DRAFT

UMBRELLA SITE TECHNICAL POSITION
POST-CLOSURE PERFORMANCE ASSESSMENT- BWIP
STP # 6.0

Geotechnical Branch
Division of Waste Management
U.S. Nuclear Regulatory Commission
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BACKGROUND

In the review of an application for Construction Authorization for a high-level waste geologic repository, the NRC is required to determine whether the site and design meet the technical criteria of 10 CFR Part 60. The NRC staff determination will be based on the answers to, and supporting analyses of, technical questions concerning groundwater flow, geochemical retardation, waste form and package performance, geologic stability, and facility design. During the process of Site Characterization, the Department of Energy (DOE) will perform the laboratory and field investigations to develop the information needed to address these basic technical questions.

The investigations needed to characterize a geologic repository are complex and require long lead times. The Nuclear Waste Policy Act of 1982 (NWPA) has established a schedule for site characterization and selection. Specifically, NWPA requires publication of Site Characterization Plans (SCP's) by DOE at an early stage of the process. Subsequent to receipt of an SCP the NRC must prepare a formal Site Characterization Analysis (SCA) for each site. NRC single-issue technical position papers, documented site reviews, and interagency technical meetings will precede and supplement the SCA's.

Because of the complexity and long lead times for site characterization investigations, it is essential that activities be organized to make possible an NRC determination of site acceptability. Proper organization necessitates early identification of technical questions (specific issues) relevant to the specific site. Therefore, this document establishes the NRC position as to the essential technical questions relevant to performance assessment of a hypothetical repository at the Hanford site. Future Site Technical Positions will address both NRC staff concerns regarding selected specific issues and acceptable technical approaches for addressing those specific issues.

Terminology used by NRC staff is as follows:

Performance assessment of the BWIP site is defined by NRC staff in the Draft Site Characterization Analysis-BWIP (DSCA-BWIP) as "the process of quantitatively evaluating component and system behavior, relative to containment and isolation of radioactive wastes, to support development of a high-level waste repository and to determine compliance with the numerical criteria associated with the regulation (10 CFR Part 60)." The high-level waste disposal performance objectives stated in 10 CFR Part 60 are:

1) The geologic setting shall be selected and the engineered barrier system and the shafts, boreholes and their seals shall be designed to assure that releases of radioactive materials to

the accessible environment following permanent closure conform to such generally applicable environmental standards for radioactivity as may have been established by the Environmental Protection Agency (EPA) with respect to both anticipated processes and events and unanticipated processes and events. (10 CFR Part 60.112)

2) Pre-emplacement groundwater travel time along the fastest path of likely radionuclide travel from the disturbed zone to the accessible environment shall be at least 1000 years, or such other time as may be approved or specified by the Commission. (10 CFR Part 60.113)

3) Containment of high-level waste (HLW) within the waste packages will be substantially complete for a period to be determined by the Commission, provided that such period shall not be less than 300 years nor more than 1000 years after permanent closure. (10 CFR Part 60.113)

4) The release rate of any radionuclide* from the engineered barrier system following the containment period shall not exceed one part in 100,000 per year of the inventory calculated to be present at 1000 years following permanent closure, or such other fraction of the inventory as may be approved or specified by the Commission. (10 CFR Part 60.113)

Site issues are defined as questions about a specific site that must be answered or resolved to complete licensing assessments of the site and design suitability in terms of 10 CFR 60. Site issues are not necessarily controversial questions. Site issues can be divided into performance issues and specific issues.

Performance issues are broad questions concerning both the operational and long-term performance of the various elements of the overall geologic repository system (e.g., waste form, waste package, geologic setting). Performance issues are derived directly from the performance objectives in 10 CFR Part 60. Development of performance issues for a geologic repository is explained in detail in Appendix C of NUREG-0960, "Draft Site Characterization Analysis of the Site Characterization Report for the Basalt Waste Isolation Project," March, 1983.

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*This criterion does not apply to any radionuclide which is released at a rate less than 0.1% of the calculated total release limit. The calculated total release rate limit shall be taken to be one part in 100,000 per year of the inventory of radioactive waste, originally emplaced in the underground facility, that remains after 1000 years of radioactive decay.

Specific issues generally are questions about conditions and processes that must be considered in assessing the performance issues. Performance issues include the integration of numerous specific issues. Performance issues establish the relationship between specific issues discussed in this Umbrella Site Technical Position and the performance objectives of 10 CFR Part 60.

The NRC requires a demonstration of "reasonable assurance" that the performance objectives of 10 CFR Part 60 listed above will be met. In response to public comment on 10 CFR Part 60, the Commission discussed the interpretation of this concept. The Commission concluded that because many uncertainties in performance assessment of HLW repositories are unquantifiable, it is inappropriate to statistically quantify the term "reasonable assurance." The Commission's discussion is included with this technical position as Appendix A.

It should be noted that the issue development herein is based on the presumption of the current proposed EPA Standard.

POST-CLOSURE PERFORMANCE ASSESSMENT ISSUES AT BWIP

Overall System Performance (10 CFR Part 60.112)

[The following technical questions related to overall system performance are predicated on the proposed EPA Standard. These questions will be reviewed and revised where appropriate if changes are made in the final adopted Standard.]

1.0 Do analyses of the natural and engineered systems provide reasonable assurance that releases of radioactive materials to the accessible environment following permanent closure conform to the proposed standards by the Environmental Protection Agency (i.e. 40 CFR Part 191)?

1.1 What is the geometric configuration of the boundary of the accessible environment at the BWIP site?

1.2 What approach has BWIP used to identify a complete set of scenarios for analysis and comparison with the numerical standards of 40 CFR 191?

1.2.1 What method has BWIP used to identify a complete set of scenarios?

1.2.2 What are the conceptual models of the release scenarios, and how well do data and observations support these conceptual models?

1.2.3 How have the synergistic effects between events and processes been addressed in the identification process?

1.2.4 What are the uncertainties associated with the identification process and how have they been addressed?

1.3 What approach has BWIP used to quantitatively estimate the probabilities of occurrence for these release scenarios?

1.3.1 What method has BWIP used to assign numerical probabilities to these release scenarios?

1.3.2 What are the uncertainties associated with these probabilities and how have these uncertainties been addressed?

1.4 How has BWIP screened the complete set of scenarios to select those scenarios which are most appropriate for analysis?

1.5 How has BWIP assessed the consequences for the scenarios selected above (1.4)?

1.5.1 What are the conceptual models of the release scenarios, and how well do data and observations support these conceptual models?

1.5.2 What mathematical models are used to represent these conceptual models and do these mathematical models adequately represent the conceptual models?

1.5.3 What analytical and numerical models are used to represent the mathematical models and do these analytical and numerical models adequately represent the mathematical models?

1.5.4 How have the synergistic effects between events and processes been addressed in the analyses?

1.5.5 How have the numerical and analytical models been documented, verified, benchmarked, and validated?

1.5.6 What are the uncertainties in the consequence assessment and how have these uncertainties been addressed?

1.6 How has BWIP combined the consequences from individual release scenarios to assess the cumulative release of radionuclides to the accessible environment and demonstrated compliance to 40 CFR Part 191?

<u>Waste Package Containment Time</u> (10 CFR Part 60.113(a)(1)(ii)(A))

2.0 Will containment of HLW within the waste packages be substantially complete for a period of not less than 300 to 1000 years (period to be determined by the Commission) after permanent closure of the geologic repository?

2.1 What are the predicted physical and chemical properties of the waste package environment through the period of containment?

2.1.1 What approach has BWIP used to predict this environment?

2.1.2 How have the empirical models, which have been based on results of short-term laboratory and <u>in-situ</u> tests, been extrapolated for the duration of the containment period?

2.1.3 What are the conceptual models that are used to predict the waste package environment and how well do data and observations support these conceptual models?

2.1.4 What mathematical models are used to predict this environment and do these mathematical models adequately represent the conceptual models?

2.1.5 What analytical and numerical models are used to predict the environment and do these analytical and numerical models adequately represent the mathematical models?

2.1.6 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

2.1.7 What are the uncertainties associated with this assessment and how have these uncertainties been addressed?

2.2 What are the anticipated events that may prematurely cause failure of the waste package and what are their effects on the repository?

2.2.1 What are the conceptual models used to predict the effects of anticipated events on the waste packages and how well do data and observations support these conceptual models?

2.2.2 What mathematical models are used to predict these effects and do these mathematical models adequately represent the conceptual models?

2.2.3 What analytical and numerical models are used to predict these effects and do these analytical and numerical models adequately represent the mathematical models?

2.2.4 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

2.2.5 What are the uncertainties associated with the assessment of the significance of these anticipated events and how are they addressed in the assessment?

2.3 How has BWIP assessed the performance of the waste package and demonstrated compliance with the containment criterion, in light of the predicted environment and the effects of anticipated events?

2.3.1 What approach has BWIP used to assess compliance of the waste packages with the containment time performance objective?

2.3.2 How has BWIP addressed waste package reliability in their determination of compliance with the containment time criterion?

2.3.3 What conceptual models are used in the assessment and how well do data and observations support these conceptual models?

2.3.4 What mathematical models are used to make the assessment and do these mathematical models adequately represent the conceptual models?

2.3.5 What analytical and numerical models are used to make the assessment and do these analytical and numerical models adequately represent the mathematical models?

2.3.6 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

2.3.7 What are the uncertainties associated with this assessment of compliance and how are they addressed in the assessment?

Release Rate of the Engineered Barrier System (10 CFR Part 60.113(a)(1)(ii)(B))

3.0 Is the release rate of any radionuclide from the engineered barrier system less than or equal to one part in 100,000 per year of the inventory of that radionuclide calculated to be present at 1,000 years following permanent closure?

3.1 What is the predicted radionuclide inventory at 1,000 years following permanent closure of the repository?

3.2 What is the predicted repository environment following permanent closure?

3.2.1 What approach has BWIP used to predict the physical and chemical properties of the repository environment?

3.2.2 What are the conceptual models of the repository environment and how well do data and observations support these conceptual models?

3.2.3 What mathematical models are used to predict the repository environment and do mathematical these models adequately represent the conceptual models?

3.2.4 What analytical and numerical models are used to predict the repository environment and do these analytical and numerical models adequately represent the mathematical models?

3.2.5 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

3.2.6 What are the uncertainties associated with this prediction and how have they been addressed in the assessment?

3.3 What are the anticipated events that may significantly affect the ability of the engineered system to meet the release rate performance objective?

3.3.1 How likely are these anticipated events?

3.3.2 What are the conceptual models of these anticipated events and how well do data and observations support these conceptual models?

3.3.3 What are the uncertainties associated with the development of these conceptual models and how are they addressed in the development?

3.4 What effects do these anticipated events have on the engineered barrier system relevant to the release rate performance objective?

3.4.1 What approach has BWIP used to predict these effects?

3.4.2 What are the conceptual models that are used to assess these effects and how well do data and observations support these conceptual models?

3.4.3 What mathematical models are used to assess the effects and do these mathematical models adequately represent the conceptual models?

3.4.4 What analytical and numerical models are used to assess the effects and do these analytical and numerical models adequately represent the mathematical models?

3.4.5 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

3.4.6 What are the uncertainties associated with the assessment of these effects and how have they been addressed?

3.5 How has BWIP demonstrated compliance of the engineered barrier system with the release rate performance objective?

3.5.1 What approach has BWIP used to demonstrate compliance of the engineered barrier system with the release rate performance objective?

3.5.2 What are the conceptual models that are used to demonstrate compliance and how well do data and observations support these conceptual models?

3.5.3 What are the mathematical models that are used to predict performance of the engineered barriers and do these mathematical models adequately represent the conceptual models?

3.5.4 What analytical and numerical models are used to predict performance of the engineered barrier system and do these analytical and numerical models adequately represent the mathematical models?

3.5.5 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

3.5.6 What uncertainties are associated with this assessment and how are they addressed?

Pre-Emplacement Groundwater Travel Time (10 CFR Part 60.113(a)(2))

4.0 Is the prewaste-emplacement groundwater travel time along the fastest path of likely radionuclide travel from the disturbed zone to the accessible environment greater than 1000 years (or such other period as may be approved or specified by the Commission)?

4.1 What is the proposed geometric configuration and extent of the disturbed zone?

4.1.1 What predicted physical and chemical changes will significantly affect the performance of the repository?

4.1.2 What approach has BWIP used in estimating the proposed extent and configuration of the disturbed zone?

4.1.3 What are the conceptual models that are used to estimate the extent and configuration of the disturbed zone and how well do data and observations support these conceptual models?

4.1.4 What mathematical models are used to predict the extent of the disturbed zone and do these mathematical models adequately represent the conceptual models?

4.1.5 What analytical and numerical models are used to predict the extent of the disturbed zone and do these analytical and numerical models adequately represent the mathematical models?

4.1.6 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

4.1.7 What uncertainties are associated with this estimation and how are these uncertainties addressed in the assessment?

4.2 What is the fastest path of likely radionuclide travel from the disturbed zone to the accessible environment?

4.2.1 What approach has BWIP used to predict the fastest path of likely radionuclide travel?

4.2.2 What are the conceptual models that are used to predict the fastest path of likely radionuclide travel and how well do data and observations support these conceptual models?

4.2.3 What mathematical models are used to predict this path and do these mathematical models adequately represent the conceptual models?

4.2.4 What analytical and numerical models are used to predict the fastest path of likely radionuclide travel and do these analytical and numerical models adequately represent the mathematical models?

4.2.5 How have these analytical and numerical models been documented, verified, benchmarked and validated?

4.2.6 What are the uncertainties associated with this assessment and how have these uncertainties been addressed?

4.3 What is the prewaste-emplacement groundwater travel time along the fastest path of likely radionuclide travel from the disturbed zone to the accessible environment, and how has BWIP demonstrated compliance with the minimum groundwater travel time performance objective?

4.3.1 What approach has BWIP used to predict the pre-waste emplacement groundwater travel time along the fastest path of likely radionuclide travel from the disturbed zone to the accessible environment?

4.3.2 What are the conceptual models that are used to predict these travel times and how well do data and observations support these conceptual models?

4.3.3 What mathematical models are used to predict these travel times and do these mathematical models adequately represent the conceptual models?

4.3.4 What analytical and numerical models are used to predict the travel times and do these analytical and numerical models adequately represent the mathematical models?

4.3.5 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

4.3.6 What are the uncertainties associated with this prediction and how have these uncertainties been addressed?

DISCUSSION

Overall System Performance

[The following technical questions related to overall system performance are predicated on the proposed EPA Standard. These questions will be reviewed and revised where appropriate if changes are made in the final adopted Standard.]

1.0 Do analyses of the natural and engineered systems provide reasonable assurance that releases of radioactive materials to the accessible environment following permanent closure conform to the proposed standards by the Environmental Protection Agency (40 CFR Part 191)?

1.1 What is the geometric configuration of the boundary of the accessible environment at the BWIP site?

Before determining compliance with 40 CFR 191 and 10 CFR 60, BWIP must identify the proposed extent of the accessible environment at the BWIP site. This proposal must be consistent with the descriptions of the boundary of the accessible environment in 40 CFR 191 and 10 CFR 60. Predictions of cumulative radionuclide releases to the "accessible environment" that precede this proposal will be considered by NRC staff as demonstrations of the BWIP methodology and not rigorous performance assessment.

1.2 What approach has BWIP used to identify a complete set of scenarios for analysis and comparison with the numerical standards of 40 CFR Part 191?

1.2.1 What method has BWIP used to identify a complete set of scenarios?

The NRC staff interprets the proposed EPA Standard (40 CFR 191) as requiring a comprehensive evaluation of events and processes which might affect repository performance. This assessment begins with the identification of a complete set of release scenarios, including both natural and human-induced releases.

NRC recognizes that the identification of scenarios is likely to require the use of subjective judgement. Any method used to identify scenarios must, however, be done in a systematic, unbiased manner in order to mitigate the subjectivity to the fullest extent possible. The method and application should be thoroughly documented to enable review by affected Indian tribes, state and federal governments, the technical community, and other interested parties. The identification methodology should encourage strong involvement by all of these interested

1.3.1 What method has BWIP used to assign numerical probabilities to these release scenarios?

To comply with the NRC and EPA regulatory criteria, two distinct evaluations of scenario probabilities are required. The NRC requires a qualitative classification of events and processes as being either "anticipated" or "unanticipated" based on the historical record during the Quaternary Period (see discussion of anticipated and unanticipated processes and events in 10 CFR 60.2). The performance objectives of the waste isolation subsystems must be achieved only for anticipated events and processes. Additionally, the proposed EPA Standard requires a quantitative probability (or frequency) estimate for each significant event or process. Releases from these events, including very unlikely events, must comply with the release limits of the Standard.

1.3.2 What are the uncertainties associated with these probabilities and how have these uncertainties been addressed?

The assignation of numerical probabilities to release scenarios is, in many cases, a subjective process due to the uncertainties in extrapolating limited scientific and historical knowledge to periods up to 10,000 years. The probabilities assigned must be shown to be reasonable based on current knowledge.

1.4 How has BWIP screened the complete set of scenarios to select those scenarios which significantly contribute to the cumulative release of radionuclides to the accessible environment?

Once the scenarios have been systematically identified, the assessment methodology should be applied to screen scenarios which have insignificant risks compared to the overall risk of the repository (not to the overall risk implied by the standard). Similar scenarios may be grouped together and evaluated if they can be demonstrated to have similar consequences and associated risks. The NRC staff considers that a fairly rigorous analysis of either the probability or the consequences of a scenario will be necessary to support the deletion of a scenario from further consideration or the combination of scenarios to implement the assessment methodology.

1.5 How has BWIP assessed the consequences for the scenarios selected above (1.4)?

1.5.1 What are the conceptual models of the release scenarios and how well do data and observations support these conceptual models?

parties in order that they may be satisfied that their concerns have been addressed fairly.

1.2.2 What are the conceptual models of the release scenarios, and how well do data and observations support these conceptual models?

The conceptual models of the release scenarios will serve as a foundation of the performance assessment of the repository. Before the consequences of the release scenarios can be estimated numerically, alternative conceptual models of the system under both anticipated and unanticipated conditions must be developed. The development of these scenarios must integrate available site specific data and interpretations of the natural and engineered barrier system.

1.2.3 How have the synergistic effects between events and processes been addressed in the identification process?

Some scenarios may involve processes which evolve gradually rather than discrete events which occur geologically instantaneously. Scenarios may be synergistically affected by the occurrence of other scenarios. Furthermore, some events and processes may be characterized by degrees of intensity (success or failure) unlike the total success or failure approach commonly taken by fault tree/event tree analyses. NRC staff anticipates that these difficulties in implementing the EPA Standard might be overcome by "discretizing" processes, events, and failure conditions. This approach would permit the use of modified logic diagrams similar to event tree/fault tree techniques for scenario identification, but not necessarily for probability or consequence assessments.

1.2.4 What are the uncertainties associated with this identification process and how have they been addressed?

Identifying a complete set of scenarios that may disrupt a repository over a period of 10,000 years is complicated by the uncertainties in projecting man's limited historical information base far into the future. Also, certain scenarios may be overlooked because of an inadequate scientific understanding of physical and chemical processes on all scales of time and space. These and other sources of uncertainty in the identification process must be identified by BWIP and evaluated with respect to their effect on a determination of "reasonable assurance" that the repository performance objective of 10 CFR Part 60.112 will be met.

1.3 What approach has BWIP used to quantitatively estimate the probabilities of scenario occurrence?

about the applications of computer codes to make these predictions, they will contribute to the demonstration of the reliability of the codes in making these predictions. This reliability will add credence to the demonstration of compliance with the performance objectives. NRC staff has issued guidance on suggested formats for and content of computer code documentation (NUREG-0856). Additional informal guidance on code verification and benchmarking is available through review of the NRC code benchmarking project (see NUREG/CRs-2782, -3066, and -3097).

The applicability of computer codes to address specific issues of performance assessment must be demonstrated. It is obviously not possible to validate a code used for projecting repository performance by comparing prediction to observation over thousands of years. The codes selected by the BWIP program for use in performance assessment must be justified by using the results of BWIP site experiments and comparing code predictions with appropriate natural analogs. NRC staff considers that formal guidance on acceptability criteria for code verification and validation is not appropriate at this time and suggests the use of peer review to determine acceptability and applicability.

1.5.6 What are the uncertainties in the consequence assessment and how have these uncertainties been addressed?

Sources of uncertainties must be identified, since uncertainties in the assessment detract from demonstration of reasonable assurance that the repository will meet performance objectives. Examples of uncertainties include, but are not limited to, uncertainties in primary data, interpreted data, extrapolated data, application of mathematical models, application of analytical and numerical models, numerical probabilities, and future political and socioeconomic conditions. Quantification of the magnitude of the uncertainties and their impact on performance assessment of the repository must be determined.

1.6 How has BWIP combined the consequences from individual release scenarios to assess the cumulative release of radionuclides to the accessible environment and demonstrated compliance to 40 CFR Part 191?

NRC staff interprets that the proposed EPA standard requires consequences of the identified release scenarios to be expressed as a probability distribution function of radionuclide release to the accessible environment. Once these probabilistic consequences have been determined, they are then multiplied by the probability of scenario occurrence. Compliance with the EPA standard is then

Refer to Section 1.2.2.

1.5.2 What mathematical models are used to represent these conceptual models and do these mathematical models adequately represent the conceptual models?

Mathematical models will be used in the performance assessment of HLW repositories as approximations of the conceptual models of the physical system. NRC staff considers this approximation to be significant to the extent that misapplication of mathematical models may pre-determine the computed consequences and limit the accuracy of the long-term predictions. Use of mathematical models in performance assessments must be justified by the available site-specific data.

1.5.3 What analytical and numerical models are used to represent the mathematical models and do these analytical and numerical models adequately represent the mathematical models?

The use of analytical and numerical models in performance assessment represents a secondary approximation to the conceptual models of the physical system. The specific models used to approximate the mathematical models must be identified and justified as adequately representing the mathematical models. Analytical and numerical models should be evaluated not only for their stability in application, but also for their numerical accuracy. In complex systems where considerable uncertainty is introduced through the use of phenomenologically untestable models, bounding and extreme analytical approaches will be acceptable to the NRC staff provided that these approaches can be rigorously justified and demonstrated as being conservative estimates of repository performance.

1.5.4 How have the synergistic effects between events and processes been addressed in the analysis?

Synergistic effects (i.e. interactions between events and processes that contribute to radionuclide release to the accessible environment) complicate the use of logic diagrams and/or equations to determine scenarios probabilities and consequences.

1.5.5 How have the numerical and analytical models been documented, verified, benchmarked, and validated?

NRC staff acknowledges the importance of numerical and analytical modeling in determining compliance with the performance objectives in 10 CFR 60 and 40 CFR 191. Although benchmarking, verification, documentation, and validation of the predictive computer codes will not eliminate uncertainties

demonstrated by integrating all of the probabilistically weighted consequences into a complementary cumulative distribution function (a Rasmussen-style risk curve). This function should then be compared against the step function release limits required by 40 CFR 191 (i.e. releases with probabilities between 1 and 0.01 in 10,000 years must have magnitude less than the limits in Table 2, releases with probabilities between 0.01 and 0.0001 in 10,000 years must have magnitude less than 10 times the limits in Table 2).

Waste Package Containment Time

2.0 Will containment of HLW within the waste packages be substantially complete for a period of not less than 300 to 1000 years (period to be determined by the Commission) after permanent closure of the geologic repository?

2.1 What are the predicted physical and chemical properties of the waste package environment through the period of containment?

2.1.1 What approach has BWIP used to predict this environment?

Before the performance of the waste packages can be defensibly predicted, the BWIP program must predict the host environment of the waste packages. This prediction requires an understanding of the effects of coupled processes (i.e. thermal-mechanical-hyrological-chemical-radiolytic interactions) on the repository environment. The approach BWIP uses to predict these effects and process interactions is critical to the demonstration of waste package performance. [A more detailed development of this technical question will be provided in an upcoming NRC Site Technical Position on Waste Form and Package Issues.]

2.1.2 How have the empirical models, which have been based on results of short-term laboratory and in-situ tests, been extrapolated for the duration of the containment period?

NRC staff recognizes that predictions of waste package environment will be largely based on empirical models that have been formulated with limited temporal data. Although validation of these models is not possible for the hundreds of years of waste package containment, the staff advises BWIP to maximize the use of the site characterization, in-situ testing program, and performance confirmation period assessments to generate the data necessary to validate these empirical models for the short-term (10s of years). [A more detailed development of this technical question will be provided in an upcoming NRC Site Technical Position on Waste Form and Package Issues.]

2.1.3 What are the conceptual models that are used to predict the waste package environment?

The conceptual models of waste package environment will serve as a foundation of the performance assessment of the waste package containment. Before the consequences of the waste package failure scenarios can be estimated numerically, alternative conceptual models of how the repository environment will change in response to anticipated and unanticipated events must be developed. The development of these models must integrate available data and interpretations of the natural and engineered barrier systems. [A more detailed development of this technical question will be provided in an upcoming Site Technical Position on Waste Form and Package Issues.]

2.1.4 What mathematical models are used to predict this environment and do these mathematical models adequately represent the conceptual models?

Refer to section 1.5.2.

2.1.5 What analytical and numerical models are used to predict this environment and do these analytical and numerical models adequately represent the mathematical models?

Refer to section 1.5.3.

2.1.6 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

Refer to section 1.5.5.

2.1.7 What are the uncertainties associated with this assessment and how have these uncertainties been addressed?

All evaluations to demonstrate compliance with the performance objectives in 10 CFR 60 and 40 CFR 191 must clearly identify and address the impact of uncertainties on repository performance. In addition to addressing the uncertainties listed in 1.5.6 (with the exception of uncertainties in future political and socioeconomic conditions), particular attention should be placed on the uncertainties in temporal extrapolation of limited data and on the appropriateness of the empirical models developed on these data in predicting the repository environment.

2.2 What are the anticipated events that may prematurely cause failure of the waste package and what are their effects on the repository?

2.2.1 What are the conceptual models used to predict the effects of anticipated events on the waste package and how well do data and observations support these conceptual models?

Consistent with 10 CFR 60, the assessment to demonstrate compliance of the waste packages with the containment criterion must consider the effects of anticipated events. The effects of anticipated events on the waste packages will be first addressed by the development of alternative conceptual models of these events. The development of these scenarios requires the integration of available site and system data.

2.2.2 What mathematical models are used to predict these effects and do these mathematical models adequately represent the conceptual models?

Refer to section 1.5.2.

2.2.3 What analytical and numerical models are used to predict these effects and do these analytical and numerical models adequately represent the mathematical models?

Refer to section 1.5.3.

2.2.4 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

Refer to section 1.5.5.

2.2.5 What are the uncertainties associated with the assessment of the significance of these anticipated events and how are they addressed in the assessment?

Sources of uncertainties must be identified, since uncertainties in the assessment detract from demonstration of reasonable assurance that the repository will meet performance objectives. Examples of uncertainties include, but are not limited to, uncertainties in primary data, interpreted data, extrapolated data, application of mathematical models, application of analytical and numerical models, and numerical probabilities. Quantification of the magnitude of the uncertainties and their impact on performance of the repository must be determined.

2.3 How has BWIP assessed the performance of the waste package and demonstrated compliance with the containment criterion, in light of the predicted environment and the effects of anticipated events?

2.3.1 What approach has BWIP used to assess compliance of the waste packages with the containment time performance objective?

NRC staff anticipates that this approach will incorporate the predictions of repository environment and the predicted effects of anticipated events into the evaluations of waste package performance. If the evaluations of waste package performance use bounding or conservative estimates of these effects or environmental conditions, they must be technically justified and internally consistent with other assessments of repository performance. The approach used by BWIP should be comprehensive and systematic.

2.3.2 What approach has BWIP used to assess waste package reliability during the containment period?

NRC staff will offer guidance to BWIP in the form of a draft technical position on determining waste package reliability.

2.3.3 What conceptual models are used in this assessment and how well do data and observations support these conceptual models?

The NRC staff anticipates that the conceptual models used for this assessment will incorporate the conceptual models used to predict repository environment and the effects of anticipated events.

2.3.4 What mathematical models are used to make the assessment and do these mathematical models adequately represent the conceptual models?

Refer to section 1.5.2.

2.3.5 What analytical and numerical models are used to make the assessment and do these analytical and numerical models adequately represent the mathematical models?

Refer to section 1.5.3.

2.3.6 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

Refer to section 1.5.5.

2.3.7 What are the uncertainties associated with this assessment of compliance and how are they addressed in this assessment?

Refer to section 2.2.5.

Release Rate of the Engineered Barrier System

3.0 Is the release rate of any radionuclide from the engineered barrier system less than or equal to one part in 100,000 per year of the inventory of that radionuclide calculated to be present at 1,000 years following permanent closure?

3.1 What is the predicted radionuclide inventory at 1,000 years following permanent closure of the repository?

Radionuclide decay and the production of daughter radionuclides must be accounted for in the calculation of the radionuclide inventory present at 1,000 years after permanent closure. The radionuclides which are leached from the engineered barrier system prior to 1,000 years following permanent closure are not to be subtracted from the calculated total inventory at 1,000 years.

3.2 What is the predicted repository environment following permanent closure?

3.2.1 What approach has BWIP used to predict the physical and chemical properties of the repository environment?

Refer to section 2.1.1.

3.2.2 What are the conceptual models of the repository environment and how well do data and observations support these conceptual models?

Refer to section 2.1.3.

3.2.3 What mathematical models are used to predict the repository environment and do these mathematical models adequately represent the conceptual models?

Refer to section 1.5.2.

3.2.4 What analytical and numerical models are used to predict the repository environment and do these analytical and numerical models adequately represent the mathematical models?

Refer to section 1.5.3.

3.2.5 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

Refer to section 1.5.5.

3.2.6 What are the uncertainties associated with this prediction and how have they been addressed in the assessment?

Refer to section 2.2.5.

3.3 What are the anticipated events that may significantly affect the ability of the engineered system to meet the release rate performance objective?

3.3.1 How likely are these anticipated events?

To demonstrate compliance with the release rate performance objective, DOE must evaluate the effects of only anticipated events on the performance of the engineered barrier system. Anticipated events, as defined in 10 CFR 60.2, are those events that are reasonably likely to occur during the period the intended performance objective must be achieved. Processes operating in the geologic setting during the Quaternary period are assumed to continue to operate during the post-waste emplacement period with the superposition of the perturbations caused by the emplacement of the waste.

3.3.2 What are the conceptual models of these anticipated events and how well do data and observations support these conceptual models?

Consistent with 10 CFR 60, the assessment to demonstrates compliance of the engineered barrier system with the 10^{5} release rate criterion must consider the effects of anticipated events on the repository system. The effects of the anticipated events will be initially addressed by the development of alternative conceptual models of these events. The development of these scenarios requires the integration of available data and interpretations of the natural and engineered barrier systems.

3.3.3 What are the uncertainties associated with the development of these conceptual models and how are they addressed in the development?

Refer to 2.2.5.

3.4 What effects do these anticipated events have on the engineered barrier system relevant to the release rate performance objective?

3.4.1 What approach has BWIP used to predict these effects?

To demonstrate with reasonable assurance compliance with the release rate criterion, BWIP must predict the effects of single and multiple anticipated events. NRC staff anticipates that

this demonstration will require the use of predictive numerical and analytical modeling of the conceptual models identified in section 3.3.2.

3.4.2 What are the conceptual models that are used to assess these effects and how well do data and observations support these conceptual models?

Conceptual models of the engineered barrier system will serve as a foundation of the demonstration of compliance with the release rate performance objective. These models must account for the coupled processes that have been demonstrated to significantly affect the release rate of the engineered barrier system as well as those processes that may control the physical and chemical properties of the repository environment.

3.4.3 What mathematical models are used to assess the effects and do these mathematical models adequately represent the conceptual models?

Refer to Section 1.5.2.

3.4.4 What analytical and numerical models are used to assess the effects and do these analytical and numerical models adequately represent the mathematical models?

Refer to Section 1.5.3.

3.4.5 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

Refer to Section 1.5.5.

3.4.6 What are the uncertainties associated with the assessment of these effects and how have they been addressed?

Refer to Section 2.2.5.

3.5 How has BWIP demonstrated compliance of the engineered barrier system with the release rate performance objective?

3.5.1 What approach has BWIP used to demonstrate compliance of the engineered barrier system with the release rate performance objective?

To demonstrate compliance with 10 CFR 60.113(a)(ii)(B), BWIP must integrate the assessments of radionuclide inventory, repository design, predicted repository environment, and the effects of anticipated events on the performance of the engineered barrier system. This demonstration should also be

consistent with the reliability assumptions invoked to demonstrate compliance of the waste packages with the containment time requirement. NRC staff anticipates that complex numerical and analytical modeling will be required to predict release rates from the engineered barrier system and compare these releases with the 10 release rate performance objective.

3.5.2 What are the conceptual models that are used to demonstrate compliance and how well do data and observations support these conceptual models?

The predictive numerical and analytical models introduced in Section 3.5.1 will be based on 3-dimensional conceptual models of the underground facility and surrounding host rock. The development of these models must integrate available data and interpretations of the natural and engineered barrier systems.

3.5.3 What are the mathematical models that are used to predict performance of the engineered barrier system and do these mathematical models adequately represent the conceptual models?

Refer to Section 1.5.2.

3.5.4 What analytical and numerical models are used to predict performance of the engineered barrier system and do these analytical and numerical models adequately represent the mathematical models?

Refer to Section 1.5.3.

3.5.5 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

Refer to Section 1.5.5.

3.5.6 What uncertainties are associated with this assessment and how are they addressed?

Refer to Section 2.2.5.

Pre-Emplacement Groundwater Travel Time (10 CFR Part 60.113(a)(2))

4.0 Is the prewaste-emplacement groundwater travel time along the fastest path of likely radionuclide travel from the disturbed zone to the accessible environment greater than 1000 years (or such other period as may be approved or specified by the Commission)?

4.1 What is the proposed geometric configuration and extent of the disturbed zone?

4.1.1 What predicted physical and chemical changes will significantly affect the performance of the repository?

The disturbed zone, as defined in 10 CFR 60.2, is that portion of the controlled area where physical or chemical properties have changed as a result of underground facility construction or as a result of the heat generated by the emplaced wastes such that the resultant change in properties may have a significant effect on repository performance. The concept was introduced into the rule to provide for conservative estimates of the performance of the geologic system based on data collectable during the site characterization period. The portion of the controlled area outside of the disturbed zone must therefore be shown to remain an effective barrier to radionuclide migration during the post-waste emplacement period. By defining the extent of the disturbed zone and not considering groundwater travel time through this zone, the effects of uncertainties caused by the presently inadequate understanding of the coupled process phenomena in the vicinity of the emplaced waste are reduced.

To propose the extent of the disturbed zone after waste-emplacement, however, requires that BWIP identify and evaluate all of the physical and chemical changes induced by underground facility construction or by the heat generation of emplaced waste in terms of their possible effect on repository performance. A thorough analysis of the post-emplacement chemical, mechanical, thermal, and hydrological conditions in the vicinity of the underground facility will be necessary to identify the physical and chemical changes which will affect the extent of the disturbed zone. Once these processes have been identified, BWIP should evaluate the significance of these processes as they affect repository performance.

4.1.2 What approach has BWIP used in estimating the proposed extent and configuration of the disturbed zone?

NRC staff anticipate that this approach will incorporate available data regarding thermal, mechanical, and hydraulic properties and conditions into evaluations of post-emplacement coupled process interactions in the vicinity of the underground facility. The evaluations of coupled process interactions must compare predicted repository performance under post-emplacement conditions, in terms of the numerical system and subsystem criteria of 10 CFR 60, to predictions of repository performance which ignore the changes introduced by repository construction and by heat generation of emplaced waste. Any permanent or

transient changes in physical or chemical properties which are shown by this analysis to significantly affect repository performance will be considered to be within the disturbed zone.

4.1.3 What are the conceptual models that are used to estimate the extent and configuration of the disturbed zone and how well do data and observations support these conceptual models?

The NRC staff anticipates that the conceptual models used for this assessment will incorporate the conceptual models used to predict repository environment, and conceptual models of coupled process interactions which have been supported by the scientific community.

4.1.4 What mathematical models are used to predict the extent of the disturbed zone and do these mathematical models adequately represent the conceptual models?

Refer to Section 1.5.2.

4.1.5 What analytical and numerical models are used to predict the extent of the disturbed zone and do these analytical and numerical models adequately represent the mathematical models?

Refer to Section 1.5.3.

4.1.6 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

Refer to Section 1.5.5.

4.1.7 What uncertainties are associated with this estimation and how are these uncertainties addressed in the assessment?

Refer to Section 1.5.6.

4.2 What is the fastest path of likely radionuclide travel from the disturbed zone to the accessible environment?

4.2.1 What approach has BWIP used to predict the fastest path of likely radionuclide travel?

As stated in 10 CFR 60.113(2). pre-emplacement groundwater travel time along the fastest path of likely radionuclide travel from the disturbed zone to the accessible environment must exceed 1,000 years or such other period as may be approved or specified by the Commission. Determination of the fastest path of likely radionuclide travel requires calculations of the travel time along the locus of potential flow paths from the disturbed zone boundary to the accessible environment boundary.

4.2.2 What are the conceptual models that are used to predict the fastest path of likely radionuclide travel and how well do data and observations support these conceptual models?

The NRC staff anticipates that the conceptual models used to predict the fastest path of likely radionuclide travel will incorporate the conceptual models used to predict the geologic environment from the disturbed zone to the accessible environment.

4.2.3 What mathematical models are used to predict this path and do these mathematical models adequately represent the conceptual models?

Refer to Section 1.5.2.

4.2.4 What numerical and analytical models are used to predict the fastest path of likely radionuclide travel and do these numerical and analytical models adequately represent the mathematical models?

Refer to Section 1.5.3.

4.2.5 How have these analytical and numerical models been documented, verified, benchmarked, and validated? Refer to Section 1.5.5.

4.2.6 What are the uncertainties associated with this assessment and how have these uncertainties been addressed?

Refer to Section 1.5.6.

4.3 What is the prewaste-emplacement groundwater travel time along the fastest path of likely radionuclide travel from the disturbed zone to the accessible environment, and how has BWIP demonstrated compliance with the minimum groundwater travel time performance objective?

4.3.1 What approach has BWIP used to predict the pre-waste emplacement groundwater travel time along the fastest path of likely radionuclide transport from the disturbed zone to the accessible environment?

In order to provide reasonable assurance of compliance with the groundwater travel time criterion of 10 CFR 60.113(2), NRC staff anticipates that the approach to prediction of groundwater travel time will include numerical modeling, hydrogeochemical analyses, and groundwater age dating, and must account for uncertainties in the conceptual, analytical, mathematical and numerical models of the hydrogeologic system.

These analyses must be integrated to provide defensible, conservative predictions of groundwater travel time.

4.3.2 What are the conceptual models that are used to predict these travel times and how well do data and observations support these conceptual models?

The conceptual models of the hydrogeologic system will serve as the foundation of the performance assessment of groundwater travel time. The NRC staff considers that BWIP should evaluate the relative importance of alternative conceptual models of the hydrogeologic system which can be supported (or can not be eliminated from consideration) by available data to calculations of pre-emplacement groundwater travel time.

4.3.3 What mathematical models are used to predict these travel times and do these mathematical models adequately represent the conceptual models?

Refer to Section 1.5.2.

4.3.4 What analytical and numerical models are used to predict the travel times and do these analytical and numerical models adequately represent the mathematical models?

Refer to Section 1.5.3.

4.3.5 How have these analytical and numerical models been documented, verified, benchmarked, and validated?

Refer to Section 1.5.5.

4.3.6 What are the uncertainties associated with this prediction and how have these uncertainties been addressed?

Refer to Section 1.5.6.

APPENDIX A: REASONABLE ASSURANCE

The Commission included the following discussion of "reasonable assurance" in the Supplementary Information for 10 CFR 60 (48 FR 28204).

Reasonable Assurance

The proposed rule stated that with respect to the long-term objectives and criteria under consideration, "what is required is reasonable assurance, making allowance for the time period and hazards involved, that the outcome will be in conformance with those objectives and criteria." A number of commenters took exception to this formulation on the ground that it provides inadequate guidance as to the required level of proof. Others were concerned that "reasonable assurance" was too weak a test and that the Commission should not license DOE activities without a "high degree of confidence" that releases would be very small. Some commenters suggested that a statistical definition of acceptability should be employed. For the reasons set forth below, the Commission has not modified the language.

In the Commission's view, the "reasonable assurance" standard neither implies a lack of conservatism nor creates a standard which is impossible to meet. On the contrary, it parallels language which the Commission has applied in other contexts, such as the licensing of nuclear reactors, for many years. See 10 CFR 50.35(a) and 50.40(a). The reasonable assurance standard is derived from the finding the Commission is required to make under the Atomic Energy Act that the licensed activity provide "adequate protection" to the health and safety of the public; the standard has been approved by the Supreme Court, Power Reactor Development Co. v.

Electrical Union 367 U.S. 396, 407 (1961). This standard, in addition to being commonly used and accepted in the Commission's licensing activities, allows the flexibility necessary for the Commission to make judgmental distinctions with respect to quantitative data which may have large uncertainties (in the mathematical sense) associated with it.

The Commission has not modified the language, but has explained elsewhere (see Anticipated/Unanticipated Processes and Events discussion in the Supplementary Information for Part 60) how the concept will be applied. The Commission expects that the information considered in a licensing proceeding will include probability distribution function for the consequences from anticipated and unanticipated processes and events. Even if the calculated probability of meeting the Commission's standards is very high that would not be sufficient for the Commission to have "reasonable assurance"; the Commission would still have to assess uncertainties associated with the models and data that had been considered. This involves qualitative as well as quantitative assessments. The Commission would not issue a license unless it were to conclude, after such assessments, that there is reasonable assurance that the outcome will in fact conform to the relevant standards and criteria.

It is important to keep in mind this distinction between, first, a standard of performance and, second, the quality of the evidence that is available to support a finding that the standard of performance has been met. In principle, there is no reason why the first of these - the performance standard - cannot be expressed in quantitative terms. The rule does this is several places - notably, in including as performance objectives a designed containment period, a radionuclide release rate, and a pre-waste-emplacement groundwater travel time. Similarly, EPA's standard will establish limits on concentrations or quantities of radioactive material in the general environment.

Expressing a requisite level of confidence in quantitative terms is far more problematical. To be sure, measurement uncertainties are amenable to statistical analyses. Even though there may be practical limitations on the accuracy and precision of measurements of relevant properties, it is possible to make some quantitative statement as to how well these values are known. The licensing decisions which the Commission will be called upon to make involve additional uncertainties - those pertaining to the correctness of the models being used to describe the physical systems - which are not quantifiable by statistical methods. Conclusions as to the performance of the geologic repository and particular barriers over long periods of time must largely be based upon inference; there will be no opportunity to carry out test programs that simulate the full range of relevant conditions over the periods for which waste isolation must be maintained.

The validity of the necessary inferences cannot be reduced, by statistical methods, to quantitative expressions of the level of confidence in predictions of long-term repository performance. Similarly, the Commission will not be able to rigorously determine the probability of occurrence of an outcome that fails to satisfy the performance standards. It must use some other language, such as "reasonable assurance," to characterize the required confidence that the performance objectives will be met. In practice, this means that modeling uncertainties will be reduced by projecting behavior from well understood but simpler systems which conservatively approximate the systems in question. Available data must be evaluated in the light of accepted physical principles; but, having done so, the Commission must make a judgment whether it has reasonable assurance that the actual performance will conform to the standards the Commission has specified in this rule.

It should also be borne in mind that the fact-finding process is an administrative task for which the terminology of law, not science, is appropriate. The degree of certainty implied by statistical definition has never characterized the administrative process. It is particularly inappropriate where evidence is "difficult to come by, uncertainty or conflicting because it is on the frontiers of scientific knowledge." Ethyl Corp. v. EPA, 541 F. 2d 1, 28 (D.C. Cir. 1976).

APPENDIX B - DEFINITIONS

Accessible environment. (1) the atmosphere, (2) land surfaces, (3) surface water, (4) oceans, and (5) the portion of the lithosphere that is outside the controlled area. The overall system performance for the geologic repository is calculated at this boundary (§60.2).

Computer code. A set of computer instructions for performing the operations specified in a numerical model.

Consequence analysis. A method by which the consequences of an event is calculated and expressed in some quantitative way, e.g., money loss, deaths, or quantities of radionuclides released to the accessible environment.

Controlled area. A surface location, to be marked by suitable monuments extending horizontally no more than 10 km in any direction from the underground facility, and the underlying subsurface, which area has been committed to use as a geologic repository and from which incompatible activities would be restricted following permanent closure (§60.2).

Disturbed zone. That portion of the controlled area whose physical or chemical properties have changed as a result of underground facility construction or from heat generated by the emplaced radioactive wastes such that the resultant change of properties may have a significant effect on the performance of the geologic repository. The minimum groundwater travel time is calculated between this boundary and the accessible environment (§60.133(a)(2)).

Engineered barrier system. The waste packages and the underground facility. The maximum radionuclide release rate is measured at this boundary (§60.113(a)(1)(ii)(B)).

Finding. A determination of compliance or noncompliance with a specific requirement. A finding addressing a numerical performance objective will be reached after the following are weighed: the results of a reliability analysis and the laboratory and field tests upon which it is based, expert opinion, and empirical studies.

Licensing assessment. An assessment of whether a license application complies with all of the requirements that it purports to meet. For this program it is the sum of the individual findings for each of the requirements of 10 CFR 60.

Mathematical model. A mathematical representation of a process, component, or system.

Model. A representation of a process, component, or system.

Numerical method. A procedure for solving a problem primarily by a sequence of arithmetic operations.

Numerical model. A representation of a process, component, or system using numerical methods.

Performance assessment. The process of quantitatively evaluating component and system behavior, relative to containment and isolation of radioactive wastes, to support development of a high-level waste repository and to determine compliance with the numerical criteria associated with the regulation (10 CFR 60).

Performance confirmation. The program of tests, experiments, and analyses that is conducted to evaluate the accuracy and adequacy of the information used to determine reasonable assurance that the performance objectives for the period after permanent closure can be met.

Quality assurance. Those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service, or that a product such as a mathematical analysis or a data measurement will be sufficiently free from error to serve its intended purpose.

Reliability. The probability that a system or component, when operating under stated environmental conditions, will perform its intended function adequately for a specified interval of time.

Reliability analysis. An analysis that estimates the reliability of a system or component.

Risk. A measure of the probability and severity of adverse effects (consequences); the expected detriment per unit time to a person or a population from a given cause.

Risk analysis. An analysis that combines estimates of the probabilities of scenarios with estimates of the consequences of those scenarios, while considering the uncertainties associated with both.

Scenario. An account or sequence of a projected course of action or events.

Scenario analysis. The process of identifying scenarios and estimating the probability of their occurrence.

Sensitivity analysis. An analysis in which one or more parameters are varied to observe their effects on the performance of a system or some part of it. Such an analysis requires definition of a system, the ranges of parameters over which the system is to be investigated, and the characteristics of the system which is to be observed.

Uncertainty analysis. An analysis that estimates the uncertainty in a system's performance resulting from the uncertainty of one or more factors associated with the system. Such an analysis requires definition of a system, description of the uncertainties in the factors that are to be investigated, and the characteristics of the system that is to be observed.