derived from the SSPA but updated to reflect the final Environmental Protection Agency compliance standards for a Yucca Mountain Repository) and the Risk Information report represent the best information currently available. The use of these results is appropriate for NRC's pre-application review and should be sufficient to close those KTI agreements that are identified as being most amenable to using the risk-informed approach.

In addition, no changes in the conclusions and no significant changes in the numerical results of these sensitivity and analyses are expected as a result of the evolution of the TSPA-LA and the associated data qualification, software verification, and model validation in accordance with the requirements of the QARD. Changes in data, models and software that could potentially affect the results of these sensitivity analyses will be evaluated under full QA controls based on the TSPA-LA models, data, and software following completion of the TSPA-LA analyses.

#### **Evaluation:**

The currently available qualified information and information from supplemental risk-prioritization/sensitivity studies provide a risk-informed approach that should permit the NRC to assess the adequacy of the DOE's technical approach to closing some KTI agreements. This should provide the NRC with confidence that the DOE is focusing on the issues that are important to safety and waste isolation and that adequate information will be available to support LA review. The DOE also believes that the models and information developed to support the LA, when complete and fully qualified, will be consistent with the conclusions reached based on the information provided to close the KTI agreements.

The relevant information for the NRC staff's licensing review will be in the LA and its supporting documents, and will build on the body of work developed up to the time of LA submittal. This body of work includes previous versions of TSPA, supplemental sensitivity analyses, and the information provided to the NRC in response to KTI agreements prior to LA submittal. The LA will provide the licensing case of record to address post-closure repository performance requirements and support required NRC findings. If any of the pre-LA results cannot be determined to be consistent with analyses conducted under full QA controls for the LA, a revised approach to resolution will be developed for each impacted KTI agreement item.

The NRC staff will be informed if the basis for earlier review of KTI agreements changes as a result of the analyses supporting the LA.

**Conclusion:**

The DOE is implementing a risk-informed approach using the results of sensitivity studies that provides the NRC with the basis for closure of some KTI agreements. The information and analyses used in this risk-informed approach were conducted under controls appropriate for this intended use. The DOE will continue to maintain communication and interactions with the NRC staff to keep the NRC informed on the development of the LA Technical Basis, and the DOE will keep the NRC informed if the basis for earlier review of the KTI agreements changes substantially as a result of the analysis supporting the LA.