February 26, 2003

Mr. Joseph D. Ziegler, Acting Director
Office of License Application and Strategy
U.S. Department of Energy
Office of Repository Development
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SUBJECT: NRC REVIEW OF *'RISK INFORMATION TO SUPPORT PRIORITIZATION OF PERFORMANCE ASSESSMENT MODELS', TDR-WIS-PA-000009 REV 01 ICN 01, AUGUST 2002*

Dear Mr. Ziegler:

This letter and enclosure provide the Nuclear Regulatory Commission's (NRC) review of the U.S. Department of Energy (DOE) report titled "Risk Information to Support Prioritization of Performance Assessment Models" (The Risk Prioritization Report). DOE's objective for the Risk Prioritization Report is to provide risk information to support risk-informed, performance-based prioritization of performance assessment models to address model validation and NRC Key Technical Issue agreements. The NRC encourages the use of risk assessment and sensitivity analysis to help identify data, models, and barriers that are most important to performance and to focus appropriate resources on those items.

DOE has proposed to satisfy a subset of the total prelicensing agreements reached between DOE and NRC by providing risk information in lieu of the originally requested information. Where the risk information, in combination with other available information, is considered to provide the information that the NRC staff believes will be necessary to support a detailed review of a potential license application, then the NRC staff can consider the relevant agreements to have been satisfied.

On January 27, 2003, the NRC provided its initial feedback on DOE's approach to risk-informed issue resolution. The purpose of this letter is to provide DOE with additional feedback on the Risk Prioritization Report. Detailed comments associated with NRC's review of the Risk Prioritization Report can be found in the enclosure. As a result of our review, the NRC has comments on the following areas that DOE should address:

1) The model validation approach and the validation levels assigned to some models,
2) The justification for the magnitude of the changes applied to parameters or models during the sensitivity analyses for a subset of the analyses,
3) The documentation associated with the sensitivity analyses with respect to the changes made to the models and the explanation of the results, and
4) The combined effects analyses.

In the Risk Prioritization Report, DOE proposed providing a level of model confidence commensurate with a model's importance to waste isolation. Using a graded approach to model confidence building is consistent with NRC's risk-informed, performance-based regulatory philosophy, but it is not currently described in the Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description (QARD), DOE/RW-0333P. Regardless of the validation level assigned to a model, model validation activities should be completed for all models in accordance with the QARD and applicable quality assurance program implementing procedures for model development and use such as AP-SIII.10Q, *Models*, the Scientific Processes Guidelines Manual, and training materials distributed to project staff. Model validation activities should provide appropriate information that would allow the NRC to evaluate the model support acceptance criteria in the Yucca Mountain Review Plan.

DOE should recognize the programmatic risk of using the current, unqualified performance assessment model for sensitivity analyses in order to resolve issues using risk arguments and to establish validation levels for models. It is important to have confidence in the model, the analysis, and the resultant decisions.

If you have any specific questions regarding this letter or enclosure, 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

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NRC Comments on 'Risk Information to Support Prioritization of Performance Assessment Models', *TDR-WIS-PA-000009 REV 01 ICN 01*, August 2002

SUMMARY:

The 'Risk Information to Support Prioritization of Performance Assessment Models' report (hereafter referred to as the *Risk Prioritization Report*) provided sensitivity analyses, a strategy whereby models would be validated to varying levels of confidence, and a partitioning of Total-System Performance Assessment (TSPA) models to validation levels. The report provides risk information to support risk-informed, performance-based prioritization of performance assessment models to address model validation and key technical issue (KTI) agreements between the Nuclear Regulatory Commission (NRC) and the Department of Energy (DOE). In general, the Risk Prioritization Report is a positive initial effort and further analyses and explanation of the results by DOE is encouraged.

DOE proposes providing a level of model confidence commensurate with a model's importance to waste isolation. Using a graded approach to model confidence building is consistent with NRC's risk-informed, performance-based regulatory philosophy, but it is not currently described in the Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description (QARD), DOE/RW-0333P. Regardless of the validation level assigned to a model, model validation activities should be completed for all models in accordance with the QARD and applicable quality assurance program implementing procedures for model development and use such as AP-SIII.10Q, *Models*, the Scientific Processes Guidelines Manual, and training materials distributed to project staff. Model validation activities should provide appropriate information that would allow the NRC to evaluate the model support acceptance criteria in the Yucca Mountain Review Plan.

DOE should recognize the programmatic risk of using the current, unqualified performance assessment (PA) model for sensitivity analyses to resolve issues using risk arguments and to establish validation levels for models. It is important to have confidence in the model, the analysis, and the resultant decisions. As discussed in the January 27, 2003 letter to DOE, the NRC believes it is important to provide a confirmatory analysis with the final, fully-qualified performance assessment model that supports the conclusions made with the results from the current unqualified TSPA model. The NRC staff does not expect that DOE will have to use a fully-qualified — and, consequently, validated — model to determine the degree of validation necessary for the constituent models. However, using the results of an unqualified model to assign validation levels may lead to erroneous assumptions about the importance of the constituent models.

As the number of issues addressed via risk arguments increases, the importance of considering the combined effects of uncertainties on risk increases. Conditional 'risks' are generated by the DOE through one-off (or equivalent) sensitivity analysis to evaluate uncertainties that are not part of the base case performance assessment model. The 'risk' is described as being conditional because it depends on the rest of the performance assessment model behaving at its nominal state. The conditional 'risk' is not the only information that DOE should use for its decision making. In a performance assessment (PA) model, consideration of the combined

effect of uncertainties[1] will likely dictate the extent to which the DOE approach can be used. Thus DOE needs to address the combined uncertainties during its decision making. Insignificance of a particular model or uncertainty can result from the compensation of other barriers (relative), or the PA model may be truly insensitive to that model or uncertainty (absolute). Relative or absolute insignificance have different implications. For instance, relying on results that reflect relative uncertainty may lead to increased reliance on a limited number of barriers which, in turn, could possibly make the results of the PA less robust with respect to unresolved uncertainties. In this regard, decisions drawn from results that reflect relative uncertainty may lead to erroneous conclusions.

It is important that the DOE adequately document the analyses and provide sufficient discussion of the results for the NRC to develop confidence in the analyses and the results. DOE should provide what was changed in an analysis (compared to the nominal case). The results of the analysis may in some cases be counterintuitive. Adequate explanation of why the model output is reasonable is essential to developing confidence in the result. Where possible, simple physical arguments should be provided with the recognition that some processes or models may be inherently complicated and may not be easily described in a simple way.

Ideally, the models supporting the performance assessment should be as realistic as possible considering the supporting information and uncertainties. However, it is not always technically or economically practical to devote additional resources to increased realism. A recognized approach to the management of uncertainty is to introduce pessimism or conservatism. For instance, engineered structures and safety systems are typically designed taking into account safety factors. The use of bounding and physically unrealistic models within the PA model may confound the interpretation of the risk-significance of models that were developed with comparatively more realism.

The risk information contained in the Risk Prioritization Report typically takes the form of a one-off sensitivity analysis. The amount of additional uncertainty introduced into the model in these types of analyses is an important consideration in determining whether the amount of information provided is sufficient to address the agreement. NRC has reviewed and is providing preliminary comments below on the amount of uncertainty introduced in the analyses. It is expected that as risk information is submitted to the NRC for the resolution of specific agreements, NRC will review the amount of uncertainty introduced in the model. For example, DOE increased the infiltration rate more than an order of magnitude to address the impact of the uncertainty with respect to shallow infiltration. In the Risk Prioritization Report sensitivity studies, DOE set the infiltration rate to 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). The explanation for the amount of uncertainty introduced to the net infiltration model provided in the November 22, 2002 letter from Ziegler to Schlueter (‘*Transmittal of Report Addressing Key Technical Issue (KTI) Agreement Item Unsaturated and Saturated Flow Under Isothermal Conditions (USIFC) 3.02*') is a good example of an appropriate level of justification.

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[1] Associated with the subset of technical agreements being resolved with risk arguments.

As a result of our review, the NRC has comments on the following areas that DOE should address:

1) The model validation approach and the validation levels assigned to some models,
2) The justification for the magnitude of the changes applied to parameters or models during the sensitivity analyses for a subset of the analyses,
3) The documentation associated with the sensitivity analyses with respect to the changes made to the models and the explanation of the results, and
4) The combined effects analyses.

These concerns are further expanded with specific examples in the sections that follow.

I. <u>Review of Model Validation Approach:</u>

I.1) General - DOE proposed the following validation levels in the Risk Prioritization Report:

Level I validation:	Ensuring that model development used a reasonable scientific and engineering approach
Level II validation:	Level I validation **AND** Demonstration of model conservativeness **OR** Corroboration of model prediction by data/observation
Level III validation:	Level I validation **AND** Corroboration of model prediction by data/observation

The validation criteria appear to be inconsistent with quality assurance procedure AP-SIII.10Q, *Models*, the Scientific Processes Guidelines Manual (September 2002), and training materials distributed to project staff. For example, in the Scientific Processes Guidelines Manual, DOE indicates that Level III validation should include Level II criteria and documentation that demonstrates that model predictions are reasonably corroborated by at least two post-development model validation methods identified in Section 5.4.1c of AP-SIII.10Q. DOE should resolve the differences between the quality assurance requirements and the approach used in the Risk Prioritization Report.

The report suggests consistency with physical principles, such as conservation of mass and energy, for Level I validation. The document, however, does not elaborate further on what is a “reasonable scientific and engineering approach”. Developing confidence in the conceptual models used in a TSPA is essential to developing confidence in the results of the TSPA. DOE should provide a discussion on what is a “reasonable scientific and engineering approach”. DOE should address how such an approach would provide the information required for the NRC to evaluate the model support acceptance criteria of the Yucca Mountain Review Plan.

I.2) General - DOE established thresholds (i.e., dose intervals) to provide a numerical criterion for when various levels of validation will be used. If the dose <u>change</u> between the base case and the sensitivity case exceeds 0.1 mrem/year, then level II validation will be used, and if it exceeds 1 mrem/yr, then Level III validation will be used. The establishment of thresholds based on a finite dose fraction of the standard would not likely address the combined effects of uncertainties. It may be more appropriate to utilize relative change as well as the absolute change in dose to assign validation levels. The assignment of validation levels using either relative changes or absolute changes will be dependent on the number of models that can affect the base case dose. DOE should provide a discussion on the use of absolute change to dose when assigning validation levels. In particular, DOE should explain how this approach takes into account the combined effect of uncertainties. An additional consideration applies to models that are already considered to be pessimistic in the base case for the current (i.e., unqualified) analyses. Changes to a pessimistic model may exceed a dose interval for validation (i.e., exceed 0.1 or 1 mrem/yr), while the same changes may not exceed a dose interval had the model been more realistic in the base case.

II. <u>Review of Model Validation Levels:</u>

The NRC is providing preliminary feedback on DOE's initial assignment of validation levels based on analysis in the Risk Prioritization Report. In addition to the specific comments found below, DOE should take into account other pertinent sections of this report that would influence the assignment of validation levels.

II.1) In-Drift Chemistry and Moisture - DOE has adopted a multi-faceted approach to demonstrating engineered barrier system (EBS) performance. Arguably the largest element to demonstrating EBS performance is the empirical determination of waste package and drip shield performance. DOE did not provide sufficient technical basis for the validation level assigned to the reasonably credible range of environmental conditions. The complexity of the problem and the maturity of the computational tools would seem to warrant level III validation. For example, there are numerous sources of uncertainty and the evaporation process can result in moderate uncertainties in the concentration of species in solution propagating into large effects on brine compositions. The corrosion behavior of the engineered system has chemical environment boundary conditions applied to the evaluation. DOE should provide adequate justification for the validation level for the chemical environment for corrosion, considering the discussion in comment III.6.

II.2) Radionuclide Release Rates and Concentrations - The level of pessimism applied to the radionuclide release rates may influence the interpretation of the significance of the processes. While a demonstrably conservative model may not demonstrate risk-significance through sensitivity because that model or area has limited performance, the conservative model could affect evaluation of other pertinent models (e.g., conservative diffusional release modeling could impact conclusions of significance for advective release modeling). DOE should consider the impact of conservatism as it affects understanding of the performance assessment, particularly with respect to release modeling.

II.3) Igneous Activity - Evaluation by the NRC using the Total-system Performance Assessment code and other analyses, suggests that consequences from igneous activity can be sensitive to parameter selection and models for atmospheric transport and biosphere models (e.g., wind speed and direction and mass loading). DOE's analysis in the Risk Prioritization Report shows variability in wind direction can have a large impact on igneous consequences (a factor of 20). DOE should provide adequate justification for the validation level for the atmospheric transport and biosphere models for the igneous scenario.

II.4) General - Caution should be employed when assigning validation levels to natural system components from analyses where the engineered system is functioning in the base case. First, future information may not support the current performance of the engineered system. Second, the one-off analyses and combined uncertainty evaluation is incomplete for reasons identified in this report. It would be reasonable to assign level I validation to natural system components only if the analyses of the physical processes associated with that component demonstrate a low impact to the TSPA results. There should be sufficient understanding of the physical processes to bolster the conclusions of the analyses. For example, if an analysis of the saturated zone flow determined that the groundwater travel times were only hundreds of years, then it would be likely that water flow rates could be assigned validation level I. DOE should provide basic physical information such as intermediate outputs as justification for the assignment of validation levels.

II.5) Drip Shield - The drip shield has been assigned validation level I with an inadequate technical basis. The waste package performance is validation level III because of its influence on system performance. The only significant *modeled* capability of the drip shield in the TSPA is to prevent water contact with the waste package. However, waste package degradation has not been demonstrated to be independent of the drip shield performance. The drip shield may prevent failure of the waste packages from mechanical processes (e.g., rockfall, drift collapse) or from aggressive chemical environments contacting the waste package during the thermally perturbed period. DOE should provide a basis for the validation level of the drip shield that considers relevant features, events, and processes that may not be represented in the TSPA model due to the presence of the drip shield.

III. Review of Sensitivity Studies:

III.1) General - The approach taken by the DOE was to change a parameter distribution, group of parameter distributions, or model to understand the significance of uncertainties in the model. Significance was defined as the ability to influence the overall performance objective (10 CFR 63.113(b)). In many cases the analyses were being performed to address uncertainties that were unquantified and were not yet represented in the base case performance assessment model. In essence, the analyses were being performed to determine whether information needs to be collected and the uncertainty added to the base case performance assessment. The basis for the amount of uncertainty introduced in the various analyses lacks support in some models. A reasoned physical/technical argument for the amount of uncertainty introduced is essential to these types of analyses. In general, DOE should provide additional technical basis for the amount of uncertainty introduced in the various analyses.

III.2) General - The level of analysis information provided in the report, in most instances, does not allow an independent reviewer to verify the analyses and conclusions without recourse to the originating analyst. While the intent of the report may not have been to provide this level of detail, the NRC must have confidence in the results of the analyses. The analyses were not performed under DOE quality assurance procedures. When DOE is not following quality assurance requirements, clarification should be provided as to what requirements were not followed. DOE should provide the detailed information describing the analyses (and an explanation of the results of the analyses) that would allow independent verification of the results. For example, the following should be explained in the documentation:

Figure 23 on page F-23. What causes the peak in the 100x Waste Form Colloid Concentration curve for the igneous scenario?

Figure 25 on page F-25. Why does the igneous result show sensitivity to irreversibly sorbed waste form colloids and the nominal scenario does not?

From the DOE documentation, it is unclear what changes were made to the numerous logic statements related to ionic strength and colloid concentrations in the TSPA model. DOE should explain what changes were made to the ionic strength and colloid concentration expressions.

III.3) General - Inadequate discussion was provided for setting parameter distributions to their 5^{th} or 95^{th} percentile values for the pessimistic model state. The reasonableness of the 95^{th} percentile value will depend upon the underlying information. It may be appropriate to use the 95^{th} percentile value when a parameter distribution is derived from site characterization measurements or relevant experimental data. However, for distributions using very limited site data or where the distribution is drawn from generic data, this choice may not be robust. The results may be strongly affected by the tails and use of the 95^{th} percentile or 5^{th} percentile may not lead to a reasonable result. In addition, parameter distribution shape may influence the conclusions of the analyses and was not investigated or discussed in DOE's report.

DOE has used a mix of approaches, in some cases "neutralizing" a barrier and in other cases using the 5^{th} and 95^{th} percentiles. The magnitude of the sensitivity results may be an artifact of differences in modeling approaches for the sensitivity studies as opposed to real differences in the models. As an example, the probability distributions for all factors of the biosphere model were set to their 95^{th} percentile values. Since some parameters have an inverse effect on the biosphere dose conversion factor (e.g., increases in the crop yield, mass per area, decrease the biosphere dose conversion factor), setting all parameters to their 95^{th} percentile values may not result in the 95^{th} biosphere dose conversion factor (if that was the intent).

Consistent with comment III.1 DOE should provide an adequate basis for the additional uncertainty introduced (e.g. the pessimistic model states).

III.4) General - In some cases the model abstractions and their couplings may no longer be valid for the assumptions made in the Combined Effects Sensitivity Study. For example, the mean infiltration rate was increased from 12 mm/yr to 150 mm/yr (increased by a factor of 12.5), and the average seepage flux was increased by a factor of ten. The dependence of capillary diversion on percolation rate over the very large range of percolation rates was not described. In addition, fracture flow was assumed in the unsaturated zone below the repository horizon but not for the unsaturated zone above the repository horizon. The relationships among infiltration, percolation, seepage, and flow in the unsaturated zone above and below the repository appear to have been de-coupled. An additional example is with respect to waste package neutralization. It is unclear what changes are made to parameter values such as diffusivity, water in the waste package, and water for the zero concentration boundary condition at the waste package surface with respect to diffusional releases. DOE should provide information about the validity of the model assumptions when the TSPA model is 'stretched' in an analysis such as the combined effects sensitivity study.

III.5) Section 3.3, Seepage and Infiltration - The one-off sensitivity analyses reported in sections 3.3.1 to 3.3.3 provide insight into the conditional importance of these components in the repository system. The sensitivity of these components measured by mean annual dose is likely to be significantly influenced by the presence of other barriers, since the drip shield eliminates any water contacting the waste form for longer than 10,000 years. For the cases of increased infiltration or seepage, it appears that secondary effects, such as changes in humidity, corrosion rates, and chemistry, are not considered. DOE should provide information that addresses how redundancy of system components is evaluated in one-off sensitivity analyses. Technical basis should be provided for lack of consideration of secondary effects with respect to increased infiltration or seepage.

III.6) Section 3.3, Engineered Barriers - The analysis for engineered barriers performance including the chemical environment for corrosion may be too limited. It is not clear that setting the general corrosion rate for the waste package to eight times its nominal value and the general corrosion rate for the drip shield to five times its nominal value appropriately captures the range of uncertainties relevant to the evolution of the near-field environment and engineered barrier system corrosion. There is limited objective evidence to eliminate localized and/or transpassive corrosion of the engineered barrier system in the reasonably credible environmental condition regime of temperatures above 95°C and a high ratio of aggressive species to inhibiting species. The enhancement to drip shield corrosion rate appears to be arbitrary. For instance, the rate can go up by orders of magnitude in some combinations of groundwater chemistry (Brossia et al., 2001), but may also be limited by the flux of flouride. Additional uncertainty (compared to the base case) with respect to the juvenile failure of waste packages was not included in the analyses. DOE should provide an analyses of engineered barrier and chemical environment for corrosion with adequate justification for the amount of uncertainty introduced and include it in the combined effects sensitivity study.

III.7) Section 3.3, Igneous - The igneous analysis that varied the wind direction over 360 degrees claimed a factor of 20 reduction in the mean annual dose without including remobilization. Remobilization may become more important, in a relative sense, when the wind blows away from the Reasonably Maximally Exposed Individual (RMEI) (when radionuclide concentrations in soil from remobilized tephra exceed those from the initial deposition at the RMEI location).

Unlike the other one-off analyses, the sensitivity for tephra deposit thickness was not analyzed with the same TSPA basecase model (CRWMS M&O, 2000). Instead, the results from the SSPA-TSPA (BSC, 2001a,b) biosphere dose conversion factors at two tephra thicknesses were compared to the FEIS-TSPA (BSC, 2001c) biosphere dose conversion factor.

The analysis for sensitivity to eruptive volume (page 3-23) needs further explanation. It is expected that as the eruptive volume changes the concentration of radionuclides (and therefore the risk) would change directly. Figure 39 shows essentially no sensitivity. DOE needs to demonstrate that the volumes being used are representative of the type of eruption which can be expected in the Yucca Mountain area.

DOE should discuss limitations in the igneous sensitivity analysis and explain the deviation from the other one-off analyses for the tephra deposit thickness. Further explanation for the eruptive volume insensitivity is needed.

III.8) Section 3.4, Combined Effects - DOE needs to provide further explanation of the choice of the nine changes implemented in the Combined Effects Sensitivity Study and omission of others. TSPA model components such as Biosphere Dose Conversion Factors (BDCF)s, probability of igneous eruption, amount of waste erupted and others were not included in the analysis. Inadequate justification is provided for the reasoning behind the saturated zone flow and radionuclide transport being excluded in the Combined Effects Sensitivity Study. DOE should provide justification for the omission of models/processes from the combined effects sensitivity study, in particular saturated flow and radionuclide transport.

References

CRWMS M&O. "Total System Performance Assessment for the Site Recommendation." TDR-WIS-PA-000001. Rev. 00 ICN 01. Las Vegas, Nevada: CRWMS M&O. 2000.

Bechtel SAIC Company. "FY01 Supplemental Science and Performance Analyses, Volume 1: Scientific Bases and Analyses." TDR-MGR-MD-000007 Rev 00. Las Vegas, Nevada: Bechtel SAIC Company. 2001a.

Bechtel SAIC Company. "FY01 Supplemental Science and Performance Analyses, Volume 2: Performance Analyses" TDR-MGR-PA-000001 Rev 00. Las Vegas, Nevada: Bechtel SAIC Company. 2001b.

Bechtel SAIC Company. "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" SL986M3 Rev 00 ICN 01. Las Vegas, Nevada: Bechtel SAIC Company. 2001c.

Brossia, C.S. et al., Effect of Environment on the Corrosion of Waste Packages and Drip Shield Materials, CNWRA 2001-03, Center for Nuclear Waste Regulatory Analyses, San Antonio, TX. 2001.

Letter to J. Ziegler from J. Schlueter dated February 26, 2003
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