January 27, 2003

Mr. Joseph D. Ziegler, Acting Assistant Manager
Office of Licensing and Regulatory Compliance
U.S. Department of Energy
Yucca Mountain Site Characterization Office
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North Las Vegas, NV 89036-8629

SUBJECT: USE OF RISK AS A BASIS FOR CLOSURE OF KEY TECHNICAL ISSUE AGREEMENTS

Dear Mr. Ziegler:

The U.S. Nuclear Regulatory Commission (NRC) and the U.S. Department of Energy (DOE) reached agreements on a number of issues during prelicensing interactions that identify additional information to be provided by DOE prior to submitting a license application. This information would assist the NRC in conducting a review of a potential license application.[1] DOE submitted information, in two letters dated July 11, 2002, to address three agreements, Total System Performance Assessment and Integration (TSPAI) Agreement 3.03, TSPAI Agreement 3.19, and Unsaturated and Saturated Flow Under Isothermal Conditions (USFIC) Agreement 3.01. In lieu of the originally agreed upon information, DOE requested that NRC consider allowing DOE to use risk information to meet the intent of these agreements. The DOE has also provided, by letter dated September 13, 2002, the report titled 'Risk Information to Support Prioritization of Performance Assessment Models' (the Risk Prioritization Report).

The NRC has a policy of risk-informed, performance-based regulatory decision-making that encourages the use of risk assessments and sensitivity analyses to help identify data, models, and barriers that are most important to repository performance and to focus available resources on those items. Consistent with this policy, staff reviewed the information provided by DOE in the Risk Prioritization Report and the responses to the aforementioned three agreements. The purpose of this letter is to provide DOE with feedback on its approach to providing risk information in lieu of other types of information to satisfy agreements. Based on the current status of the DOE program, it is our opinion that DOE will be able to successfully address various agreement items by using risk information, but that the current arguments are incomplete. Although the DOE report provides risk results, the report provides little, if any, discussion that explains DOE's understanding of the risk result. Some discussion regarding DOE's understanding of the risk results is necessary to provide context and credibility for the results, especially when results are counterintuitive or vary from previous performance assessments (e.g., sensitivity to infiltration). As such, this letter identifies three elements which NRC staff believes should be included as part of DOE's initiative to address agreements using risk information. These proposed risk program elements are derived from regulatory requirements pertaining to timing and magnitude of the dose (63.114 (e), 63.114 (f)), uncertainty (63.114 (b), 63.114 (c)), and multiple barriers (63.115)). Enclosure I is a full description of the NRC proposed elements. Comments on specific aspects of the Risk Prioritization Report (e.g., particular analyses contained therein) will be provided to DOE in a

[1] The purpose of issue resolution is to assure that sufficient information is available on an issue to enable the NRC to docket a proposed license application. Resolution at the staff level does not preclude an issue being raised and considered during the licensing proceedings, nor does it prejudge what the NRC staff evaluation of that issue will be after its licensing review.

separate forthcoming letter since our highest priority was to provide feedback on the agreements which are currently under NRC review.

The NRC staff has reviewed the material provided by DOE, as it relates to the three specific agreements. The full text of the agreements are provided in Enclosure II. When risk arguments are proposed as the basis for closing agreements, DOE needs to provide sufficient supporting information, as discussed below and in Enclosure I. The supporting information must allow NRC to evaluate whether the risk arguments acceptably address the NRC's questions such that no information beyond that provided, or agreed to, will likely be required at the time of initial license application. The ultimate disposition of TSPAI Agreements 3.03 and 3.19, USFIC 3.01, and other agreements that are proposed to be resolved via risk arguments, will be determined after DOE adequately addresses NRC's concerns with its approach to resolving agreements via risk arguments.

A full description of the proposed risk program elements (summarized below) can be found in Enclosure I. DOE's approach to resolving Key Technical Issue agreements via risk arguments should include the following elements:

1. Enhanced consideration of the combined effect of uncertainties
2. Transparent and traceable documentation that allows the results to be verified independently
3. Information pertaining to the variability in the results

The NRC's interest in the information requested in the agreements is to support a detailed review of the potential license application. The NRC will consider risk information provided by DOE in conjunction with other factors, when evaluating whether sufficient information exists for NRC to conduct a detailed review of a potential license application. Consequently, the NRC may need to continue to request the original information sought in an agreement if we are not satisfied that the risk-information provided is adequate.

If you have any specific questions regarding this letter or the enclosures, please contact David Esh of my staff. He can be reached at (301) 415-6705.

Sincerely,
/RA/

Janet Schlueter, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

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Summary of NRC Insights on DOE's Use of Risk to Resolve Technical Agreements

In sensitivity analyses presented to date, DOE has adopted an approach of attempting to select a pessimistic state for the uncertainty in the parameter or model subsystem being addressed and then comparing calculated doses with NRC's regulatory standard. If the outcome for the pessimistic state is significantly less than the radiological standard, then the particular aspect of the problem being examined is deemed to be insignificant to meeting the radiological standard. The implicit conclusion is that the information requested for related agreements is not necessary for NRC to docket a proposed license application.

The information supplied by DOE to satisfy the agreements noted in Attachment II provides a good example to illustrate NRC's concerns. In the analysis, DOE increased the infiltration rate more than an order of magnitude to address the impact of the uncertainty in shallow infiltration. In the Risk Prioritization Report sensitivity studies, DOE set the infiltration rate at 150 mm/yr, whereas infiltration flux in the base case was approximately 12 mm/yr over the next 10,000 years. A stochastic sensitivity analysis was performed to compare the expected risks from the model from each case (e.g., 12 mm/yr versus 150 mm/yr). Based on NRC's current understanding of the repository system, such an increase could lead to the following conditions: (1) an increase in the number of packages that are dripped on; (2) an increase in advective releases from the waste package; (3) potential affects on water chemistry that could alter corrosion rates of the waste package and drip shield; and (4) reduced travel times in the unsaturated zone below the repository. Although the DOE has discussed the fact that the dose is not affected, a more thorough discussion of the result is needed to understand the risk significance. The DOE should identify and discuss which other aspects (barriers) of the repository system are compensating for the increased infiltration. It is important to understand if there is increased reliance on other barriers, because it could influence the interpretation of the risk-significance. The approach to sensitivity analyses that only considers the change in the dose may oversimplify the understanding of performance of a barrier or subsystem such that the risk significance is not fully presented.

Lack of consideration of the combined effects of uncertainties may result in an incorrect conclusion regarding the risk significance of a particular barrier, system or phenomena. For example, an analysis may be completed where infiltration is increased to address an uncertainty. Performance of a barrier (e.g., the drip shield) may limit the impact of increased infiltration on the dose. A second analysis that pessimistically evaluates the other barrier (e.g., the drip shield) while leaving infiltration at its base level might also show little impact on the dose from infiltration. Thus, one might conclude that infiltration is insignificant. However, these two analyses rely on at least one of the components of the system to be functioning at its base level of performance. Such an approach does not take into account combinations of reasonably degraded performance.

The lack of sensitivity of dose estimates to a particular system characteristic is based on results from the current total-system performance assessment model for the existing design (i.e., the revised supplemental model used for DOE's site suitability evaluation). A number of the key technical issue agreements address uncertainties that may result in different models being implemented in the future. For example, uncertainty in the longevity of drip shields and waste packages is the subject of several key technical issue agreements. Changes to models of drip shield and waste package performance could significantly alter conclusions regarding the relative importance of other system characteristics in a risk-based performance assessment. The analysis supporting risk-informed resolution of agreements will need to be robust with respect to the results of the performance assessment model. That is, procedures should be in place to perform confirmatory analyses for the conclusions of the current analyses (i.e., those used to support risk-informed resolution of agreements) with the final, fully-supported and qualified performance assessment model used for a license application.

The following three additional information needs and clarifications represent risk program elements that NRC believes should be addressed by DOE when using risk information to address agreements:

1. Enhanced consideration of the combined effect of uncertainties

The sensitivity analyses are intended to evaluate the potential impact of uncertainty on a characteristic of the system (e.g., shallow net infiltration, cracking of the drip shields). The performance assessment model is used to probabilistically represent the global effects of parameter uncertainty. However, DOE is using a risk-informed, performance-based approach to evaluate whether to provide additional information for a number of agreement items (e.g., TSPAI 3.03, TSPAI 3.19) or to replace the originally agreed upon information with risk-information. The TSPA is a system model designed to evaluate the combined effects of parameter and model uncertainty. The combined effect of uncertainties (for all agreements addressed with a risk argument) needs to be evaluated before the individual uncertainties can be dropped from further consideration. Otherwise, the situation could arise where moderate increases in risk are considered insignificant, but the combined effects of numerous uncertainties could be significant even when using a risk-based performance metric.

The Risk Prioritization Report attempted to address the combined effect of uncertainties in Section 3.4. While Section 3.4 is a good initial effort and it provides the appropriate type of information for the NRC to review, the analyses and explanations are incomplete. Apparently the analyses have not considered uncertainties in saturated zone radionuclide transport, which would be appropriate if no agreements for the saturated zone are being addressed via risk arguments. Secondly, the analyses for evolution of the near-field environment and engineered barrier system corrosion appear to be too narrow. It is not clear that setting the general corrosion rate for the engineered barrier system to eight times its nominal value appropriately bounds the uncertainties surrounding evolution of the near-field environment and engineered barrier system corrosion. In particular, there is very sparse objective evidence to eliminate localized and/or transpassive corrosion of the engineered barrier system in the environmental condition regime of temperatures above 95°C and a high ratio of aggressive species to inhibiting species. The results shown on Figure 46 of the Risk Prioritization Report have a projected dose that would approach and exceed the radiological standard at slightly after 20,000 years. It is not clear that the addition of uncertainty in saturated zone transport and a more appropriate representation of the potential effect of uncertainty in environmental conditions and engineered barrier system performance would support unambiguously DOE's conclusion about the magnitude of the combined effects of the uncertainty. An expanded analysis of the combined effect of uncertainties being addressed with risk arguments is needed.

2. Transparent and traceable documentation that allows the results to be verified independently

To further support the analysis results, DOE should provide, in documentation submitted to close an agreement on the basis of risk, an adequate description of the changes to models and intermediate outputs that were made to evaluate the cases. The documentation of the analysis should be transparent and traceable such that the results can be verified independently. For example, in the analyses using extreme infiltration rates it is clear that the increased infiltration rates were applied to the unsaturated zone transport model. However, it is not clear how inputs to the seepage abstraction dynamic linked library (DLL) were modified for the sensitivity analyses. With the description and

explanation of the analysis to close an agreement on the basis of risk, DOE should provide adequate information (e.g., in tabular format) that would allow independent verification by the NRC of the changes that were made to the TSPA model. The information should show which parameters and models were changed and the magnitude of the changes. DOE should perform reviews of calculations to ensure that evaluation of 'extreme' cases does not result in the use of models outside of their intended ranges. In addition, enhanced confidence in the analysis could be developed by providing a more detailed explanation of the results.

3. Information pertaining to the variability in the results

To convey uncertainty and variability in the analyses, DOE should provide information on the variability of simulation results (for the pessimistic compared to the nominal case)—for example, by plotting the 5^{th} and 95^{th} percentiles of nominal-case dose estimates along with the mean dose estimates. The explanation of the results should demonstrate adequate physical understanding that would support the numerical outcome. It is our understanding that information pertaining to the variability in the results is readily available within the DOE program.

Wording of the Agreements:

USFIC.3.01 states: "Provide the documentation sources and schedule for the Monte Carlo method for analyzing infiltration. The U.S. Department of Energy (DOE) will provide the schedule and identify documents expected to contain the results of the Monte Carlo Analyses in February 2002."

TSPAI.3.19 states: "DOE will provide justification for the use of its evapotranspiration model, and defend the use of the analog site temperature data (UZ1.3.1). DOE will provide the justification for the use of the evapotranspiration model, and justify the use of the analog site temperature data. The justification will be documented in an update to the Simulation of Net Infiltration for Modern and Potential Future Climates AMR (ANL–NBS–HS–000032) and the Future Climate Analysis AMR (ANL–NBS–GS–000008). The AMRs are expected to be available to NRC in FY 2003."

TSPAI.3.03 states: "Provide the technical basis for crack arrest and plugging of crack openings (including the impact of oxide wedging and stress redistribution) in assessing the impact of SCC of the drip shield and waste package in revised documentation (ENG1.1.2 and ENG1.4.1). DOE will provide the technical basis for crack arrest and plugging of crack openings (including the impact of oxide wedging and stress redistribution) in assessing the stress corrosion cracking of the drip shield and waste package in an update to the Stress Corrosion Cracking of the Drip Shield, Waste Package Outer Barrier, and the Stainless Steel Structural Material AMR (ANL-EBS-MD-00005) in accordance with the scope and schedule for existing agreement item CLST 1.12."

Letter to J. Ziegler from J. Schlueter dated January 27, 2003

cc:

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