COMPLIANCE DETERMINATION STRATEGY
6.1 Assessment of Compliance with the Requirement for Cumulative Releases of Radioactive Materials

PRIMARY REGULATORY CITATION:

10 CFR 60.112

TYPES OF REVIEW:

Acceptance Review (Type 1)
Safety Review (Type 3)
Detailed Safety Review Supported by Analyses (Type 4)
Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations (Type 5)

RATIONALES FOR TYPE OF REVIEW:

Acceptance Review (Type 1) Rationale:
This regulatory requirement is considered to be License Application-related because, as specified in the License Application content requirements of 10 CFR 60.21 and the Format and Content Regulatory Guide (NRC, 1990), it must be addressed by DOE in its license application. Therefore, the staff will conduct an Acceptance Review of the license application for this regulatory requirement.

Safety Review (Type 3) Rationale:
This regulatory requirement is related to radiological safety and waste isolation. It is a requirement for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31 (i.e., regulatory requirements in Subparts E, G, H, I, and 10 CFR 60.21). Therefore, the staff will conduct a Safety Review of the license application to determine compliance with the regulatory elements of proof (REOPs) for this regulatory requirement.

The overall system performance objective (10 CFR 60.112) stipulates that DOE provide, through tests, data, and analyses, reasonable assurance that the overall repository system (i.e., the geologic barrier provided by the site together with the engineered barriers incorporated in the system by design) will meet the "generally applicable standards for protection of the general environment from off-site releases from radioactive material in repositories" as set by the U.S. Environmental Protection Agency (EPA) in 40 CFR Part 191 (*Code of Federal Regulations*, Title 40, "Protection of the Environment"). This is the highest level of performance placed on the geologic repository and DOE is expected to utilize great amounts of site characterization and design data, in addition to some subjective information obtained through expert elicitation, to show compliance with this requirement. Moreover, DOE's compliance demonstration methods are expected to be based largely on predictive mathematical models of varying complexity.

The containment requirements portion of the total system performance requirement focuses on the cumulative release of radionuclides to the accessible environment for the 10,000 years following permanent closure. The existing EPA standards (EPA, 1985; 50 *FR* 38086) require that "all significant processes and events that may effect the disposal system" be considered in the calculation of such releases. In its proposed conforming amendments to 10 CFR Part 60, the staff determined that for the purposes of compliance demonstration with the containment requirements, consideration of "all significant processes and events" is equivalent to consideration of "anticipated" and "unanticipated" processes and events under 10 CFR Part 60 (NRC, 1986; 51 *FR* 22291).

Detailed Safety Review Supported by Analyses (Type 4) Rationale:
The staff considers that the findings made under this regulatory requirement may be highly uncertain and controversial due to several Key Technical Uncertainties. Therefore, the results from analyses of overall system performance with respect to the containment requirements may vary widely and may lead to unwarranted conclusions regarding public health and safety. Thus, the possibility of error with respect to determining compliance with this regulatory requirement must be minimized.

The regulatory requirements to be considered in a demonstration of compliance with the containment requirements of 40 CFR Part 191 are materially different from those for the individual and groundwater protection requirements of the existing 1985 EPA standard. There are three main differences. First, the containment requirements are probabilistic in nature, in that they specify not only numerical performance limits but also numerical probability levels at which they must be met. On the other hand, the individual protection and ground-water protection requirements are deterministic, specifying only numerical criteria to be met. Secondly, the period of performance for the containment requirements is 10,000 years, while for the individual and ground-water protection requirements, the period is 1,000 years. Finally, demonstrations of compliance with the containment requirements must include analyses for anticipated and unanticipated conditions. In contrast, analyses for the individual and ground-water protection requirements need only consider anticipated conditions.

For the Yucca Mountain site, the following Key Technical Uncertainties require a Type 4 review because they pose a high potential risk of non-compliance with this regulatory requirement.

Key Technical Uncertainty Topic: Conceptual model representations of the natural and engineered systems

Description of Uncertainty: Conceptual models of the site regarding the presence and origin of tectonic and magmatic/volcanic features and the potential flow and transport paths (for the aqueous and gas phase radionuclides) through the variably saturated, fractured, heterogeneous rock of Yucca Mountain are highly uncertain. Similarly, long-term stability of the engineered barriers (waste packages, borehole seals, etc.) is also difficult to predict. In addition, the environment to which the engineered barriers will be subjected soon after waste emplacement will be considerably different from the ambient due to the thermal pulse

as well as to other disturbances introduced during repository construction.

While some of these technical uncertainties are expected to be resolved by the time of the License Application submittal, significant residual uncertainties are expected to remain, as is evidenced at the WIPP site (SNL, 1991) and noted in the Phase 1 demonstration of a performance assessment capability by the NRC staff (Codell, *et al.*, 1992).

Performance Objectives at Risk and Associated Regulatory Requirement: 10 CFR 60.112, 40 CFR 191.13

Explanation of Nature of Risk: Omission of a plausible conceptual model, either for the natural system or the engineered barriers, by DOE in its overall performance assessment, directly affects conclusions related to public health and safety.

Description of Resolution Difficulty: DOE's site characterization program will provide data which will be used, in part, to help distinguish among alternative conceptual models of site performance. However, considerable uncertainties may remain. DOE will need to consider various reasonable alternative conceptual models in its overall performance assessment to assure that the effects on overall repository performance are adequately characterized. Although difficult to resolve, additional data, together with bounding the uncertainty with alternatives, is a reasonable resolution approach.

Key Technical Uncertainty Topic: Variability (temporal, spatial, etc.) in model parametric values

Description of Uncertainty: Many features of a repository system can be measured directly in situ or in a laboratory (e.g., ground-water levels or corrosion rates) or can be inferred from direct measurements (e.g., hydraulic conductivity). In natural heterogeneous systems like Yucca Mountain, parameters will vary both temporally and spatially. In addition, even in direct measurements, there may be significant uncertainties associated with the applicability of test methods, potential instrument errors, and procedural errors. Thus, it is not uncommon to have large uncertainty bands for geologic parameters; sometimes the standard deviations of these parameters may be orders of magnitude greater than their mean values.

DOE, through performance allocation tables in its Site Characterization Plan (DOE, 1988), has stated a target for acceptable levels of uncertainties. Some of these will invariably be revised as site characterization proceeds, but some targets may not be met in the end. Under this eventuality, DOE is expected to modify its initial performance allocation. At issue in all these iterations of performance allocation is technical support for the estimated uncertainty bands. DOE is expected to estimate parameter values for its performance assessment models based on a combination of site and design data and expert elicitation.

Performance Objectives at Risk and Associated Regulatory Requirement: 10 CFR 60.112, 40 CFR 191.13

Explanation of Nature of Risk: Results obtained from the overall performance assessment models are strongly dependent upon the parameters included in the assessment and the ranges of values deemed acceptable to represent the uncertainty in the parameters. Inappropriate parametric values can lead to unwarranted conclusions.

Description of Resolution Difficulty: Model parameters often are not directly measured, but rather are derived from measured data through the application of "accepted" theories. In addition, the physical dimensions of the site preclude a complete understanding and measurement of the entire range in the various parametric values. In its overall performance assessments, a reasonable approach is for DOE to assign reasonable and conservative ranges to the parameters important to repository performance to adequately bound the uncertainty in the values.

Key Technical Uncertainty Topic: Appropriateness of assumptions and simplification in mathematical models

Description of Uncertainty: To perform analyses of overall repository system performance, mathematical models and numerical computer codes will be developed to represent a conceptual understanding of the important processes operative at the site. Various assumptions and simplifications will be required in these models and codes so that the important processes (e.g., groundwater flow through unsaturated, fractured rock) can be represented as realistically as possible and yet not be so detailed as to be unworkable. Some of the simplifications will necessarily be due to computer hardware constraints (e.g., computer code run times). These assumptions and simplifications will in general be non-unique and, perhaps, controversial.

Performance Objectives at Risk and Associated Regulatory Requirement: 10 CFR 60.112, 40 CFR 191.15

Explanation of Nature of Risk: Results of performance assessment analyses can be extremely sensitive to the assumptions and simplifications made in mathematical models used in the analyses. Unless this sensitivity is adequately investigated and understood, unwarranted and inappropriate conclusions may result.

Description of Resolution Difficulty: Because the natural system must necessarily be represented by mathematical models in performance assessment analyses, this uncertainty cannot be completely resolved. Site investigations and field and laboratory testing can reduce the uncertainty in the conceptual models on which the mathematical models are based; however, the appropriateness of particular equations or approaches used to represent various processes will remain a point of contention. In addition, numerical calculations of overall system performance have and will require the use of high-speed super computers for potentially

hundreds to thousands of real-time and computer hours. Simplifications in modeling approaches are necessary to keep the analyses tractable. The observance of good software quality assurance practices should help reduce the uncertainty associated with the implementation of mathematical models in computer programs.

Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations (Type 5) Rationale:
Because the following key Technical Uncertainties are the most difficult to resolve, there may be the highest potential risk of non-compliance with the performance objectives specified below. For these uncertainties, very little can be done to reduce the risk, or compensate for the risk using, for example, favorable site conditions or engineered features.

The following Key Technical Uncertainties require a Type 5 review.

Key Technical Uncertainty Topic: Validation of mathematical models

Description of Uncertainty: Since mathematical models will be used for compliance demonstration, the "truthfulness" of models is at issue. Mathematical models are abstract representation of "reality" as perceived by the analyst. The models depend upon the scales of representation, the processes under consideration, the type and extent of measurements available from the site, and the available computer hardware. While the testing and benchmarking of models (and associated computer codes) is reasonably well defined and understood, validation is expected to be an open issue at the time of review of the License Application. Provisions of 10 CFR 60.21 require that models be validated with data from an appropriate combination of such methods as field tests, *in-situ* tests, laboratory tests, and natural analog studies. However, a model validation strategy has yet to be formulated either by DOE or NRC. Most likely, this strategy will define the acceptable levels of validation, since it is known that full and unequivocal validation of models is not possible.

Performance Objectives at Risk and Associated Regulatory Requirements: 10 CFR 60.112, 40 CFR 191.13

Explanation of Nature of Risk: Risk in using models whose validity has not been checked, documented, and accepted by the technical community at large lies in the great uncertainty it may cause in the final decision. However, since the licensing procedure must reach a conclusion, the tests used for model validation require the highest level of scrutiny including independent evaluations by the NRC staff.

Description of Resolution Difficulty: Closure of this issue will be difficult because currently, it is not possible to define a rational scientific method for "full" validation of a model. Partial, but acceptable, validation levels will remain controversial. This is especially true when long-term (i.e., greater than 10,000 years) probabilistic predictions are required for non-linear systems (such as the repository at Yucca Mountain) as is demanded by 40 CFR Part 191.

Key Technical Uncertainty Topic: Prediction of future system states (i.e., disruptive scenarios)

Description of Uncertainty: This performance objective requires that repository performance be estimated (in terms of cumulative radionuclides released to the accessible environment) for a period of 10,000 years following permanent closure, for both anticipated and unanticipated processes and events. Such calculations necessitate the identification of appropriate future conditions to consider and estimate their probabilities of occurrence. EPA's standards require some precision in the estimation of these probabilities. If not entirely subjective, a significant amount of expert judgment is expected in this process. Thus, substantial uncertainty is expected to remain through the time of License Application submittal.

In order to identify likely future states of the repository system, it is necessary to gain an understanding of the processes that have operated and the events that have occurred in the past within the geologic setting of the site. Based on this understanding, reasonable projections about those potential processes and events which could affect a geologic repository during the period of performance are possible. This appears to work very well in a qualitative sense, especially if the time periods involved are long -- on the order of millions of years. The regulatory period of interest -- 10,000 years -- is short for such geologic predictions (both of the processes and events of interest and their probabilities of occurrence). It is for this reason that a significant dependence on expert elicitation is inevitable for defining scenarios.

Performance Objectives at Risk and Associated Regulatory Requirements: 10 CFR 60.112, 40 CFR 191.13

Explanation of Nature of Risk: The complementary cumulative distribution function required by this regulatory requirement depends upon identification of the scenarios and their corresponding probabilities of occurrence. Therefore, uncertainties with respect to the scenarios will be reflected in the complementary cumulative distribution function which may cause difficulties in arriving at a finding of "reasonable assurance" that this regulatory requirement has been met.

Description of Resolution Difficulty: It is not possible to fully resolve this uncertainty because: (1) there is no current technology that can objectively predict the future system states; (2) there is no general agreement among the experts about which disruptive scenarios must be included in the analyses; and (3) assigning probabilities to rare events and processes is subject to argument and debate, even within the technical community. There can be significant residual uncertainties because either some of the scenarios were not included in the analyses or because the probability assignments were not appropriate. The scenarios defined by other repository programs internationally can provide a basis for review but significant uncertainties are expected to remain.

REVIEW STRATEGY:

Acceptance Review (Type 1)
In conducting the Acceptance Review of the containment portion of the total system performance regulatory requirement (10 CFR 60.112), the reviewer will determine whether the information presented in the license application and its references for determining compliance with this regulatory requirement is complete in technical breadth and depth as identified in the Draft Regulatory Guide DG-3003 (NRC, 1990).

The information in the license application should be presented in such a manner that the assumptions, data, and logic leading to a demonstration of compliance with this requirement are clear and do not require the reviewer to conduct extensive analyses or literature searches. The review should also determine that controversial information and appropriate alternative interpretations and models have been adequately described and considered.

Finally, the reviewer shall determine if DOE has either resolved all the NRC staff objections to the SCP that apply to this requirement or provided all the information requested in Section 1.6 of DG-3003 for unresolved objections. The reviewer will evaluate the effects of any unresolved objections, both individually and in combinations with others on: (1) the reviewer's ability to conduct a meaningful and timely review; and (2) the Commission's ability to make a decision regarding construction authorization within the three-year statutory period.

Safety Review (Type 3)
In conducting the Safety Review, the reviewer will, as a minimum, determine the adequacy of the data and analyses presented in the license application to determine DOE's compliance with the total system performance regulatory requirement. Staff's objectives of the Safety Review would be to: (1) understand and evaluate DOE's compliance demonstration logic; (2) conduct a preliminary review of the data base used for compliance demonstration to determine which parts of the data are most uncertain or that may be incomplete (e.g., with respect to potentially adverse conditions); and (3) determine whether portions of the data and/or analyses submitted should be subjected to further detailed review (in addition to those areas requiring Type 4 and 5 detailed reviews specified below).

The specific aspects of the license application on which the review will focus are discussed in Section 6.1 of DG-3003 (NRC, 1990) and the acceptance criteria will be identified on Section 3 of this review plan. In general, the Safety Review will look at: (1) the basic approach to demonstrating compliance; (2) the description of the system; (3) the screening of events and processes; (4) the development and screening of scenarios; (5) the estimates of cumulative releases; (6) the probability estimates; and (7) the model and code verification and validation activities.

This Safety Review will also assure that: (1) all of the favorable conditions (10 CFR 60.122(b)) and potentially adverse conditions (10 CFR 60.122(c)), that have been determined to be present, are included in the compliance demonstration

for this regulatory requirement; and (2) consideration of any potentially adverse condition that has been determined to be present will use assumptions that are not likely to underestimate its effects (10 CFR 60.21(c)(1)(ii)(C)).

In order to conduct an effective Safety Review, the reviewer will rely on his expertise and independently acquired knowledge, information, and data in addition to that provided by DOE in its License Application. As a minimum, the reviewers must, in particular, be familiar with the iterative performance assessments conducted by the staffs of DOE (e.g., Barnard *et al.*, 1992), NRC (e.g., Codell *et al.*, 1992), and EPA (with respect to the WIPP site) and, in general, with those conducted internationally by the time of the License Application submittal. Such knowledge gathered from previous performance assessments should be used to determine: (1) if the uncertainties have been appropriately considered; and (2) whether appropriate scenarios have been included in the analyses.

Detailed Safety Review Supported by Analyses (Type 4)

A detailed safety review and analysis will be needed for evaluation of the Key Technical Uncertainties related to: (1) conceptual model representations of the natural and engineered systems; (2) variability in model parametric values; and (3) validation of mathematical models. This review will make use of models, analyses, and methodologies developed by DOE and/or other parties and reviewed and found to be acceptable by the staff. These evaluations will include detailed analyses of certain critical aspects related to the consideration of conceptual model and mathematical model uncertainties, as well as a conservative estimate of the performance of the total system. The staff will conduct sensitivity/uncertainty analyses of the total system performance to determine if there is reasonable assurance of meeting the performance objectives even when alternatives not included by DOE are considered. This will ensure that DOE has adequately demonstrated Items (1)-(3) listed in the previous section (Safety Review, paragraph 1).

Activities performed in this Detailed Safety Review will help to assure that DOE has adequately addressed and resolved these Key Technical Uncertainties so that they do not lead to non-compliance with the performance objective.

The Detailed Safety Review of the Key Technical Uncertainty related to conceptual model uncertainty will require staff to examine closely the data, analyses, and assumptions used by DOE to propose or reject various alternative conceptual models from consideration for the site. As it is anticipated that more than one conceptual model of a particular process or set of processes may fit the available database, the staff must assure that all reasonable conceptual models are addressed by DOE and assessed in their overall repository performance analyses. In addition, staff's own analyses should include conceptual models not considered by DOE, if appropriate.

The Key Technical Uncertainty related to variability in parametric values will require a Detailed Safety Review. This review will include activities such as: (1) selected review of raw data collected by DOE and techniques used by DOE in parameter estimation to assure that appropriate uncertainty bands were assigned to such estimates; and (2) review of the estimation of parameters critical to the calculation of overall system performance. These parameters will be identified

by DOE through its performance assessments, as well as by the NRC staff from its own calculations, through sensitivity and uncertainty analyses.

The Detailed Safety Review of the Key Technical Uncertainty related to the appropriateness of assumptions and simplifications in mathematical models will involve evaluation of these assumptions and simplifications with regard to whether they are sufficiently justified by DOE on technical grounds. This will likely include review of references to the License Application regarding model documentation. The detailed review will also involve the comparison of output from DOE models with that generated using models developed by other parties, to assure that inappropriate conclusions do not result.

Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations (Type 5)

A detailed safety review, independent staff modeling, and use of the results of staff investigations will be needed for the Key Technical Uncertainties related to the validation of mathematical models and to the prediction of future system states. In this review, it will be necessary for the staff to resolve whether the models used by DOE incorporate all of the important processes, coupled in appropriate ways and detailed to an appropriate degree, so that compliance demonstrations will hold under the uncertainty band inherent to the geologic system. This will ensure that DOE has adequately demonstrated Items (1)-(3) listed in a prior section (Safety Review, paragraph 1).

The Detailed Safety Review for the Key Technical Uncertainty related to validation of mathematical models will be supported by the results of staff investigations and research into the issue of model validation, in addition to analyses conducted under the NRC Iterative Performance Assessment (IPA) program. Detailed review will be required of DOE's data, analyses, and documentation supporting the validity of the models used in their compliance demonstration. In reviewing this information, the staff must assure that the models used provide an acceptable and adequate representation of the processes operating at the site, with guidance on acceptable levels of validation, potentially provided by a staff model validation strategy. In addition, tests of DOE models and comparison with staff-developed models will be conducted as a part of this detailed review.

With respect to the Detailed Safety Review of the Key Technical Uncertainty related to prediction of future system states, the staff must assure that appropriate scenarios and corresponding probability estimates have been identified and considered by DOE in its overall system performance assessment. Particular areas requiring the staff's attention include: (1) DOE's definition of the term "scenario" and how this concept has been propagated through the analysis to the construction of the complimentary cumulative distribution function; (2) the methodology and justifications used to screen processes, events, and scenarios from consideration; and (3) the data, analyses, and support for the estimates of probabilities of occurrence for the relevant processes and events. In addition, analyses will be performed using an alternative scheme of defining scenarios. This review will be supported by work performed under the staff's IPA program, as well as from staff investigations and research.

Contributing Analysts:
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Date of Analysis: September 21, 1992

APPLICABLE REGULATORY REQUIREMENTS:
Type 3:
10 CFR 60.112, 40 CFR 191.13, 10 CFR 60.21 (c)(1)(ii)(C)

Type 4:
10 CFR 60.112, 40 CFR 191.13, 10 CFR 60.21 (c)(1)(ii)(C)

Type 5:
10 CFR 60.112, 40 CFR 191.13, 10 CFR 60.21 (c)(1)(ii)(C)

NOTE: These REOPs will change when: (1) 40 CFR Part 191 is finalized; (2) 10 CFR Part 60 is amended to conform it to 40 CFR Part 191.

REFERENCES:

Barnard *et al.*, "TSPA 1991: An Initial Total-System Performance Assessment for Yucca Mountain," Sandia National Laboratories, SAND91-2795, July 1992. [Prepared for the U.S. Department of Energy.]

Code of Federal Regulations, "Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes," Part 191, Chapter I, Title 40, "Protection of the Environment."

Codell, R.B., *et al.*, "Initial Demonstration of the NRC's Capability to Conduct a Performance Assessment for a High-Level Waste Repository," Nuclear Regulatory Commission, NUREG-1327, May 1992.

Nuclear Regulatory Commission, "Draft Regulatory Guide DG-3003: Format and Content For the License Application for the High-Level Waste Repository," Office of Nuclear Regulatory Research, DG-3003, November 1990.

Nuclear Regulatory Commission, "NRC Post-Closure Performance Assessment Strategy for a High-Level Nuclear Waste Repository," Division of High-Level Waste Management, 1991 (unpublished).

Sandia National Laboratories, "Preliminary Comparison with 40 CFR Part 191, Subpart B for the Waste Isolation Pilot Plant, December 1991," WIPP Performance Assessment Division, SAND91-0893, 3 vols., December 1991. [Prepared for the U.S. Department of Energy.]

U.S. Department of Energy, "Chapter 8, Site Characterization Program," in "Site Characterization Plan, Yucca Mountain Site, Nevada Research and Development Area, Nevada," Office of Civilian Radioactive Waste Management, DOE/RW-0199, vol. VII, Part B, December 1988.

U.S. Environmental Protection Agency, "Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes; Final Rule," *Federal Register*, vol. 50, no. 182, September 19, 1985, pp. 38066-38089.

COMPLIANCE DETERMINATION STRATEGY
6.2 Assessment of Compliance with the Individual Protection Requirements

PRIMARY REGULATORY CITATION:

10 CFR 60.112

TYPES OF REVIEW:

Acceptance Review (Type 1)
Safety Review (Type 3)
Detailed Safety Review Supported by Analyses (Type 4)

RATIONALES FOR TYPE OF REVIEW:

Acceptance Review (Type 1) Rationale:
This regulatory requirement is considered to be License Application-related because, as specified in the License Application content requirements of 10 CFR 60.21 and the Format and Content Regulatory Guide (NRC, 1990), it must be addressed by DOE in its license application. Therefore, the staff will conduct an Acceptance Review of the license application for this regulatory requirement.

Safety Review (Type 3) Rationale:
This regulatory requirement is related to radiological safety and waste isolation. It is a requirement for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31 (i.e., regulatory requirements in Subparts E, G, H, I, and 10 CFR 60.21). Therefore, the staff will conduct a Safety Review of the license application to determine compliance with the regulatory requirements.

The overall system performance objective (10 CFR 60.112) stipulates that DOE provide, through tests, data, and analyses, reasonable assurance that the overall repository system (i.e., the geologic barrier provided by the site together with the engineered barriers incorporated in the system by design) will meet the "generally applicable standards for protection of the general environment from off-site releases from radioactive material in repositories" as set by the U.S. Environmental Protection Agency (EPA) in 40 CFR Part 191 (*Code of Federal Regulations*, Title 40, "Protection of the Environment"). This is the highest level of performance placed on the geologic repository and DOE is expected to utilize great amounts of site characterization and design data, in addition to some subjective information obtained through expert elicitation, to show compliance with this requirement. Moreover, DOE's compliance demonstration methods are expected to be based largely on predictive mathematical models of varying complexity.

The individual protection portion of the total system performance requirement focuses on the radiation dose received by any future individual for the 1,000 years following permanent closure. As stated in the existing EPA standards (EPA, 1985; 50 *FR* 38086), such doses would be calculated considering "undisturbed

performance of the disposal system." In its proposed conforming amendments to 10 CFR Part 60, the staff determined that for the purposes of compliance demonstration with the individual protection requirements, "undisturbed performance" is equivalent to consideration of "anticipated" processes and events under 10 CFR Part 60 (NRC, 1986; 51 *FR* 22289).

Detailed Safety Review Supported by Analyses (Type 4) Rationale:
The staff considers that the findings made under this regulatory requirement may be highly uncertain and controversial due to several Key Technical Uncertainties. Therefore, the results from analyses of overall system performance with respect to the containment requirements may vary widely and may lead to unwarranted conclusions regarding public health and safety. Thus, the possibility of error with respect to determining compliance with this regulatory requirement must be minimized.

The regulatory requirements for individual protection are deterministic in nature (i.e., specifying numerical criteria to be met), and the demonstration of compliance will require analyses covering the first 1,000 years after permanent closure for anticipated conditions only. In these ways, it is similar to the conditions for the ground-water protection requirements of 40 CFR Part 191. However, it differs significantly from the regulatory requirements for containment, which are probabilistic in nature, apply to the 10,000 years following closure, and require analyses for both anticipated and unanticipated conditions.

For the Yucca Mountain site, the following Key Technical Uncertainties require a Type 4 review because they pose a high potential risk of non-compliance with this regulatory requirement.

> **Key Technical Uncertainty Topic**: Conceptual model representations of the natural and engineered systems
>
> Description of Uncertainty: Conceptual models of the site regarding the presence and origin of tectonic and magmatic/volcanic features and the potential flow and transport paths (for the aqueous and gas phase radionuclides) through the variably saturated, fractured, heterogeneous rock of Yucca Mountain are highly uncertain. Similarly, long-term stability of the engineered barriers (waste packages, borehole seals, etc.) is also difficult to predict. In addition, the environment to which the engineered barriers will be subjected soon after waste emplacement will be considerably different from the ambient due to the thermal pulse as well as to other disturbances introduced during repository construction.
>
> While some of these technical uncertainties are expected to be resolved by the time of the License Application submittal, significant residual uncertainties are expected to remain, as is evidenced at the WIPP site (SNL, 1991) and noted in the Phase 1 demonstration of a performance assessment capability by the NRC staff (Codell, *et al.*, 1992).

Performance Objectives at Risk and Associated Regulatory Requirements: 10 CFR 60.112, 40 CFR 191.15

Explanation of Nature of Risk: Omission of a plausible conceptual model, either for the natural system or the engineered barriers, by DOE in its overall performance assessment, directly affects conclusions related to public health and safety.

Description of Resolution Difficulty: DOE's site characterization program will provide data which will be used, in part, to help distinguish among alternative conceptual models of site performance. However, considerable uncertainties may remain. DOE will need to consider various reasonable alternative conceptual models in its overall performance assessment to assure that the effects on overall repository performance are adequately characterized. Although difficult to resolve, additional data, together with bounding the uncertainty with alternatives, is a reasonable resolution approach.

Key Technical Uncertainty Topic: Variability (temporal, spatial, etc.) in model parametric values

Description of Uncertainty: Many features of a repository system can be measured directly in situ or in a laboratory (e.g., ground-water levels or corrosion rates) or can be inferred from direct measurements (e.g., hydraulic conductivity). In natural heterogeneous systems like Yucca Mountain, parameters will vary both temporally and spatially. In addition, even in direct measurements, there may be significant uncertainties associated with the applicability of test methods, potential instrument errors, and procedural errors. Thus, it is not uncommon to have large uncertainty bands for geologic parameters; sometimes the standard deviations of these parameters may be orders of magnitude greater than their mean values.

DOE, through performance allocation tables in its Site Characterization Plan (DOE, 1988), has stated a target for acceptable levels of uncertainties. Some of these will invariably be revised as site characterization proceeds, but some targets may not be met in the end. Under this eventuality, DOE is expected to modify its initial performance allocation. At issue in all these iterations of performance allocation is technical support for the estimated uncertainty bands. DOE is expected to estimate parameter values for its performance assessment models based on a combination of site and design data and expert elicitation.

Performance Objectives at Risk and Associated Regulatory Requirements: 10 CFR 60.112, 40 CFR 191.15

Explanation of Nature of Risk: Results obtained from the overall performance assessment models are strongly dependent upon the parameters included in the assessment and the ranges of values deemed acceptable to represent the uncertainty in the parameters. Inappropriate parametric values can lead to unwarranted conclusions.

Description of Resolution Difficulty: Model parameters often are not directly measured, but rather are derived from measured data through the application of "accepted" theories. In addition, the physical dimensions of the site preclude a complete understanding and measurement of the entire range in the various parametric values. In its overall performance assessments, a reasonable approach is for DOE to assign reasonable and conservative ranges to the parameters important to repository performance to adequately bound the uncertainty in the values.

Key Technical Uncertainty Topic: Appropriateness of assumptions and simplification in mathematical models

Description of Uncertainty: To perform analyses of overall repository system performance, mathematical models and numerical computer codes will be developed to represent a conceptual understanding of the important processes operative at the site. Various assumptions and simplifications will be required in these models and codes so that the important processes (e.g., groundwater flow through unsaturated, fractured rock) can be represented as realistically as possible and yet not be so detailed as to be unworkable. Some of the simplifications will necessarily be due to computer hardware constraints (e.g., computer code run times). These assumptions and simplifications will in general be non-unique and, perhaps, controversial.

Performance Objectives at Risk and Associated Regulatory Requirements: 10 CFR 60.112, 40 CFR 191.15

Explanation of Nature of Risk: Results of performance assessment analyses can be extremely sensitive to the assumptions and simplifications made in mathematical models used in the analyses. Unless this sensitivity is adequately investigated and understood, unwarranted and inappropriate conclusions may result.

Description of Resolution Difficulty: Because the natural system must necessarily be represented by mathematical models in performance assessment analyses, this uncertainty cannot be completely resolved. Site investigations and field and laboratory testing can reduce the uncertainty in the conceptual models on which the mathematical models are based; however, the appropriateness of particular equations or approaches used to represent various processes will remain a point of contention. In addition, numerical calculations of overall system performance have and will require the use of high-speed super computers for potentially hundreds to thousands of real-time and computer hours. Simplifications in modeling approaches are necessary to keep the analyses tractable. The observance of good software quality assurance practices should help reduce the uncertainty associated with the implementation of mathematical models in computer programs.

Given the existing (1985) EPA standard, the staff considers that a Type 4 (Detailed Safety Review) will be sufficient for this regulatory requirement for the following reasons. First, because this performance objective is

deterministic and requires analyses for "undisturbed performance" only, development of disruptive scenarios is not necessary. In the Compliance Determination Strategy for the containment requirements of 40 CFR Part 191, the Key Technical Uncertainty related to prediction of future system states (i.e., disruptive scenarios) required a Type 5 Detailed Safety Review.

A second reason for selecting a Type 4 review is related to the period of performance for this regulatory requirement. Given that analyses are needed only for the initial 1,000 years after permanent closure, DOE may opt to demonstrate compliance with this requirement entirely through engineering design and demonstrations of the stability of the engineered barriers for the period of performance. It is less likely that such an approach would be followed for a 10,000-year performance period. Nonetheless, the staff considers it likely that total system performance assessment analyses will be used in DOE's demonstration of compliance for this regulatory requirement, due to the uncertainties inherent in predicting engineered barrier performance.

As a final note, current working drafts for the revised EPA standard indicate that the time period of performance for this total system performance regulatory requirement may be changed to 10,000 years. If this change is promulgated, this criteria will be more restrictive, and this review strategy will need to be revised to accommodate the change.

REVIEW STRATEGY:

Acceptance Review (Type 1)

In conducting the Acceptance Review of the containment portion of the total system performance regulatory requirement (10 CFR 60.112), the reviewer will determine whether the information presented in the license application and its references for determining compliance with this regulatory requirement is complete in technical breadth and depth as identified in the Draft Regulatory Guide DG-3003 (NRC, 1990).

The information in the license application should be presented in such a manner that the assumptions, data, and logic leading to a demonstration of compliance with this requirement are clear and do not require the reviewer to conduct extensive analyses or literature searches. The review should also determine that controversial information and appropriate alternative interpretations and models have been adequately described and considered.

Finally, the reviewer shall determine if DOE has either resolved all the NRC staff objections to the SCP that apply to this requirement or provided all the information requested in Section 1.6 of DG-3003 for unresolved objections. The reviewer will evaluate the effects of any unresolved objections, both individually and in combinations with others on: (1) the reviewer's ability to conduct a meaningful and timely review; and (2) the Commission's ability to make a decision regarding construction authorization within the three-year statutory period.

Safety Review (Type 3)

In conducting the Safety Review, the reviewer will, as a minimum, determine the adequacy of the data and analyses presented in the license application to determine DOE's compliance with the total system performance regulatory requirement. Staff's objectives of the Safety Review would be to: (1) understand and evaluate DOE's compliance demonstration logic; (2) conduct a preliminary review of the data base used for compliance demonstration to determine which parts of the data are most uncertain or that may be incomplete (e.g., with respect to potentially adverse conditions); and (3) determine whether portions of the data and/or analyses submitted should be subjected to further detailed review (in addition to those areas requiring Type 4 and 5 detailed reviews specified below).

The specific aspects of the license application on which the review will focus are discussed in Section 6.1 of DG-3003 (NRC, 1990) and the acceptance criteria will be identified on Section 3 of this review plan. In general, the Safety Review will look at: (1) the basic approach to demonstrating compliance; (2) the description of the system; (3) the estimates of individual doses; and (4) the model and code verification and validation activities.

This Safety Review will also assure that: (1) all of the favorable conditions (10 CFR 60.122(b)) and potentially adverse conditions (10 CFR 60.122(c)), that have been determined to be present, are included in the compliance demonstration for this regulatory requirement; and (2) consideration of any potentially adverse condition that has been determined to be present will use assumptions that are not likely to underestimate its effects (10 CFR 60.21 (c)(1)(ii)(C)).

In order to conduct an effective Safety Review, the reviewer will rely on his expertise and independently-acquired knowledge, information, and data in addition to that provided by DOE in its License Application. As a minimum, the reviewers must, in particular, be familiar with the iterative performance assessments conducted by the staffs of DOE (e.g., Barnard, *et al.*, 1992), NRC (e.g., Codell *et al.*, 1992), and EPA (with respect to the WIPP site) and, in general, with those conducted internationally by the time of the License Application submittal. Such knowledge gathered from previous performance assessments should be used to determine: (1) if the uncertainties have been appropriately considered; and (2) whether appropriate scenarios have been included in the analyses.

Detailed Safety Review Supported by Analyses (Type 4)

A detailed safety review and analysis will be needed for evaluation of the Key Technical Uncertainties related to: (1) conceptual model representations of the natural and engineered systems; (2) variability in model parametric values; and (3) validation of mathematical models. This review will make use of models, analyses, and methodologies developed by DOE and/or other parties and reviewed and found to be acceptable by the staff. These evaluations will include detailed analyses of certain critical aspects related to the consideration of conceptual model and mathematical model uncertainties, as well as a conservative estimate of the performance of the total system. The staff will conduct sensitivity/uncertainty analyses of the total system performance to determine if there is reasonable assurance of meeting the performance objectives even when alternatives not included by DOE are considered. This will ensure that DOE has

adequately demonstrated Items (1)-(3) listed in the previous section (Safety Review, paragraph 1).

Activities performed in this Detailed Safety Review will help to assure that DOE has adequately addressed and resolved these Key Technical Uncertainties so that they do not lead to non-compliance with the performance objective.

The Detailed Safety Review of the Key Technical Uncertainty related to conceptual model uncertainty will require staff to examine closely the data, analyses, and assumptions used by DOE to propose or reject various alternative conceptual models from consideration for the site. As it is anticipated that more than one conceptual model of a particular process or set of processes may fit the available database, the staff must assure that all reasonable conceptual models are addressed by DOE and assessed in their overall repository performance analyses. In addition, staff's own analyses should include conceptual models not considered by DOE, if appropriate.

The Key Technical Uncertainty related to variability in parametric values will require a Detailed Safety Review. This review will include activities such as: (1) selected review of raw data collected by DOE and techniques used by DOE in parameter estimation to assure that appropriate uncertainty bands were assigned to such estimates; and (2) review of the estimation of parameters critical to the calculation of overall system performance. These parameters will be identified by DOE through its performance assessments, as well as by the NRC staff from its own calculations, through sensitivity and uncertainty analyses.

The Detailed Safety Review of the Key Technical Uncertainty related to the appropriateness of assumptions and simplifications in mathematical models will involve evaluation of these assumptions and simplifications with regard to whether they are sufficiently justified by DOE on technical grounds. This will likely include review of references to the License Application regarding model documentation. The detailed review will also involve the comparison of output from DOE models with that generated using models developed by other parties, to assure that inappropriate conclusions do not result.

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APPLICABLE REGULATORY REQUIREMENTS:
Type 3:
10 CFR 60.112
40 CFR 191.15, 10 CFR 60.21 (c)(1)(ii)(C)

Type 4:
10 CFR 60.112, 40 CFR 191.15, 10 CFR 60.21 (c)(1)(ii)(C)

NOTE: The above requirements will change when: (1) 40 CFR Part 191 is finalized; (2) 10 CFR Part 60 is amended to conform it to 40 CFR Part 191.

REFERENCES:

Barnard, R.W., et al., "TSPA 1991: An Initial Total-System Performance Assessment for Yucca Mountain," Sandia National Laboratories, SAND91-2795, July 1992. [Prepared for the U.S. Department of Energy.]

Code of Federal Regulations, "Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes," Part 191, Chapter I, Title 40, "Protection of the Environment."

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Nuclear Regulatory Commission, "Draft Regulatory Guide DG-3003: Format and Content For the License Application for the High-Level Waste Repository," Office of Nuclear Regulatory Research, DG-3003, November 1990.

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