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OVERNIGHT MAIL

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RESOLUTION OF U.S. NUCLEAR REGULATORY COMMISSION (NRC) SITE CHARACTERIZATION ANALYSIS (SCA) COMMENT 3, AND OTHER COMMENTS RELATED TO USE OF EXPERT ELICITATIONS IN HIGH-LEVEL WASTE PROGRAM

- References: (1) Ltr, Austin to Milner, dtd 12/26/96
 (2) Ltr, Austin to Milner, dtd 12/31/96
 (3) Ltr, Austin to Milner, dtd 1/7/97

Based on the U.S. Department of Energy's (DOE) comments on the "Branch Technical Position (BTP) on the Use of Expert Elicitation in the High-Level Radioactive Waste Management Program" (NUREG-1563), and additional information provided by the DOE, the NRC proposed a path forward to resolve a number of NRC comments related to the application of expert elicitation in the Site Characterization Program (Reference 1). The comments for resolution include:

- Site Characterization Analysis (SCA) Comment 3 on the reliance of expert judgment to supply licensing information;
- SCA Comment 7 on the need to clarify the role of subjective methods (expert judgement) in site characterization;
- Comment No. 2 on the 1994 Topical Report entitled the "Methodology to assess Fault Displacement and Vibratory Ground-Motion Hazards At Yucca Mountain"; and
- Comment Nos. 12 and 13 on Revision 2 of Study Plan 8.3.1.8.1.1 "Probability of Magmatic Disruption of the Repository."

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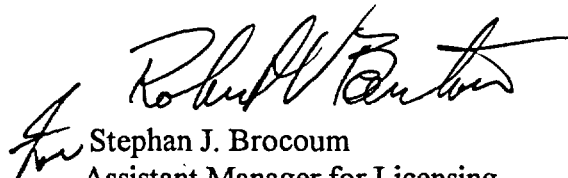
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The NRC's basis for resolution is for the DOE to either implement the recommendations provided in Appendix E of NUREG-1563, to provide an equivalent course of action, or to demonstrate that these comments are now obsolete.

The DOE accepts the recommendations in Appendix E of NUREG-1563 and presents an approach to implement the recommendations in Enclosure 1. This approach will result in revisions to the Quality Assurance Requirements Document and development of an implementation procedure for expert elicitation.

Subsequent to receipt of Reference 1, the NRC provided additional comments related to the implementation of NUREG-1563 in References 2 and 3. Enclosure 2 presents DOE's responses to the NRC's comments in the subsequent letters related to updating the results of elicitations, documenting the elicitation process, the potential for introduction of bias by the Technical Facilitator/Integrator, and the need to document potential conflicts of interest.

We believe that we have provided the basis to resolve the referenced NRC comments. If the NRC agrees, we ask for documentation that the comments are resolved. If you have any questions, please contact J. Timothy Sullivan at (702) 794-5589 or April V. Gil at (702) 794-5578 of my staff.


Stephan J. Brocoum
Assistant Manager for Licensing

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Enclosures:

1. Responses to NRC Recommendations in NUREG-1563, Appendix E
2. Responses to subsequent NRC Letters on expert elicitation

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Enclosure 1

Responses to NRC's Recommendations in NUREG-1563, Appendix E

Recommendation 1:

The [DOE's] 1995 *Principles and Guidelines for Formal Use of Expert Judgement by the Yucca Mountain Site Characterization Project Office* should be revised to reflect DOE's acceptance of the staff's Branch Technical Position (BTP). Moreover, DOE's *Principles and Guidelines* should be revised to address recommended changes to the format and content noted in NRC's comments.

DOE Response: Our comments on the draft BTP were provided to NRC on May 13, 1996; DOE is in substantial agreement with the process requirements of the draft BTP, and this conclusion has not changed with the final version. *DOE's Principles and Guidelines* was prepared solely as a DOE policy statement and tool to assist in resolving the basis for SCA comment 3. In acting on NRC's recommendations in Appendix E of NUREG-1563, and the guidance provided in the BTP, the DOE is revising the Quality Assurance Requirements Document to address expert elicitation and is developing an implementing procedure on expert elicitation rather than revising DOE's Principles and Guidelines.

Recommendation 1a:

Correct and clarify [in *Principles and Guidelines*] DOE's use of the terms, "expert judgment", "expert elicitation", and "peer review."

DOE Response: Although NRC points out some discrepancies in *Principles and Guidelines* regarding references to these closely related concepts, and advocates that these definitions be clarified, we believe that our acceptance of the guidance provided in NUREG-1563 obviates the need to revise this document. The *Principles and Guidelines* were written to provide guidelines on the application of expert judgement processes to meet the first condition in NRC's original recommendation (NUREG-1347, p.4-10) for resolving comment 3, "State the criteria for the formal use of expert judgement to ensure that objective, quantitative, analyses based on empirical data are used in preference to expert elicitation, wherever possible." The *Principles and Guidelines* were not intended to be a procedure to explain the steps or to define process requirements for any specific type of application. The terms "expert judgement", "expert elicitation" and "peer review" are well defined in NUREG-1563 and therefore, we see no need to revise the *Principles and Guidelines*.

Recommendation 1b:

[Provide] substantive discussion [in *Principles and Guidelines*] regarding the specific procedures *per se* that the Department and its contractors would follow when conducting a formal elicitation.

DOE Response: Using NUREG-1563 as guidance, DOE is revising the Quality Assurance Requirements Document to define circumstances when expert elicitation is appropriate, and the basic process and documentation requirements for conducting an elicitation. Until NUREG-1563 was available, DOE's controls on expert elicitation consisted of a planning document stating the goals and basic steps for the elicitation and a final report that documented that process, or a procedure developed by an affected organization that explained the steps for implementation. Because there has been good communication between DOE and NRC prior to development and approval of NUREG-1563, and because NRC has observed previous expert elicitation conducted before this guidance was available, such as the "Probabilistic Volcanic Hazards Analysis", the process requirements in the NUREG and those used by DOE have had minimal differences (Reference 2). DOE has used NRC's observations to improve our process. Consistent with NRC's recommendations, DOE is revising the QARD to address the process for expert elicitation and is developing a procedure that implements the new QARD requirements for expert elicitation.

Recommendation 1c:

[Provide] direction [in *Principles and Guidelines*] to DOE management and staff regarding how to address the potential for conflict of interest when conducting a formal elicitation.

DOE Response: For the reasons described in the response to NRC's recommendation 1a, DOE finds no useful purpose in revising *Principles and Guidelines* because of the planned revision to the QARD and procedure on expert elicitation. However, we agree that clear direction regarding addressing potential conflict of interest is necessary when conducting a formal elicitation. The requirement to document conflict of interest will be part of both the QARD revision, and the implementing procedure referenced in the response to recommendation 1b. The DOE has reviewed NRC's guidance on documenting potential conflict of interest (Reference 3). We appreciated NRC's recommendations and information on documentation for potential conflict of interest. The conflict of interest documentation used by the National Academy of Sciences has been adapted for use in ongoing expert elicitations (Reference 3).

Recommendation 2:

The current version of the QARD should be revised to include a discussion of the treatment of "formal" expert elicitation comparable to the discussion that already exists for "peer reviews".

DOE Response: DOE is revising the QARD to identify appropriate circumstances for expert elicitation, and the process and documentation requirements for conducting one. NUREG-1563 was used as guidance to develop these QARD controls. An implementing procedure will also be developed. See also the response to recommendation 1b.

Recommendation 3:

DOE decisions on the need to use formal expert elicitation should be transparent. DOE's *Principles and Guidelines* should be revised to ensure that its management and staff prepare the necessary documentation to permit tracking of such decision-making.

DOE Response: Our reasons for not revising the *Principles and Guidelines* document has been stated elsewhere in this enclosure. However, NRC's recommendation bears upon the general expectation that the rationale for DOE's decision-making needs to be available for a licensing process. DOE has taken steps to develop a white paper with respect to the manner in which DOE now documents decisions, and that identifies the need for additional procedural controls or management processes to improve the existing documentation. We have discussed this white paper with NRC management and staff during its development, and will continue to do so when it is completed. We intend to request feedback from the NRC on the adequacy of our documentation processes as presented in this paper.

With respect to the decision to conduct a specific expert elicitation, the planning document will state the goals and purpose for its conduct, as it has under current practice, for example, the Unsaturated Zone Flow Model Project.

Summary

DOE has explained our intentions to fulfill the recommendations made by the NRC that were seen as a path toward resolving SCA comment 3. On the basis that DOE accepts NRC's recommendations, we believe that we have provided the basis to resolve SCA comment 3. If the NRC agrees, then the DOE requests documentation stating this conclusion.

Enclosure 2

Responses to NRC Letters (Austin to Milner 12/31/96 and 1/7/97) on Implementation of NUREG-1563 and Documenting Potential Conflict of Interest

1) Comments on the Implementation of NUREG-1563

Comment 1:

It is not clear what DOE's plans and procedures are for evaluating whether to update the results of an elicitation, as set forth in Technical Position No. 3 of the BTP...the staff believes that it is important for the Department to give consideration to the possibility for the need to re-examine and update the results of elicitations. This updating could include a number of measures other than repeating the original elicitation.

DOE Response: The DOE agrees with the NRC staff and is developing a procedure to document DOE's process for the use of expert elicitation. This procedure will provide steps that define the process for re-evaluating and updating the results of elicitations, as appropriate.

Comment 2:

Step 9 of Technical Position 2 describes the need to provide sufficient documentation of the elicitation. In the documentation accompanying the PVHA, it was noted that the initial elicited results of the experts had been changed based on feedback received after completion of the initial elicitation and subsequent aggregation. However, the PVHA report provided little insight as to how, why, or to what extent the original elicited judgments had been changed...The staff believes that this type of information is an important part of the elicitation record and should be preserved as part of any formal licensing documentation.

DOE Response: The PVHA Report only documents the expert's final assessments. The DOE believes that the subject matter experts should be allowed to revise their assessments using the feedback process and the final report should only document their final assessment. The elicitation process should allow the experts the flexibility to revise their assessments in a manner that does not anchor the experts to their initial assessment. The first draft and final drafts of the expert assessments are maintained in the administrative record for the PVHA.

During the PVHA, the feedback process provided a forum for the expert's opinions to be reviewed, discussed, and challenged by other members of the panel. Examples of feedback loops included:

- The experts presented their interpretations of key issues for their review and discussion in the fourth workshop
- Preliminary PVHA results were developed from the expert's preliminary assessments and presented to the experts in the fourth workshop to help the experts evaluate their preliminary assessments
- Sensitivity analyses were provided to the experts to allow the experts to better understand the implications of their assessments
- Members of the Methodology Development Team reviewed the elicitation summaries for technical consistency, clarity, and adequacy of documentation

The goal of the feedback and revision process during the PVHA was to place the burden of defending and revising the expert assessments on the experts and to focus the experts on providing adequate documentation of their opinions.

Comment 3:

Finally, during the Appendix 7 meeting, DOE noted that the PSHA elicitation, as in PVHA, would rely on the use of the technical facilitator/integrator (TFI) concept as first proposed by the Senior Seismic Hazard Analysis Committee (SSHAC)....The staff believes that although the TFI serves a similar function as the "generalist" defined in the BTP, the TFI possesses authorities beyond those assigned to the generalist, such as downweighting outliers during the aggregation of elicited judgments and conducting modeling exercises during the elicitation. Because there is no formal guidance on their implementation, specifically, there may exist a potential for the TFI to misuse the power and inject personal biases or artificially narrow the range of elicited views. To avoid the potential abuse of these authorities, the staff believes that the Department should consider developing and documenting a formal procedure for the use of the TFI concept.

DOE Response: The DOE does not agree that there is a potential for the TFI to misuse the power and interject personal biases or artificially narrow the range of elicited views of the panel. The role of the TFI is, in fact, to help to limit bias by creating a sufficiently structured expert interaction so that equal weights are appropriate for each expert's assessment. The TFI, working in the context of a methodology development team, ensures that: 1) the panel is carefully selected, 2) each panelist commits appropriate time and effort throughout the project: 3) A complete and uniform database is provided to the panel: 4) the experts in elicitation methodologies are trained, 5) a free exchange of data and interpretations, and scientific debate takes place: 6) feedback and sensitivity analyses is provided to the panel: and 7) the experts have an opportunity to revise their assessments in light of the feedback. For the PSHA and the PVHA, the TFI consisted of a team rather than an individual with the authority to act independently. As proposed in the SSHAC report (page 30), "it is more reasonable that the TFI will consist of a small group of individuals." The role of the TFI will be documented in the project plan for an elicitation if the DOE employs this concept.

The goal of our ongoing expert elicitations is one of weighting the experts equally. The role of the TFI is to assist in avoiding the problems that may lead to the need to downweight an expert assessment. As noted in the PVHA, downweighting of an expert's opinion is considered when problems have occurred on multi-expert studies. These problems may include: 1) experts playing the role of a proponent and being unwilling to evaluate alternative interpretations; 2) outlier experts whose interpretation is extreme relative to the larger technical community and may be over represented on a small expert panel; 3) insufficient expert interaction such that experts misunderstand the hypotheses presented by others; 4) uneven access to pertinent data sets such that experts are relying on different data to arrive at their interpretations without knowledge of other data, and 5) insufficient feedback such that experts are not aware of the significant issues or the relative impact of each part of their assessments. If downweighting is deemed necessary, the rationale for this decision will be clearly documented in the final report.

Modeling activities are performed by the Methodology Development Team solely for the convenience of the experts. For example, in the PVHA, the Methodology Development Team made a variety of modeling tools available for the experts. Some experts completed calculations themselves; other specified approaches and reviewed the calculations made by the Methodology Development Team. In addition, preliminary hazard calculations along with sensitivity analyses were completed using the expert's preliminary assessments and presented to the experts in the fourth workshop as part of the feedback process. The hazard calculations were applied consistently across the experts and were intended to provide the experts with a focus for evaluating their preliminary assessments.

In the case of the Unsaturated-Zone Flow Model Expert Elicitation, some experts completed calculation themselves; others specified sensitivity analyses that were completed by LBNL using the LBNL unsaturated zone site-scale model. The experts reviewed the results of the sensitivity analyses as part of the feedback process and were free to consider the sensitivity studies, if appropriate, in finalizing their assessments.

2) NRC Guidance on Potential Conflict of Interest

NUREG-1563 states that all potential conflicts of interest should be documented and disclosed when selecting experts for an elicitation. The NRC staff provided further guidance on approaches for documenting and disclosing potential conflict of interest in the January 7, 1997 letter from John Austin to Ronald Milner (Reference 3). The DOE has implemented a process for documenting potential conflict of interest that is modified from the approach used by the National Academy of Science. The documentation of potential conflict of interest will be maintained in the administrative record for each expert elicitation.