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Mr. Hubert Miller
U.S. Nuclear Regulatory Commission
Office of Nuclear Materials Safety
and Safeguards
Division of Waste Management
SS - 623
Washington, D.C. 20555

Dear Mr. Miller:

We have completed our review of Draft Generic Technical Position (GTP) on Licensing Assessment Methodology for High-Level Waste Geologic Repositories. Based on this review it is our opinion that the GTP provides a reasonable and workable technical position. However, we do have pertinent comments on the GTP, which are attached.

Additionally, in the meeting of April 17, 1985, pertaining to Performance Allocation issues, DOE agreed to comment on the definition of "reliability" vs that for "level of confidence" and also to attempt to reconcile the DOE and NRC logic flow diagrams for site characterization activities that were circulated at that meeting. The definitions are discussed in comments 9 and 10. The logic flow chart in Figure 2 of the GTP actually differs only slightly from DOE's understanding of the site characterization process, as noted in the comments on the GTP (Comment 13). Otherwise we believe that DOE's logic flow chart differs only in that it provides a different level of detail than does the NRC chart.

We appreciate the opportunity to comment on the GTP and hope that we will be able to meet to close on the definitions and logic chart. I have instructed Dr. Donald Alexander of my staff to arrange a mutually acceptable date for a second meeting on performance assessment with Seth Coplan of your staff.

Sincerely,

Ralph Stein

Ralph Stein, Director
Engineering and Licensing Division
Office of Civilian Radioactive
Waste Management

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Comments on the Draft Generic Technical Position (GTP)
On Licensing Assessment Methodology for
High-Level Waste Geologic Repositories

1. The GTP does not address all licensing considerations. For example, in spite of intentions expressed in the introduction to address qualitative assessment, the guidance in the document addresses the assessments almost exclusively in terms of the quantitative requirements. There is no guidance provided with respect to NRC's expectations for qualitative evaluations in the assessments for licensing. The title of the GTP should be changed to cover only performance assessment (as defined in Section 1.2.1) or the document should be expanded.
2. The GTP provides very limited guidance with regard to the licensing assessments for the preclosure system. For example, the discussion of the nature of the technical findings through permanent closure (Section 1.2.2.1 (1), Page 5) addresses only accidental releases. From this discussion DOE concludes that a dose commitment limit of 0.5 rem to the whole body or any organ of an individual in an unrestricted area is appropriate for assessment of a preclosure accident.
3. The GTP provides an interpretation of the EPA standard in Section 1.2.2.2. This standard has not yet been finalized and this text should be revised to reflect only the final version of this standard.
4. The GTP interprets (Section 1.2.2.2, Page 7) that the EPA Standard will require probabilistic risk assessment (PRA). While the NRC has consistently taken the position that uncertainties will have to be taken into account in any licensing assessment, the Commission has been very cautious about recommending that any formal methodology for PRA be incorporated into this process. A commitment to a course similar to that "used for the analysis of nuclear power plants and other applications" may be premature. The recommendation to account for the uncertainties in the system is reasonable. The recommendation at this stage for a formal PRA treatment of the post-closure system is not.
5. The GTP stresses that license application must quantify to the extent practicable the full range of uncertainties in the assessments (e.g., Section 1.2.2.2, page 7). It is not clear that such a specification will always be necessary, even when practicable. For example, in some cases to account for uncertainties bounding cases may be presented for a particular process or credit may not be taken for some element of the system. In these cases, when supported by appropriate data and analyses, specification of the "full range of uncertainty" in a parameter may be irrelevant. The SCP should of course provide plans to determine to what extent bounding analyses are anticipated or credit may be taken for elements of the system.

6. Throughout the GTP, there is considerable attention on scenarios which entail, according to the definitions, "an account or sequence of a projected course of action or events". The GTP does not explicitly recognize that many of the uncertainties of the system will be considered under the category of "expected conditions" under which no sequence of events is hypothesized. This omission places undue emphasis on the uncertainties associated with the definition of the probability of the scenario (e.g., the probability of the initiating event). This emphasis may be inconsistent with the representation of the system that will emerge from the site characterization process and is therefore premature.
7. The GTP emphasizes that scenarios and probabilities for these scenarios must be specified in the license application (e.g., 1.2.2.2, Page 8). The methodology to treat scenarios may depend upon the scenarios themselves and data to identify and define these scenarios may not be available until well into or after the characterization process. The GTP should recognize this possibility. Likewise some models and numerical methods may not be developed, verified, and validated until the site is characterized. Therefore, the GTP should recognize that the SCP may only contain plans to find information to identify these models rather than to develop them or apply them.
8. The section on the nature of the HLW decision process (Section 1.2.3, Page 9) describes the hearing of multiple, coequal parties in the proceeding. A requirement to respond to unsupported statements or positions by other parties could place an exorbitant burden on DOE.
9. There is an ambiguity in the definition of "reliability" and "confidence level" in the GTP (e.g., Section 3.1.1, Page 11). The term reliability is related to failure of a component. An accepted definition is "the probability that failure does not occur in or over a specified time interval" (Cf. Henley and Kumamoto, Reliability Engineering and Risk Assessments, Page 289). Thus the term is suited for components in which failure has a well-defined sense such as engineered components with a specified mission in the system. For a postclosure repository system, failure may not be a well-defined term. For example waste package degradation under postclosure conditions does not necessarily mean failure of containment as it would for a preclosure system. "Reliability" is clearly an inappropriate term for characteristics of the natural system such as permeability or porosity.

On the other hand, the term "confidence level" is "the probability that the true value is at least (or at most) a specified value" (Henley and Kumamoto, Page 245). It is recommended that this term be used when discussing the value of any measurable parameter of the system, including those that relate to failure. While "reliability" may apply to some aspects of the assessment, extrapolation to unusual applications of the term has led to confusion. The use of "confidence level" however appears to be much less ambiguous and would resolve the problems that arise.

One example of a confidence level can be given for the discussion of corrosion rates of waste package components. The confidence level in a specified rate would be the probability that the true rate is no more than the specified value. A second example can be given for the hydraulic properties of a shaft seal. The confidence level in the hydraulic conductivity is the probability that the actual value is not more than that specified.

10. The GTP indicates that confidence levels in proposed levels of performance be specified at the beginning of the site characterization process (Section 3.1.1, Page 11, 12). In some cases such specification can be done in the SCP. In other cases it may not be meaningful to establish confidence levels until well along in the characterization program. The first case applies to the tests in which the confidence level can be directly determined from the statistics of the tests. In this case, a pre-set confidence level can be used to help determine the number, kind, and utility of the tests. Thus, many short-term, laboratory tests for characteristics of engineered components may be discussed in this way.

The second case applies to those situations where the probability distribution function is determined less directly from the tests; for example, parameter uncertainties determined from testing may be folded into an analysis. In this case the probability distribution function would depend not only on the test results but upon the particular conceptualization and the assumptions of the analysis. In such a case it is not possible to do the inverse problem, i.e., to directly relate the confidence levels to the number and kind of tests that provide the data that go into the analyses. Specification of levels before such tests is not meaningful nor helpful in evaluating the test program and the analyses are likely to be used to attack the testing program when arbitrary levels are not met.

11. In Section 3.3.1 (Page 18), the GTP discusses plans to develop a pre-closure risk-analysis methodology. The GTP should explicitly note that a PRA methodology is not necessarily required in order to demonstrate, with a reasonable degree of assurance, compliance with radiological limits.
12. The definition of the engineered barrier system on page 2 of the definitions should not refer to a measured rate of release, but a prediction based upon tested models.
13. Figure 2 of the GTP gives the logic flow of the site characterization process anticipated by the NRC. The DOE does not believe that system sensitivity studies are the only kind of analyses that will be used to develop assessment methods or to establish component requirements as might be implied by this diagram. Subsystem analyses, uncertainty

analyses, and professional judgement based upon specific assessments using the assessment methods may also be used. This point is apparently recognized by the NRC, because the descriptive text that supports this figure in the GTP refers to sensitivity studies simply as an example of the kind of studies that may be conducted (Section 3.1, Page 11). It is recommended that the element labeled "system sensitivity studies" in Figure 2 be relabeled with a somewhat more general term consistent with this supporting text, such as "performance analyses".